Cervical cancer screening and management of cervical pre-cancers

Training of health staff in colposcopy, LEEP and CKC

Trainees’ handbook
Training of health staff in colposcopy, LEEP and CKC – Trainees’ handbook

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Cervical cancer screening and management of cervical pre-cancers

Training of health staff in
colposcopy, LEEP and CKC

Trainees’ handbook

World Health Organization
Regional Office for South-East Asia
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

• Teaching aids
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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 Rashmi 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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Technical support in finalization of this package was provided by Dr Arvind Mathur, Dr Neena Raina, Dr Anoma Jayathilaka, Dr Priya Karna, WHO Regional Office for South-East Asia, New Delhi, India.

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## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIS</td>
<td>adenocarcinoma in situ</td>
</tr>
<tr>
<td>C4GEP</td>
<td>Comprehensive Cervical Cancer Control: A Guide to Essential Practice</td>
</tr>
<tr>
<td>CA</td>
<td>cancer</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>ECC</td>
<td>endocervical curettage</td>
</tr>
<tr>
<td>ESU</td>
<td>electrosurgical unit</td>
</tr>
<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<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>
</tr>
<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>IFCPC</td>
<td>International Federation of Cervical Pathology and Colposcopy</td>
</tr>
<tr>
<td>LEEP</td>
<td>loop electrosurgical excision procedure</td>
</tr>
<tr>
<td>LMIC</td>
<td>low and middle income countries</td>
</tr>
<tr>
<td>LMP</td>
<td>last menstrual period</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>TZ</td>
<td>transformation zone</td>
</tr>
<tr>
<td>VIA</td>
<td>visual inspection with acetic acid</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Section 1: General guidelines for training
1.1 How to use this manual

The Trainees’ handbook is designed to train gynaecologists and non-specialist clinicians in performing colposcopy and treatment of cervical precancerous conditions so they can provide the necessary diagnostic and therapeutic services in a cervical cancer screening programme. The Trainees’ handbook contains guidelines and information intended to be used both by trainees and facilitators while participating in the structured training programme on cervical cancer screening and treatment. The Trainees’ handbook contains different modules intended to assist trainees to develop their knowledge and learn the correct steps to perform colposcopy and treatment procedures. 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 at 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 colposcopy and management of cervical pre-cancers by loop electrosurgical excision procedure (LEEP) and cold knife conization (CKC) aims to enhance the knowledge and skills of gynaecologists and non-specialist clinicians so they can perform these diagnostic and therapeutic procedures at the secondary and tertiary levels of healthcare.

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

• counsel women before and after the interventions;
• perform colposcopy;
• make decisions related to treatment and/or referral;
• treat precancerous conditions of the cervix by excision techniques;
• ensure appropriate follow-up of the women;
• maintain records of the women in an appropriate format.

The objectives include both knowledge enhancement and skills development.

Knowledge-based objectives

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

• explain how to screen for cervical cancer;
• describe the pathogenesis of cervical cancer with special reference to HPV;
• narrate the principles and techniques of colposcopy and interpretation of findings;
• explain the management of women with abnormalities detected on colposcopy;
• state the principles and techniques of LEEP and CKC;
• narrate the infection prevention practices.

**Skill-based objectives**

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

• demonstrate how to counsel a woman;
• perform colposcopy step-by-step;
• identify features of normal and abnormal cervix using a colposcope;
• perform LEEP or CKC as appropriate;
• follow appropriate infection prevention practices;
• manage women with procedure-related complications;
• conduct follow-up of women after treatment;
• document and maintain records;
• provide quality services as per standard operating procedures.

### 1.3 Trainees’ profile

All gynaecologists and non-specialist clinicians designated by the national cervical cancer screening programme or the local health authorities to provide colposcopy and treatment services at secondary and tertiary levels of healthcare need to be trained. Specialist gynaecologists are expected to learn about the screening techniques and treatment by cryotherapy during their postgraduate training. Non-specialist clinicians will be eligible for training in colposcopy and management of pre-cancers after successful completion of the course on VIA, HPV detection tests and cryotherapy and 6 months of actively practising these procedures.

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 the appropriate response*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1. Name:</td>
<td></td>
</tr>
<tr>
<td>2. Designation:</td>
<td></td>
</tr>
<tr>
<td>3. Age:</td>
<td></td>
</tr>
<tr>
<td>4. Sex:</td>
<td></td>
</tr>
<tr>
<td>5. Contact no.:</td>
<td></td>
</tr>
<tr>
<td>6. Place of posting:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Govt/Non-govt./Private</td>
</tr>
<tr>
<td>7. Highest educational qualification:</td>
<td></td>
</tr>
<tr>
<td>Year of passing:</td>
<td></td>
</tr>
<tr>
<td>8. Duration of work experience:</td>
<td></td>
</tr>
<tr>
<td>9. Have you ever been trained to do cervical cancer screening?</td>
<td>Yes</td>
</tr>
<tr>
<td>10. If yes, on which of the following procedures have you been trained? VIA/Taking pap smear/Taking sample for HPV test/others</td>
<td></td>
</tr>
<tr>
<td>11. Have you ever been trained to do colposcopy and treatment of pre-cancers?</td>
<td>Yes</td>
</tr>
<tr>
<td>12. If yes, on which of the following procedures have you been trained? Colposcopy/ Cryotherapy/LEEP/CKC/Others</td>
<td></td>
</tr>
<tr>
<td>13. Current job responsibilities: Clinical/Training/Supervision/Others</td>
<td></td>
</tr>
<tr>
<td>14. Do you practise the following in your work?</td>
<td></td>
</tr>
<tr>
<td>a) Colposcopy:</td>
<td>Yes</td>
</tr>
<tr>
<td>b) Cryotherapy:</td>
<td>Yes</td>
</tr>
<tr>
<td>c) LEEP:</td>
<td>Yes</td>
</tr>
<tr>
<td>d) CKC:</td>
<td>Yes</td>
</tr>
</tbody>
</table>
1.4 Training materials

The following training materials will be provided:

• Trainees’ Handbook for *Training of health staff in colposcopy, LEEP and CKC*


• Counselling cards and flip chart

1.5 Duration of training

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

1.6 Ground rules for trainees

• Adhere to the training schedule and session plans.

• Maintain the attendance record for certification by the facilitator.

• Revise 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 schedule.

• Participate in 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 the privacy and rights of clients in examination rooms.
1.7 Dos and don’ts for trainees

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

1.8 Recommended 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>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Counselling</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>2.</td>
<td>Colposcopy with/without punch biopsy</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>3.</td>
<td>LEEP</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>4.</td>
<td>CKC</td>
<td>2</td>
<td>1</td>
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</table>
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<th>Session</th>
<th>Time</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Registration</td>
<td>8:30 a.m.–9:00 a.m.</td>
<td>Registration of trainees and facilitators</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Filling in of experience records of trainees</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Signature of trainees on attendance sheet</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Handing over of training folders</td>
</tr>
<tr>
<td></td>
<td>Opening session</td>
<td>9:00 a.m.–10:00 a.m.</td>
<td>Welcome of participants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Introduction of facilitators and trainees</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Assessment of trainees’ expectations</td>
</tr>
<tr>
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<td></td>
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<td>Presentation of training objectives</td>
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<td></td>
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<td></td>
<td>Ground rules and information about logistics of training</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>Agenda of training</td>
</tr>
<tr>
<td></td>
<td>Session 1: Introduction to cervical cancer screening</td>
<td>10:00 a.m.–11:00 a.m.</td>
<td>Magnitude of problem of cervical cancer</td>
</tr>
<tr>
<td></td>
<td>Interactive presentation</td>
<td></td>
<td>Principles of cervical cancer screening</td>
</tr>
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<td></td>
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<td></td>
<td>Need for cervical cancer screening</td>
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<td>Concept of organized screening programme</td>
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<td></td>
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<td>Protocol for cervical cancer screening</td>
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<td>Screening tests for cervical cancer</td>
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<td>Target population for cervical cancer screening</td>
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<td>Frequency of cervical cancer screening</td>
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<td>Informed consent for cervical cancer screening</td>
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<td></td>
<td>National cervical cancer screening protocol</td>
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<td>Day</td>
<td>Session</td>
<td>Time</td>
<td>Contents</td>
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</tbody>
</table>
|     | Session 2: Pathogenesis of cervical cancer with special reference to HPV infection | 11:00 a.m.–12:00 p.m. | Risk factors of cervical cancer  
Epidemiology of HPV infection  
Mechanism of carcinogenesis by HPV infection  
Natural history of cervical intra-epithelial neoplasia |
|     | Interactive presentation | | |
|     | Session 3: Counselling | 12:00 p.m.–1:00 p.m. | Necessity of counselling  
Being a good counsellor  
Steps of counselling  
Using checklists, flip chart and counselling cards  
Counselling messages |
|     | 3 a: Interactive presentation | | |
|     | 3 b: Facilitated group learning activity | | Role play |
|     | Lunch break | 1:00 p.m.–2:00 p.m. | |
|     | Session 4: Principles of colposcopy | 2:00 p.m.–3:30 p.m. | Introduction to colposcopy  
Microscopic features of epithelium of cervix  
Squamocolumnar junction and its importance  
Squamous metaplasia  
Transformation zone (TZ)  
Vascular patterns  
Role of 5% acetic acid  
Role of Lugol's iodine |
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<td>4 b: Facilitated group learning activity</td>
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<td>Digital image recognition skill – presentation and discussion</td>
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<td>Session 5: Instrumentation and technique of colposcopy</td>
<td>3:30 p.m.–4:30 p.m.</td>
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|     | 5 a: Interactive presentation | | Indications of colposcopy  
|     | | | Instruments required  
|     | | | Consumables required  
|     | | | Steps of colposcopy  
<p>|     | 5 b: Facilitated group learning activity | | Digital image recognition skill – presentation and discussion |
|     | Summary of the day’s activities | 4:30 p.m.–4:45 p.m. | Presentation of key points by trainees |
|     | Discussion of the next day’s agenda | 4:45 p.m.–5:00 p.m. | Discussion to be led by facilitators |
| Day 2 | Review of previous day’s activities and doubt clearance | 9:00 a.m.–9:30 a.m. | Presentation of key-points by trainees |
| | | | Discussion to be led by facilitators for doubt clearance |
| | Session 6: Colposcopic features of normal, benign, pre-cancer and cancer of cervix | 9:30 a.m.–11:00 a.m. | |</p>
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| 6 a | Interactive presentation | 11:00 a.m.–12:30 p.m. | Normal colposcopy findings  
Abnormal colposcopy findings  
Early invasive and invasive carcinoma  
Miscellaneous findings  
Management algorithms |
| 6 b | Facilitated group learning activity | 11:00 a.m.–12:30 p.m. | Digital image recognition skill – presentation and discussion  
Case studies and discussion |
| 11:00 a.m.–12:30 p.m. | Session 7: Treatment of cervical pre-cancers by loop electrosurgical excision procedure (LEEP) and follow-up | Session 7: Treatment of cervical pre-cancers by loop electrosurgical excision procedure (LEEP) and follow-up |
| 7 a | Interactive presentation | 11:00 a.m.–12:30 p.m. | Principles of LEEP  
Instruments and consumables required  
Eligibility criteria for LEEP  
Steps of LEEP  
Post treatment advice  
Advantages and disadvantages  
Management of treatment complications  
Appropriate infection prevention practices |
<p>| 7 b | Group learning activity | 11:00 a.m.–12:30 p.m. | Case studies/role play |
| 12:30 p.m–1:00 p.m. | Session 8: Treatment of cervical pre-cancers by cold knife conization (CKC) and follow-up | 12:30 p.m–1:00 p.m. |</p>
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<td>8 a</td>
<td>Interactive presentation</td>
<td>1:00 p.m.–2:00 p.m.</td>
<td>Principles of CKC, Instruments and consumables required, Eligibility criteria for CKC, Steps of CKC, Post treatment advice and follow-up, Advantages and disadvantages, Management of treatment complications, Appropriate infection prevention practices</td>
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<tr>
<td>8 b</td>
<td>Group learning activity</td>
<td>2:00 p.m.–2:30 p.m.</td>
<td>Case studies</td>
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<td>Lunch break</td>
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<td></td>
<td>Session 9: Infection prevention practices</td>
<td>2:30 p.m.–3:30 p.m.</td>
<td>Importance of infection prevention practices</td>
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<td>9 a</td>
<td>Interactive presentation</td>
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<td>Preventing spread of infection, Processing of instruments, Waste disposal</td>
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<tr>
<td>9 b</td>
<td>Group learning activity</td>
<td></td>
<td>Role play</td>
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<td></td>
<td>Session 10: Ensuring quality of services and programme monitoring in</td>
<td>3:30 p.m.–4:00 p.m.</td>
<td>Ensuring quality of services by healthcare providers, Programme monitoring and its necessity, Indicators to monitor cervical cancer screening programme</td>
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<td></td>
<td>cervical cancer screening</td>
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<tr>
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<td>Quality assurance and quality control</td>
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<td>Framework for effective quality assurance</td>
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<td>Supportive supervision guidelines and tool</td>
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<td>Evaluation of programme performance</td>
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<td>Using evaluation results for quality improvement</td>
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<td></td>
<td>Summary of the day's activities</td>
<td>4:30 p.m.–4:45 p.m.</td>
<td>Presentation of key points by trainees</td>
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<tr>
<td></td>
<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 facilitator</td>
</tr>
<tr>
<td>Day 3</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. Discussion to be led by facilitator for doubt clearance</td>
</tr>
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<td></td>
<td>Organization of groups for clinic based sessions</td>
<td>9:30 a.m.–10:00 a.m.</td>
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<td></td>
<td>Demonstration session (clinic-based)</td>
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<tr>
<td></td>
<td>i) Getting to know the colposcope</td>
<td></td>
<td>Introduction to different parts of the colposcope</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Functions of each part of the equipment</td>
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<td></td>
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<td>Connections and adjustment</td>
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<td></td>
<td>Equipment maintenance</td>
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<td>Troubleshooting</td>
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<td></td>
<td>ii) Getting to know the instrument tray for colposcopy</td>
<td></td>
<td>Introduction to different instruments and consumables used for colposcopy</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Working with the instruments</td>
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<td></td>
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<td></td>
<td>Decontamination and sterilization of instruments</td>
</tr>
<tr>
<td></td>
<td>Clinical skills training</td>
<td>11:00 a.m.–3:00 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>Day</td>
<td>Session</td>
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<tr>
<td></td>
<td>i) Counselling</td>
<td>3:00 p.m.–4:30 p.m.</td>
<td>Individual counselling/group counselling/couple counselling using Skills Checklists, counselling cards and flip chart</td>
</tr>
<tr>
<td></td>
<td>ii) Colposcopy</td>
<td></td>
<td>Procedure to be observed on client</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Procedure to be performed under supervision</td>
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<td></td>
<td>Procedure to be performed independently on client</td>
</tr>
<tr>
<td></td>
<td>Demonstration session</td>
<td>3:00 p.m.–4:30 p.m.</td>
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</tr>
<tr>
<td></td>
<td>i) Preparation of dilute acetic acid</td>
<td>4:30 p.m.–4:45 p.m.</td>
<td>Introduction to ingredients and consumables, method of preparation, storage and use, precautions</td>
</tr>
<tr>
<td></td>
<td>ii) Preparation of Lugol’s iodine</td>
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<td>iii) Preparation of Monsel’s paste</td>
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<td></td>
<td>iv) Preparation of 0.5% chlorine solution</td>
<td>4:45 p.m.–5:00 p.m.</td>
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<tr>
<td></td>
<td>Summary of the day’s activities</td>
<td>4:30 p.m.–4:45 p.m.</td>
<td>Presentation of key points by trainees</td>
</tr>
<tr>
<td></td>
<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 facilitators</td>
</tr>
<tr>
<td>Day 4 –</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. Discussion to be led by facilitators for doubt clearance</td>
</tr>
<tr>
<td>Day 5</td>
<td>Classroom training</td>
<td></td>
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<td></td>
<td>Image recognition session/video presentation</td>
<td>9:30 a.m.–10:30 a.m.</td>
<td>Presentation of images and videos of procedures being performed and discussion</td>
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<tr>
<td></td>
<td>Clinic-based training</td>
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<td></td>
<td>Demonstration session in the clinics</td>
<td>10:30 a.m.–11:30 a.m.</td>
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<td>Day</td>
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</table>
|           | i) Getting to know LEEP equipment and accessories                       | 11:30 a.m.–4:00 p.m. | Introduction to electrosurgical unit  
                |                                                                         |                  | Electrical connections and setting-up of the unit  
                |                                                                         |                  | Functions of all parts of the unit  
                |                                                                         |                  | Equipment maintenance  
                |                                                                         |                  | Troubleshooting  
|           | ii) Getting to know the LEEP instrument tray                           |                  | Introduction to different instruments and consumables used for LEEP  
                |                                                                         |                  | Working with the instruments  
                |                                                                         |                  | Decontamination and sterilization of instruments  
|           | iii) Getting to know the instrument tray for CKC                       |                  | Introduction to different instruments and consumables used for CKC  
                |                                                                         |                  | Working with the instruments  
                |                                                                         |                  | Decontamination and sterilization of instruments  
|           | **Clinical skills training**                                           | 11:30 a.m.–4:00 p.m. |                                                                                         |
|           | **Lunch break**                                                         | 1:00 p.m.–2:00 p.m.  |                                                                                         |
|           | i) Counselling                                                          |                  | Individual counselling /group counselling/couple counselling using skill checklists, counselling cards and flip chart  
|           | ii) Colposcopy                                                         |                  | Procedure to be observed on client  
                |                                                                         |                  | Procedure to be performed under supervision on client  
                |                                                                         |                  | Procedure to be performed independently on client  
|           | iii) Treatment by LEEP                                                 |                  | Simulated learning  
                |                                                                         |                  | Procedure to be observed on client  
                |                                                                         |                  | Procedure to be performed under supervision on client  
                |                                                                         |                  | Procedure to be performed independently on client  

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<td>4:00 p.m.–4:15 p.m.</td>
<td>Presentation of key points by trainees</td>
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<tr>
<td></td>
<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 facilitators</td>
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<tr>
<td></td>
<td><strong>Preparation for mid-course assessment (Day 5)</strong></td>
<td>4:30 p.m.–5:00 p.m.</td>
<td>Orientation to mid-course assessment, explanation of the assessment process (knowledge assessment and skills assessment)</td>
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<td><strong>Day 6</strong></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. Discussion to be led by facilitators for doubt clearance</td>
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<td></td>
<td><strong>Mid-course assessment</strong></td>
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<td></td>
<td><strong>Knowledge assessment</strong></td>
<td>9:30 a.m.–11:00 a.m.</td>
<td>Administration of assessment questionnaire</td>
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<td></td>
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<td></td>
<td>Image recognition skills assessment</td>
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<td></td>
<td><strong>Clinical skills assessment</strong></td>
<td>11:00 a.m.–3:30 p.m.</td>
<td>Counselling, colposcopy (with/without punch biopsy) and treatment by LEEP</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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<td></td>
<td><strong>Review of filled in knowledge assessment questionnaires and image recognition forms and filling in of assessment matrix sheets</strong></td>
<td>3:30 p.m.–4:45 p.m.</td>
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<tr>
<td></td>
<td><strong>Discussion of the next day's agenda</strong></td>
<td>4:45 p.m.–5:00 p.m.</td>
<td>Presentation of key points by trainees. Discussion to be led by facilitators</td>
</tr>
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<td><strong>Day 7–</strong></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. Discussion to be led by facilitators for doubt clearance</td>
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<td><strong>Day 8</strong></td>
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<td><strong>Classroom training</strong></td>
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<td></td>
<td><strong>Image recognition session/video presentation</strong></td>
<td>9:30 a.m.–10:30 a.m.</td>
<td>Presentation of images and videos of procedures being performed for discussion</td>
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<tr>
<td>Clinic-based training</td>
<td>10:30 a.m.–4:00 p.m.</td>
<td>Procedure to be observed on client</td>
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<tr>
<td>Lunch break</td>
<td>1:00 p.m.–2:00 p.m.</td>
<td>Procedure to be performed under supervision</td>
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<tr>
<td>Clinical skill training</td>
<td>10:30 a.m.–1:00 p.m.</td>
<td>Procedure to be performed on client</td>
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</tr>
<tr>
<td>i) Colposcopy</td>
<td></td>
<td>Procedure to be observed on client</td>
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<tr>
<td>ii) Treatment by LEEP</td>
<td></td>
<td>Simulated learning</td>
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<tr>
<td>iii) Treatment by CKC</td>
<td></td>
<td>Procedure to be observed on client</td>
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<tr>
<td>Summary of the day’s activities</td>
<td>4:00 p.m.–4:15 p.m.</td>
<td>Presentation of key points by trainees</td>
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<tr>
<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 facilitator</td>
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<tr>
<td>Preparation for the final assessment (Day 8)</td>
<td>4:30 p.m.–5:00 p.m.</td>
<td>Explanation of assessment process (knowledge assessment and skills assessment)</td>
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<td>Day 9</td>
<td>Final assessment</td>
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<tr>
<td>Knowledge assessment</td>
<td>9:00 a.m.–10:30 a.m.</td>
<td>Administration of assessment questionnaire</td>
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<tr>
<td>Clinical skills assessment</td>
<td>10:30 a.m.–3:30 p.m.</td>
<td>Image recognition skill assessment</td>
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<td></td>
<td></td>
<td>Counselling, colposcopy (with/without punch biopsy) and treatment by LEEP/CKC</td>
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<tr>
<td>Day</td>
<td>Session</td>
<td>Time</td>
<td>Contents</td>
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<tr>
<td>Lunch break</td>
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<td>1:00 p.m.–2:00 p.m.</td>
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<tr>
<td>Day 10</td>
<td><strong>Filling in feedback forms</strong></td>
<td>9:00 a.m.–12:30 p.m.</td>
<td>Counselling, colposcopy and treatment by LEEP, CKC</td>
</tr>
<tr>
<td></td>
<td>Filling in feedback forms</td>
<td>12:30 p.m.–1:00 p.m.</td>
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<td></td>
<td>Lunch break</td>
<td>1:00 p.m.–2:00 p.m.</td>
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<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 and knowledge assessment sheets</td>
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<td></td>
<td>Certificate distribution and comments from trainees</td>
<td>3:00 a.m.–4:00 p.m.</td>
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<td>Closing</td>
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Section 3: Modules

Module 1: Introduction to cervical cancer screening
Module 2: Pathogenesis of cervical cancer with special reference to HPV infection
Module 3: Counselling
Module 4: Principles of colposcopy
Module 5: Instrumentation and technique of colposcopy
Module 6: Colposcopic features of normal, benign, pre-cancer and cancer of cervix
Module 7: Treatment of cervical pre-cancers by loop electrosurgical excision procedure (LEEP) and follow-up
Module 8: Treatment of cervical pre-cancers by cold knife conization (CKC) and follow-up
Module 9: Infection prevention practices
Module 10: 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 gynaecologists and non-specialist clinicians understand the concept of screening for cervical cancer. The module will also provide an overview of the different techniques of cervical cancer screening and the components of an organized screening programme. 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 5.2 – cervical cancer screening).

