Northern Ireland Cervical Screening Programme

Protocol for the Audit of Invasive Cervical Cancers

DECEMBER 2014

Version:	**1.0**
Author:	**Mrs J Jamison**
Edited by:	**Dr T Owen**
Approved By:	**CSP Laboratory QA subgroup**
Date Approved:	**10 September 2014**
Review Date:	**September 2015**

1 Introduction

The purpose of cervical cancer audit is to monitor the effectiveness of the screening programme, to identify areas of good practice and to identify where further improvements can be made. Audit looks for recurring themes and trends over time when individual cases are analysed together.

An audit process for invasive cervical cancers has been operational in England through the NHS Cervical Screening Programme for a number of years. This work is facilitated by Cancer Research UK. Although the intentions were that Northern Ireland would also participate in this audit and contribute cases, it has proved difficult to get local buy-in given that the national audit does not provide any results or feedback at a local level.

The aim of this document is to re-energise the audit process and define a new protocol for an invasive cancer audit specific to Northern Ireland. While closely based on the process used in England, a local approach will engender local ownership and participation, providing opportunities for local feedback and educational benefits within the screening programme. The audit should be closely linked to training, as by streamlining and standardising procedures to ensure consistency across all trusts, clearer and tighter guidance will be provided to remove ambiguities.

This new protocol, associated forms, and relevant slide review procedures are applicable to all new cervical cancers diagnosed in Northern Ireland from 1 January 2014.

Cervical cancer audit should be taken on as part of the organisational clinical governance arrangements in each trust and each individual/team/directorate within a trust, as well as trust management, should determine how audit should work in their own structure. Both reporting the results of audit and learning local lessons from audit should be incorporated into each trust's clinical audit framework and clinical governance arrangements.

2 Scope of the audit

The audit of invasive cervical cancers should not be confused with the classification of invasive cancer cases submitted to the NI Cancer Registry. However, in order to avoid duplication of work, data collected as part of the audit of invasive cervical cancers can also be used for the classification of invasive cancer cases.

In order to understand the reasons that cervical cancers occur despite the existence of a high quality population screening programme, it is necessary to collect data from different sources representing the full screening pathway: screening invitations, cytology results, colposcopy attendance, and histology. This will be undertaken by each trust providing cervical screening services and will be the responsibility of the Hospital Based Programme Coordinator (HBPC) in each trust.

Additionally, there is an important educational purpose behind the audit: to review any previous contacts with the screening programme, to review the management, 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 colposcopy report can be compared (though it is still possible to determine whether the patient was managed according to national guidelines).

All Trusts who provide cervical screening services are expected to participate in the audit as good practice and as part of their quality assurance responsibilities for cervical screening. Cytology slides that meet the conditions for external review as defined in this paper must be made available by all Trusts. This will necessitate suitable arrangements for the transport of these slides.

At this point, the audit will not include colposcopy review, which has been introduced in England for cervical cancers diagnosed from April 2013. It is intended to allow time for the new laboratory slide review processes to become established, before considering whether the Northern Ireland audit should be extended to include colposcopy review.

3 Identification of cases

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

4 Audit process

A summary of the audit process is outlined in Appendix A. This sets out the role of the HBPC and the QARC information officer in coordinating the completion of the audit returns and collating the findings. The process closely follows that set out in NHSCSP Publication 28[1,2].

5 Audit documentation

The data collection forms used for the audit are the same as those produced by the NHSCSP for England (version issued April 2012). This will allow any findings in Northern Ireland to be compared with those reported in England. In addition, an electronic version of the audit forms has been prepared, so Trusts can choose to capture data on either the paper or electronic versions.

6 Case review

6.1 Screening History

The full screening history of the case should be determined and recorded. This will require a search of a number of databases: call recall database (NHAIS/Exeter system), the laboratory system (LabCentre) and colposcopy records.

The dates and outcomes of all previous cytology specimens should be recorded in Section B of the audit proforma.

The findings of any colposcopic assessment for which records are available should be recorded in Section C of the audit proforma. This will include dates of all

appointments, whether the patient attended, procedures carried out and any colposcopic impression and treatment.

