NHS Cervical Screening Programme

NHS Cancer Screening Programmes

Protocol changes to the audit of invasive cervical cancers: to be implemented April 2013

Addendum 2 to NHSCSP PUBLICATION No 28

MARCH 2013

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Document Information Protocol changes to the audit of invasive cervical cancers, to be implemented April 2013	
Electronic publication date	Wednesday, 20 March 2013
Review date (1)	30 September 2013
Authors	Alejandra Castanon
Comments	Comments may be sent to Alejandra Castanon, a.castanon@qmul.ac.uk, in readiness for review
Document objective	To modify the current audit to include colposcopy, and to provide clarification on protocol.
Clinical/healthcare/social questions covered	How to conduct the audit for invasive cervical cancers for the year April 2013-April 2014.
Population affected	Women diagnosed with invasive cervical cancer after screening in the NHSCSP
Target audience	Programme managers, QADs, laboratories, colposcopists.
Archived	Current document

CONTENTS

1 INTRODUCTION

1.1 Purpose of the audit of invasive cervical cancers

The purpose of the audit of invasive cervical cancers 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). Both elements of the service have been incorporated into the audit protocol since April 2013.

1.2 Changes outlined in this document

Guidelines for the audit of invasive cervical cancers were first published in NHS Cervical Screening Programme (NHSCSP) publication number 28. Modifications to the protocol were introduced in a further document, *Protocol changes to the audit of invasive cervical cancers,* published April 2012.

The current document supersedes the latter publication, introducing a further set of modifications. 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 current document follows the new British Society for Clinical Cytology (BSCC) classification for abnormal cervical cytology, as outlined in the third edition of *Achievable standards, Benchmarks for reporting, and Criteria for evaluating cervical cytopathology*, published January 2013. Table 1, below outlines the guidance that is applicable to each audit period:

Table 1 Guidance applicable to each audit period

Cases diagnosed	Guidance to follow
April 2007-April 2012	Follow guidelines in NHSCSP publication no 28.
April 2012-April 2013	Follow guidelines in NHSCSP publication no 28, plus modifications outlined in the document *Protocol Changes to the Audit of Invasive Cervical Cancers, 2012-13,* published April 2012.
April 2013-April 2014	Follow guidelines in NHSCSP publication no 28, plus modifications outlined in this document.
April 2014 onwards	Follow updated version of NHSCSP publication no 28 (forthcoming).

1.3 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 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 NHSCSP 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).

Audit is mandatory, and all Trusts that 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 transport arrangements.

1.4 Identification of cases

Responsibility for deciding whether a case requires audit lies with the Hospital-Based Programme Coordinator (HBPC) at the NHS Trust at which 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 must have an HBPC in position. The HBPC may be employed in any discipline within the programme, but their responsibilities are the same, whether they are from cytology, histopathology or colposcopy.

The role of the HBPC may vary between Trusts. Cooperation may therefore be necessary between Trusts to ensure that the audit is successfully completed.

With regards to this audit, HBPCs are responsible for ensuring reviews are carried out:

- on all cases diagnosed within their own Trusts
- on cases where the HBPC's Trust provides service elements no longer provided by the diagnosing Trust requiring review, e.g. following cytology service transfer, where the original reporting laboratory no longer undertakes cytology.

In addition to these responsibilities, when a case diagnosed within a Trust requires local review, the HBPC at that Trust must notify HBPC colleagues in other Trusts (either directly or via the QARC). The latter will organise the local review and return paperwork to the HBPC in the diagnosing Trust. It remains the responsibility of the HBPC at the diagnosing Trust to correlate all sections of the audit and to notify the relevant QARC(s) and Cancer Registries.

QARCs will provide HBPCs with support and guidance on all aspects of the audit, including contact details for HBPCs in other Trusts. QARCs will also establish working relationships with one or more training centres, who will assist HBPCs in all aspects of the cytology review process.

1.5 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 audit forms published before April 2012 should be used.
- if a slide review has not yet been initiated for a case diagnosed before 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 NHSCSP intranet.
- 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.

Cases diagnosed from April 2013 onwards

- for cases diagnosed from 01/04/13 onwards, the guidelines set out in this document must be followed, including colposcopy review.

1.6 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 latest national report on results obtained from this audit is available from:

http://www.cancerscreening.nhs.uk/cervical/publications/index.html

Subsequent annual reports will appear each spring.

2. CHANGES TO THE AUDIT GUIDELINES

2.1 Cytology review

2.1.1 Slides that do not require review

For the purpose of the NHSCSP 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 Papanicoloau slides need no longer be examined.