1.2. Module contents

- Magnitude of the problem of cervical cancer
- Principles of cervical cancer screening
- Need for cervical cancer screening
- Concept of an organized 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 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 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 at 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 symptoms or not. The tests applied are called 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. Among Asian women, cervical cancer ranks second after breast cancer. The cancer causes a large number of deaths among women in the countries of South-East Asia (Table 1.1). Cervical cancer affects women at a relatively young age causing great personal, social and economic loss. Screening helps to detect the cancer at a potentially curable precancerous stage. Detection of precancerous conditions through screening tests and their appropriate treatment help prevent the cancer and avoid untimely deaths of women from the disease.

Table 1.1: The burden of cervical cancer in South-East Asian countries

<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>4th</td>
<td>265 672</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>11 956</td>
<td>19.2</td>
<td>2nd</td>
<td>6582</td>
</tr>
<tr>
<td>Bhutan</td>
<td>37</td>
<td>12.8</td>
<td>1st</td>
<td>19</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>1881</td>
<td>12.4</td>
<td>4th</td>
<td>1119</td>
</tr>
<tr>
<td>India</td>
<td>122 844</td>
<td>22.0</td>
<td>2nd</td>
<td>67 477</td>
</tr>
<tr>
<td>Indonesia</td>
<td>20 928</td>
<td>17.3</td>
<td>2nd</td>
<td>9498</td>
</tr>
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<td>Maldives</td>
<td>14</td>
<td>11.0</td>
<td>2nd</td>
<td>7</td>
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<td>Myanmar</td>
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<td>20.6</td>
<td>2nd</td>
<td>2998</td>
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<tr>
<td>Nepal</td>
<td>2332</td>
<td>19.0</td>
<td>1st</td>
<td>1367</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>1721</td>
<td>13.1</td>
<td>2nd</td>
<td>690</td>
</tr>
<tr>
<td>Thailand</td>
<td>8184</td>
<td>17.8</td>
<td>2nd</td>
<td>4513</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>46</td>
<td>13.3</td>
<td>3rd</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 per cent 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 2. 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 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 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.
Organized screening is more efficient and cost-effective than opportunistic screening.

**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.

### 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, able to provide results immediately (at point of care), acceptable to the women and inexpensive. There are a number of tests available for cervical cancer screening. (Fig. 1.2) The screening tests and their advantages and disadvantages are given in Table 1.2.

**Fig. 1.2: Screening tests for cervical cancer**

```
Screening tests

Cytology
  - Conventional
  - Liquid based

Visual techniques
  - VIA
  - VIIL

HPV detection
  - DNA detection
  - E6/E7 mRNA detection
```
Table 1.2: Different screening tests for cervical cancer and their advantages and disadvantages

<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 by a provider or by the woman herself using a brush or a swab. 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 within 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 by 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 providers to ensure satisfactory 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 |
### Liquid-based Cytology (LBC)

<table>
<thead>
<tr>
<th>a trained cytotechnician or pathologist</th>
<th>• Training and mechanisms for QC and QA are well established</th>
<th>• Requires functioning laboratory, storage facilities for slides and consumables</th>
<th>• Arrangement for specimen transport may be complex</th>
</tr>
</thead>
<tbody>
<tr>
<td>A provider collects cervical cells in a liquid preservative using a brush. The cells are spread and stained on slides to be examined by a trained cytotechnician or a pathologist</td>
<td>• Slides are easier to read and take less time</td>
<td>• Samples can also be used for molecular testing (such as for HPV DNA test)</td>
<td>• Results are not immediately available</td>
</tr>
<tr>
<td></td>
<td>• Training and mechanisms for QC and QA are well established</td>
<td></td>
<td>• Interpretation is subjective</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Supplies and laboratory facilities are more expensive than for conventional cytology</td>
<td>• Requires rigorous quality control at each step</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Other limitations are the same as for conventional cytology</td>
<td></td>
</tr>
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</table>

#### 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 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 country 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 National Cervical Cancer Screening Protocol?

The key points 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 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

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
</table>
| 1. Screening is defined as the 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 a screening test for cervical cancer?   | a) Pap test  
                       | b) VIA  
                       | c) Colposcopy  
                       | d) HPV DNA |
| 3. The following are advantages of HPV DNA testing over VIA, 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 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) An organized screening programme is less cost effective |

<table>
<thead>
<tr>
<th>Answer key</th>
</tr>
</thead>
</table>
| 1 – b      | 2 – c  
| 3 – c      | 4 – b  
| 5 – a      |
Module 2: Pathogenesis of cervical cancer with special reference to HPV infection

2.1. Module overview
This module is designed to train gynaecologists and non-specialist clinicians about how HPV infection leads to the development of cervical pre-cancer, which may progress to cervical cancer if left untreated. 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).

2.2. Module contents
• Risk factors for cervical cancer
• Epidemiology of HPV infection
• Mechanism of cervical carcinogenesis
• Natural history of cervical intra-epithelial neoplasia

2.3. 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;
• explain the natural history of cervical cancer originating from HPV infection.

2.4. Key points for discussion
2.4.1. Which categories of women are at a higher risk of developing cervical cancer?
• Women above the age of 40 years who have ever been sexually active
• Women whose sexual debut was 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 socio-economic strata of the society
• Women who have never been screened for cervical cancer
• Women who smoke
• Women who have lower genital tract infection with chlamydia/HSV
• HIV-infected women and women with poor immunity

The most important cause of cervical cancer is persistent infection with 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.

2.4.2. What is human papillomavirus (HPV)?

HPV is a double stranded DNA virus. Structurally the virus has two main components – a covering layer of surface protein and a double stranded DNA (containing genetic material) within. HPVs are classified into more than 200 different types based on the variations in the genetic make-up (genotypes). Depending on their potential to cause malignancy, 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. The covering layer (capsid) mostly comprises L1 (late) protein (Fig. 2.1) that is the target for the existing vaccines against the virus.

Fig. 2.1: Structure of the HPV virus
2.4.3. 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 women with high risk HPV infection do not develop cervical cancer, as the majority of infected women clear the infection through natural immunity. In fact, cervical cancer is a rare outcome of HPV infection. Women who are infected with HPV types 16 and 18 have significantly higher risk of having persistent infection and developing cervical cancer in the future as compared to those infected with other high risk types or noninfected women.

2.4.4. How does HPV infection spread?

HPV infection spreads through sexual contact. In fact, HPV 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 infected women clear the infection due to natural immunity that gradually overcomes the infection. It takes nearly 1 to 2 years to clear the HPV infection. Women who cannot clear the infection and have persistent 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. HPV is transmitted through fomites and also vertically from mother to the newborn.

2.4.5. What are the symptoms and signs of HPV infection?

HPV infection is asymptomatic. Symptoms appear only when the infection causes diseases like genital warts or cancer in its advanced stage. Similarly, there are no characteristic signs to detect the virus infection clinically until it leads to the development of genital warts or cervical neoplasias (pre-cancer or cancer).
2.4.6. How does HPV cause cervical cancer?

The HPV virus 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 nuclei of cells and the viral division is synchronized with epithelial cell division. As the epithelial cells divide, mature and move towards the surface, the replicating viruses also move with them and finally come out of the epithelium (Fig. 2.2). Since most women can clear the viral infection due to natural immunity, they do not develop cervical neoplasia. The malignant process starts if the infection is persistent and the viral DNA gets 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.

2.4.7. What are the precancerous conditions of the cervix?

Persistent HPV infection and unregulated division of the squamous cells of cervical epithelium lead to a precancerous condition known as cervical intraepithelial neoplasia (CIN), previously known as dysplasia. The neoplastic or the dysplastic cells are bigger in size and have large nuclei with more chromatin and irregular nuclear membrane. 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. 2.3).

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

CIN lesions do not always progress to cancer and many may spontaneously regress. While CIN 1 lesions rarely progress to invasive cancer, the possibility of progression of CIN 2 or CIN 3...
lesions is 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 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. 2.4).

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. 2.3: Grades of cervical intraepithelial neoplasia (CIN)
2.4.8. How to prevent HPV infection

HPV infection can be prevented by practising safe sex, avoiding multiple partners and regular use of condoms. HPV infection can also be prevented through vaccination of girls and boys before they initiate sexual activities. Two types of vaccines are available for the prevention of HPV infection (Table 2.1). Both the vaccines are highly effective, safe and protect against HPV 16 and 18, the most virulent types. Recently a 9-valent vaccine targeting nine HPV types has been launched. 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 that all girls should be vaccinated against HPV between the ages of 9 to 13 years. As vaccines do not protect against all types of HPV, screening is required later in life even among the vaccinated population.

Table 2.1: Characteristics of HPV vaccines

<table>
<thead>
<tr>
<th></th>
<th>Quadrivalent vaccine (Fig. 2.5a)</th>
<th>Bivalent vaccine (Fig. 2.5b)</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 muscle</td>
<td>0.5 ml, intramuscular, upper arm, deltoid muscle</td>
</tr>
<tr>
<td>Schedule at the WHO recommended age of 9 to 13 years</td>
<td>Two doses at 0 and 6 months</td>
<td>Two doses at 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. 2.5: The composition of bivalent (2.5a) and quadrivalent (2.5b) vaccines

(2.5 a) Bivalent vaccine

[Diagram showing the composition of a bivalent vaccine with HPV 16 VLPs, HPV 18 VLPs, Adjuvant (Al(OH)₃), and MPL (Monophosphoryl lipid).]

(2.5 b) Quadrivalent vaccine

[Diagram showing the composition of a quadrivalent vaccine with HPV 16 VLPs, HPV 18 VLPs, HPV 6 VLPs, HPV 11 VLPs, and Aluminium salt (amorphous aluminium hydroxyphosphate sulphate).]

VLP: Virus like particles; the artificially produced L1 protein self-assembles into the shape of a virus (the VLPs are non-pathogenic as they contain only the viral protein but no viral DNA).

Points to remember

- Infection from high risk HPV is a necessary but not sufficient cause of cervical cancer.
- HPV is a very common sexually transmitted virus and majority of 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 intraepithelial neoplasia (CIN) is the precancerous condition of the 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 an 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, 15, 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 progresses to cancer
   - b) In CIN 1, abnormal dysplastic cells are limited to the basal one third of epithelium
   - c) All CIN 2 lesions regress spontaneously
   - d) CIN 3 lesions do not need treatment

## Answer key

<table>
<thead>
<tr>
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<th>1</th>
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<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>a</td>
<td>d</td>
<td>a</td>
<td>a</td>
<td>c</td>
<td>b</td>
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</table>
Module 3: Counselling

3.1. Module overview

This module is designed to train gynaecologists and non-specialist clinicians in the art and techniques of counselling women attending the cervical cancer screening facilities for screening, diagnosis and treatment. The module is 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).

3.2. Module contents

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

3.3. Learning objectives

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

• understand the concept and the importance of counselling;
• counsel women prior to and after colposcopy;
• counsel women prior to and after treatment for cervical pre-cancers.

3.4. Key points for discussion

3.4.1 What is counselling?

Counselling is face-to-face, confidential communication in which the counsellor helps a client to make decisions and then act on them. Counselling during cervical cancer screening, colposcopy and treatment is essential to educate and inform women and help them to take an informed decision to undergo different procedures.

3.4.2 Why is counselling necessary for colposcopy and treatment?

Women referred for colposcopy are likely to have disease and may require treatment. Most of these women do not have any symptoms and are often reluctant to have any further procedures and treatment. They have poor understanding of the true implications of a positive screening test and the purpose of colposcopy and are often apprehensive about the procedures. Counselling
helps women to make informed decisions about participation and specially to undergo treatment, if necessary. Counselling also helps to overcome the embarrassment and anxiety associated with gynaecological check-ups, tests and procedures. Individual face-to-face counselling by the clinician is valuable in motivating women to undergo follow-ups if required and also to come back for the next round of screening. Thus, counselling ensures compliance to services, improves morale and self-esteem of the women by allowing them to take decisions for themselves.

3.4.3. How to be a good counsellor

A good counsellor should:

• 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 to those questions.
• Ask open-ended questions (that begin with who, what, where, when, why, or how) to encourage the woman to give more complete and meaningful responses.
• 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 and smiling and maintaining good eye contact throughout.
• Be sensitive to any cultural and religious considerations.
• Give the woman written information (if available and appropriate) to remind her of the instructions.

<table>
<thead>
<tr>
<th>Strategies for counselling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individual counselling</strong></td>
</tr>
<tr>
<td>- Ensures privacy</td>
</tr>
<tr>
<td>- Allows responding to personal questions</td>
</tr>
<tr>
<td>- Allows addressing specific needs</td>
</tr>
<tr>
<td><strong>Group counselling</strong></td>
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<tr>
<td>- Helps to raise general awareness about screening</td>
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<tr>
<td>- Maximizes time</td>
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<tr>
<td><strong>Couple counselling</strong></td>
</tr>
<tr>
<td>- Enables the male partner to provide necessary support</td>
</tr>
<tr>
<td>- Allows the woman to discuss matters freely with her partner</td>
</tr>
</tbody>
</table>

Group counselling

Individual counselling

Couple counselling
3.4.4. What messages should be conveyed to a woman while counselling her for colposcopy and treatment?

A woman who has attended a colposcopy clinic for colposcopy, and treatment if required, should be given the following information:

- Reasons for the examination and its importance in preventing cervical cancer
- The examination procedure step-by-step
- The discomfort that she may experience during and after the procedure
- The necessity of treatment if indicated
- Treatment procedures
- Possible discomfort during treatment and potential treatment complications
- Consequences of not being tested and/or treated
- That she will have to give consent to the procedures

Ensure privacy during counselling to protect the dignity of the woman and to encourage her to communicate freely.

3.4.5. What are the steps of counselling?

See Skills Checklists 3.6.1, 3.6.2 and 3.6.3

3.5. Group learning activities

3.5.1. Role play

Counselling cards and flip chart should be used for role plays

Role play 1: Counselling a woman with positive VIA test to undergo colposcopy

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Pen-chan, a 30-year-old woman having one child, who has attended the clinic at the district hospital for colposcopy
  - Kulap, a doctor who performs colposcopy at the district hospital
  - Sukhon, a nurse at the district hospital to whom Pen-chan reports before seeing the doctor
- The entire group including the role players should know the following background situation:
At the primary health centre, Pen-chan has been advised to have colposcopy in view of VIA positivity. She has been told that colposcopy is necessary to confirm or exclude the presence of disease. She is very apprehensive that the test may be painful and has strong fears of getting a diagnosis of cancer.

Focus of the role play

The focus of the role play is the interaction between a doctor and a woman seeking colposcopy. Sukhon will first go through Pen-chan’s records and confirm that colposcopy is necessary for her. Sukhon guides Pen-chan to Dr Kulap for colposcopy. Dr Kulap makes Pen-chan feel comfortable and then assesses her knowledge about cervical cancer and its early detection through screening. Dr Kulap explains the necessity of colposcopy in view of Pen-chan’s VIA positivity and tells her about the possibility of underlying pre-cancer or cancer. The doctor also informs that the disease, if detected, can be treated and arrangements will be made for that. Dr Kulap then explains the procedure in simple language and reassures Pen-chan that the test is not painful but she may experience some discomfort. Dr Kulap also explains that she will do the treatment if she finds it necessary after doing the colposcopy. She also briefly describes the treatment procedure. To alleviate the fear of cancer in Pen-chan’s mind, Dr Kulap explains that there is a small possibility of getting a cancer diagnosis. However, by undergoing colposcopy Pen-chan will have the benefit of getting the disease diagnosed at an early stage when treatment can cure the cancer. The test and subsequent treatment will ensure a long life to Pen-chan. Dr Kulap thanks Pen-chan for her time.

Time allotted for the role play: 10 minutes

Role play 2: Counselling a woman with normal colposcopy findings

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Radha, a 35-year-old woman having three children, who has undergone colposcopy at a district hospital
  - Uma, a doctor who performs colposcopy at the district hospital
  - Rama, an accompanying community health worker
- The entire group including the role players should know the following background situation:
  - Radha underwent colposcopy at the district hospital because she had a positive VIA test result. Her colposcopy report is normal. She is being reassured by
Focus of the role play

The focus of the role play is the interaction between a doctor and a woman who has undergone colposcopy. Uma, the doctor will take Radha to her consulting chamber after performing colposcopy and tell her the findings of colposcopy. Radha wants Rama to be present when her reports are discussed. Uma informs them that VIA is a screening test and it may be positive even in the absence of a precancerous lesion. However colposcopy is done under magnification and is a diagnostic test. It is a better test and in Radha's case, the findings of colposcopy suggest that she does not have any condition that may cause cancer in future, though such condition was suspected on VIA. Hence, she can go back home as she does not require any further treatment. However, she should report to the centre for repeat screening by VIA after 5 years. At this point, Rama informs Radha's about the nearby healthcare facilities where such screening services are available. She asks Radha to avail of the services at the prescribed interval even though she has tested negative at this visit. She also asks Radha to keep her screening card and colposcopy records safely for future references. Uma thanks Radha for her time.

Time allotted for the role play: 10 minutes

Role play 3: Counselling a woman who has suspected high grade lesion on colposcopy and requires LEEP

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Catherine, a 37-year-old woman having two children, who has undergone colposcopy at the district hospital as she was HPV test positive
  - Mary, a doctor who performs colposcopy at the district hospital
  - Peter, Catherine's partner who accompanies her
- The entire group including the role players should know the following background situation:
  
  *At the primary health centre, Catherine has been advised to have colposcopy in view of her positive HPV test. She undergoes colposcopy at the district hospital. Her*
Focus of the role play

The focus of the role play is the interaction between a doctor and a woman who has undergone colposcopy and has been detected to have cervical pre-cancer. Dr Mary takes Catherine to her consulting chamber to discuss the results of her colposcopy and the recommended plan of action. She also asks Peter to be present during this counselling session. Dr Mary shares the findings of colposcopy with Catherine and Peter. She reassures them that Catherine does not have cervical cancer but is suspected to have a change of the cervix that may turn into cancer after 5 to 10 years if not treated. She informs them that the treatment is very simple, will not require hospital admission, will not take much time and that Catherine will be able to go home today itself after treatment. She explains, in brief, that the planned treatment is known as LEEP and involves removal of a small portion of the cervix including the precancerous area. She informs them that the treatment is very effective with very high possibility of complete cure. She explains in detail the probable problems and complications Catherine may encounter after this procedure. She tells Catherine and Peter about the precautions after treatment and the necessity of follow-up after 1 year. Dr Mary informs them that the treatment procedure necessitates Catherine to give consent for the procedure. Peter asks if removing the uterus by surgery will be a better option. Dr Mary explains that hysterectomy is not necessary for this condition, does not have any additional benefit and has much higher rates of immediate or long term complications.

Dr Mary thanks Catherine and Peter for their time.

Time allotted for the role play: 10 minutes

Role play 4: Counselling a woman who has suspected invasive cancer on colposcopy and needs referral to an oncology centre

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Rehana, a 48-year-old woman with five children, who has undergone colposcopy at the district hospital
  - Afroza, a doctor who performs colposcopy and treatment procedures at the district hospital
  - Fatima, a nurse at the district hospital
- The entire group including the role players should know the following background situation:
  At the primary health centre, Rehana has been advised to have colposcopy as her VIA test result was suspicious of invasive cancer. She attends the district hospital where Dr Afroza performs colposcopy and suspects cervical cancer.
Focus of the role play

The focus of the role play is the interaction between a doctor who performs colposcopy at a district hospital and a woman who has undergone colposcopy and needs referral to an oncology hospital. After the procedure, Dr Afroza asks Rehana to accompany her to the consulting chamber to discuss the results of her colposcopy. Doctor asks Rehana if she would like to have any member of her family or friends to be present during discussion. Rehana wants Fatima to be present as Fatima has been known to her for a long time. Dr Afroza informs Rehana that there is a very high possibility that the change in her cervix is cancer. At the same time the doctor explains that the cancer is most likely at a very early stage and appropriate and prompt treatment will cure the disease. Dr Afroza refers Rehana to a cancer centre as the district hospital does not have adequate facilities to treat her. She explains to Rehana that a very small piece of tissue from the affected area will be taken for confirmation of diagnosis following which the treatment procedure will start. She also discusses the probable investigations and treatment procedures that Rehana may need to undergo after confirmation of diagnosis. Dr Afroza identifies and addresses Rehana’s concerns, doubts and fears regarding the treatment procedures. Rehana is asked to repeat the important messages to make sure she has understood all that has been discussed. At this point, Fatima tells Rehana about the location of the hospital and how to reach it. Fatima also informs Rehana about the registration time and registration procedures at the oncology hospital. Rehana is provided with the referral form. Fatima again reassures Rehana and tells her that she should reach the oncology centre within 1 week without fail. Dr Afroza thanks Rehana for her time.

