CervicalCheck
THE NATIONAL CERVICAL SCREENING PROGRAMME

Guide for smeartakers

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Freephone information helpline number

1800 45 45 55

Website address:

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.

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National University of Ireland, Galway
Ollscoil na hÉireann, Gaillimh

RCSI

icgp

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Introduction

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I have pleasure in presenting the 'Guide for smeartakers' - a publication of The National Cervical Screening Programme.

This guide has been developed as the reference for General Practitioners and Practice Nurses who take cervical smears 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 smears for women in their community in line with the CervicalCheck Women's Charter.

This guide has been developed by the Smeartaker Training Unit which has been established in the Programme office in Limerick. This Unit facilitates a training programme that is delivered through a number of professional academic bodies, currently the Royal College of Surgeons in Ireland, the National University of Ireland Galway and the Irish College of General Practitioners.

This work is the culmination of learning gained through the authors' engagement in cervical screening and smeartaker training from the Irish Cervical Screening Programme Phase 1.

I would like to acknowledge the pivotal role that smeartakers play in promoting and delivering cervical screening to women. Together we aim to reach an 80 per cent coverage target of our eligible population in order to reduce the incidence of and mortality associated with cervical cancer in Ireland. This guide is an essential resource in working towards the success of a quality assured national programme.

Dr Marian O'Reilly

Head of Cervical Screening
National Cancer Screening Service
October 2008

Governance of the Irish Cervical Screening Programme was transferred to the National Cancer Screening Service in January 2007.

The authors wish to express their appreciation for all the guidance and support that has been received to date from colleagues, professional and academic bodies and international cervical screening programmes.

They acknowledge the critical feedback from women on their smeartaking experiences for inclusion in this Guide. They would also like to thank the following people for their help and expertise in the writing and compilation of this guide:

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First published in October 2008 by The National Cancer Screening Service.

This guide is intended primarily for use by smeartakers for 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
- as a resource for clinical practice
- as a support for education and training in the Smeartaker Training Programme
- as a checklist to support supervision
- as an aid to assist smeartakers to give quality information to women who present for screening.

The development of the guide was based on the following:

- a comprehensive review of national and international literature and research findings
- inputs from a management group consisting of experts in the field
- recurrent reviews of the Guide at each stage of development by a range of external experts.

The underlying principles that directed the development of the guide included:

- the importance of screening in reducing the incidence of and mortality from cervical cancer
- the importance of well-trained smeartakers who have access to up-to-date information based on sound scientific evidence
- the rights of women to have a positive smeartaking experience in an overall quality assured programme
- the development of a culture of quality, measurement, outcomes, education and research as per the 2006 Strategy for Cancer Control in Ireland.

The guide is composed of six sections with associated appendices and references for further reading, a Glossary and a Useful contacts list. It can be used as a whole or users can focus on the sections that are relevant to their practice or to specific situations. Examples, recommended procedures, checklists and cross-references to other sections within the guide are clearly set out in separate boxes within the text. The guide is presented to allow for regular updates[1] in evolving practices in clinical care and to accommodate emerging research developments and regulatory changes.

If you have any queries about this Guide, or any other aspect of the Programme, we will be delighted to deal with these.

Please contact the CervicalCheck Team at
stu@cervicalcheck.ie or **1800 45 45 55** or **061 461390**
CervicalCheck – The National Cervical Screening Programme
PO Box 161, Limerick

1 *The date of issue, section and page numbers are at the foot of each page. Please ensure that your copy is the most up-to-date version of the Guide by checking the CervicalCheck website www.cervicalcheck.ie*

SECTION 1

CervicalCheck - The National Cervical Screening Programme

An overview

CervicalCheck - an overview

Aim of section
The aim of this section is to provide an overview of the background, the organisation and the processes of CervicalCheck and how it applies 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 – 60 years. CervicalCheck's target coverage is a minimum of 80 per cent of the eligible population in the Programme's catchment area.

CervicalCheck maintains a population register containing demographic data of eligible women for the purposes of screening. This register, which is a computerised information system, allows CervicalCheck to call and recall women for screening and treatment. The screening interval for women aged 25 - 44 is three years and for women aged 45 – 60 years is five years.

Cervical screening is based in routine primary care practice and participating smeartakers are required to register with the Programme. CervicalCheck provides training and also maintains a database of all registered smeartakers.

Key tasks of CervicalCheck

- Maintain and update the population register
- Identify and invite eligible women for cervical screening
- Send out call and recall letters as appropriate and inform women when results are available
- Ensure that attempts are made to contact women requiring further investigation – failsafe process
- Check that smears with 'not normal' results are followed up and outcomes recorded
- Register doctors and nurses as CervicalCheck smeartakers and process payments for smears taken
- Provide training and education initiatives for smeartakers
- Quality assures the Programme
- Co-ordination and provision of quality assured laboratory services
- Co-ordination of quality assured colposcopy and clinic services

1.2 Background to CervicalCheck

Based on the 1996 Report of the Department of Health Cervical Screening Committee, a Ministerial decision was taken in 1997 to set up a national cervical screening programme.

Also in 1997, a National Expert Advisory Group on Cervical Screening was set up which was a key group in informing the policy for the national programme. In addition to national expertise and advice, the experience gained in other cervical screening programmes was examined, in particular in programmes in the UK, Australia, New Zealand and Finland.

Phase 1 of the Irish Cervical Screening Programme (ICSP) subsequently 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.

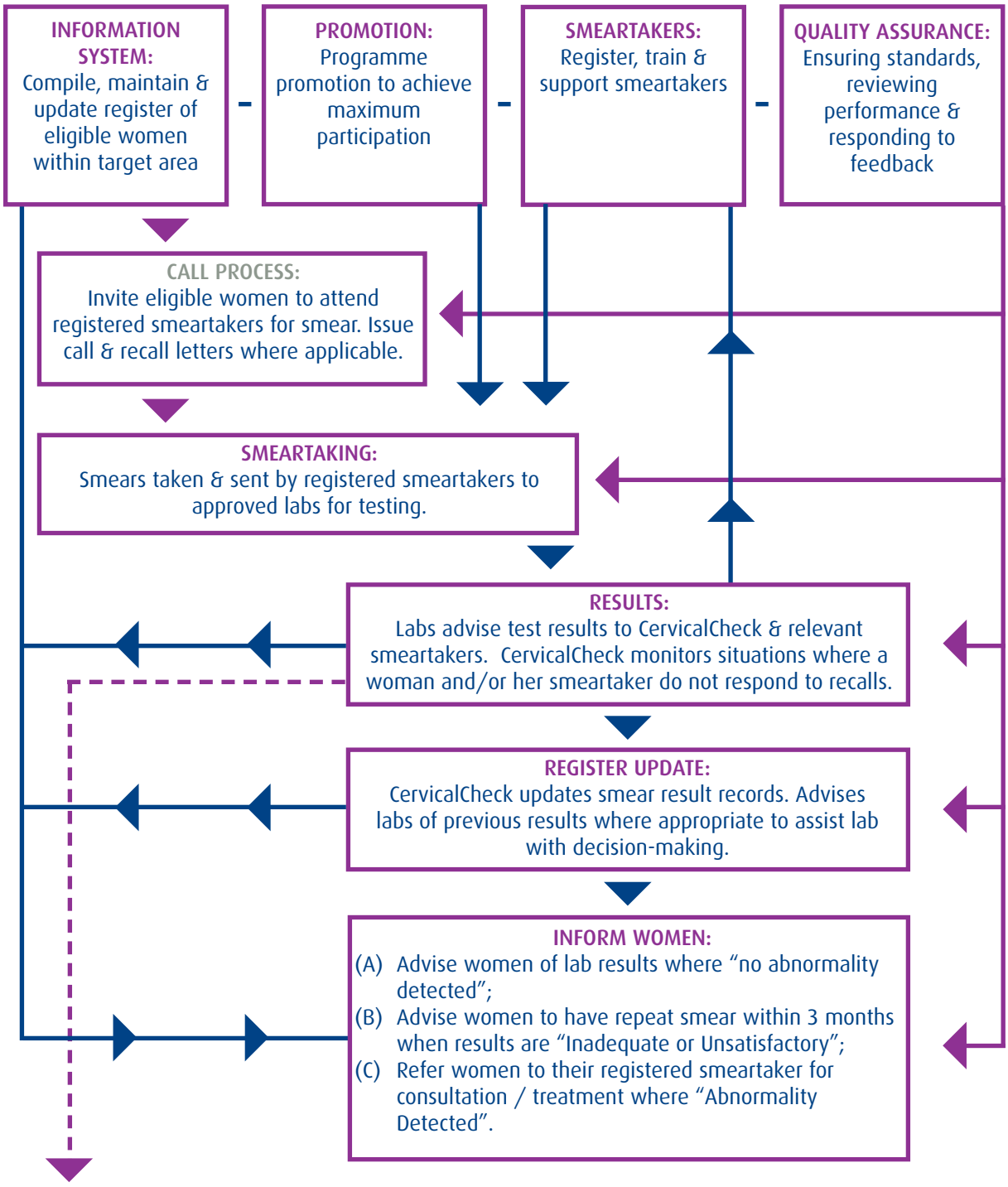
Since that time, the Programme has evolved and progressed incorporating the findings from two external reviews in 2004. These reviews not only acknowledged the success to date but also enabled the Programme to identify a number of areas for further improvement. These have since and are currently being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

Other developments that have impacted on the direction of the Programme include the launch of A Strategy for Cancer Control in Ireland 2006. More recently in 2007, the National Cancer Screening Service (NCSS) was established, encompassing BreastCheck - The National Breast Screening Programmme and CervicalCheck (ICSP orginally) - The National Cervical Screening Programmme under a single clinical governance model. 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 National Cervical Screening Programme.
2000	Phase 1 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	CervicalCheck - The National Cervical Screening Programme implementation.

1.3 The organisation - system process



FAILSAFE PROCESS*

CervicalCheck aims to ensure that all recommendations requiring recall or referral are appropriately actioned. The failsafe process is the action followed by CervicalCheck in situations where a woman and/or her doctor do not respond to the CervicalCheck recall for a recommended repeat smear following a previous 'not normal' smear result and/or management recommendation.

** See Appendices 1g Woman Failsafe and 1h GP Failsafe*

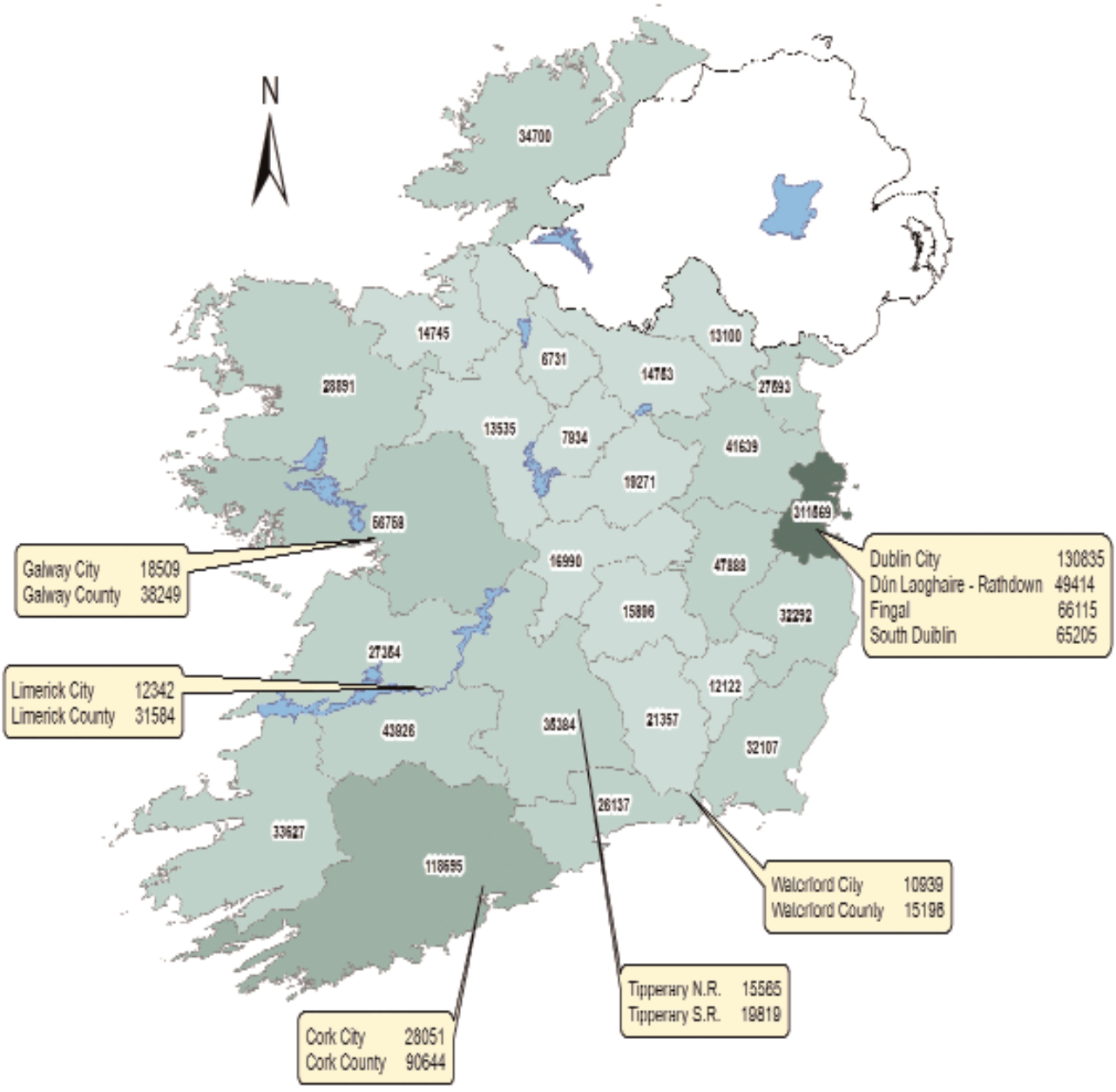
ANTICIPATED OUTCOME

Regular screening & earlier detection / treatment of cervical cancer results in reductions in incidence of & mortality from cervical cancer for women.

1.4 The target population

The eligible screening population in Ireland is approximately 1.1 million women aged 25-60, based on the 2006 census. Eligible women will be offered screening over a five year interval.

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



Source: Census of Population 2006, CSO

1.5 The information system

Of key importance to the working of CervicalCheck is the Population Register. This is a computerised information system, centrally located, containing demographic data of women in the CervicalCheck target area from which eligible women can be contacted for screening. It also contains clinical data so that women who have had smear tests can be contacted for follow-up treatments and clinical referral recommendations. The Register thus provides a concise view of all data of significance to CervicalCheck thereby facilitating its communication tasks and its quality audits of the system's performance and reliability.

The Health (Provision of Information) Act, 1997 provides the legislative framework for the compilation of the Population Register which has meant that data from the Department of Social & Family Affairs can be used to establish and update this Register.

Data from smeartakers' referrals and from self-referrals is also used to complement the data from the Department of Social & Family Affairs. CervicalCheck encourages women to register themselves to ensure that their details are complete and accurate. Women can do so by using the Freephone information line, through the CervicalCheck website or by completing a self registration leaflet available from a variety of community outlets.

See **Appendix 5** for further information on Data Protection

In compliance with current Data Protection legislation and good practice, CervicalCheck recognises its legal responsibilities regarding personal data stored on the Register. All staff are required to sign confidentiality agreements and the Register is securely maintained and systematically updated to guarantee data integrity. CervicalCheck also ensures that any requests for data are dealt with in accordance with the Freedom of Information Act, 1997.

The CervicalCheck Minimum Dataset is the key data that is maintained on each woman in the Register. This dataset covers unique identity details that remain unchanged throughout a woman's lifetime (1 to 6 below) together with other key data that ensures the accurate recording, retrival and updating of each individual woman's records.

CervicalCheck's Minimum Dataset

1. DOB
2. Forename
3. Surname at birth
4. Mother's maiden name
5. PPS Number
6. Middle names
7. Surname
8 Address
9. Phone number

1.6 THE CALL PROCESS

1.6.1 Calls and Recalls

The call process commences for a woman within the first five years of being registered with CervicalCheck. This involves a call letter being issued to the woman, for whom no previous smear/call history is known, as she reaches one of the following age intervals:

25 / 30 / 35 / 40 / 45 / 50 / 55 / 56 / 57 / 58 / 59 / 60

This normally corresponds to the woman's birthday.

For further information on the Call Process see **Section 3** The Screening Interval

The screening interval thereafter for women aged 25-44 years is three years with each subsequent call being issued 30 months from the previous call date. The screening interval for women aged 45-60 years is generally five years and each subsequent call is issued 54 months from the previous call date. The situation of the five-yearly interval is further refined in the following scenarios:

- the woman is aged ≥ 45 and < 61, has a minimum of two consecutive negatives with at least one negative result occurring after she turns 45;
- a woman (aged ≥ 45 and < 61) with no smear history who has not responded to call letters.

When the woman is aged ≥ 61 on entry to the Programme, one negative smear is required before she exits the Programme. This woman will not get a five-year recall.

Within a given period of time, each call letter is followed by two reminder letters if the woman does not have a laboratory smear notification received by CervicalCheck. Of key relevance to CervicalCheck and its target group is that any woman who presents to her doctor with an invitation letter (see Appendix 1) from CervicalCheck is eligible for a free cervical smear test.

