

Guide for smeartakers

SECOND EDITION

Guide for smeartakers

Freephone information helpline number

1800 45 45 55

Website address:

www.cervicalcheck.ie



THE NATIONAL CERVICAL SCREENING PROGRAMME

Introduction

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The Guide for Smertakers has been developed as a reference for General Practitioners and Practice Nurses who take cervical smear tests in the primary care setting.

It provides an overview of how CervicalCheck – The National Cervical Screening Programme operates and reflects current best practice in the taking and management of quality smear tests for women in their community, in line with the CervicalCheck Women's Charter.

Smertakers play a pivotal role in promoting and delivering cervical screening to women. This guide is an essential resource in working towards the success of a quality assured national programme.

This guide is intended primarily for use by smertakers for CervicalCheck – The National Cervical Screening Programme. This guide can be used by doctors, nurses, supervisors and trainers as:

- A reference manual, providing up-to-date information about screening for cervical cancer
- A resource for clinical practice
- A support for education and training in the Smertaker Training Programme
- A checklist to support supervision
- An aid to assist smertakers to give quality information to women who present for screening

The National Cancer Screening Service is part of the Health Service Executive National Cancer Control Programme. It encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme.

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Section 1

CervicalCheck The National Cervical Screening Programme

An overview

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CervicalCheck - The National Cervical Screening Programme

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CervicalCheck - an overview

Aim of section

The aim of this section is to provide a background to the establishment of CervicalCheck, in addition to an overview of the organisation and CervicalCheck processes and how they apply in the primary care setting.

1.1 Summary of CervicalCheck

CervicalCheck offers a free cervical screening service that aims to reduce the incidence of and mortality from cervical cancer in women aged 25 to 60 years.

CervicalCheck has a target coverage of a minimum of 80 per cent of the eligible population in the programme's catchment area (Republic of Ireland) by the end of the second full screening round. Coverage is defined as the number of unique women who have had at least one satisfactory smear test taken within the defined screening interval, expressed as a percentage of the total number of eligible women.

CervicalCheck maintains a Cervical Screening Register (CSR), incorporating a population register which contains demographic data of eligible women for the purposes of screening. This register, which is a computerised information system, allows CervicalCheck to call and re-call women for screening and colposcopy treatment.

Women aged 25 to 44 are invited for screening every three years and women aged 45 to 60 are invited every five years. Regardless of age women must have two consecutive 'no abnormality detected' results at three yearly intervals before going onto a five yearly screening interval.

Cervical screening is based in primary care settings and participating smertakers are required to register with the programme. CervicalCheck maintains a database of all registered smertakers and provides smertakers with training and education initiatives.

Key tasks of CervicalCheck

- Maintains and updates the Cervical Screening Register (CSR)
- Identifies and invites eligible women for cervical screening
- Sends out call and re-call letters as appropriate
- Sends out letters informing women that their results are now available from their smertaker
- Ensures that attempts are made to contact women requiring further investigation – failsafe process
- Checks that smear tests with 'not normal' results are followed up and outcomes recorded
- Registers doctors and nurses as CervicalCheck smertakers and processes payments for smear tests taken
- Provides training, education initiatives and clinical updates for smertakers
- Quality assures all aspects the programme
- Co-ordinates and provides quality assured laboratory services
- Co-ordinates and provides quality assured colposcopy services

1.2 Background to CervicalCheck

Phase One of the Irish Cervical Screening Programme (ICSP) commenced in the Mid Western Health Board Region in 2000. This phase was seen as an important period in the programme during which key operational issues were prepared and tested before the full national programme could be rolled out.

Since that time, the programme has evolved and progressed, incorporating the findings from two external reviews in 2004. These reviews not only acknowledged the success to date but also enabled the programme to identify a number of areas for further improvement. These improvements have since been implemented.

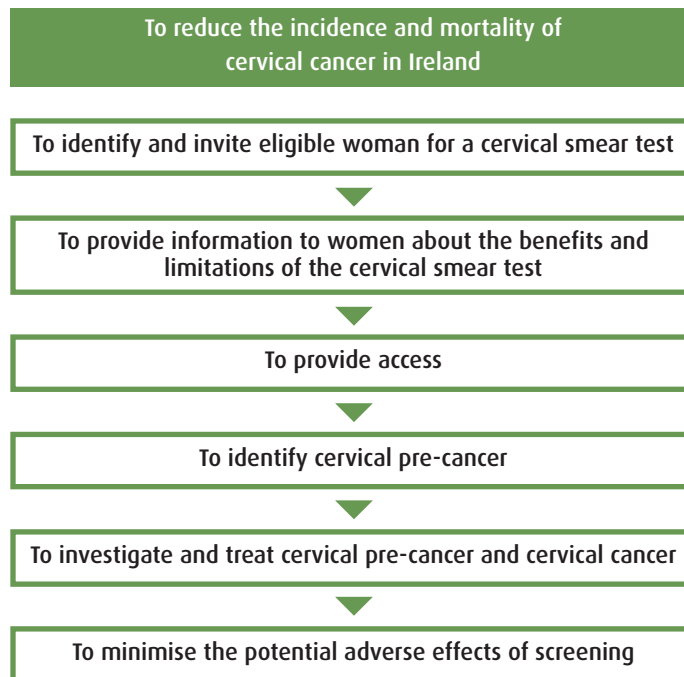
Other developments that have impacted on the direction of the programme include the launch of 'A Strategy for Cancer Control in Ireland 2006'. In 2007, the National Cancer Screening Service (NCSS) was established and governance of BreastCheck – The National Breast Screening Programme and the Irish Cervical Screening Programme Phase One were transferred to the Board of the NCSS. The NCSS implemented CervicalCheck – The National Cervical Screening Programme in 2008.

Cervical screening in Ireland - key dates

1996	Report of the Department of Health Cervical Screening Committee.
1997	Ministerial decision to set up a national cervical screening programme.
2000	Phase One of ICSP established in the Mid Western Health Board Region.
2004	External review by Dr E McGoogan, Edinburgh.
2004	External review by the Women's Health Council.
2006	A Strategy for Cancer Control in Ireland 2006 launched.
2007	National Cancer Screening Service Board and The National Cancer Screening Service established.
2008	Implementation of CervicalCheck – The National Cervical Screening Programme.
2009	CervicalCheck introduced a systematic organised call/re-call method of invitation.
2009	Launch of the 'Guidelines for Quality Assurance in Cervical Screening'.
2010	National Cancer Screening Service Board dissolved and the National Cancer Screening Service (NCSS) became part of the HSE National Cancer Control Programme.

1.3 CervicalCheck programme objectives

CervicalCheck objectives



The 'Guidelines for Quality Assurance in Cervical Screening' define the measures, as outlined below, for the reduction in the incidence of and the mortality from cervical cancer. These reductions are to be calculated following the completion of two rounds of screening (10 years).

	Category	Description of Standard	Standard
2.1.1	Incidence	To reduce the incidence of cervical cancer among screened population	35%

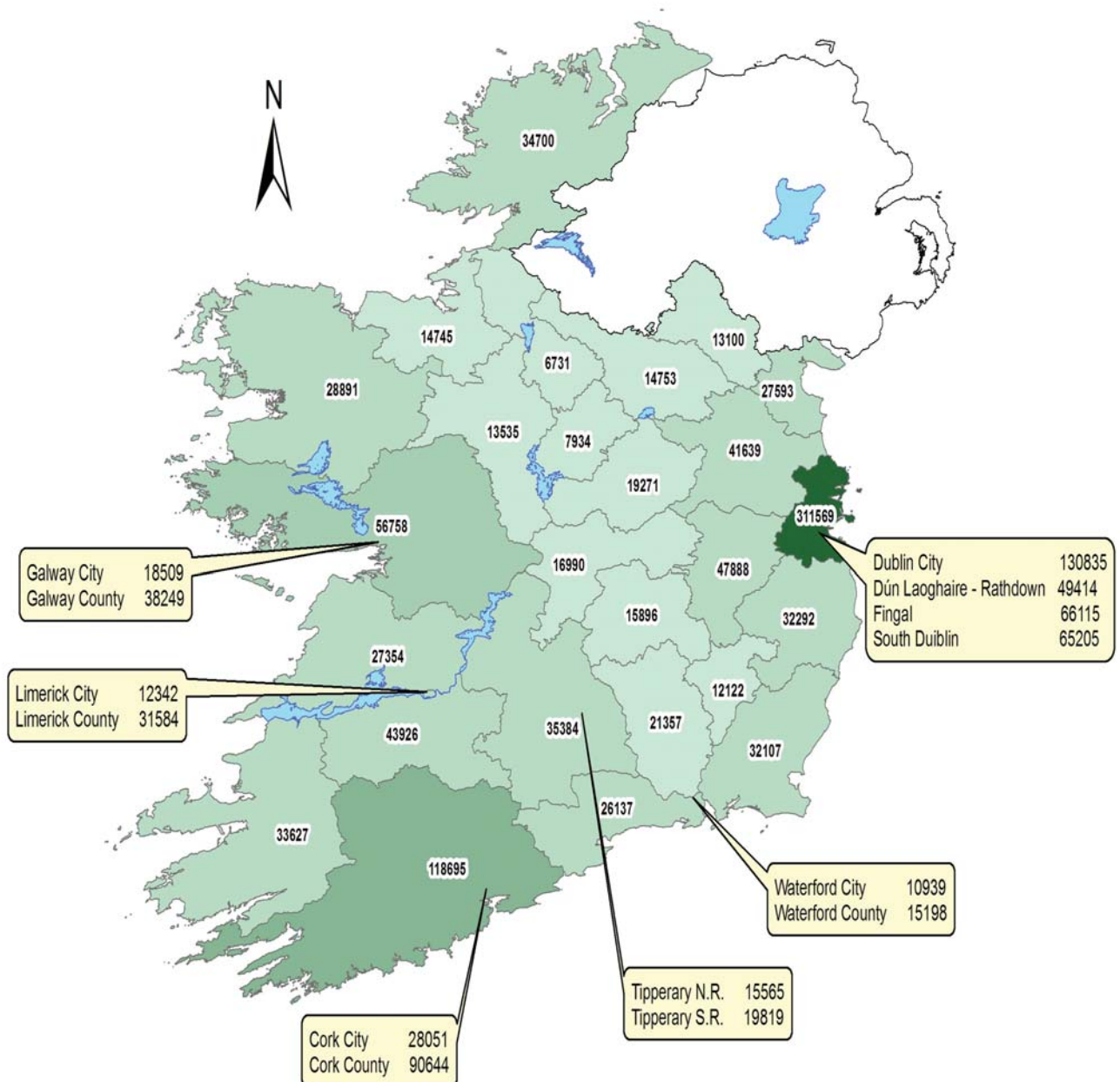
	Category	Description of Standard	Standard
2.1.2	Mortality	To reduce the mortality from cervical cancer among screened population	50%

The Programme will strive over the long term towards a mortality reduction of 80 per cent as has been achieved in Finland over the course of the last four decades.

1.4 The target population

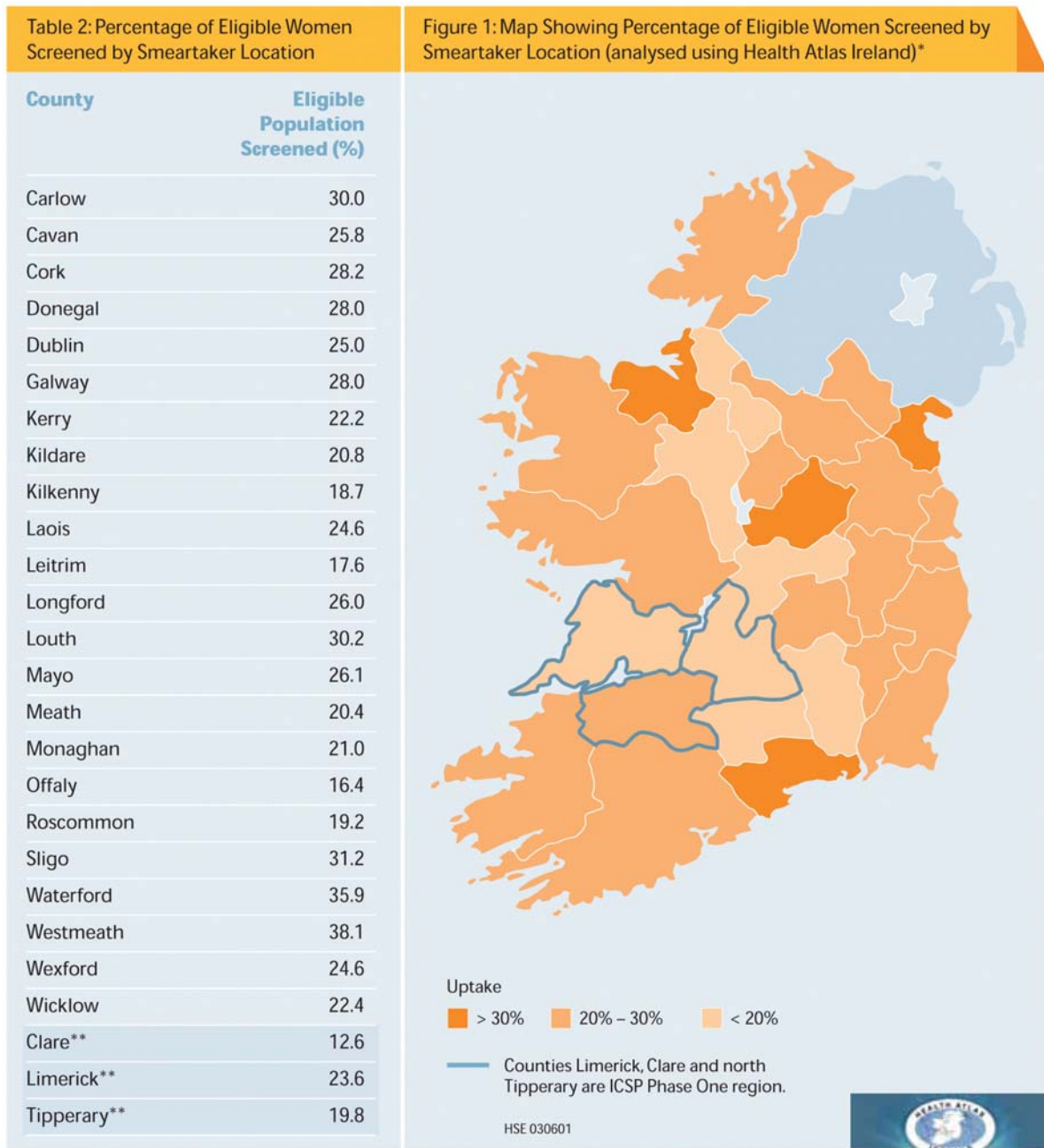
The eligible screening population in Ireland is over 1.1 million women aged 25 to 60, based on the 2006 census. Eligible women entering the programme will be offered screening over a three year interval. Eligible women must be normally resident and have a postal address in the Republic of Ireland.

Map1.1 CervicalCheck target population – females aged 25 to 60 by county, 2006



Source: Census of Population 2006, CSO

Table 1.1 Eligible women screened by smeartaker location
(1st September 2008 – 31st August 2009)



* Population data based on Census 2006 numbers extrapolated to 2009

** ICSP Phase One region

**The former Irish Cervical Screening Programme (ICSP) Phase One provided cervical screening to women living in Counties Limerick, Clare and north Tipperary from October 2000 to August 2008. Many women in these counties have availed of free smear tests prior to September 2008. Consequently the numbers screened in these counties reflect the previous availability of organised screening.

See the CervicalCheck Programme Report; 1st September 2008 – 31st August 2009 for further information.

1.5 The Cervical Screening Register

The Cervical Screening Register (CSR) is a secure electronic database containing records of personal health information of women in the eligible population – aged 25 to 60 years – that supports the accurate identification and appropriate management of women throughout their participation in the programme.

The Health (Provision of Information) Act 1997 provides the legislative framework for the compilation of the Cervical Screening Register which has meant that data from the Department of Social Protection can be used to establish and update this register. A woman's demographic data may also be submitted directly by her to CervicalCheck. Data related to a woman's screening history is acquired only following signed and informed consent by the woman. This consent should be recorded on the Cervical Cytology Form in the form of a signature at the time the woman has her first programme smear test and thereafter. A tick box indicating previous consent is used for all further smear tests.

The CSR is used to control the issuing of programme letters to women, including:

- Invitation (call) letters, to invite women to participate in the programme by attending for a smear test with a registered cervical smearer
- Re-call letters, to invite previously screened women to attend for another smear test at defined intervals
- Letters informing women of management recommendations for the results of their smear tests
- Failsafe letters to women and their doctors to ensure follow-up of not normal cytology results

The following principles guide the use of data held on the CSR:

- One woman with one set of demographics
- Personal health information belongs to the woman to whom it relates
- Women sign consent to empower CervicalCheck to hold their screening history data
- Security and confidentiality
- CervicalCheck will act to minimise the risk to women

See Section 5, Appendix 5C for further information on Data Protection

Each woman on the CSR is assigned a CervicalCheck identification number known as the Cervical Screening Programme ID (CSP ID). A woman's record includes her demographic details and details of her screening history communicated to the programme – results of cervical smear tests, colposcopy procedures and biopsies taken in a colposcopy clinic, if any, and the results of histology examinations. The CSR provides a woman's screening history to contracted service providers – cytology and histology laboratories, and colposcopy clinics.

1.6 The call, re-call process

The call/re-call process operates by issuing letters to women on the Cervical Screening Register inviting them to make an appointment with a registered smearer to attend for their first or next due programme smear test.

1.6.1 Call process

The **call process** operates for women whose demographic details are stored on the CSR and for whom there is **no previous smear test or call history**.

Women are selected for call at three yearly intervals as they reach the following age levels:

25 / 28 / 31 / 34 / 37 / 40 / 43 / 46 / 49 / 52 / 55 / 58 / 59 / 60

The number of women issued with a letter of invitation at any time may be determined by reference to the age profile of the target population and/or to uptake statistics and/or available capacity, as deemed necessary.

1.6.2 Re-call process

The **re-call process** operates for women whose details are stored on the CSR and for whom **previous smear test and/or previous call history** exists.

The smear test interval for women aged 25 to 44 is three years. The woman will be re-called three to six months in advance of the due date.

The smear test interval for women aged 45 to 60* years is five years, provided the last two smear test results are negative, otherwise the interval is three years.

Keypoint

*A woman is considered to be 60 years until she reaches her 61st birthday.

When the woman is 61 years of age or older on entry to the programme, two negative smear tests are required before she exits the programme. This woman will get a three-year re-call. If two negative smear test results are recorded the woman will not be called again and will be informed of this by a letter from the programme.

Within a given period of time, each call letter (see Appendix 1A) is followed by two reminder letters if the woman does not have a laboratory smear notification received by CervicalCheck. A woman's invitation to go for a smear test remains open until a notification of a smear test is received.

The conditions for eligibility of women for a programme smear test are provided in the 'Eligibility for Cervical Screening Framework' available on www.cervicalcheck.ie

CervicalCheck offers free smear tests to women aged 25 to 60. There are a number of exemptions to the screening age range and interval including:

- Women over the age of 60 who have never had a smear test
- Women under the age of 25 who have attended a colposcopy service and require follow-up
- Women who are post organ transplant
- Women who have Human Immunodeficiency Virus (HIV)
- Women who are on renal dialysis

For further information on the call, re-call process see Section 3.9: The Screening Interval.

Keypoint

Regardless of the age that a woman enters the programme, she requires two normal smear test results three years apart, before going onto a five yearly screening interval.

1.6.3 Deferral

Deferral is the delaying of a smear test call or re-call date to another future date due to temporary reasons such as the women being under other medical treatment, being on holiday, a smear test not required at present etc.

A Woman may contact CervicalCheck in order to defer a scheduled smear test following a call (invitation) or re-call. She may do this by telephone or email providing the requested period of deferral of the smear test due date does not exceed 12 months. Informing the programme will stop reminder letters being issued. The woman's call/invitation remains open and she can have the test taken at any time.

Keypoint

Where a smear test is due for a previously abnormal result, deferral should not happen.

See Section 4.2D and 6.4.4 for further information on pregnancy and cervical screening.

Pregnancy and cervical screening

There is no need for a woman who is pregnant or postpartum to have a routine cervical smear test, unless she is due one according to CervicalCheck recommendations. Unless a pregnant woman with a negative history has gone beyond three years without having cervical screening then the test may be deferred. A smear is best left until three months post partum.

1.6.4 Opt-off process

1. Opt-off by woman

The opt-off process provides a woman with the option, for whatever reason, to choose to withdraw her participation in CervicalCheck.

A woman who wishes to opt-off the CervicalCheck programme must complete the opt-off form. If after opting-off the programme the woman decides to have a CervicalCheck programme smear test, she will become part of the programme again by providing her consent on the Cervical Cytology Form.

2. Opt-off by a medical practitioner

In the following circumstances a woman may be opted-off the programme by the Medical Practitioner. They may include:

- Women for whom the Medical Practitioner deems the smear test to be inappropriate
- Women who are patients in psychiatric hospitals
- Women with severe physical disabilities in care/at home
- Women with intellectual disabilities in care/at home

The following are the main reasons why it may be inappropriate to screen the woman:

- Woman does not have the capacity to consent
- Cervical screening is not physically possible
- Cervical screening is not required

Following completion of the Opt-off by Medical Practitioner (see Appendix 1H), the woman will be made 'inactive' on the Cervical Screening Register and will receive no further communication from CervicalCheck.

See Appendix 1I for further information.

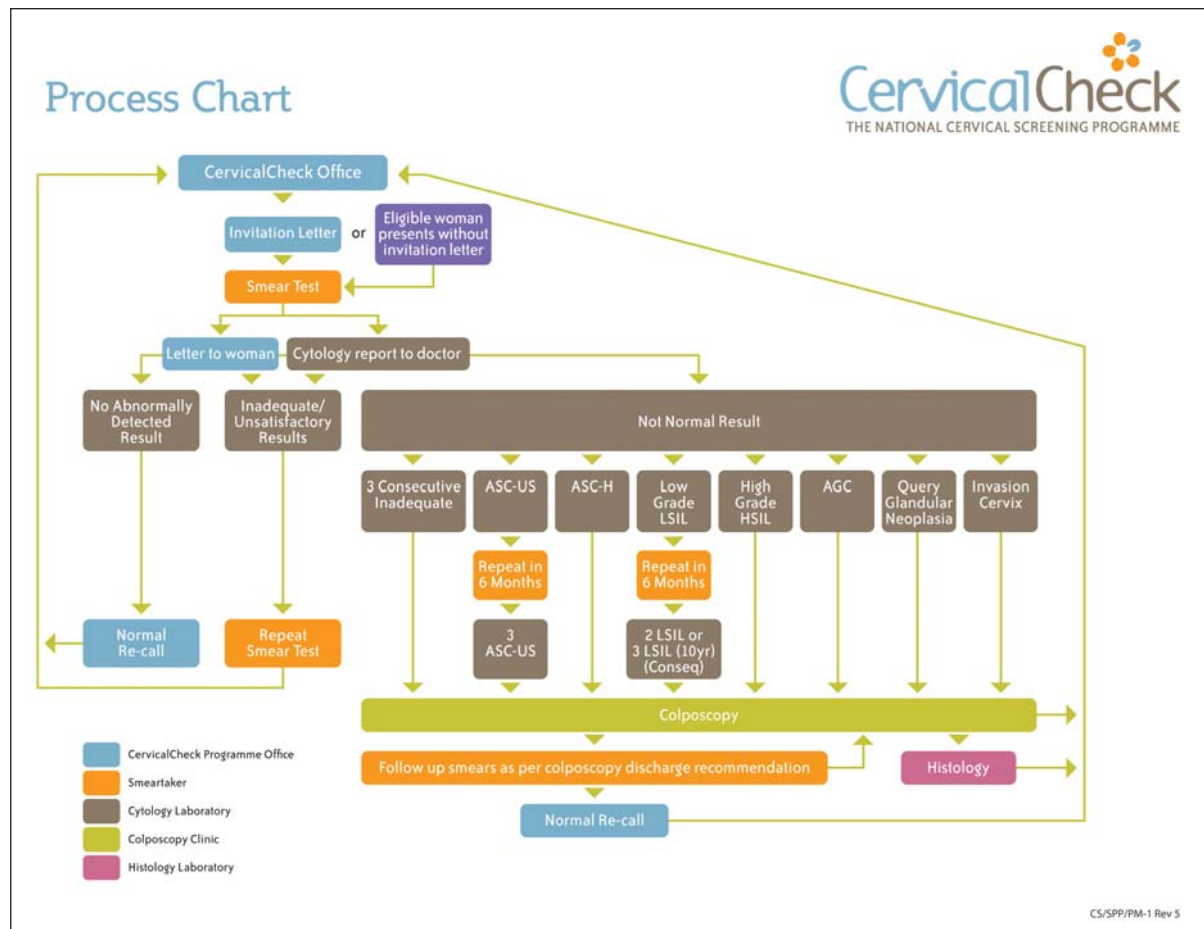
1.7 The result process

Smear test results are categorised as 'normal results' (no abnormality detected), 'unsatisfactory/ inadequate' and 'not normal' results.

Figure 1.1 Overview of results categories with follow-up actions

<p>Normal results</p> <p>No abnormality detected</p>	<p>In the case of normal results, CervicalCheck and the smeartaker with clinical responsibility will receive a copy of the results from the laboratory.</p> <p>A letter informing the woman of a 'no abnormality detected' result will be sent by the CervicalCheck office.</p> <p>Based on the smear test result and the clinical information provided, the letter will also indicate a date for the woman's next smear test (see Appendix 1).</p> <p>The CervicalCheck office will also issue a further call letter to the woman in the months in advance of her next smear test.</p>
<p>Unsatisfactory/ inadequate results</p>	<p>In cases where results are deemed to be 'unsatisfactory/inadequate, a report is sent by the laboratory to CervicalCheck and to the smeartaker with clinical responsibility.</p> <p>The woman is then advised to have a repeat smear test after a three-month period (see Appendix 1).</p>
<p>Not normal results</p>	<p>In cases where results are deemed 'not normal', a report is sent by the laboratory to CervicalCheck and to the smeartaker with clinical responsibility.</p> <p>CervicalCheck then issues a letter to the woman informing her that her smear test result is available from her smeartaker and requires follow-up. This advice will depend on the degree of abnormality of her smear test e.g. she should attend her smeartaker for a repeat smear test in six months or attend her smeartaker for consultation and follow-up treatment (see Appendix 1).</p>

Figure 1.2 Summary of the results process



See Section 6 for further information on women's participation in cervical screening.

1.8 Communication with women

The cervical screening process should be explained to the woman. The woman should have sufficient information and understanding to enable her to make an informed decision to have a smear test and to participate in the cervical screening programme.

Screening promotion

The overall strategic aim of screening promotion in CervicalCheck is to maintain and further develop an equitable, quality assured, innovative and women-centred approach to increasing awareness/understanding and uptake of cervical screening. To implement this there is a screening promotion team for the National Cancer Screening Service (NCSS). Based on the evidence base, the screening promotion team use a multi-strategy approach to promote cervical screening and encourage attendance. The team can be contacted by emailing screening.promotion@cancerscreening.ie.

See Section 1, Appendix 1J for a copy of The Women's Charter.

1.8.1 The Women's Charter

The CervicalCheck Women's Charter outlines the commitments and parameters of service delivery that the programme will aim to deliver to women. Moreover, in its drive to encourage women to attend cervical screening, CervicalCheck works in close collaboration with smertakers to promote screening participation.

Figure 1.3 CervicalCheck promotional literature



1.8.2 CervicalCheck website

The website provides women with key information about CervicalCheck and the cervical screening process. It addresses some of the questions that are most frequently asked by women attending for their smear test.

Women can check to see if they are registered with the programme through the website's 'Check the Register' facility. This facility allows women to update their details and advises them when they are eligible for their smear test.

1.9 Smeartaker co-ordination

Smeartaker co-ordination supports and facilitates registered smeartakers in the provision of smeartaking services to eligible women.

1.9.1 Support and monitoring

Smeartaker co-ordination supports and interfaces with:

- Registered smeartakers – doctors and nurses
- Non-medical staff in GP practices and clinics
- Other healthcare professionals, including potential smeartakers
- Women (where the query relates to a smeartaker or smeartaking experience)
- Cytology laboratories personnel interfacing with registered smeartakers (typically regarding samples reception and inspection, and provision of results)
- Colposcopy clinics personnel interfacing with registered smeartakers (typically regarding referrals and discharges)

Smeartaker activity and performance monitoring

The principal areas of activity include:

- Experience of women during smeartaking process
- Eligibility of women for programme screening
- Appropriateness of screening for specific women
- Smeartaking practice and environment
- Samples handling (e.g. appropriate packaging and dispatch, directing to correct laboratory, submission time to laboratory, correctly labelled)
- Smear test sample adequacy for screening (i.e. unsatisfactory rate)
- Follow up with women following results (e.g. contacting women, referring to colposcopy, arranging and recommending repeat smear tests, response to failsafe requests)

Smeartaker activity and performance are monitored against the 'Guidelines for Quality Assurance in Cervical Screening', contract requirements and the 'Eligibility for Cervical Screening Framework'.

See Section 2.1 for further information on smeartaker registration.

1.9.2 Smeartaker registration

1.9.3 CervicalCheck website

Eligibility check facility

An eligibility check facility is available online at www.cervicalcheck.ie. This facility enables smeartakers to determine whether or not a woman is eligible for a free smear test. Two pieces of information will be required to identify the woman e.g. CSP ID or Personal Public Service Number (PPS No) and date of birth. The eligibility status of the woman will be given and if the woman is not eligible, the smeartaker will be informed when the woman's next smear test is due.

Smeartakers can also check the eligibility status of the woman by calling CervicalCheck on Freephone 1800 45 45 55.