Time allotted for the role play: 10 minutes

3.6. Skill development

3.6.1. Steps for counselling a woman for colposcopy (colposcopy is normal)

<table>
<thead>
<tr>
<th>Skills Checklist: Counselling skills for colposcopy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps</strong></td>
</tr>
<tr>
<td>Counselling prior to colposcopy</td>
</tr>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
</tr>
<tr>
<td>2. Explain the screening test result and its implication</td>
</tr>
</tbody>
</table>
3. Explain the necessity of colposcopy to confirm the presence or absence of disease

4. Describe how colposcopy will be done and the possible results

5. Give information about the possibility of obtaining biopsy or treatment

6. Explain the treatment options and the treatment procedures that may be required

7. Reassure the woman that the colposcopy procedure causes minimum discomfort

8. Inform the woman that the procedure will take a longer time and the discomfort may be a little more, if treatment is done

9. Explain the expected side effects and potential complications of treatment, in brief

10. Respond to the woman’s possible concerns

Post-colposcopy counselling: Colposcopy is normal

11. Help the woman to get up from the table and be comfortably seated

12. Discuss the results of colposcopy and the significance of a normal test result

13. Tell her when and where to go for the next screening

14. Assure her that she can return to the clinic for any medical advice or attention if required

15. Maintain your record

*The highlighted steps are considered critical

Score achieved: 

Facilitator’s signature

Facilitator’s remarks
3.6.2. Steps for counselling a woman for colposcopy (colposcopy is abnormal and the woman needs LEEP)

<table>
<thead>
<tr>
<th>Steps</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselling prior to colposcopy</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
<td></td>
</tr>
<tr>
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</tr>
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<tr>
<td>5. Give information about the possibility of obtaining a biopsy or treatment</td>
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<tr>
<td>6. Explain the treatment options and treatment procedures that may be required</td>
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<td>7. Reassure the woman that the colposcopy procedure causes minimum discomfort</td>
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<tr>
<td>9. Explain the expected side effects and potential complications of treatment, in brief</td>
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<tr>
<td>10. Respond to the woman’s possible concerns</td>
<td></td>
</tr>
<tr>
<td>Post colposcopy counselling: Colposcopy is abnormal and LEEP is necessary</td>
<td></td>
</tr>
<tr>
<td>11. After completing colposcopy, ask the woman if she is more comfortable discussing the test results while lying down or sitting up on the table</td>
<td></td>
</tr>
<tr>
<td>12. Inform the woman about colposcopy findings and the significance of positive results</td>
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<tr>
<td>13. Give her detailed information about how treatment will benefit her</td>
<td></td>
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<tr>
<td>14. Give detailed information about the LEEP procedure</td>
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<tr>
<td>15. Explain the side effects she may experience during and after the procedure</td>
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<tr>
<td>16.</td>
<td>Encourage the woman to ask questions and respond with care</td>
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<tr>
<td>17.</td>
<td>Give the woman some time to decide</td>
</tr>
<tr>
<td>18.</td>
<td>Obtain informed consent for LEEP</td>
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<tr>
<td>Post-LEEP counselling</td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td>Provide the woman with instructions for self-care at home</td>
</tr>
<tr>
<td>20.</td>
<td>Inform her that she should seek medical attention if she experiences the following within 4 weeks of treatment:</td>
</tr>
<tr>
<td></td>
<td>• Fever with shaking chills and/or &gt;38 °C</td>
</tr>
<tr>
<td></td>
<td>• Foul smelling purulent discharge</td>
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<tr>
<td></td>
<td>• Severe lower abdominal pain/cramps</td>
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<tr>
<td></td>
<td>• Vaginal bleeding &gt;2 days or with clots other than expected menstrual bleeding</td>
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<tr>
<td>21.</td>
<td>Provide instructions for using condoms/sanitary pads (if supplied)</td>
</tr>
<tr>
<td>22.</td>
<td>Ensure that the woman has understood the instructions fully</td>
</tr>
<tr>
<td>23.</td>
<td>Answer any questions the woman may ask</td>
</tr>
<tr>
<td>24.</td>
<td>Schedule a follow-up visit</td>
</tr>
</tbody>
</table>

*The highlighted steps are considered critical*

Score achieved: Facilitator's signature

Facilitator's remarks
3.6.3. Steps for counselling a woman for colposcopy (invasive disease is suspected on colposcopy)

<table>
<thead>
<tr>
<th>Steps</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
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</tr>
<tr>
<td>2. Explain the screening test result and its implication</td>
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</tr>
<tr>
<td>3. Explain the necessity of colposcopy to confirm the presence or absence of disease</td>
<td></td>
</tr>
<tr>
<td>4. Describe how colposcopy will be done and the possible results</td>
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<tr>
<td>5. Give information about the possibility of obtaining biopsy or treatment</td>
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<tr>
<td>9. Explain the expected side effects and potential complications of treatment, in brief</td>
<td></td>
</tr>
<tr>
<td>10. Respond to woman’s possible concerns</td>
<td></td>
</tr>
</tbody>
</table>

Post colposcopy counselling: Cancer is suspected on colposcopy

<table>
<thead>
<tr>
<th>Steps</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Help the woman to get up from the table and be comfortably seated</td>
<td></td>
</tr>
<tr>
<td>12. Express concerns about the test findings and ask the woman if she would like to have any of her relatives or friends with her</td>
<td></td>
</tr>
<tr>
<td>13. Inform the woman about the colposcopy findings and their implications</td>
<td></td>
</tr>
<tr>
<td>14. Reassure the woman that appropriate treatment for the condition is available and arrangements will be made for that</td>
<td></td>
</tr>
</tbody>
</table>
15. Emphasize the fact that early treatment is most crucial

16. **Give detailed and specific information on the referral centre that she needs to visit for treatment**

17. If biopsy has been taken during colposcopy, inform the woman about the date and place from where the biopsy report needs to be collected

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

*The highlighted steps are considered critical*

Score achieved:  
Facilitator’s signature

### Points to remember

- Counselling is face-to-face, confidential communication.
- Counselling can be group, individual or couple counselling.
- The woman should be given information that is adequate, specific and relevant to her particular situation.
- 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 way, develop a cordial relationship, and assure her that the conversation is confidential.
- Use supportive nonverbal communication, such as nodding and smiling and maintain good eye contact all along.
- Be sensitive to any cultural and religious considerations.
Multiple choice questions

1. Counselling should involve all, except:
   a) Confidentiality
   b) Privacy
   c) Use of open-ended questions
   d) Continuous use of medical terminology

2. During counselling prior to colposcopy, the client should be told about:
   a) Need for colposcopy to confirm the presence of disease
   b) Available treatment options if colposcopy is abnormal
   c) Possibility of the woman experiencing some discomfort during the procedure
   d) All of the above

3. The true statement about counselling prior to colposcopy is:
   a) Counselling involves face-to-face communication
   b) Counselling is optional and depends on the client’s education
   c) Women may get scared due to counselling and opt out of colposcopy
   d) During counselling, women should not be told about treatment side effects

4. While counselling a woman with colposcopy findings suspicious of invasive cancer, she should be told about all, except:
   a) Need for collecting a biopsy report
   b) A specific referral centre
   c) Necessity of early treatment
   d) Cancer is infectious and the woman should stay away from children

5. Which of the following is a false statement about post-LEEP advice?
   a) Abstinence for 4 weeks
   b) Report immediately if slight bleeding occurs
   c) Use sanitary napkins
   d) Report if purulent vaginal discharge occurs

Answer key
1 – d  2 – d  3 – a
4 – d  5 – b
Module 4: Principles of colposcopy

4.1. Module overview

This module is designed to train gynaecologists and non-specialist clinicians on the basic principles of colposcopy. Understanding the physiological and pathological changes on the cervix and how they can influence the colposcopic appearance is essential to perform and decide on further management. 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 5.4 and Practice Sheets 5.8 and 5.9).

4.2. Module contents

• Introduction to colposcopy
• Microscopic features of epithelium of the cervix
• Squamocolumnar junction and its importance
• Squamous metaplasia
• Transformation zone (TZ):
  a) Identification of TZ
  b) Features of TZ
  c) Types of TZ
• Vascular patterns
• Role of acetic acid
• Role of Lugol’s iodine
• Group learning activities
  ▪ Digital image recognition

4.3. Learning objectives

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

• understand the gross and microscopic anatomy of the cervix;
• explain the significance of identification of squamocolumnar junction;
• describe the physiology of the transformation zone of cervix;
• identify various vascular patterns of the cervix;
• describe the role of acetic acid and Lugol’s iodine in colposcopy.
4.4. Key points for discussion

4.4.1. What is colposcopy?

A colposcope is a tool to examine the lower genital tract under stereoscopic binocular vision using variable magnification that ranges from 4x to 30x. It has a powerful variable intensity light source to illuminate the area being examined. While performing colposcopy of the cervix, a colposcopist aims to differentiate between normal cervix, non-neoplastic conditions, low grade neoplasias, high grade neoplasias and invasive lesions. Disease categorization is based on the changes observed on the cervical epithelium after cleaning the cervix with normal saline and subsequent application of 5% acetic acid for at least 1 minute and painting the cervix with 5% Lugol’s iodine. The final diagnosis is made after synthesizing all the findings.

Colposcopy is not a screening test. It is a diagnostic tool to evaluate women with positive screening tests for cervical cancer.

4.4.2. What are the microscopic features of normal cervical epithelium?

The ectocervix (externally visible part of the cervix) is generally lined by non-keratinized stratified squamous epithelium. The epithelium has multiple (15–20) layers of cells and is separated from the stroma by the basement membrane. The squamous epithelium is divided into basal, parabasal, intermediate and superficial layers (Fig. 4.1a). The basal layer is a single row of round or cuboidal cells with large dark-staining nuclei and little cytoplasm that rests on the basement membrane. Basal cells divide to form parabasal cells, which in turn divide and differentiate into intermediate and superficial cells. Overall, from the basal to the superficial layer, the squamous epithelial cells become more flat, larger in size and have smaller nuclei.

Fig. (4.1 a): Microscopic features of normal squamous epithelium
Cells of the superficial and intermediate layer contain abundant glycogen in their cytoplasm under oestrogenic influence. If oestrogen is lacking, full maturation and glycogenation does not take place. Hence, after menopause, cells do not mature beyond the parabasal layer and the epithelium lacks glycogen.

The endocervix extending from the internal to the external os of cervix is lined by mucin-secreting columnar epithelium (Fig. 4.1b). The columnar epithelium is composed of a single layer of tall cells with dark-staining nuclei close to the basement membrane. The columnar epithelium is thrown into multiple longitudinal folds protruding into the lumen of the canal, giving rise to papillary (finger-like) projections. It forms several invaginations into the substance of the cervical stroma, resulting in the formation of endocervical crypts (sometimes referred to as endocervical glands). The crypts lined by columnar epithelium may extend up to 5 mm into the stroma from the surface of the cervix. Cells of the columnar epithelium do not contain glycogen.

Fig. (4.1 b): Microscopic features of normal columnar epithelium

4.4.3. What is the squamocolumnar junction (SCJ) and what is its significance?

The junction between the stratified squamous epithelium of the ectocervix and the columnar epithelium of the endocervix is called the squamocolumnar junction (SCJ) (Fig. 4.2). The SCJ is visualized as a sharp border due to the difference in the height of the two types of epithelia. The position of SCJ is influenced by age (Fig. 4.3) hormonal status, birth trauma, oral contraceptive use and pregnancy. 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. Visualization of the SCJ in its entirety is very crucial in colposcopy to detect early neoplasias.
Fig. 4.2: Histopathology of the squamocolumnar junction

(a) Squamous epithelium
(b) Squamocolumnar junction Columnar epithelium

Photo courtesy PGIMER, Chandigarh, India

Fig. 4.3: Changes in location of SCJ with age

(a) Before menarche
(b) After puberty and during early reproductive age
4.4.4. What is ectropion?

Ectropion results from the eversion of the columnar epithelium onto the ectocervix. The cervix grows rapidly under the influence of oestrogens after menarche and during pregnancy. As a consequence the SCJ moves out on the ectocervix and the columnar epithelium becomes visible on the ectocervix (Fig. 4.4). This condition is also known as ectopy. Ectropion appears as a red congested area on the ectocervix surrounding the external os on speculum examination.

4.4.5. What is squamous metaplasia?

Metaplasia is a physiological condition that refers to the replacement of one type of epithelium by another type. The process of metaplasia starts when columnar cells of the cervical ectropion get exposed to the acidic environment of the vagina. This causes proliferation of reserve cells underlying the columnar epithelium. The proliferating reserve cells that eventually replace the columnar cells on the ectocervix are called metaplastic cells. The metaplastic cells give rise to mature squamous epithelium with advancing age of the woman. This process through which the columnar epithelium lining the ectocervix is gradually replaced with squamous epithelium is called metaplasia of the cervix (Fig. 4.5).
4.4.6. What is the transformation zone?

The area of the cervix where columnar epithelium has been replaced or is in the process of being replaced by metaplastic squamous epithelium is referred to as the transformation zone (TZ). Squamous metaplasia usually begins at the original SCJ at the distal limit of the ectropion and gradually moves inwards (centripetally) towards the external os. The SCJ as a result also moves towards the external os. The TZ is the area between the original SCJ and the new SCJ (SCJ visible during colposcopy) formed as a result of metaplasia (Fig. 4.6).

Examination of the TZ is of great importance because almost all cervical pre-cancers and squamous cell carcinomas occur in this area. The whole TZ should be carefully observed during colposcopic examination before interpretation of the result. Correct identification of the extent of the TZ is crucial to make decisions regarding treatment of cervical pre-cancers.

Fig. 4.6: Transformation zone of the cervix
4.4.7. What are the features of a normal transformation zone?

The features of normal TZ are as follows:

- Immature metaplasia characterized by tongue like projections of thin transparent newly formed squamous epithelium (Fig. 4.5b).
- Crypt openings that appear as small black dots (Fig. 4.7a).
- Nabothian cysts formed due to the blockage of the crypt openings by the metaplastic epithelium. These are white or yellow coloured cysts (pimples) on the cervix (Fig. 4.7b).
- Islands of columnar epithelium not yet covered by metaplastic epithelium ‘skip areas’ (Fig. 4.7c).
- The position of the crypt opening or the nabothian cyst farthest from the SCJ helps to identify the distal limit of the TZ (the proximal limit of the TZ is always the SCJ).

Fig. 4.7: Features of the transformation zone

<table>
<thead>
<tr>
<th>Crypt opening</th>
<th>Nabothian cyst</th>
<th>Island of columnar epithelium</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>b)</td>
<td>c)</td>
</tr>
</tbody>
</table>

Reproduced with permission from Atlas of Colposcopy and Management of Cervical Pre-cancers. IARC, Lyon. (Forthcoming)

4.4.8. What are the types of TZ?

Depending on the location of the SCJ, the TZ is designated as any of the following types:

- TZ Type 1: The TZ is completely ectocervical. SCJ is fully visualized either at the external os or on the ectocervix (Fig. 4.8a).
- TZ Type 2: The TZ is fully visible with an endocervical component. The SCJ is fully visualized but is located in the endocervical canal fully or partially (Fig. 4.8b).
- TZ Type 3: The TZ is not fully visible. The SCJ is within the endocervical canal and is only partially visualized or not visualized at all (Fig. 4.8c).

The approach to treat a precancerous lesion of the cervix depends on the type of TZ. This has been discussed in detail later in the Trainees' handbook.
Fig. 4.8: Classification of the transformation zone

a)* Type 1 Transformation zone

b)* Type 2 Transformation zone

c) Type 3 Transformation zone

*Reproduced with permission from Atlas of Colposcopy and Management of Cervical Pre-cancers. IARC, Lyon. (Forthcoming)

4.4.9. How to distinguish between normal and abnormal blood vessel patterns

- The vascular architecture of the cervix is better visualized after application of normal saline and using a green/blue filter.
- Normal blood vessels have a branching pattern with a central stem from which smaller branches spread out (Fig. 4.9a).
- A network of capillaries or fine hairpin like blood vessels may be visible at the periphery of the cervix.
• The network of interconnecting blood vessels running parallel to the surface of the epithelium resulting in a cobble-stone appearance on colposcopy is called mosaic (Fig. 4.9b). Mosaics can be fine or coarse.

• In fine mosaic, the capillaries are fine and uniform in calibre and disposition.

• In coarse mosaic, the blood vessels are prominent, irregular in calibre and are absent at places (Fig. 4.9c).

• While fine mosaic is commonly seen in immature metaplasia, HPV lesions or low grade lesions, coarse mosaic is the hallmark of high grade lesions or cancer.

• A zone of red dots representing stromal papillae and blood vessel loops reaching the surface epithelium and producing a stippling appearance is known as punctation (Fig. 4.9b). Punctations can be fine or coarse in nature.

• In fine punctuation the capillaries are fine and evenly distributed.

• In coarse punctuation the red dots are prominent, raised from the surface, irregularly spread and may bleed at touch (Fig. 4.9c).

• Fine punctations are commonly seen in an inflamed cervix, immature metaplasia and low grade lesion while coarse punctations signify high grade lesions or cancer.

• Atypical blood vessels have bizarre shapes, no definite branching patterns and unequal thickness (Fig. 4.9d). They are often raised from the surface, shiny and easily bleed at touch.

In post-menopausal women the cervical epithelium is thin and there may be subepithelial bleeding due to trauma to the stromal blood vessels. Such bleeding points are called petechial haemorrhagic spots and can be confused with punctations (Fig. 4.8c).

Fig. 4.9: Normal and abnormal vascular patterns
4.4.10. How does acetic acid help in detecting lesions?

During the colposcopy procedure freshly prepared 5% acetic acid is applied to the cervix for 1 minute. The acetic acid causes reversible coagulation and precipitation of cellular proteins that may make the epithelium white and opaque. The effect of the acetic acid depends upon the amount of cellular proteins present in the epithelium. In normal squamous epithelium, the superficial layers of cells are almost devoid of protein as the nuclei are very small, contain very little chromatin and the cytoplasm is replaced by glycogen. When acetic acid is applied to the normal squamous epithelium, there is little protein to coagulate and there is no change in colour (Fig. 4.11a). Areas of CIN and invasive cancer undergo maximal coagulation due to their high

Fig. 4.11 a: Before and after application of acetic acid: No acetowhite areas
content of cellular and nuclear protein (in view of the large number of undifferentiated cells contained in the epithelium). The higher the grade of CIN, the higher is the concentration of abnormal cellular and nuclear protein and more dense is the acetowhiteness (Fig. 4.11b).

Fig. 4.11 b: Before and after application of acetic acid: Acetowhite area is visible

<table>
<thead>
<tr>
<th>Acetowhiteness due to</th>
<th>Acetowhiteness due to conditions other than CIN/cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIN/cancer</td>
<td></td>
</tr>
<tr>
<td>More dense</td>
<td>Less dense, pale, often translucent</td>
</tr>
<tr>
<td>Thick and opaque with well demarcated margins</td>
<td>Patchy with ill-defined margins</td>
</tr>
<tr>
<td>Restricted to the TZ</td>
<td>May be distributed widely in the cervix</td>
</tr>
<tr>
<td>Appears quickly, persists for more than 1 minute</td>
<td>Quickly disappears, usually within 30–60 seconds</td>
</tr>
</tbody>
</table>

4.4.11. How does Lugol’s iodine help in detecting lesions?

Application of iodine solution results in uptake of iodine in glycogen-containing epithelium due to the affinity of iodine to glycogen. The normal glycogen-containing squamous epithelium stains mahogany brown or black after application of iodine. CIN and invasive cancer, condylomas, columnar epithelium, immature squamous metaplastic epithelium, leukoplakic areas and inflammatory conditions of the squamous epithelium contain little or no glycogen. Such conditions do not stain with iodine solution (Fig. 4.12).
4.5. Group learning activities

Digital image recognition

- Identification of squamous epithelium, columnar epithelium and SCJ
- Identification of TZ and types of TZ
- Distinguishing between normal and atypical vascular patterns

Points to remember

- A colposcope is a tool to examine the lower genital tract under stereoscopic vision using variable magnification.
- The area of the cervix where the columnar epithelium has been replaced by the metaplastic squamous epithelium is referred to as the transformation zone.
- Type 1 TZ is completely ectocervical, SCJ is fully visualized either at the external os or on the ectocervix.
- Type 2 TZ is fully visible with an endocervical component, SCJ is fully visualized but is located fully or partially in the endocervical canal.
- Type 3 TZ is not fully visible, SCJ is within the endocervical canal and is only partially visualized or not visualized at all.
- Normal blood vessels have a branching pattern with a central stem from which smaller branches spread out.
- Atypical blood vessels have bizarre shapes, no definite branching patterns and unequal thickness.
Multiple choice questions

1. Colposcopy involves all, except:
   a) Visualization of the cervix without magnification
   b) Differentiation between normal cervix, low grade and high grade precancerous lesions
   c) Visualization of the cervix after application of 5% acetic acid
   d) Visualization of the cervix after application of Lugol's iodine

2. Which of the following statements is true?
   a) Ectropion is a result of precancerous lesions of the cervix
   b) Ectropion is eversion of columnar epithelium onto the ectocervix
   c) Ectropion is formed under the influence of progesterone
   d) Ectropion, unless treated, may cause cervical cancer

3. Which of the following statements is false about the TZ?
   a) Most pre-cancers/cancer of cervix arise from the TZ
   b) Crypt openings are normal findings of the TZ
   c) TZ is fully visible is Type 3 TZ
   d) The whole of TZ should be visible for satisfactory colposcopy

4. Which of the following statements is false?
   a) Fine punctations are indicative of high grade lesions
   b) Fine mosaic is seen in immature metaplasia
   c) Atypical vessels have bizarre shapes with no definite branching pattern
   d) Vasculature is better visualized using a green filter

5. Acetowhite appearance can be seen in the following:
   a) Metaplastic epithelium
   b) Condyloma
   c) Precancerous lesion of the cervix
   d) All the above

Answer key
1 – a
2 – b
3 – c
4 – a
5 – b
Module 5: Instrumentation and technique of colposcopy

5.1. Module overview

This module is designed to train gynaecologists and non-specialist clinicians on the correct technique of performing colposcopy step-by-step. Trainees will also learn the interpretation of colposcopic findings and documentation using correct colposcopic terminology. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Chapter 5 – Screening for cervical cancer, Section 5.4 and Practice Sheet 5.8 and 5.9).

