AUDIT OF INVASIVE CERVICAL CANCERS

NHSCSP Publication No 28
December 2006

Published by:

NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 271 1060
Fax: 0114 271 1089
Email: info@cancerscreening.nhs.uk
Web site: www.cancerscreening.nhs.uk

ISBN 978 1 84463 040 0

Further copies of this publication are available from the Department of Health Publications Orderline quoting NHSCSP Publication No 28

Tel: 08701 555 455
Fax: 01623 724 524
Email: doh@prolog.uk.com

Typeset by Prepress Projects Ltd, Perth (www.prepress-projects.co.uk)
Printed by Duffield Printers

CONTENTS

ACKNOWLEDGEMENTS

The NHS Cervical Screening Programme would like to thank the following for their contribution to the development of this publication:

Members of the Advisory Committee on Cervical Screening

Members of the NHSCSP Laboratory Group (Chair Dr Paul Cross) and the Audit Working Party:

Mr Phil Bullock	Advanced Practitioner in Cervical Cytology, Gloucestershire Royal Hospital, Gloucester
Dr Paul Cross	Consultant Pathologist, Queen Elizabeth Hospital, Gateshead
Dr Alistair Deery	Consultant Cytologist, St George's Hospital, London
Dr Keith McCarthy	Consultant Histopathologist, Cheltenham General Hospital, Cheltenham
Dr Bill Young	Clinical Scientist Cytology, Hull Infirmary, Hull

Members of the London QA team and the West Midlands QA team

Mr Patrick Walker	Consultant Gynaecologist, Royal Free Hospital, London
Dr Terry Rollason	Consultant Histopathologist, Birmingham Women's Hospital, Birmingham
Sue Hudson	IT consultant
Professor Peter Sasieni	Cancer Research UK
Dr Alejandra Castañon	Cancer Research UK
Mr Chris Carrigan	National Cancer Registry Coordinator for England

The editor is Mrs Julietta Patnick, Director, NHS Cancer Screening Programmes.

1. INTRODUCTION

1.1 Aim of this publication

The purpose of cervical cancer audit is to monitor the effectiveness of the screening programme and to identify areas of good practice and where improvements can be made. Audits yield information at a national, local and personal level, and the findings consist of the patterns that emerge when the results of the audits of individual cases are analysed together. The aim of this publication is to define a national protocol for audit of cases of invasive cervical cancer in order that standardised data can be pooled and analysed meaningfully.

Judgement about the effectiveness of the NHS Cervical Screening Programme (NHSCSP) depends on accurate data on incidence and mortality from cancer registries linked to individual level information regarding screening uptake and outcome. Data should be validated and consistently reported, and all parties in the NHSCSP should follow these guidelines. Audit has influenced practice both at bench and clinic levels and in terms of policy development. Sometimes, findings are answers to known questions, and sometimes further questions are identified. There are also times when findings are quite unexpected. This audit will allow future policy and practice to follow the evidence, will allow the promotion of good practice and may identify areas where further attention is needed.

1.2 Evaluating the effectiveness of the NHSCSP

The objective of the NHSCSP is to reduce the incidence of, and mortality from, invasive cervical cancer. For women aged 25–64 who are screened in the UK every 3–5 years, it is estimated that cervical screening prevents 75% of invasive cervical cancers by detecting and treating cervical abnormalities which, if left untreated, place women at high risk of developing invasive disease.[1]

In order to ascertain whether the programme is achieving its objectives, various evaluations are carried out. In particular, the cervical cancer incidence and mortality rates are monitored closely. These show that in recent years the NHSCSP has been very successful. Cervical screening by the NHS in England reduced the incidence of cancer from 15.4 per 100 000 in 1986 to 9.6 per 100 000 in 2000, and increased the rate at which mortality fell from 1–2% per year to 7% per year in 1995.[2] Although this rate has since decreased to 5% per year, mortality is now 3.5 per 100 000 (in 2004).[3] There are now fewer than 2500 cases of cervical cancer each year, and fewer than 1000 deaths.

However, incidence and mortality alone do not give the complete picture of the programme's effectiveness. They depict how effective the programme is, not how effective it could be if its activities were all optimised. Audit of the programme will provide this information. Furthermore, because cervical screening by means of a Papanicolaou sample has never been subjected to the randomised controlled trials that are today's gold standard, there are also many questions about its effectiveness that can be answered only by auditing the operational programme in different ways.