1.6.2 Self-referrals

A woman may also present to a CervicalCheck registered smeartaker without having received an invitation letter from CervicalCheck. At the smeartaker's discretion, she can at that point enter into the Programme by having her first smear taken. Screening intervals thereafter will be determined as above in accordance with the CervicalCheck policy.

1.6.3 Deferrals

Deferrals or the delaying of a smear call or recall date can occur due to a number of reasons e.g. the woman is pregnant, she may be receiving other medical treatment, etc. The woman herself may also request a deferral due to personal reasons. In order to process the deferral, a written request from the woman or her doctor must be sent to the CervicalCheck office indicating her preferred date to be recalled and the reason for deferral. An acknowledgement letter of deferral will then be issued by CervicalCheck to the woman. At the end of the deferral period, the Programme will contact her again.

See also 6.2.4 in **Section 6**

A woman may choose not to participate in the Programme and can do so by writing to CervicalCheck. She will no longer be entitled to the benefits of being registered and she will receive no further communication from the Programme. If she decides to rejoin the Programme at any time, she can do so by presenting for a smear test and signing the consent form.

Keypoint

Regardless of age women must have two normal smear results before going onto a five yearly screening interval.

See **Section 3** for further information on the CIN Classification

1.7 The result process

Smear test results are categorised into three grades of the CIN classification (Cervical Intraepithelial Neoplasia). This is an internationally recognised system that allows a laboratory to grade the smear test results into varying degrees of abnormality.

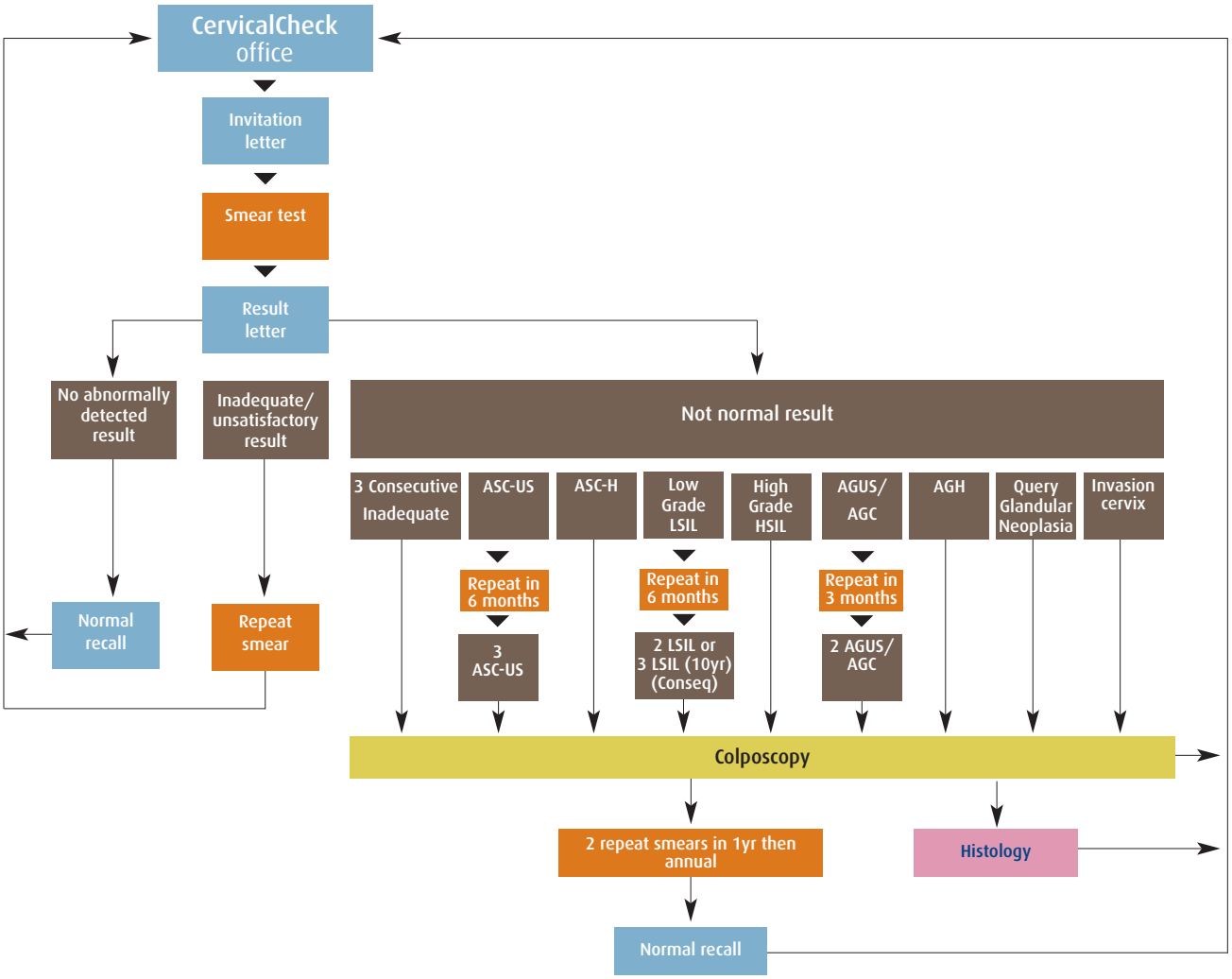
Figure 1.1 Overview of results categories with follow-up actions

Normal results **No abnormality detected**	In the case of normal results, CervicalCheck and the smeartaker with clinical responsibility will receive a copy of the results from the laboratory. A letter informing the woman of a *'No abnormality detected'* result will be sent by the CervicalCheck office. 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). The CervicalCheck office will also issue a further call letter to the woman in the months in advance of her next smear.

Unsuitable **Inadequate** **Unsatisfactory results**	In cases where results are deemed to be *Unsuitable / Unsatisfactory / Inadequate,* a report is sent by the laboratory simultaneously to CervicalCheck and to the smeartaker with clinical responsibility. The woman is then advised to have a repeat smear within a three-month period (see Appendix 1).

Not normal results	In cases where results are deemed *'Not normal'*, a report is sent by the laboratory to CervicalCheck and to the smeartaker with clinical responsibility. CervicalCheck then issues a letter to the woman informing her that her smear result is available and requires follow-up. This advice will depend on the degree of abnormality of her smear e.g. she should attend her smeartaker for a repeat smear in six months or attend her smeartaker for consultation and follow-up treatment (see Appendix 1).

Figure 1.2 Summary of the results process



1.8 Communication with women

See **Section 6** for further information

Communication with women is an essential component of the Programme as outlined previously with the registration process, the call process and in the results process. CervicalCheck also has a strategic approach for promoting both its services and the importance of regular cervical screening for eligible women. It does so through information materials that explain the benefits and limitations of cervical screening and which are disseminated through a wide range of outlets such as doctors' surgeries, health centres, other public venues accessed by women and through promotional campaigns and the CervicalCheck website.

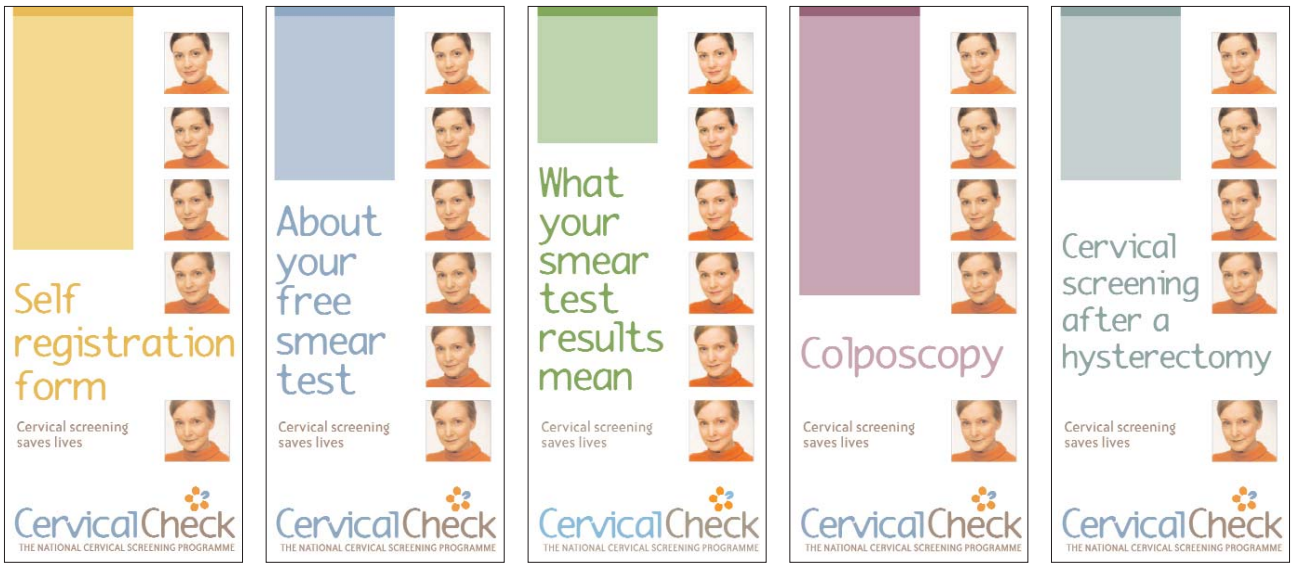
1.8.1 The Women's Charter

See **Section 1** Page 21 for further information

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 Smeartakers to promote screening participation.

Figure 1.3 CervicalCheck promotional literature



1.9 Smeartaker co-ordination

1.9.1 Model of co-ordination & support

CervicalCheck ensures that there are efficient processes in place for the registration, training and payment of smeartakers and that there is an effective system to promote regular communication between the Programme and the smeartakers.

See **Section 2** for information on smeartaker registration.

1.9.2 Smeartaker registration

1.9.3 Smeartaker training

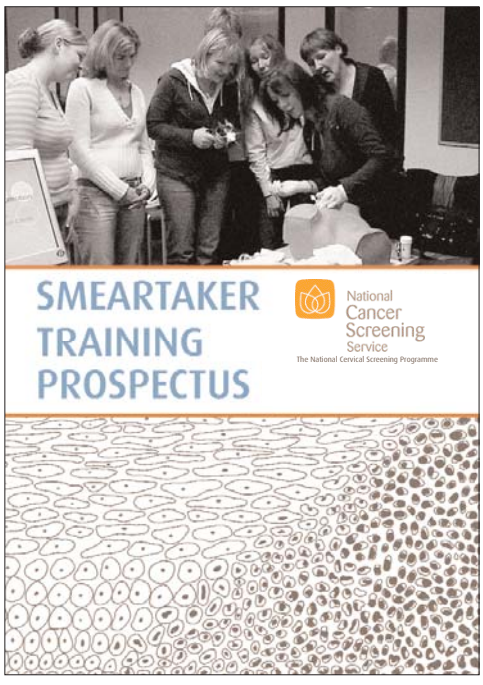
CervicalCheck undertakes a range of training initiatives to support smeartakers by

- Organising training and education events
- Developing support documentation
- Monitoring smeartaker trainee's performance
- Providing one-to-one support on quality issues

CervicalCheck facilitates the development and delivery of accredited programmes of smeartaker training and education. The European Guidelines for Quality Assurance in Cervical Cancer Screening (2008) state that *'Each country should establish minimum training requirements for each type of smear-taker fulfilling the present European guidelines'* (p31). In partnership with the Royal College of Surgeons in Ireland, the National University of Ireland (Galway) and the Irish College of General Practitioners, CervicalCheck has developed and delivers accredited programmes of smeartaker training.

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.

Figure 1.4 Smeartaker Training Prospectus



Key achievable objectives have been identified in the delivery of training programmes as outlined below:

Figure 1.5 CervicalCheck smeartaker training objectives

CERVICALCHECK SMEARTAKER TRAINING		
OBJECTIVES	**TARGET**	**MEASURE**
Clinical competency To equip the health professionals to be competent and confident smeartakers in line with quality assurance best practice.	85%	85% of smeartaker trainees. will meet this requirement.
Satisfaction (trainee) The smeartaker training process will meet the training and education needs of at least 75% of the trainees.	75%	Measured through training evaluation forms.
Customer satisfaction (the woman) The smeartaker training process will contribute to a positive screening experience for women.	80% (CS/F/ST-4)	Measured through client feedback forms.

1.9.4 Smeartaker communication

CervicalCheck's communication with smeartakers is delivered via a number of channels such as bulletins, mailshots, through the website and at meetings with professional organisations at local and national level. Effective communication with the smeartakers is important in order that the Programme can respond promptly to smeartakers' concerns which may ultimately impact on the woman's screening experience.

A key element within the communication process is that CervicalCheck provides registered smeartakers with feedback on the quality of the smears taken. 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 smears taken in the training period.
2. In the course of daily practice, CervicalCheck issues summary reports for individual smeartakers on cytology outcomes for all the smears taken by them together with the Programme averages (see Fig 1.6). These reports are generated using the smeartaker's I.D., i.e. the Medical Council Number/ An Bord Altranais number.

Figure 1.6 Summary report issued to smeartakers on cytology outcomes

Dear Colleague,

Please find below a report on smears taken by you. The report is generated using your Smeartaker ID and is confidential to you.

This report outlines the cytology outcomes for the smears taken by you and also gives the Programme averages. It is a cumulative report and covers all smears taken by you since the first reported smear you took with the Programme.

Reporting period : 17 Apr 2002 to 20 Dec 2007
Number of smears reported for this reporting period : 43

Individual Smeartaker

	Numbers Reported	As a % of the total smears taken
Negative/NAD	36	83.72 %
Borderline Nuclear Abnormalities (Squamous)	1	2.33 %
Mild Dyskaryosis	1	2.33 %
Unsatisfactory/Inadequate	5	11.63 %
Total Reported	43	
Percent		100.00 %

Programme Averages

Cytology outcome category	Numbers Reported	% of all ICSP smears by outcome category
Negative/NAD	124842	83.24 %
Borderline Nuclear Abnormalities (Glandular)	176	0.12 %
Borderline Nuclear Abnormalities (Squamous)	4544	3.03 %
Broken or Damaged Slide	576	0.38 %
Mild Dyskaryosis	4410	2.90 %
Moderate Dyskaryosis	1784	1.19 %
Query Glandular Neoplasia	50	0.03 %
Query Invasive Carcinoma	58	0.04 %
Severe Dyskaryosis	1552	1.04 %
Unsatisfactory/Inadequate	11939	7.97 %
Total Reported	149731	
Percent		100.00 %

Yours sincerely,

Signature:

Name:

Title:

1.10 Quality assurance

1.10.1 Quality assurance & 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.

1.10.2 Standards

Within the CervicalCheck office, the Quality Assurance Department oversees the development and setting of standards for all aspects of the Programme. The ICSP Administration has achieved the ISO 9001 -2000 quality certification and maintains this standard through regular internal and external audit.

A Quality Assurance (QA) Committee for the Programme was established in 2007 to review international standards and recommend best practice. The QA Committee reports to the Chief Executive Officer of the National Cancer Screening Service Board who has overall responsibility for quality assurance in the National Cancer Screening Service programmes. The QA Committee, supported by specialist subgroups, is currently working on the QA Guidelines for CervicalCheck with completion date anticipated for 2009.

1.10.3 Feedback & 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 smeartakers, 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 or in writing 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 shortcomings and capturing positive feedback so that identified areas of the Programme can be improved.

1.10.4 Monitor outcomes

CervicalCheck has identified a number of key targets for the performance and outcomes of the Programme. For example, CervicalCheck aims to ensure that there is 80 per cent of the target group availing of the Programme. An analysis of participation rates and other such data are one method used to examine performance.

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** within the next two weeks.

Regular smear tests are important as they may find early changes in the cells at the neck of the womb. The earlier a change is found the easier it is to treat successfully.

To have this free test, please make an appointment with a doctor or practice nurse who takes smears and is registered with our programme. (For details of registered smeartakers phone 1800 45 45 55 or visit www.cervicalcheck.ie).

It is important that you take this letter with you when going for your smear.
CervicalCheck will send you a letter about your results in four weeks. The result of your test is also available from your smeartaker.

Please read the leaflet enclosed and take advantage of this opportunity to take care of your health.

Yours sincerely,

[signature]
[name]
[title]

Ref: INV [BatchReference](REV K)
[eof]

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. The result of your smear test taken on the [testdate] has been reported as **'no abnormality detected'** at this time.

You will be recalled every three years if you are aged 25 – 44; or every five years if you are aged 45 – 60.

However, if in the meantime you have any irregular vaginal bleeding, spotting, discharge or other such concerns please contact your doctor.

Please let us know if you change your name or your address.

Yours sincerely,

[signature]
[name]
[title]

Ref: NAD3_5 ([Batchreference])(REV H)
[eof]

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 the [testdate] has been reported as 'inadequate or unsatisfactory'. This simply means that the laboratory could not read the smear.

As this repeat smear needs to be taken in three months, you should contact your chosen smeartaker to have this free smear test at a suitable time soon after [next_3month_appt].

Please read the leaflet enclosed and take advantage of this opportunity to take care of your health.

Yours sincerely,

[signature]
[name]
[title]

Ref: U/I ([BatchReference])(REV G)
[eof]

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. Your test taken on the [testdate] has been reported as **'needing a repeat smear in six months'.**

You should contact your chosen smeartaker to have your next smear test at a suitable time soon after [next_6month_appt].