5.2. Module contents

- Indications of colposcopy
- Instruments required
- Consumables required
- Steps of colposcopy
- Procedure of colposcopy guided cervical biopsy
- Interpretation of colposcopy findings
- Documentation of colposcopic findings
- Post-colposcopy tasks
- Common problems in colposcopy
- Group learning activities:
  - Digital image recognition
  - Preparation of dilute acetic acid
  - Preparation of Lugol’s iodine
  - Preparation of Monsel’s paste
- Checklist for steps of colposcopy
- Checklist for counselling steps

5.3. Learning objectives

By the end of this module, trainees will be able to:
- efficiently organize colposcopy services;
- perform colposcopy competently;
- use correct colposcopic terminology;
- interpret colposcopic findings and make provisional diagnosis;
- identify cases for appropriate management;
- counsel women before and after colposcopy.
5.4. Key points for discussion

5.4.1. What are the indications for colposcopy?

- Women positive on any screening test for cervical cancer
- Suspicious cervix on visual examination
- Assessment of lesions prior to treatment
- Post-treatment follow-up
- Persistently unsatisfactory cytology
- Women with symptoms suggestive of invasive cancer (post-coital bleeding, intermenstrual bleeding, post-menopausal bleeding, etc)

5.4.2. What are the parts of a colposcope?

Colposcope is an instrument used to examine the cervix and other parts of the lower genital tract (Fig. 5.1). There are three essential parts to the colposcope.

- Head containing the optics
- Light source
- Body

Parts of the colposcope head (Fig. 5.1b)

- Two eyepieces to be adjusted according to the colposcopist’s eye position that may be focussed by turning the dioptr e ring
- Green filter to visualize blood vessels in a better way
- Focus adjustment knob
- Magnification changer

The light source is usually a halogen or LED light source

The body of the colposcope comprises a base and the height adjustment facility.

Fig. 5.1: Binocular colposcope and digital video colposcope

*Reproduced with permission from Atlas of Colposcopy and Management of Cervical Pre-cancers. IARC, Lyon. (Forthcoming)
5.4.3. What are the instruments and consumables required for colposcopy?

<table>
<thead>
<tr>
<th>Instruments/equipment required for colposcopy</th>
<th>Consumables required for colposcopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Examination table</td>
<td>• Gloves (sterile/gloves after high-level disinfection/disposable)</td>
</tr>
<tr>
<td>• Screen to ensure privacy</td>
<td>• Sterile cotton swabs, cotton swab sticks</td>
</tr>
<tr>
<td>• Focusing light</td>
<td>• Normal saline</td>
</tr>
<tr>
<td>• Colposcope</td>
<td>• Dilute acetic acid (5%) solution (freshly prepared)</td>
</tr>
<tr>
<td>• Colposcopy instrument tray containing:</td>
<td>• Lugol’s iodine</td>
</tr>
<tr>
<td>- Kidney tray</td>
<td>• Monsel’s solution/paste</td>
</tr>
<tr>
<td>- Gallipot</td>
<td>• 10% formaldehyde</td>
</tr>
<tr>
<td>- Self-retaining vaginal specula</td>
<td>• Lubricant jelly</td>
</tr>
<tr>
<td>- Vaginal side-wall retractor</td>
<td>• Waste disposal bag</td>
</tr>
<tr>
<td>- Sponge-holding forceps</td>
<td>• Case record forms</td>
</tr>
<tr>
<td>- Endocervical speculum</td>
<td>• 0.5% chlorine solution</td>
</tr>
<tr>
<td>- Endocervical curette</td>
<td></td>
</tr>
<tr>
<td>- Téischler’s punch biopsy forceps</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 5.2: Colposcopy requirements
5.4.4. What are the steps of colposcopy?

Please refer to checklist 5.6.1

5.4.5. What are the steps of a colposcopy directed biopsy?

- Use low power magnification to obtain a panoramic view of the cervix
- Select the biopsy site from the area with maximum disease severity
- Obtain multiple biopsies if the lesion is in multiple quadrants
- Sample the posterior cervical lip first to prevent obscuring due to bleeding
- Position the biopsy forceps directly over the lesion to be biopsied
- Orient the opened biopsy forceps in such a way that the fixed jaw end of the forceps is placed close to or within the os
- Hold the biopsy instrument handles upside down while taking a biopsy from the posterior lip
- To prevent slipping of the forceps from the biopsy site push the cervix backwards with the open biopsy forceps as much as possible
- Quickly squeeze the forceps handles together while asking the patient to cough
- Lock the jaws of the forceps and pass it to the assistant
- Confirm colposcopically that the intended area has been adequately sampled
- Secure haemostasis by applying Monsel’s paste for 30–60 seconds
- After colposcopy directed biopsy, endocervical curettage is to be performed if:
  - SCJ is not completely visible
  - Lesion extends into the endocervical canal
5.4.6. How to document colposcopy findings

The following IFCPC 2011 colposcopy reporting format is to be used to document colposcopy findings.

<table>
<thead>
<tr>
<th>General assessment</th>
<th>Normal colposcopic findings</th>
<th>General principles</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adequate/inadequate (reason):</td>
<td>Original squamous epithelium:</td>
<td>Location of the lesion: Inside TZ / outside TZ / both inside and outside TZ:</td>
</tr>
<tr>
<td>• SCJ visible: Completely visible/partially visible/not visible</td>
<td>• Mature</td>
<td>• Clock position (Please mark below)</td>
</tr>
<tr>
<td>• Transformation zone: 1 / 2 / 3</td>
<td>• Atrophic</td>
<td>• Number of quadrants involved: 1 / 2 / 3 / 4</td>
</tr>
<tr>
<td></td>
<td>Columnar epithelium:</td>
<td>• Size of lesion: &lt;25% / 25–50% / 50–75% / &gt;75%</td>
</tr>
<tr>
<td></td>
<td>• Ectopy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Metaplastic squamous epithelium:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Nabothian cysts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Crypt openings</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Abnormal colposcopic findings</th>
<th>Grade 1 (minor)</th>
<th>Grade 2 (major)</th>
<th>Non-specific</th>
<th>Suspicious for invasion</th>
<th>Miscellaneous finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thin AW epithelium</td>
<td>Dense AW epithelium</td>
<td>Leukoplakia</td>
<td>Atypical vessels/fragile vessels/irregular surface/exophytic lesion, necrosis/ulceration (necrotic)/tumour/gross neoplasm</td>
<td>CTZ</td>
<td>Stenosis</td>
</tr>
<tr>
<td>Irregular, geographic border</td>
<td>Rapid appearance of acetowhitening</td>
<td>Erosion</td>
<td></td>
<td>Condyloma</td>
<td>Congenital anomaly</td>
</tr>
<tr>
<td></td>
<td>Cuffed crypt openings</td>
<td>Lugol's staining (Schiller's test): stained/non-stained</td>
<td></td>
<td>Polyp</td>
<td>Post-treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inflammation</td>
<td></td>
</tr>
</tbody>
</table>
5.4.7. How to interpret colposcopic findings

After completion of colposcopy, the Swede score is to be calculated based on five variables (Table 5.1). For each variable 0, 1 or 2 points are ascribed. The sum of the points helps to arrive at a diagnosis and decide further management. A Swede score of less than 5 indicates that the probability of any neoplastic lesion is very low and no biopsy is required. A score between 5 to 7 generally is seen in low grade lesions or condylomas (HPV induced benign lesions). High grade intraepithelial lesions or cancers usually have scores of 8 and above.

The provisional colposcopic diagnosis of normal, low grade squamous intraepithelial lesions (LSIL), high grade squamous intraepithelial lesions (HSIL), adenocarcinoma in situ or invasive cancers is made after taking into consideration the IFCPC grade of the findings and the Swede score.

Table 5.1: Swede scoring system for colposcopic diagnosis

<table>
<thead>
<tr>
<th>Score 0</th>
<th>Score 1</th>
<th>Score 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aceto uptake</td>
<td>Zero or transparent</td>
<td>Thin, milky</td>
</tr>
<tr>
<td>Margin and surface</td>
<td>Zero or diffuse</td>
<td>Sharp but irregular, jagged, geographical, satellites</td>
</tr>
<tr>
<td>Vessels</td>
<td>Fine, regular</td>
<td>Absent</td>
</tr>
<tr>
<td>Lesion size</td>
<td>&lt;5 mm</td>
<td>5–15 mm or two quadrants</td>
</tr>
<tr>
<td>Iodine staining</td>
<td>Brown</td>
<td>Fainty or patchy yellow</td>
</tr>
</tbody>
</table>

5.4.8. What are the common problems of colposcopy?

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lax vaginal walls in multiparous women may fill up vagina between the blades of the speculum and obstruct vision</td>
<td>Use large Cusco speculum or cover ends of blades with a non-lubricated condom or finger of glove (with tips cut) or use lateral vaginal wall retractor</td>
</tr>
<tr>
<td>Severe vaginitis</td>
<td>Severe vaginitis should be treated prior to colposcopy</td>
</tr>
<tr>
<td>Mucus making visualization of SCJ difficult and may be misinterpreted as acetowhite patch</td>
<td>Remove the mucus with a cotton swab Removal is easier after acetic acid application</td>
</tr>
</tbody>
</table>
Incomplete visualization of TZ in post-menopausal women

Thinned out cervical epithelium in post-menopausal women, causing bleeding

Lack of correlation between colposcopy and histopathological diagnosis

Inadequate biopsy for histopathology evaluation

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete visualization of TZ in post-menopausal women</td>
<td>Advise oestrogen vaginal cream or oral tablets for 2 to 3 weeks and repeat colposcopy after 1 month</td>
</tr>
<tr>
<td>Thinned out cervical epithelium in post-menopausal women, causing bleeding</td>
<td>Gentle insertion of speculum, lubrication of speculum, gentle wiping of blood with saline or acetic acid will help adequate visualization</td>
</tr>
<tr>
<td>Lack of correlation between colposcopy and histopathological diagnosis</td>
<td>Take biopsy from acetowhite area near SCJ and take multiple biopsies if there are large lesions</td>
</tr>
<tr>
<td></td>
<td>Use freshly prepared acetic acid of appropriate dilution and wait for at least 1 minute after application of acetic acid</td>
</tr>
<tr>
<td>Inadequate biopsy for histopathology evaluation</td>
<td>Use sharp cutting biopsy forceps. If necessary, take biopsy with small loop</td>
</tr>
</tbody>
</table>

5.4.9. How to maintain the colposcope

The colposcope requires meticulous care and maintenance. When moving the colposcope, be careful not to bump or jar the optics out of alignment to avoid seriously compromising colposcopic images:

1) Cover the colposcope at the end of each day to prevent dust accumulation, specially on the optics and the lens. The lens should be cleaned only with soft and clean tissue paper, if at all necessary.

2) Protect fibreoptic light cables from trauma, twisting or bending to avoid breaking the encased glass strands.

3) Replace light bulbs and fuse as necessary. Always keep spares handy.

4) Decontaminate the colposcope at least once a day after the clinic is over. Remove potentially infected secretions and blood with a safe disinfectant to wipe portions of the colposcope that come in regular contact with clinicians. No disinfectant liquid should get into the optics.

5) Ensure the machine is serviced by a trained technician at least once a year.
5.5 Group learning activities

5.5.1 Digital image recognition

5.5.2 Preparation of dilute acetic acid (Fig. 5.3)

5.5.3 Preparation of Lugol’s iodine (Fig. 5.4)

5.5.4 Preparation of Monsel’s paste

5.5.2: Preparation of 100 ml of 5% acetic acid

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

Apparatus and consumables required
- Graduated measuring cylinder or beaker (capacity 100 ml)
- Glass bottle to store 5% acetic acid
- Pair of gloves
- 10 ml syringe

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

Labelling
Label glass bottle as ‘5% dilute acetic acid’ and mention 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 burn 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.
5.5.3: Preparation of 100 ml of 5% Lugol’s iodine

Ingredients required
- Potassium iodide 10 g
- Distilled water 100 ml
- Iodine crystals 5 g

Apparatus and consumables required
- Electronic top pan balance
- Measuring cylinder
- Glass beaker
- Glass stick
- Filter paper
- Amber coloured glass bottle
- Laboratory apron

Preparation
Dissolve 10 gm of potassium iodide in 100 ml of distilled water. Slowly add 5 gm iodine crystals, while shaking. Filter and store.
Labelling
Label container as ‘5% Lugol’s iodine’ and mention the date of preparation.

Storage
Keep stored in the tightly capped glass bottle. Can be stored for up to 1 month.

Fig. 5.4: Preparation of Lugol’s iodine

1. Wear gloves
2. Measure 10 g of potassium iodide
3. Dissolve potassium iodide in 100 ml of distilled water
4. Add 5 g of iodine crystals to the solution
5. Stir to dissolve iodine crystals
6. Filter the solution
7. Pour the filtered solution into an amber coloured glass bottle
8. Label the bottle with the date of preparation, store it tightly capped

Can be stored for up to 1 month.
### 5.5.4 Preparation of Monsel’s paste

#### Ingredients
- Ferric sulfate base: 15 gm
- Ferrous sulfate powder: few grains
- Sterile water for mixing: 10 ml
- Glycerol starch: 12 gm

#### Apparatus and consumables required
- Electronic top pan balance
- Measuring cylinder
- Mortar
- Glass beaker
- Glass stick
- Brown glass bottle
- Laboratory apron

#### Preparation
1) Add a few grains of ferrous sulfate powder to 10 ml of sterile water in a glass beaker and shake.
2) Dissolve the ferric sulfate base in the solution by stirring with a glass stick till the solution becomes crystal clear.
3) Weigh the glycerol starch in a glass mortar and mix well.
4) Slowly add ferric sulfate solution to glycerol starch, constantly mixing to get a homogeneous mixture.
5) Place in a 25 ml brown glass bottle.
6) For clinical use, most clinics prefer to allow enough evaporation to give the solution a sticky paste like consistency that looks like mustard. This may take 2 – 3 weeks, depending on the environment. The top of the container can then be secured for storage. If necessary, sterile water can be added to the paste to make it thin.

*Caution: The reaction is exothermic (emits heat)*

#### Labelling
Label bottle as ‘Monsel’s paste; External use only; Use by (date)’

#### Storage
Can be kept for 6 months
## 5.6. Skill development

### 5.6.1. Steps of colposcopy

<table>
<thead>
<tr>
<th>Steps</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation for colposcopy</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>1. Keep necessary instruments ready (see list of equipment)</td>
<td></td>
</tr>
<tr>
<td>2. Check availability of consumables (see list of consumables)</td>
<td></td>
</tr>
<tr>
<td>3. Ensure that the colposcope is functioning and is ready to use</td>
<td></td>
</tr>
<tr>
<td>4. Position colposcope and check for adequacy of intensity of light source</td>
<td></td>
</tr>
<tr>
<td>5. Adjust the eye pieces to get well focused stereoscopic vision</td>
<td></td>
</tr>
<tr>
<td>6. Arrange instruments and supplies on a high-level disinfected tray or container</td>
<td></td>
</tr>
</tbody>
</table>

### History taking (ask questions/check records)

| 7. Personal information: Name, age, husband’s name, address, telephone number and LMP |
| 8. Obstetric history |
| 9. History of past illnesses |
| 10. Check referral records and review the cause of referral |

### Counselling and consent

<p>| 11. Ask for any of the following symptoms: |
| - Persistent foul smelling white vaginal discharge |
| - Post-coital vaginal bleeding |
| - Post-menopausal vaginal bleeding |
| - Irregular menstrual bleeding |
| 12. Record all relevant information on a case record form |
| 13. Follow checklist for counselling 5.6.2 |</p>
<table>
<thead>
<tr>
<th>Step-wise colposcopy procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Obtain informed consent</td>
</tr>
<tr>
<td>15. Check that the woman has emptied her bladder</td>
</tr>
<tr>
<td>16. Help her onto the examining table, help her to undress and drape her</td>
</tr>
<tr>
<td>17. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry</td>
</tr>
<tr>
<td>18. Put one pair of new examination gloves on both hands</td>
</tr>
<tr>
<td>19. Inspect external genitalia and check urethral opening for discharge</td>
</tr>
<tr>
<td>20. Select speculum of appropriate size and lubricate the blades with lubricant jelly or saline</td>
</tr>
<tr>
<td>21. Insert speculum and adjust it so that the entire cervix can be seen</td>
</tr>
<tr>
<td>22. 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. Adjust the colposcope to bring the cervix into sharp focus using appropriate magnification (usually 6x or 8x)</td>
</tr>
<tr>
<td>24. If the cervix cannot be exposed properly or is obscured by excessive inflammation or bleeding or scar, the colposcopy is to be considered inadequate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What to do if visualized</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. Examine the cervix for cervicitis, growth, ulcers or contact bleeding</td>
</tr>
<tr>
<td>26. Apply normal saline to the cervix with cotton swabs to gently remove the mucus and discharge</td>
</tr>
<tr>
<td>27. Identify the external os and the SCJ</td>
</tr>
<tr>
<td>28. Examine blood vessels with the help of a green (or blue) filter. Increase magnification if required</td>
</tr>
<tr>
<td>29. Soak a clean swab in 5% acetic acid and apply it to the cervix</td>
</tr>
<tr>
<td>30. Wait for 1 minute for any acetowhite change to appear</td>
</tr>
</tbody>
</table>
31. Locate the SCJ again and determine the type of TZ

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

33. If an aceto-white area appears, look for the following features:
   - Density
   - Margin characteristics
   - Location in relation to SCJ or external os
   - Number of quadrants involved
   - Vascular pattern

34. Use endocervical speculum to visualize the endocervix if necessary

35. After completion of examination with acetic acid, use a fresh swab to remove any remaining acetic acid from the cervix and the vagina

36. Apply Lugol’s iodine and inspect for colour change

37. Use Swede score for interpretation of colposcopy findings

38. Perform cervical biopsies (or proceed for treatment) depending on Swede score

39. Obtain punch biopsy(s) from the worst identified lesion(s) close to SCJ

40. Apply Monsel’s solution (paste) to biopsy site to control bleeding

41. Remove the speculum

42. Help woman to get up from the examination table and sit comfortably and tell her that you will explain the test findings soon

**Post-colposcopy tasks**

43. Dispose-off the swabs in appropriate disposal bags

44. Immerse the speculum in 0.5% chlorine solution

45. Immerse both gloved hands in 0.5% chlorine solution
   Remove gloves by turning them inside out
46. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry

47. Record the colposcopy findings in the woman’s case record form

48. i) If colposcopy test is normal, counsel the woman as per Skills Checklist 3.6.1

ii) If punch biopsy has been taken, label the specimen and fill in the lab requisition form and give post-biopsy instructions

iii) If colposcopy is abnormal and immediate LEEP is planned proceed for counselling as per Skills Checklist 3.6.2

iv) If invasive cancer is suspected on colposcopy, counsel the woman as per Skills Checklist 3.6.3

*The highlighted steps are considered critical

Score achieved: Facilitator’s signature

**Facilitator’s remarks**

**Points to remember**

- Indications of colposcopy include positive screening test for cervical cancer, suspicious cervix on visual examination, assessment of lesions prior to treatment, post-treatment follow-up and persistently unsatisfactory cytology.

- Colposcopic findings should be documented as per the IFCPC 2011 classification.

- Swede score is used to assist in colposcopy diagnosis and decide on management.

- Freshly prepared 3–5% dilute acetic acid should be used. Undiluted acetic acid can cause burns.
Multiple choice questions

1. The following are Grade 1 findings on colposcopy, except:
   a) Fine mosaic
   b) Fine punctation
   c) Dense acetowhite epithelium
   d) Irregular geographic border

2. Major findings on colposcopy include all, except:
   a) Sharp border
   b) Inner border sign
   c) Ridge sign
   d) Slow appearance of acetowhiteness

3. Swede score involves assessment of all the following, except:
   a) Depth of lesion
   b) Margins and surface
   c) Acetowhite uptake
   d) Vessels

4. At what Swede score is “see and treat” approach recommended?
   a) 5–7
   b) <5
   c) >8
   d) 1–2

5. During counselling of a woman with abnormal colposcopy findings, the woman should be told all, except:
   a) Significance of abnormal colposcopy
   b) Need for taking biopsy
   c) Possible need of treatment by cryotherapy/LEEP/CKC
   d) After colposcopy and treatment the woman will not require any further follow-up

Answer key

1 – c 2 – d 3 – a
4 – c 5 – d
Module 6: Colposcopic features of normal, benign, pre-cancer and cancer of cervix

6.1. Module overview
This module is designed to train gynaecologists and non-specialist clinicians on how to identify colposcopic features of a normal cervix and to detect the pre-cancers, cancers and other miscellaneous conditions of the cervix. The contents of the module have been designed to familiarize trainees with the IFCPC 2011 colposcopy nomenclature. The module is to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Chapter 5 – Screening for cervical cancer and Practice Sheet 5.8).

6.2. Module contents
- Normal colposcopy findings
- Benign changes of cervix detected on colposcopy
- Abnormal colposcopy findings:
  - Grade 1/Grade 2/nonspecific
  - Findings suggestive of early invasive and invasive carcinoma
- Miscellaneous findings
- Management algorithms:
  - Group learning activities:
    - Digital image recognition
    - Case studies

6.3. Learning objectives
By the end of this module, trainees will be able to:
- identify normal colposcopic features;
- identify abnormal colposcopic features and categorize them according to the IFCPC 2011 classification;
- recognize colposcopic features of early invasive and invasive cervical cancer;
- identify other miscellaneous findings on colposcopy;
- manage women with abnormal colposcopic findings.
6.4. Key points for discussion

6.4.1. What are the colposcopic features of mature squamous epithelium?

Mature squamous epithelium is bluish or pink in colour and may have fine capillaries or normal branching blood vessels. There are no features suggestive of active metaplastic process like crypt openings, nabothian cysts, metaplastic epithelium or islands of columnar epithelium. There is no acetowhite change after application of acetic acid (Fig. 6.1). Mature squamous epithelium is the native epithelium of the cervix that is commonly seen at the periphery of the ectocervix. However, the metaplastic epithelium over the TZ also becomes fully mature with advancing age. Mature squamous epithelium will be evenly stained with Lugol’s iodine.

6.4.2. What are the colposcopic features of atrophic squamous epithelium?

Atrophic squamous epithelium (Fig. 6.2) is thin and pale pink in colour. The cervix becomes flush with vagina and SCJ recedes inside the endocervical canal. Normal blood vessels may be prominently seen through the thin epithelium. There may be subepithelial bleeding (petechial haemorrhagic spots) during manipulation. No acetowhite area is seen after application of acetic acid. The epithelium is either not stained or partially stained with Lugol’s iodine.

