

**AUDIT OF INVASIVE CERVICAL CANCERS:
PROTOCOL CHANGES FOR 2012-13**

Withdrawn

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NHS CSP Publication No 28: Protocol changes 2012 -13

May 2012

1. INTRODUCTION

This document outlines changes to the audit protocol described in NHS Cervical Screening Programme (NHS CSP) publication number 28. The aim is to improve the audit by linking it more closely to training, by streamlining and standardising procedures to ensure consistency across all Quality Assurance Reference Centres (QARCs), and by providing clearer and tighter guidance to remove ambiguities. The recommendations represent minimum standards, and attempts to exceed the guidance where this is felt to be locally valuable are encouraged.

The following table outlines the guidance that is applicable to each audit period:

Cases diagnosed	Guidance to follow
April 2007-April 2012	Follow guidelines in NHS CSP publication no 28.
April 2012-April 2013	Follow guidelines in NHS CSP publication no 28, plus modifications outlined in this document.
April 2013 onwards	Follow updated version of NHS CSP publication no 28 (forthcoming).

The British Society for Clinical Cytology (BSCC) recently revised its classification for abnormal cervical cytology. These changes will be outlined in the third edition of *Achievable standards, Benchmarks for reporting, and Criteria for evaluating cervical cytopathology*, to be published in the summer of 2012. While the old terminology is used throughout this document, future audit documents will utilise the new classification.

1.1 Scope of audit

The audit of invasive cervical cancers should not be confused with the classification of invasive cancer cases (submitted to the cancer registries) or with the disclosure of audit results to women who are diagnosed with this disease (governed by locally determined protocols that form part of the clinical governance arrangements of every Trust). However, in order to avoid duplication of work, data collected as part of the NHS CSP audit of invasive cervical cancers can also be used both for the classification of invasive cancer cases and for the disclosure exercise (though it should be noted that the latter requires a full review of all cytology and histology slides within 10 years of diagnosis, whereas this audit requires examination of a smaller subset of slides).

One aim of the audit is to understand the reasons that cervical cancers occur despite the existence of an excellent screening programme, and to identify modifications that might reduce the number of cancers. Fulfilling this objective necessitates the collation of data from different sources: screening invitations, cytology results, colposcopy attendance, and histology.

Additionally, there is an important educational purpose behind the audit: to review the original management of each case of invasive cancer, and to determine whether it was appropriate. This is more straightforward for pathology, where slides can be reviewed, than for colposcopy, where there are no standard, quality controlled images against which the colposcopic report can be compared (though it is still possible to determine whether the patient was managed according to national guidelines). The review of colposcopy will be

incorporated into the audit protocol from April 2013 onwards, once the details of relevant processes have been finalized.

Audit is mandatory, and all Trusts who provide cervical cytology must participate. Slides that meet the conditions for external review (defined in this paper) **must** be made available by all Trusts. This will necessitate suitable arrangements for the transport of these slides.

1.2 Identification of cases

Responsibility for deciding whether a case requires audit lies with the Hospital-Based Programme Coordinator (HBPC) at the NHS Trust where the case was histologically identified. To ensure the success of the cervical screening audit, it is essential that all Trusts involved in the delivery of any part of the cervical screening programme have an HBPC in position.

1.3 Implementation timeline

We propose that the new protocol, associated forms, and relevant slide reviewing procedures are introduced in a phased process:

Cases diagnosed before the 1st of April 2012

- For cancers diagnosed up to 31/03/2012, the previous audit forms should be used.
- If a slide review has not yet been initiated for a case diagnosed prior to 01/04/2012, there is no need to complete this as part of the audit.

Cases diagnosed from 1st of April 2012 to the end of June 2012

- For cancers diagnosed on or after 01/04/2012, the new forms (and database) must be used to collect the following data: case details, National Health Applications & Infrastructure Services (NHAIS) system download (cytology history), colposcopy, and histology. These forms are available on the NHS CSP website.
- Slide review for cancers diagnosed during this period is not mandatory.

Cases diagnosed from July 2012 onwards

- For cases diagnosed from 01/07/12 onwards, the guidelines set out in this document must be followed, including those pertaining to slide review.

1.4 Feedback

All comments and suggestions received throughout the last three years have been considered by the group responsible for revising this protocol. Not all of the requests have been incorporated into this revision, however, because the intention has been to provide a slimmer, more efficient set of auditing procedures that will enhance the quality and usefulness of the data. The guidelines will continue to be reviewed on an annual basis.