Please read the leaflet enclosed and take advantage of this opportunity to take care of your health.

Yours sincerely,

[signature]
[name]
[title]

Ref: ABN6 ([BatchReference])(REV F)
[eof]

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],

The result of your smear taken on the [testdate] is now back. This smear has been reported as 'needing follow-up'. You should contact your smeartaker for more information about this result.

It is very important that you do this.

Please read the leaflet enclosed and take advantage of this opportunity to take care of your health.

Yours sincerely,

[signature]
[name]
[title]

Ref: ABNGP ([BatchReference])(REV F)
[eof]

Appendix 1f Deferral of woman's smear test by doctor

RE: Woman's Name: «Title» «FirstName» «LastName»
Address: «Address1»
«Address2»
«Address3»
«Address4»
«Address5»

DOB: «DOB»
PPSN: «PPSN»
CSP ID: «CSP ID»
Surname At Birth: «Surname At Birth»
Mothers Maiden Name: «Mother's Maiden Name»

Previous Smear Test - Date:
Result:
Laboratory:

I wish to defer this client's smear for the following reason:

Pregnant _____

Illness _____

Other (please specify) _____

Postpone CervicalCheck Invitation until: _ _ / _ _ / _ _

Signature of Doctor _____ Date: _ _ / _ _ / _ _

Doctor's Stamp

[1] CervicalCheck expects that women with a smear test result that is not normal will not be deferred.

Appendix 1g Woman Failsafe

Date: [system_date]

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

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

Dear Ms [Surname],

Smear result - reminder

The result of your smear test taken on the [testdate] recommended 'follow-up'. It is important that you contact the doctor or nurse who took your smear test about this result. If you can't do this, or you have already contacted whoever took your smear, please let us know.

If we do not get information that you have attended for this smear test, we plan to continue to invite you for further free smear tests every three years – if you are aged 25 – 44; or every five years – if you are aged 45 – 60.

Yours sincerely,

[signature]
[name]
[title]

CS/F/CC-3 ([BatchReference]) Rev 9
[eof]

Appendix 1g GP Failsafe

Smear Test, Colposcopy Referral and
Post Colposcopy Treatment Follow up Form

To: Dr. [Doctorname] Date: [system_date]

Re: [fullname],
[Client address]
DOB: [DOB]
PPS No: [PPSN] CSP ID: [csp_id]

Date Smear Taken: [testdate]

The purpose of this form is to ensure that all laboratory recommendations requiring recall or referral to Colposcopy are actioned. Only one of the following scenarios,B,C,D applies to this woman:
CervicalCheck – The National Cervical Screening Programme, has not received evidence of a repeat smear test or attendance at the Colposcopy Clinic for the woman named above. As you are the clinically responsible doctor please complete this form and return it to CervicalCheck so that we can update our records. Please return completed form to CervicalCheck at the address below.

A) Are you aware if this woman has received her results Yes No

B) Was a Repeat Smear taken and sent for testing?
(Please circle as appropriate) Yes No
If yes please fill in the following:
Name of laboratory **Date of smear**

C) Was the woman referred for Colposcopy? Yes No
If yes please fill in the following:
Name of clinic **Date**

D) Was a Post Colposcopy Smear taken
and sent for testing? *(Please circle as appropriate)* Yes No
If yes please fill in the following:
Name of laboratory **Date of smear**

E) Is the woman to the best of your knowledge?
still at the address on record Yes No

If No and you know her new address, please fill it in here:
New address

Signature of Doctor _____

Date _____

CS/F/REG-16 GP FAILSAFE Rev 4
[eof]

CervicalCheck Charter for Women

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 smeartaker 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 smeartaker 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 smeartaker 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

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

See **Section 1** for information on CervicalCheck training programmes

Doctors and other health care professionals in primary care settings who provide cervical screening services are requested to register with CervicalCheck. When registering, the General Practitioner (GP) in primary care settings is required to sign a contract with the NCSS 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 Number for doctors and to An Bord Altranais Number for nurses.

Practice nurses who register with CervicalCheck must nominate a doctor who will assume clinical responsibility for their smears. GP registrars and locums working in a registered smeartaker's practice for a period of more than one month and who are involved in smear taking 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 smears 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 both the individual screening test process and the subsequent handling of results.

Each initial smear taken within the Programme is paid for by CervicalCheck even in cases where women had not previously received a letter of invitation from CervicalCheck. Subsequent smears, including post colposcopy smears, are paid for only if taken according to the laboratory's recommendations from the previous report. Smears 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 e.g. women under 25 years or over 60 years of age, etc.

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

Each practice should develop a tracking system for smear 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 smears 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

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.	See **Section 4 & 6** for further information
Consent	To explain the consent process to the woman so that she understands why she is signing consent.	See **Section 4 & 6** for further information
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 to be correctly interpreted and her results appropriately managed.	See **Section 4** for further information
Taking a quality smear	This is discussed in detail in Section 4.	See **Section 4** for further information
Transporting the smear	To ensure that the smear is transported to the laboratory in a timely fashion.	See **Section 4** for further information
Record keeping	To ensure that a record of the smear is kept in the practice. This record may be either manual or electronic.	See **Section 5** for further information
Reviewing results	To check that all smear results have been received.	See **Section 5** for further information
Communicating normal results	To notify the woman of a normal result.	See **Section 5** for further information
Following-up on not normal results	To notify the doctor with clinical responsibility of any action recommended on the smear result.	See **Section 5** for further information
Carrying out recommendations	To take a repeat smear if this has been recommended.	
Equipment	To use the recommended equipment to comply with all EU sterilisation standards for equipment.	See **Section 4** for further information
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

Responsibility for all smears	To hold responsibility for all smears taken in the practice and to ensure that the patient environment complies to quality standards and is conducive in terms of privacy, heating and lighting.	
Inform CervicalCheck of deferrals	To complete and return the deferral form to the CervicalCheck office.	See **Section 1** for further information
Follow-up on smear tests	To follow-up on all smears 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.	See **Section 5** for further information
Counsel women about results	To counsel women about their results. Counselling about abnormal results should typically take place in a face-to-face setting.	See **Section 6** for further information
Further investigation	To initiate further investigation or referral as indicated by the smear test result.	See **Section 5** for further information
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.	
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.	
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 smeartakers in the practice e.g. doctors, practice nurses, locums or GP registrars, etc. are competent and registered with CervicalCheck.	See **Section 1** for further information

SECTION 3

Cervical cancer and screening

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. While all cancer accounts for approximately 20 per cent of deaths in women in Ireland[1] and for 40 per cent of premature deaths, cervical cancer accounts for 1.8 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 cancer die within five years.

3.2.2 Incidence of cervical cancer

In Ireland, there is an average of 180 new cases of cervical cancer diagnosed (Table 3.1) and 73 deaths reported each year. In the absence of a full screening programme in Ireland, deaths from cervical cancer have been increasing by an average of 1.5 per cent per year since 1978 (Figure 3.1). The incidence rates fall within the mid-range of rates observed across Europe but exceed that seen in the USA. Ireland is the only region of the British Isles where the mortality rate continues to rise. In particular, the rate of reduction in deaths from cervical cancer in the UK was seen to accelerate when a more stringent call and recall system was introduced in 1988 (Quinn et al, 1999). Prior to the establishment of a National Cervical Screening Programme, it is believed that an appropriate number of smears were taken opportunistically in Ireland. However, as the whole population who are at risk were not being screened, this smear taking activity has had little or no impact on the detection and appropriate management of cervical disease.

The following table provides an outline of the incidence rates of cervical cancer in Ireland between 1994-2005 as documented by the National Cancer Registry Ireland. The increase in the number of cases of cervical cancer has kept pace with our increasing population.

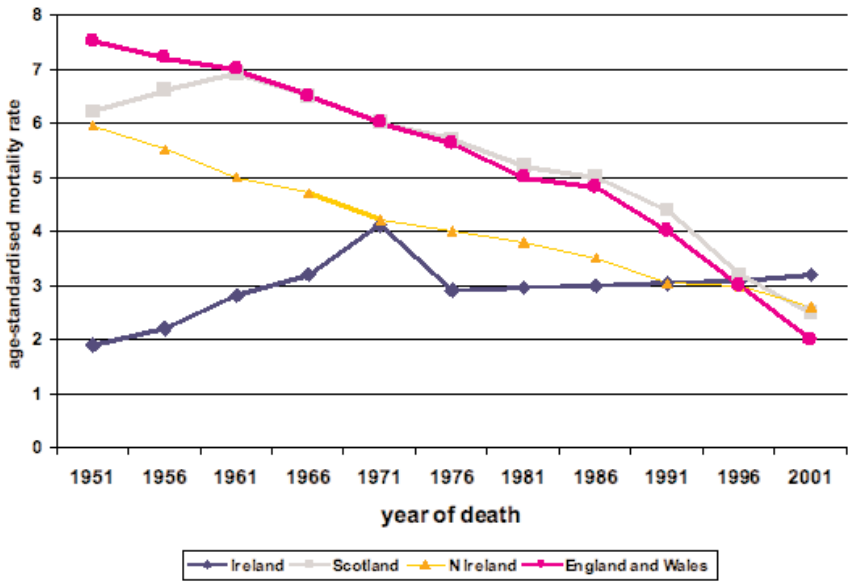
1 *CSO: Vital Statistics, 1999.*

Table 3.1 Incidence of cervical cancer in Ireland, 1994-2005

Year	NUMBER OF CERVICAL CANCER CASES	% OF TOTAL NUMBER OF CASES
1994	174	1.8%
1995	156	1.63%
1996	212	2.09%
1997	173	1.66%
1998	182	1.75%
1999	154	1.45%
2000	189	1.68%
2001	185	1.59%
2002	207	1.71%
2003	203	1.57%
2004	200	1.49%
2005	252	1.81%

Source: The National Cancer Registry of Ireland

Figure 3.1 Deaths from cervical cancer, Ireland & Britain 1951-2002



Source: Comber, H. & A Gavin, A (2004): British Journal of Cancer 91, 1902 -1904

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 mild, moderate and severe dyskaryosis. 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** 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. The benefits of screening are that these and less severe changes can be identified and treated before they cause symptoms, resulting in an earlier diagnosis of cervical cancer than otherwise might have occurred. Screening tests offer the best opportunity to detect cervical cancer at an early stage when successful treatment is likely, and 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. Borderline Nuclear Abnormality or BNA 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 HPV.

See **Section 5** for further information

More severe changes are termed dysplasia or Cervical Intraepithelial Neoplasia (CIN) or squamous intraepithelial lesion depending on the terminology adopted by the laboratory (Table 3.2). These changes represent long term viral persistence.

Table 3.2 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
Cacinoma in Situ	CIN 3	HGSIL

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

Table 3.3 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 3.3 Outcomes relating to CIN classifications

Dysplasia Classification	CIN 1	CIN 2	CIN 3
Regress	57%	43%	32%
Persist	32%	35%	56%
Progress	11%	22%	-
Ca in Situ (Invasive)	1%	5%	>12%

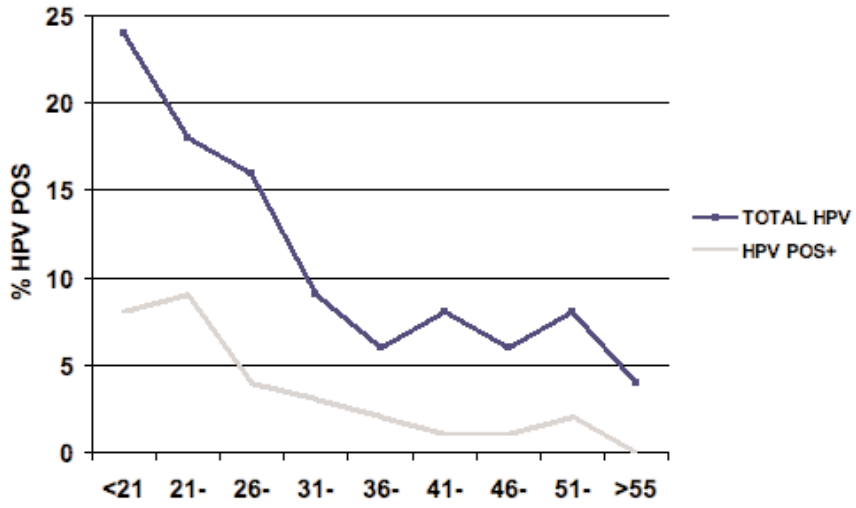
Source: Ostor (1993)

3.4 Risk factors and the role of the HPV

3.4.1 Infection with HPV

It is now understood that cervical infection with one of approximately fifteen 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% of sexually active women become infected with HPV (Winer et al, 2003). However, most women either clear or immunologically "contain" the viral infection and only a small percentage of those infected go on to develop cervical cancer.

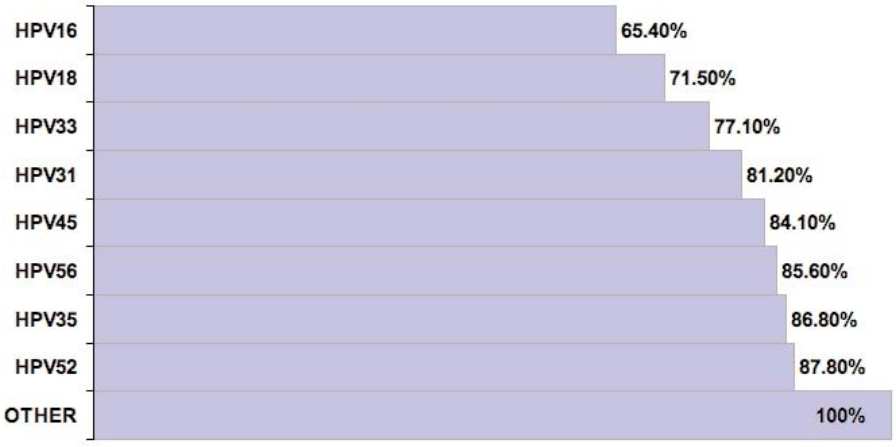
Figure 3.2 HPV prevalence by age



Source: ARHP (2001) Permission kindly granted by Article author.

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. 87.8 per cent of cancers are caused by eight particular types; 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

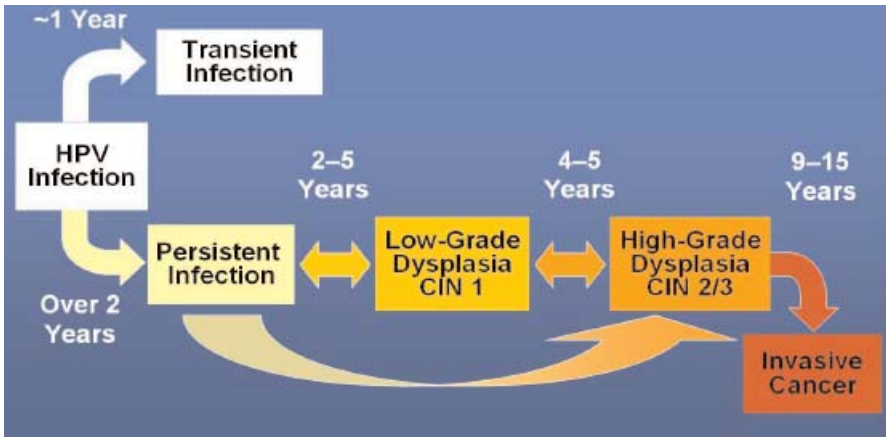


Source: Adapted from Muñoz (2000)

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.

Research has shown that cervical lesions CIN 3 and cervical cancer is a smoking-related disease with an odds ratio of 1.5 with both an increase of incidence and greater likelihood of progression of the disease in those who smoke (Gram, 1992). Immuno-compromised patients, for example those with HIV or on immunosuppressant medication, are also at greater risk of cervical cancer.

Figure 3.4 Natural history of high risk HPV infection & progression to cervical cancer



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

Figure 3.4 shows the possible relationship of a HPV infection and outcomes with the probable timeline relationship depending on the individual's immune reaction to HPV.

3.5 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. The first quadrivalent vaccine has been developed from Virus Like Particles (VLP) and offers protection from infection by HPV 6, 11, 16 and 18. The first two types cause visible warts and the latter, HPV16 and HPV18, have been estimated to cause 71 per cent of cervical cancer.

The first bivalent vaccine contains VLPs of HPV 16 and 18. The vaccine results in almost 100 per cent seroconversion and subsequent protection to the development of CIN 2 and more severe cytological changes (Paavonen et al, 2007). Results from the Phase IIb and III trials show that these vaccines offer women who were not yet exposed to HPV, a very high level of protection from persistent infection and cervical intra-epithelial lesions. Phase IV studies are required to show protection against cervical cancer and verify duration of protection. These phase IV studies are also required to define future policies of screening of vaccinated cohorts. Furthermore, there is a danger that there may be an increased prevalence of other HPV oncogenic types i.e. the occurrence of cancers by non-vaccine types. 29 per cent of cervical cancers are caused by other types of HPV for which there is no vaccine at this time.

Following a request from the National Cancer Screening Service Board, the Health Information and Quality Authority agreed in July 2007 to carry out a Health Technology Assessment (HTA) on the role of vaccination against HPV in reducing the risk of cervical cancer in Ireland. The Authority asked the National Centre for Pharmacoeconomics to undertake the HTA. The purpose of this assessment was to establish the cost-effectiveness of a combined national HPV vaccination and cervical cancer screening programme compared to a cervical cancer screening programme alone.