6.4.3. What are the colposcopic features of ectropion?

Ectropion or ectopy is characterized by the presence of columnar epithelium on the ectocervix up to varying distance from the external os (Fig. 6.3). The SCJ can be easily identified on the ectocervix especially after application of acetic acid. Prior to the application of acetic acid, columnar epithelium is visible as a red patch with normal branching blood vessels. The columnar epithelium becomes more prominent after application of acetic acid. Finger-like projections of villi of columnar epithelium give a velvet-like granular appearance. Often the fissures are visible. Columnar epithelium may become white immediately after application of acetic acid due to the blanching of the blood vessels. However, this acetowhite change is transient and the original red colour is restored after a few seconds. The columnar epithelium is not stained with Lugol’s iodine and retains its original red colour.
6.4.4. What is erosion?

Denudation of cervical epithelium is called erosion (Fig. 6.4). Erosion is detected by the absence of surface epithelium, the thin spider like blood vessels in the exposed stroma and the peeled off denuded epithelium visible at the edge. The peeled off epithelium seen hanging loosely is known as rag sign. Erosion can be differentiated from ectropion (columnar epithelium on the ectocervix) by the absence of the finger-like projections of the villi of columnar epithelium. Erosion is commonly seen in grossly infected cervix or in postmenopausal cervix. However, erosion can be seen in presence of high grade cervical neoplasias or even in cancer. Therefore, an area of erosion over the TZ should be carefully evaluated for any evidence of high grade lesion in the surrounding areas. If necessary, multiple punch biopsies should be obtained from such eroded areas and the surrounding epithelium. Erosion is a nonspecific finding according to the IFCPC 2011 classification.

6.4.5. What are the colposcopic features of metaplastic squamous epithelium?

At the initiation of the metaplastic process, the villi of columnar epithelium become flattened and merge with each other. Metaplasia may be visible as multiple glassy islands of newly formed squamous epithelium overlying the columnar epithelium or as pale, translucent in-growths of metaplastic epithelium (tongue like projections) from the original squamous epithelium (Fig. 6.5). These islands and tongues of metaplasia can coalesce into sheets of immature metaplasia, often with a thin acetowhite line at the advancing border. Immature metaplasia is pale pink in colour, often has fine mosaic patterns and can turn acetowhite. The patent crypt openings visible as black dots surrounded by thin acetowhite rim are characteristic of metaplastic epithelium and are useful to delineate the extent of the TZ. Nabothian cysts look like white or yellowish blisters or pimples on the TZ with flattened branching blood vessels on the surface.

6.4.6. What are the characteristic changes in pregnancy?

In pregnancy, the cervix enlarges, becomes soft and congested and is covered by copious mucus (Fig. 6.6). The columnar epithelium becomes averted and hypertrophied. The stroma of the cervix may undergo focal decidual change in second and third trimester, which appears as a raised plaque or as a pseudo polyp. The blood vessels are prominent.
6.4.7. What is congenital transformation zone?

In congenital transformation zone (CTZ), there is abnormal maturation of the squamous epithelium with excessive maturation of the superficial layers and incomplete maturation of the deeper layers. CTZ appears as a large oblong shaped thin acetowhite area on the cervix often extending from anterior to posterior vaginal fornices (Fig. 6.7). The area has fine mosaic patterns and is not stained with iodine. CTZ is seen in 4–5% of women undergoing colposcopy and does not have any malignant potential. No treatment is required. CTZ is a miscellaneous finding according to the IFCPC 2011 classification.

6.4.8. What are the different cervico-vaginal inflammations and what are their features?

The most common pathological condition of cervix and vagina is inflammation caused by various microbial agents. The common infective agents are Candida albicans (fungus), Trichomonas vaginalis (protozoa), Chlamydia trachomatis (bacteria), Gardnerella vaginalis (bacteria), Escherichia coli (bacteria) and Streptococci (bacteria). In rare cases, Herpes simplex virus can also infect the cervix. During colposcopic examination, the character of the discharge seen in the vagina and that covering the cervix should be noted to detect the type of infection. Trichomonas infection causes frothy, greenish foul smelling discharge (Fig. 6.8b). Candida infection is characterized by curdy white, often sticky discharge (Fig. 6.8a). Greenish or yellowish discharge with fishy smell is commonly seen in bacterial infections. An inflamed cervix (also called cervicitis) appears red and swollen with pus coming out from the external os, commonly seen in chlamydia or gonococcal infections. Inflamed areas may bleed on contact. The cervix is often tender on movement. Infection with the trichomonas may produce a “strawberry” appearance of the cervix with alternating areas of red epithelium and pale dots on the surface of the cervix (Fig. 6.8c). Application of Lugol's iodine produces the typical leopard skin appearance due to multiple iodine negative patches. Herpes infection may give rise to formation of vesicles or small multiple ulcers on the cervix, vagina and vulva. Inflammation is a miscellaneous finding according to the IFCPC 2011 classification.
6.4.9. What are the features of condyloma or genital wart of the cervix?

Genital condyloma (wart) is caused by low risk HPV infection. Condyloma can affect the external genitalia, vagina and cervix and are frequently multiple. Cervical condyloma (Fig. 6.9) usually appears as a distinct lumpy, irregular lesion on the surface of the affected area. The colour may be bright white and the surface irregular, pitted or spiky. Sometimes there may be finger-like projections on the surface with a central capillary in each of the projections. Majority of the condylomas of the cervix are not visible prior to the application of acetic acid. Acetowhite patches with irregular geographical margins and multiple satellite lesions, often away from the TZ, are characteristic of these subclinical papilloma virus infections (SPI). Condyloma is a miscellaneous finding according to the IFCPC 2011 classification.

6.4.10. What are the features of the cervical polyp?

Cervical polyp is a localized overgrowth of the endocervical columnar epithelium and may be visible as single or multiple reddish mass(s) protruding from the external os (Fig. 6.10). The polyp is usually mobile and can be pushed in different directions to visualize the SCJ. Polyp can be acetowhite due to metaplastic changes on the surface and does not stain with Lugol’s iodine. Polyp is a miscellaneous finding according to the IFCPC 2011 classification.

6.4.11. What are the features of endometriosis of the cervix?

Endometriosis usually presents as small blue or red surface nodules, a few millimetres in diameter, located on the portio or in the cervical canal. Endometriosis is a miscellaneous finding according to the IFCPC 2011 classification.

6.4.12. What is leukoplakia?

A white patch visible on the cervical epithelium even before application of acetic acid is known as Leukoplakia (Fig. 6.11). Typically they look like white plaques on the cervix with shiny surface and are due to deposition of keratin in the epithelial cells. Leukoplakia can be due to condylomas or may be idiopathic. Leukoplakia can also hide a high grade lesion or cancer underneath. So, all leukoplakic patches on the TZ of the cervix should be biopsied. Leukoplakia is a “non-specific abnormal colposcopic finding” according to the IFCPC 2011 classification.
6.4.13. What are the Grade 1 changes on colposcopy?

A thin acetowhite area with irregular (feathered) or angular (geographical) margins (Fig. 6.12a) and flat surface appearing on the TZ indicates Grade 1 or minor abnormality. Fine mosaic (Fig. 6.12b) or fine punctations (Fig. 6.12c) and satellite lesions away from the SCJ are also included in this group. Grade 1 abnormalities are seen in low grade abnormalities (CIN 1). They can be seen in immature metaplasia or condylomas also.

Fig. 6.12: Grade 1 changes of the cervix on colposcopy

6.4.14. What are the Grade 2 changes on colposcopy?

A dense acetowhite area on the TZ with well-defined flat or elevated regular margins (Fig. 6.13a) is the characteristic of Grade 2 abnormality on colposcopy. There may be associated vascular abnormalities like coarse mosaics (Fig. 6.13b) and coarse punctations (Fig. 6.13c). Presence of cuffed crypt openings, inner border sign and ridge signs are the other features of Grade 2 abnormalities and are described later in the Trainees’ handbook. Grade 2 abnormalities signify the presence of high grade lesions (CIN 2/ CIN 3). The higher the grade of abnormality, the denser is the acetowhitening. An acetowhite area that appears rapidly and persists for a longer time is likely due to high grade neoplasia.

Fig. 6.13: Grade 2 changes of the cervix on colposcopy
6.4.15. What is cuffed crypt opening?

A normal crypt opening appears as a black dot surrounded by a thin rim of acetowhite line in the TZ. If the crypt opening is large, prominent and the acetowhite rim is dense white and raised from the surface (like a doughnut), it is called a cuffed crypt opening (Fig. 6.14). Such a cuffed crypt opening is usually located in the dense acetowhite area but may be isolated also. Cuffed crypt openings indicate extension of the neoplasia inside the crypt and are usually associated with high grade lesions.

6.4.16. What is a ridge sign?

When the acetowhite area is thick and elevated and is projected near the SCJ as the top of a wall or ridge it is called a ridge sign (Fig. 6.15). A ridge sign indicates the presence of a high grade lesion.

6.4.17. What is an inner border sign?

Low grade and high grade lesions may coexist and there may be internal margins (borders) due to the abrupt change in the nature of a lesion(s) (Fig. 6.16). This is called “lesion within a lesion” or “inner border sign” and is a feature of high-grade neoplasia, with the inner, more proximal lesion being more severe.

6.4.18. What are the features suggestive of invasive cancer?

Invasive lesions (Fig. 6.17) will have any of the following features:

- growth or ulcer with necrotic areas;
- dull dense acetowhite area, usually large, on the TZ;
• acetowhite area with raised well demarcated margins and the surface is elevated at places;
• atypical vessels (bizarre shapes, no definite branching patterns, unequal thickness along the stem, often raised from the surface, shiny and easily bleed at touch), coarse mosaic, coarse punctuation or combinations of these;
• erosion of the surface that bleeds easily;
• uniform iodine negative area.

6.4.19. What are the features of adenocarcinoma in situ and adenocarcinoma?

Glandular lesion should be suspected if there is a dense acetowhite area on the columnar epithelium (Fig. 6.18) that is persistent for a long time. The multiple dense acetowhite areas seen on the columnar epithelium due to adenocarcinoma in situ is typically described as a grated coconut appearance. In adenocarcinoma, the dense acetowhite area on the columnar epithelium is irregular on the surface and has abnormal blood vessels. Quite often, glandular abnormalities coexist with high grade squamous lesions.

6.4.20. How to manage women on the basis of colposcopy diagnosis

Post-colposcopy management is based on the availability of histopathology facilities. Flowchart 6.1 shows the algorithm of management after colposcopy if histopathology facilities are available. Flowchart 6.2. shows the algorithm of management if histopathology is not feasible and the management is solely based on colposcopy diagnosis.
Flowchart 6.1: Management of screen positive women based on colposcopy and histopathology diagnosis

VIA/HPV test positive

Colposcopy; biopsy if lesion suspected

Histopathology diagnosis

Colposcopy and/or biopsy normal

CIN 1

Cryotherapy / LEEP/ CKC

Repeat screening in 3 years

Persistent or progressive disease

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

CIN 2/3

Micro-invasive CA

Invasive CA

CKC / LEEP

Treatment based on stage

Follow-up

Follow-up at 9 to 12 months (Screening test /colposcopy)

Fig. 6.2: Management of screen positive women based on colposcopy diagnosis

VIA/ HPV test positive

Colposcopy

Normal

Suspected CIN

Suspected cancer

Repeat screening within 3 years

Histopathology facilities available

Histopathology facilities not available

Obtain biopsy and manage according to histopathology report

Eligible for cryotherapy

Not eligible for cryotherapy

Cryotherapy

LEEP or CKC
6.5. Group learning activities

6.5.1. Digital image recognition

6.5.2. Case studies

Case study 1
Case history: 45-year-old multiparous woman was positive on VIA. She was referred for colposcopy.

Question: Describe the findings
Answer: The SCJ is entirely visible and the TZ is Type 1. Thin acetowhite area with indistinct and irregular margin is seen at 11 o'clock position. The lesion is on the TZ and covers one quadrant of the cervix.

Question: Describe the findings
Answer: Partial iodine uptake is seen at 11 o'clock position.

Question: What is the final colposcopic diagnosis?
Answer: Grade 1 (minor) abnormalities involving one quadrant, likely to be a low grade lesion.

Question: What is the Swede score?
Answer: The Swede score is 4
- Thin milky – 1
- Irregular margins -1
- Absent vessels – 1
- 1 quadrant involvement – 0
- Partial iodine staining – 1
Question: Is she eligible for cryotherapy?
Answer: Yes – TZ Type 1, lesion purely ectocervical, limited to one quadrant and can be covered fully by cryotherapy probe.

Question: What will be the post treatment advice?
Answer: – The woman should be told to avoid sexual intercourse for 4 weeks, in case complete abstinence is not possible, condom should be used.
– She should avoid vaginal douches or use of tampons for 4 weeks.
– She should use sanitary napkins to avoid staining of clothes as watery discharge or spotting can occur for 2–3 weeks.
– She should attend a health facility or consult a doctor if she has profuse and foul-smelling vaginal discharge with or without fever and lower abdominal pain. She should also seek advice if there is vaginal bleeding more than normal menstrual bleeding.
– The woman should have a follow-up visit at 1 year.

Time allotted for the case study: 15 minutes
**Case study 2**

Case history: A 47-year-old woman (parity 3) was positive on VIA. She was referred for colposcopy.

<table>
<thead>
<tr>
<th>Question</th>
<th>Describe the findings seen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Answer</td>
<td>Congested cervix with prominent vessels. The vessels have a branching pattern. Squamocolumnar junction cannot be seen.</td>
</tr>
</tbody>
</table>

**Colposcopy image before acetic acid application**

<table>
<thead>
<tr>
<th>Question</th>
<th>Describe the findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Answer</td>
<td>The prominent vessels are better appreciated.</td>
</tr>
</tbody>
</table>

**Colposcopy image before acetic acid application and with a green filter**
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the type of TZ?</td>
<td>TZ is of Type 3 as the SCJ is inside the canal and cannot be seen completely.</td>
</tr>
<tr>
<td>Describe the findings</td>
<td>Dense acetowhite area with sharp raised border is seen involving all the 4 quadrants. Coarse punctations are visible. Cuffed crypt openings are also present at 9 o’clock position. The dense white large lesions with surface irregularity and raised border are indicative of invasive cancer.</td>
</tr>
<tr>
<td>Describe the findings</td>
<td>The acetowhite area is uniformly iodine negative.</td>
</tr>
<tr>
<td>What is the Swede score for this case?</td>
<td>The Swede score is 10</td>
</tr>
<tr>
<td>• Distinct stearin acetowhite – 2.</td>
<td></td>
</tr>
<tr>
<td>• Sharp border and difference in surface levels – 2.</td>
<td></td>
</tr>
<tr>
<td>• Atypical vessels – 2.</td>
<td></td>
</tr>
<tr>
<td>• 3–4 quadrant involvement – 2.</td>
<td></td>
</tr>
<tr>
<td>• Distinct yellow iodine non-stained area – 2.</td>
<td></td>
</tr>
<tr>
<td>How will you manage the case?</td>
<td>The lesion is suspicious of invasive cancer. Multiple punch biopsies should be obtained. The woman should be referred to a higher centre for staging and further management if the histology report shows invasive cancer.</td>
</tr>
</tbody>
</table>
Points to remember

- Mature squamous epithelium is pink in colour and may have fine capillaries or normal branching blood vessels.
- Atrophic squamous epithelium is thin and pale pink in colour.
- Ectropion is the presence of columnar epithelium on the ectocervix.
- Erosion is the denudation of cervical epithelium.
- The cervix enlarges, becomes soft and congested and is covered with copious mucus in pregnancy.
- A thin acetowhite area with irregular geographical margin and flat surface appearing on the TZ, fine mosaic or fine punctations indicate Grade 1 or minor abnormality.
- A dense acetowhite area on the TZ with well-defined flat or elevated regular margins, coarse mosaics, coarse punctations, cuffed crypt openings, inner border sign and ridge sign indicate Grade 2 abnormalities.
- A growth or ulcer with necrotic areas indicates invasive lesions.
### Multiple choice questions

1. **Which of the following statements is false?**
   
   a) Mature epithelium evenly stains with Lugol’s iodine  
   b) Dense acetowhite areas are seen after application of acetic acid on normal atrophic epithelium  
   c) Petechial haemorrhagic spots may appear after manipulation in postmenopausal women  
   d) SCJ recedes into the endocervical canal in post-menopausal women

2. **Decidual changes in pregnancy include all, except:**
   
   a) Congested cervix  
   b) Atypical blood vessels  
   c) Evoli of columnar epithelium  
   d) Stromal changes in the form of pseudopolyp or plaque

3. **Which of the following is true for cuffed crypt opening?**
   
   a) Large crypt opening with dense acetowhite rim  
   b) Flattened surface  
   c) Associated with a low grade lesion  
   d) None of the above

4. **Invasive cervical cancer is indicated by all the following, except:**
   
   a) Cervical growth  
   b) Uniform brown staining after Lugol’s iodine application  
   c) Abnormal vessels  
   d) Dense acetowhite area

5. **Which of following statements is true about congenital TZ?**
   
   a) Has a coarse mosaic pattern  
   b) Has a malignant potential progressing to invasive  
   c) Needs follow-up  
   d) Does not stain with iodine

### Answer key

1 – b  
2 – b  
3 – a  
4 – b  
5 – d
Normal cervix

A. Nulliparous cervix: Pin point external os
B. Multiparous cervix: Slit like external os
C. Mature cervix: Normal mucoid discharge from external os
D. Atrophic cervix: Pale ectocervix

Photo courtesy PGIMER, Chandigarh, India

Photo reproduced with permission from Atlas of Colposcopy and Management of Cervical Pre-cancers. IARC, Lyon. (Forthcoming)
Ectropion

A. Ectropion: Presence of columnar epithelium on ectocervix

B. Large ectropion: Columnar epithelium has a red velvet like appearance

C. Large ectropion: Squamocolumnar junction clearly visible on the ectocervix

D. Large ectropion: Columnar epithelium extending over the entire ectocervix

Photo courtesy PGIMER, Chandigarh, India

Photo reproduced with permission from Atlas of Colposcopy and Management of Cervical Pre-cancers. IARC, Lyon. (Forthcoming)
Features of squamous metaplasia

A. Columnar epithelium villi become flattened and fuse together giving a thin glassy appearance

B. Metaplasia progresses from the squamocolumnar junction towards the external os

C. Metaplastic epithelium appears faintly acetowhite with tongue-like projections towards external os. Note the islands of columnar epithelium

D. Metaplastic epithelium is faintly acetowhite
E. Crypt openings seen on the posterior lip of the cervix

F. Crypt openings on the anterior lip of the cervix

G. Nabothian cyst seen as a blister on the anterior lip of the cervix

H. Multiple nabothian cysts on the anterior lip of the cervix

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

Photo courtesy PGIMER, Chandigarh, India
Cervico-vaginal infections

A. Trichomoniasis: Frothy discharge

B. Trichomoniasis: Frothy discharge, often foul smelling

C. Trichomoniasis: Frothy discharge with multiple red spots on the cervix (strawberry cervix)

D. Trichomoniasis: Multiple red patches on the cervix (strawberry cervix)
E. Candidiasis: Thick cheesy white discharge on the cervix

F. Candidiasis: Thick curdy white discharge covering the cervix

G. Bacterial vaginosis: Thick creamy discharge covering the cervix

H. Bacterial vaginosis: Thick creamy discharge covering the cervix
Normal colposcopic findings

Case 1

A. After normal saline application

B. With a green filter

Multiple nabothian cysts and a mucus polyp are visible

No abnormal vessels seen

C. After acetic acid application

D. After Lugol’s iodine application

Squamocolumnar junction is visible around the external os. Thin acetowhite areas on the anterior and posterior lips with irregular margins occupying <25% of the ectocervix

Patchy yellow areas seen on the anterior and posterior lips of the cervix

Swede score: 1+1+1+0+1=4

Provisional diagnosis: Type 2 transformation zone; squamous metaplasia

Management: Cervical cancer screening after 3 to 5 years

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## Case 2

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Squamocolumnar junction is fully visible on the ectocervix</td>
<td>No abnormal vessels seen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol’s iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Squamocolumnar junction distinctly seen as a thin white line. No acetowhite area. Columnar epithelium bleeds to touch</td>
<td>Columnar epithelium is not stained by Lugol’s iodine</td>
</tr>
</tbody>
</table>

Swede score: 0+0+0+0+0=0

Provisional diagnosis: Type 1 transformation zone; ectropion

Management: Cervical cancer screening after 3 to 5 years

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*All photos on this page courtesy PGIMER, Chandigarh, India*
Case 3

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Squamocolumnar junction visible on the ectocervix</td>
<td>Normal vessels seen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol's Iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transparent acetowhite area at 12 o'clock position with indistinct margins occupying &lt;25% of the ectocervix</td>
<td>Faint yellow area over the anterior lip at 12 o'clock position</td>
</tr>
</tbody>
</table>

Swede score: 0+0+1+0+1=2
Provisional diagnosis: **Type 1 transformation zone; ectropion with metaplastic changes**
Management: Cervical cancer screening after 3 to 5 years

All photos on this page courtesy PGIMER, Chandigarh, India
Case 4

A. After normal saline application

Large ectropion. Cervix covered with mucoid discharge

B. With a green filter

No abnormal vessels noted

C. After acetic acid application

Transparent acetowhite area at 12 o’clock position with indistinct margins occupying <25% of the ectocervix

D. After Lugol’s iodine application

Patchy yellow area on anterior lip at 12 o’clock position. Squamous epithelium has stained mahogany brown

Swede score: 0+0+1+0+1=2

Provisional diagnosis: Type 1 transformation zone; ectropion with metaplastic changes

Management: Cervical cancer screening after 3 to 5 years

All photos on this page courtesy PGIMER, Chandigarh, India
**Abnormal colposcopic findings: Grade 1 – minor**

**Case 1**

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCJ not visible</td>
<td>No abnormal vessels seen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol's iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thin acetowhite areas noted at 12 o'clock and 6 o'clock positions with sharp margins. Lesions occupying two quadrants (25–50%) of the cervix</td>
<td>Distinct yellow areas on the anterior and posterior lips of the cervix</td>
</tr>
</tbody>
</table>