A website has been created (<http://www.csad.org.uk/>), to host background information on the audit, recently released updates, and frequently asked questions. The first national report on results obtained from this audit was published in July 2011 (<http://www.cancerscreening.nhs.uk/cervical/publications/index.html>).

Subsequent annual reports will appear each February.

2. CHANGES TO THE AUDIT GUIDELINES

2.1 Cytology review

2.1.1 Slides that do not require review

For the purposes of the NHS CSP audit of invasive cervical cancers, slide review is an educational exercise. Since there is no educational value in reviewing slides from a technology that is no longer used as part of the screening programme, conventional Papanicolaou slides no longer need to be examined.

As stated in NHS CSP 28, there is no requirement to review slides taken more than 10 years prior to diagnosis, even where these are still available on file.

Additionally, since the aim of this part of the review is to improve education through the assessment of potential errors, it is **not** necessary to review any abnormal samples that were reported as moderate dyskaryosis or worse, provided that these were taken within **three** months of diagnosis, and led to the immediate referral of the woman. Laboratories are encouraged to continue reviewing these slides if they are of local educational value (an example of best practice), but results do not need to be reported as part of this audit.

2.1.2 Local review

All slides relating to cases identified by the HBPC (other than those excluded in section 2.1.1) must be reviewed. The first, or local, review must be undertaken in the host laboratory* by a Consultant Pathologist or Consultant Biomedical Scientist (BMS) who routinely reports on cervical cytology on behalf of the NHS and who satisfies current NHS CSP criteria for reporting.¹

The person performing the review must **not** have reported on the slide previously and need **not** have access to the original report. For audit purposes, there is no need for more than one local person to review each slide and only the opinion of the Pathologist or Consultant BMS needs to be recorded. However, exceeding this guidance and reviewing the cases at local multi-headed slide meetings would carry obvious educational value and is considered by the NHS CSP to be best practice.

The opinion of the Pathologist or Consultant BMS must be recorded in Section E of the audit proforma (titled 'Cytology Review'). Any original dots must not be removed from the slide. If new dots are added, these must be made using a different colour of ink, and their addition should be noted on form E, which has been altered to accommodate this information.

* The working group acknowledge that there have been a number of mergers and amalgamations of laboratories over the past few years, and that this trend will continue. For the purposes of this audit, which is primarily concerned with ongoing education, the host laboratory is the organisation where cytology reporting is *currently* undertaken.

2.1.3 External review

Bearing in mind the educational purpose of this audit, the following must be reviewed externally:

- All slides taken during the two years prior to diagnosis that were originally reported as negative or inadequate,[†] irrespective of the review diagnosis.
- All slides reported as negative or inadequate that were subsequently upgraded at local review to moderate dyskaryosis or worse, irrespective of when they were taken.
- Any slides originally reported as showing borderline change or mild dyskaryosis that were subsequently upgraded at local review to severe dyskaryosis, glandular neoplasia, or invasive carcinoma.

Review of all negative and inadequate slides, irrespective of the local review diagnosis, is intended to act as a quality control measure. The two year cut-off was chosen to ensure that the number of cases sent for review remains within practical limits and to focus on those slides taken close to the time of diagnosis.

Note that **only** those slides that fall into the above categories need to be sent for external review, **not** all of the slides from an individual case. The external review of negative samples taken within two years of diagnosis will assess how likely laboratories are to agree with the original report.

Table 1 defines the local review results that require additional external review. External reviews must take place at NHS CSP-approved Cytology Training Centres. Such reviews will offer the Centres access to educational cases, and will provide an unbiased opinion on the laboratory's assessment.

In England, funding will be made available to Training Centres from the national programme, on a per-slide basis, to facilitate both the reviews and subsequent review meetings. The Training Centre review must be undertaken by either the Assistant Director/Training Centre Manager and/or the Medical Director. Those undertaking the review must be currently practising in the same modality (Surepath™/Thinprep®) as the reporting laboratory.

For the purposes of the audit, the initial or consensus report from the Training Centre will be taken as the final opinion. It must be recorded on form E, together with a comment on the reason for the potential false negative/positive. Oversight of the external review process will continue to be the responsibility of the appropriate QARC.

Where the Training Centre review does not agree with the local review, then the local staff must be given the opportunity to review the case with the Training Centre staff. The purpose of this review is educational, so the Training Centre opinion will **not** be changed. The meeting between laboratory and Training Centre staff would normally take place at the reporting Training Centre, but could take place at a local Trust if necessary. Wherever the reviews take place, the costs associated with travel to such meetings must be borne by the requesting NHS Trust, i.e. the original laboratory that reviewed the sample.