Useful downloads and forms

Smeartakers can access a range of useful forms and resources through the CervicalCheck website. Documents which can be downloaded include:

- Eligibility Framework and Referral Pathways
- Cervical Cytology Form
- Colposcopy Referral Form
- Histology Referral Form for Cervical Specimens
- Hysterectomy Data Collection Form
- Opt-off by Medical Practitioner
- Opt-off Form by Women
- General Terminology in Cervical Screening
- Cytology Terminology Translation Table
- Cervical Cytology Management Recommendations Explanatory Guide

1.9.4 Smeartaker communication

Communication between CervicalCheck and smeartakers is delivered via a number of channels such as direct mail, through the website ('Frequently asked questions for health professionals') and at meetings with professional organisations at local and national level. Effective communication with the smeartakers is important to enable the programme to respond promptly to smeartakers' concerns which may ultimately impact on the woman's screening experience. The information in the 'Health professionals' section of the CervicalCheck website (www.cervicalcheck.ie) is updated regularly.

The provision of feedback to registered smeartakers on the quality of smear tests taken is a key element of the communication process. This is provided within two contexts:

1. In the course of training, feedback is provided by identifying the presence/absence of transformation zone sampling on a minimum of 30 smear tests taken in the training period.
2. CervicalCheck issues summary reports for individual smeartakers on cytology outcomes for all the smear tests taken by them, with the programme averages (see Fig 1.4). These reports are confidential to each individual smeartaker and are generated using the smeartaker's I.D., i.e. the Medical Council Number/ An Bord Altranais number.

Figure 1.4 Sample Smeartaker Performance Report

Name
Address

Date:

Smeartaker ID (Smeartaker ID is the Medical Council Number/An Bord Altranais Number)

Dear Colleague,

Please find below a report outlining the cytology outcomes for the smears taken by you in the period shown, and also providing the programme averages for the same period. The report is generated using your Smeartaker ID and is confidential to you.

Reporting Period: 01 Jan 2010 to 31 Dec 2010

Number of smears reported for this reporting period: 306

P Code	Cytology Outcome Category	Smeartaker Numbers Reported	%	Programme %
P1	Unsatisfactory or Inadequate	3	0.98%	0.90%
P2	Negative or NAD	261	85.29%	85.39%
P3	ASC-US or ASC-H	17	5.56%	5.38%
P3a	ASC-US	3	0.98%	3.07%
P3b	ASC-H	1	0.33%	0.21%
P4	LSIL	19	6.21%	3.10%
P5	HSIL (Moderate Dyskaryosis)	1	0.33%	0.49%
P6	HSIL (Severe Dyskaryosis)	0	-	0.49%
P7	Query Invasive Carcinoma	0	-	0.01%
P8	AGC or AGH	1	0.33%	0.38%
P8a	AGC (Atypical Glandular Cells)	0	-	0.11%
P8b	AGC (Atypical Glandular Cells – Favour neoplastic)	0	0.03%	
P9	Query Glandular Neoplasia or AIS	0	-	0.01%
P10	Broken or Damaged or expired Vial		0	0.44%
Total Reported:		306		
Percent:			100%	100%

For information on smeartaker training programmes and clinical updates, please email stu@cervicalcheck.ie or call (061) 406565/564.

Yours sincerely,

Name
Smeartaker Co-ordinator

Name
Head of Cervical Screening

1.10 Smeartaker training

The Smeartaker Training Unit has responsibility for the co-ordination and delivery of all education and training initiatives for smeartakers registered with CervicalCheck on an ongoing basis. The unit facilitates learning through the delivery of accredited Smeartaker Training Programmes in partnership with the Irish College of General Practitioners (ICGP), the Royal College of Surgeons in Ireland (RCSI) and the National University of Ireland, Galway (NUIG).

In accordance with Objective 4.4 of the National Cancer Screening Service 'Guidelines for Quality Assurance in Cervical Screening', smeartaker training has been identified as critical in the provision of a quality assured screening programme for the women of Ireland. The 'Guidelines for Quality Assurance in Cervical Screening' refer to training for new smeartakers (standard 4.4.4), initial training programmes (standard 4.4.2) and update training (standard 4.4.2). The Smeartaker Training Unit facilitates the training of GP trainees and GPs through the GP Training Schemes and CME.

The unit also facilitates learning through the organisation of clinical updates and the development of related educational resources.

The 'Smeartaker Learning and Resource Centre' is an e-learning platform. This platform will explore the potential and possibilities of e-learning as a means of supporting smeartaker knowledge.

'CervicalCheck smeartakers will be provided with training opportunities – initial and update –by the Programme on an ongoing basis to foster and maintain quality cervical smeartaking.'

(National Cancer Screening Service; Guidelines for Quality Assurance in Cervical Screening, Standard 2.4.1, First Edition 2009).

The Smeartaker Training Prospectus, which is available from the CervicalCheck office and website, outlines the programmes of smeartaker training available in each academic year with details on how to access training.

Smeartaker training programmes aim to provide core knowledge and development of the necessary technical and communication skills to enable health professionals deliver a quality service. Regular updated evidence based papers are available for Health Professionals through the CervicalCheck website.

Figure 1.5 Smeartaker Training Prospectus



1.11 Quality assurance

1.11.1 Quality assurance and CervicalCheck

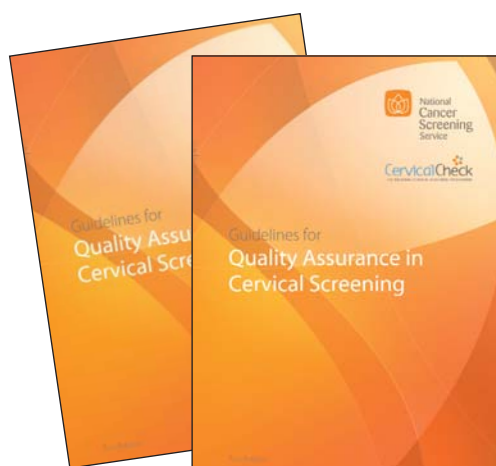
Quality Assurance is the core process within the programme which supports, maintains and develops the quality systems and facilitates feedback. CervicalCheck is committed to the model of continuous improvement and ensures all aspects of the programme are quality assured so that the programme's aims are achieved.

1.11.2 Standards and monitoring

A Quality Assurance Committee for CervicalCheck has been established to provide assurance that the screening programme is operating to the highest possible standards.

The 'Guidelines for Quality Assurance in Cervical Screening' have been developed by the Quality Assurance (QA) Committee, supported by specialist subgroups, to provide a framework which will guide smertakers in primary care who provide a service for CervicalCheck. These guidelines have been prepared to inform, enable and ensure that all the key components of a quality assured process are being addressed.

Figure 1.6 'Guidelines for Quality Assurance in Cervical Screening'



The purpose of the QA Committee is to monitor adherence to standards of practice contained within the NCSS 'Guidelines for Quality Assurance in Cervical Screening'. This will enhance the quality of service provision by addressing areas for improvement across the programme.

CervicalCheck has identified a number of key performance indicators (KPIs) for the programme. These are reported periodically to monitor programme outcomes such as coverage, referral rates to Colposcopy, cancer incidence etc. In addition the CervicalCheck programme monitors and reports periodically on performance indicators such as 'unsatisfactory or inadequate reporting rates' for individual smertakers.

Within the CervicalCheck office, the Quality Assurance Department oversees the development and monitoring of standards in conjunction with the Quality Assurance (QA) Committee for all aspects of the programme.

The CervicalCheck Office has also achieved the ISO 9001:2008 quality certification and maintains this standard through regular internal and external audit.

1.11.3 Feedback and complaints

In accordance with national legislation (Part 9 of the Health Act, 2004) and in line with quality management principles, CervicalCheck has a robust complaints system which allows not only for optimum complaints management but also an effective system to ensure the flow of feedback between smertakers, service users and the programme.

The complaints-handling system is designed so that steps for making a complaint are simple and transparent. The methods for making a complaint (or for providing feedback) can be verbally via the Freephone information line (1800 45 45 55) or in writing (via letter or email) to the CervicalCheck office. All complaints are forwarded to the Complaints Officer and are followed-up in a timely fashion. CervicalCheck acknowledges that a good complaints or feedback system contributes to a higher quality service by highlighting areas for improvement and capturing feedback (both positive and negative).

APPENDIX 1

Appendix 1A CervicalCheck invitation letter to eligible women

Date: [system_date]

[fullname]
[address1]
[address2]
[address3]
[address4]
[address5]

Cervical Screening Programme ID: [csp_id]
PPS No: [PPSN]

Dear Ms [Surname],

CervicalCheck – The National Cervical Screening Programme invites you to make an appointment for a free smear test.

Regular smear tests are important as they can find early changes in the cells of the cervix (neck of the womb). The earlier cell changes are found, the easier they are to treat.

To have this free smear test, please make an appointment now with a General Practitioner or Clinic to have your test in the next six weeks. General Practitioners and Clinics that offer this service are listed on www.cervicalcheck.ie

Please ensure that you take this letter with you when going for your smear test as your doctor or nurse will ask to see it.

You will find more information about having a smear test in the leaflet enclosed.
I do hope you take this opportunity to look after your health.

Yours sincerely,

Appendix 1B Letter to women reporting 'no abnormality detected' result

Date: [system_date]

[fullname]
[address1]
[address2]
[address3]
[address4]
[address5]

Cervical Screening Programme ID: [csp_id]
PPS No: [PPSN]

Dear Ms [Surname],

Thank you for taking part in CervicalCheck – The National Cervical Screening Programme. Your smear test taken on the [testdate] detected no abnormalities. You will find more information about your smear test results in the leaflet enclosed.

CervicalCheck will remind you to have your next routine smear test in three years or five years time as appropriate. Please let us know if you change your name or address before your next smear test is due.

If at any time you have any concerns such as irregular vaginal bleeding, spotting or discharge please contact your doctor without delay.

Yours sincerely,

Appendix 1C Letter to women reporting 'Inadequate' or 'Unsatisfactory' result

Date: [system_date]

[fullname]
[address1]
[address2]
[address3]
[address4]
[address5]

Cervical Screening Programme ID: [csp_id]
PPS No: [PPSN]

Dear Ms [Surname],

Thank you for taking part in CervicalCheck – The National Cervical Screening Programme. Your smear test taken on [testdate] has been reported as unsatisfactory or inadequate. This simply means that the laboratory could not read your smear test clearly.

Your doctor or practice nurse can provide more information about your smear test result and you may also find the leaflet enclosed helpful.

You will need to have another smear test taken in three months. You should contact your doctor or practice nurse to make an appointment for this smear test.

I do hope you take this opportunity to look after your health.

Yours sincerely,

Appendix 1D Letter to women reporting 'Needing a repeat in six months'

Date: [system_date]

[fullname]
[address1]
[address2]
[address3]
[address4]
[address5]

Cervical Screening Programme ID: [csp_id]
PPS No: [PPSN]

Dear Ms [Surname],

Thank you for taking part in CervicalCheck – The National Cervical Screening Programme. The result of your smear test taken on the [testdate] recommends that you have another smear test in six months time.

Your doctor or practice nurse can provide more information about your smear test result and you may also find the leaflet enclosed helpful.

To arrange your next smear test you should contact your doctor or practice nurse.

I do hope you take this opportunity to look after your health.

Yours sincerely,

Appendix 1E Letter to women reporting 'needing a follow-up'

Date: [system_date]

[fullname]
[address1]
[address2]
[address3]
[address4]
[address5]

Cervical Screening Programme ID: [csp_id]
PPS No: [PPSN]

Dear Ms [Surname],

Thank you for taking part in CervicalCheck – The National Cervical Screening Programme. The result of your smear test taken on the [testdate] is now available.

You need to contact the doctor or practice nurse who took your test to discuss the result and provide you with more information. You may also find the leaflet enclosed helpful.

It is very important that you follow the recommendations we have given you.

Yours sincerely,

Appendix 1F Woman failsafe

Date: [system_date]
[fullname]
[address1]
[address2]
[address3]
[address4]
[address5]

Cervical Screening Programme ID: [csp_id]
PPS No: [PPSN]

Dear Ms [Surname],

CervicalCheck – The National Cervical Screening Programme would like to remind you again that the result of your smear test taken on the [testdate] recommended that you arrange another smear test or to contact your doctor or practice nurse.

It is very important that you follow the recommendations we have given you. Please contact the doctor or practice nurse who took your test to discuss the result and arrange what is needed next.

If we do not hear from you, we will invite you for further free smear tests every three years if you are aged 25 to 44; or every five years if you are aged 45 to 60.

I strongly encourage you to take this advice.

Yours sincerely,

Appendix 1G GP failsafe*

[Doctorname]
 [Doctoraddress1]
 [Doctoraddress2]
 [Doctoraddress3]
 [Doctoraddress4]
 [Doctoraddress5]

Woman's CSP ID: [csp_id]
 Woman's PPS No: [PPSN]

Doctor ID: [Provider_Number]

Date: [system_date]

Follow Up - Repeat Smear Test

Dear Doctor,

The woman below was recommended for a repeat smear test following the earlier smear test noted. CervicalCheck has not yet received notification of the repeat smear test.

It is important to follow up this woman. As the clinically responsible doctor for her last smear test, could you please advise by return on the woman's current status. Thank you.

[fullname] [Clientaddress]
 DOB: [DOB] Date Smear Taken: [testdate]

Yes, woman has attended for a Repeat Smear Test

Laboratory:

Date of Smear: / /

Additional information:

If pregnant EDD: / /

Yes, contact has been made with the woman since the repeat smear test due date

Date of contact: / /

Contact method:

Change of address

of woman?

Doctor's Signature:

Date: / / Doctor's stamp:

*Refer to Section 5.3.3 for further information on the failsafe process.

*Refer to Section 5.3.3 for further information on the failsafe process.

Appendix 1H Opt-off by Medical Practitioner

**The completed form is to be returned to
CervicalCheck – The National Cervical
Screening Programme
Freepost LK407 Limerick**



Opt-Off by Medical Practitioner

(to cease a woman's participation in CervicalCheck)

Woman's Details

Name (BLOCK LETTERS):

Address (BLOCK LETTERS): DOB (dd/mm/yyyy)

--	--	--	--	--	--	--	--	--	--

..... PPS No. (if known)

--	--	--	--	--	--	--	--	--	--

..... CSP ID (if known)

--	--	--	--	--	--	--	--	--	--

Name of Care Facility (if applicable):

I have considered the above woman's cervical screening needs and advise that this woman does not require cervical screening.

Please tick the appropriate reason(s) for this:

- ☐ Woman does not have the capacity to consent
- ☐ Cervical screening is not physically possible
- ☐ Cervical screening is not required

Medical Practitioner (name in BLOCK LETTERS):

Signed: _____

MCRN

--	--	--	--	--	--	--	--	--	--

Date (dd/mm/yyyy)

--	--	--	--	--	--	--	--	--	--

Doctor's stamp:

Note:

This form should only be used where the woman does not have the capacity, or it is inappropriate for her, to use the *Opt-Off by Woman* form to cease participation in CervicalCheck. For further information, refer to the '*Opt-Off Factsheet*' (CS/PUB/P-1).

Appendix 1I “Opt-Off” Fact sheet

OPT-OFF BY WOMAN

What is Opt-Off by Woman?

Women can choose not to be part of the CervicalCheck screening programme by completing an Opt-Off by Woman form. Women who have opted themselves off will no longer receive letters from CervicalCheck inviting them for free smear tests.

OPT-OFF BY MEDICAL PRACTITIONER

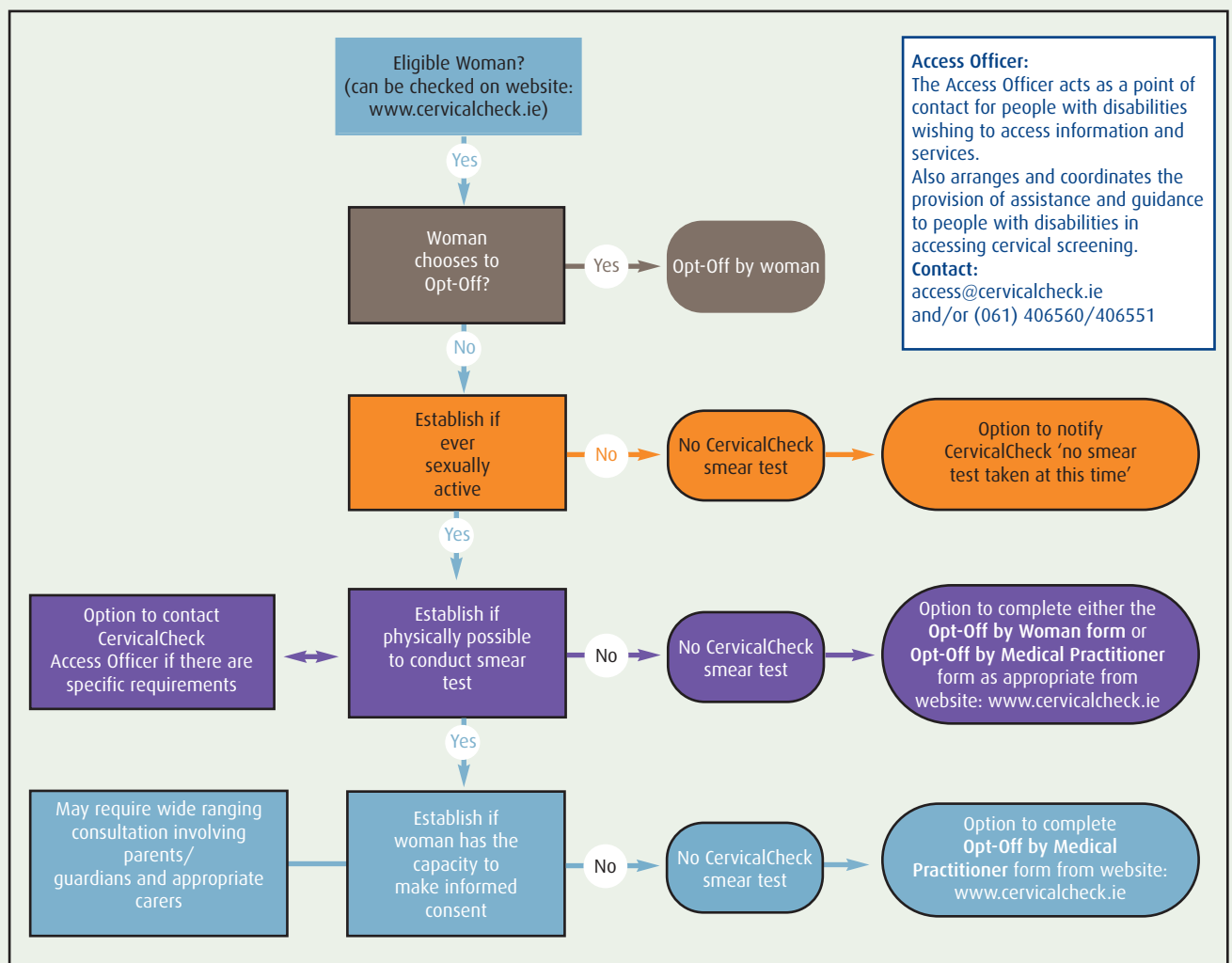
What Opt-Off by Medical Practitioner means?

Women whom the Medical Practitioner deems not to require cervical screening can be made inactive on the Cervical Screening Register (CSR) and will receive no further communication from the programme. This requires that an Opt-Off by Medical Practitioner form is completed and signed by the medical practitioner and forwarded to CervicalCheck.


When to use the Opt-Off by Medical Practitioner form:

This should be used in any of the following circumstances where:

- the woman does not have the capacity to consent
- the woman does not have the capacity to opt herself off the programme
- it is not physically possible for the woman to have a smear test
- the woman is terminally ill



Appendix 1J CervicalCheck Women's Charter



CervicalCheck

THE NATIONAL CERVICAL SCREENING PROGRAMME

WOMEN'S CHARTER

Screening commitment:

- CervicalCheck – The National Cervical Screening Programme offers a free, complete quality assured programme of care
- You choose your smearer from a wide range of eligible service providers registered with the Programme
- You may change your preferred provider for subsequent Programme screening
- All Programme staff will respect your privacy, dignity, religion, race and cultural beliefs
- Your screening records will be treated in the strictest confidence
- You will always have the opportunity to make your views known and to have them taken into account
- Once you become known to the Programme you will be invited every three years for screening while you are aged 25 to 44 and every five years while you are aged 45 to 60
- Your smear test will be screened in an accredited, quality assured laboratory
- Your result and any treatment recommendation will be provided to you and your nominated smearer by the Programme within four weeks.

We aim:

- To ensure pleasant and comfortable surroundings during screening.

If you require further treatment, we aim:

- To ensure that you will be offered an appointment at a quality assured colposcopy clinic (*within four weeks for high grade cell changes and within eight weeks for low grade cell changes*).

Tell us what you think:

- Your views are important to us in monitoring the effectiveness of our services and in identifying areas where we can improve
- You have a right to make your opinion known about the care you received
- If you feel we have not met the standards of this Charter, let us know by telling the people providing your care or in writing to the Programme
- We would also like to hear from you if you feel you have received a good service. It helps us to know that we are providing the right kind of service – one that satisfies you
- Finally, if you have any suggestions on how our service can be improved, we would be pleased to see whether we can adopt them to further improve the way we care for you.


Ways you can help us:

- Please make your appointment with a registered smearer on receipt of your invitation letter from the Programme
- Please bring your PPS number with you to your appointment
- Please read any information we send you
- Please try to be well informed about your health.


Let us know:

- If you change your address
- What you think – your views are important.

Freephone 1800 45 45 55
www.cervicalcheck.ie



CervicalCheck
THE NATIONAL CERVICAL SCREENING PROGRAMME



National Cancer Screening Service

The National Cancer Screening Service encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme.

CS/PUB/CC-5 Rev 3

References & further reading

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Section 2

Smeartakers – how to participate in CervicalCheck

SECTION 2

Smeartakers

How to participate in CervicalCheck

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Smeartakers – How to participate in CervicalCheck

Aim of section

The aim of this section is to provide new smeartakers with an understanding of how to participate in CervicalCheck.

2.1 Participation in CervicalCheck

2.1.1 Registration of a smeartaker

To register with CervicalCheck, a smeartaker must be a medical doctor or a registered general nurse. When registering, the General Practitioner (GP) in primary care settings is required to sign a contract which outlines the key obligations of the smeartaker and of the programme.

When registering, CervicalCheck records the smeartaker's details on the CervicalCheck Smeartakers' Register and each smeartaker is provided with a registration number, the Smeartaker I.D. This unique I.D. number is linked to the Medical Council Registration Number for doctors and to An Bord Altranais Number for nurses.

See Section 1.10 for information on the CervicalCheck Smeartaker Training Programmes.

Practice nurses who register with CervicalCheck must nominate a doctor who will assume clinical responsibility for their smear tests. GP registrars and locums working in a registered smeartaker's practice for a period of more than one month and who are involved in smeartaking must also register with the programme. The principal obligations of smeartakers are outlined later in this section.

While the majority of women choose to have their smear tests taken in their usual GP practice, some may attend GPs who are not registered with the NCSS and do not provide cervical screening services. In this context, all smeartakers registered with the programme are asked to accommodate eligible women even if those women do not normally attend their practice.

2.1.2 Payment for smeartaking services

The payment is a set fee. It is based on the smear test undertaken by a smeartaker for which he/she is the clinically responsible doctor and which is notified to CervicalCheck by the laboratory. The fee covers:

- The individual screening test process
- Posting and delivering the sample to the designated laboratory
- The subsequent handling of results and facilitating counselling if required
- Referral to colposcopy if required

Each initial smear test taken within the programme is paid for by CervicalCheck. Subsequent smear tests, including post colposcopy tests, are paid for only if taken according to the laboratory's recommendations from the previous report. Smear tests taken at shorter intervals than those recommended by the laboratory will not be paid for by CervicalCheck.

CervicalCheck is not responsible for the costs incurred for smear testing or follow-ups in the case of women who are not eligible clients of CervicalCheck. Refer to www.cervicalcheck.ie for the 'Eligibility for Cervical Screening Framework'. Issues that may arise at the time of smeartaking in relation to prescriptions, other tests and their follow-up may generate a fee at the discretion of the GP.

2.1.3 Provision of equipment and materials for smeartaking

The contract between the NCSS and the General Practitioner in primary care settings details information regarding materials and provides Cervical Cytology Forms and smear test kits containing vials, brush and transport boxes. Kits and disposable speculum can be ordered from suppliers listed in the 'Contact list' section in this guide. Other equipment and services required relating to the smear test such as lighting, couch, clinical waste disposal and postage is the responsibility of the smeartaker.

2.1.4 Managing cervical screening within a clinical practice

It is recommended that a lead smeartaker takes responsibility for managing the cervical screening procedures in the practice/clinic. Each practice should develop a tracking system for smear test results as there are a range of responsibilities that must be effectively managed and allocated as part of the screening process. In the first instance, it is the responsibility of the smeartaker, which includes doctors and nurses working in the practice, to take smear tests according to the screening programme guidelines. The doctor with clinical responsibility, who may also be a smeartaker, holds both the responsibility of overseeing the clinical work carried out in the practice and the responsibility of the clinical management of abnormal results in smear tests. In delivering cervical screening services within a practice, it is important that the doctor with clinical responsibility can ensure that each staff member is able to answer the following questions:

- What information must be given to the client?
- Who will take the smear?
- Who will see the results?
- Where and how is each result recorded?
- How are patients contacted for normal and abnormal results?
- Who will organise further referrals?

The following figures outline the key responsibilities of the smeartaker (Figure 2.1) and of the doctor with clinical responsibility (Figure 2.2).

Figure 2.1 Principal obligations of smeartakers

Obligation	Description	'Guidelines for Quality Assurance in Cervical Screening' Standard/Objective Reference
Information	To ensure that the woman understands what the smear test is so that she is informed to decide whether it is appropriate for her to undergo screening. At the time of taking the smear, the woman should be advised about the results process and have a clear understanding about how and when she can expect to receive her smear results.	4.7.2
Consent	To explain the consent process to the woman so that she understands why she is signing consent.	4.7.2
Completing the Cervical Cytology Form	To ensure that the Cervical Cytology Form is fully completed so that the woman's demographic and clinical details are accurate allowing her smear test to be correctly interpreted and her results appropriately managed.	4.6.1
Taking a quality Smear test	This is discussed in detail in Section 4.	4.8.4

Transporting the Smear test	To ensure that the smear test is transported to the laboratory in a timely fashion within five working days.	4.9.4
Record keeping	To ensure that a record of the smear test is kept in the practice. This record may be either manual or electronic.	4.10.1
Reviewing results	To check that all smear test results have been received.	4.10.2 4.10.3 4.11.1
Communicating normal results	To notify the woman of a normal result.	4.10.4
Following-up on not normal results	To notify the doctor with clinical responsibility of any action recommended on the smear result.	4.11
Carrying out recommendations	To take a repeat smear if this has been recommended.	4.11.1
Equipment	To use the recommended equipment to comply with all EU sterilisation standards for equipment.	4.5.10
Best practice	To adhere to best practice standards.	
Contract with NCSS	To comply with the terms of the contract with the NCSS.	

Figure 2.2 Principal obligations of doctors with clinical responsibility

Obligation	Description	'Guidelines for Quality Assurance in Cervical Screening' Standard/Objective Reference
Responsibility for all smear tests	To hold responsibility for all smears taken in the practice and to ensure that the patient environment complies with quality standards.	
Inform CervicalCheck of deferrals	To complete and return the deferral form to the CervicalCheck office.	
Follow-up on smear tests	To follow-up on all smear tests undertaken in the practice. To ensure that the smear test results and any recommendations by the designated laboratory are conveyed to the client and dealt with by the designated General Practitioner within the practice.	4.11
Counsel women about results	To counsel women about their results. Counselling about abnormal results should typically take place in a face-to-face setting.	4.10.4

Further investigation	To initiate further investigation or referral as indicated by the smear test result.	4.12.1
Contact non-attendees	To ensure all reasonable attempts are made to contact women who do not attend for further investigation following a smear test result that is not normal. At least two attempts should be made to contact the woman, one of which should be written. These attempts should be noted in the woman's medical record.	4.11.2
Information for staff	To ensure that all practice staff including the receptionist, secretary, practice nurse and partners have the necessary information to implement the screening service.	4.4
Best practice	To ensure that all staff adhere to best practice standards as outlined in the course of training and relevant practice guidelines.	
Staff training & registration	To ensure that all smertakers in the practice e.g. doctors, practice nurses, locums or GP registrars, etc. are competent and registered with CervicalCheck.	4.4.2 4.4.3 4.4.6

Section 3

Cervical cancer and screening

SECTION 3

Cervical cancer and screening

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Cervical cancer and screening

Aim of section

The aim of this section is to provide an overview of the epidemiology, the natural history, the risk factors and the role of the Human Papilloma Virus (HPV) in cervical cancer. It also highlights the value of vaccination in preventing disease and the importance of screening.

3.1 Introduction

Recent advances in medical research and practice have greatly enhanced our knowledge of the natural history of cervical cancer with a deeper understanding of the Human Papilloma Virus (HPV) and the role it plays as the necessary, but not sole, causative agent.