Swede score: $1+1+1+1+2=6$

Provisional diagnosis: **Type 3 transformation zone; low grade squamous intraepithelial lesion**

Management: Cervical punch biopsy for diagnosis

Histopathology: CIN1

*All photos on this page courtesy PGIMER, Chandigarh, India*
Case 2

A. After normal saline application
Cervix covered with mucus. Strawberry-like appearance noted. SCJ partially visible

B. With a green filter
No abnormal vessels seen

C. After acetic acid application
SCJ fully visible at the external os. Thin acetowhite area with irregular margins noted in three quadrants. Fine mosaics seen

D. After Lugol’s iodine application
Faint yellow areas seen. Leopard-skin appearance noted

Swede score: 1+1+0+2+1=5
Provisional diagnosis: Type 1 transformation zone; low grade squamous intraepithelial lesion; trichomoniasis
Management: Cervical punch biopsy for diagnosis
Histopathology: Chronic cervicitis

All photos on this page courtesy PGIMER, Chandigarh, India
### Case 3

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ectocervix appears normal. SCJ is partially visible</td>
<td>No abnormal vessels noted</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol’s iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCJ is partly inside the endocervical canal but fully visible. Thin acetowhite areas noted in three quadrants with feathery and geographical margins</td>
<td>Faintly stained yellow areas occupying three quadrants of the cervix</td>
</tr>
</tbody>
</table>

Swede Score: 1+1+1+2+1=6  
Provisional diagnosis: **Type 2 transformation zone; low grade squamous intraepithelial lesion**  
Management: Cervical punch biopsy for diagnosis  
Histopathology: CIN1

*All photos on this page courtesy PGIMER, Chandigarh, India*
Case 4

<table>
<thead>
<tr>
<th>A. After normal saline application:</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCJ partially visible</td>
<td>No abnormal vessels seen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol's iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCJ inside the canal and not fully visible. Thin acetowhite area noted at 6–7 o'clock position with geographical margins</td>
<td>Faint yellow partial iodine non-uptake areas seen</td>
</tr>
</tbody>
</table>

Swede score: 1+1+1+0+1=4  
Provisional diagnosis: Type 3 transformation zone; subclinical papillomavirus infection (condyloma)  
Management: Cervical punch biopsy for diagnosis

All photos on this page courtesy PGIMER, Chandigarh, India
Case 5

A. After normal saline application

SCJ not completely visible

B. With a green filter

No abnormal vessels seen

C. After acetic acid application

SCJ partly inside the endocervical canal but fully visible. Thin acetowhite area noted on the anterior lip with irregular, geographical margins. Satellite lesions seen on the anterior lip

D. After Lugol’s iodine application

Faint yellow areas on the anterior lip. Multiple satellite lesions seen

Swede score: 1+1+1+1+1=5

Provisional diagnosis: Type 2 transformation zone; subclinical papillomavirus infection (condyloma)

Management: Cervical punch biopsy for diagnosis

All photos on this page courtesy PGIMER, Chandigarh, India
**Case 6**

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCJ completely visible; multiple nabothian cysts</td>
<td>No abnormal vessels seen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol's iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 TZ, thin acetowhite area seen all around the cervix, involving &gt;3 quadrants. Fine mosaics present</td>
<td>Patchy yellow areas involving &gt;3 quadrants of the cervix</td>
</tr>
</tbody>
</table>

Swede score: $1 + 1 + 0 + 2 + 1 = 5$

Provisional diagnosis: **Type 1 transformation zone; low grade squamous intraepithelial lesion.**

Management: Cervical punch biopsy for diagnosis

Histopathology: **CIN 1**

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*IARC, Lyon. (Forthcoming)*
Abnormal colposcopic findings: Grade 2 (major)

**Case 1**

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCJ partly visible</td>
<td>No abnormal vessels noted</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol’s iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 TZ: Dense acetowhite area with sharp margins seen on the anterior lip occupying &gt;2 quadrants of cervix</td>
<td>Distinct yellow area after Lugol’s iodine application</td>
</tr>
</tbody>
</table>

Swede score: $2+2+1+2+2=9$

Provisional diagnosis: **Type 2 transformation zone; high grade squamous intraepithelial lesion**

Management: LEEP

Histopathology: CIN 3

*All photos on this page courtesy PGIMER, Chandigarh, India*
Case 2

A. After normal saline application

SCJ completely visible

B. With a green filter

No atypical vessels seen

C. After acetic acid application

Type 1 TZ; dense acetowhite lesion at 4–7 o’clock with sharp margins occupying two quadrants

D. After Lugol’s iodine application

Distinct yellow area with Lugol’s iodine

Swede score: 2+2+1+1+2=8

Provisional diagnosis: Type 1 transformation zone; high grade squamous intraepithelial lesion

Management: LEEP

Histopathology: CIN 3

All photos on this page courtesy PGIMER, Chandigarh, India
Case 3

A. After normal saline application
SCJ not completely visible, minimal mucoid discharge

B. With a green filter
No abnormal vessels noted

C. After acetic acid application
Type 3 TZ; dense acetowhite area with sharp margins seen in all four quadrants of the cervix

D. After Lugol’s iodine application
Distinct yellow area occupying all quadrants of the cervix

Swede score: 2+2+1+2+2=9
Provisional diagnosis: Type 3 transformation zone; high grade squamous intraepithelial lesion
Management: LEEP
Histopathology: CIN 3

All photos on this page courtesy PGIMER, Chandigarh, India
Case 4

A. After normal saline application

SCJ partly visible

B. With a green filter

Atypical vessel at 12 o’clock position

C. After acetic acid application

Type 2 TZ; Dense acetowhite area on the anterior lip with raised margin occupying two quadrants

D. After Lugol’s iodine application

Distinct yellow area on anterior lip of the cervix

Swede score: 2+2+2+1+2=9

Provisional diagnosis: Type 2 transformation zone; high grade squamous intraepithelial lesion

Management: LEEP

Histopathology: CIN 3

*All photos on this page courtesy PGIMER, Chandigarh, India*
Case 5

A. After normal saline application

SCJ not completely visible

B. With a green filter

No abnormal vessels noted

C. After acetic acid application

Type 3 TZ: Dense acetowhite areas with sharp margin involving all quadrants of the cervix. Note the areas of missing epithelium on both the anterior and posterior lips

D. After Lugol’s iodine application

Distinct yellow areas involving all quadrants of the cervix

Swede score: 2+2+1+2+2=9

Provisional diagnosis: Type 3 transformation zone; high grade squamous intraepithelial lesion

Management: LEEP

Histopathology: CIN 3

All photos on this page courtesy PGIMER, Chandigarh, India
Case 6

A. After normal saline application

Type 3 TZ: Dense acetowhite area all around the cervix with sharp borders; Ridge sign seen

B. With a green filter

Coarse punctations seen

C. After acetic acid application

D. After Lugol’s iodine application

Acetowhite area is unstained with iodine

Swede score: 2+2+2+2+2=10

Provisional diagnosis: Type 3 transformation zone; suspicious of early invasive cancer

Management: Multiple punch biopsies from anterior and posterior lips of cervix

Histopathology: CIN 3

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Abnormal colposcopic findings: Non-specific

- Erosion: Denudation of surface epithelium exposing the stroma underneath
- Leukoplakia: White patches noted covering the cervix

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Suspicious for invasion

Case 1

A. After normal saline application

B. With a green filter

SCJ apparently visible
Atypical vessels seen

C. After acetic acid application

D. After Lugol's iodine application

Type 3 TZ: Columnar epithelium has become densely acetowhite with irregular surface
Distinct yellow areas

Swede's score: 2+2+2+2+2=10
Provisional diagnosis: Suspicion of invasive cancer, probably adenocarcinoma
Management: Multiple punch biopsies
Histopathology: Adenocarcinoma

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**Case 2**

<table>
<thead>
<tr>
<th>A. After normal saline application</th>
<th>B. With a green filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix appears congested and bleeds to touch</td>
<td>Atypical vessels seen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C. After acetic acid application</th>
<th>D. After Lugol’s iodine application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dense acetowhite areas partly obscured by bleeding</td>
<td>Distinct yellow areas on the entire cervix</td>
</tr>
</tbody>
</table>

Swede score: $2+2+2+2+2=10$

Provisional diagnosis: **Suspicion of invasive cancer**

Management: Multiple punch biopsies

Histopathology: **Squamous cell carcinoma**

*All photos on this page courtesy PGIMER, Chandigarh, India*
Case 3

A. After normal saline application

B. With a green filter

Erosion seen on the cervix
Vessels have branching pattern

C. After acetic acid application

D. After Lugol's iodine application

Type 1 TZ with dense acetowhite area all around the cervix; cuffed crypt openings also noted
Distinct yellow areas seen

Swede score: 2+2+2+2+2=10
Provisional diagnosis: Type 3 transformation zone; suspicious of early invasive cancer
Management: Multiple punch biopsies from anterior and posterior lips of cervix
Histopathology: Squamous cell carcinoma

All photos on this page courtesy PGIMER, Chandigarh, India
Case 4

A. After normal saline application

Nabothian cyst seen

B. With a green filter

Atypical blood vessels noted (green arrow). Columnar epithelium (blue arrow)

C. After acetic acid application

Dense acetowhite area over columnar epithelium

D. After Lugol’s iodine

Distinct yellow area

Swede score: 2+2+2+2+2=10

Provisional diagnosis: Type 2 transformation zone; suspected malignancy

Management: LEEP (type 3 excision) with endocervical curettage. Cold knife conization can also be done.

Histopathology: Adenocarcinoma in situ

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Miscellaneous findings

A. Large thin acetowhite area extending to the fornices with fine mosaics on the surface

B. Acetowhite area extending to anterior fornix

C. Fine mosaic pattern seen with a green filter

D. Iodine non-uptake area after Lugol’s iodine application

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Raised white shiny lesions on posterior lip of cervix, away from the SCJ*

Post- Cryotherapy: note the area of fibrosis*

Cervical mucus polyp**

Long parallel blood vessels (marked by blue arrow)*

**Photo courtesy PGIMER, Chandigarh, India

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Module 7: Treatment of cervical pre-cancers by loop electrosurgical excision procedure (LEEP) and follow-up

7.1. Module overview
This module is intended to train gynaecologists and non-specialist clinicians on the principles and techniques of loop electrosurgical excision procedure (LEEP), which is an excision 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 for cervical cancer, Section 5.5.2 and Practice Sheet 5.11).

7.2. Module contents
• Principles of LEEP
• Instruments and consumables required
• Eligibility criteria for LEEP
• Steps of LEEP
• Post-treatment advice
• Advantages and disadvantages
• Management of treatment complications
• Appropriate infection prevention practices
• Group learning activities:
  ▪ Case studies
  ▪ Role play
  ▪ Simulated learning
• Checklist for treatment by LEEP

7.3. Learning objectives
At the end of this module, trainees will be able to:
• describe parts of the electrosurgical unit;
• identify eligibility criteria for treatment with LEEP;
• perform the technique following correct steps;
• recognize probable treatment complications;
• offer appropriate management of complications;
• follow infection prevention practices applicable for LEEP technique.
7.4. Key points for discussion

7.4.1. What are the principles of LEEP?

LEEP is an excisional method of treating cervical intraepithelial neoplasias. In this procedure, a wire loop electrode powered by an electrosurgical unit is used to remove the entire TZ along with the lesion. The heat from a high voltage electrical arc between the operating electrode and tissue allows the operator to cut by vaporizing the tissue. A blend of cutting and coagulation current is used. The excision of the TZ treats the abnormality effectively and provides a specimen for detailed histological evaluation. The width of the loop ranges from 10 mm to 20 mm and the depth ranges from 10 mm to 15 mm. The appropriate size of the loop is chosen to achieve adequate depth and width of the cut depending on the size and position of the lesion. Since the disease can extend along the crypts of the TZ and the average depth of a crypt is 5 mm, the extent of excision should be at least 8 mm to 10 mm to get an adequate disease-free margin. (Fig. 7.1)

7.4.2. What are the different types of excision?

The type of excision depends on the type of TZ and the extent and nature of the lesion.

- **Type 1 excision**: Involves excision of Type 1 TZ (Fig. 7.2a). This type of excision need not include much of the endocervical canal. Type 1 excision is adequate for CIN 2/3 lesions if the SCJ is fully visible on the ectocervix.

- **Type 2 excision**: Involves excision of Type 2 TZ. This type of excision includes endocervical component of the TZ depending on the extent of the lesion inside the endocervical canal (Fig. 7.2b). Type 2 excision is indicated if there is a CIN 2/3 lesion extending to the endocervical canal and the upper margin of the lesion is clearly visible.

- **Type 3 excision**: Involves excision of Type 3 TZ. In this type of excision, a significant amount of the endocervical canal is excised (1.5 cm to 2 cm) as the upper limit of the TZ or the lesion is not visible (Fig. 7.2c). Type 3 excision is required for CIN 2/3 lesions with Type 3 TZ or glandular lesion or micro invasive cancer.
7.4.3. What instruments and consumables are required for LEEP?

### Instruments/equipment required for LEEP

- Examination table with leg support
- Focusing light for examination
- Smoke evacuator with tubing for attachment to speculum
- Colposcope
- Electrosurgical unit (with patient return electrode, hand switch or foot operated switch)
- Loop/ball electrodes
- Insulated self-retaining speculum with smoke extraction channel
- Sponge holding forceps
- Lateral vaginal wall retractor
- Kidney tray
- Syringe for injecting local anaesthetic (dental syringe preferred)

### Consumables required for LEEP

- Gloves (sterile/gloves after high-level disinfection/disposable)
- Sterile cotton swabs, cotton swab sticks
- Normal saline
- Freshly prepared 5% acetic acid
- Lugol’s iodine
- Monsel’s paste
- Local anaesthetic (1 or 2 % lignocaine) with or without 1:100 000 epinephrine
- Lubricant jelly
- Vials containing 10% formaldehyde
- Waste disposal bag
- Chlorine solution (0.5%) or 2% glutaraldehyde
- Case record form
7.4.4. What are the indications for LEEP?

**Indications for LEEP**

- CIN of any grade
- Lesions not amenable to treatment by ablative techniques
- Discordance between the cytology, colposcopy and punch biopsy, especially if a high grade disease is suspected
- High grade squamous intraepithelial lesion (HSIL) on cytology; colposcopy normal with Type 3 TZ
- Glandular abnormality on cytology, punch biopsy or endocervical curettage
- Treatment failures (after ablative or excision procedure)

7.4.5. What are the contraindications for LEEP?

**Contraindications for LEEP**

- Pregnancy
- Severe infection/inflammation of cervix
- Less than 2 months postpartum

7.4.6. How to perform LEEP step-by-step

Refer to Skills Checklist 7.6.1
7.4.7. What is the post-treatment advice?

- Inform the woman about the expected symptoms like watery discharge or blood-stained discharge for about 4 weeks.
- Advise her to use sanitary napkins, as required, to avoid staining of clothes.
- Advise her to avoid sexual intercourse for about 4 weeks (or to use condoms if sexual intercourse can not be avoided).
- Advise her to use vaginal tampons or douche for about 4 weeks.
- Advise her to attend for check-up after 1 month when the histology report would be available.
- Advise her to report back if she has any of the following symptoms within 4 weeks of treatment:
  - fever for more than 2 days;
  - foul smelling purulent vaginal discharge;
  - severe lower abdominal pain/cramps;
  - vaginal bleeding heavier than menstrual bleeding;

7.4.8. What are the advantages and disadvantages of LEEP?

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple outpatient procedure</td>
<td>Electricity required</td>
</tr>
<tr>
<td>High efficacy</td>
<td>Requires more skill than ablative techniques</td>
</tr>
<tr>
<td>Tissue available for histological evaluation</td>
<td>Small risk of bleeding during and after the procedure</td>
</tr>
<tr>
<td>Can be performed under local anaesthesia</td>
<td>Small risk of adverse obstetric outcome</td>
</tr>
<tr>
<td>Minimal complications</td>
<td></td>
</tr>
</tbody>
</table>

7.4.9. What are the possible complications of LEEP?

- Excessive bleeding during or immediately after surgery (usually can be controlled by diathermy, fulguration and/or by applying Monsel’s paste)
- Secondary haemorrhage due to post-operative infection
- Post-operative infection/PID (characterized by presence of foul smelling yellowish discharge or blood mixed discharge and/or fever and/or pain. Appropriate management with antibiotics and other anti-inflammatory medicines is indicated)
- Cervical stenosis
- Cervical incompetence
- Premature rupture of membranes and pre-term labour in subsequent pregnancies
Management of secondary haemorrhage after LEEP

- Admit for observation
- Appropriately resuscitate if heavy bleeding
- Coagulate bleeding points using ball electrode
- Apply Monsel’s paste
- Apply tight vaginal pack if bleeding still persists and remove after 24 hours
- Start antibiotics
- In rare cases, cervical stitches are required to control bleeding

7.4.10. How to manage the common problems encountered during LEEP?

During treatment with LEEP, common problems that may be encountered are as follows:

<table>
<thead>
<tr>
<th>Problems</th>
<th>Reasons</th>
<th>Suggested solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficult exposure of the cervix</td>
<td>Laxity of vaginal walls</td>
<td>Put a non-lubricated condom or the cut finger of a glove on the speculum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insert lateral vaginal wall retractors</td>
</tr>
<tr>
<td>Patient feels pain during cutting</td>
<td>Inadequate infiltration of local anaesthetic</td>
<td>Inject sufficient local anaesthetic</td>
</tr>
<tr>
<td></td>
<td>Poor contact with patient return electrode (dispersive plate)</td>
<td>Adjust patient return electrode (dispersive plate) so as to establish a complete electrical circuit and prevent electrical burns to the patient</td>
</tr>
<tr>
<td>Loop does not cut properly/ gets stuck while cutting</td>
<td>Inappropriate power setting of the diathermy machine</td>
<td>Choose the power setting that is appropriate for that particular diathermy machine. Ideally this should be predetermined and the machine set accordingly before starting the procedure. Increase the cutting power gradually, 5W each time, till the loop starts excising the tissue smoothly</td>
</tr>
<tr>
<td>Field of vision in obscured due to smoke</td>
<td>Smoke evacuation system malfunctioning</td>
<td>Check the smoke evacuator tube and change if necessary</td>
</tr>
</tbody>
</table>
7.4.11. How to decontaminate LEEP equipment
See Module: 9 on infection prevention practices

7.4.12. What are the routine maintenance procedures and safety precautions for the electrosurgical unit used for LEEP?

- The safety and effectiveness of electro surgery is dependent, to a large degree, upon the skill of the user. The user should read, understand and follow the operating instructions supplied with the electrosurgical unit and should have adequate knowledge of the principles and use of such systems.
- Electrosurgery should not be done in the presence of flammable gases, flammable liquids or flammable objects in oxygen-enriched atmospheres or in the presence of other oxidizing agents.
- The electrical cord of the electrosurgical unit should be connected to a properly grounded receptacle. Extension cords and/or adapter plugs should be avoided.
- Old or worn accessories should not be used.
- Safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge and practical experience to perform these tests.
- The equipment should be decontaminated at the end of the day and kept properly covered to avoid dust.

7.5 Group learning activities

7.5.1 Role play
Counselling cards and flip chart should be used for role plays

Role play 1: Consent procedure and counselling for LEEP

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Maria, a 45-year-old woman having five children, who has undergone colposcopy at the district hospital.
  - Sebastian, a doctor who performs colposcopy at the district hospital.
  - Vitali, Maria’s husband, who accompanies her.
- The entire group including the role players should know the following background situation:

  At the primary health centre, Maria has been advised to have colposcopy in view of VIA positivity. She undergoes colposcopy at the district hospital. The colposcopy report is suggestive of a high grade lesion and requires a LEEP procedure. Dr Sebastian explains the necessity of LEEP, how the procedure will be done, benefits and side effects to Maria and takes informed consent.
Focus of the role play

The focus of the role play is the interaction between a doctor and a woman who has undergone colposcopy and needs treatment by LEEP. Dr Sebastian explains to Maria and Vitali that on colposcopy, he has seen a large white patch on the cervix that he suspects to be precancerous, which means if the patch is not treated it can give rise to cancer after a few years. The treatment is simple and the procedure is called LEEP. A special type of equipment is used to take out the abnormal area. The procedure is done under local anaesthesia, and for that a special drug will be injected on the cervix so that Maria will not feel any pain. Colposcopy will be repeated to do the procedure and the entire surgery will be completed in 10 minutes. Maria will be able to go home 1 hour after the surgery but will have to follow certain precautions. She will experience blood stained vaginal discharge and spotting for a few days and may have slight vaginal bleeding. She must report to the hospital if she has foul smelling vaginal discharge, excessive vaginal bleeding with clots, or pain of the lower abdomen with fever. Dr Sebastian advises Maria and Vitali not to have sexual intercourse for 1 month to avoid bleeding and infection. Sebastian asks about the necessity of further check-ups after the surgery. Doctor informs that he would like to see Maria after 1 month just to make sure that everything is fine with her. He will check the biopsy report that will be available by that time. The next visit for Maria will take place only after 1 year for a repeat colposcopy if there is nothing more serious in the biopsy report. Dr Sebastian enquires if Maria and Sebastian have any other questions and if they agree to have the surgery. Both of them agree and Maria signs the consent form. Dr Sebastian thanks Maria and Vitali.