Women who develop invasive cervical cancer despite participating in the programme often wish to know why this has happened. Audit of their personal history can yield such information and can provide valuable information on population and operational aspects of the programme. In addition, review of events and specimens from previous years can highlight valuable learning points for the health professionals. The results of such activity nationwide, collected over several years, will yield a great deal of information about the effectiveness of cervical screening.

1.3 Local audit arrangements

Although national data collection will enable policy makers to determine whether current policy and practice is working effectively to reduce the morbidity and mortality toll of cervical cancer, local trusts will also be able to use audit to monitor and improve their own practice. It is recommended that cervical cancer audit is taken on as part of the organisational clinical governance arrangements in each trust and that each individual/team/directorate within a trust, as well as trust management, determines 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 own clinical audit framework and clinical governance arrangements.

2. ARRANGEMENTS FOR AUDIT OF CERVICAL CANCERS

2.1 Background

There are often several reasons why women develop invasive cervical carcinoma in a country with an effective population based screening programme. These reasons were recognised before the NHSCSP was implemented in 1988, and were taken into account in previous recommendations for audit.[4] It is very likely that the majority of cancers detected in the screening age group will occur in women who have previously been screened at some time during their lives because five year coverage has been more than 80% since 1993.

This guidance is not intended to replace local audit and review practice. Frequently, clinicians review women's management and specimens for their own professional education. Often, if women have been seen at colposcopy, and particularly if they have been treated, this is carried out on a multidisciplinary basis. Where this is the practice, clinicians are encouraged to continue with these reviews, although care should be taken not to compromise the formal audit described here.

Audit of cervical cancer, irrespective of FIGO (International Federation of Gynecology and Obstetrics) stage, is a multidisciplinary procedure involving all elements of the NHSCSP.[5] Coordination is vital at all levels to ensure that information is gathered and correlated in a timely and accurate manner. Health professionals who diagnose cervical cancer cases must identify these cases to their hospital based programme coordinator (HBPC).

2.2 Aims and objectives

The success of the NHSCSP is reflected in the falling incidence and death rate from cervical cancer. Monitoring the failure of the programme to prevent cervical cancer is also important, increasingly so as changes are made to the technology used and to the age and frequency with which women are called for screening. The national audit of cervical cancers will provide a contemporaneous pattern of disease incidence, including data not recorded by the cancer registries. It will offer the opportunity to explain why some cases occurred, for example in previously unscreened women or if colposcopic treatment has failed, and what proportion were screen detected. It will also, for example, be capable of indicating in a timely fashion whether the alterations in the screening ages and frequencies have affected the incidence of cervical cancer. All cervical cancers should be included in the audit, irrespective of clinical stage or the age of the woman at the time of diagnosis.

The aims of national audit are to:

- provide educational feedback to all those involved in the NHSCSP
- contribute to monitoring of changes introduced to the NHSCSP
- provide a further improvement in cervical screening by identifying areas of good practice and where the programme may be failing.

The objectives of national audit are to:

- identify screening uptake in women who developed cervical cancer
- have accurate comprehensive data on the disease that essentially represent the outcome of the screening programme
- develop a protocol driven by the quality assurance (QA) offices, based on standard reporting systems
- identify where systematic improvements may be made in national policies, laboratories, call and recall systems and colposcopy clinics
- compare screening histories of those women who have cervical cancer with those women who do not.

The audit will collate regional data on a national basis and will be published annually alongside other nationally collected data for regular analysis. It is proposed to present the findings at an annual meeting. Anonymised data will be stored in a national database. Details of the national audit dataset and arrangements for data collection are given in Appendix 1.

2.3 Roles within audit

The basic outline and sequence of events in audit are described in Figure 1, and an audit process map is shown in Figure 2. Certain individuals within the programme have been identified as having key roles. Cases of invasive cervical cancer may be identified from a number of sources, including histology laboratories, gynaecology clinics, genitourinary medicine clinics, oncology clinics and cancer registries. When a case is identified clinically (and confirmed histologically), the clinician treating the woman should ensure that the HBPC and the regional quality assurance reference centre (QARC) are informed in order for a cascade of audit activities to begin. There are several key roles in the audit process, some of which may be fulfilled by the same individual, eg the HBPC and lead consultant in cytology may be the same individual. Delegation of the roles is acceptable, but responsibility remains with the identified individual and the delegated roles must be identified and agreed by all parties.

The roles can be summarised as follows.