3.2 Epidemiology

3.2.1 Introduction

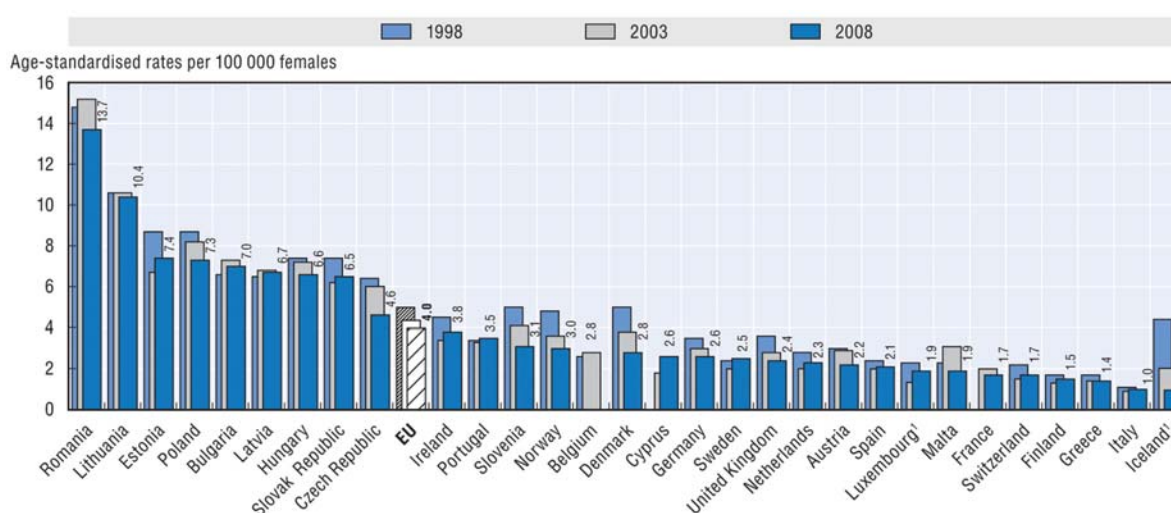
Cervical cancer is a female specific cancer with 80 per cent of cervical cancer occurring in the developing world. While all cancer accounts for approximately 29 per cent of deaths in women in Ireland (CSO, 2008) and for 30 per cent of premature deaths, cervical cancer accounts for 1.95 per cent of total cancer deaths. This is a cancer of young women where the mean age of death is 56 years and 50 per cent of all cases are diagnosed in women aged ≤ 46 years. Each woman who dies from cervical cancer loses, on average, 25 years of life. Just over one third of women diagnosed with cervical cancer die within five years.

3.2.2 Incidence and mortality of cervical cancer

Europe

Mortality rates for cervical cancer are higher in eastern European countries (Figure 3.1). Between 1998 and 2008 the rates declined for most European countries, with larger improvements for Iceland, Denmark, Slovenia, the Czech Republic and Norway.

Figure 3.1 Cervical cancer mortality 1998 to 2008



1. Rates for Iceland and Luxembourg are based on a three-year average to reduce year-to-year variation due to small numbers.

Source: Eurostat Statistics Database (mortality data are age-standardised to the WHO European standard population).

StatLink <http://dx.doi.org/10.1787/888932337243>

Source: OECD (2010)

Ireland

In Ireland, there is an average of 240 new cases of cervical cancer diagnosed (Table 3.1) and 83 deaths reported each year.

Table 3.1 Incidence of cervical cancer in Ireland, 2003-2008

YEAR	NUMBER OF CERVICAL CANCER CASES	INCIDENCE RATE (cases per 100,000 per year)
2003	204	10.53
2004	201	10.02
2005	259	12.71
2006	232	10.96
2007	294	13.50
2008	253	11.38

Source: The National Cancer Registry of Ireland

The following table provides an outline of the mortality rates of cervical cancer in Ireland between 2003-2006 as documented by the National Cancer Registry Ireland.

Table 3.2 Mortality from cervical cancer in Ireland, 2003-2006

YEAR	NUMBER OF CERVICAL CANCER DEATHS	MORTALITY RATE (cases per 100,000 per year)
2003	66	3.42
2004	93	4.49
2005	82	3.98
2006	83	4.17

Source: The National Cancer Registry of Ireland

3.3 Natural history

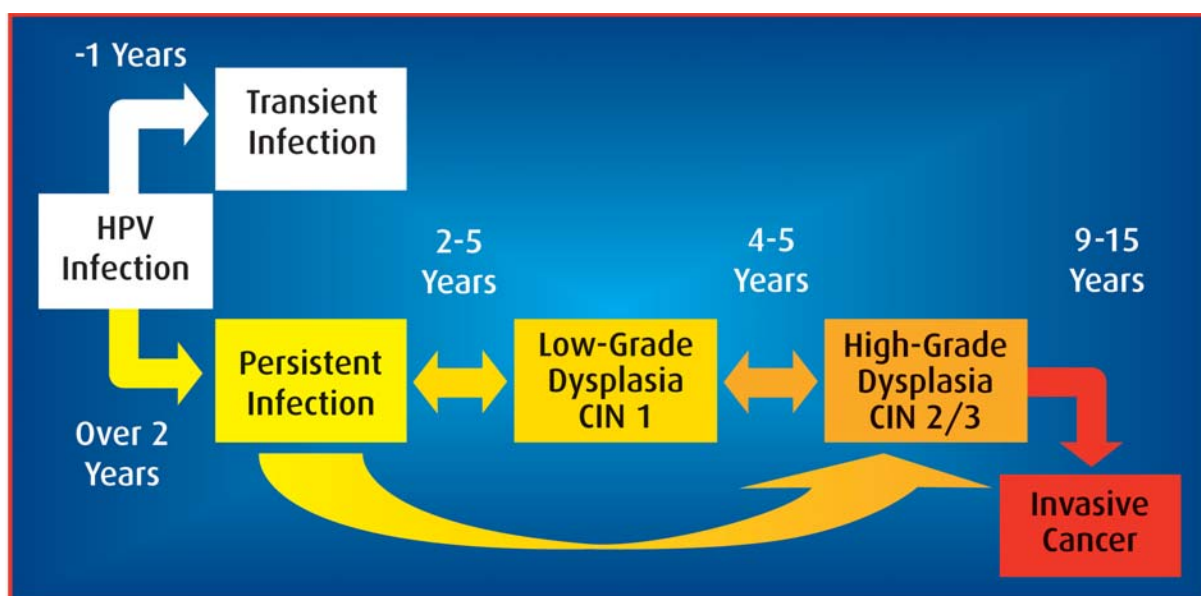
Cervical cancer in most cases develops gradually over a period of time, commencing with early abnormal 'pre-cancerous' changes to the cells in the cervix. These pre-cancerous changes are categorised as low grade or high grade. More than 800 women per year are diagnosed in Ireland with the pre-cancerous abnormality described as carcinoma in situ where there is minimal stromal invasion. These women are diagnosed at an average age of 32 years.

See Section 5.2 for further information on the classification systems.

These pre-cancerous abnormalities do not produce symptoms, cannot be seen by the naked eye but can be detected by screening. Screening tests offer the best opportunity to detect cervical cancer at an early stage, when successful treatment is likely. Screening can actually prevent most cervical cancers by detection and treatment of abnormal cervix cell changes before they have a chance to develop into a cervical cancer.

The first changes occur at the squamo-columnar junction. Both invasive squamous cell cervical cancer and the preceding pre-malignant cellular changes occur at the Transformation Zone of squamo-columnar junction. At cytology, the first changes are seen in the nuclei i.e. Atypical Squamous Cells of Undetermined Significance or ASC-US with more extensive cellular dysplasia becoming evident at a later stage. These changes may also be reported as viral changes and represent infection by and immunological response to the Human Papilloma Virus (HPV).

Figure 3.2 Natural history of high risk HPV infection & progression to cervical cancer



Source: Pagliusi SR (2004), Aguado MT. *Vaccine*. 23:569-578

Figure 3.2 shows the possible relationship of a HPV infection and outcomes with the probable timeline relationship depending on the individual's immune reaction to HPV.

More severe changes are termed dysplasia or Cervical Intraepithelial Neoplasia (CIN) or squamous intraepithelial lesion depending on the terminology adopted by the laboratory (Table 3.3). These changes represent long term viral persistence. Progression from low to high grade dysplasia and invasive disease is rare in the absence of HPV (Khan et al, 2005).

Table 3.3 Grading schemes for pre-invasive histological abnormalities of the uterine cervical squamous epithelium.

DYSPLASIA CLASSIFICATION	CERVICAL INTRAEPITHELIAL NEOPLASIA	BETHESEDA CLASSIFICATION SYSTEM
Mild Dysplasia	CIN 1	LGSIL
Moderate Dysplasia	CIN 2	HGSIL
Severe Dysplasia	CIN 3	HGSIL
Carcinoma in Situ	CIN 3	HGSIL

Source: IARC Handbook of Cancer Prevention Vol 10. *Cervix Cancer Screening* 2005

Table 3.4 represents the continuum of disease changes and range of outcomes. Outcomes for example relating to rates of regression of CIN 1 appear to be up to 60 per cent with progression in only 10 per cent. Studies have indicated that it is safe to monitor women in this category with cytological follow-up (Ostor, 1993). Treatment with excision is indicated with lesions of CIN 2 and CIN 3 where regression is less common.

Table 3.4 Outcomes relating to CIN classifications

OUTCOME	CIN1	CIN2	CIN3
Regress	57%	43%	32%
Persist	32%	35%	56%
Progress	11%	22%	-
Ca in Situ (Invasive)	1%	5%	>12%

Source: (Ostor 1993)

Moscicki et al 2004 found that 91 percent of low grade cytology in women under the age of 23 regress spontaneously.

3.4 Invasive cervical cancer

3.4.1 Symptoms and signs

It is unusual for women to have any symptoms associated with the pre-cancerous state or early cancer. Symptoms of post-coital bleeding, inter-menstrual bleeding and an unusual discharge are associated with more advanced cancer but can be produced by other causes. Invasive cancer can present as an ulcerated cervix.

Key point

- A smear test may be negative in the presence of invasive carcinoma
- Where suspicion of an invasive carcinoma exists, urgent referral to gynaecology should not await smear test results
- A woman with symptoms or signs suggestive of cervical cancer should be referred to diagnostic gynaecology, regardless of the actual smear test result

A cervix having CIN3 may appear normal macroscopically. Well-advanced invasive carcinoma may only show necrotic material on sampling but the following features can be present:

- Contact bleeding
- Raised irregular contour
- Friable easily detached epithelium
- Palpable mass at the vaginal vault

(Refer to Section 4: Figure 4.24)

See Section 5.4 for further information on colposcopy.

3.4.2 Investigation

Abnormal clinical findings need gynaecological investigation. Colposcopy, where the cervix is viewed under a microscope, plays a central role in determining management of pre-invasive cervical carcinoma. The diagnosis of pre-invasive disease is usually made when patients undergo colposcopically directed biopsies following an abnormal smear test. Both ablative and excisional procedures are employed when pre-invasive disease is found. The laser loop excision of the Transformation Zone (LLETZ) allows excision of the required area with least morbidity. Cone biopsy is associated with long-term morbidity (cervical stenosis and incompetence) but is indicated for women with CIN3 on smear testing and no colposcopically detected visible abnormality or for women where the full extent of the lesion cannot be visualised colposcopically.

Treatment options in cervical cancer are principally determined by two factors -

Stage and tumour size:

- For early stage disease – (where the cancer is clinically localised to the cervix) and small tumours (less than 4cm) surgical resection is the treatment of choice
- With progressive disease, negative surgical margins become difficult to achieve and chemo – radiotherapy provides a more attractive treatment option

3.4.3 Management of invasive cervical cancer

The management of women with invasive disease depends on the FIGO (Federation Internationale de Gynecologie Obstétrique) stage and status of the patient.

Table 3.5 Treatment options

FIGO (1995) Stage 1a1	
<ol style="list-style-type: none"> 1. Fertility to be preserved - Cone biopsy (negative margins) 2. Fertility not a consideration - Simple total hysterectomy 	
If Lymphovascular Space Involvement (LVSI) present consider pelvic lymphadenectomy but therapeutic implication unclear with no evidence to support this.	
FIGO (1995) Stage 1a2	
<ol style="list-style-type: none"> 1. Modified radical hysterectomy + Pelvic Lymphadenectomy 2. Large Cone Biopsy/ Radical trachelectomy and pelvic lymphadenectomy 3. Intracavitary RT +/- External beam XRT pelvis 	
FIGO Stage 1b1 and 2a (<4cm diameter)	
Consider MRI prior to surgery to measure and evaluate extent	
1. Surgery:	Radical trachelectomy + pelvic lymphadenectomy Radical hysterectomy + Pelvic Lymphadenectomy
2. Non surgical:	Combination chemotherapy and pelvic radiotherapy

FIGO Stage 1b2 – 2a (>4cm diameter)

1. Surgery: Radical trachelectomy + pelvic lymphadenectomy
 Radical hysterectomy + Pelvic Lymphadenectomy
2. Non surgical: Combination chemotherapy and pelvic radiotherapy

FIGO 2b or More

1. Non surgical: Combination chemotherapy and pelvic radiotherapy

Cervical cancers

Fifty five per cent of cervical cancers at diagnosis are stage 11 and above. Thirty five per cent of patients with invasive cancer of cervix have persistent and recurrent disease after treatment.

Table 3.6 Cervical cancer and five-year survival according to stage

FIGO (Federation Internationale de Gynecologie Obstrétrique) Stage	Survival
All stages	55%
0	99%
1A	97%
1B	79%
11A	55%
11B	52%
111A	40%
111B	27%
1VA	14%
1VB	2%

Fertility sparing treatment

Radical trachelectomy is an important advance in fertility-preserving surgery and is appropriate from women with stage 1A1 cervical cancer with extensive lymph vascular space invasion or with stage 1A2 or 1B1 when the lesions are less than or equal to 2cm (Stehman et al. 2003).

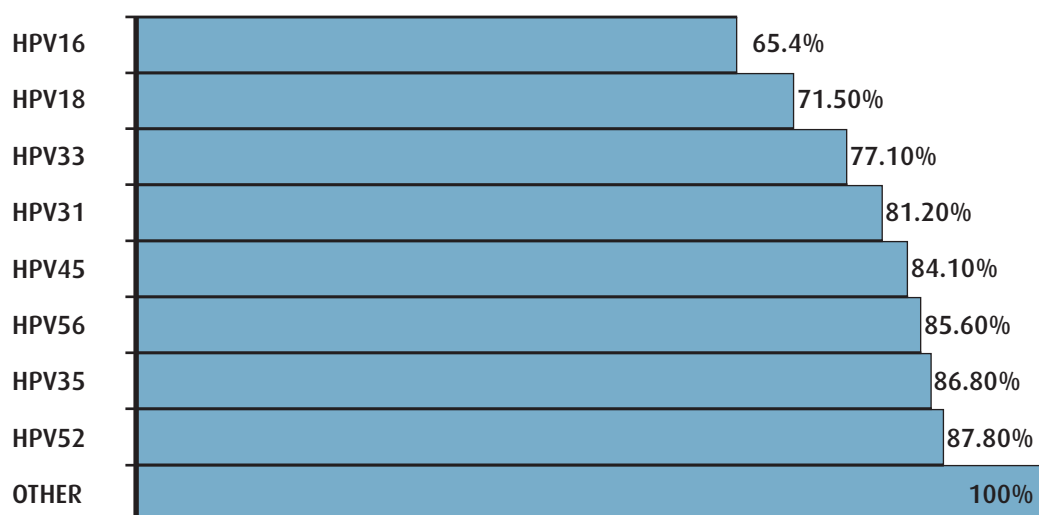
3.5 Risk factors and the role of the HPV

3.5.1 Infection with HPV

It is now understood that cervical infection with one of approximately 15 types of HPV is the necessary but not the only pre-requisite cause of cervical cancer worldwide. HPV is an extremely common sexually transmitted infection that occurs in most sexually active women. It is estimated that 80 per cent of sexually active women become infected with HPV (Winer et al, 2003). However, most women either clear or immunologically 'contain' the viral infection.

HPV positivity declines with age, reflecting the transient nature of most HPV infections due to immune suppression. Only a small percentage of those infected go on to develop cervical cancer. Immunological data show that those women who develop cervical disease have a persistence of both viral DNA and are serologically positive. Certain HPV types are noted to be more oncogenic than others. Eight particular types of HPV cause 87.8 per cent of cancers and four types account for 81.2 per cent of cervical cancers i.e. types 16, 18, 31 and 33 (Figure 3.3).

Figure 3.3 HPV types by related levels of oncogenicity



Source: Adapted from Muñoz (2000)

Multiple epidemiological studies (McIntyre-Seltman et al, 2005) have identified secondary risk factors (HPV co-factors) that are associated with the development of CIN 3 such as long duration of oral contraceptive use, multi-parity, smoking (Ho et al, 1998), host immune function and possibly non-HPV sexually transmitted infections. Smokers have an increased risk of persistent HPV infection (Matsumoto et al, 2010). Smoking can promote carcinogenesis by suppressing cell mediated immunity against HPV infection.

The dangers of developing cancer remain higher in those who have had treatment for high grade lesions (Souther et al, 2006). Immuno-compromised patients, for example those with HIV or on immunosuppressant medication, are also at greater risk of cervical cancer.

3.6 HPV Q&A

The answers to the following questions will help smertakers understand the role of HPV in cervical cancer.

Q1

What is HPV and what do smertakers need to know about HPV?

- Smertakers need to know that the Human Papillomavirus (HPV) causes cervical cancer
- HPV is a DNA virus that infects skin or mucosal cells
- HPV is transmitted through sexual contact and it is thought to infect three quarters of the reproductive age population
- There are more than 100 known HPV genotypes, at least 13 of which cause cancers. These are known as oncogenic or high risk genotypes
- Oncogenic HPV types cause cancers of the cervix, anogenital cancers and some cancers of the head and neck
- The two most common of these (genotypes 16 and 18) cause approximately 70% of all cervical cancers
- HPV Types 6 and 11 cause genital warts, a common benign condition.

Q2

How common is HPV infection?

- HPV is so common that estimates of exposure of up to 80% of the population are likely to be accurate. However, the estimated prevalence of genital warts is only about 1%. Less than 10% develop detectable cervical subclinical HPV-induced lesions
- HPV is highly transmissible with peak incidence of infection soon after the beginning of sexual activity
- Most people acquire the infection at some time in their life
- It is the most commonly diagnosed sexually transmitted infection in developed countries.

Q3

What are the risk factors for HPV infection and cervical cancer?

- Although HPV is sexually transmitted, penetrative sex is not required as transmission may occur through skin to skin contact
- Contributing factors to the development of cervical cancer after HPV infection include immune suppression, multiparity, cigarette smoking, long term use of hormonal contraceptives, and co-infection with Chlamydia Trachomatis, common among women with HIV.

Q4

What is the immune response to HPV?

- Only 50-60% of women develop serum antibodies after natural infection
- The degree of protection and duration of immunity after natural infection are not known. Re-infections with the same genotype are thought to occur
- HPV infection persists longer in immunosuppressed individuals
- Cigarette smoking is known to reduce the immune response to HPV infection.

Q5

What are the stages leading up to cervical cancer after HPV infection?

- HPV infection is associated with cellular changes which can be detected early on microscopic examination
- Changes cannot be detected by the naked eye until the later stages of pre-cancerous lesions or invasive cancer
- HPV infection usually clears without treatment, within a few months. About 90% of infections clear within two years
- Persistence of infection beyond 12 months is associated with an increased risk of cancer
- Early HPV infections may be accompanied by mild changes in the epithelium, the majority of these low grade lesions revert to normal within a few months, without treatment
- Where HPV infection persists it can lead to high grade changes which if untreated has a high probability of progressing to cancer.

Q6

What is the relationship between HPV and cervical cancer?

- HPV DNA is found in 99.7% of cervical cancers and the virus is found in up to 94% of women with squamous intraepithelial neoplasia (CIN)
- It is not fully known why it is that some women who are infected with HPV do not experience any cervical cellular changes; whereas others develop pre-cancerous changes and others go on to develop invasive cancer.

Q7

How can HPV testing be useful in preventing cervical cancer?

- HPV testing can identify women with high-risk HPV infections that can cause cervical cancer, enabling diagnosis and treatment to be put in place before cervical cancer develops
- The integration into the cervical screening process, in certain circumstances, of tests for these viruses has been evaluated in recent years and three potential roles for HPV testing have been identified. These include:
 - Post-treatment surveillance following active treatment for CIN
 - As a triage for women with low grade or atypical/borderline cells
 - As a primary screening test for women over 35 or vaccinated women either alone or in conjunction with conventional cytology.

Q8

What is the HPV vaccination programme for school girls?

- The introduction of the HPV vaccines has been described by some experts as one of the most significant recent public health initiatives
- The HPV vaccination programme, which commenced in 2010, will be administered to girls in the early years of second level education
- The HPV vaccination programme will use the quadrivalent vaccine.

Q9

How does the HPV vaccine work?

- The vaccine works in the same way as other vaccines. The body reacts by making antibodies which will help the immune system fight HPV infection
- The HPV vaccine does not contain any viral DNA
- The HPV vaccine is not a live vaccine
- The HPV vaccine is not infectious.

Q10

Is it a safe vaccine?

- The World Health Organisation (WHO) conducted a review of HPV vaccine safety in 2009 and stated "no concerns with the safety profile were identified
- The most frequently reported side effects are local redness and /or swelling at the point of injection, and fever. These are typical and usually mild and temporary reactions to any kind of vaccination.

Q11

How will HPV vaccination impact on cervical cancer and cervical screening in the future in Ireland?

- Innovative approaches will be required to integrate vaccination into a comprehensive cervical cancer control strategy
- HPV vaccination has the potential to reduce but not eliminate the risk of all cervical cancer
- Vaccinated women will continue to require cervical screening
- Preliminary data suggests there may be some cross protection between genotypes
- Cervical screening remains the most effective way of reducing the incidence of cervical cancer.

3.7 Prevention by vaccination

Recognition of the role played by HPV in the genesis of cancer of the cervix prompted the development of a vaccine against the most commonly recognised oncogenic types. There are currently two vaccines. Both are designed to protect against HPV 16 & 18, and one also protects against low risk types 6 & 11.

The vaccines are prepared from virus-like particles (VLPs). As they do not contain any live biological product or DNA, they are not infectious. The vaccines are given as a series of three 0.5ml intramuscular injections over a six month period.

HPV vaccines induce serum antibodies in virtually all vaccinated individuals (WHO, 2007) and antibody levels after vaccinations are several times higher than those seen after natural HPV infection in all age groups evaluated in vaccine trials to date. The HPV vaccines are designed to be prophylactic not therapeutic.

The protection provided by the vaccines is therefore lower among women who have already been infected with the vaccine-related HPV genotype than among those who have not yet been infected.

It is worth noting that 29 per cent of cervical cancers are caused by other types of HPV for which there is no vaccine at this time. Since current HPV vaccines do not eliminate the risk of cervical cancer, cervical screening will still be required to minimise cancer incidence (FT Cutts et al, 2007).

3.8 The case for screening

Screening has been defined as the examination of asymptomatic people in order to detect their probability to having or developing a disease. The following figure outlines the key principles of screening as applied to cervical cancer. Screening aims to improve survival, limit morbidity and improve the quality of life for those who have developed cancer ('A Strategy for Cancer Control in Ireland', 2006).

Figure 3.4 Screening as applied to cervical cancer

KEY PRINCIPLES OF SCREENING	AS APPLIED TO CERVICAL CANCER
The condition should pose an important health problem.	Cervical disease is a growing killer of young women.
The natural history of the disease should be well understood and should have a recognisable early stage.	It is possible to recognise cervical cell changes that are asymptomatic by smear testing. The presence of CIN can be inferred from the degree of dysplasia seen on a smear test.
There should be a suitable and acceptable test.	The cervical smear test is reliable, valid, safe and is largely acceptable to the eligible population.
Treatment of the disease at an early stage should be of greater benefit than that started at a later stage.	Relatively simple treatment eradicates the disease in those with cell changes detected on smear testing.
There should be adequate facilities for the diagnosis and treatment of the abnormalities detected.	Facilities have been put in place to manage the outcomes of cervical screening, including diagnostic and treatment facilities.
The test should be repeated at intervals where the disease is insidious.	The screening interval for cervical cancer has been well studied internationally.
The chance of physical and psychological harm to those screened should be less than the chance of benefit.	While there is a chance of over-treatment of lesions that might well regress if left alone, the physical dangers of over treatment are minor compared to the disease outcome. The psychological sequelae can be managed by appropriate counselling.

Adapted from Wilson, J.M.G. & Junger, G. WHO (1968)

Reports on the incidence of cervical cancer where screening programmes have been organised, illustrate a fall in the rate of new cases. Organised screening programmes report a decrease in the incidence of and mortality from cervical cancer, whereas opportunistic smearing appears to have little impact at a population level. In Finland, the decrease in mortality was of the order of 60 per cent (Hakama, 1988). Similar results have been reported from the UK (Quinn et al, 1999) and British Colombia (Anderson et al, 1988). In Sweden the overall incidence of cervical cancer declined by 67 per cent over a 40 year period between 1965-2005 (Socialstyrelsen, 2007).

3.9 The screening interval

While the greatest risk of cervical cancer is never having a smear test, one smear test gives only a 20 per cent risk reduction and regular smear tests are required to make a meaningful impact on the disease (Miller, 1992).

Table 3.7 Screening Interval and Cumulative Risk Reduction

INTERVAL BETWEEN SMEAR TESTS (YEARS)	REDUCTION IN CUMULATIVE INCIDENCE RISK (%)	NUMBER OF SMEAR TESTS IN A LIFETIME (25-60 YRS)
1	93.3	35
2	92.5	17
3	91.2	11
5	83.6	8
10	64.1	3
Single smear at age 40	20	1

See Section 1.6.1 for further information on screening intervals and the call, re-call process of invitation to screening.

Ref: Miller, WHO (1992); Hakama, et al, IARC (1986))

Three-yearly smear tests will give a reduction in cumulative risk of 91 per cent which would involve a woman having 11 smear tests during her screening lifetime (25-60 years). Annual smear tests confer a risk reduction of 95 per cent but at a cost of women having 35 smears in their lifetime.

CervicalCheck screening interval

The current screening interval policy of CervicalCheck (informed by the McGoogan Report, 2004) for women aged 25 to 44 years is at three yearly intervals and for women aged 45 to 60 years is every five years. Cervical screening guidelines and recommendations should be followed by smear takers. There is no requirement for increased screening if the woman has a history of genital warts, is a cigarette smoker, is using the contraceptive pill or if the woman has an Intra Uterine Contraceptive Device (IUD). (Standard 4.3.3; 'Guidelines for Quality Assurance in Cervical Screening').

Screening under 25

Sasieni et al, 2009, found no evidence that screening women in the UK aged 22 to 24 decreased the incidence of cervical cancer at ages 25 to 29. Authors concluded that cervical screening in women aged 20 to 24 has little or no impact on invasive cancer rates up to the age of 30.

Key point:

Women who have previously had treatment for CIN represent a high risk group, with a risk of abnormality which is five times greater than women with a normal smear test history (Soutter et al, 2006). The danger of developing cancer remains higher in those who have had treatment for HSIL. Recent evidence from Sweden (Strander, 2007) suggests that this surveillance may need to be extended to 20 years or longer. Smear takers are advised to follow the colposcopy discharge recommendations.

APPENDIX 3

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Section 4

Taking cervical smear tests

SECTION 4

Taking cervical smear tests

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Taking cervical smear tests

Aim of section

The aim of this section is to deal with the technical and communication skills that ensure a competent smear taker. This Section is designed for new smear takers and those smear takers wishing to maintain competency.

4.1 The importance of the smear taker

One of the most important factors in effective screening programmes is that the screening test and management of the test result are performed competently. The smear taker must learn to harvest the cells of the squamocolumnar junction of the cervix when smear taking and deal with the sample and each woman appropriately. Moreover, it is important that the woman has a positive experience every time she attends for cervical screening.

In order that a woman can make informed decisions about participation in screening, it is important that she has a sufficient understanding of cervical cancer and the risks and benefits of screening. Ensuring that each woman understands the purpose and procedures involved in cervical screening is an essential task for smear takers. This is clearly explained in the 'Information Sheet for Women' attached to each Cervical Cytology Form. In addition to ensuring a quality clinical environment, the smear taker has a key role in communicating issues of consent and confidentiality.

See this section at 4.2A & Section 6 for further information on consultation and communication

4.2 The smear taking process


This section considers the technical and practical process of smear taking and covers the following areas.