[†] The introduction of the Surepath™ Focalpoint system means that slides labelled for archiving without human screening (No Further Review/NFR) may now require review. For the purposes of this audit, these slides should be regarded as negative, and reviewed where appropriate.

Local Review ↓	Original →							
	Inadequate	Negative	Borderline	Mild	Moderate	Severe	?Invasive	?Glandular
Inadequate								
Negative								
Borderline change								
Mild dyskaryosis								
Moderate dyskaryosis								
Severe dyskaryosis								
?Invasive								
?Glandular								
	For external review if slide was taken during the 2 years preceding diagnosis		For External Review		External Review Not Required			

In a small number of cases, the initial training centre review may result in a very different diagnosis from the local review. In these circumstances, a second training centre review must take place when:

- The initial Training Centre review differs from the local review by two grades of abnormality.
- A lesion is identified as squamous by the local reviewer, and as glandular by the Training Centre, or vice versa.
- A slide is reported as abnormal by the local reviewer but as negative or inadequate by the Training Centre, or vice versa.

At the second review, the Assistant Director/Training Centre Manager and Medical Director must review the slide together, and reach a consensus (or agree to disagree).

Training Centres will record the outcome of the review and highlight cases that may be of value for training courses. They may also take images of the slides. They should not, however, retain the slides, which should instead be returned to the local laboratory within one calendar month. Laboratories will make the slides available upon request in future, so that they can be used in training courses. In order to streamline this process, Training Centres will be encouraged to develop specific training activities that revolve around the review cases, e.g. incorporating the review of these slides into training days.

The Training Centres undertaking these reviews will record the learning outcomes from the review process and send them to the QARC for collation and presentation at an annual meeting, which can be combined with the annual External Quality Assurance (EQA) review day.

2.1.4 Role of the QARC in organising external review

External reviews will be organised through the QARC. Since some laboratories do not have access to a locally funded Training Centre, local agreements may need to be reached between the regional QARC and a NHS CSP approved Training Centre. The Training Centre and the laboratory under review must use the same liquid-based cytology modality.

QARCs and Training Centres should reach local arrangements regarding the transport of slides between submitting laboratories and the appropriate Training Centre. Slides identified for external review do not need to be sent to the QARC; instead, local laboratories can process and forward[‡] the slides directly to the Training Centre. However, the QARC must be informed that the slides have been sent, and a record of the submitted slides must be kept by both the QARC and the laboratory. The QARC will oversee the choice of Training Centre, and will be responsible for ensuring that it holds NHS CSP approval.

If the case originated in the host laboratory for the Training Centre, then the laboratory must liaise with the local QARC to request review by a different Training Centre. In such circumstances, local agreements between QARCs and Training Centres will be required.

2.2 Histology review

All histology samples taken over the 10 years preceding diagnosis must be reviewed, with the exception of the diagnostic sample and any samples taken after the diagnostic sample. Reviews must be performed by a histopathologist who routinely reports cervical histology on behalf of the NHS. The reviewer must not have reported the specimen originally and need not have access to the original report. If the above criteria are met, then the review prepared for the cancer multidisciplinary team meeting as part of the NHS CSP audit of invasive cervical cancers may be used.

The result of the histology review must be recorded in Section F. Please refer to section 2.3.2 (part F) for details of the fields that need to be reported.

An external review should only be performed where an abnormality is detected that was not formerly reported and/or where earlier detection would have led to further clinical review or treatment in that clinical unit, rather than discharge of the patient back to the GP. (This rule applies to non-cervical biopsies also).

External reviews will be organised through the QARC and must be performed by a specialist gynaecopathologist in a local cancer centre appointed by QARC. Whenever the external reviewer does not agree with the local reviewer, the two should discuss the case and reach a consensus (or agree to disagree). The result of this review must be recorded in Section F. Learning outcomes from external reviews will be collated by the QARC and results presented at an annual meeting. Trusts are expected to cover any costs associated with external review of histological samples.

[‡] The labelling, packaging, and transport of slides to the Training Centre must be performed according to instructions provided by the QARC. It is important that the QARC has a list of the slides sent for external review, and that they are able to identify those that are required for the annual meeting at which learning outcomes are shared.

2.3 Changes to the NHAIS system download and the audit paper forms

Changes to the database and forms will coincide with the implementation of the new audit guidelines. These will be available on the 1st April 2012.

2.3.1 Call/Recall: NHAIS system download (AJ-CRUK)

The following fields have been added to the NHAIS system download to facilitate data collection.