2.3.1 Hospital based programme coordinator (HBPC) in trust reporting initial histological diagnosis

- Report to treating gynaecologist/oncologist when the review process of the patient is initiated.
- Identify the units involved in the patient's screening history.
- Request that local review processes are instigated in all laboratories holding cytology or histology cases via the appropriate HBPC (generally those cytology laboratories involved within the previous 10 years).
- Request that local review processes are instigated in all units holding colposcopy histories.
- Request the patient's screening history from the Exeter database managers as appropriate.
- Report the outcome of the completed review to the treating gynaecologist/oncologist.

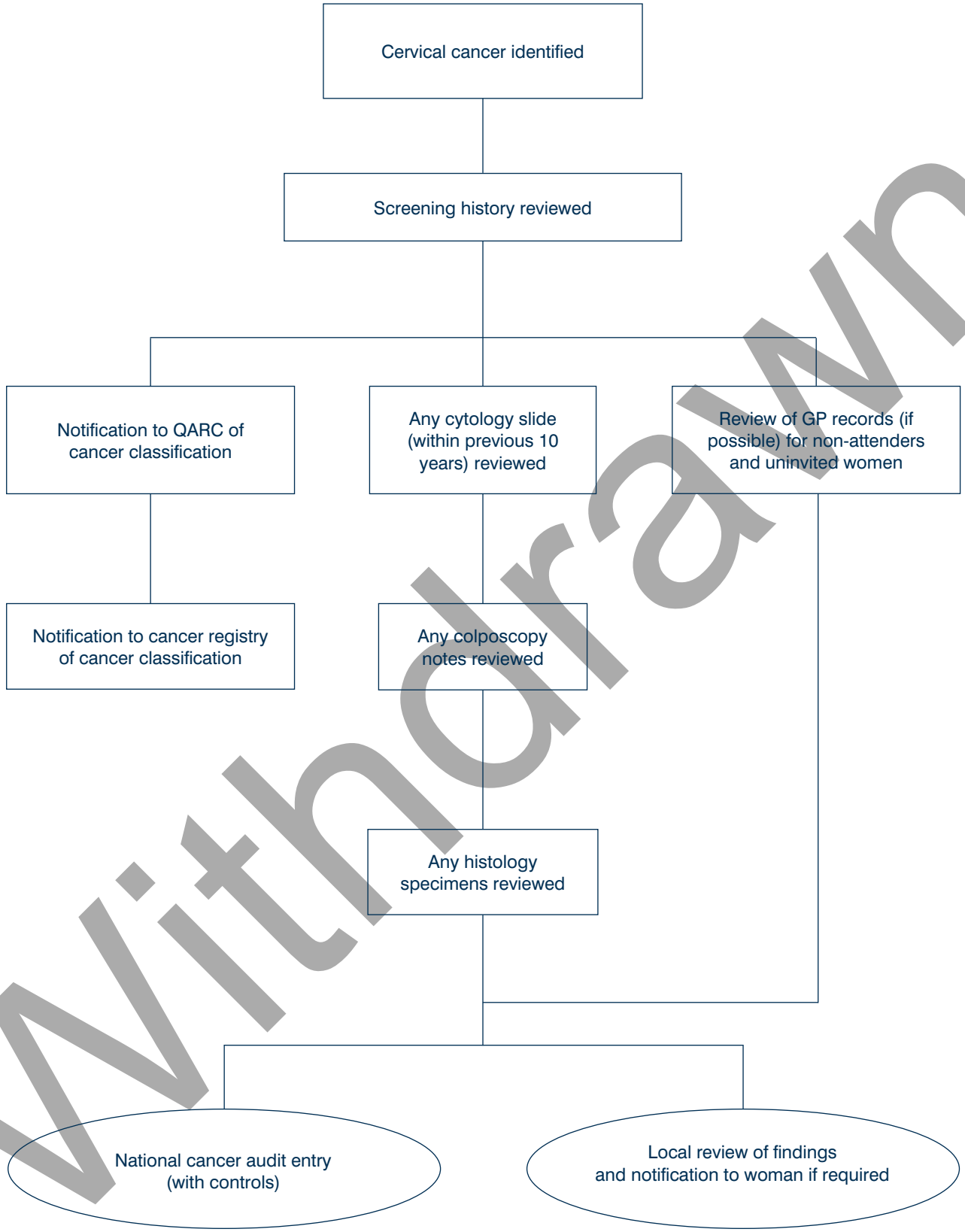

Figure 1 Outline of audit sequence.

