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5.1 Anatomy And Physiology

The cervical epithelium is made up of the multi-layered squamous epithelium on the ectocervix and the thinner columnar epithelium on the endocervix. The transformation zone is at the junction between the squamous epithelium and the endocervical columnar epithelium.

The position of the transformation zone varies during a woman’s lifetime. At puberty the transformation zone lies at the external cervical os. Hormonal changes at puberty and in pregnancy cause the cervix to change shape and the lower part of the endocervical canal becomes everted. After puberty and before the menopause a woman’s squamo-columnar junction usually lies on the ectocervix. In post-menopausal women there is a reduction in the size of the cervix. The squamo-columnar junction comes to lie within the endocervix.

Acidic fluid within the vaginal secretion break downs the migrating columnar epithelium, which is replaced by squamous cells. This is a normal process called metaplasia. Immature metaplastic cells - those in the process of changing - are more sensitive to carcinogens than mature cells.

Most cancers of the cervix develop from abnormal epithelial changes. Early changes are called cervical intraepithelial neoplasia (CIN). Microscopic examination of cells scraped from the surface of the epithelium of the cervix can determine whether CIN is present. CIN may occupy only a small area of the transformation zone.

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1. Squamous epithelium
2. Columnar epithelium
3. Squamo-columnar junction
4. Everted columnar epithelium
5. Transformation zone
6. Gland openings in transformation zone

**Figure 12: Cervical Epithelium**
5.2 Environment And Equipment

5.2.1 Environment
Care should be taken in establishing an environment that enables and encourages communication with the woman and that facilitates the smear taking process.

Some women find a smear test difficult. A suitable environment will help to establish rapport, and to relax and encourage the woman.

Smears should be taken in an area that is quiet, warm, well lit and comfortable. The area should be located away from the noise of voices and other disturbances if possible. There should be a lock on the door or a curtain that can be drawn, as privacy is very important. Hangers for clothing should be provided. A cover should be available should the woman like to use it.

A chaperone should be offered, and available if requested.

All equipment for smear taking should be prepared and ready. The use of a trolley is recommended, as noted below.

5.2.2 Equipment Required

<table>
<thead>
<tr>
<th>EQUIPMENT</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand washing facilities</td>
<td>The smeartaker’s hands should be washed before and after any duty that involves close contact with the patient</td>
</tr>
<tr>
<td>Illumination</td>
<td>An adjustable halogen spotlight provides one of the better sources of illumination</td>
</tr>
<tr>
<td>Examination couch</td>
<td>The examination couch should be placed in a position to allow easy vaginal examination with the woman in either the left lateral or dorsal position</td>
</tr>
<tr>
<td>Gloves</td>
<td>Vinyl or latex disposable gloves are recommended. Be aware that some women are allergic to latex rubber</td>
</tr>
<tr>
<td>Sheet, blanket, pillow</td>
<td>A disposable sheet, pillow and blanket cover should be used for patient comfort</td>
</tr>
<tr>
<td>Cytology Referral Forms</td>
<td>The ICSP Cytology Referral Form is a 3-piece form that comprises:</td>
</tr>
<tr>
<td></td>
<td>- Cover page for the patient</td>
</tr>
<tr>
<td></td>
<td>- Laboratory request sheet</td>
</tr>
<tr>
<td></td>
<td>- Smeartakers’ copy</td>
</tr>
<tr>
<td>Pencil and ballpoint pen</td>
<td>Use a pencil to label the slide (pen and ballpoint ink dissolve in the staining process). A sharp-tipped pen for filling out the Cytology Referral Form helps to ensure that each copy is legible</td>
</tr>
</tbody>
</table>