KEY AREAS FOR THE SMEARTAKER TO CONSIDER	KEY POINTS
A. Consultation	<ul style="list-style-type: none"> Poor techniques can result in 20 per cent or more of pre-cancerous abnormalities being missed. An inadequate sample may result in a negative report or a report which underestimates the degree of abnormality present.
B. The smear test procedure	
C. Locating and visualising the cervix	
D. Assessment of the cervix	
E. Cervical Cytology Form	
F. Anatomy and physiology	
G. Environment and equipment	




4.2A Consultation

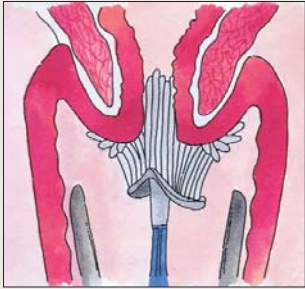
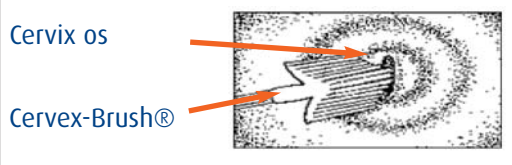
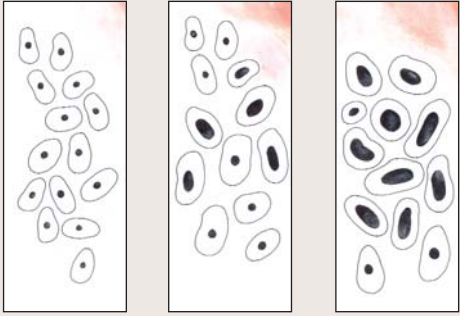
COUNSELLING & CONSENT	KEY POINTS
<p>Counselling</p> <p>Women having a cervical smear test taken should be counselled before, during and after the procedure. The woman's understanding of the test and her concerns about its implications need to be fully addressed. Clear language should be used. It is important to check with the woman that she understands all the information provided.</p> <p>It must be clear to all women having the test what a cervical smear does and does not detect, and that the test relates only to the cervix. No information is 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 test result.</p> <p>Women should be given an estimated time in which they may expect to receive the result of their smear test and be informed that CervicalCheck will send a notification of their result to the woman at the address on the Cervical Cytology Form. Details will be provided by their smearer or doctor with clinical responsibility.</p>	<p>See Section 6.2 on key information that smear takers should provide to women.</p> <p>A charter of women's rights is available on the CervicalCheck website.</p> <p>It should be emphasised that the smear test is not a test for cancer. It is a screening test only.</p>
<p>Results</p> <p>Each woman must be given the opportunity to discuss the result of her test and its implications and should be advised that an appointment can be made with the smearer or the doctor with clinical responsibility free of charge to her. Each woman should fully understand the significance of the test result. Care should be taken not to generate unnecessary anxiety.</p> <p>All counselling related to the smear test must be readily available to the woman. Women undergoing colposcopic assessment and treatment are entitled to counselling from their smearer. For CervicalCheck registered smear takers, all such counselling is included in the smearer's contract fee so no charge should be levied.</p>	<p>'Normal' results can be discussed by phone. Face to face consultation for all other results is recommended, with adequate time allowed for questions and explanation (<i>see Section 5.3.2 on communicating results</i>).</p> <p>A counselling session should ensure privacy, confidentiality, trust and sensitivity.</p>

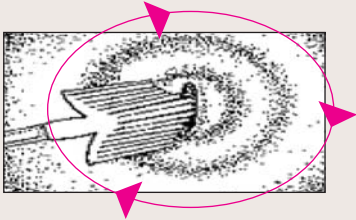
COUNSELLING & CONSENT	KEY POINTS
<p>Informed consent</p> <p>Informed consent must be obtained without duress. Consent to have the smear test taken is implicit when the woman allows the test to occur. However, this should only occur after a full explanation as outlined earlier.</p> <p>Why does the woman need to give consent?</p> <p>Written consent is required to allow CervicalCheck to receive, hold and use a woman's personal details and information about her smear test sample. This information may include past smear tests and colposcopy results.</p> <p>CervicalCheck will use the information recorded on the Cervical Cytology Form for the purposes of providing each woman with cervical screening services, including future calls and re-calls for screening and follow-up where necessary.</p>	<p>See Appendix 4B for a copy of the 'Information Sheet for Women'.</p> <p>See Section 6 for further details on informed consent.</p> 


4.2B The smear test procedure


STAGE OF PROCEDURE	KEY POINTS
<p>Chaperone</p> <p>In Ireland, the Irish Medical Council guidelines for doctors states that any intimate examination should be accompanied by an explanation and the patient, irrespective of age or gender, should be offered a chaperone.</p> <p>Before the test</p> <p>The smearer should ensure that the necessary supplies and equipment are ready (see Section 4.2G).</p> <p>An appropriate history-taking and consultation with the woman is undertaken and any Individual special requirements should be accommodated. (See 4.2A & 6)</p> <p>The woman should be allowed an opportunity to empty her bladder.</p>	<p>A chaperone must be facilitated if the woman requires one.</p> <p>The Smearer may need to ask the woman if she has ever been sexually active. (See 4.3.9)</p> <p>The smearer should wash his/her hands before and after any procedure which involves close contact with the patient.</p> <p>The smearer must check that the vials are not expired.</p> <p>Smear activity must be provided in a private and secure setting.</p>

STAGE OF PROCEDURE	KEY POINTS
<p>Background to examination</p> <p>The 'cervix' as the name suggests is the 'neck' of the uterus. It is usually situated high in the vagina and is identified as a firm cylindrical structure with an opening into the endocervical canal.</p> <p>The smeartaker should sample all of the vulnerable area of the cervix and should transfer all of the harvested cells to the laboratory. The vulnerable area is the junction between the thick resilient squamous epithelium of the ectocervix and the thin columnar epithelium that lines the endocervix and everts outwards at stages in a woman's life. The everted area will over time transform from thin columnar epithelium to thicker tougher squamous epithelium. The area changing is the Transformation Zone. (See Section 4.2F)</p> <p>This is the area where metaplastic change occurs (see Section 3).</p> <p>The cervix brush (Cervex-Brush®) is used to remove cells from the cervix and these cells must reach the laboratory in a condition that allows the cells to be examined.</p>	<p>The test is to check for abnormal cells that if left untreated may turn cancerous. It is not a test for cancer. It does not tell anything about the ovaries or uterus. It is appropriate to advise the woman of this.</p> <p>Explain to the woman what you are doing at each stage and check that she understands e.g. tell the woman.</p> <div data-bbox="847 633 1342 965"> <p><i>"I need to take the sample from the right place on your cervix. I will hold back the vaginal walls with this speculum in order to get a good look at the cervix."</i></p> </div>
<p>Ideal conditions for a test</p> <p>The best time for a smear test to be taken is mid-menstrual cycle to facilitate optimal cytological conditions and when it is unlikely there will be any remaining menstrual blood (Vooijs, 1987). However, this does not mean that a smear test cannot be taken at a different time in a woman's cycle but should be avoided if there is menstrual blood present.</p> <p>Contraception used by women may change their bleeding pattern. This is documented in the Cervical Cytology Form (See Section 4.2E & 4.3)</p>	<p>All women making appointments for a smear test need to be advised that the optimal time for the test is mid cycle - that is approximately 10 to 14 days after the first day of her period (if the woman is having periods). Reception staff should be made aware of this.</p>
<p>Type of test used</p> <p>The single test for smear tests taken in Ireland is liquid-based cytology (LBC). The sampling tool is the Cervex-Brush®. The transport medium is a liquid-filled vial.</p> <p>The endocervical brush is sometimes used in a colposcopy setting.</p>	<p>Figure 4.1 Vial and Cervex-Brush®</p>  <p>Kind permission to use images received from Hologic Inc.</p>

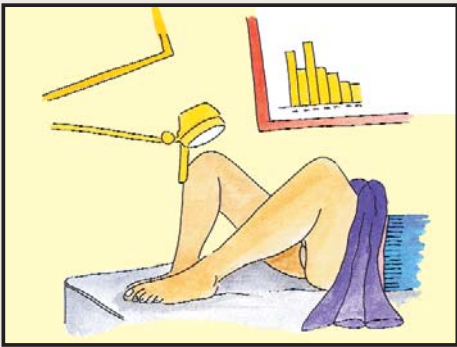
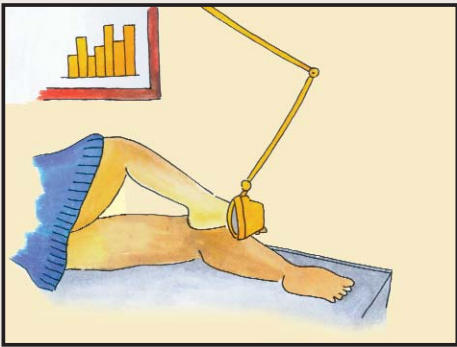

STAGE OF PROCEDURE	KEY POINTS
	<p>Figure 4.2 Cervex-Brush® in Cervix</p>  
<p>What smeartakers need to understand about the test</p> <p>Liquid-based cytology allows for separation of cervical cells from blood, mucus and non-diagnostic debris in the laboratory by a spinning process and a slide is then made from the harvested cervical cells. The filters can be blocked by excessive debris or lubricant.</p>	<p>Figure 4.3 Slide made with LBC harvested cells</p>  <div style="display: flex; justify-content: space-around;"> <div data-bbox="911 1406 1034 1462">Showing normal cells</div> <div data-bbox="1241 1406 1414 1462">Dyskaryotic cells with large nuclei</div> </div>

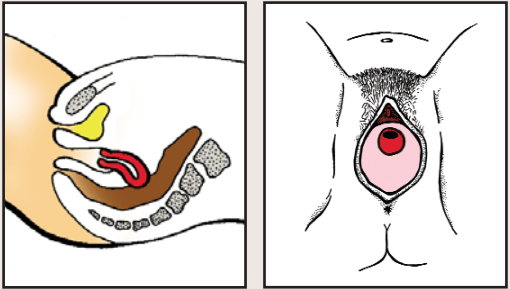
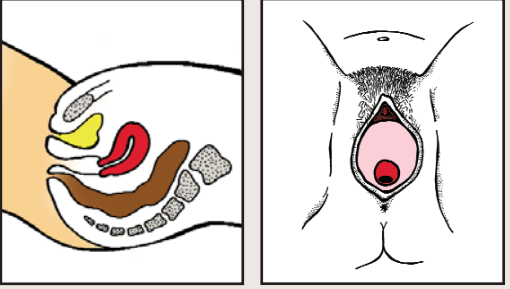
STAGE OF PROCEDURE	KEY POINTS
<p>Taking the sample</p> <p>See 4.2C and 4.2D of this section for information on insertion of the speculum, the visualisation, assessment and interpretation of the cervical findings. Smear-taking activities must adhere to the infection control procedures of the practice/clinic (See 4.2G of this section).</p> <p>Having visualised the entire cervix and identified the squamocolumnar junction, the long central bristles of the Cervex-Brush® are inserted into the external cervical os, ensuring good contact is made. The smearer should sweep the brush around the whole Transformation Zone including the margins.</p> <p>It is important that the sample is taken with care so that the Cervex-Brush® is firmly rotated to a full 360 degrees, five times in a clockwise direction. This should be done using 'pencil' pressure by rolling the stem between the thumb and the forefinger, ensuring that the lateral bristles bend against the ectocervix and maintain good contact throughout.</p> <p>Copious cervical mucous can be removed before taking the smear test by gently twisting the other end of the Cervex-Brush® in the mucous, avoiding contact with the cervix, and then 'lifting' the mucous off the cervix.</p>	<p>It is vital to rotate in a clockwise direction as the plastic bristles are bevelled and only harvest cells when rotated in this direction.</p> <p>The smearer must visualise the cervix and sample the whole circumference of the cervical os, including the Transformation Zone.</p> <p>If it is necessary to take a swab for purposes other than the smear test, it must be taken after the smear test. It is usual to advise the woman that a swab has been taken in addition to the smear test and will require separate follow up.</p> <p>Figure 4.4 Rotation of Cervex-Brush® Five times in a clockwise direction</p>  <p>Five times in a clockwise direction</p>

STAGE OF PROCEDURE	KEY POINTS
<p>Preparation of sample for the laboratory</p> <p>The cells need to be transferred directly into the liquid and this is done immediately with vigorous 'mash and bash' action to ensure maximum yield. It is recommended that the bristles of the brush are pushed vigorously against the bottom of the specimen vial ten times, ensuring that the bristles are pushed apart. It should look distorted when the sample has been prepared.</p> <p>The Cervex-Brush® should then be rinsed by rotating the shaft of the brush between the finger and thumb and should be inspected for any residual material. Any remains should be removed by passing the brush over the edge of the vial but do not stand Cervex-Brush® in liquid at any time.</p> <p>The cap should be tightened, but not over-tightened, so that the line on the cap passes the torque line on the vial. The vial can be shaken if any material has been placed on the edge of the vial. The Cervex- Brush®/ sampler may then be discarded with the clinical waste.</p>	<p>The vial should be prepared immediately and not left standing while dealing with the speculum, woman or the Cervical Cytology Form.</p> <p>In order to be accepted at the laboratory, a vial must contain at a minimum: the woman's surname, first name/initial and date of birth.</p> <p>If a printed label is used, it must clearly be adhered to the existing label and must not obscure the laboratory's view of the liquid in the vial.</p> <p>These details must all exactly match the details on the Cervical Cytology Form.</p> <p>Figure 4.5 Preparing sample for laboratory</p>  <p>Kind permission to use images received from Hologic Inc.</p>

STAGE OF PROCEDURE	KEY POINTS
<p>Submitting samples to the laboratory</p> <p>The vials can be left at room temperature and should not be placed in a fridge and must be posted within five working days, even if the transport box is not full.</p> <p>Boxes are reusable and should not be written on. It is advisable to log the day of posting the smear test and one 'bar code' label should be retained when posting to allow for tracing in the event that a package is lost in transit.</p>	<p>To facilitate the delivery of a result to a woman within four weeks it is important to dispatch the sample promptly. It is the responsibility of the Smear taker (not the woman) to dispatch/post samples.</p> <p>Marked vials and forms must be packaged in the transport containers provided.</p>  <p>Figure 4.6 Vial in transport box</p>


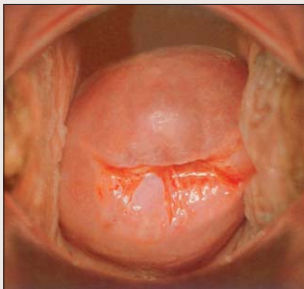


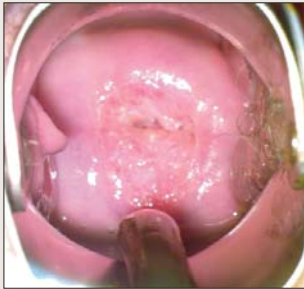
4.2C Location and visualising the cervix



STAGE OF PROCEDURE	KEY POINTS
<p>Prepare the woman</p> <p>Ask the woman to undress from the waist down and to lie on the couch. The woman may be more comfortable leaving her skirt on but removal of trousers is needed to allow for adequate exposure and good lighting of the perineum. Ensure that privacy is maintained by using a couch roll as a cover rather than a blanket or sheet where infection control could be compromised.</p> <p>The position of the woman is important and the time spent ensuring she is in the correct position will make finding the cervix easier.</p> <p>Smear tests can be taken in the dorsal position or in the left lateral position. The dorsal position allows for better communication and observation of the woman and is the most common position to take a smear test. 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. If there is difficulty when smearing, it can be effective to reposition the woman and for her to place her fists under her buttocks.</p> <p>Some women may be used to having smear tests taken in the left lateral position and may put themselves in that position. The left lateral position may be better for visualising the cervix if the uterus is acutely anteverted or retroverted.</p>	<p>It is important to help the woman to relax. For some women, explanation of the various steps in the procedure helps them to relax.</p> <p>A confident, unrushed demeanour is helpful and good practice recommends that the first touch to the woman should be on her arm or leg by way of reassurance.</p> <p>Figure 4.7a Positioning of the woman – dorsal</p>  <p>Figure 4.7b Positioning of the woman – left lateral</p> 
<p>Choose a speculum</p> <p>A tray or trolley with the appropriate equipment and full range of specula should be close at hand. When choosing a speculum, the age, parity and size of the woman should be taken into consideration.</p> <p>When using a disposable speculum, the package should not be opened until ready for use. When using reusable specula, a range of sizes should be available and in a sterile state.</p>	<p>Ensure used or non-sterile instruments are kept separate from clean/sterile instruments.</p> <p>Figure 4.8 Specula - different sizes</p> 



STAGE OF PROCEDURE	KEY POINTS
<p>Position of the light</p> <p>Good lighting is vital in finding and assessing the cervix and taking a smear test. Wall-mounted or floor standing lights with halogen bulbs ensure a flexible bright light.</p> <p>The light source should be angled to allow clear visualisation of the cervix and vaginal walls and should be adjusted as necessary during the course of the procedure. A speculum light (a small bright light source that can be attached to the speculum) can be helpful.</p> <p>To prevent contamination, the light should be handled with a paper towel or elbowed out of the way, when gloved.</p>	<p>It is important that the smearer moves away from the light when transferring the cells as strong lighting can cause cells to dry out before fixing them in the liquid.</p>
<p>Vulval inspection</p> <p>It is good practice that the first touch of the patient is not her vulva. A hand on the patient's knee or checking the temperature of the speculum against the woman's thigh can prepare the woman for the feel of the examination.</p> <p>Before taking the smear test it is important to inspect the vulva, recognise the anatomical landmarks and make a general assessment of the area.</p>	
<p>What to understand about locating the cervix</p> <p>Finding the cervix and visualising it in its entirety is not always easy. In some women after introducing a speculum the cervix is very obvious, in others it is more difficult to find and inspect.</p> <p>An anteverted uterus is the usual position for the uterus where the cervix tilts slightly backward. Less common is the uterus that is retroverted where the cervix lies behind the pubic bone or anteriorly in the vagina.</p> <p>Some women have small tight vaginas, some will have larger vaginas and some due to loss of muscular tone will have 'floppy' vaginal walls (usually those who have had vaginal deliveries) that can make it difficult to visualise the cervix.</p>	<p>The smear test should not be taken if the smearer is unable to identify and visualise the entire cervix.</p> <p>Figure 4.9a Anteverted uterus Cervix will be found posteriorly</p>  <p>Figure 4.9b Retroverted uterus Cervix will be found anteriorly</p> 

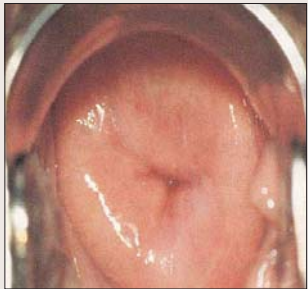

STAGE OF PROCEDURE	KEY POINTS
<p>Insertion of the speculum</p> <p>The largest size speculum that can be comfortably inserted should be chosen. The appropriate size will be helpful in holding back the vaginal walls. A long speculum is usually required for tall women. It can also be useful when the cervix is in a posterior position. In obese women, or women with a lax vagina, sheathing the speculum with the finger of a large surgical glove, having cut the tip of the finger (this forms a cylinder) may prevent the vaginal walls from obscuring the cervix.</p> <p>The smearer should check the temperature of the speculum and adjust to body temperature. This, however, is not necessary with disposable plastic specula which are preferred by some women. After inspection of the vulva, the labia should be separated and the speculum inserted gently but firmly along the axis of the introitus, with the speculum pointing downwards and backwards.</p> <p>When the speculum is half way up the vagina, it should be rotated gently through 90 degrees. It is important to angle the speculum towards the patient's coccyx and not to open the speculum until it is fully inserted. Opening and closing the speculum and changing the angle of insertion should bring the cervix into view.</p> <p>A common error is failure to insert the speculum far enough into the vagina. It is helpful to allow a little time after passing the speculum to allow the woman to relax.</p> <p>Lubrication of the speculum is usually not necessary but if the vagina is very dry, 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 and with the woman's consent, a gentle digital examination to locate the cervix may be carried out and any vaginal secretions used to lubricate the speculum along its sides. On digital examination, the cervix should feel like the tip of the nose with a firm consistency. Encouraging the woman to relax or cough or tipping her pelvis by asking her to put her fists or a folded towel under the buttocks, may be helpful in bringing the posterior positioned cervix into view.</p>	<p>Message for the woman: <i>"The more relaxed you can be, the easier it will be to find the cervix and take a sample of cells from the right area".</i></p> <p>A woman's request to stop the procedure at any time must be respected.</p> <p>If visualisation proves difficult it may be helpful to start again and re-position the woman. (see 4.3 in this section)</p> <p>Figure 4.10 Insertion of the speculum</p>  <p>In the clinical notes, record difficulty and any solution that may be helpful on the next occasion e.g. 'This woman has a retroverted uterus and cervix is found anteriorly in the vagina' or 'The cervix very posterior and longest speculum useful', etc.</p> <p>If the cervix is present but you cannot visualise it, do not take the smear test.</p> <p>Consider that sometimes it may not be obvious that it is the cervix you are visualising, extra care should be taken where there is uncertainty.</p> <p>Excessive amounts of lubricant may compromise the test and possibly lead to an unsatisfactory result.</p>




4.2D Assessment of the cervix

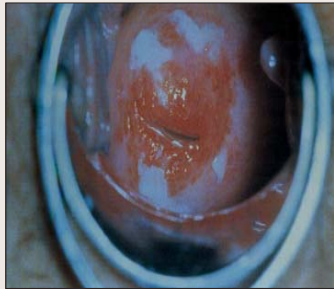

ASSESSMENT	KEY POINTS
<p>The appearance of the cervix</p> <p>Inspection of the vulva and vagina will aid the smearer when assessing the cervix. Viral warts or evidence of a discharge may be visible which may have a direct influence on the assessment and interpretation of the cervical findings.</p> <p>Once visualised, the cervix has a wide range of appearances depending on age, parity, hormonal status, presence of infection and/or previous surgery. Such variety may be confusing and the smearer must become familiar with the different appearances of the normal cervix. It is not possible to identify the presence or absence of cellular abnormalities at the time of smearing and pre-cancerous abnormalities are invisible to the naked eye.</p> <p>The cervix varies in size, shape and also position in the vagina. A nulliparous cervix may be small with a minute opening at the ectocervix and found high in the vagina. A multiparous woman may have a large irregular cervix found low in the vagina. It is vital to visualise and inspect the entire cervix and the Transformation Zone is the area that should be sampled when taking the smear test (see 4.2F of this section on Anatomy & Physiology). Microscopic examination of the cells brushed from the epithelium can determine if there is an abnormality present.</p>	<p>The cervix may look normal even if there is an abnormality present.</p> <div data-bbox="906 477 1211 763">  <p>Figure 4.11a Normal cervix</p> </div> <div data-bbox="906 779 1211 1066">  <p>Figure 4.11b Multiparous cervix</p> </div> <div data-bbox="906 1081 1211 1368">  <p>Figure 4.11c Cervical eversion (Ectropion)</p> </div> <div data-bbox="906 1384 1211 1671">  <p>Figure 4.11d Normal cervix – eversion undergoing change into squamous epithelium in the Transformation Zone</p> </div> <div data-bbox="906 1686 1211 1973">  <p>Figure 4.11e View of normal cervix eversion almost completely transformed into squamous epithelium</p> </div>

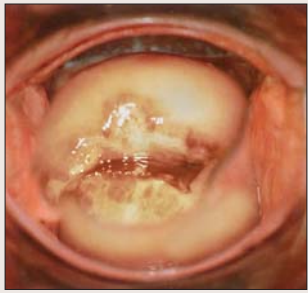


ASSESSMENT	KEY POINTS
<p>Bleeding when taking the test</p> <p>Contact bleeding when screening is not uncommon and liquid based cytology can remove some red blood cells. Where there is concern about undiagnosed bleeding, Appendix 4A is available to instruct clinically responsible doctors and smearthakers that should be consulted.</p> <p>Refer to Appendix 4A for further information.</p> <p>Chlamydia infection can be a cause of bleeding at the time of the smear test and any swabs taken if required for diagnosis should be taken after the smear test and not before.</p>	<p>It is recommended that the best time to take a smear test is mid-cycle and menstrual smear tests should not be taken. (See Section 4.3.5 – Bleeding patterns)</p>
<p>Cervical mucous</p> <p>The cervix secretes mucous that covers the endocervical canal and the vaginal epithelium.</p> <p>Mucous production is controlled by hormones, with the amount and viscosity changing as the concentration of oestrogen and progesterone change. It is believed that mucous acts in a variety of ways to prevent microorganisms from colonising and infecting the cervix.</p> <p>Vaginal discharge may be encountered (See Figure 4.20 & Section 4.3.6). Sexually transmitted infection (STI) screening is not part of the cervical screening process.</p>	<p>Figure 4.12a Mid-cycle mucous</p>  <p>Figure 4.12b Excess mucous</p>  <p>Excess mucous may obscure the smearthaker's view of the entire cervix and can sometimes interfere with sampling. Gentle removal without touching the cervix is advised. If this proves difficult, proceed with smear test anyway.</p>

ASSESSMENT	KEY POINTS
<p>Common physiological changes</p> <p>Cervical eversion involves migration of cells from the inner lining of the endocervical canal or endocervix to the outer portion of the cervix or ectocervix. An eversion used to be called an erosion or ectropion.</p> <p>Eversion is a physiological change that the cervix undergoes with growth and the influence of hormones. Though large eversions can look alarming, they are common and the smearer might expect to see an eversion if the woman is taking hormonal contraception.</p> <p>If a wide eversion is present (Fig 4.14), the smearer should use a wide sweeping action around the everted squamocolumnar junction. The cervical sample should include squamous and endocervical cells and cells from the Transformation Zone.</p>	<p>Figures 4.13 Normal cervix with no eversion noted</p>  <p>It should be noted that the position of the Transformation Zone varies during a woman's lifetime.</p> <p>Figure 4.14 Normal cervix with large eversion (ectropion)</p>  <p>Ref A&P Section 4.2F</p>
<p>During and after pregnancy</p> <p>The cervix during pregnancy is engorged, has a purple hue and may bleed more easily.</p>	<p>If a woman is due a routine smear test and is pregnant, the smear can be delayed until three months after the birth. (See section 6.4.4 and 1.6.3).</p>
<p>Breast feeding</p> <p>Under normal screening circumstances, it is reasonable to wait until breast feeding is finished but if deferral is greater than three months it is advisable to proceed with the smear test.</p>	<p>Remember some women will breast feed for two years, may then become pregnant and so a lengthy delay in screening may ensue.</p>

ASSESSMENT	KEY POINTS
<p>Post-menopausal</p> <p>The post-menopausal cervix appears shrunken and the squamocolumnar junction having receded into the endocervical canal (Fig 4.15a). The cervix may look pale and dry, and bleed easily (Fig 4.15b). The vagina may be dry or inflamed and is known as 'atrophic vaginitis'. It can be difficult to harvest sufficient cells and may also be difficult to sample the Transformation Zone. In such circumstances, the smear test may be reported as inadequate.</p> <p>In order to take a quality smear test in older women, a course of local oestrogen for four weeks (if there are no contraindications) sometimes may be needed to allow the columnar epithelium to 'evert'. This will allow the Transformation Zone to be sampled adequately. Fees that arise relating to prescriptions should be agreed between the woman and the smeartaker.</p>	<p>Three inadequate smear tests warrant referral for colposcopy. After one inadequate smear test result, the older woman should be offered local oestrogen and the smear test repeated soon afterwards.</p> <p>The minimum interval for a repeat of an inadequate smear test is three months which allows the cells of the cervix to regenerate.</p> <p>Figure 4.15a Post-menopausal cervix</p>  <p>Figure 4.15b Post-menopausal cervix</p> 

ASSESSMENT	KEY POINTS
<p>Anomalies, nabothian follicles & cervical polyps</p> <p>There are a number of physiological changes that the cervix may undergo.</p> <p>Nabothian follicles are mucous filled cysts on the surface of the cervix (Fig 4.16). They are usually caused when stratified squamous epithelium of the ectocervix grows over the columnar epithelium of the endocervix. The tissue growth can block the cervical crypts, trapping cervical mucous inside the crypts. They are often visible on the cervix at various stages of ripeness.</p> <p>There are two distinct types of cervical polyps: pedunculated (Fig 4.17) and sessile (Fig 4.18) and where present, smears should be taken as usual. Referral for removal may be indicated.</p>	<p>Figure 4.16 Nabothian follicles</p>  <p>Figure 4.17 Pedunculated polyp</p>  <p>Figure 4.18 Sessile polyp</p> 

ASSESSMENT	KEY POINTS
<p>Infections</p> <p>The vulva vagina may show evidence of infections which can affect the smear test result. Infections may be acute or chronic.</p> <p>The cervix can look different to normal because of the presence of infections either viral, bacterial, fungal (moniliasis) or due to the overgrowth of normal organisms with a shift in bacterial flora causing some discharge and inflammation. Inflammation may be present due to mechanical, physical and/or chemical trauma.</p>	<p>A routine smear test is a search for abnormal cervical cells and should not be confused by the presence or management of other clinical conditions.</p> <p>It is important to note that the smearer is primarily interested in a quality test – the diagnosis and management of infections is outside the scope of this guide.</p>
<p>Vaginal candida (Moniliasis)</p> <p>Vaginal candida is an overgrowth of a normal organism in the vagina and vulva. The woman may complain of itch. If the infection is severe with a copious, white 'cheesy' discharge and the woman is likely to return for her smear test, it may be more appropriate to treat the candida/thrush infection before proceeding to a smear test.</p>	<p>The likely presence of thrush should be noted on the Cervical Cytology Form.</p> <p>Figure 4.19 Vaginal candida</p> 
<p>Non-specific cervicitis</p> <p>Acute, non-specific cervicitis may result from direct trauma, and/or from the use of douches and ointments.</p> <p>Chronic, non-specific cervicitis is another gynaecological disorder, which may be due in part to a low grade infection in a locally altered cervical environment.</p> <p>Purulent discharge from the cervical os</p> <p>A heavy discharge from the cervical os is distinguished from cervical mucous by the copious amount of discharge, the colour and smell of the discharge and the inflamed appearance of the cervix. A smear test taken while there is cervicitis will be more difficult to interpret due to the obscuring of cervical cells with inflammatory cells. The most prevalent bacterial STI is Chlamydia.</p>	<p>Figure 4.20 Purulent discharge</p>  <p>Consideration should be given to identifying and treating an infection before smear testing.</p>

ASSESSMENT	KEY POINTS
<p>Herpes infections</p> <p>Primary infections are usually very painful and it is unlikely that a smear test could be taken. Symptoms of recurrent disease are less severe and herpetic lesions should be noted on the Cervical Cytology Form if identified at the time of smeartaking.</p>	<p>Figure 4.21 Herpes infection</p> 
<p>Human Papilloma Virus (HPV) & warts</p> <p>HPV produces two types of changes on the cervix. Clinical condylomata are visible but the sub-clinical, non-condylomatous type is only obvious after the application of acetic acid. Visible warts on the cervix can be flat or proliferative. Warts may be visible on vulva and vaginal walls but not on the cervix.</p> <p>HPV infection is usually not visible to the naked eye. Cytologically, the presence of the Human Papilloma Virus causes a large perinuclear halo and other nuclear changes.</p> <p>Warts (clinical condylomata) are caused by Human Papillomavirus types 6 & 11. These are not the oncogenic types of HPV.</p>	<p>Figure 4.22 Vulval warts</p>  <p>Figure 4.23 Warts on the cervix and vaginal walls</p>  <p>Message for the woman:</p> <p><i>There is no requirement for increased screening if the woman has a history of having genital warts, screening intervals should be on the management recommendations from the laboratory.</i></p> <p>(see Section 3.5 for more information on HPV)</p>

ASSESSMENT	KEY POINTS
<p>Cancerous changes of the cervix</p> <p>Advanced invasive cancer of the cervix (Fig 4.24) is very rarely seen and occasionally, there may be a small area of suspicion. Invasive cancer may be confined initially to only a small area of the cervix and for this reason; the entire cervix must be seen at each smear test.</p> <p>Invasive cancer of the cervix is rarely seen by regular smetakers and if suspected, referral to a gynaecologist is urgently required.</p> <p>A smear test taken in this case will probably cause bleeding, but, worryingly, may indeed be reported as normal due to rapidly dividing cells and so is unreliable. There may be a report of inflammation as many types of primary malignant tumours are associated with an inflammatory reaction both within the tumour and in the adjacent stroma.</p>	<p>The cervix should be visualised at each smear test.</p> <p>Undiagnosed abnormal bleeding requires investigation. (Refer to Appendix 4A)</p> <p>Abnormal cells may occupy only a small area of the Transformation Zone.</p> <p>Figure 4.24 Advanced cancer of the cervix</p> 
<p>A vault smear test</p> <p>There are occasions when it is advised that a smear test should be taken even though the cervix has been removed along with the uterus at hysterectomy. This is what is called taking a vault smear test. The most common reason to continue screening in this situation is if the woman has had a hysterectomy because of abnormal cells that have micro-invaded or recurred following treatment.</p> <p>The upper end of the vagina must be inspected for any abnormal looking lesions and cells harvested from the area where the vaginal scar is visible. If the scar is not visible an extensive brush action sweeping in a clockwise direction, where possible, five times is advised.</p>	<p>Figure 4.25 Vaginal vault post total hysterectomy</p>  <p>(See Section 6.4.5 for further information on hysterectomy)</p>

ASSESSMENT	KEY POINTS
Removal of the speculum Withdraw the speculum gently with the blades apart until the cervix is no longer within the blades. Allow the speculum to close and continue to withdraw without pinching the vaginal walls.	