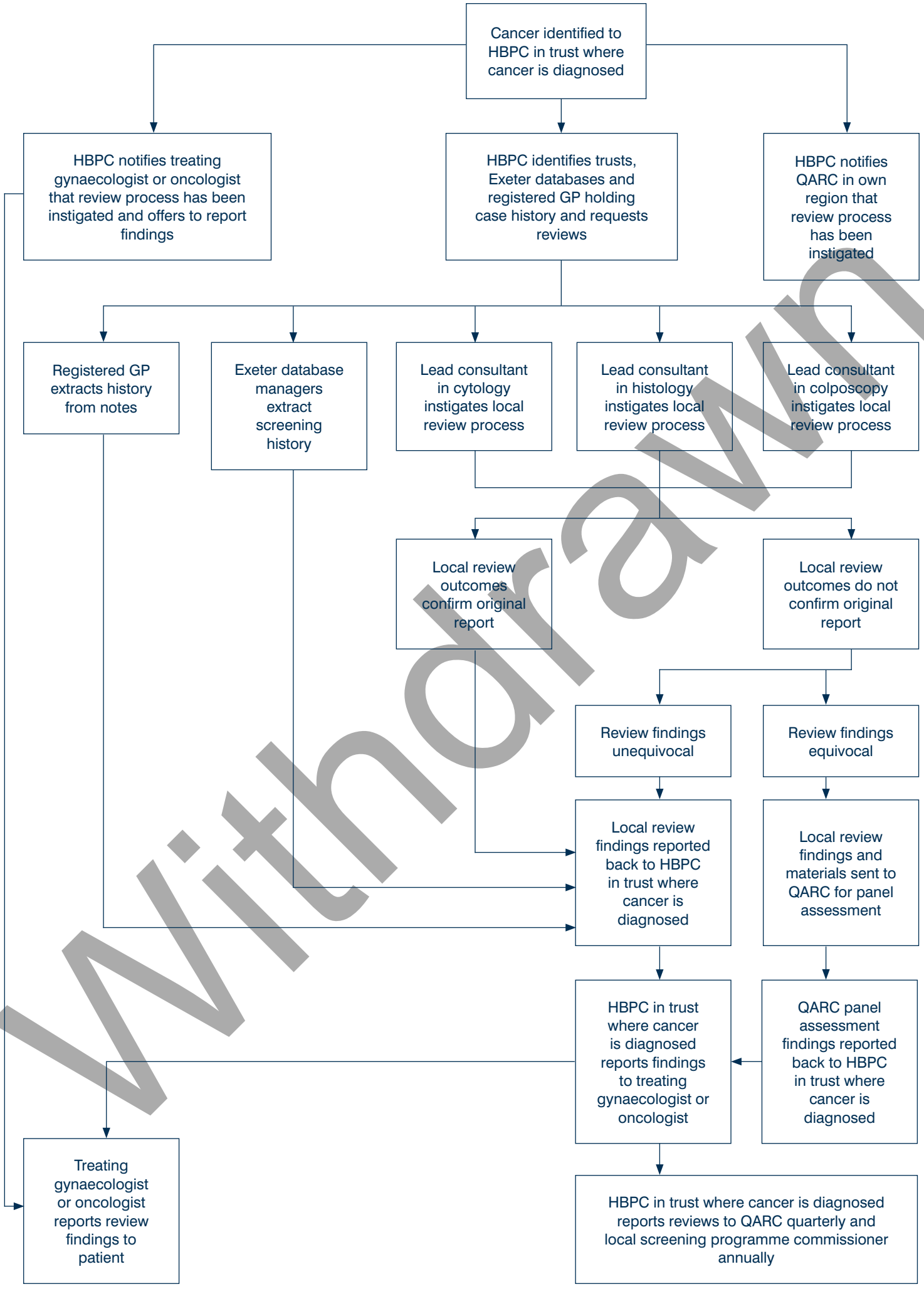

Figure 2 NHSCSP prospective audit of cervical cancers audit process map.

- Assist with feedback to the patient as required.
- Ensure a fail safe system is in place in local laboratories to identify all cervical cancers.
- Report completed reviews using standard forms to the QARC (see Appendix 1).
- Notify the local screening commissioner of audit outcomes on an annual basis.