Continued over leaf
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speculum (see Figure 13)</td>
<td>At least 3 different sizes of bivalve vaginal speculum (Cusco’s speculum) should be available: small, medium, and large. A very small speculum (virgin speculum) and a long-bladed narrow speculum may occasionally be needed.</td>
</tr>
<tr>
<td>Sampler – Spatula</td>
<td>The Aylesbury spatula has an extended tip that helps to improve the accuracy of smear taking.</td>
</tr>
<tr>
<td>Sampler – Broom and Cytobrush (see Figure 15)</td>
<td>The plastic broom is used in liquid based cytology. An endocervical brush should also be available.</td>
</tr>
<tr>
<td>Glass microscope slide</td>
<td>A slide measuring 7.6 x 2.5cms with a frosted end for labelling.</td>
</tr>
<tr>
<td>Liquid-based cytology (LBC) vial (see Figure 14)</td>
<td>A vial containing transport medium for liquid-based cytology.</td>
</tr>
<tr>
<td>Fixative spray</td>
<td>95% alcohol and carbonwax or 5% acetic acid. Check it is in date.</td>
</tr>
<tr>
<td>Slide holders</td>
<td>Different ones are available.</td>
</tr>
<tr>
<td>Padded envelopes for slide mailing</td>
<td>Padding is important to reduce the risk of transit breakage.</td>
</tr>
<tr>
<td>LBC transport boxes</td>
<td>Supplied by the LBC supplier.</td>
</tr>
<tr>
<td>Waste disposal bags</td>
<td>Clinical waste needs to be disposed of with care, especially used disposable speculums, brushes and spatulas.</td>
</tr>
<tr>
<td>Patient information leaflets</td>
<td>Available from the ICSP.</td>
</tr>
<tr>
<td>Smear taking trolley</td>
<td>A pre-set trolley to hold all smear taking equipment is recommended.</td>
</tr>
<tr>
<td>Area for ‘drying’ slides</td>
<td>A shelf for slides to allow them to dry adequately before insertion into holder.</td>
</tr>
</tbody>
</table>

Figure 13: The range of sizes of Cusco’s specula

Figure 14: Liquid Based Cytology System

Figure 15: Use of Broom, Cytobrush and Spatula
5.3 Infection Control

Some women may not attend for smear tests because, for them, the worry of acquiring infection through this procedure outweighs the risk of cervical cancer.

The vagina and cervix are not sterile areas

1. Prevent cross infection between patient and smeartaker
   The smeartaker's hands should be washed before and after any duty that involves close contact with the patient. Disposable seamless gloves should be used, and changed between patients. Plastic speculums and samplers should be discarded after each individual patient use. Disposable paper sheets should be used, and changed between patients.

2. Prevent contamination of the environment
   There should be separate sinks for hand washing and washing instruments. There should be paper towels for hand drying. Lever taps and soap dispensers are preferable. Objects touched during the course of the procedure e.g. lamp, should be cleaned with a dry paper towel.

3. Dispose of contaminated articles safely
   Safe disposal of used instruments and equipment is important. These should be disposed as clinical waste.

5.3.1 Sterilisation

There are no nationally approved standards for sterilisation of surgical instruments in general practice in Ireland

5.3.2 ICSP Recommendations

- Steam-sterilised speculum must be sterilised according to best practice sterilisation guidelines
- Reusable speculum processed via an accredited sterilisation unit can be used
- There are no guidelines available for dry autoclave sterilisation - it is not recommended
- Chemical disinfection is inadequate and therefore not satisfactory
5.4 **Counselling, Consent And Confidentiality**

5.4.1 **Counselling**

Women having a cervical smear taken should be counselled before, during and after the procedure. The woman’s understanding of the test and concerns about its implications need to be fully addressed. Clear language should be used. It is important to check with the woman that she understands all the information provided.

The smearaker should make use of the ‘Information For Women’ cover sheet of the ICSP Cytology Referral Form and other leaflet information concerning cervical screening.