4.2E The Cervical Cytology Form

THE CERVICAL CYTOLOGY FORM

KEY POINTS

What is the Cervical Cytology Form?

The Cervical Cytology Form is designed to ensure that the right woman gets the right result. Complete, current and accurate demographic information is necessary and all information recorded in the Cervical Cytology Form must be legible.

CervicalCheck currently holds records on all women who have had smear tests within the programme. This information is available through the electronic link to the laboratory which allows for each woman's smear test history, once on the system, to be easily retrieved should she move location or change smearer.

Consequences of inaccuracies on the Cervical Cytology Form:

- Waiting time for results increase
- Women get tagged with inaccurate past medical history that affects management
- Women with cervical changes go untreated
- Women receive inaccurate results
- Increased risk of litigation

The image shows a sample of the Cervical Cytology Form. A pink oval highlights the 'Demographic details' section, which includes fields for name, date of birth, address, and phone number. A pink arrow points from this section to the text block titled 'Demographic details – accuracy of information'.

Demographic details – accuracy of information

There is a minimum data set of information required when completing the Cervical Cytology Form, which helps to match the right results to the right woman. The CervicalCheck Minimum Dataset is as follows (see also Section 1.5):

- Date of birth (DOB)
- Forename
- Surname at birth
- Mother's maiden name
- Personal Public Service Number (PPS No)
- Middle names
- Surname
- Address
- Phone number

The address on the Cervical Cytology Form is the address to which all letters and contacts with the woman are directed. Eligible women must be normally resident and have a postal address in the Republic of Ireland.

Women and smear takers need to understand the importance of informing the programme if an address changes.

Accurate information is vital for identification.

The woman's contact phone number on the Cervical Cytology Form can be useful in cases where there is any doubt about the woman's identity. It may be used to contact the woman.

Women can use the Freephone information line (1800 45 45 55) to inform the programme of any changes to their personal details.

Demographic details should be printed one letter per box.

Fill in the form at the time of smearing in the presence of the woman to check the accuracy of personal details.

THE CERVICAL CYTOLOGY FORM	KEY POINTS
<p>Personal Public Service Number (No)</p> <p>The success of the delivery of the screening programme requires the use of the unique identifier, the Personal Public Service Number (PPS No). It is vital that all smertakers understand the importance of the unique identification number to ensure accuracy in the follow-through of a woman's smear test processing stages and that all women should have a PPS Number.</p>	<p>PPS Numbers can be found from the following:</p> <ul style="list-style-type: none"> • Social Welfare Office • CervicalCheck information line (Freephone 1800 45 45 55) or invitation letter • On GMS Medical Card or Drugs Cost Subsidy Card
<p>Using the Information Line</p> <p>Smertakers can use the information line 1800 45 45 55 to access smear information, PPS Numbers and eligibility about women presenting for smear tests, etc.</p> <p>Women can use the line to make changes to their demographic details and check issues related to their smear tests.</p>	<p>The Freephone information line 1800 45 45 55 is open from 9.00am – 5.00pm weekdays with the exception of bank holidays.</p> <p>Clinical details are not made available to women via this information line. Clinical information is only available from the smertaker.</p>
<p>Pre-screening and form filling</p> <p>The key question the smertaker needs to ask at the pre-screening stage is whether the woman has ever been sexually active. She will need to have regular smear tests if she answers positively. Questions about a woman's sexual history and the number of partners are irrelevant and need not be asked.</p> <p>Her personal identity and contact details should then be entered on the Cervical Cytology Form at this point.</p>	<p>It is important that the woman's details are not copied from a previous form or notes without checking with the woman that her details are correct. It is also important to obtain a contact telephone number for the woman.</p> <p>The Cervical Cytology Form is the only form in use when taking a screening smear within the CervicalCheck programme.</p> <p>The Cervical Cytology Form is used to connect the 'right woman' with the 'right result'.</p> <p>It is essential that the information provided is:</p> <ul style="list-style-type: none"> • Legible information • Correct information • Complete information

See sample of completed Cervical Cytology Form in Appendix 4B



THE CERVICAL CYTOLOGY FORM

KEY POINTS

Information for women about consent

(See also Section 4.2A, Appendix 4b & Section 6)

This information sheet explains to women why they need to give consent to be part of the programme.

- Research evidence indicates that information which women can take with them is valuable
- Leaflets designed for the woman are of help to both the smearer and the woman and will assist in making the screening a more positive experience for women

Consent

There are a number of aspects regarding consent:

- Consent is required and information surrounding consent is included on the information attached to the Cervical Cytology Form
- Informed consent includes the giving of all necessary information by the smearer; this includes the benefits and limitations of cervical screening
- Consent is required for transfer of personal health information between service providers in the cervical screening pathway
- Women should be given a copy of the Information Sheet for Women (Appendix 4B) which accompanies the Cervical Cytology Form

“Consent given by the patient is the exercise of a voluntary choice; it is the giving of permission for the intervention to be carried out by competent professionals, where possible in such a way as to ensure that patients do not feel that their consent is simply a formality or a signature on a page.

As part of the informed consent process, patients must receive sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. This refers to the disclosure of all significant risks of grave adverse consequences”.

(Medical Council; Guide to professional conduct and ethics for registered medical practitioners) 2009.

The woman participating in the screening programme must sign her consent on the Cervical Cytology Form when she first enters the programme. Thereafter consent may be indicated by ticking the box on the Cervical Cytology Form.

Women who are unable to sign their consent may indicate their consent in the presence of the smearer. The smearer should record this on the Cervical Cytology Form.

History taking

Questions to ask the woman that are useful and which will assist in ensuring her comfort, and in focusing the smearer on each individual smear:

1. Any abnormal bleeding:
 - Post-coital bleeding (PCB)?
 - Inter-menstrual bleeding (IMB)?
 - Post-menopausal bleeding (PMB)?

(Refer to Appendix 4A)

2. Any unusual vaginal discharge?
3. Any pain or discomfort with sexual intercourse?

Smearers should be aware that women may have concerns or symptoms that relate to their bleeding pattern.

The most common symptom of cervical or endometrial cancer is abnormal vaginal bleeding.

CLINICAL DETAILS	KEY POINTS
Date of smear test The date of current smear test.	<p>It is vital to record the date of smearing.</p> <p>It aids laboratory interpretation based on where the woman is in relation to her cycle.</p> <p>It is important for the calculation of sample validity.</p>
Relevant clinical detail required (Boxes to tick on Cervical Cytology Form) <ul style="list-style-type: none"> • Cervix visualised • LMP • HRT • Pregnant • Post colposcopy smear • IUCD • Post menopausal 	<p>This information helps the cytologist to make an accurate recommendation when viewing cells at cytology.</p>
Cervix visualised The cervix must be visualised in its entirety.	<p>It is the responsibility of the smearer to visualise and assess the cervix at every smear test.</p>
Why is information about the woman's hormonal status required? Eversions may be present if a woman is using the oral contraceptive pill (OCP) or replacement oestrogen. There may be changes in the appearance of the squamous cells when women are using Hormone Replacement Therapy (HRT). The sample cytology may appear similar to a mid-cycle ovulatory slide. Women on HRT can shed endometrial cells which may be present on the cervical smear and hormonal information will help the cytologist exclude dyskaryotic cells. The presence of IUCD/coils should be noted as there is a greater likelihood of inflammatory cells including actinomyces which may give rise to cellular changes that mimic dyskaryosis.	<p>All hormonal methods including:</p> <ul style="list-style-type: none"> • Nuva Ring • Implanon • Depo-provera • Evra/Contraceptive patch • OCP • HRT <p>should be recorded by ticking the hormonal box.</p> <p>A Mirena coil is an intrauterine system and a hormonal method.</p> <p>Refer to Section 4.3.5</p>

Laboratory recommendations are dependent on cells presented, on the clinical findings and the previous smear history of each woman. Diligent completion of the Cervical Cytology Form will help the cytologist make an informed assessment of each smear test.

CLINICAL DETAILS	KEY POINTS
<p>Relevant clinical findings (free text box on Cervical Cytology Form)</p> <p>Describe what you see at the time of smearing on the referral form.</p> <p>Discharge warts, polyps may be of relevance to the cytologist and should be recorded in the clinical findings box.</p>	<p>Suggested terms to describe the cervix include:</p> <ul style="list-style-type: none"> • Normal looking cervix • Eversion • Contact bleeding <p>The laboratory recommendation for clinically described 'suspicious cervix' is referral for colposcopy even if the smear test result is negative.</p>
<p>Previous smear history</p> <p>Women accessing the programme may have a previous smear test history. In the course of an organised screening programme, the result and management of information on each woman who participates in the programme will be compiled. In order for the laboratory to make a recommendation the following information should be entered in the appropriate part of the Cervical Cytology Form:</p> <ul style="list-style-type: none"> • Previous two smear test results if available (whether normal or abnormal) • Information and details of abnormal smear tests in the past (especially in the last 10 years) 	<p>It is important that the smearer checks, as far as possible, the woman's relevant clinical history by referring to her records.</p> <p>Laboratory recommendations could be inappropriate without complete information.</p> <p>The smear test history must be documented on the form.</p>
<p>Previous treatment history</p> <p>Information relating to any previous colposcopy treatment of the cervix should be recorded where available, including year of treatment and discharge recommendations.</p>	<p>The danger of developing cancer remains higher in those who have a treatment at colposcopy.</p> <p>Smearers are advised to follow the discharge colposcopy recommendations for repeat smear tests.</p>
<p>The Cervical Cytology Form and the laboratory</p> <p>Each vial reaching the laboratory must be accompanied by a corresponding Cervical Cytology Form.</p> <p>The laboratory will reject the sample if it cannot match the details on the form to the details on the sample.</p>	<p>It is recommended that the samples are posted to the laboratory on the day of the test.</p>

4.2F 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 the epithelium proximal to the squamo-columnar junction, where the epithelium is undergoing change from columnar to squamous epithelium known as squamous metaplasia. This vulnerable area is known as the Transformation Zone where changes tend to occur. The squamo-columnar junction is at the junction between the squamous epithelium and the endocervical columnar epithelium.

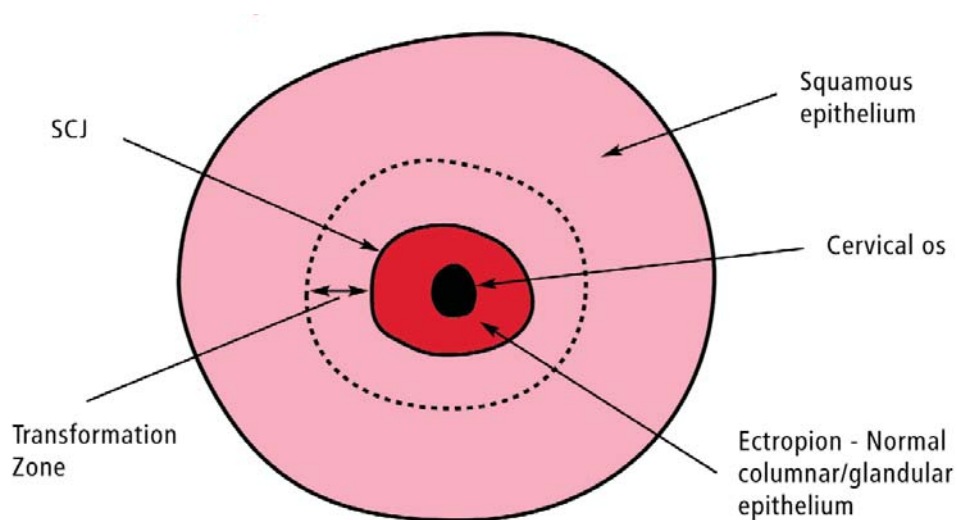
The position of the Transformation Zone varies during a woman's lifetime. At puberty, the Transformation Zone lies at the external cervical os. Hormonal changes at puberty and in pregnancy cause the cervix to change shape and the lower part of the endocervical canal becomes everted.

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 squamocolumnar 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 i.e. those in the process of changing, are more sensitive to carcinogens than mature cells.

Microscopic examination of cells scraped from the surface of the epithelium of the cervix can determine whether pre-cancerous changes are present. These changes may occupy only a small area of the Transformation Zone.

Figure 4.26 Cervical Eversion



4.2F Anatomy and physiology contd.

Figure 4.27 The Transformation Zone

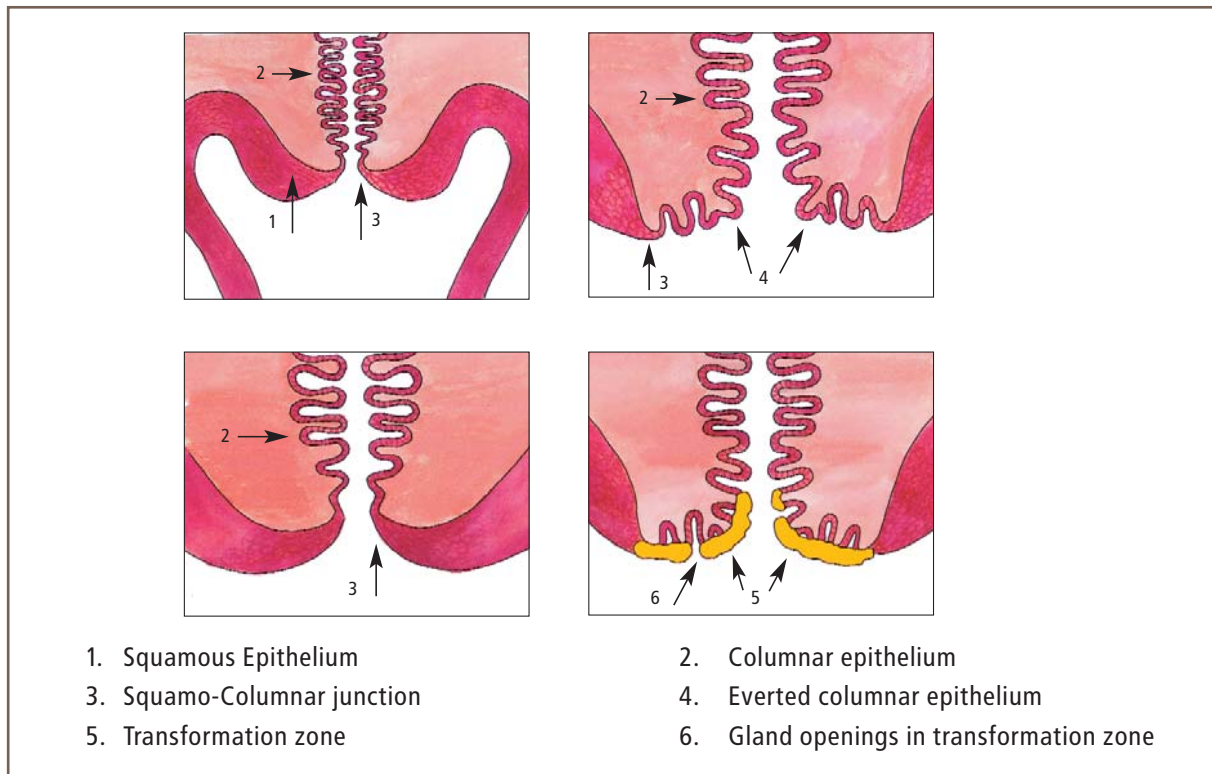
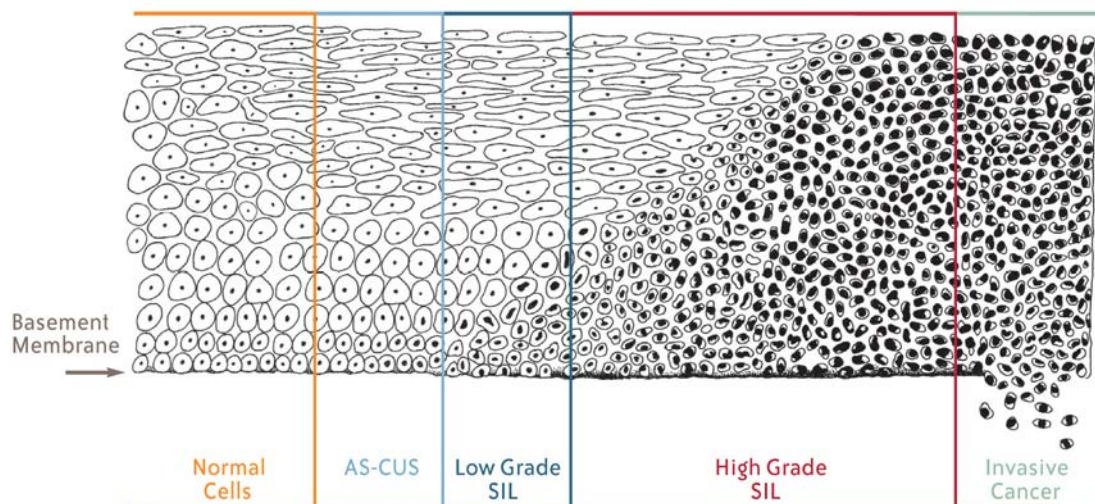


Figure 4.28 Abnormal changes in the cells of the cervix



4.2G Environment and equipment

ENVIRONMENT	KEY POINTS
Infection control Some women may not attend for smear tests due to their concerns of acquiring an infection in the course of a test. For them, the risk of infection outweighs the risk of cervical cancer.	It is important that women are assured of a safe environment to ensure screening participation.
Prevent cross infection between patient & smearer The smearer's hands should be washed before and after any duty that involves close contact with the patient. Disposable seamless gloves should be used and disposed of after use.	The vagina and cervix is not a sterile area. Smear activity must adhere to the infection control procedures of the practice/clinic (Standard 3.8, 'Guidelines for Quality Assurance in Cervical Screening').
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 such as a lamp, should be cleaned with a dry paper towel. Instruments must be cleaned, rinsed and dried; used/non-sterile instruments should be kept separate from clean instruments. Disposable paper sheets should be used and changed between patients. Couches should be cleaned regularly with soap and water.	It is essential that used instruments and equipment are disposed of safely as clinical waste.
ENVIRONMENT	KEY POINTS
Infection control Some women may not attend for smear tests due to their concerns of acquiring an infection in the course of a test. For them, the risk of infection outweighs the risk of cervical cancer.	It is important that women are assured of a safe environment to ensure screening participation.

ENVIRONMENT	KEY POINTS
<p>Single-use instruments and sterilisation</p> <p>There are no nationally approved standards for the sterilisation of surgical instruments in general practice in Ireland.</p> <p>It is recommended that single use speculae are used when smearing in primary care. Packages must only be opened at the time of smearing. The speculum must not be reused. The speculum should be disposed of in clinical waste.</p> <p>Sterilised speculum must be sterilised according to best practice (NHS) sterilisation guidelines.</p> <p>Where single devices cannot be used, the use of central sterilisation units is recommended. Re-usable speculum processed via an accredited sterilisation unit can be used.</p> <p>For in-house sterilisation, careful attention is required in the use and maintenance of sterilising equipment. Specula must be thoroughly cleaned before sterilising. Operators of bench top sterilisers should be trained and manufacturers' instructions should be followed with care. Records should be maintained on the testing of such equipment.</p>	<p>Sterilising equipment for use during cervical screening procedures need to guarantee that specula are sterile when used.</p> <p>Sterilised instruments must be stored in a clean dry place.</p> <p>Chemical cleaners are for hand use only and not for clinical use.</p> <p>Single use disposable specula should be disposed of as clinical waste (Standard 3.9, 'Guidelines for Quality Assurance in Cervical Screening').</p> <p>Reusable specula must be decontaminated using either:</p> <p>Sterilisation preferred where practicable or High level disinfection (Chapter 4 Appendix 2, 'Guidelines for Quality Assurance in Cervical Screening').</p>
REQUIRED EQUIPMENT	KEY POINTS
<p>Hand washing facilities/chemical cleaning liquid</p> <p>The smear taker's hands should be washed or chemically cleaned before and after any duty that involves close contact with the patient.</p>	
<p>Paper towels</p> <p>Paper towels should be used for hand washing and for handling and positioning of the light.</p>	See Section 4.2C above.
<p>Illumination</p> <p>Good lighting is essential for cervical screening procedures. An adjustable halogen spotlight provides one of the better sources of illumination and a speculite can be used.</p>	See Section 4.2C above.
<p>Examination couch</p> <p>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. It should allow ease of access for women with a physical disability.</p>	See Section 4.2C above.

REQUIRED EQUIPMENT	KEY POINTS
Gloves Vinyl or latex disposable gloves are recommended.	Some women are allergic to latex rubber.
Ballpoint pen Label the vial with a pen.	Care should be taken when using pre-printed labels.
Cervical Cytology Forms The CervicalCheck Cervical Cytology Form is a two-leaf form.	GP software systems facilitate an electronic version of the Cervical Cytology Form.
Sheet, blanket, pillow A disposable sheet, pillow and blanket cover should be used for patient comfort.	
Steriliser – if using reusable specula A systematic and documented system must be in place that follows manufacturers' guidelines.	See 'Environment' above in this section. (Appendix 2, 'Guidelines for Quality Assurance in Cervical Screening').
Speculum At least three 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.	See Figure 4.8, Section 4.2C. Specula packaging should be opened immediately prior to procedure to avoid contamination.
Sampler – Cervex-Brush® The plastic brush is used in liquid based cytology.	See Figure 4.2, Section 4.2B.
Liquid-Based Cytology (LBC) vial A vial is the transport medium for liquid-based cytology.	See Figure 4.1, Section 4.2B Smear-taking consumables must be within their expiry date.
Soluble lubricant- KY Jelly A soluble lubricant such as KY Jelly should be used carefully if the vagina is very dry. Care must be taken to use only a little on the shaft and avoid use at the tip of the speculum.	
Swabs Chlamydia swabs and charcoal swabs should be available for the evaluation of infectious discharge.	See Section 4.2C above

LBC transport boxes LBC transport boxes are supplied by the LBC supplier.	See Figure 4.6, Section 4.2B
Waste disposal bags Clinical waste needs to be disposed of with care, especially used disposable specula and samplers.	
A pedal bin A pedal bin helps to avoid contamination of the environment.	
Patient information leaflets A range of information leaflets for women are available from CervicalCheck.	

Message for the woman

No test is 100 per cent accurate. This is why regular screening is important. Any abnormal bleeding or discharge needs to be reported to the doctor even with a recent normal smear test result.

SUMMARY	KEY POINTS
<ol style="list-style-type: none"> 1. Write the woman's identification details on the Cervical Cytology Form and the liquid base vial. 2. Choose the appropriate speculum for the woman. 3. Identify and visualise the cervix. 4. Take a sample from the entire squamocolumnar junction. 5. Rinse the cells immediately into the vial and cap. 6. Put into a suitable transport container. 7. Record details of the smear test on the Cervical Cytology Form and in the woman's clinical notes. 8. Enter the smear test in a practice tracking system, manual or electronic. 9. Post promptly to the laboratory to minimise turnaround time 10. The successful smearer will not only take a good test but will also provide the woman with a good experience and so encourage regular screening. 	<p>The smearer should wash his/her hands before and after any procedure involving close contact with the patient.</p> <p>In order to take an adequate sample the cervix must be visualised in its entirety.</p> <p>Attention to detail is of vital importance to ensure a quality smear test.</p> <p>Poor sampling may lead to failure to detect abnormalities.</p> <p>A negative or inadequate smear test result can occur in invasive cancer of the cervix and endometrial cancer. If the smearer suspects invasive cancer on inspection of the cervix, urgent referral is recommended to the local gynaecologist without waiting for the result of the smear test.</p> <p>Ensure that all results are received and recommendations acted upon.</p> <p>Responsibility for posting the smear lies with the smearer.</p>

4.3 Managing difficulties that may arise when taking a smear test

4.3.1 Anticipating difficulties

Smeartaking is a clinical skill that needs to be acquired with experience and even the most experienced smeartaker may encounter difficulties in the course of a procedure when taking a smear test. If such difficulties are anticipated in advance and given due consideration, there is a greater possibility that many can be managed and the smear test will be taken competently.

It is important that the smeartaker is decisive and above all relaxed when a difficulty arises. It may be useful to explain the difficulties to the patient so that the patient's fears are dispelled and to allow the smeartaker more time to take the smear test. This approach can be applied to all types of problems that can arise when taking a smear test to ensure the best outcome. The following are examples of typical problems that cause most difficulty for smeartakers and some solutions are offered.

4.3.2 The anxious, tense patient

The key in dealing with the anxious and tense patient is to help her to relax. The smeartaker should reassure her that the procedure can be stopped at any time at her request. Giving the woman control of the situation will ensure the best chance of a successful outcome. Deep breathing can be suggested and a chaperone may help (see Section 4.2A). The smeartaker should offer to talk the woman through the steps of the procedure and should enquire whether the woman has particular fears.

The woman may worry that the procedure will be uncomfortable if she suffers from arthritis of her hips or chronic lower back pain. The smeartaker should explain that an alternative position, if necessary, can be arranged and the left lateral position should be considered (see Section 4.2C above). Prescribing an anxiolytic prior to the procedure in the absence of any contraindications can be considered if the patient is extremely anxious.

4.3.3 Patient becomes upset during the procedure

Sometimes a woman may appear to be comfortable about having a smear test initially and then become upset during the procedure. When this situation arises, the smeartaker must stop and try to calm the woman.

The smeartaker must be aware that taking a smear test is a very intimate examination and may trigger sensitive issues like sexual abuse, past or present, partner impotence or lack of libido. If possible, the test should not be deferred particularly when it has elicited such strong emotions.

4.3.4 Difficulty in visualising the cervix

This is the most common problem that arises for smeartakers and can give rise to an unfortunate circle e.g. the smeartaker is unable to find the cervix, the patient becomes more anxious, she contracts her pelvic floor muscles, the cervix becomes more difficult to locate and the smeartaker becomes frustrated. The cervix will become easier to find if the following adjustments are made.

4.3 Managing difficulties that may arise when taking a smear test contd.

Adjustments to address difficulties in visualising the cervix

Key points:

1. Get the woman to lie flat. If the head-rest of the couch is elevated it can cause the pelvis to become tilted thus making the cervix less visible.
2. Elevate the pelvis. Place a folded towel under the gluteal region or get the patient to put her fist under the gluteal area.
3. Use the largest/longest speculum that is comfortable for the patient. Often the cervix is not visualised because the speculum is too short. Consider the woman's size, parity and degree of relaxation when choosing the speculum. It is important to angle the speculum towards the patient's coccyx. It is helpful to allow a little time after passing the speculum to allow the woman to relax. Do not open the speculum until it is fully inserted. Opening and closing the speculum slightly, rocking it from side to side and changing the angle of insertion may help to bring the cervix into view.
4. If the cervix is still not visible check the notes to ensure that the woman has not had a total hysterectomy. Having clarified that she does have a cervix, a pelvic examination can be done gently to locate the position of the cervix, being careful not to disturb the cells of the cervix prior to sampling. Perhaps the cervix is anteverted or retroverted thus making it difficult to locate which will become clear on careful pelvic examination.
5. Sometimes the cervix is obscured by flaccid vaginal walls. If using a longer wider speculum does not hold back the vaginal walls, the following procedure can be helpful. Cut a disposable rubber/latex glove 1cm from the top of the thumb digit; pull the open ended rubber thumb digit over the closed speculum; pass the speculum with the remainder of the disposable glove hanging out of the vagina; as the speculum is opened, the glove digit holds back the flaccid vaginal walls and allows the cervix to come into view.
6. In patients who are heavy or with poor range of movement of their hips e.g. with M.S. or arthritis, the left lateral position may be more comfortable. It is important that a full explanation is given to the patient and this position is only adopted with their consent.
7. The cervix can be obscured by excess mucus. To inspect the cervix fully, this mucus may have to be removed. It is important that the cells of the cervix are not disturbed prior to sampling. Very gently place the non bristle end of the Cervex-Brush® into the mucus at the outer edge of the cervix. Rotate the brush into the mucus and the mucus will lift off. Now with the bristle end of the Cervex-Brush®, take the smear, lifting off the undisturbed cells on the cervix and transferring them to the vial.