2.3.2 Lead consultant in cytology in all laboratories holding cytology slides

- Instigate the local cytology review process.
- Report the outcome of review to the coordinating HBPC using the standard forms.
- Refer appropriate cases to QARC for further review via the trust HBPC.

2.3.3 Lead consultant in histology in all laboratories holding histology cases

- Instigate the local histology review process.
- Report the outcome of review to the coordinating HBPC using the standard forms.
- Refer appropriate cases to QARC for panel review via the trust HBPC.

2.3.4 Lead colposcopist in all units holding colposcopy histories

- Instigate the local colposcopy review process.
- Report the outcome of review to the coordinating HBPC using the standard forms.
- Refer appropriate cases to QARC for panel review via the trust HBPC.

2.3.5 Call and recall system manager

- Supply screening histories to HBPC using the standard forms.
- Identify controls.
- Supply information on controls, including screening histories, to HBPC using the standard forms.

2.3.6 Primary care team

- Carry out a local audit of own practice (practices that participate in the programme may be remunerated through the Quality and Outcomes Framework (QOF)).
- Cooperate with wider audit protocols as necessary for patients in the practice.

2.3.7 Quality assurance team and QARC

- Validate local cytology, histology and colposcopy review processes in line with this protocol.
- Convene cytology, histology and colposcopy review panels to review difficult cases.
- Report the outcome of case reviews back to HBPC in all trusts involved in order to feed back to lead consultants in the trust for cytology, histology or colposcopy.
- Monitor progress and outcome of audits.

The QARC input is regional coordination of the cervical cancer history review. This will involve all elements of that review, and will also ultimately produce the national database return and assist in the collection of data regionally.

The data collected via the HBPC and passed on to the QARC will be submitted nationally by the QARC using the standard data format (see Appendix 1).

2.3.8 Screening programme commissioners

- Receive audit data annually from HBPC and incorporate into annual reports.
- Work with relevant primary care staff (GPs, practice nurses, community clinics, etc) to contribute to the audit review process as outlined above.

2.4 Role of cancer registries

Cancer registries are responsible for the identification and registration of cervical intraepithelial neoplasia 3 (CIN 3) and invasive cervical cancers diagnosed in women resident in their catchment area, and for continued collection and analysis of diagnosis and treatment data that follow diagnosis. Cancer registries are required to categorise the diagnostic route for each invasive cervical cancer, including screening status, for the National Cancer Dataset.

All cervical cancers should be categorised by the QARC into one of six categories, which in turn map to the diagnostic status required by the National Cancer Dataset used by the cancer registries. Details of the categories of cervical cancer and the requirements of the National Cancer Dataset are given in Appendix 2.

The director of each regional cancer registry should identify an individual within that registry as having lead responsibility for liaising with the QARC to ensure that the information stored by the registry includes a record of the diagnostic status (screening/interval/other/not known) of each woman with invasive cervical cancer diagnosed in the population eligible for screening.

This individual should work closely with his/her opposite number at the QARC in order to ensure complete ascertainment and analysis of all cases in women resident in the region covered by the registry and to ensure full exchange of data about women diagnosed or screened in the area but resident within another registry's area. The role of this lead person includes:

- liaison with the relevant QARC in order to achieve full ascertainment of all CIN 3 and invasive cervical cancers diagnosed in women resident in the region
- supply of data to the QARC for all diagnosed women within the screening population (whether the registry has the screening status or not)
- receiving the results of checking a woman's NHSCSP history, diagnosis and screening classification from the QARC
- assisting the QARC as required in the analysis of patterns of cases in order to identify any weaknesses that require attention.

2.5 National level

The national office of the NHSCSP will work closely with the QARC, the cancer registries and Cancer Research UK to collate and analyse data from each individual woman in order to produce information about the sensitivity and performance of the NHSCSP at a national level. This will result in scientific publications and annual data that will illustrate the numbers of women falling into each category. Details are given in Chapter 4. These national data will allow evaluations of changes in policy, year on year comparisons of the performance of the NHSCSP, international comparison of performance and comparison of performance against expectation and trials data in order to improve estimates of performance. In addition to the collation of data from regional QARCs, working closely with the cancer registries will allow classification of the cancers detected into various diagnostic categories to aid evaluation of the programme. The epidemiological audit, in collaboration with Cancer Research UK, will evaluate the programme's policies and how effectively they are implemented. The epidemiological audit will require audit of a control group.