![Figure 16: Information for women on cover sheet of Cytology Referral Form](image)

Every woman should know:

- The purpose of cervical screening
- When and how the result will be made available
- The likelihood of a normal smear result (approx. 84%)
- The meaning of a normal smear result
- The likelihood of an inadequate smear result (approx. 10%)
- The meaning of being recalled following an abnormal result
- ‘Not normal’ smear results need individual recommendations
- The programme will endeavour to follow up each result and ensure that suggested action is carried out
- Recall will be when the next smear is due as per programme recommendations
- The importance of always reporting any abnormal bleeding or discharge
- The limitations of the test
It should be emphasised that the smear test is not a test for cancer. It is a screening test only. The cervical smear looks to detect abnormal cells on the cervix that if left untreated may possibly turn cancerous. However, women should be advised that any unusual or irregular bleeding, spotting or discharge should be brought to the attention of their doctor without waiting for the next smear.

It must be clear to all women having the test what a cervical smear does not detect, and that the test relates only to the cervix. No information is necessarily obtained about the other pelvic organs. Women should be advised that normality of the ovaries and uterine functions cannot be assumed following a normal smear result.

Women should be advised that the time required to provide the result varies, depending on the laboratory and the screening test method used.

The test result is issued to the smeartaker by the laboratory. The ICSP endeavours to send a letter about the smear result to the woman’s address given on the Cytology Referral Form (unless otherwise, specifically and clearly indicated on the Form).

Each woman must be given the opportunity to discuss the result of her test and its implications. Each woman should fully understand the significance of the test result. Care should be taken not to generate unnecessary anxiety.

Only 'normal' results should be discussed by phone. Face to face consultation for all other results is required, with adequate time allowed for questions and explanation.

All counselling related to the smear must be readily available to the woman. Women undergoing colposcopic assessment and treatment are entitled to counselling from their smeartaker. For ICSP registered smeartakers, all such counselling is included in the smeartaker’s contract fee so no charge should be levied.

5.4.2 Informed Consent

Informed consent must be obtained without duress. Consent to have the smear taken is implicit when the patient allows the test to occur however this should only occur after a full explanation as outlined in 5.4.1.

Additional signed consent for ICSP registered women is for the information recorded on the ICSP Cytology Referral Form by the smeartaker to be transferred to the Central ISCP Office. This is a legal requirement. The ICSP will use the information for the purposes of providing each woman with cervical screening services, including future call and recall. The information will also be used in auditing, reviewing and monitoring the delivery of the Programme.

The ICSP may use certain information recorded on the Form for the purposes of surveys and other research. Women will be given the choice to participate in any research projects conducted by the ICSP. The 'Information for Women’ cover sheet explicitly informs women that they are consenting to all aspects of the ICSP Programme, including research and audit. The laboratory may use the cervical screening sample for research, teaching and audit purposes. Confidentiality will be upheld.

Ensure that the woman gives her consent to participate fully in the ICSP by signing the ICSP Cytology Referral Form.
5.4.3 Women Who Do Not Wish To Participate In The ICSP
A ‘non-consent sticker’ can be applied to the form should any woman decline to have her details and result sent to ICSP Office. In this case, the laboratory will forward the result to the smeartaker or doctor only. The ICSP Programme does not cover payment for this type of smear. The smeartaker must arrange directly with the woman for payment.

5.4.4 Confidentiality
The information on the ICSP Form is processed using a unique identification number - either the Personal Public Service Number, PPSN or the Cervical Screening Programme Number, CSP Number.

The ICSP will only allow access to personal records and patient information to the woman concerned, the smeartaker, laboratory and colposcopy treatment staff. All staff must sign confidentiality agreements.

5.5 History-Taking and The Cytology Referral Form

5.5.1 Appropriate Timing
Ideally, a cervical smear should be taken in the second part of the menstrual cycle to facilitate optimal cytological conditions when it is unlikely there will be any remaining menstrual blood. Preferably, the woman should not have had intercourse in the previous 24 hours. The use of a spermicidal or vaginal cream can interfere with laboratory reporting and result in an inadequate smear.

5.5.2 Pre-Screening Interview
The only question the smeartaker needs to ask is if the woman has ever been sexually active. If the answer is "yes" then she needs regular smears. Questions about a woman's sexual history and number of partners are irrelevant and need not be asked.