The results of this cost-effectiveness analysis show that universal HPV vaccination of 12 year old females would be cost-effective in Ireland. At older ages, the vaccine becomes less effective due to an increased likelihood of females being exposed to the virus before vaccination.

3.6 The case for screening

Screening has been defined as the examination of asymptomatic people in order to detect their probability to having or developing the disease. The following figure outlines the key principles of screening as applied to cervical cancer.

Figure 3.5 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 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 smeartaking appears to have little impact. 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).

3.7 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 3.4 Screening as applied to cervical cancer

INTERVAL BETWEEN SMEARS IN A (YEARS)	REDUCTION IN CUMULATIVE INCIDENCE RISK (%)	NUMBER OF SMEARS 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

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 smears during her screening lifetime (25-60 years). Annual smears confer a risk reduction of 95 per cent but at a cost of women having 35 smears in their lifetime.

See **Section 1** for further information on screening intervals and the Call Process.

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 recall at every five years.

Key point:
The danger of developing cancer remains higher in those who have had treatment for CIN 3. Recent evidence from Sweden (Strander, 2007) suggests that this surveillance may need to be extended to 20 years or longer. Smeartakers are advised to follow the colposcopy discharge recommendations.

APPENDIX 3

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Notes

SECTION 4
Taking cervical smears

Taking cervical smears

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

4.1 The importance of the smeartaker

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 smeartaker must learn to harvest the cells of the squamocolumnar junction of the cervix when smeartaking 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.

See this Section at **4.2F & Section 6** for further information on consultation & communication

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 smeartakers. In addition to ensuring a quality clinical environment the smeartaker has a key role in communicating issues of consent and confidentiality.

4.2 The smeartaking process

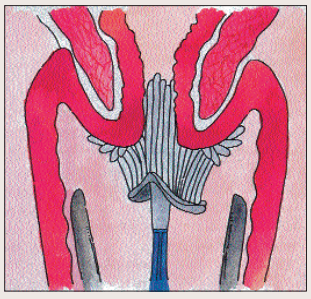
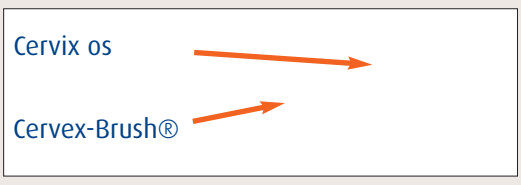
This Section considers the technical and practical process of smeartaking and covers the following areas.

KEY AREAS FOR THE SMEARTAKER TO CONSIDER	KEY POINTS
A. The smear test procedure	• 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 of dyskaryosis, which underestimates the degree of abnormality present.
B. Locating and visualising the cervix	
C. Assessment of the cervix	
D. Cervical Cytology Form	
E. Anatomy and physiology	
F. Consultation	
G. Environment and equipment	

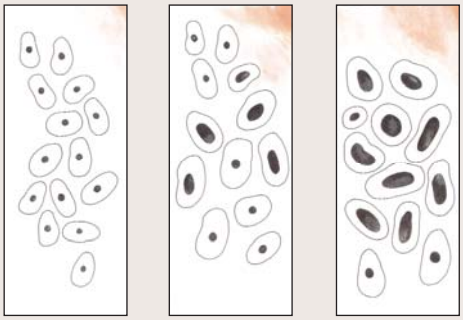
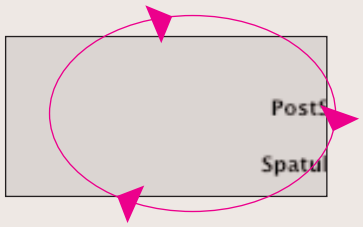
4.2A The smear test procedure

STAGE OF PROCEDURE	KEY POINTS
Chaperone 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. **Before the test** The smeartaker should ensure that the necessary supplies and equipment are ready *(see Section 4.2G).* An appropriate history taking and consultation with the woman is undertaken *(see Sections 4.2D & 6)* and any individual special requirements should be accommodated. The woman should be allowed an opportunity to empty her bladder.	There are on-going studies in the area of 'chaperone provision' particularly with reference to the primary care setting. A sensible and flexible approach is recommended (Rosental, 2005). The smeartaker should wash his/her hands before and after any procedure which involves close contact with the patient.
Background to examination 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. 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. This is the area where metaplastic change occurs (see Section 3). 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.	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. Explain to the woman what you are doing at each stage and check that she understands e.g. *"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."*

4.2A The smear test procedure contd.

STAGE OF PROCEDURE	KEY POINTS
Ideal Conditions for a Test The best time for a smear to be taken is between the 7th and 15th day of the 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 cannot be taken at a different time in a woman's cycle but should be avoided if there is menstrual blood present.	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 fourteen days after the start of menstruation. Reception staff should be made aware of this.
Type of test used The single test for smears taken in Ireland is liquid-based cytology (LBC). The sampling tool is the Cervex-Brush®. The transport medium is a liquid-filled vial. The Aylesbury spatula and the narrow 'chimney sweep' brush are NOT recommended for use. The endocervical brush is sometimes used in a colposcopy setting.	**Figure 4.1** Vial and Cervex-Brush®  Kind permission to use images received from Hologic Inc. **Figure 4.2** Cervex-Brush® in Cervix  

4.2A The smear test procedure contd.

STAGE OF PROCEDURE	KEY POINTS
What smeartakers need to understand about the test 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.	**Figure 4.3** Slide made with LBC harvested cells  Showing normal cells Dyskaryotic cells with large nuclei
Taking the sample *See 4.2B and 4.2C of this Section for information on insertion of the speculum, the visualisation, assessment and interpretation of the cervical findings.* 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 smeartaker should sweep the brush around the whole transformation zone including the margins. 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. Copious cervical mucous can be removed before taking the smear 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.	It is vital to rotate in a clockwise direction as the plastic bristles are bevelled and only harvest cells when rotated in this direction. The smeartaker must visualise the cervix and sample the whole circumference of the cervical os, including the transformation zone. 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. **Figure 4.4** Rotation of Cervex-Brush®  Five times in a clockwise direction

4.2A The smear test procedure contd.

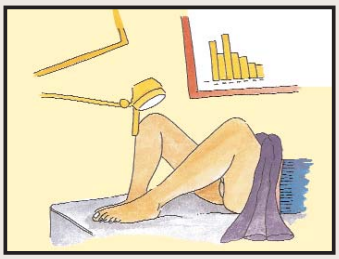
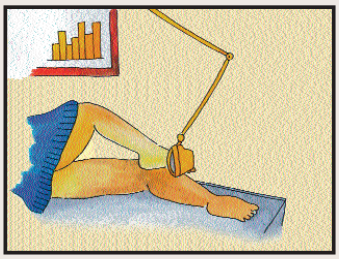
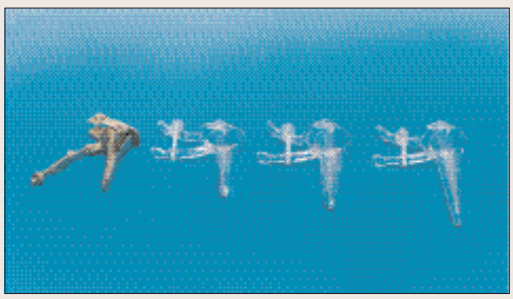
STAGE OF PROCEDURE	KEY POINTS
Preparation of sample for the laboratory The cells need to be transferred directly into the liquid and this is done immediately with vigorous *"mash and bash"* action to ensure maximum yield. It is recommended that the bristles of the brush are pushed vigorously against 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. 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. 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.	Lights in a surgery are hot and can quickly dry samples, making them unreadable in the laboratory. The vial should be prepared immediately and not left standing while dealing with the speculum, woman or the Cervical Cytology Form. In order to be accepted at the laboratory, a slide or vial must contain at a minimum: the woman's surname, first name / initial and date of birth. These details must all exactly match the details on the Cervical Cytology Form. **Figure 4.5** Preparing sample for laboratory  Kind permission to use images received from Hologic Inc.
Submitting samples to the laboratory Liquid based cytology vials must be posted within five working days, even if the transport box is not full. Boxes are reusable and should not be written on. It is advisable to log the day of posting the smear and one 'bar code' label should be retained when posting to allow for tracing in the event that a package is lost in transit.	Best practice is to dispatch the sample on the day it is taken. **Figure 4.6** Vial in transport box 

SUMMARY	KEY POINTS
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 LBC vial and cap. 6. Put into a suitable transport container. 7. Record details of the smear on the Cervical Cytology Form and in the woman's clinical notes. 8. Enter the smear in a practice tracking system, manual or electronic. 9. Post promptly to the laboratory to minimise turnaround time.	The smeartaker should wash his/her hands before and after any procedure involving close contact with the patient. In order to take an adequate sample the cervix must be visualised in its entirety. Attention to detail is of vital importance to ensure a quality smear. Poor sampling may lead to failure to detect abnormalities. A negative or inadequate smear can occur in invasive cancer of the cervix and endometrial cancer. If the smeartaker 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. Ensure that all results are received and recommendations acted upon. Responsibility for posting the smear lies with the smeartaker.

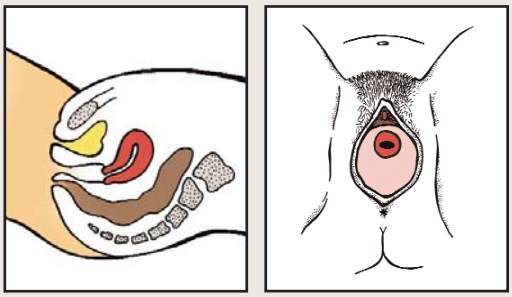
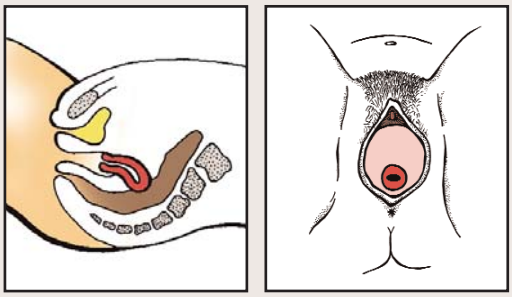
Message for woman

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.

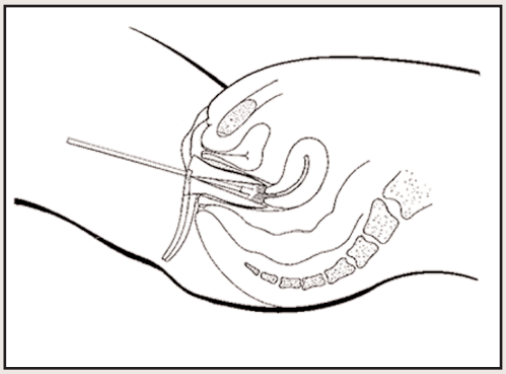
4.2B Location and visualising the cervix

STAGE OF PROCEDURE	KEY POINTS
Prepare the woman Ask the woman to undress to the waist behind the screened area 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. The position of the woman is important and the time spent ensuring she is in the correct position will make finding the cervix easier. The woman should be asked to bend her knees while keeping her feet together. 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. 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 smeartaking, it can be effective to reposition the woman and for her to place her fists under her buttocks. Some women may be used to having smears 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.	It is important to help the woman to relax. For some women, explanation of the various steps in the procedure helps them to relax. 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. **Figure 4.7a** Positioning of the woman – dorsal  **Figure 4.7b** Positioning of the woman - left lateral 
Choose a speculum A tray or trolley with the appropriate equipment and full range of speculae should be close at hand. When choosing a speculum, the age, parity and size of the woman should be taken into consideration. If using a disposable speculum, the package should not be opened until ready for use. When using reusable speculae, a range of sizes should be available and in a sterile state.	Ensure used or non-sterile instruments are kept separate from clean/sterile instruments. **Figure 4.8** Speculae - different sizes 

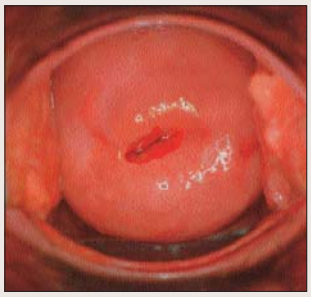
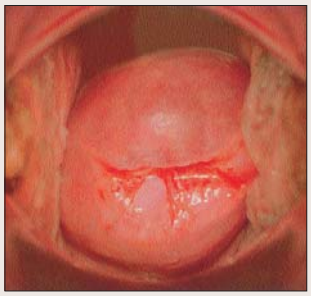
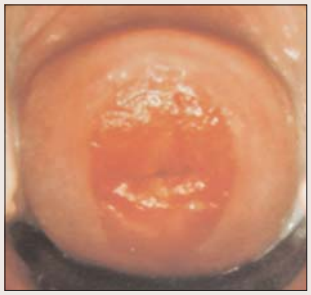
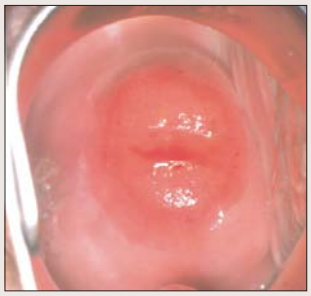
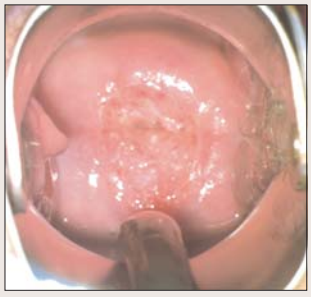
4.2B Location and visualising the cervix contd.

STAGE OF PROCEDURE	KEY POINTS
Position of the light Good lighting is vital in finding and assessing the cervix and taking a smear test. Wall-mounted or floor standing lights with halogen bulbs are recommended. 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. To prevent contamination, the light should be handled with a paper towel or elbowed out of the way, when gloved.	It is important that the smeartaker moves away from the light when transferring the cells as strong lighting can cause cells to dry out before fixing them in the liquid.
What to understand about locating the cervix 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. 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. Some women have small tight vaginas, some (usually those who have had vaginal deliveries) will have larger vaginas and some due to loss of muscular tone will have 'floppy' vaginal walls that can make it difficult to visualise the cervix.	The smear should not be taken if the smeartaker is unable to identify and visualise the entire cervix. **Figure 4.9a** Anteverted uterus  **Figure 4.9b** Retroverted uterus 

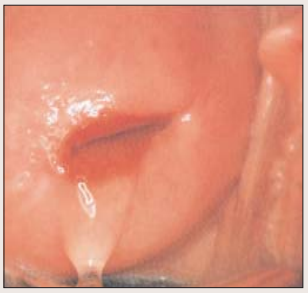
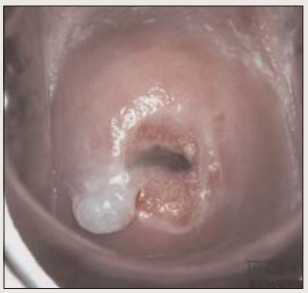
4.2B Location and visualising the cervix contd.

STAGE OF PROCEDURE	KEY POINTS
Insertion of the speculum 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 a cylinder cut from the finger of a large surgical glove may prevent the vaginal walls from obscuring the cervix. The smeartaker should check the temperature of the speculum and adjust to body temperature. This, however, is not necessary with disposable plastic speculae 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. 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. 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. 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, 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.	Message for the woman: *"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".* A woman's request to stop the procedure at any time must be respected. If visualisation proves difficult it may be helpful to start again and re-position the woman. *(see 4.3 in this Section)* **Figure 4.10** Insertion of the speculum  In the clinical notes, record difficulty and any solution that may be helpful on the next occasion e.g. *this lady has a retroverted uterus and cervix is found anteriorly in the vagina,- or the cervix very posterior and longest speculum useful, etc.* If the cervix is present but you cannot visualise it, do not take the smear test.

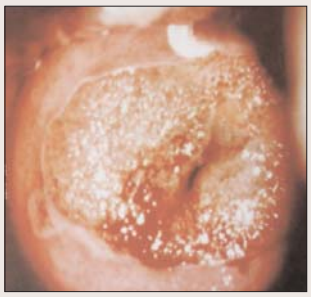
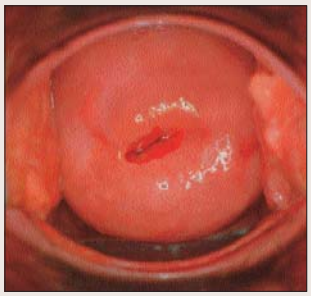
4.2C Assessment of the cervix

ASSESSMENT	KEY POINTS
The appearance of the cervix Inspection of the vulva and vagina will aid the smeartaker 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. 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 smeartaker 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 smeartaking and precancerous abnormalities are invisible to the naked eye. 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 4.2E of this Section on Anatomy & Physiology). Microscopic examination of the cells brushed from the epithelium can determine if there is an abnormality or CIN present.	The cervix may look normal even if there is an abnormality present.  **Figure 4.11a** Normal cervix  **Figure 4.11b** Multiparous cervix  **Figure 4.11c** Cervical eversion (Ectropion)  **Figure 4.11d** Normal cervix - eversion undergoing change into Squamous Epithelium in the Transformation Zone  **Figure 4.11e** View of normal cervix eversion almost Completetly transformed into squamous epithelium

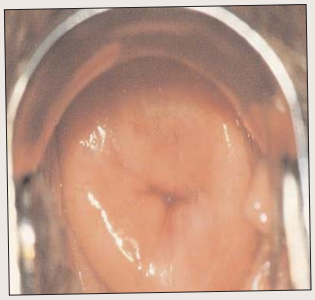
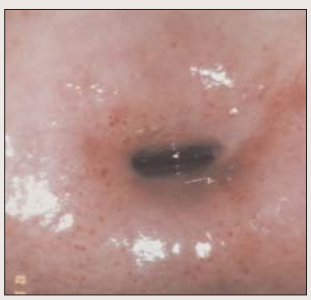
4.2C Assessment of the cervix contd.