A record of histology results should be collated to produce a complete picture of the patient's history and to facilitate slide review. Details should be documented in Section D of the proforma.

6.2 Cytology slide review

6.2.1 Slides that do not require review

For the purposes of the audit of invasive cervical cancers, slide review is an educational exercise.

Therefore, the following slides do not need to be reviewed:

- conventional Papanicoloau slides
- slides taken more than 10 years prior to diagnosis, even where these are still available on file
- samples reported as moderate dyskaryosis or worse that 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.

6.2.2 Local review

All slides relating to cases (other than those excluded above) must be reviewed.
The local review is undertaken in the host laboratory by a Consultant Pathologist or Consultant Biomedical Scientist (BMS) who routinely reports on cervical cytology on behalf of the NI cervical screening programme. The person performing the review must **not** have reported on the slide previously and does not need to 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 have obvious educational value and is considered to be best practice.

The opinion of the Pathologist or Consultant BMS should 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.

6.2.3 External review

In order to maximise the educational purpose of the audit, an external review will be undertaken of slides that meet the following criteria:

- 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.

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 will be undertaken by a panel of two Consultants (a Consultant Pathologist and/or Consultant Biomedical Scientist) who routinely report on cervical cytology on behalf of the NI cervical screening programme. The external panel for

each slide review will be selected by the QARC and involve participation from all Trusts.

Slides requiring external review

	Original report							
Local review	inadequate	negative	borderline	mild	moderate	severe	?invasive	?glandular
inadequate								
negative								
borderline changes								
mild dyskaryosis								
moderate dyskaryosis								
severe dyskaryosis								
?invasive								
?glandular								

	External review if slide taken in the 2 years before diagnosis		External review		No external review required

For the purposes of the audit, the initial or consensus report from the external panel will be taken as the final opinion. It should 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 QARC.

Where the external panel review does not agree with the local review, then the local staff will be given the opportunity to review the case with the external panel. The purpose of this review is educational. All slides will be returned to the local laboratory within one calendar month.

The slides which have an educational value will be presented by each Trust at an annual audit day. If appropriate, these slides could also be circulated to each Trust to allow all staff to discuss around a multi-head. This will be co-ordinated by the QARC.

6.2.4 Role of the QARC in organising external review

External reviews will be organised through the QARC. The QARC will liaise between external panel members and local laboratories to reach agreement on the transport of slides requiring external review. 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 panel members. 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 selection of the external panel for each slide review.

6.3 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 consultant histopathologist who routinely reports cervical histology. 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 may be used. The result of the histology review must be recorded in Section F of the audit proforma.

An external review of histology specimens 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).