3. REVIEW PROCESSES

3.1 Screening history review

The full screening history for a particular woman can be obtained only by searching a number of different databases. The first step should be to use the local computerised call/recall NHAIS computer system (the Exeter system), which holds a woman's invitation and cytology history. Only when the history is ascertained can the next steps be identified.

The history will require demographic details (name, date of birth, etc) to allow a search on the call/recall, laboratory and colposcopy computer systems. It should be possible to do this through the local call/recall office because all screening invitations, results, final non-responder cards, etc would be detailed. Access may also be required to the 'deducted' (removed) patient details.

The assistance of the local screening manager (or equivalent) and the local screening commissioner/primary care trust (PCT) and HBPC may also be required to allow the full screening history to be obtained. If the HBPC has access to the Open Exeter web browser or the new Patient Demographics Service through 'Choose and book', this may allow an initial search. However, as access to the Exeter database varies locally, each area should determine who is the most appropriate person to undertake the actual search to ensure that all records are identified.

The screening history obtained from the search outlined above should identify the full history of screening invitations, results, invitations not acted upon, etc as well as the laboratories involved in reporting the cytology and the source of sample. The latter would facilitate finding colposcopy or GP records. This Exeter derived screening history will form the basis of the screening history for the purposes of the cervical cancer audit.

All local colposcopy clinics should be contacted for relevant records. The record should include the dates of all appointments, whether the patient attended and whether any procedures were carried out (see Appendix 1, section C). It should also include 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. Information should be collected as detailed in Appendix 1, section D.

It may also be desirable to check GPs' notes on certain patients, particularly to understand any reasons for non-attendance. Such information, if obtained, should be recorded and should form part of the patient's audit.

Other episodes may be identified within non-NHS facilities, and access to records for this may also have to be obtained by the HBPC or QARC depending on local circumstances.

3.2 Control groups

In order to allow rigorous evaluation of the programme, women who did not develop cancer will be required as controls. This exercise will be carried out in cooperation with Cancer Research UK. For each woman with invasive cancer, two women who have not undergone hysterectomy should be matched for age and area of residence. The selection of controls can now be carried out automatically using the NHAIS (Exeter) system. This facility will be incorporated into the new national system that will replace NHAIS under the National Programme for IT being developed by NHS Connecting for Health. Cancer Research UK will issue separate guidance on selection of controls for the epidemiological audit.

3.3 Cytology slide review

3.3.1 General approach

Cytology slide review is a powerful tool for both audit and education. For this reason, it is best performed within the laboratory that reported the original slides. In the event of tests having been reported in more than one laboratory, each laboratory should review its own slides and forward the results to the HBPC at the laboratory generating the original histological diagnosis of cervical cancer. In the event of this not being a cervical screening laboratory, this responsibility should pass to the HBPC at the trust laboratory reporting the most recent test.

Any audit must be constructed so as to maximise the educational value for the NHSCSP as a whole. Cytology slide review should be carried out only with current staff with current knowledge of cervical cytology reporting and of its pitfalls. Although it is accepted that reporting and diagnostic criteria may have changed in the interval since the slides for review were reported, any attempt to replicate historical working practices is fraught with problems and should not be made. Difficulties in the identification of dyskaryosis are discussed in more detail in Appendix 3, which has been adapted from previously published advice.[4]

The aim of a slide review audit is not to replicate 'normal' screening practice, but rather to identify lessons for the NHSCSP as a whole. In light of this, the slide review does not have to follow traditional screening pathways in that it is not a 'test' of whether a slide should have been reported differently by different grades of staff. The purpose is to see whether there were reasons why the particular cancer in question developed, and whether there were any cytological reasons that may have contributed to this. The review is not a medicolegal review and is carried out by NHS staff for educational purposes.

The histological diagnosis of a cervical cancer is the event that will trigger a review of that woman's cervical screening history. The pathological aspect of this will require a full review of the cytology and histology history. Histology review is described in section 3.5.

The sample history can be obtained from the Exeter database either via Open Exeter or from the call/recall office. This will allow identification of where and when slides were reported. If this involves other laboratories, the HBPC at the hospital making the histological diagnosis will write to the HBPC at any other hospitals where cytology has been reported

to ask for a full screening history review to be undertaken in line with this protocol, including slide review. If these hospitals are no longer screening laboratories within the NHS or the laboratory is outside the NHS, the initiating hospital will offer to undertake this review. If the hospital making the original diagnosis is not a screening laboratory, the hospital with the most recent sample that is an NHSCSP laboratory will undertake that review.