ASSESSMENT	KEY POINTS
Bleeding when taking the test Contact bleeding when screening is not uncommon and liquid based cytology can remove some red blood cells. 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.	It is recommended that the best time to take a smear test is mid-cycle and menstrual smears should not be taken. STI screening is not part of the cervical screening process.
Cervical mucous The cervix secretes mucous that covers the endocervical canal and the vaginal epithelium. 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 micro-organisms from colonising and infecting the cervix.	**Figure 4.12a** Mid-cycle mucous  **Figure 4.12b** Excess mucous  Excess mucous will obscure the smeartaker's view of the entire cervix and interfere with sampling. Gentle removal without touching the cervix is advised.

4.2C Assessment of the cervix contd.

PHYSIOLOGICAL CHANGES	KEY POINTS
Common physiological changes Cervical ectropion involves the eversion and migration of cells from the inner lining of the endocerval canal or endocervix to the outer portion of the cervix or ectocervix. An eversion used to be called an erosion or ectropion. 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 smeartaker might expect to see an eversion if the woman is taking hormonal contraception. If a wide eversion is present, the smeartaker 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.	**Figure 4.13** Normal cervix with large eversion (ectropion)  It should be noted that the position of the transformation zone varies during a woman's lifetime. Ref A&P Section 4.2E **Figures 4.14** Normal cervix with no eversion noted 

4.2C Assessment of the cervix contd.

PHYSIOLOGICAL CHANGES	KEY POINTS
During pregnancy The cervix during pregnancy is engorged, has a purple hue and may bleed more easily.	Smears during pregnancy are usually not necessary if a woman's previous smears are normal and may be deferred until three months post partum. If the woman does need one there are usually no contra-indications to having one preformed.
Breast feeding Breast feeding mothers who are due a screening smear should be advised that though the smear test is not optimal while breast feeding due to the hormonal changes that occur at this time it is unwise to defer screening indefinitely. It is reasonable to wait until breast feeding is finished but if deferral is > 3 months it is advisable to proceed with the smear test.	Remember some women will breast feed for 2 years, may then become pregnant and so a lengthy delay in screening may ensue.
Post-menopausal The post-menopausal cervix appears shrunken and the squamocolumnar junction having receded into the endocervical canal. The cervix may look pale and dry, and bleed easily. 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 may be reported as inadequate. In order to take a quality smear in older women, a course of local oestrogen for four weeks (if there are no contraindications) may be needed to allow the columnar epithelium to 'evert'. This will allow the transformation zone to be sampled adequately.	Three inadequate smear tests, for whatever reason, warrant referral for colposcopy. After one inadequate smear result, the older woman should be offered local oestrogen and the smear repeated soon afterwards. The minimum interval for a repeat of an inadequate smear is three months which allows the cells of the cervix to regenerate. **Figure 4.15a** Post menopausal cervix  **Figure 4.15b** Post menopausal cervix 

4.2C Assessment of the cervix contd.

PHYSIOLOGICAL CHANGES	KEY POINTS

Anomalies, nabothian follicles & cervical polyps

There are a number of physiological changes that the cervix may undergo.

Nabothian follicles are mucous filled cysts on the surface of the cervix. 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.

There are two distinct types of cervical polyps: sessile and pedunculated and where present, smears should be taken as usual. Referral for removal may be indicated.

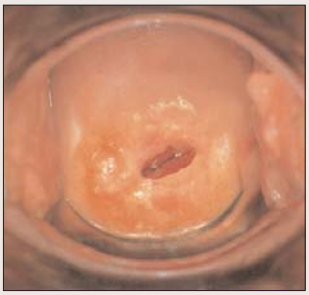


Figure 4.16 Nabothian follicles

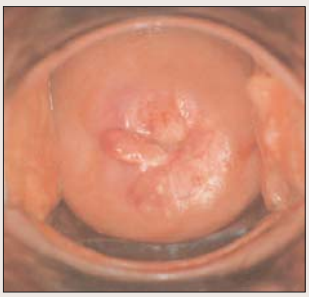


Figure 4.17 Pedunculated polyp

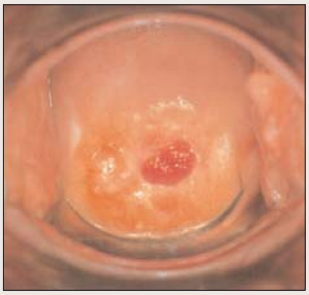
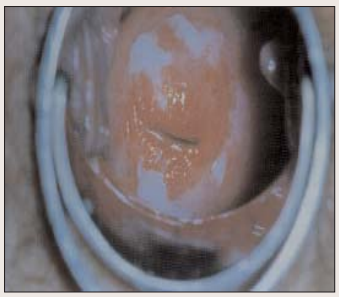
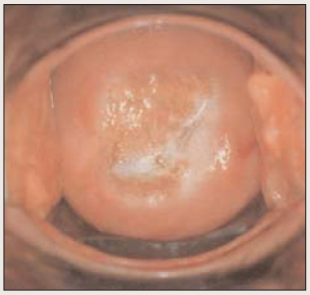
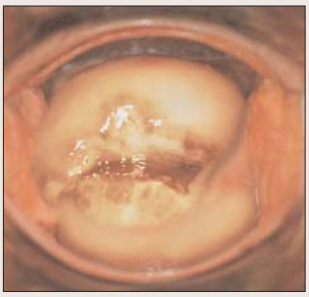
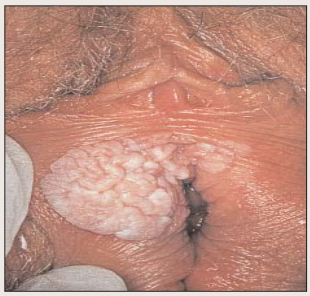
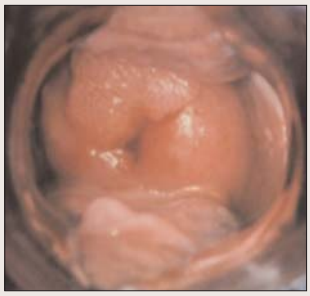


Figure 4.18 Sessile polyp

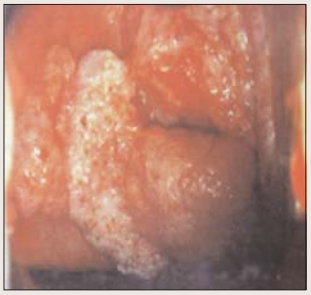
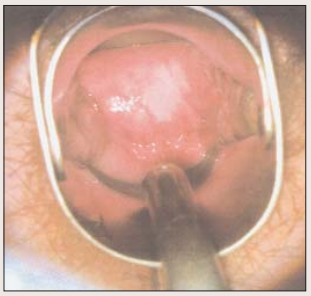
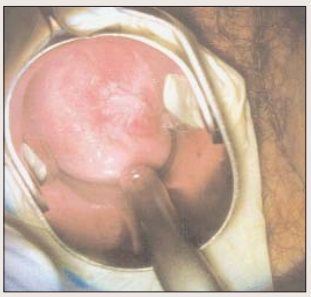
4.2C Assessment of the cervix contd.

NON-CANCEROUS DISEASES & THE CERVIX	KEY POINTS
Infections The vulva and vagina may show evidence of infection and infections can affect the smear result. The vulva vagina may show evidence of infections and infections can affect the smear result. Infections maybe acute or chronic. 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.	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. It is important to note that the smeartaker is primarily interested in a quality test - the diagnosis and management of infections is outside the scope of this Guide.
Vaginal candida (Moniliasis) 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.	The likely presence of thrush should be noted on the Cervical Cytology Form. **Figure 4.19** Vaginal candida 
Non-specific cervicitis Acute, non-specific cervicitis may result from direct trauma, and/or from the use of douches and ointments. 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. **Purulent discharge from the cervical os** 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.	Consideration should be given to identifying and treating an infection before smear testing. **Figure 4.20** Purulent discharge 

4.2C Assessment of the cervix contd.

NON-CANCEROUS DISEASES & THE CERVIX	KEY POINTS
Herpes infections 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.	**Figure 4.21** Herpes infection 
Human Papilloma Virus (HPV) & warts HPV produces two types of lesions 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. Cytologically, the presence of the Human Papilloma Virus causes a large perinuclear halo and other nuclear changes. Warts are caused by Human Papilloma Virus (see Section 3 of this Guide).	**Figure 4.22** Vulval warts  **Figure 4.23** Warts on the cervix and vaginal walls  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.

4.2C Assessment of the cervix contd.

CANCER OF THE CERVIX	KEY POINTS
Cancerous changes of the cervix Advanced invasive cancer of the cervix 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. Invasive cancer of the cervix is rarely seen by regular smeartakers and if suspected, referral to a gynaecologist is urgently required. A smear 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.	The cervix should be visualised at each smear test. Undiagnosed abnormal bleeding requires investigation. Abnormal cells may occupy only a small area of the transformation zone. **Figure 4.24** Cancer of the cervix 
A vault smear There are occasions when it is advised that a smear 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. The commonest 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. 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.	**Figure 4.25** Vault  

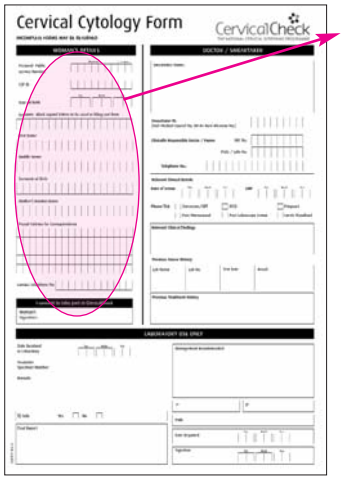
Message for the woman

The biggest risk factor for cervical cancer is never having had a cervical smear screening test.

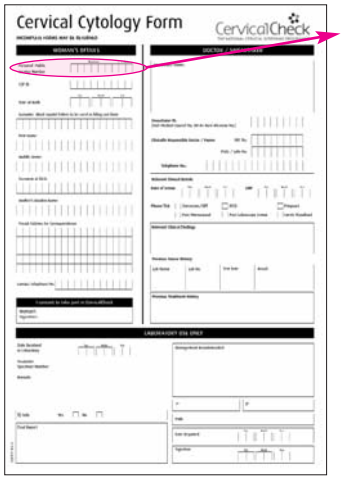
Cervical screening endeavours to pick up abnormal cells on the cervix that if left untreated may turn cancerous.

The presence of genital warts does not necessitate more frequent smear tests.

4.2D The Cervical Cytology Form

THE CERVICAL CYTOLOGY FORM	KEY POINTS
What is the Cervical Cytology Form? Over one million women will be eligible for screening in the National Cervical Screening Programme. 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. Arrangements are presently being made to allow for electronic form filling. CervicalCheck currently holds records on all women who have had smears within the Programme. This information is available through the electronic link to the laboratory which allows for each woman's smear history, once on the system, to be easily retrieved should she move location or change smeartaker.	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
 **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): • DOB • Forename • Surname at birth • Mother's maiden name • PPS Number • 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. Women and smeartakers need to understand the importance of informing the Programme if an address changes.	Accurate information is vital for identification. The contact phone number on the Cervical Cytology Form can be useful in cases where there is any doubt about the woman's identity. Women can use the Freephone information line to inform the Programme of any changes to their personal details. Demographic details should be printed one letter per box.

4.2D The Cervical Cytology Form contd.



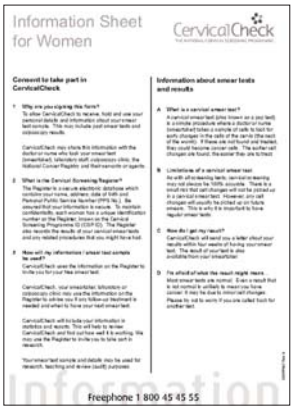
THE CERVICAL CYTOLOGY FORM	KEY POINTS
Personal Public Service Number (PPS No.) The success of the delivery of the screening Programme requires the use of the unique identifier, the Personal Public Service Number (PPS No.). It is vital that all smeartakers understand the importance of the unique identification number to ensure accuracy in the follow through of a woman's smear processing stages and that all women should have a PPS number.	PPS Numbers can be found from the following: • Social Welfare Office • NCSS/ CervicalCheck information line or invitation letter • On GMS Medical Card or Drugs Cost Subsidy Card
Using the Information Line Smeartakers can use the information line to access smear information, PPS Numbers and eligibility about women presenting for smear tests, etc. Women can use the line to make changes to their demographic details and check issues related to their smear tests.	The Freephone information line is open from 9.30am – 5.00pm weekdays with the exception of bank holidays. Clinical details are not made available to women via this information line. Clinical information is only available from the smeartaker.
Pre-screening & form filling The key question the smeartaker needs to ask at the pre-screening stage is whether the woman has ever been sexually active. She will need regular smears if she answers positively. Questions about a woman's sexual history and the number of partners are irrelevant and need not be asked. Her personal identity and contact details should then be entered on the Cervical Cytology Form at this point.	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. The Cervical Cytology Form is the only form in use when taking a screening smear within the CervicalCheck Programme. The Cervical Cytology Form is about: • Connecting the 'right woman' with the 'right result' • 'Legible' information • 'Correct' information • 'Complete' information

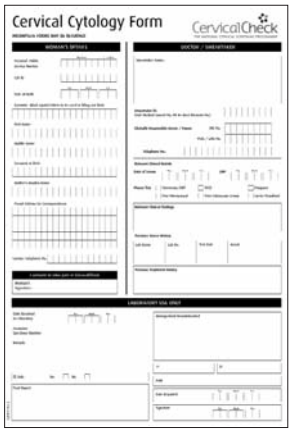
See sample of completed Cervical Cytology Form in **Appendix**

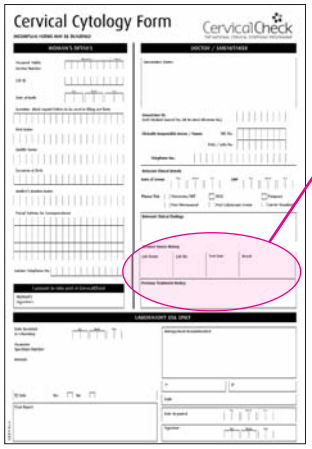
4.2D The Cervical Cytology Form contd.

THE CERVICAL CYTOLOGY FORM	KEY POINTS
Information for women & consent (See also Section 4.2F & Section 6) • Clear simple information is readily available • Research evidence indicates that information which women can take with them is valuable • Leaflets designed for the woman are of help to both the smeartaker and the woman and will assist in making the screening a more positive experience for women **Consent** (see Section 6) There are a number of aspects regarding consent: • Consent to use personal information so that it can be received and retained • Consent to use medical information arising out of the smear test as necessary and • Consent to retain and use the slide / vial for audit and research	The woman participating in the screening programme must sign consent on the Cervical Cytology Form each time she has a smear test through the Programme.

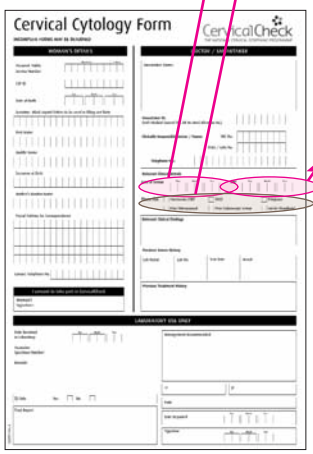
History taking
Questions to ask the woman that are useful and which will assist in ensuring her comfort, and in focusing the smeartaker on each individual smear:
1. Any abnormal bleeding:
  • Post-coital bleeding (PCB)?
  • Inter-menstrual bleeding (IMB)?
  • Post-menopausal bleeding (PMB)?
2. Any unusual vaginal discharge?
3. Any pain or discomfort with sexual intercourse?	







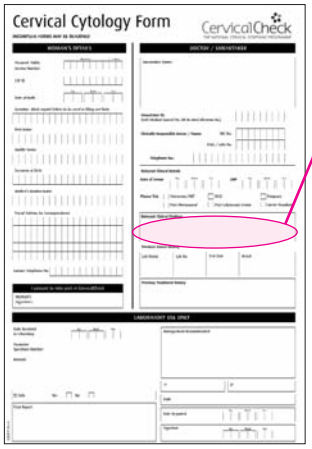
4.2D The Cervical Cytology Form contd.