4.3 Managing difficulties that may arise when taking a smear contd.

4.3.5 Bleeding patterns

Every effort should be made to time the smear test so that the woman is not bleeding. Use of implanon, mirena coil and progesterone only contraceptives may cause irregular bleeding patterns and make this difficult. Care should be taken that women due screening are not deferred indefinitely. A smear test should be undertaken and the cervix visualised.

4.3.6 Vaginal discharge

The smearer may notice a vaginal discharge. A profuse/odorous/dicoloured/ yellow or green or blood stained vaginal discharge suggests infection. If the smearer proceeds to take a smear test, swabs should be taken after the smear test. If contact bleeding occurs, the smearer should consider Chlamydia and test appropriately.

4.3.7 Anatomical variation

Smearers must be familiar with the range of physiological and anatomical variations of the vulval area. The following can cause concern if not recognised:

- Intact Hymen
- Narrow Introitus
- Cystocoele/Rectocoele
- Long labia
- Bartholin's Cysts
- Vaginal scarring e.g. post-episiotomy, female genital cutting, etc.
- Vaginal pessary rings may be in situ (smear taking may proceed)

4.3.8 Medical conditions

Clinical signs of medical conditions may be observed while taking a smear test. It may not be appropriate to deal with these during the smear test consultation, but it is important that arrangements are made to follow them up at another time. Incidental findings of alopecia or psoriasis, pubic lice, vulval ulcerated lesions or genital warts may be observed.

4.3.9 Sensitive sexual issues

All women between the ages of 25 and 60 will receive an invitation letter to have a smear test. For some women including virgins, having a smear test is not appropriate, because they have never had sexual intercourse.

Cervical cancer is rare in women who have never being sexually active (Winer et al, 2003), and the smearer should not proceed if the hymen is intact. Participation in screening can be deferred, and the woman informed that if she becomes sexually active, she should have cervical smear tests.

Vaginismus may make it impossible to pass a speculum of any size. It is important to explain to the woman that this is a medical condition which responds extremely well to appropriate therapy, and that once it has been resolved it is important that she returns to have a smear test.

4.3.10 Women who have sex with women (WSW)

Cervical screening recommendations do not differ for WSW/ lesbian women regardless of their history of sex with men. Cervical neoplasia and CIN lesions can be found in WSW who report no history of sex with men. Transmission of HPV requires only skin to skin contact. Furthermore, sexual practices among WSW could potentially allow for intra-vaginal deposition of HPV both through digital-vaginal contact and shared sex aids. Studies show that most WSW (53-99%) have had sex with men and that many (21-30%) continue to have sex with men. Among these women, acquisition of HPV from male partners presumably occurs at a rate per contact similar to that of the heterosexual population. Women infected via this route could serve as a source for subsequent viral transmission to their female partners (Marrazzo et al, 2001).

4.3.11 Obesity and morbid obesity

Obesity
Obesity BMI >30
Morbid obesity: BMI >45

Women who are obese may require extra attention in terms of time allotted and sensitivity. Referral to secondary care may be appropriate and should be agreed with the woman where feasible. Women should be aware of 'symptoms' relating to cervical abnormalities. Though every effort to do a smear test is made there are occasions where a test is not possible in the primary care setting.

Difficulties that may arise include:

- Obesity as a barrier to screening
- Woman's embarrassment
- Smear takers attitude towards obesity and screening in obese women
- Woman's attitude towards obesity
- Safety and weight load of couch
- Access to couch.
- Discomfort lying on the back with heavy weight of chest
- Speculum size
- Speculum strength
- Excess skin folds that make it difficult to find where to insert speculum
- Folds of tissue in vagina that obscure the view
- Visualising the entire cervix
- Adequacy and fear of adequacy of the test
- Weight of 'fatty apron'

Helpful techniques for taking a smear test on an obese woman:

- Reassuring the woman is important
- Having an assistant to help with the test
- Awareness that they are not the only ones who 'have a difficulty'
- Explanation of procedure
- Use a long wide blade metal speculum
- Use a cut off condom of glove finger (leave glove intact for retrieval) over the speculum to help hold back the vaginal walls
- Elevate the pelvis with the woman putting her fists under her buttocks
- A pillow might be used in a similar fashion
- The woman holding her 'fatty apron' will take some weight from the speculum blades

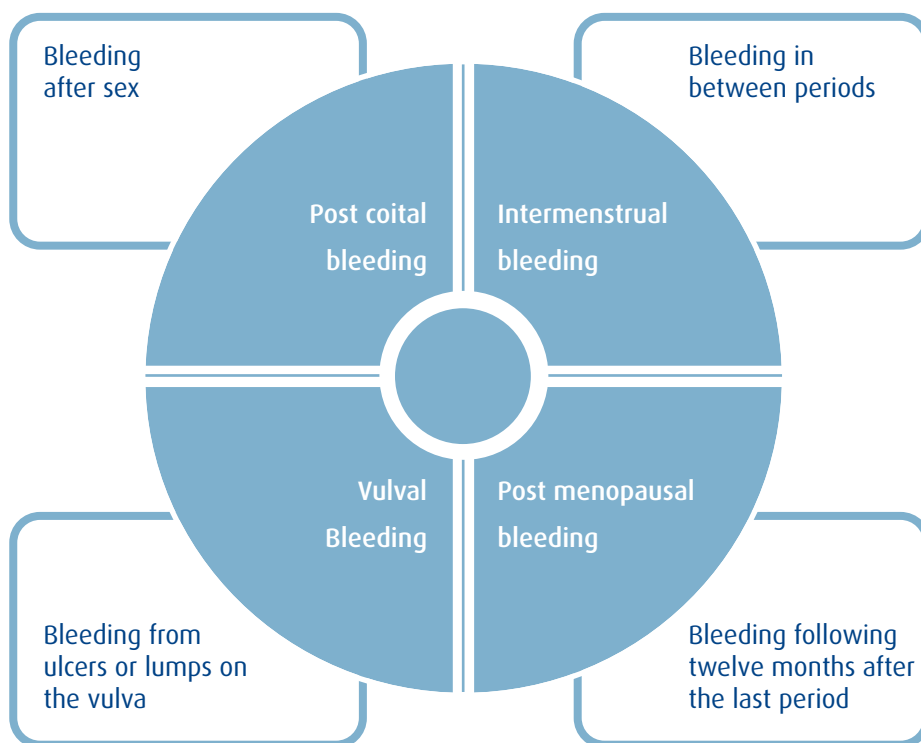
APPENDIX 4

Appendix 4A - The management of women with abnormal vaginal bleeding

Sometimes women who present for cervical screening give a history of abnormal vaginal bleeding. While irregular bleeding can be relatively common in women who are using hormonal contraception it is important to perform a thorough assessment including visualisation of the cervix with the speculum. This and a bimanual examination maybe undertaken by the GP with clinical responsibility.

When women who present for screening complain of abnormal vaginal bleeding a smear may be taken (if one is due) but it has to be remembered that cervical cytology is not a diagnostic test for bleeding. In particular where there is an anxiety about symptoms or a suspicion of cervical cancer, gynaecological referral should proceed immediately without waiting for the result. The presence of endocervical infections can be associated with abnormal bleeding in young women and testing for Chlamydia should be considered.

Abnormal vaginal bleeding



Key Points

- The clinically responsible doctor should direct the management of abnormal bleeding
- When dealing with gynaecological symptoms, the clinical doctor should be aware of the cervical screening history and current cervical status of the woman
- Heavy unusual vaginal discharge may be associated with advanced cervical cancer

Appendix 4B - The Cervical Cytology Form

Information Sheet for Women



CervicalCheck - The National Cervical Screening Programme invites women for free smear tests. This information sheet explains why you need to give your consent to be part of the CervicalCheck programme.

Why do you need to give your consent?

Giving your consent means you allow CervicalCheck to receive, hold and use your personal details and information about your smear test sample. This information may include past smear tests and colposcopy results.

CervicalCheck will share this information with the doctor or nurse who took your smear test (your smearer), laboratory staff, the colposcopy clinic and the National Cancer Registry.

Where will my information be stored?

It will be stored on the Cervical Screening Register (CSR), a secure database that lists the name, address, date of birth and Personal Public Service Number (PPS No.) of each woman who is part of the CervicalCheck programme. For confidentiality, each woman also has a unique identification number, known as the Cervical Screening Programme ID (CSP ID).

The CSR records the results of your cervical smear tests and any related procedures and laboratory results. Your personal health information is stored in line with data protection legislation.

How will my information be used?

CervicalCheck will use your information on the CSR to invite you for your free smear test. We will also include your information to compile figures and reports to help us find out how well the programme is working.

CervicalCheck, your smearer, the laboratory and/or the colposcopy clinic may use your information to tell you if you need any follow-up treatment and when to have your next smear test.

CervicalCheck may use your information to invite you to take part in research. It is your choice to take part or not.

The slide of your smear test may be used in teaching and in reviewing smearing to ensure the quality of the programme.

Your name will never be included in any reports, teaching or reviews.

How do I give consent?

If this is your first time to take part in the CervicalCheck programme, you will be asked to sign the form. If you have already taken part, you don't need to sign again. Just tell your smearer so that they can tick the correct box.

Information about smear tests and results

What is a cervical smear test?

A smear test, also known as a pap test, involves a doctor or nurse (smearer) taking a sample of cells from your cervix (the neck of your womb) to look for early changes. The earlier cell changes are found, the easier they are to treat. If changes are not found and treated, they could become cancer cells.

Limitations of a cervical smear test

As with all screening tests, cervical smear tests may not always be 100% accurate. There is a risk that a smear test will not pick up cell changes. This is why it is important to have smear tests regularly. CervicalCheck will tell you when your next smear test is due.

How do I get my result?

You can get the result of your test from your smearer. CervicalCheck will send you a letter about your results within four weeks of your smear test.

I'm afraid of what the result might mean...

Most smear test results are normal. Even a result that is not normal is unlikely to mean you have cancer – it may be due to minor cell changes. Try not to worry if you are called back for another test.

Please make sure that your personal details are correct. You can take this information sheet home with you. If you have any questions contact CervicalCheck on Freephone 1800 45 45 55 or at info@cervicalcheck.ie or visit www.cervicalcheck.ie.



Freephone 1 800 45 45 55

Cervical Cytology Form

INCOMPLETE FORMS MAY BE RETURNED


CervicalCheck
 THE NATIONAL CERVICAL SCREENING PROGRAMME

WOMAN'S DETAILS

 Personal Public Service Number
 Numbers Letters
 6 3 7 0 1 4 8 5

 CSP ID
 4 1 0 5 2

 Hospital Number
 (if applicable)

 Date of Birth
 Day Month Year
 2 4 0 5 7 6

Surname Block capital letters to be used in filling out form

M' NAMEE

First Name

SARAH

Middle Name

JANE

Surname at Birth

DRIVER

Mother's Maiden Name

CLEARLY

Postal Address for Correspondence

 6 CLOSSEY DRIVE
 MUNGRET
 LIMERICK

Contact Telephone No. 0 8 1 4 3 1 3 2 0 0

 I understand the information given to me
 I consent to take part in CervicalCheck

 Previous Consent ☐ Yes ☐ No

or if no prior consent

Woman's Signature: Sarah McNamee

DOCTOR / SMEARTAKER

Smeartaker Name: Angela Fahy

 Address:
 Meadowvale Medical Centre
 Main Street
 Broadvalley
 Co. Limerick

 Smeartaker ID:
 (MCRN or An Bord Altranais No.) 0 0 0 3 6 9 4 2

Telephone No.: 0 8 1 4 0 6 4 1 2

 Clinically Responsible Doctor ID or Clinic ID:
 (MCRN) 0 0 8 3 1 7 4 9

PCRS / GMS No. 0 0 0 9 6 4 2 6

Relevant Clinical Details:

 Date of Smear Day Month Year LMP Day Month Year
 0 5 0 1 1 1 2 2 1 2 1 0

Parity: _____

 Please Tick as Appropriate
☐ OCP/Hormones/HRT ☒ IUCD ☐ Vault
☐ Post Menopausal ☐ Post Colposcopy Smear ☐ Pregnant
☐ HPV Vaccine ☒ Cervix Visualised

Relevant Clinical Findings

 Large eversion noted
 Contact bleeding

Previous Smear History

	Lab Name	Lab No.	Test Date	Result
1	WDL	1214/056	2/6/10	ASC-US
2	UCH/G	206/01	13/5/07	Negative
3				

Previous Treatment History (and date)

LABORATORY USE ONLY

Date Received in Laboratory Day Month Year

Accession Specimen Number:

Barcode

 TZ Cells Yes ☐ No ☐

Final Report

Management Recommended

 1st 2nd

Path

Date Reported Day Month Year

Signature Day Month Year

CS/LAB-2 Rev 7

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Section 5

Management of smear test results

SECTION 5

Management of smear test results

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Management of smear test results

Aim of section
The aim of this section is to provide an overview of the key issues relating to the management of smear test results including the classification systems for reporting cytology, the management of laboratory recommendations and considerations for primary care when interpreting, communicating and recording results.

5.1 Classification systems for reporting cytology

5.1.1 Bethesda and BSCC terminologies

Smear test reporting uses either the Bethesda system of classification (TBS) or the British Society for Clinical Cytology (BSCC) CIN terminology. Until 2008, the system used for classification for reporting cytology in Ireland was the BSCC CIN terminology. Since 2008, the system used by the laboratories contracted to CervicalCheck is the Bethesda system. Smear takers registered with CervicalCheck need to be familiar with both terminologies.

Cervical Intraepithelial Neoplasia (CIN)

Most cancers of the cervix develop from abnormal epithelial changes in the cervix. These changes are called Cervical Intraepithelial Neoplasia (CIN). CIN is a term used in histology where a biopsy is analysed. The equivalent term in cytology where individual cells are viewed is dyskaryosis. Dyskaryosis is identified in the cells as nuclear changes. Histology will determine the degree of CIN in tissue biopsies. Laboratory reports equate mild dyskaryosis with CIN 1 (LSIL), moderate dyskaryosis with CIN 2 (HSIL) and severe dyskaryosis with CIN 3 (HSIL).

Table 5.1 Cytology Terminology Translation Table

Table 5.1 provides a breakdown for both BSCC terminology and Bethesda terminology and illustrates a direct correlation between both terminologies and the management recommendations of these reported results.

Table 5.1 Cytology Terminology Translation Table

Cytology Terminology Translation Table				
Office Use	Bethesda Terminology	BSCC Terminology 1986	Office Use	Management Recommendation
P1	Unsatisfactory/Inadequate	Unsatisfactory/Inadequate	R6 R7	3 month repeat Refer to colposcopy
P2	Negative/NAD (No Abnormality Detected)	Negative/NAD	R1 R2 R3 R4 R7	Exit programme 3/5 year recall 12 month repeat 6 month repeat Refer to colposcopy
P3a	ASC-US (Atypical Squamous Cells of Undetermined Significance)	Borderline Nuclear Abnormalities (BNA) (Squamous)	R4 R7	6 month repeat Refer to colposcopy
P3b	ASC-H (cannot exclude High Grade)	BNA-H (cannot exclude High Grade)	R7	Refer to colposcopy
P4	LSIL (Low Grade Squamous Intraepithelial Lesion)	Mild Dyskaryosis	R4 R7	6 month repeat Refer to colposcopy
P5	HSIL (High Grade)	Moderate Dyskaryosis	R7	Refer to colposcopy
P6	HSIL (High Grade)	Severe Dyskaryosis	R7	Refer to colposcopy
P7	Query Squamous Cell Carcinoma	Query Squamous Cell Carcinoma	R7	Refer to colposcopy
P8a	AGC (Atypical Glandular Cells)	Borderline Nuclear Abnormalities (Glandular)	R7	Refer to colposcopy
P8b	AGC (Atypical Glandular Cells) Favour Neoplastic Process	Borderline Nuclear Abnormalities (Glandular)	R7	Refer to colposcopy
P9	Query Glandular Neoplasia /AIS/Adenocarcinoma	Query Glandular Neoplasia /AIS/Adenocarcinoma	R7	Refer to colposcopy
P10	Broken/Damaged/Expired Vial	Broken or Damaged Vial	R6	3 month repeat
<p>Glossary</p> <p>Atypical Squamous Cells of Undetermined Significance (ASC-US) Atypical Squamous Cells, Favour Neoplastic process (ASC-H) Atypical Glandular Cells (AGC)</p> <p>Atypical Glandular Cells, Favour Neoplastic process Adenocarcinoma In Situ (AIS) Borderline Nuclear Abnormalities High Grade (BNA-H)</p> <p>Low Grade Squamous Intraepithelial Lesion (LSIL) High Grade Squamous Intraepithelial Lesion (HSIL)</p>				

5.1.2 Overview of the Bethesda system of classification (TBS)

The Bethesda model, first developed in 1988, was modified in 2001 to take into account the results of new research and the previous years' experience with the terminology. The Bethesda terminology relates to cytology and recognises the need to move away from terminology that suggests an inevitable progression from CIN 1 through to CIN 2, CIN 3 and to cancer. Such progression is now recognised to be a rare event. CIN 1 reflects an infective process. Progression to more significant disease is related to persistent HPV infection over many years.

See also
Tables 3.2
and 3.3 in
Section 3

The Bethesda classification also aims to unify terminology thereby improving patient management. The dysplasia/CIN spectrum has been simplified in the Bethesda system as low grade and high grade squamous intraepithelial lesion (LSIL and HSIL) whereas CIN recognises three grades CIN 1, CIN 2 and CIN 3.

5.2 Smear taker reports

Table 5.2 Bethesda 2001 system terminology for reporting the results of cervical cytology

BREAKDOWN	DETAILS
Specimen adequacy	<p>Satisfactory for evaluation (<i>note presence/ absence of endocervical /Transformation Zone component.</i>)</p> <p>Unsatisfactory for evaluation (<i>specify reason</i>)</p> <ul style="list-style-type: none"> • Specimen rejected/not processed (<i>specify reason</i>) • Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of reason e.g. <ul style="list-style-type: none"> • Scant cellularity • Presence of foreign material • Obscuring inflammation • Obscuring blood • Excessive cytolysis or autolysis (broken cells usually caused by bacteria)
General categorisation (<i>Optional</i>)	<p>Negative for intraepithelial lesion or malignancy</p> <p>Epithelial cell abnormality</p> <p>Other</p>
Interpretation / result	<p>NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY</p> <p>There are two sub-categories of this where abnormal findings not related to the risk of cancer are reported:</p> <p>Organisms</p> <ul style="list-style-type: none"> • Trichomonas vaginalis • Fungal organisms morphologically consistent with Candida species • Shift in flora suggestive of bacterial vaginosis • Bacteria morphologically consistent with Actinomyces species • Cellular changes consistent with Herpes simplex virus <p>Other non-neoplastic findings (<i>optional to report; list not inclusive</i>)</p> <ul style="list-style-type: none"> • Reactive cellular changes associated with inflammation (includes typical repair) • Radiation • Intrauterine contraceptive device (IUD) • Glandular cells status post hysterectomy • Atrophy <p>EPITHELIAL CELL ABNORMALITIES</p> <p>Squamous cell</p> <ul style="list-style-type: none"> • Atypical squamous cells of undetermined significance (ASC-US) • Atypical squamous cells cannot exclude HSIL (ASC-H) • Low grade squamous intraepithelial lesion (LSIL) encompassing: HPV/mild dysplasia/CIN 1 • High grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, CIS/CIN 2 and CIN 3 • Squamous cell carcinoma

	Glandular cell <ul style="list-style-type: none"> Atypical glandular cells (AGC) (specify endocervical, endometrial or not otherwise specified) Atypical glandular cells, favour neoplastic (specify endocervical or not otherwise specified) Endocervical adenocarcinoma in situ (AIS) Adenocarcinoma OTHER (LIST NOT COMPREHENSIVE) Endometrial cells in a woman 40 years of age.
Automated review & ancillary testing	Include as appropriate
Educational notes & suggestions	Optional

Source: Solomon et al, 2001

5.2.1 Specimen adequacy and results using the Bethesda system (TBS)

The Bethesda system comments on specimen adequacy. Women should be referred for colposcopy after three consecutive inadequate smear test results. The consensus opinion is that invasive cancers may be associated with inflammatory processes and contact bleeding. Women with persistent inadequate samples should undergo colposcopy to exclude invasive cancer.

Table 5.3 Specimen adequacy and results using the Bethesda system (TBS)

RESULTS	COMMENTS
Negative for Intraepithelial Lesion or Malignancy (NILM)	NILM is the report given to a negative smear test result. However, it may contain a text report comment on numerous variants of benign cellular findings such as atrophic changes or the presence of organisms.
Low Grade Squamous Intraepithelial Lesions (LSIL)	LSIL cannot be distinguished from transient HPV infection by cytology alone, which is the rationale for surveillance to identify the minority that progress to high grade lesions.
High Grade Squamous Intraepithelial Lesions (HSIL)	Despite apparently successful treatment of HSIL, published studies show that this group of women remains at higher risk of cervical cancer than women who never have had an abnormality (Strander, 2007).

RESULTS	COMMENTS
Atypical Squamous Cells of Undetermined Significance (ASC-US)	This category has been shown to be associated with approximately 10% of high grade lesions on biopsy (Arbyn, 2004).
Atypical Squamous Cells – High Grade Not Excluded (ASC-H)	This is a subgroup of atypical/borderline changes in which the changes are suspicious of HSIL and occasionally cancer. It is sometimes used when the abnormal cells are so few that the diagnosis is uncertain.
Invasive Squamous Cell Carcinoma	It is important to remember that a normal smear test result does not rule out an invasive cancer and if clinically suspicious, urgent referral for a gynaecological opinion is recommended. The diagnosis of invasive cancer requires a histological biopsy but there are cytological changes that suggest the possibility of invasion. TBS recognises the importance of reporting such changes and define a separate category for the commonest type of invasive cancer i.e. squamous cell carcinoma or for changes in which the cell type of invasive cancer is not evident.
Glandular Abnormalities	Glandular lesions are less common than their squamous cell counterparts but form an important group as they are more difficult to detect by cytology screening and more difficult to recognise at colposcopy.
Atypical Glandular Cells (AGC)	AGC on a smear test is frequently associated with a clinically significant diagnosis.
Atypical Glandular Cells Favouring Neoplastic Process (AGH)	This category is used when the cell changes are thought to favour glandular neoplasia but are insufficient for a firm diagnosis. The higher rate of invasive cancer diagnosis within two years of a report of glandular abnormality justifies referral to colposcopy as the management recommendation. (NHMRC Guidelines, 2005).
Endocervical Adenocarcinoma in Situ (AIS)	Defined as replacement of endocervical glandular epithelium by cytologically malignant cells. AIS is confined to the surface of the cervix.
Other	Endometrial cells in a woman over 40 years of age. The presence of these cells indicates an increased risk for endometrial cancer of 0.2 per cent. (NHMRC Guidelines, 2005). Bethesda requires the laboratory to note the presence of normal looking endometrial cells in an otherwise negative smear test in women over 40 as there is a small chance of this indicating endometrial adenocarcinoma. It should be interpreted clinically based on a woman's menstrual history and examination.

See Appendix 5 B for Sample Cytology Report using the Bethesda classification

5.3 Cervical Cytology management recommendations

5.3.1 Management recommendations

CervicalCheck, in consultation with laboratory specialists, has agreed recommendations for the management of the range of possible smear test results. In the national programme every eligible screening test will carry a management recommendation.

Table 5.4 Detailed management recommendation table

RESULT TYPE	RECOMMENDATION
Unsatisfactory/Inadequate The European Guidelines for Quality Assurance in Cervical Screening states in section 6.3.1. <i>'The cervical epithelium needs time to regenerate after cytology. Repeat cytology should not be performed less than 3 months after a previous Pap smear.'</i>	If this is the first unsatisfactory smear test or there has been no more than two unsatisfactory smear tests in a row – repeat after 3 months.
	If this is the third consecutive unsatisfactory smear test – refer to colposcopy.
	If this is the first smear test following a treatment for CIN – refer to colposcopy.
	If indicated by the cytopathologist – refer to colposcopy. (A specialist gynaecological referral is optimal)
	If the woman has had any three smear test results that are not normal in the previous 10 years and has not had a colposcopy – refer to colposcopy.
Negative for Intraepithelial Lesion or Malignancy/No Abnormality Detected (NAD) – (woman has either no screening history or negative screening history)	Routine re-call If the woman is between 25 and 44 years – repeat in 3 years.
	Routine re-call If the woman is between 45 and 60 years – repeat in 5 years. Regardless of age, women must have two negative/NAD results at 3 yearly intervals before going on to a 5 yearly screening interval.
Negative (NAD) for Intra Intraepithelial Lesion or Malignancy - HIV+ patients/post transplant patients/renal dialysis patients/DES exposed patients	Annual smear tests are required (from age 20).

RESULT TYPE	RECOMMENDATION
Negative for Intra Intraepithelial Lesion or Malignancy/No Abnormality Detected (NAD) – follow-up smear tests	<p>Following a result or treatment for ASC-US or LSIL – 3 negative smear tests are required at 6 monthly intervals before returning to routine re-call.</p> <p>Following a result or treatment for HSIL – 2 negative smear tests are required at 6 monthly intervals with annual negative smear tests for the subsequent 9 years before returning to routine re-call.</p> <p>Following treatment at colposcopy for AIS – 2 negative smear tests are required at 6 monthly intervals with annual negative smear tests for the subsequent 9 years before returning to routine re-call.</p>
Negative for Intra Intraepithelial Lesion or Malignancy/No Abnormality Detected (NAD) – follow-up post hysterectomy	<p>For women on routine re-call for at least 10 years prior to hysterectomy and no CIN in the sample at hysterectomy, no vault cytology is required.</p> <p>For women with less than 10 years routine re-call and no CIN at hysterectomy, a sample should be taken from the vault 6 months after surgery and there should be no further cytology follow-up if it is negative (NAD).</p> <p>For women with completely excised CIN at hysterectomy, a sample should be taken from the vault at 6, 12 and 18 months after surgery and there should be no further cytology follow-up if all are negative (NAD).</p> <p>For women with incomplete or uncertain excision of CIN, follow-up should be conducted as if the cervix was still in situ.</p>
ASC-US – Atypical Squamous Cells of Undetermined Significance	<p>If this is the first ASC-US smear test or if there has been no more than 2 consecutive smear tests showing ASC-US – repeat the smear test in 6 months.</p> <p>If this is the third consecutive ASC-US smear test – refer to colposcopy.</p> <p>If the woman has had any 3 smear test results that are not normal in the previous 10 years and has not had colposcopy – refer to colposcopy.</p>
ASC-US Follow-up	<p>If the woman has had a previous smear test showing LSIL and this result is within the follow-up period – refer to colposcopy.</p>
ASC-US Follow-up Post Treatment	<p>If this is the first smear test following a treatment for CIN – refer to colposcopy.</p>

RESULT TYPE	RECOMMENDATION
LSIL – Low Grade Squamous Intraepithelial Lesion	If this is the first LSIL smear test – repeat the smear test in 6 months.
	If this is the second consecutive LSIL smear test – refer to colposcopy.
	If the woman has had any 3 smear test results that are not normal in the previous 10 years and has not had colposcopy – refer to colposcopy.
LSIL – follow-up	If the woman has had a previous smear test showing ASC-US or LSIL and the woman has not returned to routine re-call – refer to colposcopy.
LSIL – follow-up post treatment	Refer to colposcopy if the woman has not been returned to routine re-call.
LSIL – Low Grade Squamous Intraepithelial Lesion – HIV+ patients/post transplant patients/renal dialysis patients/DES exposed patients	Refer to colposcopy.
ASC-H Atypical Squamous Cells Cannot Exclude High Grade	Refer to colposcopy.
HSIL – High Grade Squamous Intraepithelial Lesion	Refer to colposcopy.
Query Squamous Cell Carcinoma	Refer to colposcopy.
Suspicious Cervix	Refer to colposcopy (a specialist gynaecological referral is optimal).
AGC – Atypical Glandular Cells (borderline changes in glandular cells)	Refer to colposcopy.

RESULT TYPE	RECOMMENDATION
Query Glandular Neoplasia	Refer to colposcopy.
Broken/Damaged/Expired Vial	Repeat in 3 months.

Key point

If a woman has a single ASC-US or LSIL result and her subsequent smear test is normal she requires a further two negative smear test results six months apart before returning to routine re-call.

Women should be referred for colposcopy if they have three test results reported as abnormal at any grade in a 10 year period even if returned to routine re-call on one or more occasions in that period.

5.3.2 Communication of results

Practice/clinic protocol should include clear direction on the provision and communication of smear test results to women (4.10.4 of 'Guidelines for Quality Assurance in Cervical Screening').

Each practice should have a process in place for notification of smear test results to women. CervicalCheck has developed 'A Simple Guide to the Language Used in Cervical Screening' to help smearthakers to explain results in a simple format. The following outlines the various processes in communicating different types of results. Refer to Section 1, Appendix 1B–1E for examples of CervicalCheck results letters.