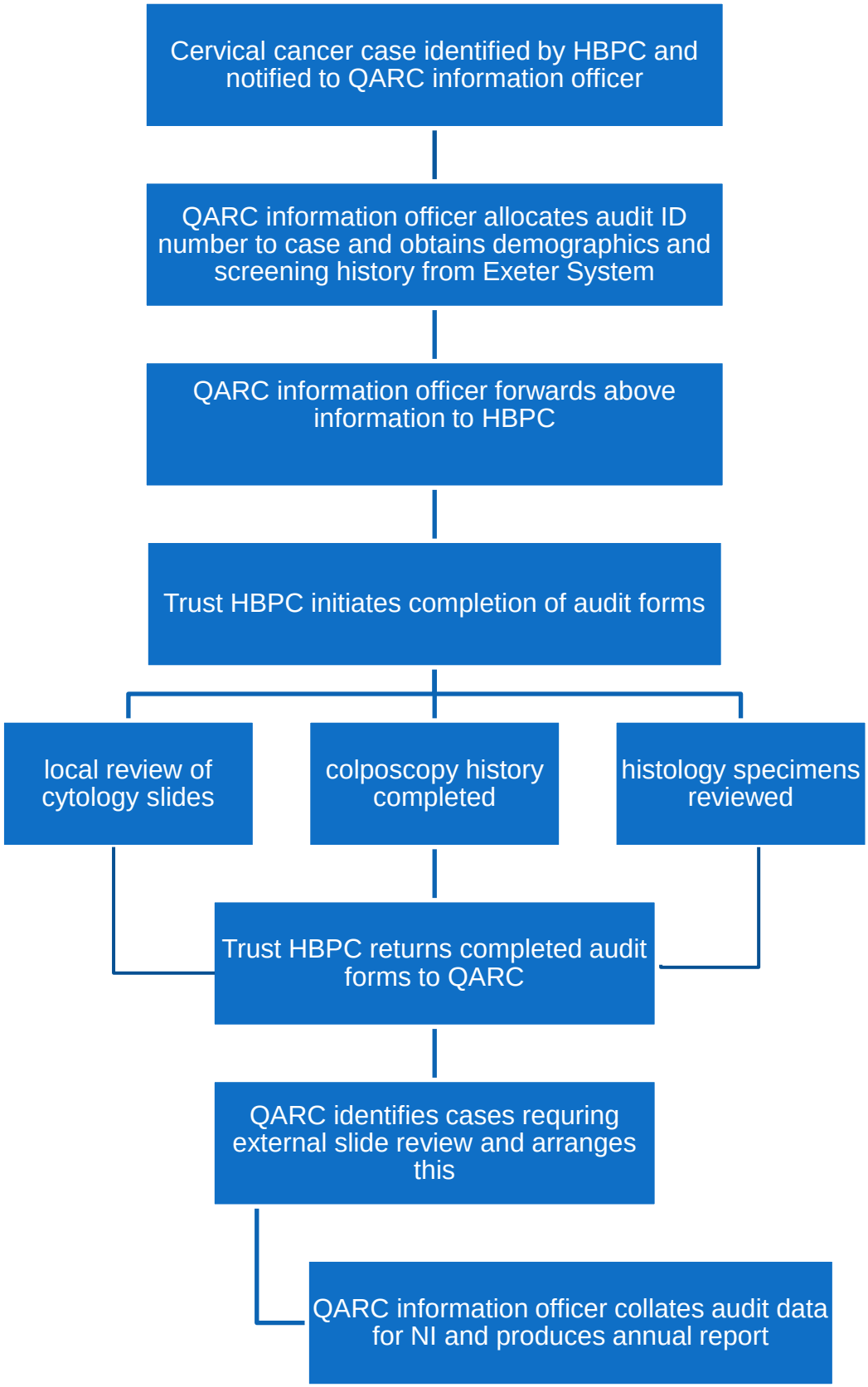
External reviews will be organised through the QARC and must be performed by a gynae-pathologist in a cancer unit or centre. Whenever the external reviewer does not agree with the local reviewer, the two should discuss the case and reach a consensus (or agree to disagree). The result of this review must be recorded in Section F. The QARC will communicate the outcome the review to the HBPC in the initiating Trust and to other HBPCs involved in the case. Learning outcomes from

external reviews will be collated by the QARC and results presented at the annual audit meeting. The QARC will maintain a log of all slides sent for external review.

7 Feedback and review

The audit protocol will be reviewed annually by the Regional Laboratory QA Advisory Group in association with the Regional Colposcopy QA Advisory Group. The Quality Assurance Reference Centre (QARC) will produce an annual audit report.

Appendix A


Cervical cancer case identified by HBPC and notified to QARC information officer
QARC information officer allocates audit ID number to case and obtains demographics and screening history from Exeter System
QARC information officer forwards above information to HBPC
Trust HBPC initiates completion of audit forms
local review of cytology slides
colposcopy history completed
histology specimens reviewed
Trust HBPC returns completed audit forms to QARC
QARC identifies cases requring external slide review and arranges this
QARC information officer collates audit data for NI and produces annual report

References

[1] Audit of invasive cervical cancers. NHSCSP Publication No. 28, December 2006

[2] Audit of invasive cervical cancers: Protocol changes for 2012-13. NHSCSP Publication No.28: Protocol changes 2012-13, May 2012.