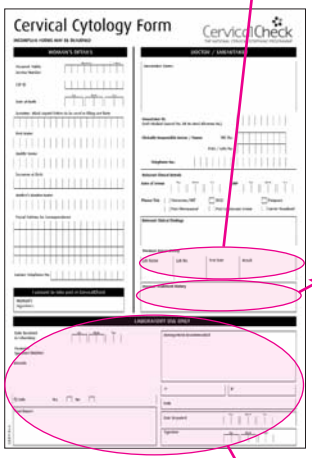
CLINICAL DETAILS	KEY POINTS
Date of smear test The date of **current** smear test.	It is vital to record the date of smeartaking.
Relevant clinical detail required (Boxes to tick on Form) • Cervix visualised • LMP • HRT • Pregnant • Post colposcopy smear • IUCD • Post menopausal	This information helps the cytologist to make an accurate recommendation when viewing cells at cytology.
Cervix visualised The cervix must be visualised in its entirety.	It is the responsibility of the smeartaker to visualise and assess the cervix at every smear test.
Why information related to LMP is required Endometrial cells are normally present in the first 12 days of the cycle. Outside these days or in post-menopausal women, they may be considered abnormal and are reported by the cytologist. The problem is that endometrial cells can look very similar to high grade dyskaryotic cells on the stained smear and hence the LMP can help the cytologist to decide whether they are abnormal cells or endometrial cells.	

4.2D The Cervical Cytology Form contd.

CLINICAL DETAILS	KEY POINTS
Why information about the woman's hormonal status is 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 actinomycosis which may give rise to cellular changes that mimic dyskaryosis.	All hormonal methods including: • Nuva Ring • Implanon • Depo-provara • Evra • OCP and • HRT should be recorded by ticking the hormonal box. A Mirena coil is an intrauterine system and a hormonal method. It does not interfere with the smear test.
Relevant clinical findings (free text box on Form) Describe what you see at the time of smeartaking on the referral form. Discharge warts, polyps may be of relevance to the cytologist and should be recorded in the clinical findings box.	Suggested terms to describe the cervix include: • Normal looking cervix • Eversion • Contact bleeding The laboratory recommendation for clinically described 'suspicious cervix' is referral for colposcopy even if the smear result is negative.



4.2D The Cervical Cytology Form contd.



CLINICAL DETAILS	KEY POINTS
Previous smear history Most women accessing the Programme will have a previous smear 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 minimum dataset to be entered in the appropriate part of the Cervical Cytology Form: • Previous two smear results if available (whether normal or abnormal) • Date of the last smear • Laboratory where processed (on result form) • Laboratory numbers were available (on result form) • Information and details of abnormal smears in the past (especially in the last 10 years), including date and laboratory accession number if known	It is important that the smeartaker checks, as far as possible, the woman's relevant clinical history by referring to her records and documents the smear history on the Form. Laboratory recommendations could be inappropriate without complete information.
Previous treatment history Information relating to any previous colposcopic treatment of the cervix should be recorded where available.	The danger of developing cancer remains higher in those who have a treatment for CIN 3. Smeartakers are advised to follow the discharge colposcopy recommendations for request smears.
The Cervical Cytology Form and the laboratory Each vial reaching the laboratory must be accompanied by a corresponding Cervical Cytology Form. The laboratory will reject the sample if it cannot match the details on the form to the details on the sample.	It is recommended that the samples are posted to the laboratory on the day of the test.

Laboratory recommendations are dependant 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.

4.2E 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 methaplasia. This vunerable area is known as the transformation zone where CIN 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 squamo-columnar junction comes to lie within the endocervix.

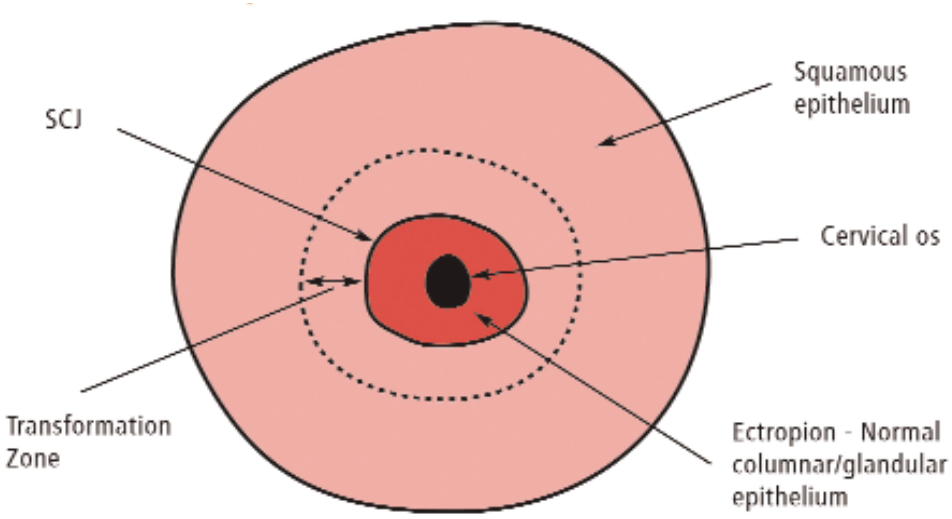
Acidic fluid within the vaginal secretion break downs the migrating columnar epithelium, which is replaced by squamous cells. This is a normal process called metaplasia. Immature metaplastic cells i.e. those in the process of changing, are more sensitive to carcinogens than mature cells.

See **Sections 3 & 5** for further information on CIN and the Classification Systems

Most cancers of the cervix develop from abnormal epithelial changes. Early changes are called Cervical Intraepithelial Neoplasia (CIN).

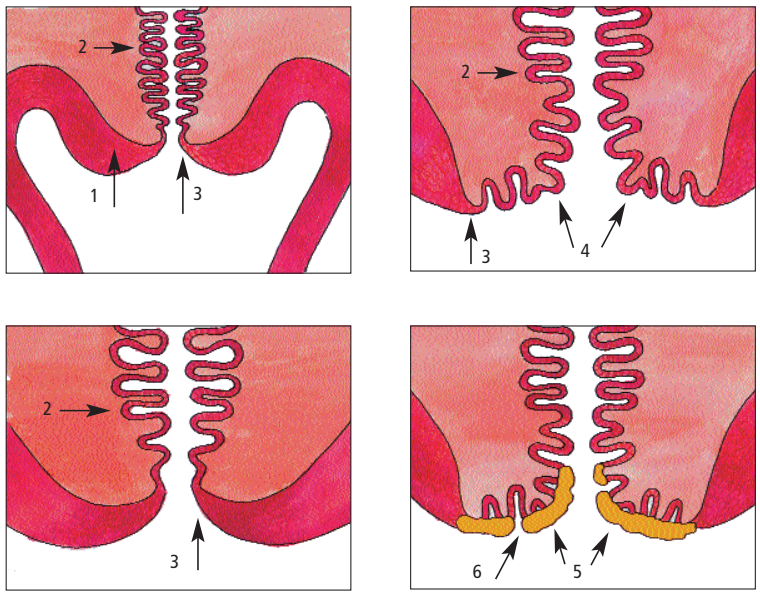
Microscopic examination of cells scraped from the surface of the epithelium of the cervix can determine whether CIN is present. CIN may occupy only a small area of the transformation zone.

Figure 4.26 Cervical Ectropion



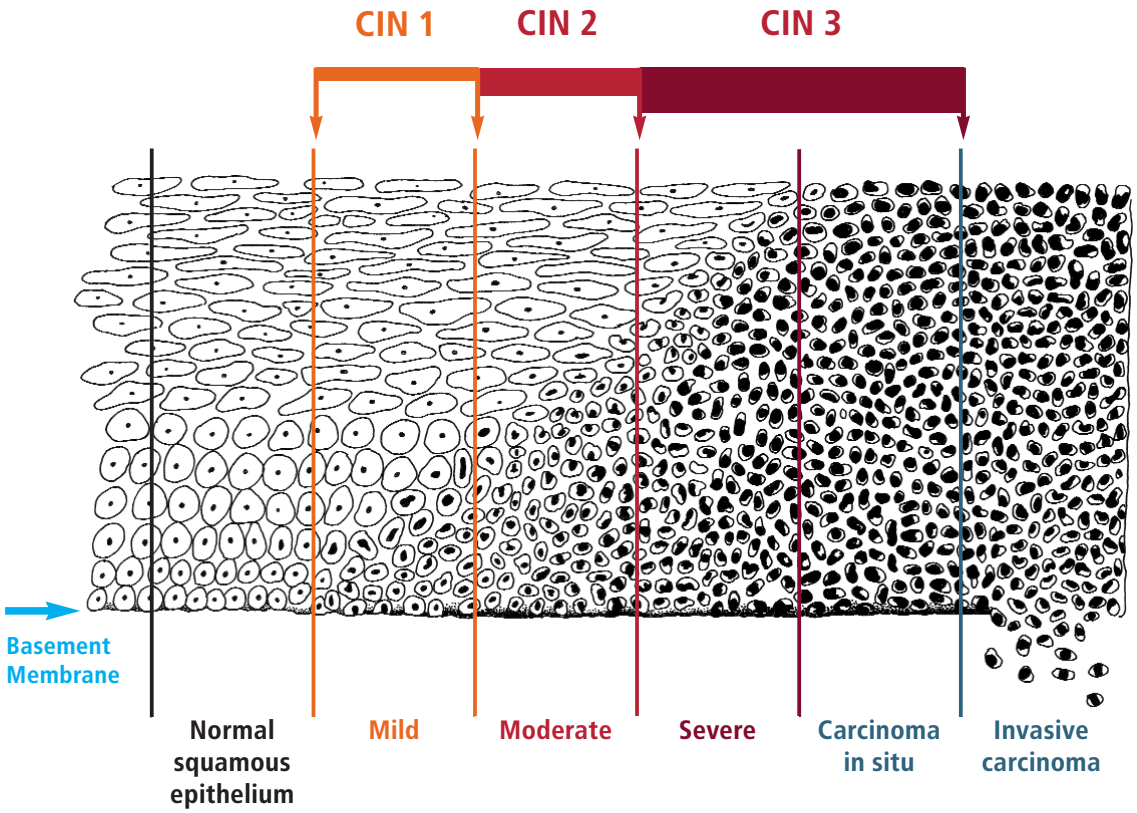
4.2E Anatomy and physiology contd.

Figure 4.27 The transformation zone



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

Figure 4.28 Cervical Intraepithelial Neoplasia



4.2F Consultation

COUNSELLING & CONSENT	KEY POINTS
Counselling Women having a cervical smear 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. It must be clear to all women having the test what a cervical smear does not detect, and that the test relates only to the cervix. No information is obtained about the other pelvic organs. Women should be advised that normality of the ovaries and uterine functions cannot be assumed following a normal smear result. Women should be given an estimated time in which they may expect to receive the result of their smear and 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 smeartaker or doctor with clinical responsibility.	**Figure 29.** Information for women  Information Sheet for Women CervicalCheck Freephone 1 800 45 45 55 Information See Section 6 on key information that smeartakers should provide to women. A charter of women's rights is available on the CervicalCheck website. It should be emphasised that the smear test is not a test for cancer. It is a screening test only.
Results 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 smeartaker 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. All counselling related to the smear must be readily available to the woman. Women undergoing colposcopic assessment and treatment are entitled to counselling from their smeartaker. For CervicalCheck registered smeartakers, all such counselling is included in the smeartaker's contract fee so no charge should be levied.	'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 (see Section 5 on communicating results). A counselling session should ensure privacy, confidentiality, trust and sensitivity.

4.2F Consultation contd.

COUNSELLING & CONSENT	KEY POINTS
Informed consent Informed consent must be obtained without duress. Consent to have the smear taken is implicit when the woman allows the test to occur. However, this should only occur after a full explanation as outlined earlier. Written consent is for permission to transfer information recorded on the CervicalCheck Cervical Cytology Form by the smeartaker to a third party. This is a legal requirement. CervicalCheck will use the information for the purposes of providing each woman with cervical screening services, including future call and recall. The information will also be used in auditing, reviewing and monitoring the delivery of the Programme. See Section 4.2D above. Should any woman decline to have her details sent to the CervicalCheck Office, she should not sign the consent form. CervicalCheck will not cover payment for this type of smear or the laboratory processing fee.	The 'Information for women' explicitly informs women that they are consenting to all aspects of CervicalCheck, including research and audit. See section 4.2D above. However, women will be given the choice not to participate in any research projects conducted by CervicalCheck. See Section 6 for further details on Informed Consent.

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 & smeartaker The smeartaker's hands should be washed before and after any duty that involves close contact with the patient. Disposable seamless gloves should be used and changed between patients.	The vagina and cervix is not a sterile area.

4.2G Environment and equipment

ENVIRONMENT	KEY POINTS
Prevent contamination of the environment There should be separate sinks for hand washing and washing instruments. There should be paper towels for hand drying. Lever taps and soap dispensers are preferable. Objects touched during the course of the procedure e.g. lamp, should be cleaned with a dry paper towel. 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.
Single-use instruments and sterilisation There are no nationally approved standards for the sterilisation of surgical instruments in general practice in Ireland. It is recommended that single use speculae are used when smeartaking in primary care. Packages must only be opened at the time of smeartaking. The speculum must not be reused. The speculum should be disposed of in clinical waste. Sterilised speculum must be sterilised according to best practice (NHS) sterilisation guidelines. 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. For in-house sterilisation, careful attention is required in the use and maintenance of sterilising equipment. Speculae 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.	Sterilising equipment for use during cervical screening procedures need to guarantee that speculae are sterile when used. Sterilised instruments must be stored in a clean dry place. Chemical cleaners are for hand use only and not for clinical use.

4.2G Environment and equipment contd.

REQUIRED EQUIPMENT	KEY POINTS
Hand washing facilities / chemical cleaning liquid The smeartaker's hands should be washed or chemically cleaned before and after any duty that involves close contact with the patient.	
Paper towels Paper towels should be used for hand washing and for handling and positioning of the light.	See Section 4.2B above.
Illumination 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.	See Section 4.2B above.
Examination couch 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.	See Section 4.2B above.
Gloves Vinyl or latex disposable gloves are recommended.	Some women are allergic to latex rubber.
Ballpoint pen Label the vial with a pen.	
Cervical Cytology Forms The CervicalCheck Cervical Cytology Form is a two-leaf form.	See Section 4.2D
Sheet, blanket, pillow A disposable sheet, pillow and blanket cover should be used for patient comfort.	
Steriliser if using reusable speculae A systematic and documented system must be in place that follows manufacturers' guidelines.	See 'Environment' above in this section.

4.2G Environment and equipment contd.

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 4.2B. 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 4.2A
Liquid-Based Cytology (LBC) vial A vial is the transport medium for liquid-based cytology.	See Figure 4.1, Section 4.2A
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 4.2A
Waste disposal bags Clinical waste needs to be disposed of with care, especially used disposable speculums 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.**	

4.3 Managing difficulties that may arise when taking a smear

4.3.1 Anticipating difficulties

Smear taking 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. If such difficulties are anticipated in advance and given due consideration, there is a greater possibility that many can be managed and the smear 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. This approach can be applied to all types of problems that can arise when taking a smear 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 (see Section 4.2A) may help. The smeartaker should offer to talk the patient 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 4.2B above).

Prescribing an anxiocytic 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 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 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 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 fisted hands 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 Vaginal discharge

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

4.3.6 Anatomical variation

Smeartakers 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 (smeartaking may proceed)

4.3.7 Medical conditions

Clinical signs of medical conditions may be observed while taking a smear. It may not be appropriate to deal with these during the smear 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.

Women who are immuno-compromised may need more frequent screening. This is currently not facilitated by the CervicalCheck call/ recall system.

4.3.8 Sensitive sexual issues

All women between the ages of 25 and 60 will receive an invitation letter to have a smear. For some women e.g. 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 (Bankhead & Austoker, 2003), and the smeartaker 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 smears.

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.

4.3.9 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 per cent) have had sex with men and that many (21-30 per cent) 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).

APPENDIX 4

* Fictional demographics used for illustration purposes.

Cervical Cytology Form

CervicalCheck
THE NATIONAL CERVICAL SCREENING PROGRAMME

INCOMPLETE FORMS MAY BE RETURNED

WOMAN'S DETAILS

Personal Public Service Number (Numbers / Letters): 6 3 7 0 1 4 8 T

CSP ID: 4 1 0 5 2

Date of Birth (Day / Month / Year): 24 / 05 / 76

Surname *Block capital letters to be used in filling out form*: Mc NAMEE

First Name: SARAH

Middle Name: JANE

Surname at Birth: DRIVER

Mother's Maiden Name: CLEARY

Postal Address for Correspondence:
6 CLOSSEY DRIVE
MUNGRET
LIMERICK

Contact Telephone No.: 081 4313720

I consent to take part in CervicalCheck

Woman's Signature: Sarah McNamee

DOCTOR / SMEARTAKER

Smeartaker Name: Angela Fahy

Address:
Meadowvale Medical Centre
Main Steet
Broadvalley
Co Limerick

Smeartaker ID: 00036942
(derived from Medical Council or An Bord Altranais No.)

Telephone No.: 081 4064122

Clinically Responsible Doctor ID or Clinic ID: 00831749
(derived from IMC No.)

PCRS / GMS No.: 00096426

Relevant Clinical Details:

Date of Smear (Day / Month / Year): 08 / 07 / 08

LMP (Day / Month / Year): 23 / 06 / 08

Parity: _____

Please Tick
- ☐ Hormones/HRT
- ☒ IUCD
- ☐ Pregnant
- ☐ Post Menopausal
- ☐ Post Colposcopy Smear
- ☒ Cervix Visualised

Relevant Clinical Findings
Large eversion noted
Contact bleeding

Previous Smear History

Lab Name	Lab No.	Test Date	Result
UCHG	1214/0	11/1/05	Negative

Previous Treatment History

LABORATORY USE ONLY

Date Received in Laboratory (Day / Month / Year):

Accession Specimen Number:

Barcode

Management Recommended

1°

2°

TZ Cells Yes ☐ No ☐

Path

Final Report

Date Reported (Day / Month / Year):

Signature (Day / Month / Year):

CS/F/PM-7 Rev 5

References and further reading

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Notes

Notes

SECTION 5

Management of smear results

Management of smear results

Aim of section
The aim of this section is to provide an overview of the key issues relating to the management of smear 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 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 smear will carry a management recommendation. The EU recommended guidelines for best practice is a turnaround time of ten days in laboratories.