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

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 LEEP.
  - Preeti, the doctor who performed LEEP.
- The entire group including the role players should know the following background situation:

  *Meena had colposcopy at a district hospital and had LEEP simultaneously. She wants to know about the postoperative care and check ups.*

Focus of the role play

The focus of the role play is the interaction between a woman who has just undergone LEEP and the doctor who performed LEEP. Preeti, the doctor, asks Meena if she is feeling all right and if she can comfortably get down from the table and sit on a chair. Meena says that she is fine and sits on the chair. She asks the doctor about what to do next. Dr Preeti tells Meena that the procedure went well and Meena can go home after resting at the clinic for half an hour. Dr Preeti informs her that, like many other women
Case study 1

A 38-year-old multiparous woman has been referred to the district hospital from the primary health centre for colposcopy as she has a VIA result. The appearances of the cervix on colposcopy are as follows:

**Question 1:** Describe the findings on colposcopy?

**Answer:** An endocervical polyp is seen. SCJ is not visible.

**Question 2:** Are there any visible vascular abnormalities?

**Answer:** No vascular abnormalities are seen.

Focus of the role play

having the procedure, Meena may notice a watery or blood-mixed vaginal discharge for up to 4 weeks and she may need to use sanitary pads. There is a small chance of developing infection, that can be treated by antibiotics. She advises Meena to avoid sexual intercourse for about 4 weeks. She also tells her that if sexual contact is unavoidable, condoms may be used. Dr Preeti informs Meena that she should visit the hospital for consultation with her biopsy report. However there are certain situations when Meena should attend the hospital promptly:

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

Dr Preeti thanks Meena and advises her to continue to attend for follow-up check-ups every year.

7.5.2 Case studies
Colposcopic appearance of the cervix after application of acetic acid

| Question 3 : What are the colposcopy findings? | Answer : SCJ is partly in the endocervical canal. The TZ is of Type 2. There is a dense acetowhite area with a sharp regular border over the anterior lip. The lesion is on the TZ and partially extending to the endocervix. The lesion is occupying two quadrants and 25–50% of the cervix. No abnormal blood vessels are seen. The diagnosis is probable high grade squamous intraepithelial lesion. |
| Question 4 : What is the proposed management? | Answer : The woman should be offered treatment based on colposcopy diagnosis of high grade lesion. The importance and benefits of completing treatment at the same visit should be explained to her. Alternatively, a biopsy can be taken from the lesion and treatment can be based on the histopathology report if the histopathology facility exists and the woman is willing to come back for the treatment on another date. |
| Question 5 : Is it possible to treat the lesion with cryotherapy? | Answer : The lesion is not suitable for cryotherapy as the TZ is Type 2 and part of the lesion is extending to the endocervix. She should be treated by LEEP. |

Images courtesy PGIMER, Chandigarh, India
7.5.3 Simulated learning

Practice sessions on LEEP procedure by simulation should be done under the guidance of a facilitator.

7.6. Skill development

7.6.1 Steps of LEEP

<table>
<thead>
<tr>
<th>Skills Checklist: Clinical skills in LEEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steps</td>
</tr>
<tr>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Pre-LEEP counselling</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. Tell her about the side effects she may expect and the alternatives to LEEP</td>
</tr>
<tr>
<td>4. Listen to her problems and concerns and respond to her queries</td>
</tr>
<tr>
<td>5. Ensure that the woman is not pregnant</td>
</tr>
<tr>
<td>6. Obtain informed consent for LEEP</td>
</tr>
</tbody>
</table>

Getting ready

<table>
<thead>
<tr>
<th>Steps</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Check that instruments, supplies and colposcope are available and ready to use</td>
<td></td>
</tr>
<tr>
<td>8. Check that the ESU and the smoke evacuator are ready for use</td>
<td></td>
</tr>
<tr>
<td>9. Check that the woman has recently (not more than 30 minutes previously) emptied her bladder</td>
<td></td>
</tr>
<tr>
<td>10. Help her onto the examining table, help her to undress and drape her</td>
<td></td>
</tr>
<tr>
<td>11. Place a reusable patient return electrode under her buttocks or on her thigh and connect it to the ESU</td>
<td></td>
</tr>
<tr>
<td>12. Wash hands thoroughly and air dry them</td>
<td></td>
</tr>
<tr>
<td>13. Put on new examination or high-level disinfected surgical gloves</td>
<td></td>
</tr>
<tr>
<td>14. Arrange instruments and supplies on a high-level disinfected tray or container</td>
<td></td>
</tr>
</tbody>
</table>
## Doing the procedure

15. Insert an appropriate sized insulated speculum with smoke extraction channel and fix blades so that the entire cervix can be seen clearly

16. Connect the smoke evacuator tubing to the insulated speculum

17. Place a lateral vaginal wall retractor, if required

18. Manipulate colposcope to focus clearly on the cervix

19. Apply 5% dilute acetic acid and identify:
   - Squamocolumnar junction
   - TZ and area to treat
   - Limits of the lesion

20. **Apply Lugol’s iodine to delineate the lesion clearly**

21. Inject 10 ml of 1% lignocaine with adrenaline into the stroma of the ectocervix (just beneath the epithelium) at the periphery of the lesion avoiding 3 o’clock and 9 o’clock positions

22. Set the power setting of the ESU to a blend of 50 watts of coagulation and 50 watts of cutting currents

23. Select an appropriate sized loop depending on the size and endocervical extent of the lesion so as to remove the lesion with minimum number of passes

24. Introduce the loop into the tissue 2–3 mm outside the outer margin of the lesion (either left or right or lower margin, but not the upper margin) and activate the ESU by pressing the cutting switch

25. **Direct the loop gradually into the cervix until the cross bar nearly comes in contact with the epithelial surface**

26. **Guide the loop parallel to the surface of the cervix across the endocervical canal till the opposite outer margin of the lesion is reached**

27. Gradually withdraw the loop and, as soon as it is out of the tissue, release the switch to stop the ESU

28. Remove the excised tissue with a pair of forceps

29. Fulgurate the defect on the cervix with a ball electrode using the pure coagulation current from the ESU to control the bleeding
30. If necessary, use multiple passes to remove the lesion entirely

31. Remove blood and clots from vagina and smear Monsel’s paste on the treated area

32. Remove return electrode. Remove speculum and place in 0.5% chlorine solution for 10 minutes

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

**Post-LEEP tasks**

34. Dispose-off the swabs and other disposable items in appropriate disposal bags

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

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

37. Check to be sure the woman is not having any discomfort or bleeding

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

39. Document the treatment done in the case record form along with the follow-up plan

*The highlighted steps are considered critical*

Score achieved: ____________________________ Facilitator’s signature

Facilitator’s remarks

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Points to remember

• To perform the LEEP procedure a wire loop electrode powered by an electro-surgical unit is used to remove the entire TZ along with the lesion.

• A blend of cutting and coagulation current is used.

• LEEP can be used to treat CIN of any grade, lesions not amenable to treatment by ablative techniques, the cervix with discordant cytology, colposcopy and punch biopsy reports especially if high grade disease is suspected or there is suspected glandular abnormality.

• Contraindications to LEEP include pregnancy, severe infection/inflammation of the cervix and less than 2 months postpartum.
## Multiple choice questions

1. Which of the following is not an indication for LEEP?
   - a) Glandular abnormality on punch biopsy
   - b) Discordance between cytology, colposcopy and punch biopsy
   - c) Treatment failure with ablative therapy
   - d) Cervical polyp

2. Which of the following is not a contraindication for LEEP?
   - a) Pregnancy
   - b) Severe local infection
   - c) Two months postpartum
   - d) CIN 3 with type 1 TZ

3. Patient should report to emergency if any of following symptoms occurs, except:
   - a) Fever of more than 38 °C lasting two days
   - b) Mild vaginal bleeding
   - c) Foul smelling purulent discharge per vaginum
   - d) Severe lower abdominal pain

4. All the following are advantages of LEEP, except:
   - a) Can be performed under local anaesthesia
   - b) Tissue is available for histological evaluation
   - c) Small risk of adverse obstetric outcome
   - d) Outpatient procedure

5. All the following are complications of LEEP, except:
   - a) Excessive bleeding
   - b) Cervical stenosis
   - c) Preterm labour in subsequent pregnancies
   - d) Increased risk of ovarian cyst

## Answer key

1 – d  
2 – d  
3 – b  
4 – c  
5 – d
Module 8: Treatment of cervical pre-cancers by cold knife conization (CKC) and follow-up

8.1. Module overview

This module is intended to train gynaecologists and non-specialist clinicians on the principles and technique of cold knife conization (CKC), an excision method of treatment for cervical pre-cancers and early malignancies (micro invasive cancer). The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Chapter 5 – Screening for cervical cancer, Section 5.5.3 and Practice Sheet 5.12).

8.2. Module contents

- Principles of CKC
- Instruments and consumables required
- Eligibility criteria for CKC
- Steps of CKC
- Post-treatment advice and follow-up
- Advantages and disadvantages
- Management of treatment complications
- Appropriate infection prevention practices
- Group learning activities:
  - Case studies
  - Role play

8.3. Learning objectives

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

- select cases for treatment with CKC;
- perform the technique following correct steps;
- recognize probable treatment complications;
- offer appropriate management of complications;
- follow infection prevention practices for CKC.
8.4. Key points for discussion

8.4.1. What are the principles of CKC?

CKC is the procedure to remove a cone shaped portion of the cervix using a knife. The cone has to include both the ectocervix and endocervix to ensure removal of the entire TZ and the lesion (Fig. 8.1). The width and length of the cone will depend on the extent and severity of the disease. The only indications for CKC are biopsy proved micro invasive cancer and adenocarcinoma in situ. However, CKC can also be used to treat high grade CIN lesions not suitable for ablative treatment, if LEEP facilities are not available. The advantages of the procedure are that the entire portion of tissue can be removed in one piece and margins can be evaluated better.

Fig. 8.1: Cold knife conization
8.4.2. What instruments and consumables are required?

### Instruments/equipment required for CKC

- Operation table with leg support
- Focusing light for examination
- Electrosurgical unit (with patient return electrode, hand switch or foot operated switch)
- Ball electrodes
- Posterior vaginal speculum
- Sponge holding forceps
- Single tooth tenaculum
- Kidney tray
- Number 11 scalpel with blade
- Needle holder
- Syringe for injecting vasoconstricting agents on cervix (dental syringe preferred)

### Consumables required for CKC

- Gloves (sterile/ gloves after high-level disinfection/disposable)
- Sterile cotton swabs, cotton swab sticks
- Lugol’s iodine
- Monsel’s paste
- Local anaesthetic (1 or 2% xylocaine/lidocaine) with 1:100 000 epinephrine
- Suture (2–0 polygalactin with needle)
- 5 mm ball electrode
- Lubricant jelly
- Vials containing 10% formaldehyde
- Waste disposal bag
- Chlorine solution (0.5%) or 2% glutaraldehyde
- Case record form
**8.4.3. What are the indications for CKC?**

<table>
<thead>
<tr>
<th>Indications for CKC</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adenocarcinoma in situ on punch biopsy or in endocervical curettings</td>
</tr>
<tr>
<td>• Microinvasive cancer on punch biopsy</td>
</tr>
<tr>
<td>• CKC can replace LEEP if facilities to perform LEEP are not available</td>
</tr>
</tbody>
</table>

**8.4.4. What are the contraindications for CKC?**

<table>
<thead>
<tr>
<th>Contraindications for CKC</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pregnancy</td>
</tr>
<tr>
<td>• Severe infection/inflammation of cervix</td>
</tr>
<tr>
<td>• Less than 2 months postpartum</td>
</tr>
</tbody>
</table>
8.4.5. How to perform CKC step-by-step

Refer to Skills Checklist 8.6.1

**Measures to reduce bleeding during surgery**

- Injecting adrenaline in combination with lignocaine in a 1:100 000 dilution or dilute vasopressin solution (diluted by adding 10 units of vasopressin to 30 ml of sterile water). Maximum 10 ml of solution is to be injected into cervical stroma around TZ in 1 ml increments.
- Placing sutures at 3 o’clock and 9 o’clock positions preconization to tie the descending cervical arteries (avoids side effects of vasoconstrictor drugs like tachycardia or blood pressure changes).
- Performing conization in the first half of the menstrual cycle.

8.4.6. What is the post-treatment advice for a woman after CKC?

The post-treatment advice after CKC is the same as for LEEP.

8.4.7. What are the advantages and disadvantages of CKC?

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Margin of the excised cone specimen can be evaluated better to assess the completeness of excision</td>
<td>General or regional anaesthesia required</td>
</tr>
<tr>
<td>Invasive cancer can be detected or ruled out from the tissue available for histological evaluation</td>
<td>Requires highly skilled provider</td>
</tr>
<tr>
<td>The procedure has high cure rate to treat high grade CIN lesions</td>
<td>Patient needs hospitalization and an operating room is essential for the procedure</td>
</tr>
<tr>
<td></td>
<td>Higher risk of bleeding during and after surgery compared to LEEP</td>
</tr>
<tr>
<td></td>
<td>Higher risk of cervical incompetence and pre-term delivery compared to LEEP</td>
</tr>
</tbody>
</table>

8.4.8. What are the possible complications of CKC?

The complications of CKC are the same as those for LEEP.
8.5. Group learning activities

8.5.1 Case studies

Case study 1

Case history: A 49-year-old multiparous woman was screened at a primary health centre and VIA was positive.

The appearance of her cervix on colposcopy was as follows:

Question: Describe the findings on colposcopy
Answer: A dense acetowhite lesion with sharp raised borders is visible on the TZ. Atypical blood vessels and irregular surface indicate early invasive disease. TZ is of Type 3 as the SCJ is not visible.

Question: What is the suggested management?
Answer: Multiple punch biopsies should be obtained from the lesion.

Question: The histopathology report was microinvasive carcinoma. How will you treat her?
Answer: She should have cold knife conization.

Question: If the histopathology report of CKC specimen shows invasive cancer, what will be the next step of management?
Answer: She should be referred to an oncology centre for staging and treatment based on the stage of the disease.

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Case study 2

Case history: A 48-year-old multiparous woman was screened using HPV test. Her test report was positive and she was referred for colposcopy.

The appearance of cervix on colposcopy was as follows:

<table>
<thead>
<tr>
<th>Appearance of the cervix before application of acetic acid</th>
<th>Question: Describe the findings</th>
<th>Answer: Cervix appears congested. Frothy mucoid discharge is seen on the cervix.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance of the cervix with a green filter before application of acetic acid</td>
<td>Question: Describe the colposcopy findings using a green filter</td>
<td>Answer: The entire cervix is covered with coarse mosaics and coarse punctations.</td>
</tr>
<tr>
<td>Appearance of the cervix after acetic acid application</td>
<td>Question: What is the type of TZ?</td>
<td>Answer: The TZ is of Type 3. The SCJ is entirely inside the endocervical canal and cannot be seen.</td>
</tr>
<tr>
<td></td>
<td>Question: Describe the findings on colposcopy</td>
<td>Answer: Dense acetowhite area is seen on all quadrants of the cervix. The surface is elevated near the external os. Coarse mosaics and punctuations are visible. The features are suggestive of invasive cancer.</td>
</tr>
<tr>
<td></td>
<td>Question: What is the suggested management?</td>
<td>Answer: Multiple cervical punch biopsies should be obtained from both anterior and posterior lips of the cervix. Further management should be according to the histopathology report.</td>
</tr>
</tbody>
</table>

Time allotted: 15 minutes

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8.6. Skill development

8.6.1 Steps of CKC

<table>
<thead>
<tr>
<th>Skills Checklist: Clinical skills in CKC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps</strong></td>
</tr>
<tr>
<td>Pre-CKC counselling</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 including the anaesthesia details</td>
</tr>
<tr>
<td>3. Tell her about the side effects she may expect</td>
</tr>
<tr>
<td>4. Listen to her problems and concerns and respond to her queries</td>
</tr>
<tr>
<td>5. Ensure that the woman is not pregnant</td>
</tr>
<tr>
<td>6. Obtain informed consent for CKC under anaesthesia</td>
</tr>
</tbody>
</table>

Preparing for anaesthesia

<table>
<thead>
<tr>
<th>Steps</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Check the investigation reports and fitness for anaesthesia</td>
<td></td>
</tr>
<tr>
<td>8. Check that the woman is at least 6 hours fasting</td>
<td></td>
</tr>
<tr>
<td>9. Check that the woman has recently (not more than 30 minutes previously) emptied her bladder</td>
<td></td>
</tr>
<tr>
<td>10. Make the woman lie down on the OT table and inform the anaesthetist</td>
<td></td>
</tr>
</tbody>
</table>

Preparing for the procedure

<table>
<thead>
<tr>
<th>Steps</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Check that instruments, supplies and colposcope are available and ready to use</td>
<td></td>
</tr>
<tr>
<td>12. Check that the ESU is ready for use</td>
<td></td>
</tr>
<tr>
<td>13. Put the patient in the lithotomy position</td>
<td></td>
</tr>
<tr>
<td>14. Place a reusable patient return electrode under her buttock or on her thigh and connect to the ESU</td>
<td></td>
</tr>
<tr>
<td>15. Wash hands thoroughly and air dry them</td>
<td></td>
</tr>
<tr>
<td>16. Put on sterile surgical gloves</td>
<td></td>
</tr>
<tr>
<td>17. Arrange instruments and supplies on high-level disinfected tray or container</td>
<td></td>
</tr>
</tbody>
</table>
CKC procedure

18. Clean the vulva, vagina and perineum with antiseptic solution and drape the patient

19. Insert an appropriate sized speculum and expose the cervix

20. Grasp the anterior lip of the cervix with a tenaculum

21. **Apply Lugol’s iodine to delineate the lesion**

22. Place a suture at the 12 o’clock position for the orientation of the specimen

23. Insert stitches lateral to the cervix (at 3 o’clock and 9 o’clock positions) – optional

24. Use an appropriate haemorrhage reducing technique. Inject 5–10 ml premixed solution of 2% lignocaine and epinephrine in a concentration of 1:100 000 into the stroma of the ectocervix (just beneath the epithelium) at the periphery of the lesion avoiding 3 o’clock and 9 o’clock positions

25. **Use a number 11 surgical blade to make a circular incision starting at 12 o’clock on the face of the cervix**

26. Angle the tip of the blade towards the endocervical canal till about 15–20 mm of endocervix is resected

27. Remove cone specimen in one piece, preferably

28. Remove the excised tissue with a pair of forceps

29. If necessary, use multiple passes to remove the lesion entirely

30. **Fulgurate the defect on the cervix with a ball electrode using the pure coagulation current from the ESU to control the bleeding**

31. Perform endocervical curettage

32. Remove blood and clots from vagina

33. If bleeding is heavy, do either:
   - Fulguration
   - Apply haemostatic sutures
   - Apply Monsel’s paste
   - Vaginal packing can be done

34. Remove return electrode. Remove speculum and place it in 0.5% chlorine solution for 10 minutes
### Post-CKC Tasks

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.</td>
<td>Dispose-off the swabs and other disposable items in appropriate disposal bags</td>
</tr>
</tbody>
</table>
| 36. | Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out:  
  - If disposing-off the gloves, place in a leak-proof container or plastic bag.  
  - If reusing surgical gloves, submerge in 0.5% chlorine solution for 10 minutes for decontamination |
| 37. | Wash hands thoroughly with soap and water and air dry them |
| 38. | Ensure that the patient is monitored properly in the recovery room |
| 39. | Check after 4–6 hours if the woman is fit to go home and is not having any bleeding or discomfort |
| 40. | Advise about post-treatment care and follow-up instructions |
| 41. | Document the treatment done in the case record form along with the follow-up plan |

*The highlighted steps are considered critical*

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**Score achieved:**  
Facilitator’s signature  

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**Facilitator’s remarks**

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**Points to remember**
- CKC is the procedure to remove a cone shaped portion of the cervix using a knife.  
- CKC should include both the ectocervix and endocervix to ensure removal of the entire TZ and the lesion.  
- The only indications for CKC are biopsy-proved micro invasive cancer and adenocarcinoma in situ.  
- Contraindications to CKC are pregnancy, severe infection/inflammation of the cervix, less than 2 months postpartum or any contraindication for general or regional anaesthesia.  
- Margin can be evaluated better for complete excision.
## Multiple choice questions

1. **Which of the following is not an indication for CKC?**
   - a) Adenocarcinoma in situ
   - b) Micro invasive cancer
   - c) LEEP facilities not available
   - d) Ectropion

2. **All the following are contraindications for CKC, except:**
   - a) Pregnancy
   - b) Severe cervical infection
   - c) Two months postpartum
   - d) Type 3 TZ

3. **Which of the following is an advantage of CKC?**
   - a) Better pathologic evaluation of cone margins
   - b) Local anaesthesia is required
   - c) Skilled manpower is not required
   - d) Lower risk of cervical incompetence

4. **The cone of CKC has to include:**
   - a) 25% of the TZ
   - b) 50% of the TZ
   - c) 75% of the TZ
   - d) Entire TZ

5. **All the following can be used to control post-operative bleeding after CKC, except:**
   - a) Fulguration
   - b) Hemostatic sutures
   - c) Vaginal packing
   - d) Lignocaine epinephrine solution

### Answer key

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>d</td>
</tr>
<tr>
<td>2</td>
<td>d</td>
</tr>
<tr>
<td>3</td>
<td>a</td>
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<tr>
<td>4</td>
<td>d</td>
</tr>
<tr>
<td>5</td>
<td>d</td>
</tr>
</tbody>
</table>
Module 9: Infection prevention practices

9.1. 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).

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

9.3. Learning objectives
At 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.

9.4. Key points for discussion

9.4.1. Why is infection prevention 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.

9.4.2. How to prevent the 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 risk of infection transmission. The following are standard universal precautions of infection prevention:
• washing hands before and after examining each client (Fig. 9.1);
• 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.

Fig. 9.1: Steps of handwashing

1. Wet hands with water
2. Apply soap to cover hand surfaces
3. Rub hands palm-to-palm
4. Rub right palm over left dorsum with interlaced fingers and vice versa
5. Palm to palm with fingers interlaced
6. Rub backs of fingers to opposing palms with fingers interlocked
7. Rotational rubbing of left thumb clasped in right palm and vice versa
8. Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa
9. Rotational rubbing of left wrist with right hand and vice versa
10. Rinse hands with water
11. Your hands are safe after drying
9.4.3. 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:

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. 9.2a). This step rapidly inactivates microorganisms like hepatitis B virus, hepatitis C virus and HIV and makes items safer to handle. Surfaces of procedure table and parts of any equipment/instrument that may have come in contact with body fluids should also be decontaminated by wiping with 0.5% chlorine solution or 90% ethyl alcohol before reuse.