The slide review process must have access to the original report as issued and to the original request/report card wherever possible. Any laboratory records or 'in house' comments should also be available for review.

Many slides will have screening dots on them already. It is possible that as part of the review new ones may be added to identify areas of interest. To aid in this, it is recommended that a copy of the slide is taken prior to any review (often a simple photocopy or use of a slide graticule will suffice). If new dots are added, then the slide should be copied again after the review. The dots will aid in any discussion/education based on slide review as part of the audit process.

3.3.2 *Internal laboratory review*

The internal laboratory review process must entail a review of the original slides. A model for this is outlined below. Figure 3 outlines the process as a flow diagram.

- The slides identified will be reviewed independently by two members of the screening staff, one a screener and one a checker, and the results recorded on the data collection sheets shown in Appendix 1. Given that slides should be kept for at least 10 years, this should not produce a large workload for any one laboratory.
- Once completed, the slides and forms are given to a consultant pathologist or advanced biomedical scientist practitioner currently reporting samples within the NHSCSP for a third review and for collation of the three slide reviews. This will identify slides where there is agreement or non-agreement, either with the original report as issued or with the review opinions themselves. Discussion should also take place between the reviewers to aid in this process, and to maximise the educational value for the reviewers involved.
- The information is then passed to the regional QARC for entry into the regional, and then national, cervical cancer audit database via the HBPC in the laboratory initiating the review. Any cases where there is a lack of agreement following case discussion, where all review slides are classed as non-dyskaryotic or where the reviewing laboratory asks for a further opinion are referred to the QARC for panel and/or expert review as considered appropriate. The process for review should, in most cases, be completed within 6–8 weeks of the original histological diagnosis.
- If any cytology slides are not available for review, this must be noted on the QARC return.
- The reviews undertaken by other laboratories apart from the initial hospital must be returned to the HBPC at the initiating hospital within one month of receipt, and this information is then passed to the regional QARC of the initiating hospital.