As stated in NHSCSP 28, there is no requirement to review slides taken more than 10 years before 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 NHSCSP 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 person to review each slide locally, 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 NHSCSP 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 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 before 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 high-grade dyskaryosis (moderate) or worse, irrespective of when they were taken.
- any slides originally reported as showing borderline change or low-grade dyskaryosis that were subsequently upgraded at local review to high-grade dyskaryosis (severe), 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 cutoff 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 2 defines the local review results that require additional external review. External reviews must take place at NHSCSP-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. Since the purpose of this review is educational, 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, negative slides identified as NFR should be regarded as negative, and reviewed where appropriate.

Table 2 Local review results that require external review

Original → / Local Review ↓	Inadequate	Negative (codes 2 and N)	Borderline (squamous/ endocervical) (codes 8,9,B,E)	Low-grade dyskaryosis (includes 3 and M)	High-grade dyskaryosis (moderate)	High--grade dyskaryosis (severe)	High-grade dyskaryosis/ ?Invasive squamous carcinoma	?Glandular neoplasia of endicervical type/ glandular neoplasia non-cervical
Inadequate								
Negative								
Borderline (squamous/endocervical)								
Low-grade dyskaryosis								
High-grade dyskaryosis (moderate)								
High-grade dyskaryosis (severe)								
High-grade dyskartosis/?invasive squamous carcinoma								
?Glandular neoplasia of endocervical type/ ?glandular neoplasia (non-cervical)								

	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. Both the individuals carrying out the review and the programme as a whole should benefit from the lessons that emerge from the audit.

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 NHSCSP-approved training centre that can deal with the slides for review. The training centre and the laboratory under review must use the same liquid-based cytology modality.

QARCs and training centres must 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 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 has been approved by the NHSCSP.

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 NHSCSP. The reviewer must not have reported the specimen originally and does not need to have access to the original report. If the above criteria are met, then the review prepared for the cancer multidisciplinary team meeting 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 gynae-pathologist at 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.

2.2.1 Guidance on completing Section D and F (Histology & review)

The introduction in April 2012 of new fields on the Histology form for audit purposes caused confusion. It was unclear which pieces of information should be entered in which fields.

This section provides clarification and guidance on how to complete these sections.

Changes have been made to the ordering and labelling of the data fields on the forms, which we hope will make data entry simpler.

In general, all fields that require a YES/NO answer will be amended to allow a Not Available/ Applicable option.

Excision status: when one or more of the margins is complete and one or more is incomplete, report the excision status as INCOMPLETE

Distance to closest margin: only report this field when the excision status is COMPLETE

Excision margin: only report this field when excision status is INCOMPLETE

Margin involved by CIN, CGIN, SMILE or invasive cancer: only report this field when excision status is INCOMPLETE

Lymphovascular space invasion: only report this field when the pathological diagnosis is invasive cancer.

2.3 Colposcopy review

Review of an individual's colposcopic history will be incorporated to the NHSCSP audit from April 2013. The colposcopy review will have its own form, named 'part C2'. Full guidelines on which appointments need to be reviewed can be found in the document *Audit of invasive cervical cancers: colposcopy review 2013-14* (Addendum to publication no 28, issued September 2012), along with details on the information that needs to be taken into consideration by the reviewer.

Briefly, any colposcopic examinations that predate the index referral by up to five years should be reviewed, since these examinations (and the associated management of the individual) may have impacted on the development of cervical cancer.

Since the aim of this part of the review is to improve education through assessment of potential errors, any colposcopic examination associated with the index referral cytology and made within 18 weeks of the subsequent diagnosis of cervical cancer does **not** require routine review.

2.4 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 have been available since the 1st April 2012.

2.4.1 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):

- 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.

2.4.2 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 C: Colposcopy

- The section gathering details of all colposcopic examinations preceding diagnosis will not change, but will be renamed 'part C1'
- The drop-down option ‘punch biopsy’ (in the field for specimen type) will be replaced by the option ‘cervical biopsy’, to enable other types of biopsy, such as wedge biopsies, to be reported under this heading
- Colposcopy review will have its own form, named 'part C2'. This section will only need to be completed for a subsection of women diagnosed with cervical cancer (see section 2.3).

Part D: Histology

- The pathological diagnosis codes remain unchanged, but up to three different codes can now be recorded for each specimen to allow for multiple diagnoses

- The drop-down option 'punch biopsy' (in the field for specimen type) will be replaced by the option 'cervical biopsy', to enable other types of biopsy, such as wedge biopsies, to be reported under this heading.
- The order of the dropdown boxes has been changed to facilitate data entry.

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) dataset[2] 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).

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.

Guidance on when these fields must be completed can be found in section 2.2.1.

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 this 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 this information is no longer required. However, individual pilot projects to explore the potential of collecting this 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 NHSCSP is now implementing HR-HPV triage and test of cure nationally.

2.4.3 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 score

Section B

- HR-HPV infection code.

Section C: Colposcopy

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

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

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March 2013