2. **Cleaning** refers to scrubbing the instruments with a brush (an old toothbrush works well), using detergent and water to remove blood, other body fluids, organic material, tissue and dirt (Fig. 9.2b). 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. 9.2c) 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/inch²). 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. 9.2d) for eight 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. 9.2: Processing of instruments after use for infection prevention

Fig. 9.3: HLD by boiling

9.4.4. 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:

1) 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. 9.3).
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 seven 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. Begin timing 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 discolor metals and cause rust. Because 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 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. 9.4

Fig. 9.4: Instrument processing cycle
9.4.5. 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.

9.4.6. How to decontaminate instruments after performing LEEP

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

1. **Insulated instruments:** These include speculums, vaginal wall retractors, pick-up forceps, tenaculum, or any other insulated metallic instrument.
   - Insulated instruments should be cleaned thoroughly with a soft brush and soapy water, and then rinsed at least thrice, with clean water and air drying. **DO NOT** use bleach (chlorine solution) to decontaminate.
   - After cleaning, sterilize these instruments using an autoclave.

---

**Table 9.1: 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>
• The insulated speculum and other insulated instruments used for LEEP may also be disinfected with glutaraldehyde solution. The manufacturer’s instructions must be precisely followed because these solutions are corrosive and failure to follow correct procedure will cause instruments to degenerate over time.

➢ Do not leave the instruments in a disinfectant solution for more than two hours. Rinse-off all traces of the disinfectant solution with sterile water.

• Inspect the instrument insulation frequently before and after each use for cracks, nicks, cuts, and depressions which may decrease the effectiveness of the insulation and may lead to electric burn or shock when in contact with a charged electrode.

• Avoid contact with sharp instruments.

• Always verify that metal is not visible underneath the insulation coating.

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

• Fully submerge used instruments in a container filled with 0.5% chlorine solution for only 10 minutes.

• After 10 minutes, clean instruments with a brush and soapy water (wearing examination gloves), then rinse at least thrice with clean water and dry properly.

• After cleaning, these instruments may be autoclaved.

3. Rubbers and plastics: Electrical cords, hand switches and smoke evacuator tubes can be decontaminated with 0.5% chlorine:

• Submerge them in a plastic container filled with 0.5% chlorine solution for 10 minutes.

• After 10 minutes, clean them with a brush and soapy water (wearing examination glove). Rinse items at least thrice with clean water and dry properly.

• After decontamination, place them in high-level disinfection solution (glutaraldehyde) for 20–90 minutes.

• Pack items and place in a clean and dry place for storage.

9.4.7. How would you manage healthcare wastes from 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 the screening clinics is encouraged. Long storage of wastes within the premises should be avoided. The leak proof container/plastic bag should be sent for proper disposal/incineration.
9.4.8. What are the methods of disposal of biomedical wastes?

There are different categories of biomedical wastes that need to be treated differently as shown below in Table 9.2. The types of colour coded containers used for disposal of biomedical wastes are given in Table 9.3.

Table 9.2: Categories of biomedical waste and their disposal

<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/micro waving and mutilation shedding)</td>
<td>Needles, syringes, scalpels 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/micro waving</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/micro waving and mutilation shedding</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 9.3: Colour coding and type of container for disposal of biomedical waste (Fig. 9.5)

<table>
<thead>
<tr>
<th>Colour coding</th>
<th>Type of container</th>
<th>Waste category</th>
<th>Treatment options</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. 9.5: Different colour-coded bags for waste disposal
### 9.5. Group learning activities

#### 9.5.1 Preparation of 0.5% chlorine solution

<table>
<thead>
<tr>
<th>Preparation of 0.5% chlorine solution</th>
</tr>
</thead>
</table>
| To prepare chlorine solution of a particular strength, the following formula may be used to calculate the required amount of dry powder (household bleach):

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

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

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

**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. 9.6):**
1. Put on the lab apron and wear utility gloves
2. Take 1 litre of water in the plastic bucket
3. Take 14.2 gm (approximately 3 tea spoon full) of bleaching powder and put 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 matters should be used
- Chlorine solution should be prepared in a well-ventilated area
- Wearing of gloves and laboratory apron is necessary to avoid direct contact of chlorine solution with skin
- Plastic containers should be used for preparation and storage of 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. 9.6: Steps for 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 teaspoon 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:
   
<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>1.0% Savlon solution</td>
</tr>
<tr>
<td>b)</td>
<td>0.5% chlorhexidine gluconate solution</td>
</tr>
<tr>
<td>c)</td>
<td>0.5% chlorine solution</td>
</tr>
<tr>
<td>d)</td>
<td>70% ethyl alcohol solution</td>
</tr>
</tbody>
</table>

2. Sterilization destroys:
   
<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>Bacteria</td>
</tr>
<tr>
<td>b)</td>
<td>Viruses</td>
</tr>
<tr>
<td>c)</td>
<td>Bacterial endospores</td>
</tr>
<tr>
<td>d)</td>
<td>All of above</td>
</tr>
</tbody>
</table>

3. The chemical for high-level disinfection is:
   
<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>0.6% chlorine solution</td>
</tr>
<tr>
<td>b)</td>
<td>0.4% chlorine solution</td>
</tr>
<tr>
<td>c)</td>
<td>2% glutaraldehyde</td>
</tr>
<tr>
<td>d)</td>
<td>0.2% glutaraldehyde</td>
</tr>
</tbody>
</table>

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?
   
<table>
<thead>
<tr>
<th>Option</th>
<th>Grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>14.2 gm</td>
</tr>
<tr>
<td>b)</td>
<td>20.4 gm</td>
</tr>
<tr>
<td>c)</td>
<td>11.6 gm</td>
</tr>
<tr>
<td>d)</td>
<td>28.5 gm</td>
</tr>
</tbody>
</table>

5. What are the methods for instrument processing?
   
<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>Sterilization</td>
</tr>
<tr>
<td>b)</td>
<td>Chemical sterilization</td>
</tr>
<tr>
<td>c)</td>
<td>High level disinfection</td>
</tr>
<tr>
<td>d)</td>
<td>All of the above</td>
</tr>
</tbody>
</table>

### Answer key

- 1 – c
- 2 – d
- 3 – c
- 4 – b
- 5 – d
Module 10: Ensuring quality of services and programme monitoring in cervical cancer screening

10.1 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).

10.2 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

10.3 Learning objectives
At the end of this module trainees would be able to:
• understand the importance of quality improvement and monitoring in 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.
10.4 Key points for discussion

10.4.1. 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 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 10.1)

The healthcare providers of all cadres in a facility need to work in coordination with each other to ensure safe and effective delivery of the services and make improvement if any gaps are identified.

Box 10.1: Role of healthcare providers in ensuring 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 providing 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 community 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.

10.4.1. 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 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.
10.4.2. What are the indicators to monitor a cervical cancer screening programme

To evaluate the performance of a programme, a set of benchmarks or indicators are used. 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 earlier 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 10.1

Table 10.1: 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/ Number of women within the target age group in the population x 100</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 100 000</td>
</tr>
</tbody>
</table>
10.4.3. What is quality assurance and what is quality control?

Quality assurance of any health programme ensures that the 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 the 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

10.4.4. 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 of 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. 10.1).
10.4.5. 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 gain good understanding of the underlying causes.
- Staff should be encouraged to suggest possible solutions to identified problems. This will make them accept the solution more promptly.

10.4.6. 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. 10.2.
Fig. 10.2: Guidelines for implementing 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>

<table>
<thead>
<tr>
<th>Preparation for supervision (by external supervisors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Review previous reports of supervision of the facility, if any</td>
</tr>
<tr>
<td>• Review achievements, progress of work already reported</td>
</tr>
<tr>
<td>• Decide on the points that need special attention/improvement beforehand</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Things to do during supervision</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Observe the performance of service providers and compare with standards/checklists</td>
</tr>
<tr>
<td>• Provide immediate feedback while observing</td>
</tr>
<tr>
<td>• Solve problems jointly if any performance problems are identified</td>
</tr>
<tr>
<td>• Provide technical updates and guidance</td>
</tr>
<tr>
<td>• Provide on-the-job training where necessary</td>
</tr>
<tr>
<td>• Identify opportunities for improvement</td>
</tr>
<tr>
<td>• Follow-up on previously identified problems, if any</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Things to focus on in a health facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Client registration</td>
</tr>
<tr>
<td>• Counselling</td>
</tr>
<tr>
<td>• Informed consent procedure</td>
</tr>
<tr>
<td>• Screening</td>
</tr>
<tr>
<td>• Treatment of pre-cancer</td>
</tr>
<tr>
<td>• Infection prevention practices</td>
</tr>
<tr>
<td>• Documentation and record keeping</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Things to do after supervision</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Actions and discussions are documented and shared with all cadres of staff and facility managers</td>
</tr>
<tr>
<td>• Plan ongoing monitoring of weak areas</td>
</tr>
<tr>
<td>• Suggest definite steps to improve quality of services</td>
</tr>
<tr>
<td>• Disseminate the new strategies among all concerned for implementation</td>
</tr>
</tbody>
</table>
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

10.4.7. What are the tools for supportive supervision?

Certain tools are required to conduct supportive supervision of 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 10.2. The sample check list is for a screening clinic performing VIA and cryotherapy. Similar checklists are also to be designed for the colposcopy clinics and the laboratories involved in the programme.

Table 10.2: 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></td>
<td></td>
</tr>
<tr>
<td>Who maintains the register?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the register up to date?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many women have been registered in the last 10 months?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many of them had VIA?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What was the target for the last 10 months?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the women issued registration cards?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where are the old used registered stored?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check the register for neatness and completeness of entries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counselling and informed consent process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who does counselling of the women?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where is counselling done?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all the women counselled before and after the procedures?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do the counsellors give enough time to the women?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the informed consent form filled by all clients?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>Who performs VIA?</td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------------------------</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>How many VIA screening are 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></td>
<td>Number of women treated in the last 10 months</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>Infection control</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 10.3. 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 10.3: Sample skills matrix for supportive supervision of staff at a health facility conducting VIA (screen and treat) programme

<table>
<thead>
<tr>
<th>Skills matrix for supportive supervision of staff at a VIA clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic name:</strong> Name date:</td>
</tr>
<tr>
<td><strong>Staff responsibility</strong></td>
</tr>
<tr>
<td>In charge</td>
</tr>
<tr>
<td>Lead the team</td>
</tr>
<tr>
<td>Solving problems</td>
</tr>
<tr>
<td>Participate in QA</td>
</tr>
<tr>
<td>Stock-taking and ensuring regular supplies</td>
</tr>
<tr>
<td>Maintenance of equipment</td>
</tr>
<tr>
<td>Ensuring availability of staff</td>
</tr>
<tr>
<td>Generating reports</td>
</tr>
<tr>
<td>Clinician</td>
</tr>
<tr>
<td>Supervise the nurses</td>
</tr>
<tr>
<td>Manage women with treatment complications</td>
</tr>
<tr>
<td>Support the in-charge in day-to-day work</td>
</tr>
<tr>
<td>Participate in QA</td>
</tr>
<tr>
<td>Nurse 1</td>
</tr>
<tr>
<td>Performing VIA</td>
</tr>
<tr>
<td>Performing cryotherapy</td>
</tr>
<tr>
<td>Counselling</td>
</tr>
<tr>
<td>Nurse 2</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data manager</th>
<th>Maintaining records</th>
<th>Record and data management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Updating and backing up of database</td>
<td>Computer skills</td>
</tr>
<tr>
<td></td>
<td>Tracking of women</td>
<td>Generating lists from database and contacting women</td>
</tr>
<tr>
<td></td>
<td>Generating reports</td>
<td>Data management and data synthesis</td>
</tr>
<tr>
<td></td>
<td>Participating in QA</td>
<td>Understanding concept of QA and own responsibilities</td>
</tr>
</tbody>
</table>

*Low competency:* Cannot 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.
10.4.8. 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 earlier. It will be useful to obtain additional information like number of women screened per month, total number of facilities offering services under the programme, total number of trained providers, number of non-compliant 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.

10.4.9. 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 the 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. 10.3). Clients’ rights and the provider’s needs should be the key considerations.

Fig. 10.3: 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 plan 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 and 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 gynecologists and non-specialist clinicians in colposcopy and treatment

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 content and materials
1. Relevance and quality of presentations and printed material materials 1 2 3 4 5 6 7 8 9
2. Quality of practical demonstrations 1 2 3 4 5 6 7 8 9
3. Adequate exposure to clinical procedures 1 2 3 4 5 6 7 8 9
4. The number of cases for clinical procedures 1 2 3 4 5 6 7 8 9
5. Time spent for demonstration of procedures 1 2 3 4 5 6 7 8 9
6. Overall time for the sessions and course 1 2 3 4 5 6 7 8 9

Comments

Facilitators
7. Expertise on the topic 1 2 3 4 5 6 7 8 9
8. Facilitator’s ability to stay focused on the topic 1 2 3 4 5 6 7 8 9
9. Time allowed for me to ask all my questions 1 2 3 4 5 6 7 8 9
10. My questions were appropriately answered 1 2 3 4 5 6 7 8 9
11. Assistance during the demonstration of procedures 1 2 3 4 5 6 7 8 9

Comments
Training venue

12. The cleanliness and comfort of the venue 1 2 3 4 5 6 7 8 9
13. Air conditioning or 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 colposcopy and biopsy

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 were referred to this centre since the result of the VIA test you had few days ago was positive. Being positive on VIA by itself does not indicate that you have any pre-cancer or cancer of cervix (lower part of the womb). You need a further check-up to confirm or exclude the disease. The special test that will be done is known as colposcopy. Colposcopy is the examination of the cervix and the walls of the vagina. It is performed using a lighted microscope, called a colposcope, designed to give a magnified view of the lining of the cervix and vagina. Aided by light and magnification and using simple techniques to highlight abnormal cells, your doctor is able to sample areas of abnormality for biopsy (removal of small piece of tissue to confirm the diagnosis) or to do treatment.

How will colposcopy be done?

You will be reclining on the examination table with your legs elevated on foot-rests. The procedure usually takes about 10 minutes. After placing a spoon-like instrument (speculum) to hold open the vagina, a mild solution of acetic acid (vinegar) will be swabbed on your cervix. Your doctor will then perform a thorough examination of the cervix and vagina and determine whether to proceed with collection of biopsy sample(s) or not. Finally the cervix will be painted with iodine solution. A small piece of tissue, the size of a grain of rice, will be obtained for biopsy and will be sent to the laboratory to be examined under the microscope. Your doctor may also decide to treat the abnormal area without waiting for the biopsy report. If he/she decides to treat, he/she will separately explain the procedure and take your consent.

There is very little to no discomfort from this examination and you should be able to resume your normal activities immediately. Your doctor will tell you if a biopsy has been taken. If it has, you should avoid vaginal douching, use of tampons or sexual relations for a week.

What problems can occur during or after the test?

As stated above, you may experience brief, mild discomfort during the examination, both from placement of the speculum or cervical cleansing with the acetic acid (vinegar). The procedure is otherwise very similar to a gynaecologic examination. If a cervical biopsy has been done, you may have opted for slight vaginal bleeding (spotting) or blood stained vaginal discharge for a few days. If you have treatment you may have some complications and you would need to follow certain precautions that your doctor will explain separately.
Consent for colposcopy

I acknowledge that Dr/Mr/Ms.…………………………… has explained the proposed procedure to me and has answered questions to my satisfaction.

I hereby consent to colposcopy and biopsy (if necessary).

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

…………………………  ………………………… …………………………
Witness’ name  Witness’ signature  Date
Why do you need treatment?

We just did a colposcopy examination on you since the result of the VIA test you had few days ago was positive. On examination we have seen a white patch on your cervix (lower part of the womb) that we suspect is due to pre-cancer. Such changes if left untreated may turn into cancer after a few years. We strongly recommend that you get the condition treated. We may take a biopsy and wait for the biopsy results. However, in that case you will have to return on another day and your treatment will be delayed by a few weeks. Sometimes the biopsy result is not accurate. If you are prepared, we can complete the treatment today itself. The treatment will be done under local anaesthetia and will be completed within approximately 20 minutes. You will be able to go back home today.

How will the treatment be done?

The treatment that we recommend for you is known as LEEP. In this procedure we will use special equipment to scoop out the abnormal area from your cervix. You will be reclining on the examination table with your legs elevated on foot-rests. After placing a spoon-like instrument (speculum) to hold open the vagina, a mild solution of acetic acid (vinegar) will be swabbed on your cervix. Then your cervix will be painted with iodine solution. Local anaesthetic will be injected on the cervix. Using special types of knives that are activated by an electrosurgical unit, the entire abnormal area of the cervix will be removed. The cervix will be cauterized to stop bleeding from any point. After the procedure is over you may have to rest for about 10 to 20 minutes. The removed piece of tissue will be sent to the laboratory for biopsy (examination under microscope).

What problems can occur during or after the treatment?

You may experience brief, mild discomfort during the examination, both from placement of the speculum or cervical cleansing with the acetic acid (vinegar). During the LEEP procedure you may experience mild pain or sometimes a warm sensation in your vagina. Please let us know if you feel any discomfort more than that. In rare cases, there may be bleeding more than what is expected during the procedure. That is almost always controlled by cauterization but the treatment may take a longer time.

You will have a watery vaginal discharge for a week or two that may be blood stained. This is expected and not to be worried about. Please use a sanitary napkin as long as necessary. In rare cases, you may have infection or bleeding. You must contact us or any other doctor if you have high fever, a 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 after 1 month so that we can have a look at your biopsy report. If the biopsy report is the same as the colposcopic diagnosis you will need to have a repeat check-up after one year. Such a check-up can be done at the same centre where you were initially examined. There is a small possibility that the biopsy report may show cancer and in that case we will advise you to attend an appropriate facility for further treatment.

**Do you have to take any precautions to prevent complications?**

You should not perform vaginal douching or use tampons for a 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 LEEP**

I acknowledge that Dr/Mr/Ms.…………………………… has explained the proposed procedure to me and has answered questions to my satisfaction. I am completely aware of the procedure and the risks involved.

I hereby consent to LEEP.

```
…………………………  ………………………… …………………………
                        Name                  Signature                Date
…………………………  ………………………… …………………………
                        Witness’ name    Witness’ signature        Date
```
### Annex 4

**Sample colposcopy form**

<table>
<thead>
<tr>
<th>Personal details and contact information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of registration (day/month/year):</td>
<td>[ ] [ ] / [ ] [ ] / [ ] [ ] [ ]</td>
</tr>
<tr>
<td>2. Last name:</td>
<td></td>
</tr>
<tr>
<td>3. First name:</td>
<td></td>
</tr>
<tr>
<td>4. Husband’s name</td>
<td></td>
</tr>
<tr>
<td>5. Age:</td>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>6. Date of birth (day/month/year):</td>
<td>[ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>7. Address:</td>
<td></td>
</tr>
<tr>
<td>8. Telephone number:</td>
<td>[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>9. Registration number</td>
<td></td>
</tr>
</tbody>
</table>

| 1. Date of colposcopy: (dd/mm/yyyy)       | [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ] |
| 2. Reason for examination: (1: VIA+ve; 2: HPV+ve; 3: Cytology+ve; 4: Follow-up after treatment; 5: other: ____________________________) |  |
| 3. Adequacy of colposcopic examination: (1: adequate; 2: inadequate (inadequate due to: ____________________________)) |  |
| 5. Type of transformation zone: (1: Type 1; 2: Type 2; 3: Type 3) |  |
| 6. Abnormal lesion present (1: No; 2: Yes) |  |
| 6(i) If lesion present, location: (1: In the TZ; 2: Outside the TZ) |  |
| 6(ii) Number of cervical quadrants covered: (1 qd; 2 qd; 3 qd; 4 qd) |  |
| 6(iii) % of cervix covered (1:<25%; 2:25–50%; 3:50–75%; 4:>75%) |  |
| 6(iv) Acetowhite: (1: Thin/Transparent; 2: Dense) |  |
| 6(v) Border: (1: Diffuse/Irregular/Geographic; 2: Sharp) |  |
| 6(vi) Mosaics: (1: No; 2: Fine; 3: Coarse) |  |
| 6(vii) Punctuation: (1: No; 2: Fine; 3: Coarse) |  |
| 6(viii) Inner border/ridge sign: (1: No; 2: Yes) |  |
| 6(ix) Cuffed crypt opening: (1: No; 2: Yes) |  |
| 6(x) Iodine staining: (1: Stained; 2: Non-stained; 3: Not done) |  |
| 6(xi) Erosion/leukoplakia (1: No; 2: Yes) |  |
| 6(xii) Irregular surface of AW: (1: No; 2: Yes) |  |
| 6(xiii) Asymptomatic/fragile vessels: (1: No; 2: Yes) |  |
| 6(xiv) Frank growth/ulceration/necrosis: (1: No; 2: Yes) |  |
| 6(xv) Miscellaneous (specify): |  |

**Name of colposcopy centre**
<table>
<thead>
<tr>
<th></th>
<th>Swede score:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Colposcopy provisional diagnosis: (0: normal, 1: Inflammation; 2: Leukoplakia; 3: Condyloma; 4: Low grade squamous intraepithelial lesions; 5: High grade intraepithelial lesion; 6: Suspicious for invasive cancer; 8: Other (specify: ____________________); 9: Unknown</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Biopsy taken: (1: No; 2: Yes; 3: Refused 4: Facility not available)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Histopathology report: (01: Normal; 02: Inflammation; 03: LSIL/CIN 1/atypia; 04: HSIL-CIN 2; 05: HSIL-CIN 3; 06: Adenocarcinoma in-situ; 07: Micro invasive carcinoma; 08: Squamous cell carcinoma; 09: Adenocarcinoma; 10: Other carcinoma (specify: ________________); 11: Inadequate/inconclusive; 88: other (specify: ________________));</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Treatment: (0: Not necessary; 1: Cryotherapy; 2: Cold coagulation; 3: LEEP; 4: CKC; 5: Hysterectomy; 6: Referred to oncology; 7: Refused treatment; 8: Other (specify: ___________));</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Treatment date: (dd/mm/yyyy)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Referred to</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Follow-up date</td>
<td>[ ] [ ] / [ ] [ ] [ ]</td>
</tr>
</tbody>
</table>

Name of colposcopist: Signature and date:
Cervical cancer screening and management of cervical pre-cancers

Training of health staff in colposcopy, LEEP and CKC

Trainees’ handbook