5.2 Classification systems for reporting cytology

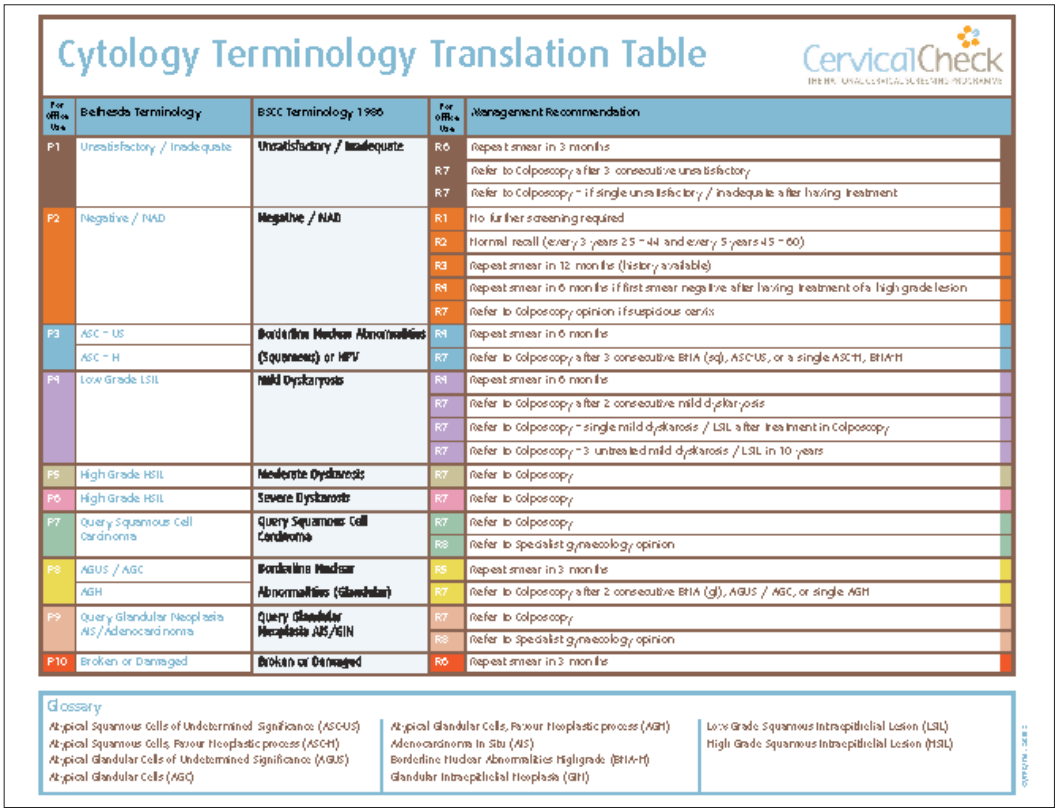
5.2.1 Bethesda and BSCC Terminologies

Smear reporting uses either the Bethesda System of Classification (TBS) or the British Society for Clinical Cytology (BSCC) CIN terminology. Bethesda terminology is used in most other countries outside of the UK and Ireland. Although the BSCC or CIN terminology has been most commonly used to date in Irish laboratories, smeartakers 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, moderate dyskaryosis with CIN 2 and severe dyskaryosis with CIN 3.

Table 5.1 Cytology Terminology Translation Table



Cytology Terminology Translation Table

CervicalCheck

For office use	Bethesda Terminology	BSCC Terminology 1998	For office use	Management Recommendation
P1	Unsatisfactory / Inadequate	Unsatisfactory / Inadequate	R6	Repeat smear in 3 months
			R7	Refer to Colposcopy after 3 consecutive unsatisfactory
			R7	Refer to Colposcopy - if single unsatisfactory / inadequate after having treatment
P2	Negative / NAD	Negative / NAD	R1	No further screening required
			R2	Normal recall (every 3 years 25 - 44 and every 5 years 45 - 60)
			R3	Repeat smear in 12 months (history available)
			R4	Repeat smear in 6 months if first smear negative after having treatment of a high grade lesion
			R7	Refer to Colposcopy opinion if suspicious cervix
P3	ASC - US	Borderline Nuclear Abnormalities	R4	Repeat smear in 6 months
	ASC - H	(Squamous) or HPV	R7	Refer to Colposcopy after 3 consecutive BNA (sq), ASC-US, or a single ASC-H, BNA-H
P4	Low Grade LSIL	Mild Dyskaryosis	R4	Repeat smear in 6 months
			R7	Refer to Colposcopy after 2 consecutive mild dyskaryosis
			R7	Refer to Colposcopy - single mild dyskaryosis / LSIL after treatment in Colposcopy
			R7	Refer to Colposcopy - 3 untreated mild dyskaryosis / LSIL in 10 years
P5	High Grade HSIL	Moderate Dyskaryosis	R7	Refer to Colposcopy
P6	High Grade HSIL	Severe Dyskaryosis	R7	Refer to Colposcopy
P7	Query Squamous Cell Carcinoma	Query Squamous Cell Carcinoma	R7	Refer to Colposcopy
			R8	Refer to Specialist gynaecology opinion
P8	AGUS / AGC	Borderline Nuclear	R5	Repeat smear in 3 months
	AGH	Abnormalities (Glandular)	R7	Refer to Colposcopy after 2 consecutive BNA (gl), AGUS / AGC, or single AGH
P9	Query Glandular Neoplasia AIS/Adenocarcinoma	Query Glandular Neoplasia AIS/GIN	R7	Refer to Colposcopy
			R8	Refer to Specialist gynaecology opinion
P10	Broken or Damaged	Broken or Damaged	R6	Repeat smear in 3 months

Glossary

Atypical Squamous Cells of Undetermined Significance (ASC-US)
Atypical Squamous Cells, Favour Neoplastic process (ASC-H)
Atypical Glandular Cells of Undetermined Significance (AGUS)
Atypical Glandular Cells (AGC)
Atypical Glandular Cells, Favour Neoplastic process (AGH)
Adenocarcinoma In Situ (AIS)
Borderline Nuclear Abnormalities Highgrade (BNA-H)
Glandular Intraepithelial Neoplasia (GIN)
Low Grade Squamous Intraepithelial Lesion (LSIL)
High Grade Squamous Intraepithelial Lesion (HSIL)

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

5.2.2 Overview of the Bethesda System of Classification (TBS)

See also Tables 3.2 & 3.3 in **Section 3**

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.

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.

5.2.3 Overview of the British Society for Clinical Cytology (BSCC)

The BSCC classification is a grading system that allows the cytologist to classify the varying degrees of dyskaryotic changes in the cells of the sample. There are three grades within this system i.e. mild, moderate and severe dyskaryosis. Mild dyskaryosis is the least severe category of change with increasing degree of abnormality through moderate to severe dyskaryosis.

In March 2002, the BSCC held a Terminology Conference at which a number of changes were recommended with a view that these changes would bring Bethesda and BSCC reporting closer together. However, these changes have yet to be agreed by other professional bodies and no implementation date has yet been proposed. The European Guidelines for Quality Assurance in Cervical Screening 2007 state that results should be 'translatable to Bethesda' (Herbert et al, 2007).

5.3 Formats in which smeartakers may receive reports

Table 5.2 Bethesda 2001 System Terminology for Reporting the Results of Cervical Cytology

BREAKDOWN	DETAILS
Specimen adequacy	Satisfactory for evaluation *(note presence/ absence of endocervical /transformation zone component.)* Unsatisfactory for evaluation... *(specify reason)* • Specimen rejected/not processed *(specify reason)* • Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of *(specify reason)*
General categorisation *(Optional)*	Negative for Intraepithelial Lesion or Malignancy Epithelial cell abnormality Other
Interpretation / result	Negative for Intraepithelial Lesion or Malignancy **Organisms** • 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 **Other non neoplastic findings** *(optional to report; list not inclusive)* • Reactive cellular changes associated with • Inflammation (includes typical repair) • Radiation • Intrauterine contraceptive device (IUD) • Glandular cells status post hysterectomy • Atrophy **Epithelial cell abnormalities squamous cell** • 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** • 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.

BREAKDOWN	DETAILS
Automated review & ancillary testing	Include as appropriate
Educational notes & suggestions	Optional

Source: Solomon et al, 2001

Table 5.3 Possible Smear Results from a Laboratory using BSCC/CIN Terminology

RESULTS	EXPLANATION
Unsuitable / Unsatisfactory / Inadequate	Most unsuitable LBC specimens are likely to be attributed to too few squamous cells present in the preparation, occurring more commonly in post-menopausal women and where insufficient pressure was used to harvest cells during smeartaking. Smears may also be deemed unsatisfactory because the reading is compromised by the presence of excess blood, menstrual debris, polymorphs or bacteria.
Negative	Normal includes simple inflammatory changes.
Borderline changes	Cellular appearances that cannot definitely be described as normal.
Mild dyskaryosis	Cellular appearances consistent with origin from CIN 1 (Mild dysplasia).
Moderate dyskaryosis	Cellular appearances consistent with origin from CIN 2 (Moderate dysplasia).
Severe dyskaryosis	Cellular appearances consistent with origin from CIN 3 (Severe dysplasia/ carcinoma in situ).
Severe dyskaryosis / query Invasive Carcinoma	Cellular appearances consistent with origin from CIN 3 but with additional features which suggest the possibility of invasive cancer.
Borderline nuclear abnormalities (glandular)	Equivocal glandular cell changes are reported on cytology as BNA (gl), although the relative rarity of glandular neoplasia should make this unusual.
Glandular neoplasia	Cellular appearances suggesting pre-cancer or cancer in the cervical canal, the endometrium or extra-uterine site. Pre-malignant change in the endocervical epithelium is commonly referred to as cervical glandular intra-epithelial neoplasia (CGIN).

Other comments on smear reports from laboratories using BSCC Terminology

Special infections:	Trichomonas, Candida and Herpes simplex can be identified.
Human Papilloma Virus (HPV):	Produces cellular appearance which may be described as koilocytosis and dyskeratosis. Varying nuclear changes will be present which may be indistinguishable from dyskaryosis.
Actinomyces:	Organisms associated with IUCD.
Endocervical cells:	These are cells from the columnar epithelium of the cervical canal. During its formation, the transformation zone will include similar epithelium. Sampling of the TZ will yield columnar (glandular) cells prior to completion of the metaplastic process.
Key note:	*Endocervical cells are not essential for an adequate smear, except in follow-up smears where the previous abnormality was seen in endocervical cells.*[1]
Metaplasia cells/ Squamous Metaplasia:	Normal cells from the transformation zone (TZ).
Key note:	*Evidence of TZ cells is not a requirement on its own for a satisfactory sample. However, it is the responsibility of the smeartaker to make every effort to sample the whole of the TZ.*[1]
Cytolysis:	A normal process of cell disintegration. The normal breakdown of cells due to the presence of lactobacilli when the vaginal environment is acidic. Most common in the second half of the menstrual cycle and in women on progesterone-only contraceptives, also common in pregnancy.
Endometrial Cells:	Cells derived from the endometrial lining of the uterine cavity. Shed during menstruation and in some other circumstances.
Inflammatory changes:	Cellular changes present in some degree in many smears which are not evidence of CIN.
Key note:	*The presence of inflammatory changes on a smear result should not be managed by repeat smear testing.*

1 NHS CSP

5.4 Smear result management in primary care

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

The Bethesda system requires at least 5,000 cells on a liquid based preparation for adequacy. Comments may be given on the report about inflammatory exudates. Women should be referred for colposcopy after three consecutive inadequate smears. 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 5.4 Specimen adequacy and results using the Bethesda system (TBS)

RESULTS	COMMMENTS
Negative for Intraepithelial Lesion or Malignancy (NILM)	NILM is the report given to a negative smear. However, it may contain a text report comment on numerous variants of benign cellular findings e.g. atrophic changes or the presence of organisms.
Low Grade Squamous Intraepithial Leisions (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 remain at higher risk of cervical cancer than women who never have had an abnormality (Strander, 2007). In view of this, the colposcopist will determine the frequency of smears post-treatment.
Atypical Squamous Cells of Undetermined Significance (ASCUS)	This category has been shown to be associated with approximately 10 per cent 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 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 recognise 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.

RESULTS	COMMMENTS
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 recognize at colposcopy.
Atypical Glandular Cells (AGC)	AGC on a smear 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).

Key Point:

Women should be referred for colposcopy if they have three test results reported as abnormal at any grade in a ten year period even if returned to routine recall on one or more occasions in that period. The doctor may be the only person to recognise this situation.

5.4.2 Communication of results

The following outlines the various processes in communicating different types of results.

RESULT TYPE	HELPFUL LANGUAGE IN DISCUSSING RESULTS
Normal 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 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 when the next smear is due.	*Assessment shows no abnormal cells.*
Inadequate/ Unsatisfactory A report is sent to CervicalCheck and the smeartaker 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. Two reminders will be sent to the woman if CervicalCheck does not receive notification that a further smear has been taken.	*The lab is unable to read this sample. This is not an abnormal result.*
Not normal 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 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 colposcopy 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 the doctor. Where a referral to a colposcopy clinic is indicated, a colposcopy referral form should be completed and a copy of the smear result should be attached. It is very important to provide adequate counselling at this point. The role of this 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 manner in which a woman is told about an abnormal test 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. 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 re-iterate the pre-malignant nature of the cellular changes seen on the smear. The fact that this is a treatable condition should also be underlined.	*If abnormal cells are found on your smear 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.* *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.*

5.4.3 Recording of results

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

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

Smear results should be recorded in the woman's medical record so that her results are immediately clear to the healthcare professional when she attends the practice for other reasons. 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 smears have been sent to the laboratory
- All results have been received by the laboratory
- All the laboratory recommendations are followed

The system can be either manual or electronic as follows:

MANUAL SYSTEM	COMPUTERISED SYSTEM
Manual records can be organised utilising 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. 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. These records can be divided into the following categories: • Smear done • Result received • Result acted upon A manual record-keeping system for these cards can be created using small storage boxes with alphabet dividers. At least two boxes are used: 1. Smear done - awaiting result 2. Result received and acted upon Additional, separate boxes may be of value for 'Action Taken' and 'Smear 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.	The procedure for entering cervical smears will vary depending on the software package being utilised. Current GP software allows recording of smear test results and the production of reports listing smears taken, results received and smears due during certain defined periods. Practices should contact their technical support or the local GP IT tutor for further information. 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.

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 5).

APPENDIX 5

Appendix 5A Colposcopy Referral Form

COLPOSCOPY REFERRAL FORM

(Please attach a copy of the referring cytology smear result form as necessary)

To: **Colposcopy Clinic** Date: Day Month Year

WOMAN'S DETAILS

Name

Address

Previous Address (if relevant)

Contact Tel Number

DOB Day Month Year

PPS Number Numbers Letters CervicalCheck ID Numbers Letters

Mother's Maiden Name Surname at Birth

CervicalCheck Smear Yes ☐ No ☐

Previous Colposcopy Yes ☐ No ☐

Referral Smear Details:

Cytology Lab Accession Number

Reporting Lab

Past Smear History:

Medical/Surgical History:

Medications:

Doctors Comment:

Referring Doctor's Stamp

Appendix 5B - 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.

References and further reading

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Notes

SECTION 6

Women's participation in cervical screening

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.

6.1 Women's participation in cervical screening

The success of any cervical screening programme is dependent on the participation of women. It is of prime importance to CervicalCheck that cervical cancer screening is effective in targeting at risk populations, and that once an abnormality has been identified, follow-up screening and treatment are provided with the minimum distress to women. The Programme aims to reduce the incidence and mortality from cervical cancer in women aged 25 to 60 years overall. The achievement of this target requires that 80per cent of the target population avail of screening. Women who have a positive experience when attending for a cervical smear 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).

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

The woman's motivation to have a cervical smear is influenced by specific attitudes, beliefs and perceptions. These include:

- The influences of her family and friends
- Her understanding of the test and possible results
- The distress and the embarrassment of the smear test
- Her perceived susceptibility to cervical cancer
- Her understanding of the importance of the disease
- The social consequences of developing the disease
- The benefits of having a cervical smear

It is important to understand the various reasons given by women who decline the opportunity to have a cervical smear. A recent study (Walsh, 2006), based on a sample of over 1,000 women who were participants of the ICSP, highlighted specific barriers associated with poor attendance (Table 6.1).

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

REPORTED BARRIERS	%
Male smeartaker	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
• Previous bad experience • Male smeartaker • Embarrassment • Fear of test • Fear of result • Not understanding test • Adverse comments about smear tests from other women or the media • Ethnic differences	• Not invited • Forgot appointment • Sick • Away • Opting out • Appointment time unsuitable • Fears about lack of confidentiality

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 smeartaker • Provision of information • Adequate time for test • Satisfactory physical environment • Explanation of how results are received • Advice on waiting times for results

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 ICSP Smeartaker Training Programme. The quotes are in response to questions as to what prompted them to attend for the smear test.