Personal Details (to facilitate the identification of woman locally and to create Index of Multiple Deprivation data automatically):

- Surname.
- First forename.
- NHS number.
- Postcode.
- Next test due date.

Cytology test information includes:

- Repeat test (months).
- Ceased/postponement date.
- Ceased/postponement reason.
- High risk humanpapillomavirus (HR-HPV) result.

The Jarman Score has been removed from the NHAIS system download, since the Index of Multiple Deprivation is now used in preference.

2.3.2 Changes to the data collection fields: sections A-H

Part A1: Personal and cancer details

- A tick box has been added to indicate that no further data are expected for a case.
- Treatment options now include palliative care, none, and unknown. 1A cancers that were treated with a diagnostic Large Loop Excision of the Transformation Zone(LLETZ)/cone biopsy must be recorded as such.
- Separate boxes are provided for the preliminary FIGO stage and the final FIGO stage.

Part B: Cytology

- Section H (HR-HPV test) has been incorporated into Part B. HR-HPV infection codes will be downloaded directly from the NHAIS system. There is no need to collect data on the type of HR-HPV test or on HR-HPV typing.
- A new form will be created to accommodate the ceased/postponement data included in the NHAIS system download (see section 2.1).

Part D: Histology

- The Pathological Diagnosis codes remain unchanged; however up to three different codes can now be recorded for each specimen to allow for multiple diagnoses.

Part E: Cytology review

- A free text box has been added to record the colour of any new dots added during the review process.
- A field to record that a slide was originally designated as 'no further review' (NFR) by the Focalpoint System has been added.

Part F: Histology review

- Sections F3 and F4 are no longer necessary.
- Fields to be reported upon review now follow the core microscopic features outlined in the Royal College of Pathologists (RCPATH) dataset² for histological reporting of cervical neoplasia.

Fields to be completed are:

- Overall review result.
- Presence of the transformation zone (TZ).
- Presence/absence of cervical intraepithelial neoplasia (CIN).
- Grade of CIN, if present.
- Presence/absence of cervical glandular intraepithelial neoplasia (CGIN).
- Grade of CGIN, if present.
- Presence or absence of stratified mucin-producing intraepithelial lesions of the cervix (SMILE).
- Presence or absence of HR-HPV.
- Presence of any invasive tumour.
- Type of invasive tumour and grading (where possible).
- Additional features (e.g. tuboendometrioid metaplasia (TEM), endometriosis, microglandular hyperplasia, etc.)

Where the specimen is a wedge, cone, or LLETZ/loop these additional fields need to be completed:

- Excision status, distance to closest margin, and type of margin.
- Excision margins (ectocervical resection margins, endocervical resection margins, deep lateral/radial resection margin).
- Whether there is lymphovascular space invasion.

Part G: GP notes

The value of collecting information on cases of invasive cervical cancers from GP notes has been questioned in light of the fact that several other current projects are also endeavouring to obtain these data (particularly those concerned with the diagnosis of cervical cancer in young women). The box designed to collect information from GP notes has therefore been removed from the list of essential fields, and active collection of these data is no longer required. However, individual pilot projects to explore the potential of collecting these data are welcomed, particularly those that are focused on the potential benefits of accessing GP electronic records.

Part H: HR-HPV DNA testing

This section has been incorporated into section B, as the NHS CSP is implementing HR-HPV triage and test of cure nationally.

2.3.3 Essential Fields list

The following data items have been added to the essential fields list.

Section A & A1: Personal and Cancer details

- Treatment.
- Index of Multiple deprivation.

Section B

- HR-HPV infection code.

Section C: Colposcopy

- Colposcopist (records the level of qualification attained by the person performing the colposcopy).

Section F

- 'Reviewed at'.
- Evidence of TZ sampling.
- Excision status.

The following sections are no longer required as part of Audit

- Section G: GP notes.
- Section F: Histology Cancer Review.

REFERENCES

1. Dudding N, Anderson N, Bingham J, *et a.* (eds) *Recommended Code of Practice for Laboratories Participating in the UK Cervical Screening Programmes*. London: British Society for Clinical Cytology, 2010, Available at: http://www.clinicalcytology.co.uk/resources/cop/BSCC_COP_2010.pdf
2. Hirschowitz L, Ganesan R, Singh N, *et al.*. *Standards and datasets for reporting cancer. Dataset for histological reporting of cervical neoplasia*. London: Royal College of Pathologists, 2011 (3rd edition). Available at: <http://www.rcpath.org/index.asp?PageID=1152>



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