RESULT TYPE	HELPFUL LANGUAGE IN DISCUSSING RESULTS
<p>Normal</p> <p>The doctor with clinical responsibility will receive a copy of the result from the laboratory. CervicalCheck will send a letter to the woman informing her that no abnormality has been detected. This letter will also indicate when the next smear test will be due. This is calculated on the basis of the smear test result and the clinical information provided on the Cervical Cytology Form. A further letter will be sent to the woman when her next smear test is due.</p>	<p>Assessment shows no abnormal cells.</p>
<p>Inadequate/Unsatisfactory</p> <p>A report is sent to CervicalCheck and the smearthaker by the laboratory. CervicalCheck will send a letter to the woman advising her that the result has been reported unsatisfactory and that she will need to return for another smear test. Two reminder letters will be sent to the woman if CervicalCheck does not receive notification from the cytology laboratory that a further smear test has been taken.</p>	<p>The lab is unable to read this sample. This is not an abnormal result.</p>
<p>Not normal</p> <p>A 'not normal' result is sent to the doctor with clinical responsibility. CervicalCheck will send a letter to the woman advising her that her smear test has been reported as needing follow-up and to contact her doctor for further information. The doctor with clinical responsibility is responsible for taking the appropriate action. A face to face consultation is recommended. CervicalCheck provides a leaflet explaining the colposcopy process which may be helpful for the woman. In the event of the woman failing to attend for follow-up, CervicalCheck will send two reminder letters to the woman and to her doctor.</p> <p>Where a referral to a colposcopy clinic is indicated, a colposcopy referral form should be completed and a copy of the smear test result should be attached. Inform the woman of this referral and provide adequate counselling at this point. The role of this</p>	<p>If abnormal cells are found on your smear test you may be referred for a colposcopy examination in order to take a closer look at the neck of the womb. This is a procedure usually done in a hospital out-patients' clinic.</p> <p>Colposcopy means looking at the cervix with a microscope. This is carried out in the same way as your smear test. During the examination, solutions are applied to the cervix, which is then viewed through the microscope. The microscope does not touch or go inside the woman's body. It just provides magnification so that any abnormal areas can be seen more clearly and treated.</p>

RESULT TYPE	HELPFUL LANGUAGE IN DISCUSSING RESULTS
<p>counselling is not only to provide information regarding the follow-up procedure but also to identify those women who are at risk of not attending the colposcopy clinic. The doctor with clinical responsibility should not override a referral to colposcopy. If the doctor overrides a recommendation for referral to colposcopy, the programme continues to 'failsafe' the woman and communicate with the doctor regardless of the clinical judgement made.</p> <p>The manner in which a woman is told about an abnormal test result will affect her likelihood to attend colposcopy and her ability to cope with any treatment or follow-up. The information provided should be clear and should not generate undue anxiety.</p> <p>Women who receive abnormal results should be offered an opportunity to speak with the general practitioner to discuss the implications of the result. Patients often assume that an abnormal result means cancer and it is important to reiterate the pre-malignant nature of the cellular changes seen on the smear test. The fact that this is a treatable condition should also be underlined.</p>	

5.3.3 Failsafe process

CervicalCheck aims to ensure that all recommendations requiring re-call or referral are appropriately actioned.

- Failsafe is a written communication (a letter) sent by CervicalCheck to the woman and to the doctor with clinical responsibility in the primary care setting (a form) when the woman does not attend for:
 - Her recommended smear test (following an 'inadequate' or 'not normal' result)
 - Her colposcopy referral
 - Her post-colposcopy cervical smear tests
- Failsafe actions refer to the CervicalCheck administrative procedures that come into effect if, for whatever reason, follow-up actions have not been taken. If follow-up actions fail, 'failsafe' will come into effect
- The smearer must make every reasonable effort (at least two recorded efforts) to ensure that the woman is contacted

"Failsafe requests are responded to in full within 10 working days"
Standard 4.11.2 – 'Guidelines for Quality Assurance in Cervical Screening'

5.3.4 Recording of results

An accurate system of recording results should be in place and records should be updated:

- At the time of smearing
- When the smear test result is received
- For all the follow-up contacts related to the smear test result

The smeartaker needs to maintain a record for every smear taken, bearing in mind that the woman may not be an attendee of that practice normally. This will ensure an efficient failsafe mechanism and is particularly relevant if there was a failure to attend for follow-up. A tracking system should also be put in place to ensure the following:

- All smear tests have been sent to the laboratory
- All results have been received by the laboratory
- All the laboratory recommendations are followed

See 4.10 of the 'Guidelines for Quality Assurance in Cervical Screening' which highlights the importance of record management procedures in practice or clinic.

The system can be either manual or electronic as follows:

MANUAL SYSTEM	COMPUTERISED SYSTEM
<p>Manual records can be organised using a manual logbook. A designated person in the clinic should be responsible for checking that the logbook is completed at each stage and that all the appropriate actions have been taken.</p> <p>Alternatively, an A5 card can be used as a separate record card with the details from the smear form submitted to the laboratory copied on to the card. All cards should be kept until all actions required are performed.</p> <p>These records can be divided into the following categories:</p> <ul style="list-style-type: none"> • Smear test done • Result received • Result acted upon <p>A manual record-keeping system for these cards can be created using small storage boxes with alphabet dividers. At least two boxes are used:</p> <ol style="list-style-type: none"> 1. Smear test done - awaiting result 2. Result received and acted upon <p>Additional separate boxes may be of value for 'Action Taken' and 'Smear Test Fee Received' in larger practices. The forms can be moved from one box to the other as appropriate. One person in the practice should be responsible for managing this system.</p>	<p>The procedure for entering cervical smear tests will vary depending on the software package being used. Current GP software allows recording of smear test results and the production of reports listing smear tests taken, results received and smear tests due during certain defined periods. Practices should contact their technical support or the local GP IT tutor for further information.</p> <p>Appropriate advice should be provided to all clinical people involved in the screening programme within the practice and one designated person should be responsible for ensuring that everybody has the necessary competence to enter data in the system correctly.</p>

In addition to record keeping within the clinical context, recording personal information on computer or in structured manual files carries with it legal responsibilities under the Data Protection Acts, 1988 and 2003 (see Appendix 5C).

5.4 Colposcopy

Colposcopy services play a key role in the success of any screening programme by ensuring optimal management of women with detected smear test abnormalities.

“Access to prompt diagnosis and effective treatment with adequate information and counselling must be available at all stages. Interventions must reduce the risk of cancer in these women while minimising the risk of any significant physical and psychosocial impact”

(‘Guidelines for Quality Assurance in Cervical Screening’; Chapter 6 - Quality Assurance in Colposcopy)

5.4.1 Referral

The doctor with clinical responsibility must ensure prompt referral to a colposcopy clinic on receipt of a recommendation from the cytology laboratory. CervicalCheck aims to assist doctors in directing referral to colposcopy clinics where women can access appointments in a timely fashion.

Smeartakers should use the CervicalCheck Colposcopy Referral Form and attach a copy of the smear test result when referring women to colposcopy – refer to Appendix 5A for a copy of the Colposcopy Referral Form. Further communication regarding the referral should be facilitated with the colposcopy clinic where necessary. Smeartakers can access the locations of CervicalCheck programme colposcopy clinics through the CervicalCheck website www.cervicalcheck.ie

Table 5.5 Indications for referral to colposcopy

Key point

Smeartakers should be aware that no letters issue from the programme while a woman is under the care of the colposcopy service. On discharge from colposcopy to primary care she becomes ‘active’ on the cervical screening register and programme letters will issue as appropriate.

RESULT	RATIONALE/RECOMMENDATION
Unsatisfactory/ Inadequate	<ul style="list-style-type: none"> 3 consecutive unsatisfactory/discretion of pathologist (gynae referral optimal) First smear test following a treatment in colposcopy Any 3 smear test results that are not normal in the previous 10 years
Negative/NAD (no abnormality detected)	<ul style="list-style-type: none"> If suspicious cervix, a gynaecology referral is optimal
ASC-US (Atypical Squamous Cells of Undetermined Significance)	<ul style="list-style-type: none"> Third consecutive ASC-US smear test Previous LSIL (within 18 months) Any 3 smear test results that are not normal in the previous 10 years First smear test following a colposcopy treatment for CIN

RESULTS	EXPLANATION
ASC-H (Cannot exclude high grade)	<ul style="list-style-type: none"> Refer to colposcopy
LSIL (Low Grade Squamous Intraepithelial Lesion)	<ul style="list-style-type: none"> Second consecutive LSIL smear test If previously attended colposcopy and not yet returned to routine re-call If HIV+/post organ transplant/DES exposed/renal dialysis Any 3 smear test results that are not normal in the previous 10 years
HSIL (High Grade Squamous Intraepithelial Lesion)	<ul style="list-style-type: none"> Refer to colposcopy
Query Squamous Cell Carcinoma	<ul style="list-style-type: none"> Refer to colposcopy
AGC (Atypical Glandular Cells)	<ul style="list-style-type: none"> Refer to colposcopy
AGC (Atypical Glandular Cells) Favour Neoplastic Process	<ul style="list-style-type: none"> Refer to colposcopy
Query Glandular Neoplasia/AIS/Adenocarcinoma	<ul style="list-style-type: none"> Refer to colposcopy

5.4.2 Principles of colposcopy examination

A colposcope is a low-power, stereoscopic, binocular field microscope with a powerful light source used for magnified visual examination of the uterine cervix to help in the diagnosis of cervical intraepithelial neoplasia (CIN).

The key ingredients of colposcopic examination are the observation of features of the cervical epithelium after application of the normal saline, three to five per cent dilute acetic acid, and Lugol's iodine solution in successive steps.

Acetic Acid (3-5%)

- This is usually applied with a cotton applicator. It helps in coagulating and clearing the mucus. Acetic acid is thought to cause swelling of the epithelial tissue, columnar and any abnormal squamous epithelial areas in particular
- Areas of CIN undergo maximal coagulation due to their higher content of nuclear protein and prevent light from passing through the epithelium
- As a result, the subepithelial vessel pattern is obliterated and less easy to see and the epithelium appears white
- This reaction is termed acetowhitening, and produces a noticeable effect compared with the normal pinkish colour of the surrounding normal squamous epithelium of the cervix, an effect that is commonly visible to the naked eye

Lugol's Iodine

- The principle behind the iodine test is that original and newly formed mature squamous metaplastic epithelium is glycogenated, whereas CIN and invasive cancer contain little or no glycogen
- Columnar epithelium does not contain glycogen. Immature squamous metaplastic epithelium usually lacks glycogen or, occasionally, may be partially glycogenated
- Iodine is glycophilic and hence the application of iodine solution results in uptake of iodine in glycogen-containing epithelium
- Therefore, the normal glycogen-containing squamous epithelium stains mahogany brown or black after application of iodine
- Columnar epithelium does not take up iodine and remains unstained, but may look slightly discoloured due to a thin film of iodine solution; areas of immature squamous metaplastic epithelium may remain unstained with iodine or may be only partially stained
- Areas of CIN and invasive cancer do not take up iodine (as they lack glycogen) and appear as thick mustard yellow or saffron-coloured areas
- The colposcopists use pattern recognition to discriminate between normal, low grade and high grade

The main goal of colposcopy is to detect the presence of high-grade CIN and invasive cancer. To effectively achieve this, the entire epithelium at risk should be well visualised, abnormalities should be identified accurately and assessed for their degree of abnormality and appropriate biopsies must be taken.

5.4.3 Treatment at colposcopy

The treatment of any identified precursors of cancer is vital to the success of any cervical screening programme. This treatment should be effective, safe and acceptable. It should aim to eradicate all cervical intraepithelial neoplasia (CIN) from the cervix and should be tailored to the circumstances of the individual woman.

The type of treatment required for cervical abnormalities is determined by evaluation of the cytology report, colposcopic assessment and assessment of any histology specimens which may have been obtained during the colposcopy procedure.

A number of other patient factors will also be taken into account, including:

- Age
- Parity
- Desire for further children

- Menstrual status
- General health
- Immune status
- Availability for follow-up and return visits

Lindeque BG (2005)

The treatment of CIN has evolved over the last 30 years away from invasive inpatient procedures such as hysterectomy and knife cone biopsy towards simpler outpatient treatments under local anaesthetic. Initially these treatments involved tissue ablation and included radical diathermy, cryotherapy, carbon dioxide laser and cold coagulation. The availability of these treatments was of significant benefit to the patient in time and money saved, as well as to the saving of hospital bed space and theatre time. They were considered particularly useful for the young patient who had not yet completed her family as they did not significantly impact on subsequent fertility.

Large loop excision of the Transformation Zone (LLETZ) was introduced in 1988 as a simple outpatient excisional procedure which allowed histological examination of the entire Transformation Zone, thus facilitating confirmation of the diagnosis and margins of excision.

LLETZ:

- LLETZ stands for 'large loop excision of the Transformation Zone'. The area of abnormal cells is removed completely. It is an outpatient treatment and the patient would usually have a local anaesthetic. This is injected directly into the cervix
- If a large area of tissue needs to be removed, or if they are very anxious about the treatment, they may occasionally have a general anaesthetic
- The Transformation Zone is cut away using a loop of wire and an electric current
- The base of the margins are cauterised, this stops bleeding and also treats any abnormal cells that might be left behind
- There will be some bleeding for about 4 weeks after LLETZ

This procedure is associated with a low morbidity and a single LLETZ does not have an adverse effect on subsequent fertility. Its ease of use and the opportunity to treat the patient at the first visit led to concerns regarding overtreatment in women with negative histology. Despite these concerns LLETZ has been established as the most widely used method of treatment in the developed world during the last decade with recommendations that treatment at the first visit be selectively employed by experienced colposcopists who are able to distinguish high grade from low grade disease.

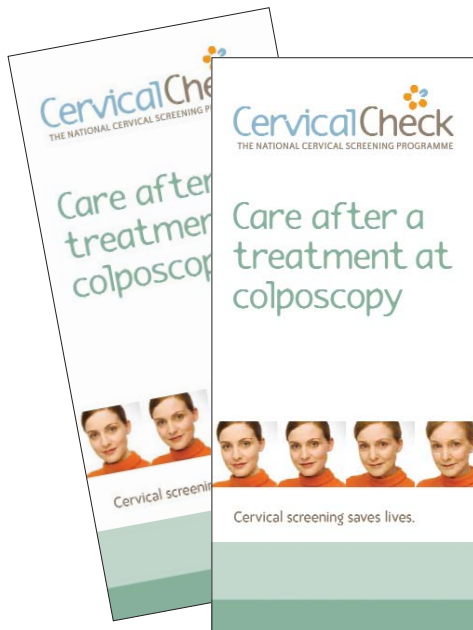
Kyrgiou et al (2006) published a review of 27 studies addressing the risk of preterm delivery after excisional treatment for cervical disease. They found that LLETZ was associated with an increased risk of preterm delivery and premature ruptures of the membranes.

LLETZ has largely superseded the use of laser in treatment because the artefactual damage to the specimen is less (improving disease detection and examination of margin status) and the risk of subsequent complications (e.g. cervical stenosis) is reduced.

Terms commonly used in colposcopy are included in the glossary.

5.4.4 Care after a treatment at colposcopy

The treatment of any identified precursors of cancer is vital to the success of any cervical screening



Post-treatment advice given at colposcopy clinics

- No tampons for 4-6 weeks
- No sexual intercourse for 4- 6 weeks
- No swimming/jacuzzis for 4-6 weeks
- Possibility of bleeding/discharge
- Provide the woman with relevant contact numbers
- Advise the woman when to come back

APPENDIX 5

Appendix 5A Colposcopy Referral Form

CervicalCheck		CervicalCheck Colposcopy Referral Form		National Cancer Screening Service			
POST or FAX this FORM to ONLY ONE of the CervicalCheck Colposcopy Services to avoid duplication. (Please ✓)							
<input type="checkbox"/> AMNCH – Tallaght Colposcopy Service <input type="checkbox"/> Cork Colposcopy Service <input type="checkbox"/> Coombe Colposcopy Service <input type="checkbox"/> Dundalk – North East Regional Colposcopy Service <input type="checkbox"/> Galway Colposcopy Service <input type="checkbox"/> Kerry Colposcopy Service <input type="checkbox"/> Letterkenny Colposcopy Service <input type="checkbox"/> Limerick Colposcopy Service	Tel: 01 4144752 Fax: 01 4144725 Tel: 021 4923300 Fax: 021 4923301 Tel: 01 4085768 Fax: 01 408 5727 Tel: 042 9364222 Fax: 042 9389850 Tel: 091 544536 Fax: 091 514021 Tel: 066 7184189 Fax: 066 7103108 Tel: 074 9104497 Fax: 074 9123635 Tel: 061 483111 Fax: 061 483112	<input type="checkbox"/> Mayo Colposcopy Service <input type="checkbox"/> NMH Colposcopy Service <input type="checkbox"/> Rotunda Colposcopy Service <input type="checkbox"/> Sligo Colposcopy Service <input type="checkbox"/> South Tipperary Colposcopy Service <input type="checkbox"/> Waterford Colposcopy Service <input type="checkbox"/> Wexford Colposcopy Service	Tel: 094 9042631 Fax: 094 9042683 Tel: 01 6373454 Fax: 01 637 3191 Tel: 01 8176841 Fax: 01 8171733 Tel: 071 9136818 Fax: 071 9174709 Tel: 052 6177983 Fax: 052 6177011 Tel: 051 842067 Fax: 051 848800 Tel: 053 9153024 Fax: 053 9153078				
Patient Details Surname: _____ First Name: _____ Date of Birth: _____ Address: _____ Mobile: _____ Landline: _____ Consent to text reminder of appointment: <input type="checkbox"/> Yes <input type="checkbox"/> No First Language: _____ Interpreter Required: <input type="checkbox"/> Yes <input type="checkbox"/> No Special Needs Assistance: <input type="checkbox"/> Yes <input type="checkbox"/> No PPSN: _____ CSP ID: _____ Mother's Maiden Name: _____ Surname at Birth: _____			Referring General Practitioner Details Name: _____ Address: _____ Telephone: _____ Fax: _____ GP Signature: _____ MCRN: _____ Date: _____				
Referral Information Reason for Referral: <input type="checkbox"/> Abnormal Smear <input type="checkbox"/> Suspicious Cervix CervicalCheck Smear: <input type="checkbox"/> Yes <input type="checkbox"/> No Referral Smear Details: Date of Smear: _____ Result of Smear: _____ Accession Number: _____ Reporting Laboratory: _____ Please attach copy of the smear report with this referral. Previous Smear History: _____ Previous Colposcopy: <input type="checkbox"/> Yes <input type="checkbox"/> No Where: _____ Previous Treatment: <input type="checkbox"/> Yes <input type="checkbox"/> No Comments: _____						Clinical Findings: Suspicious Cervix? <input type="checkbox"/> Yes <input type="checkbox"/> No Details: _____	
Past Medical History: _____ Past Surgical History: _____ Medications: _____ Allergies: _____ Smoking status: <input type="checkbox"/> Current smoker <input type="checkbox"/> Ex-smoker <input type="checkbox"/> Non-smoker							
For Hospital Use Service: <input type="checkbox"/> Colposcopy <input type="checkbox"/> Gynaecology Colposcopy Service Triage: <input type="checkbox"/> <2 weeks <input type="checkbox"/> <4 weeks <input type="checkbox"/> <8 weeks Triaged by: _____ Date: _____ Date of referral received: _____ Date of appointment offered: _____ Reason patient did not accept first appointment offered: _____ Seen within Guidelines: <input type="checkbox"/> Yes <input type="checkbox"/> No							
<small>CS/F/CLP-6 Rev 9 View CervicalCheck 'Guidelines for Quality Assurance in Cervical Screening' or download additional forms – www.cervicalcheck.ie</small>							

Appendix 5B Sample Cytology Report

SPECIMEN INFORMATION	PATIENT INFORMATION	CLIENT INFORMATION PROVIDER:
SPECIMEN: EC123456789 REQUISITION: 001234 DEPT ID: 2345667A COLLECTED: 05/01/2011 RECEIVED: 15/01/2011 REPORTED: 23/01/2011	NAME: SARAH MCNAMEE DOB: 24/05/1976 GENDER: F FASTING: N ID/MR#: 6370148T PHONE#: 089 439320	<u>Angela Fahy 0036942</u> John O Beirne Meadowvale Medical Centre Main Street Broadvalley Co. Limerick 00096426 00831749

CLINICIAN PROVIDED INFORMATION

Cervix visualised, relevant clinical findings – large eversion noted. Contact bleeding. ASC-US 2/6/10.

LMP: 22/12/2010

REPORT STATUS:
CYTOLOGY, THINPREP PAP

FINAL

SOURCE:

Cervix

STATEMENT OF ADEQUACY:

Satisfactory for evaluation
Endocervical/transformation zone component present.

INTERPRETATION/RESULT:

Negative for intraepithelial lesion or malignancy.

COMMENT:

P2: Negative/NAD
P4: Repeat smear in 6 months

Appendix 5C Data Protection guidelines

Under the Data Protection Acts, 1988 and 2003, the following eight rules must be followed when recording data:

1. Obtain and process information fairly
2. Keep it only for one or more specified, explicit and lawful purposes
3. Use and disclose it only in ways compatible with these purposes
4. Keep it safe and secure
5. Keep it accurate, complete and up-to-date
6. Ensure that it is adequate, relevant and not excessive
7. Retain it for no longer than is necessary for the purpose or purposes
8. Give a copy of his/her personal data to an individual, on request.

Source: Office of the Data Protection Commissioner website (www.dataprotection.ie)

If in any doubt about the implications of this legislation, a legal adviser or the Data Protection Commissioner should be contacted.

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Section 6

Women's participation in cervical screening

SECTION 6

Women's participation in cervical screening

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Women's participation in cervical screening

Aim of section

This section discusses the woman's participation in screening and the barriers women may experience in relation to attendance. It also discusses what information is beneficial to promote the participation of all eligible women in the programme.

See Section 1.3 for further information on CervicalCheck's incidence and mortality measures.

6.1 Women's participation in cervical screening

The success of any cervical screening programme is dependent on the participation of women. CervicalCheck aims to reduce the incidence and mortality from cervical cancer in women aged 25 to 60 years overall. Cervical screening programmes achieve success through coverage of more than 80 per cent of the defined population.

It is of prime importance that the programme is effective in offering screening to all eligible women, and that once an abnormality has been identified, follow-up screening and treatment are provided with the minimum distress to women.

Women who have a positive experience when attending for a cervical smear test will continue to participate in the programme. Adverse comments about smear tests from other women may influence a woman's attendance for a smear test (Doyle, 2006). The NCSS has identified in its functions the need to implement special measures to promote participation in its screening programmes by disadvantaged persons.

Women who have had a good experience tell others.
Women who have had a bad experience also speak freely of it.

One of the inherent disadvantages of screening is the generation of anxiety in those being screened (Freeman-Wang & Lokugamage, 2006). Smeartakers need to understand the factors that encourage uptake and the barriers to attendance for screening. The woman's motivation to have a cervical smear test is influenced by specific attitudes, beliefs and perceptions. These include:

- Her understanding of the test and possible results
- Embarrassment regarding having a smear test taken
- The influences of her family and friends
- Her perceived susceptibility to cervical cancer
- Her understanding of the importance of the disease
- The ease of getting a smear test in terms of access
- The benefits of having a cervical smear test

Message for the woman

The biggest risk factor for cervical cancer is never having had a cervical smear screening test. Cervical screening endeavours to pick up abnormal cells on the cervix that if left untreated may become cancerous.

Of those women who attend for smear tests, the factors that positively influence a woman's experience are outlined below.

POSITIVE INFLUENCES ON WOMEN'S EXPERIENCES

- Choice of smearer
- Provision of information – supported by informed consent
- Adequate time for test
- Satisfactory physical environment
- Explanation of how results are received
- Advice on waiting times for results
- Quality assured programme, organised approach, invitation & reminder letters

It is important to understand the various reasons given by women who decline the opportunity to have a cervical smear test. A study (Walsh, 2006), based on a sample of over 1,000 women who were participants of the Irish Cervical Screening Programme (ICSP), highlighted specific barriers associated with poor attendance (Table 6.1). Waller et al (2009) explored barriers to cervical screening attendance and concluded that practical barriers were more predictive of screening uptake than emotional factors such as embarrassment.

Table 6.1 Per cent reporting specific barriers to attendance for cervical screening (N=1,114)

REPORTED BARRIERS	%
Male smearer	35%
Unsuitable appointment times	22%
Other commitments	19%
Lack of time	7%
Difficulty getting to surgery	5%

Source: European Journal of Contraception & Reproductive Health Care (2006)

CervicalCheck has identified that reasons for non-attendance can be divided between personal and practical reasons as follows:

NON-ATTENDANCE DUE TO PERSONAL REASONS	NON-ATTENDANCE DUE TO PRACTICAL REASONS
<ul style="list-style-type: none"> • Previous bad experience • Male smearer • Embarrassment • Fear of test • Fear of result • Not understanding test • Adverse comments about smear tests from other women or the media • Ethnic differences 	<ul style="list-style-type: none"> • Not invited • Forgot appointment • Sick • Away • Opting out • Appointment time unsuitable • Fears about lack of confidentiality

6.2 Interventions to improve attendance

6.2.1 Women's views

CervicalCheck recognises the importance of the woman's view in relation to cervical screening. The following quotes are from women who completed client feedback forms following their smear testing with trainees enrolled in the CervicalCheck Smearmaker Training Programme.

The following quotes are in response to questions as to what prompted them to attend for the smear test:

“

"Doctor's advice"

"Nurse advised me when I was vaccinating my baby".

"My mother died so I decided to have a full check-up"

"I received a letter from CervicalCheck"

"Because it was free"

"Discussion with friends"

”

6.2.2 Provision of information

Women's attitudes towards screening can vary depending on the level of information previously received and the information available concerning the programme. Women need clear information on the indications, benefits and procedures of cervical screening. Such information is effective in increasing attendance for primary screening. Women's high levels of anxiety on the receipt of an abnormal smear test result may originate in a lack of understanding of the meaning of cervical abnormalities. The provision of information in such cases may reduce anxiety.

The following are quotes from women who were asked to give feedback on information received and their experience of the smear test:

“

"Full explanation put me at ease straight away"

"Everything was explained before and during the procedure which kept me calm"

"I felt free to ask any question even if I did think that they may sound silly"

"Due to clear explanations I was less anxious about follow-up"

"My last experience was awful. It had been extremely painful and distressing. I was in dread of attending"

"The practice nurse was very gentle and she said she would stop if I needed her to"

”

6.2.3 Health promotion

Health promotion is the process of enabling people to increase control over,
and to improve their health.

Ottawa Charter for Health Promotion, WHO Geneva 1986.

Screening promotion strategies can develop and change lifestyles, and have an impact on the social, economic and environmental conditions that determine health. Health promotion is a practical approach to achieving greater equity in health. The five strategies set out in the Ottawa Charter for Health Promotion are essential for success.

1. Building healthy public policy.
2. Creating supportive environments.
3. Re-orienting the health services.
4. Strengthening community action.
5. Developing personal skills.

The overall aim of the CervicalCheck screening promotion programme is to provide a strategic method for promoting both the services of CervicalCheck and the importance of regular cervical screening for eligible women.

Cervical cancer rates for women living in the most deprived areas are 2.6 times higher than women living in least deprived areas (Women's Health Council, 2006). This suggests that an important task for CervicalCheck is to increase the uptake of screening among socially disadvantaged women who are known to be at the highest risk of cervical cancer. Traditional approaches of encouraging marginalised women to attend for screening tend to be less effective in disadvantaged communities. There is evidence of poor attendance among older women, lower socio-economic groups and those who are less educated. The screening promotion team uses a multi-strategy approach to promote evidence-based cervical screening and to encourage attendance.

STRATEGIES TO INCREASE PARTICIPATION

- Health and screening promotion strategy
- Dedicated awareness campaigns
- Peer education
- Direct contact with local community networks
- Workplace sessions
- Information sessions

6.2.4 Sources of information for women

Providing information on cervical screening by all categories of health care providers, particularly those in primary care settings, is essential for raising awareness and reducing illness and deaths. Women can source information in a number of ways such as through CervicalCheck screening promotion initiatives, the suite of CervicalCheck information leaflets, the CervicalCheck website and Freephone information line (1800 45 45 55). However, the primary source of information for most women is their doctor.

Seventy per cent of women receive their cervical screening information from their doctor.

Primary care: The doctor and practice nurse are often the first line of contact in the primary care setting. Research suggests that one of the most effective ways of encouraging women to have a smear test is for a doctor to advise them to have one. This is particularly effective in women over 40 years of age (Cockburn et al. 1990; Brent 1992). Walsh (2006) found that the majority of women (70 per cent) get their cervical screening information from their doctor. Therefore, it is vital that smeartakers use this opportunity to provide women with appropriate information about cervical screening.

The smeartaker should use the 'Information sheet for women' at time of smeartaking and other information leaflets containing cervical screening information.

CervicalCheck literature: A suite of information leaflets has been developed by CervicalCheck to provide women with information about the programme and cervical screening, including an explanation of the various possible results of a cervical smear test.

The leaflets have been reviewed and updated based on the outcome of focus testing. The current information leaflets include:

- About your free smear
- What your smear test results mean
- Colposcopy
- Care after a treatment at colposcopy
- Cervical screening after a hysterectomy
- Pictorial Leaflet

CervicalCheck information line: The Freephone information service was developed to provide general information on the programme, details of CervicalCheck registered smeartakers, and offers a facility for women to register themselves. It is a Freephone service and is advertised on all literature. Women seeking clinical information are advised to talk to their smeartaker.

CervicalCheck website: The website www.cervicalcheck.ie provides up-to-date information on cervical screening, a facility for online registration and the opportunity to provide feedback to the programme. Women can also check to see if a smear test is due. It contains the contact and location details of registered smeartakers.

6.3 Psychological effects of cervical screening on women

When a woman has an abnormal smear, she faces issues around her sexuality, her fertility and her mortality.

Dr Patrick Walker

Many women do not attend for smear tests or return for treatment because the emotional impact is too daunting. The anxieties and distress experienced by women receiving an abnormal smear test result and attending for colposcopy are well documented (Gath et al. 1995; Fylan, 1998; Idestrom et al. 2003). Even where a screening programme is offered with follow-up diagnosis and treatment, it is often difficult to ensure that women are emotionally supported as well as medically treated. Emotional support can reduce distress and the number of psychological side effects on women. While it is beneficial to try to reduce any factors relating to fear, it is not appropriate to give blanket reassurances.

The role of the smeartaker can be significant in ensuring a positive experience in terms of the psychological impact of the smear test. The following are key areas that the smeartaker should consider in this regard.