5.5.3 Clinical History Taking
Key questions to ask the woman are:

1. Any abnormal bleeding:
   - Post-coital bleeding (PCB)
   - Inter-menstrual bleeding (IMB)
   - Post-menopausal bleeding (PMB)?
2. Any unusual vaginal discharge?
3. Date of the first day of her last menstrual period?
4. If she is using oral contraception, taking hormones or has an IUCD in place?
5. Pain or discomfort with sexual intercourse

Check as far as possible the woman’s relevant clinical history by referring to her records, including copies of previous smear forms.
5.5.4 Cytology Referral Form

Personal identity and contact details should be entered on the Cytology Referral Form.

Do not copy the woman’s details from a previous form or the woman’s notes without checking with the woman that the details are correct. Ensure that all copies are legible.

![ICSP Cytology Referral Form](image)

**Figure 17: ICSP Cytology Referral Form**

Remember to enter the date the smear was taken

The laboratory require the following minimum data set to be entered in the appropriate part of the Cytology Referral Form:

- Date of the last smear
- Last smear result (whether normal or abnormal)
- Abnormal smears in the past and, if so, when. (Lab accession number if known)

Laboratory recommendations could be inappropriate without complete information.

5.5.5 Before Proceeding

- Ascertain if the woman has any questions and answer as appropriate
- Try to accommodate any individual special requirements
- Allow the woman an opportunity to empty her bladder
5.6 Taking A Cervical Smear

Poor technique can result in 20% or more of pre-cancerous abnormalities being missed\(^\text{31}\).

An inadequate sample may result in a negative report or a report of dyskaryosis, which underestimates the degree of abnormality present.

**PROCEDURE SUMMARY**

1. Write the woman’s identification details on the slide or Liquid Base Cytology (LBC) vial - full name and date of birth
2. Choose the appropriate speculum for the woman
3. Prepare the woman
4. Identify and visualise the cervix
5. Take a sample with an appropriate sampler from the entire squamo-columnar junction (SCJ)
6. Spread the material thinly from both sides of the spatula, using longitudinal strokes, on a single glass slide
7. Immediately apply fixative, ensure slide is fully covered and allow the slide to dry in the horizontal position without draining before inserting into the transport container
8. For LBC, a broom is required. Obtain the sample in the usual manner. Rinse the cells immediately into the LBC vial. Cap and put in to suitable transport container
9. Record details of smear on the Cytology Referral Form and in the woman’s clinical notes
10. Record the smear in a logbook or a database or in a ‘Result Awaited’ Forms box
11. Practice to post promptly to laboratory to minimise turnaround time

5.7 Procedural Detail

Explain to the woman what you are doing at all times
5.7.1 Positioning The Woman

Smear tests can be taken in the dorsal position or in the left lateral position. In the dorsal position, the woman lies with the buttocks towards the light source, soles of feet together, knees bent and legs lax but wide open.

Angle the light source to allow clear visualisation of the cervix and vaginal walls. Adjust the light as necessary during the course of the procedure.

![Figure 18: Positioning of the women A. Dorsal and B Left Lateral](image)

5.7.2 Insertion Of The speculum

The largest size speculum that can be comfortably inserted should be chosen. Check the temperature of the speculum and adjust to body temperature. This is not necessary with disposable plastic speculums.

![Figure 19: Insertion of the speculum](image)

Lubrication of the speculum is usually not necessary but if the vagina is very dry and there is a risk of pinching, a little water or a small amount of soluble lubricant, such as KY jelly, can be applied. To avoid contaminating the cervix, care must be taken not to place the lubricant on the tip of the speculum. If necessary, a gentle digital examination to locate the cervix can be carried out and any vaginal wetness used to lubricate the speculum along its sides.

Insert the speculum gently along the axis of the introitus. Angle the speculum backward towards the coccyx. Opening and closing the speculum slightly or changing the angle of insertion should bring the cervix into view. Do not open the speculum completely until it is fully inserted.
5.7.3 Assessment Of The Cervix
Common problems with visualisation of the cervix include a long posterior cervix, a retroverted uterus (anterior cervix), or a 'floppy' vaginal wall (most commonly seen in multiparous women).