'Nurse enquired about last smear when I attended for bloods.'
'The practice posted me a letter to let me know my next test was due.'
'Doctor's advice.'
'Having attended a talk on Health Awareness for women by a GP in my local hall.'
'Nurse advised me when I was vaccinating my baby.'
'My mother died so I decided to have a full check up.'
'Advert.'
'Discussion with friends.'

6.2.2 Provision of information

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 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.'

'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.'

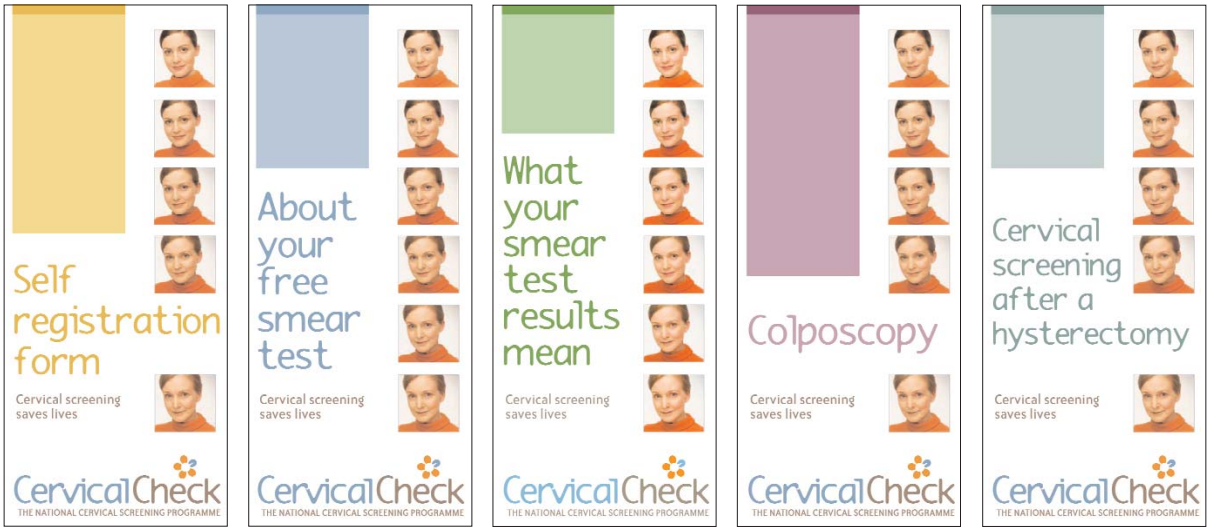
'The nurse was very gentle and put me at ease and explained everything before starting, this helped in keeping me calm during procedure.'

'My last experience was awful. It had been extremely painful and distressing. I was in dread of attending. Nurse took lots of time and did not rush when I found it sore, just gave me minutes to adjust.'

'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.



Health 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.

- Building healthy public policy
- Creating supportive environments
- Re-orienting the health services
- Strengthening community action
- 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. Thus, alternative options to increasing awareness and attendance for screening have been explored. CervicalCheck will determine its capacity to identify an area of very low uptake and consider the screening needs of women and develop appropriate strategies to support the increased participation of women as demonstrated by ICSP in the Southill Campaign Evaluation Report 2006.

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 the CervicalCheck screening promotion initiatives including the CervicalCheck information leaflets, website and freephone information Line. However, the primary source of information for most women is their doctor.

70 per cent of women get their cervical screening information from their doctor.

Sources of information on cervical screening – summary

Role of smeartaker in encouraging women to have smear test

- The doctor was the primary source (Walsh, 2003)
- The practice nurse and the ICSP were the second choice (Walsh, 2003)
- The doctor and practice nurse play major role in encouraging women to have smear (Doyle, 2006)
- Seow et al. (1995) also found that the doctor or nurse were the primary source of information on the smear test

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 may use the *'Information sheet for women'* and other information leaflets containing cervical screening.

CervicalCheck literature: A suite of information leaflets has been developed by CervicalCheck to provide women with information about the Programme with specific information on 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
- Cervical screening after a hysterectomy

CervicalCheck information line: 1800 454555 The freephone information line service has been developed to support users' needs and provides information on the Programme, CervicalCheck registered smeartakers, and offers a facility for women to register. It is a freephone service and is advertised on all CervicalCheck literature. The information line deals with approximately 700 calls per month increasing at times of media coverage or a particular promotion. Advice is of an administrative nature only and women seeking clinical information are advised to talk to their smeartaker or family doctor.

CervicalCheck website: This is an excellent resource which provides up to date information on cervical screening. The website www.cervicalcheck.ie provides a facility for on-line registration and feedback to the Programme.

Information provided to women by CervicalCheck

About CervicalCheck	CervicalCheck offers free cervical screening to women aged 25 to 60 years. Women aged 25 to 44 years will be screened every three years and women aged 45 to 60 years will be screened every five years. Women who are registered with the Programme will be sent a letter advising when to make an appointment for a free smear test with a CervicalCheck registered smeartaker of their choice. Cervical screening is a worthwhile preventative health measure. Smear tests can detect early changes in the neck of the womb; the earlier a change is found the easier it is to treat.
About the CervicalCheck register	The CervicalCheck register is a secure electronic database, which contains a woman's name, address, date of birth, Personal Public Service Number (PPS No.) and unique identification number for the Programme, known as the Cervical Screening Programme ID (CSP ID). The register also records women's screening history and results of cervical smear tests, any colposcopy procedures and any biopsies taken in a colposcopy clinic.
How a woman can register	A woman can self-register, which means she can contact CervicalCheck to give her details. She can self-register in one of three ways: 1. Ring the Freephone information line 2. Register online at the website 3. Email details directly to the CervicalCheck office If the woman's details are not already on the register, CervicalCheck will send her a letter acknowledging her self-registration.
How to defer	If a woman gets an invitation offering her a smear test that does not suit (due to having a recent smear test, going on holidays, pregnancy etc), she can arrange another date to have the smear test. The woman must contact CervicalCheck to defer having her smear test.
Opting out of the Programme	If a woman does not wish to receive the free services of the Programme, she may choose to permanently opt-out, by writing to CervicalCheck. This means that she will not be entitled to the benefits of being registered and she will receive no further communication from the Programme. However her details will remain on the register.

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 smears or return for treatment because the emotional impact is too daunting. The anxieties and distress experienced by women receiving an abnormal smear 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 the patients 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

Sexually active women under 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 smears at this time do not require treatment. Ablative treatments at colposcopy may have an effect on the subsequent competence of the cervix. Women under 25 who had an abnormal result prior to the commencement of CervicalCheck (1st sept 2008) that indicated a repeat smear test are eligible (the smeartaker is requested to attach a copy of the abnormal result & management recommendation to the referral form).

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 smears. However, women over 60 should be encouraged to have a smear if they have not done so previously. CervicalCheck will continue to call participating women who are over 60 years until a normal smear result is reported. CervicalCheck will pay for and follow-up on initial smears and on second smears after three years, assuming the first one is an adequate smear with a normal result.

6.4.3 Post-menopausal women

Post-menopausal women with atrophic cervices 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 smears from these women. The cervical cell yield from the smear test can be scanty. An atrophic smear is a smear with too few cells to allow a cytologist to report on it. Liquid-based cytology helps overcome this problem as all the cells retrieved are collected in the spinning process. The squamo-columnar junction is high up within the cervical canal. If this is apparent, local oestrogen can be used. This allows the squamo-columnar junction to evert and so avoid an atrophic result.

6.4.4 Pregnancy

It may be psychologically inappropriate or unwelcome by the women to have a smear during or shortly after pregnancy. If the woman's previous smears are normal, a smear should be deferred. A deferral form should be completed by the smeartaker and sent to CervicalCheck. A woman does not require a screening smear postnatally unless she is due to have a smear within her call/recall recommendations.

See Section **Section 1** 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) and 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. Follow-up after a hysterectomy for CIN should include three smears at six monthly intervals before discharge from the cervical screening programme.

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.

If the normality of the cervix before hysterectomy cannot be verified, CervicalCheck recommends that two vault smear tests should be taken one year apart and if both are normal, screening can stop.

6.4.6 Women who are immuno-compromised

Women who present for screening may have difficulties with their immune system. This may be due to HIV, TB or immuno-suppressant medication used in the management of arthritis, SLE / lupus, asthma, post-transplantion, etc.

Women who are infected with HIV are at a greater risk for developing dysplasia. The risk appears to increase as the number of CD4 cells (cells that play a critical role in immune responses) decreases. HIV-positive women also have a higher rate of persistent HPV infections and may be infected with the strains that are associated with severe dysplasia and cervical cancer (Cubie et al. 2000).

Women whose immune systems are suppressed for other reasons, such as by drugs that prevent rejection of organ transplants, are also at greater risk (Alloub et al. 1989). This suggests that women with weakened immunity are more likely to be infected with HPV and to have a persistent infection that does not resolve. The optimum screening interval and management for this group of women has yet to be determined but may be more frequent than three or five-yearly as per the CervicalCheck guidelines.

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 have it. Women with major lower extremity difficulties have much lower odds of receiving 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 smeartaker 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 smeartaker (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 bought 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 20-64 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 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.

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 smeartakers

There is a responsibility upon the smeartaker to ensure that non-English speakers have quality information that would allow them to be informed of the purpose and the procedure of a cervical smear. 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 smeartaker should be available as appropriate. It is also important that smeartakers are mindful that some women living in Ireland have undergone Female Genital Cutting.

6.4.9 Women with literacy difficulties

The last national literacy study conducted in Ireland found that a quarter of the Irish population is in a position where they struggle with basic literacy tasks. One in four Irish adults between the ages of 16 and 66 years have 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 liaision with NALA (The National Adult Literacy Association) 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.

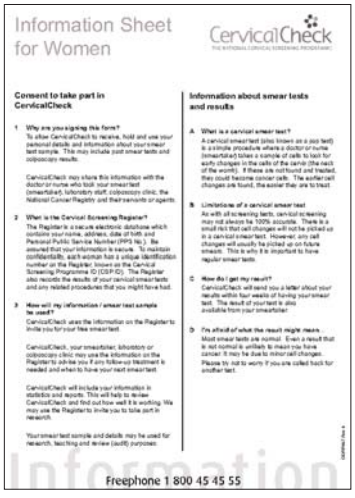
Where the smeartaker is interacting with a woman with low literacy skills, he/she will need to take greater care to ensure the woman fully understands the cervical smear. The smeartaker should not assume the woman is able to read the information provided or to complete necessary forms. Excuses like forgetting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

- Explaining everything in plain language throughout the information leaflet
- 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

Summary of key information smeartakers should provide to all women

- What the test is for and what the test involves
- Signing consent means that she agrees to be part of CervicalCheck
- CervicalCheck call and recall system
- Age and interval of smear tests
- When and how results are made available
- The limitations of smear tests
- The meaning and likelihood of a normal smear result (approx. 92 per cent)
- The meaning and likelihood of an inadequate smear result (approx. 2 per cent)
- The meaning and likelihood of an abnormal smear result (approx. 6 per cent)
- The importance of reporting abnormal bleeding or discharge even after a negative smear result
- The value of regular screening

Sample of CervicalCheck useful information for women


Information Sheet for Women

CervicalCheck

Consent to take part in CervicalCheck

Information about smear tests and results

Freephone 1 800 45 45 55

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 smeartakers 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 smeartakers

The following are some of the challenges smeartakers may face when taking smears from women with ID:

- The woman may not understand the invitation to attend for a smear
- 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	• 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	• Understand the issues relating to consent • Use one-to-one sessions with a person whom the woman knows and trusts • Use appropriate materials (picture 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	• 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 supporter who will accompany the woman understands the screening process • Discuss issues of consent with the supporter • Show the speculum and brush to the woman and allow her to handle them
Preparing the woman for the smear test	• Make sure the room is comfortable and private • Ask the woman if she wants a supporter with her during the test • Allow sufficient time to explain to the woman how the smear 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 uncooperative, stop and only proceed with her cooperation • Be prepared to make another appointment to take the smear 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
After the smear test	• Ensure that the woman receives and understands her results • Follow up as appropriate with additional support if referral to colposcopy is necessary • Most colposcopy clinics have a colposcopy nurse who is experienced in explaining the process and providing support to women on an individual basis

Good practice summary - quality smeartaking in women with ID

In addition to best practice principles for smeartaking in the general population, the smeartaker should consider 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 uncooperative, stop and only proceed with her cooperation
- 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

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Glossary

General cervical screening programme terminology

Abnormal smear	A smear which shows cells which are not typically normal or where pre-cancerous or cancerous cells are identified.
Adequate smear	A specimen which is deemed satisfactory for evaluation by the laboratory.
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 mem brane boundary of the cervical skin. Cervical cancer can be of squamous origin (approximately 85 per cent) or glandular/adeno origin (approximately 15 per cent).
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.
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. The procedure is diagnostic but may be curative as well.
Coverage	The number, percentage or proportion of women screened by a screening programme.
Diagnostic smear	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.
Dyskaryosis	Term used in cytology to describe nuclear abnormalities in cervical cells. Dyskaryotic cells are classified as mild, moderate and severe and correlate with the histological terms of CIN 1, CIN 2 and CIN 3.
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 25-60 years for whom CervicalCheck recommends and funds screening according to national policy.
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 or 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	The giving of all the necessary information by the smeartaker to the woman in order that she fully understands the smear test procedure and possible results so that she can make an educated decision to participate in the Programme. For the CervicalCheck informed consent process, the necessary information covers participation in the Programme, the transfer of data to third parties, limitations of screening, results, associated tests and treatment.
Liquid Base Cytology	The placement of harvested cervical cells into a special transport solution for sending to the laboratory where the slide is made ready for examination.
Large Loop Excision of the Transformation Zone or LLETZ	Large Loop Excision of the Transformation Zone 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.
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 predictive value	The proportion of test-negative women who do not have precancerous cervical abnormality. It is a measure of the likelihood that someone with a negative test is actually disease free.
Normal smear	A smear result that is reported to be within normal limits.

Opportunistic smear	A smear done when the opportunity presents irrespective of the woman's CervicalCheck eligibility or screening requirements.
PAP test	Another name for a 'smear test' named after George Papanicolau, 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	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.
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.
Self referral smear	When a woman presents to a CervicalCheck registered smeartaker and, at the smeartakers discretion, has her first smear test for direct entry into the CervicalCheck without having a prior invitation to do so.
Sensitivity	The ability of a test to detect a disease in all individuals in whom it is present.
Short interval smear	When a smear is undertaken before a smear is due according to the woman's screening requirements and national policy.
Smeartaker provider	A doctor or nurse who meets all the CervicalCheck registration requirements.
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.
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	A smear 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	A smear taken from the top of the vagina after a total hysterectomy.
VIN	Vulval intraepithelial neoplasia.

Contact list

CS/PUB/ST-18 Rev 2

Name	Address	Telephone/Fax	Email/Website
National Cancer Screening Service (NCSS)	King's Inns House, 200 Parnell Street, Dublin 1	Tel: 01-865 9300 Fax: 01-865 9333	Email: info@cancerscreening.ie Web: www.cancerscreening.ie
BreastCheck - The National Breast Screening Programme	King's Inns House, 200 Parnell Street, Dubin 1	Freephone information line: 1800 45 45 55	Email: info@breastcheck.ie Web: www.breastcheck.ie
Irish College of General Practitioners (ICGP)	4/5 Lincoln Place, Dublin 2	Tel: 01-6763705 Fax: 01-6765850	Email: info@icgp.ie 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	Email: facnurs3@rcsi.ie 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	Email: john.quinlivan@nuigalway.ie 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	CEO's Office, Dr Steeven's Hospital, Dublin 8	Tel: 01 635 2500 Fax: 01 635 2823	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 – 969 240 Fax :01-671 5662	Web: www.ncnm.ie Email: ipnaadmin@gmail.com
Medical Council	Lynn House, Portobello Court, Lower Rathmines Rd, Dublin 6.	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: information@nwci.ie

Screenlink LBC Consumables		Tel/Voicemail: 01-4605270 Fax: 01-4605248	Email: orders@screenlink.net
Speculum Supplier - Promed	Tulligmore, Killorglin, Co. Kerry	Tel: 1800 619 619 Fax: 1800 684 684	Web: www.promed.ie Email: comfispec@promed.ie
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

Cervical Screening Regions

CervicalCheck Region 1

Laboratory: Quest Diagnostics
Teterboro, New Jersey, USA

Tel: 1-800-657472

Lab Code: 011

Colour Code: YELLOW / GOLD

Cavan
Dublin City and County
Kildare
Laois
Longford
Louth
Meath
Monaghan
Offaly
Westmeath
Wicklow

CervicalCheck Region 2

Laboratory: Quest Diagnostics
Wood Dale, Chicago, USA

Tel: 1-800-657491

Lab Code: 010

Colour Code: WHITE

Carlow
Clare
Cork City and County
Donegal
Galway City and County
Kerry
Kilkenny
Leitrim
Limerick City and County
Mayo
Roscommon
Sligo
North Tipperary
South Tipperary
Waterford City and County
Wexford

Address for
smear tests only
Quest Diagnostics
c/o DHL Express
Airport Logistics Park
St. Margarets
Co. Dublin

Address for
written correspondence
Quest Diagnostics
P.O. Box 11425
Swords
Co. Dublin

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