- Provide appropriate, accurate information and explain how a smear is carried out
- Obtain informed consent from the woman
- Support informed consent and choice of smeartaker
- Be mindful that this is an intimate examination
- Be careful not to transmit a value judgement or attitude in the choice of words, tone of voice or demeanour
- Reassure the woman that the procedure can be stopped at any time
- Stress the importance of regular smears as a preventative measure

6.4 Specific groups

6.4.1 Women under 25 years

Sasieni et al. 2009 found no evidence that screening women in the UK aged 22 to 24 decreased the incidence of cervical cancer at ages 25 to 29. Authors concluded that cervical screening in women aged 20 to 24 has little or no impact on invasive cancer rates up to the age of 30. Sexually active women under age 25 are quite likely to have cellular changes that are transient. There is no benefit from having transient changes detected or treated. Cancer of the cervix is very rare under the age of 25 (Sasieni, 2003). When screening starts at the age of 25, lesions that are destined to progress are screen-detectable. Those that would regress will no longer be a source of anxiety. Younger women will not have to undergo unnecessary investigations and treatments.

Prevalence of HPV is highest in women under 25 years of age. However, the vast majority of women clear the virus from their systems and such transient changes reported on their smear tests at this time do not require treatment. Ablative treatments at colposcopy may have an effect on the subsequent competence of the cervix.

6.4.2 Women over 60 years

As CIN 3 rarely develops de novo after 45 years of age, it is considered that screening can be safely discontinued for women aged 60 who have been regularly screened and who have had normal smear test results.

CervicalCheck routine screening stops at 60 years. However, women over 60 who have never had a programme smear test may avail of a free CervicalCheck smear test. Consideration should be given to the woman's age, her wishes and her co-morbidities. CervicalCheck will continue to call participating women who are over 60 years until a normal smear test result is reported. CervicalCheck will pay for and follow-up on initial smear tests and on second smear tests after three years, assuming the first one is an adequate smear test with a normal result.

6.4.3 Post-menopausal women

Post-menopausal women with atrophic cervixes can be identified both from their personal details and also from the condition of the vagina and cervix. There are two main problems in taking smear tests from these women. The cervical cell yield from the smear test can be scanty.

An atrophic smear test is one with too few cells to allow a cytologist to report on it. The squamo-columnar junction is high up within the cervical canal. If this is apparent, local oestrogen may be prescribed. This allows the squamo-columnar junction to evert and so avoid an atrophic result. See Section 4.2D for further information.

6.4.4 Pregnancy

It may be psychologically inappropriate or unwelcome by the women to have a smear test during or shortly after pregnancy.

If a woman is due a routine smear test and is pregnant when she receives the invitation, the smear test can be delayed until three months after the birth.

If the woman had a result that is not normal from her last smear test and a repeat smear test is due, she should discuss with her doctor the best time to have the test repeated.

A woman does not need a smear test after having a baby unless she is due to have a smear test.

If a woman is due to have a routine smear test and is breastfeeding, she can have her smear test three months post natal.

See Section
1.6.3 for
more
information
on deferrals.

6.4.5 Hysterectomised women

Women who have had hysterectomy with CIN present are potentially at risk of developing Vaginal Intraepithelial Neoplasia (VaIN) an invasive vaginal disease (NHSCSP, 2004). Women who have undergone total hysterectomy because of invasive carcinoma of the cervix should continue to have screening via vault smears, according to specialist instruction.

Women who have had total hysterectomies for benign reasons and who have no history of abnormal or cancerous cell growth may be excluded from screening. However, women who have had a sub-total hysterectomy should continue to have screening.

Women's cervical screening needs should be considered on a case by case basis. The screening needs of a woman require a clinical judgement to be taken in clinical practice. More detail regarding the management of hysterectomised women and their screening requirements is contained in the CervicalCheck 'Cervical Cytology Management Recommendations Explanatory Guide', page 5-6 or see www.cervicalcheck.ie

6.4.6 Women who are immunosuppressed

Women who present for screening may have difficulties with their immune system. This may be due to HIV, TB or immunosuppressant medication used in the management of arthritis, SLE / lupus, asthma, post-transplantation, etc. Vigilant adherence to the national programme screening intervals is advised in these circumstances. At time of writing, there is insufficient evidence to warrant a recommendation of increased frequency of cervical screening for the women who receive immunosuppressant medications. There are special circumstances where women who are immunosuppressed require increased cervical screening.

Special circumstances include:

Women who are HIV positive

Women 20 years of age or over who are HIV positive should be offered yearly screening. Women who are HIV positive have difficulty clearing the HPV virus and are at increased risk of developing cervical cancer

Women who have undergone a transplant

Women 20 years of age or over who have had organ transplants and are receiving immunosuppressant medications should be offered screening yearly. Women with chronic kidney disease (CKD) and kidney transplants have demonstrated a greater cervical cancer risk (Brunner et al. 1995, Vajdic et al. 2006 & Kerkhoff et al. 2006)

Renal dialysis

Women undergoing regular renal dialysis should be offered screening yearly from the age of 20 years or over. Women who are on dialysis are potentially at risk of cancer for many reasons, including immunosuppressant medication, cytotoxic drugs, altered DNA repair, chronic infections, nutritional deficiencies and uraemic dysfunction (Vamvakas et al. 1998)

Primary care has an important role in ensuring that women with chronic disease are offered and encouraged to have regular cervical screening. Please refer to the 'Eligibility for Cervical Screening Framework' on www.cervicalcheck.ie

6.4.7 Women with disabilities

Women with disabilities who have ever been sexually active have similar or greater risks for cervical cancer as their peers. However, population research across various diagnostic groups has demonstrated that women with disabilities do not receive the same level of preventative health care as the general female population.

Women with physical disabilities

Women with physical disabilities are frequently seen by those around them as 'asexual' (Scuillion, 1999). Consequently they may not be told about cervical screening or advised on how to avail of it. Women with major lower extremity difficulties are less likely to receive a smear test (Lezzoni et al. 2001).

Women with physical disabilities may find it difficult to maintain the required position for obtaining a cervical screening sample. The smearer needs to be aware of the potential difficulties such women may face, and ensure that suitable locations and equipment for screening are available to enable women to have the best opportunity to be screened. The woman with a physical disability is probably the best expert on her own disability needs and this will contribute greatly to building a smooth and positive interaction. It will also reinforce the woman's sense of control and participation in her health care (Peters, 1982). Use of questions such as, 'what would make this easier for you?', 'what is the best way to transfer you to the examination table?' will make the examination easier for both the woman and the smearer (Becker et al. 1997; Welner et al. 1999).

For women with contractures, spasticity or skeletal deformities, the traditional lithotomy position for a smear test may not be possible for them to assume. The lateral recumbent and knee-chest examination positions may be suitable alternatives. In the lateral recumbent position the woman lies on her side with the superior leg brought forward over the lower leg. In the knee-chest position, the client lies face down on the examination table with her knees bent forward under her chest. In both these alternative positions the speculum is inserted posteriorly (Peters, 1982).

Women with intellectual disabilities

A study conducted on women with learning disabilities (n 398), aged 20 to 64 years, living in one English health district found that only 13 per cent had a recorded smear test in the previous five years, which is markedly lower than the cervical screening rate for the general female population (Stein & Allen, 1999).

Women with intellectual disabilities (ID) are generally considered to be low risk for cervical cancer. However, sexually active women with ID are at high risk as they are less likely to have been screened. There may be no acknowledgment within families or the organisation that they have been sexually active. Good practice guidelines in cervical screening for women with ID is discussed in more detail in Appendix 6A.

A woman's screening needs should always be considered on a case by case basis (or individual). Some women who have a disability may not be suitable for screening, may not require screening because they have never been sexually active or may not have the capacity to consent or it be physically impossible to carry out the test. In any of these circumstances the woman may be opted-off the programme.

Please see Section 1.6.4 for further information on the opt-off process.

Useful resources

The National Cancer Screening Service (NCSS) has developed a suite of CervicalCheck information materials for women in Braille and audio format. The two most commonly requested leaflets 'About your free smear test' and 'About your smear test results' have been translated into Braille and audio format. It is intended that these materials will assist women who are visually impaired to more easily avail of the CervicalCheck programme by accessing the information needed for them to make an informed choice and decision about whether to participate in screening. Braille is a tactile writing language of raised dots, mainly used by the blind and visually impaired. It is developed for a combination of the sense of touch, movement and finger pressure. In addition, the materials have been transcribed into an audio format and are available online at www.cervicalcheck.ie



CervicalCheck Access Officer

The purpose of an Access Officer is to provide access to and information about smearing services to eligible women with special needs under the provisions of the Disability Act 2005. It is the responsibility of the Access Officer to co-ordinate any queries which are received in relation to accessing smearing services for women with disabilities. The Access Officer also takes responsibility for any complaints received under the Disability Act. The CervicalCheck Access Officer can be contacted by calling CervicalCheck on Freephone on 1800 45 45 55 or by emailing access@cervicalcheck.ie

6.4.8 Women from ethnic and minority groups

Assessment of the special needs of subsets within the target population, such as ethnic or immigrant minorities with diverse cultural and religious backgrounds, warrants particular attention. Previous studies have attributed low uptake of cervical screening amongst minority women to their lack of basic information, and to their cultural beliefs and attitudes (McAvoy, 1988; Doyle, 1991; Naish et al. 1994). Non-English speaking women are enthusiastic about cervical screening when the nature of the test is explained to them in their own language (Naish et al. 1994). The Health Education Authority's report on the health and lifestyles survey of black and white minority ethnic groups in England (Rudat, 1994) has also identified a lack of information as the major reason for low uptake of cervical screening amongst minority groups. In a study conducted in New Zealand, language was consistently identified as the main barrier to screening (Lovell et al. 2007).

Advice for smertakers

- CervicalCheck has translated the "Information Sheet for Women" (Appendix 4B) into a number of languages, but the list is not comprehensive. These will be available for download on the CervicalCheck website. Smertakers may need to source additional translation aids. Useful resource: General Practice Care in a Multi Cultural Society: A Guide to Interpretation Services and Cultural Competency
- Children should not be used as interpreters
- Appointments for the smear test should be made in advance to support the woman. A link worker or an official interpreter should be allowed to attend
- In order to ensure cultural sensitivity, a female smertaker should be available as appropriate
- It is also important that smertakers are mindful that some women living in Ireland have undergone Female Genital Mutilation. Refer to the Akidwa website www.akidwa.ie for information regarding different types and up-to-date figures of prevalence in Ireland

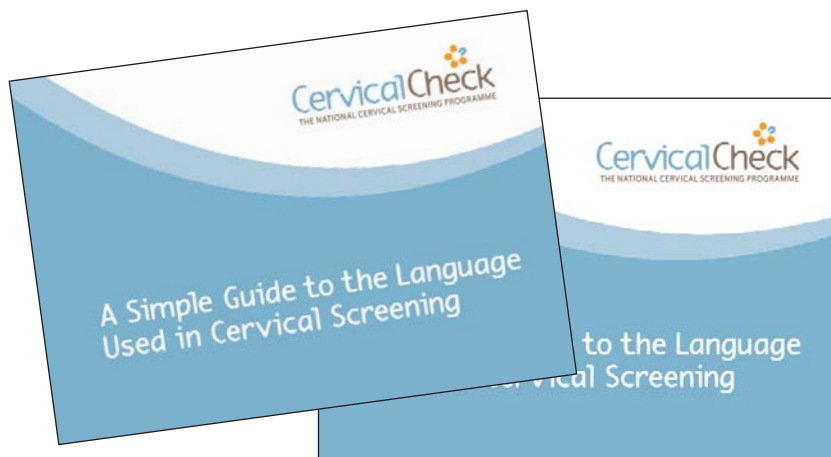
6.4.9 Women with literacy difficulties

The last national literacy study conducted in Ireland found that a quarter of the Irish population struggles with basic literacy tasks. One in four Irish adults between the ages of 16 and 66 years has very poor literacy skills and cannot satisfactorily read the instructions on medication (Department of Education, IALS, 1997). Although the CervicalCheck materials have been written in liaison with The National Adult Literacy Agency (NALA) because of literacy difficulties, many women may struggle to read and understand the information in the CervicalCheck invitation letters, CervicalCheck leaflets and the CervicalCheck consent form.

Where the smertaker is interacting with a woman with low literacy skills, he/she will need to take greater care to ensure the woman fully understands the cervical smear test process. The smertaker should not assume the woman is able to read the information provided or to complete necessary forms. Excuses like forgetting glasses, bad eyesight, bringing someone else along can be signs of literacy problems. A smertaker can help by:

- Explaining everything in plain language throughout the consultation and using the information leaflet or pictorial leaflet to help explain the process
- Using simple diagrams or images if possible
- Ensuring the woman understands everything that she needs to
- Explaining the CervicalCheck consent form in simple language before asking the woman to sign it

'A Simple Guide to the Language Used in Cervical Screening' has been developed to support CervicalCheck smertakers in the primary care setting.



APPENDIX 6

Appendix 6 A

6.5 Guidelines for good practice In taking smears in women with intellectual disability (ID)

6.5.1 Aim of guideline & context

The aim of this guideline is to help smearthakers in their practice to provide a quality service to women with an intellectual disability (ID) by outlining and addressing the particular considerations and difficulties when screening women for cervical cancer who have an ID.

Doctors have identified that they lack the necessary skills, knowledge and resources to offer health promotion and screening to women with disabilities (Kerr et al.1996). Women with ID vary widely in their degree of intellectual disability and in their ability to understand, reason and communicate. Many women with ID will be capable of making decisions and giving informed consent and in this context, it is important that each woman should be assessed with regard to her ability of making an informed choice.

Women with ID are generally considered to have a low risk of cervical cancer. However, sexually active women with ID are considered to have a high risk of cervical cancer as they are often overlooked for screening. The exclusion from screening may in part be due to the refusal by families or organisations to acknowledge that women with ID are, or have been sexually active. To assume that a woman has never been sexually active on the basis of her disability ignores the fact that women with disabilities are more likely to have experienced sexual abuse than the general female population (Muccigrosso, 1991).

Inadequate knowledge amongst general practitioners concerning disability issues coupled with attitudinal barriers provides one explanation for the low preventative screening rates of women with disabilities (Band, 1998; Lezzoni et al, 2001; Meehan et al, 1995; Singh 1997; Welner et al, 1999; Wilson & Haire, 1990).

6.5.2 Clinical challenges for smearthakers

The following are some of the challenges smearthakers may face when taking smear tests from women with ID:

- The woman may not understand the invitation to attend for a smear test
- Extra time is required for the test
- Expertise is required
- There may be difficulties in obtaining a history
- There may be ethical issues in relation to informed consent
- The woman may have additional disabilities

6.5.3 Practical advice on how best to support quality smeartaking in women with ID

Rapport/ communication	<ul style="list-style-type: none"> • Be aware that while the woman may have difficulty speaking, she may understand what you say and you should involve her in the conversation • Take time to get to know how the woman communicates • Be aware that communication may take more time than usual, expect a response and wait 10 seconds • Supplement communication with signs, gestures and facial expressions to add meaning • Use open-ended questions where possible - some women with developmental disabilities may inappropriately say 'yes' to closed ended questions • Repetition is useful to reinforce the message
Ahead of the test	<ul style="list-style-type: none"> • Understand the issues relating to consent • Use one-to-one sessions with a person whom the woman knows and trusts • Use appropriate materials (pictorial leaflets, picture books) • Provide reassurance • Arrange a preliminary visit to the surgery at a quiet time to allow the woman to become familiar with the surroundings and to meet the smeartaker • Help the women to decide whether or not it is necessary to go for cervical screening
Making the appointment	<ul style="list-style-type: none"> • Book an appointment at a time when the surgery is not busy • Be mindful that the woman may also have a physical disability and that it is important to determine any special requirements prior to the appointment • If possible, provide space for those women who find it difficult to comply with the social expectations of a waiting room • Check that the carer who will accompany the woman understands the screening process • Discuss issues of consent with the carer • Show the speculum and brush to the woman and allow her to handle them
Preparing the woman for her smear test	<ul style="list-style-type: none"> • Make sure the room is comfortable and private • Ask the woman if she wants a carer with her during the test • Allow sufficient time to explain to the woman how the smear test is taken using the picture book • Use appropriate language for the individual woman • Respect the woman's privacy and dignity at all times • Be prepared for the possibility that the woman may become distressed • Be particularly patient and gentle

Preparing the woman for the smear test cont.

- If at any time the woman is resistant or unco-operative, stop and only proceed with her co-operation
- Be prepared to make another appointment to take the smear test if the woman needs more reassurance
- Ensure that refusal at any stage before or during screening is seen positively as the woman's choice to refuse the test on this occasion
- Reflect on the outcome and whether the preparation affected the outcome

Good practice summary - quality smeartaking in women with ID

In addition to best practice principles for smeartaking in the general population, the smeartaker should ensure the following good practice is adhered to with women with ID:

- Use appropriate information materials
- Answer questions honestly to avoid the unexpected
- Two or three visits may be required before the test
- Allow sufficient time to explain the process to the woman
- Be prepared for the possibility of distress
- If at any time the woman is resistant or unco-operative, stop and only proceed with her co-operation
- Ensure that her refusal at any stage, before or during screening, is seen positively as it is the woman's choice to refuse the test on this occasion
- Try to book an appointment at a time when the surgery or clinic is not busy
- Show the screening instruments to the woman (if applicable)

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Websites

The following websites may be useful to provide multicultural information on cervical screening.

www.icgp.ie/index.cfm/loc/6-5-3.htm

www.nuigalwa.ie/dgp

www.mhcs.health.nsw.gov.au/

www.health.qld.gov.au/multicultural/policies/policies_plans.asp

www.mhcs.health.nsw.gov.au/mhcs/topics/Cancer.html

Glossary

General cervical screening programme terminology

Ablative treatment	Treatment which involves the destruction of the cervical abnormalities using a variety of techniques. It does not allow for histological examination of the whole abnormal area and strict.
Abnormal smear test	A smear test which shows cells which are not typically normal or where pre-cancerous or cancerous cells are identified.
Adenocarcinoma	A cancer affecting the cervix, but involving the columnar (endocervical) cells rather than the squamous cells. The columnar cells are involved in glandular activity.
Adequate smear test	A specimen which is deemed satisfactory for evaluation by the laboratory.
Bethesda System	A cytological system that grades intraepithelial lesions into low grade and high of Classification grade (LSIL and HSIL).
Biopsy	Removal of a sample of tissue from the body for examination under a microscope.
Cervical cancer	Cancer of the cervix. Cancer cells have spread beyond the natural basement membrane boundary of the cervical skin. Cervical cancer can be of squamous origin (approximately 85%) or glandular/adeno origin (approximately 15%).
Cervical cytology	A microscopic examination of a single layer of cells scraped from the surface of the cervix. Cervical ectropian/eversion occurs when the inside of the cervical cells (columnar) evert on to the surface of the cervix; a red roughened area may appear on the cervix. This is a normal hormonally influenced change.
Cervical intraepithelial neoplasia	CIN is not cancer but is the histological term referring to the abnormal growth of pre-cancerous cells in the surface layers of the cervix. It describes varying degrees of abnormality of the cells within and confined to the epithelium. There are three grades of CIN: CIN 1, CIN 2 or CIN 3.
Cervical smear test	A screening test where cells from the surface of the cervix are sampled, preserved immediately and sent to the laboratory for cytological analysis.
Cold coagulation	A treatment which involves the destruction of cervical tissue by heating it to high temperatures.
Colposcopy	An examination of the cervix using a specialised optic instrument (colposcope) that provides magnification to allow direct observation and study of vaginal and cervical epithelium. It identifies lesions on the cervix which can be biopsied and treated.
Cone biopsy	A surgical removal of a cone-shaped section of the cervix to remove abnormal cells. It can be achieved with a knife (knife cone), laser (laser cone) or straight electric wire (SWETZ). The procedure is diagnostic but also curative in the majority of cases.
Coverage	The number, percentage or proportion of women screened by a screening programme.

Diagnostic smear test	A smear taken outside of the normal screening interval as a part of the diagnostic assessment of a woman who has signs and symptoms which might indicate cervical cancer.
Doctor with clinical responsibility	The doctor who holds a service contract with the screening programme. All doctors with clinical responsibility are also registered smearthakers.
Dyskaryosis	Term used in cytology to describe nuclear abnormalities in cervical cells.
Effectiveness	The extent to which an established screening programme meets its defined objectives.
Efficacy	The extent to which an intervention/programme produces a beneficial result under ideal conditions. The determination of efficacy is based on the results of a randomised controlled trial.
Efficiency	The production of the result achieved in terms of minimum waste of resources and time expended on a procedure of known efficacy and effectiveness.
Eligible for screening	Women aged 25 to 60 years for whom CervicalCheck recommends and funds screening according to national policy.
Excisional treatment	Treatment which involves the removal of the abnormality in its entirety thereby allowing histological examination of the entire Transformation Zone.
Failsafe	The action taken by the clinically responsible doctor and programme office to ensure a smear result is appropriately followed-up. Laboratories and CervicalCheck also support the primary care failsafe process.
False negative	The result when the test does not detect the disease in an individual who actually has the disease.
False positive	The result when the test indicates the presence of the disease in an individual where it is not actually present.
Histology	The microscopic study of the structure and composition of body tissue.
Human Papilloma Virus (HPV)	A group of wart viruses of which a high proportion are sexually transmitted. Over 100 different types of HPV have been identified and each is known by number. Types 6 and 11 are associated with genital warts and types 16 and 18 are associated with high grade lesions.
Hysterectomy	The surgical removal of the uterus (womb) – called total if it includes the cervix or subtotal/partial if the cervix is not entirely removed.
Incidence (rate)	The number of new cases of a disease or happening that occurs in a given period in a specified population.
Informed consent	Informed consent is the giving of all the necessary information by the smearthaker to the woman in order that she can fully understand the procedure and possible results so that she can make an educated decision to participate in the screening programme.

Large Loop Excision of the Transformation Zone or LLETZ	Large Loop Excision of the Transformation Zone (LLETZ) is a diagnostic and/or treatment method to remove the cervical areas of abnormality. The procedure involves removal of the entire Transformation Zone using a thin wire electrode charged with a low-voltage, high frequency, alternating current and produces a tissue specimen suitable for histologic analysis in most circumstances.
Local destructive	Laser, cryocautery, cold coagulation and radical diathermy are treatment methods to destroy the cervical areas of abnormality.
Management recommendation	A management recommendation is based on the individual woman's cytology report and her clinical history.
Microinvasive cancer	This represents early stage cervical cancer where the abnormal cells breach the basement membrane and invade to not greater than 5mm in depth and not more than 7mm in width.
Morbidity	The number of cases of a specific disease during a defined period of time in a given population.
Mortality	The number of deaths from a specified disease during a defined period of time in a given population.
Negative	The proportion of test-negative women who do not have precancerous cervical predictive value abnormality. It is a measure of the likelihood that someone with a negative test is actually disease free.
Normal smear test	A smear test result that is reported to be within normal limits.
PAP test	Another name for a smear test, named after George Papanicolaou, who invented the process of staining cells on a slide in preparation for examination under a microscope.
Prevalence (rate)	The total number of women who have a cervical pre-cancerous lesion or cancer at a particular time (or during a particular period) divided by the population at risk of having a cervical pre-cancerous lesion or cancer at the same point in time.
Positive predictive value	The proportion of test-positive women who are truly positive. It can be considered a measure of the likelihood that a woman with a positive test truly has a pre-cancerous cervical abnormality.
PPS Number	Personal Public Service Number.
Punctuation	A zone of red dots which represent blood vessel loops reaching to the surface epithelium. When this pattern is identified through the colposcope, biopsy is indicated since this pattern is often associated with high grade CIN.
Registered smeartaker	A doctor or nurse who meets all the screening programme requirements as a smeartaker and is registered with the programme.
Screening programme	An organised approach of screening a defined population to determine the likelihood of a specific disease within the population with the aim of reducing the risk of the disease and improving the quality of life through early diagnosis.

See and treat	A process whereby women are treated at the first visit to colposcopy.
Select and treat	A process whereby women with suspected high grade disease are selectively treated at the first visit to colposcopy.
Sensitivity	The ability of a test to detect a disease in all individuals in whom it is present.
Short interval	When a smear test is undertaken before it is due according to the woman's cervical screening requirements and national policy.
Systematised Nomenclature of Medicine SNOMED Codes	A coding system for recording histological diagnosis.
Specificity	The ability of a test to accurately exclude those individuals in whom disease is not present.
Squamo-columnar junction	The transition between the multilayer squamous epithelium which covers the ectocervix and the single layered columnar epithelium.
Squamous	A type of multi-layers cells, which line the vagina and outer layer of the cervix.
Squamous cell carcinoma/cancer	The most common form of cervical cancer.
Squamous epithelium	A type of epithelium characterised by flat cells whose function is defence. It is paler in colour than columnar epithelium.
Squamous metaplasia	The normal physiologic process by which columnar epithelium evolves into squamous epithelium. This occurs under the effect of several factors including, hormonal stimulation, low pH and trauma. The area of change between the new and the old squamocolumnar junction (SCJ) is called the Transformation Zone (TZ).
Staging	A system for analysing a tumour to determine the extent or risk of spread or recurrence.
Standard	A minimum requirement against which performance can be measured.
Transformation zone	The region of the cervix where the columnar cells of the inner cervix have or are changing to outer squamous cells. The process of change is called metaplasia. It is the area most at risk of abnormal change.
Transformation zone (TZ) cells	The presence of TZ cells, i.e. metaplastic and/or endocervical cells in a sample, is considered to be a measure of smeartaker competency although not a necessary requirement to determine a smear test is adequate.
Unsatisfactory smear test	A smear test that cannot be safely read and reported by the laboratory; usually because there are insufficient cells or the cells are obscured by exudates, polymorphs or menstrual debris.

VAIN	Vaginal intraepithelial neoplasia.
Validity	The accuracy of the screening test in distinguishing those who have and those who do not have the disease in the asymptomatic population.
Vault smear test	A smear taken from the top of the vagina after a total hysterectomy.
VIN	Vulval intraepithelial neoplasia.

Contact List and Useful Links

Name	Address	Telephone/Fax	Email/Website
CervicalCheck The National Cervical Screening Programme	PO Box 161, Limerick	Tel: 061-406500 Fax: 061-406555	Email: info@cervicalcheck.ie Web: www.cervicalcheck.ie
National Cancer Screening Service (NCSS)	King's Inn House, 200 Parnell Street, Dublin 1	Tel: 01-865 9300 Fax: 01-865 9333	Email: info@cancerscreening.ie Web: www.cancerscreening.ie
BreastCheck - National Breast Screening Programme	King's Inns House, 200 Parnell Street, Dublin 1	Freephone Information line: 1800 45 45 55	Web: www.breastcheck.ie
Irish College of General Practitioners (ICGP)	4/5 Lincoln Place, Dublin 2	Tel: 01-6763705 Fax: 01-6765850	Web: www.icgp.ie
Royal College of Surgeons in Ireland (RCSI)	Faculty of Nursing & Midwifery 123 St. Stephen's Green, Dublin 2	Tel: 01-4022206 Fax: 01-4022465	Web: www.rcsi.ie
National University of Ireland, Galway (NUIG)	Dept of Nursing & Midwifery Studies Aras Moyala, NUIG, Galway	Tel: 091-495387 Fax: 091-494537	Web: www.nuig.ie

Name	Address	Telephone/Fax	Email/Website
An Bord Altranais	18/20 Carysfort Avenue, Blackrock, Co. Dublin	Tel: 01-639 8500 Fax: 01-639 8595	Web: www.nursingboard.ie
Department of Health & Children	Department of Health and Children, Hawkins House, Hawkins Street, Dublin 2	Tel: 01-6354000 Fax: 01-6354001	Web: www.dohc.ie
Health Service Executive	HSE Head Office, Oak House, Millennium Park, Naas, Co. Kildare	Tel: 01-45 880400 Fax: 1890 200893	Web: www.hse.ie
Irish Cancer Society	Irish Cancer Society, 43/45 Northumberland Road, Dublin 4	Tel: 01-2310500 Fax: 01-2310555	Web: www.cancer.ie
Irish Practice Nurses Association	Cormoy, Blackstaffs Post, Carrickmacross, Co. Monaghan	Tel: 042-969240	Web: www.irishpracticenurses.ie Email: admin@irishpracticenurses.ie
Medical Council	Kingram House, Kingram Place, Dublin 2	Tel: 01-4983100 Fax: 01-4983102	Web: www.medicalcouncil.ie
National Cancer Registry Ireland	National Cancer Registry, Ireland, Bld 6800, Cork Airport Business Pk, Kinsale Road, Cork	Tel: 021-4318014 Fax: 021-4318016	Web: www.ncri.ie Email: info@ncri.ie
National Women's Council of Ireland	9 Marlborough Court, Marlborough Street, Dublin 1	Tel: 01-8787248 Fax: 01-8787301	Web: www.nwci.ie Email: info@nwci.ie

Promed Ltd – Speculum Supplier		Tel: 1800 619 619 Fax: 1800 684 684	Web: www.promed.ie Email: comfispes@promed.ie
Screenlink LBC Consumables		Tel/Voicemail: 01-4605270 Fax: 01-4605248	Email: orders@screenlink.net
The Women's Health Council	Block D, Irish Life Centre Abbey Street Lwr., Dublin 1	Tel: 01-878 3777 Fax: 01-878 3710	Web: www.whc.ie Email: info@whc.ie

Other Useful Links

Australian National Cervical Screening Programme	Web: www.cervicalscreen.health.gov.au
Cancer Backup	Web: www.cancerbackup.org.uk
Comhairle	Web: www.citizensinformationboard.ie
Irish Health	Web: www.irishhealth.com
Marie Curie Cancer Care	Web: www.mariecurie.org.uk
Marie Keating Foundation	Web: www.mariekeating.ie
MedicineNet	Web: www.medicinenet.com
National Electronic Library for Health	Web: www.library.nhs.uk
New Zealand Screening Programmes	Web: www.nsu.govt.nz
NHS Cancer Screening Programmes	Web: www.cancerscreening.nhs.uk
UK National Screening Committee	Web: www.nsc.nhs.uk
Wales Screening Programme	Web: www.wales.nhs.uk
Women's Cancer Network	Web: www.wcn.org

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