Smeartakers commonly see nabothian follicles (mucous retention cysts), cervical eversion/ectropian and occasionally cervical polyps or cervical warts.

Figure 20: Normal Cervices A. Nulliparous and B. Multiparous

A bulky friable bleeding cervix may suggest cervical cancer. A smeartaker will rarely encounter cervical cancer. Refer to Section 1.8

5.7.4 Taking The Sample
A spatula with an extended tip (Aylesbury) should be used, as the transformation zone is more likely to be correctly sampled.

The plastic broom is always used in liquid-based cytology.

A cytobrush may be used when the squamo-columnar junction is high in the endocervical canal, where an endocervical abnormality is suspected or where the woman has had previous endocervical (glandular) abnormality. It may also be necessary to use a cytobrush if there is cervical stenosis following treatment of the cervix. Never use a cytobrush brush only. Always use the spatula first as using the cytobrush can cause bleeding and contaminate a subsequent sample.

The smeartaker must visualise the cervix and sample the whole circumference of the cervical os, including the transformation zone.

Do not take the smear if unable to identify the cervix or if the smear is likely to be heavily contaminated with blood or vaginal discharge.

Copious cervical mucous can be removed before taking the smear with the spade end of the spatula by gently twisting it in the mucous, avoiding contact with the cervix, and then 'lifting' the mucous off the cervix.

Insert the spatula into the cervical os using the bi-lobed end unless the cervix is very patulous or scarred,
when the spade end should be used. The spade end should be used if there is a wide eversion / ectropion as the squamo-columnar junction no longer lies in the endocervix.

Firmly rotate the spatula through at least 360° ensuring that the scraping spans the squamo-columnar junction at all times.

Only forward the slide to the laboratory if you are satisfied that the cervix has been visualised and completely sampled.

5.7.5 Preparing The Slide Or The LBC Vial

Details on slides, liquid based vials and Cytology Referral Forms will be checked and compared at the laboratory. In order to be accepted for screening a slide or vial must, as a minimum, contain the woman’s surname, first name /initial and date of birth. These details must all exactly match the details on the referral form.

5.7.6 Transfer The Sample To The Slide

The aim is to get a single layer of cells on the slide without damaging the cells.

Spread the material thinly on the glass slide. Use gentle longitudinal strokes rather than a circular motion.

On the rare occasions where both a cytobrush and a spatula are used, the material from the cytobrush should be spread immediately by rolling the brush along the slide onto half the slide. After this, apply the spatula sample to the other half of the slide and fix.

5.7.7 Fixing The Slide

Check the expiry date on the fixative spray before use. Halogen lamps must be switched off as the heat from them can cause the sample to dry. Avoid exposure of the slide to direct sunlight.

The slide must be fixed immediately to avoid cellular changes or drying out of the sample.

The cytological fixative spray should be held at a distance of approx. 20cm, in order to spray the entire slide. Liberally apply fixative with the slide kept horizontal. Allow drying for a minimum of 20 minutes before inserting into the container.

5.7.8 Slide To Holder

Be familiar with the open/close mechanism of the holders supplied.

Ensure that the slide is ‘smear’ side up and that the cover of the holder does not scrape off the smeared cells.

Ensure that the slide is secure in the holder and the holder is closed to prevent the slide breaking.
5.7.9 Liquid Based Cytology

Liquid-based cytology allows for separation of cervical cells from blood, mucus and non-diagnostic debris. Obtain the sample in the usual manner. Rinse the cells immediately into the liquid based cytology vials.

Ensure the vial is closed, with the cap screwed to the point where the black marks pass each other.

5.7.10 Complete Cytology Referral Form

Record relevant details of clinical impression and additional information.

The laboratory recommendation for clinically described ‘suspicious cervix’ is referral for colposcopy.

