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

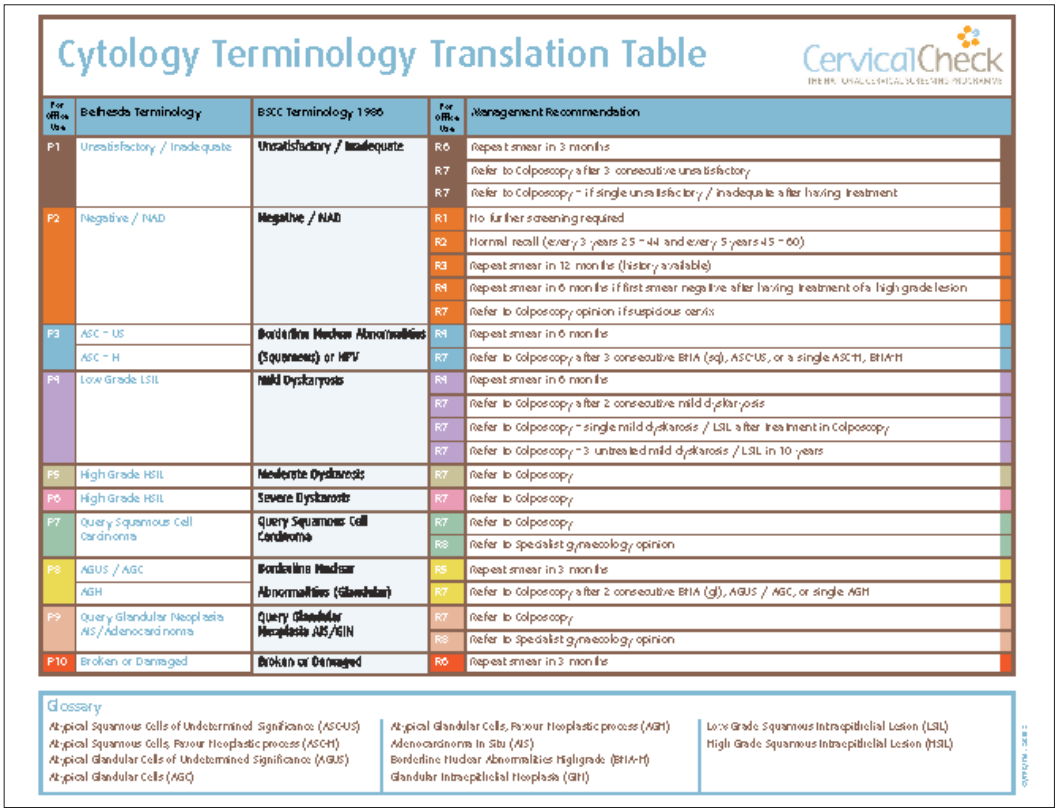
5.2.1 Bethesda and BSCC Terminologies

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.*

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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