5.7.11 Submit Samples To Laboratory

Post the smear to the appropriate laboratory promptly. This is the responsibility of the smeartaker. It is advisable to log the day of posting the smear. Ensure that the completed Cytology Referral Form accompanies each smear.

More than one slide can be sent in one envelope but note that there will be an extra postage charge.

Liquid based cytology vials must be posted within 2 weeks, even if the transport box is not full. Boxes are reusable and should not be written on. Retain one ‘bar code ‘label when posting to allow for tracing if the package becomes lost in transit.

5.8 Quality Issues

5.8.1 Accuracy Of Information

It is vital that all smeartakers understand the importance of the unique identification number to ensure accuracy in the follow through of a woman’s smear processing stages. The success of the delivery of the screening programme requires the use of the unique identifier at all times in the process and the future.

5.8.2 Quality Assurance Targets

ICSP registered smeartakers commit to the Programme’s quality assurance (QA) target of <10% annual inadequate smear rate. An inadequacy target rate for liquid-based cytology samples is being developed. With approved training programmes for smeartakers, lower target inadequacy rates are expected.

In a screening programme, there is an irreducible false negative rate that does not relate to negligence despite quality assurance targets being met.

The ICSP is committed to providing feedback on quality issues to smeartakers bi-annually. Additional support and training is made available to smeartakers with an inadequacy rate of >15%.

5.8.3 Inadequate Smears

An inadequate smear is one that the laboratory finds to be unsuitable for reading. Many of the reasons for inadequate smears are within the control of the smeartaker.

A summary of the most common reported reasons for inadequacy, and possible means of prevention, is given in the following table.
<table>
<thead>
<tr>
<th>REASON FOR INADEQUATE SMEAR</th>
<th>POSSIBLE CAUSES</th>
<th>POSSIBLE SOLUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix not visualised</td>
<td>Woman not relaxed&lt;br&gt;Acutely anteverted or retroverted uterus&lt;br&gt;Lax vaginal walls</td>
<td>Explanation&lt;br&gt;Use appropriate speculum&lt;br&gt;Try left lateral position or place a pillow under the woman’s buttocks&lt;br&gt;Use a larger speculum or use part of a condom or latex glove pulled over the speculum and this will hold back the vaginal walls</td>
</tr>
<tr>
<td>There is insufficient cellular material</td>
<td>Cervix not scraped firmly enough&lt;br&gt;Insufficient material transferred to slide&lt;br&gt;Atrophic cervix in postmenopausal women</td>
<td>Spread material both sides of the spatula&lt;br&gt;Insufficient cellularity can be a problem in postmenopausal women and this can be resolved by short-term local oestrogen</td>
</tr>
<tr>
<td>Sample poorly spread</td>
<td>A lumpy slide means that the cover slide cannot be applied properly and this causes 'air bubbles' distorting vision of cells</td>
<td>Spread material with longitudinal strokes to ensure slide material is not too thick, too thin or lump</td>
</tr>
<tr>
<td>The cervical cells are obscured. Blood, menstrual debris, polymorph exudate, bacteria or spermatozoa can obscure the cervical cells</td>
<td>Discharge or infection present</td>
<td>Investigate for infection and repeat smear after treatment&lt;br&gt;Take smear when the woman is not menstruating&lt;br&gt;Use Liquid Based Cytology&lt;br&gt;Gynaecological referral if cervical cancer or gynaecological cause of bleeding</td>
</tr>
<tr>
<td>Contaminants can obscure the cervical cells</td>
<td>Lubricants, spermicides and vaginal creams</td>
<td>Use water instead of lubricants&lt;br&gt;Consider deferring the smear</td>
</tr>
<tr>
<td>Broken slides</td>
<td>Careless handling and slide holders that are not closed properly</td>
<td>Be familiar with slide holders and take care to close firmly</td>
</tr>
<tr>
<td>Cell presentation is technically unacceptable</td>
<td>Air drying</td>
<td>Improve fixation technique by prompt fixation</td>
</tr>
</tbody>
</table>