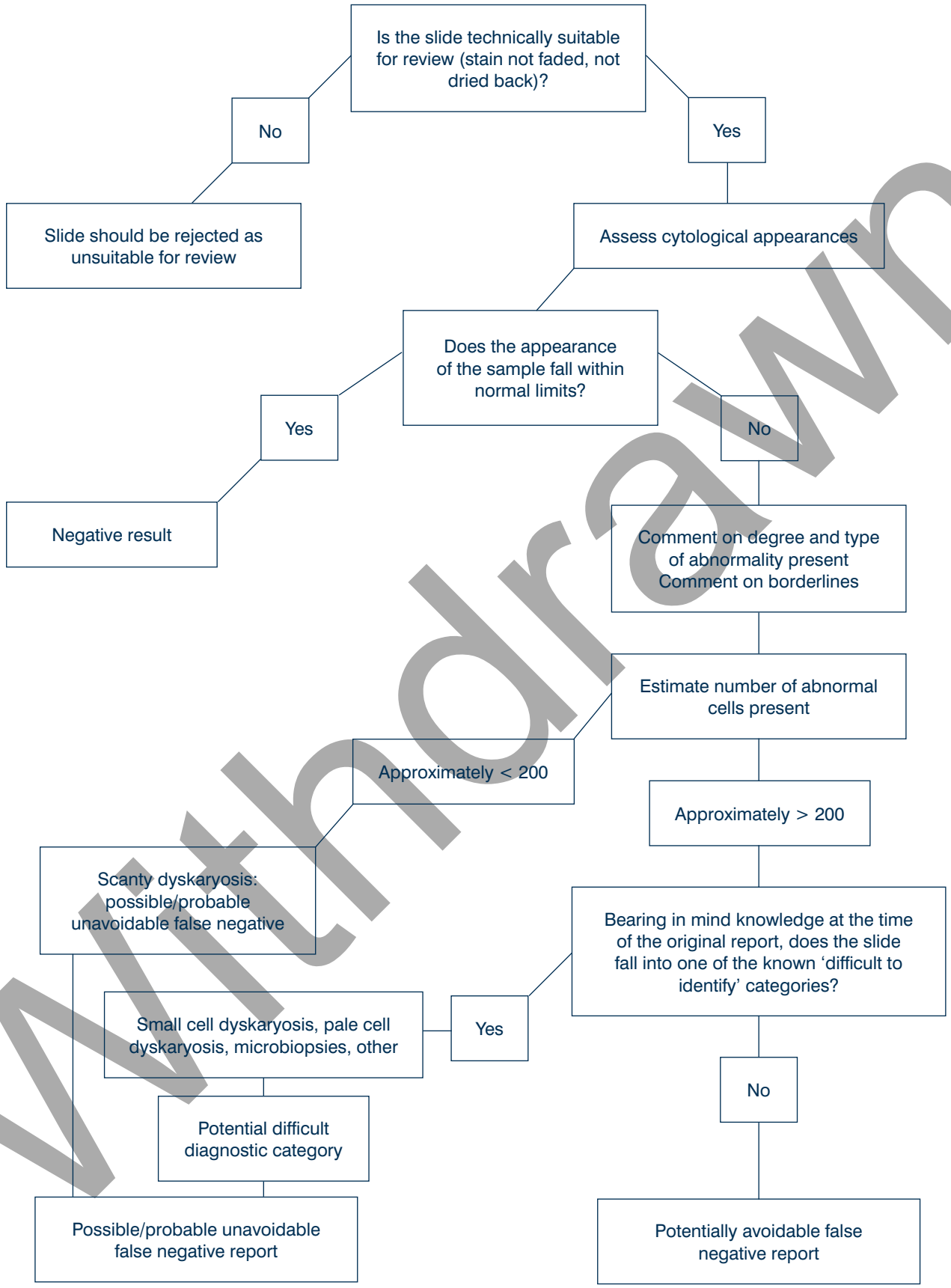

Figure 3 Slide review decision making.

- All reporting must use accepted NHSCSP/British Society for Clinical Cytology terminology.[4]
- The cytological review will record data not only on the review opinion but also on type, number and appearances of dyskaryosis (if present).

3.4 Review of gynaecological management

Where review of gynaecological/colposcopic management is required, this should be undertaken by two consultant gynaecologists who are accredited colposcopists. They should review any colposcopic assessment for which records are available.

Unlike cervical cytology and histopathology, there has traditionally been no permanent record kept of a colposcopic image taken at the time of assessment. It has always been good practice to record three features in patients' records:

- whether the new squamocolumnar junction is visible
- whether there is an abnormality present
- an impression of the degree of abnormality.

These three features are included in the standard for documentation to be recorded in *Colposcopy and Programme Management* (NHSCSP Publication No 20).[6] Most colposcopists produce a small diagram within the record demonstrating these features and recording a management plan. In recent times, the capacity to record a digital image of the colposcopic findings has become standard practice in some clinics and may be useful if available, although the degree of agreement between observers of images can be highly variable. The published guidelines indicate areas of current good practice for colposcopy.

3.5 Histological slide review

3.5.1 General approach

The histology slide review should include slides from which the diagnosis of cancer was made and also any slides from the previous 10 years. Only existing slides should be reviewed – there is no need to cut new sections. The review should also include a macroscopic examination of any blocks if there is any suggestion that all pieces have not been cut into or if there is a clear discrepancy found in the review. Pathologists may wish to cut additional slides to seek further information that might change the grade of CIN originally reported or to identify possible invasion.

Audit of cervical cancer will also include a full review of any relevant histological material. This will include cervical biopsies and cervical excisions (e.g. large loop excision of the transformation zone, loop or knife cones, etc). The identification of such material may be more problematic than that of the cervical sample slides in that there is no one database for this material that is similar to the cytology history held on the Exeter system. However, referral to this database will usually give a good indication of when a woman was referred for colposcopy and therefore when histology specimens were likely to have been taken. The

primary care record could also be used to identify relevant colposcopy episodes and hence potential histological material.

Histology can be identified by review of pathology laboratory computer or other record keeping systems at all hospitals where slides were reported. Hospitals will know their own referring patterns locally, and this may mean contacting other centres not involved in reporting cervical samples. The colposcopy history review may also identify centres where colposcopy was undertaken, and hence where histological material may be kept.

3.5.2 Conduct of the review

The review should use the original slides and have access to the original report as it was issued.

- The histological review can be undertaken only by consultant pathologists. Ideally, these would be consultants who participate in the national gynaecological pathology EQA scheme and who routinely report on NHSCSP histological material. The opinion of one, but preferably two, consultants should be obtained and recorded using the data collection sheets shown in Appendix 1.
- It is important to indicate whether a specimen was received in one piece or piecemeal. The presence or absence of CIN, cervical glandular intraepithelial neoplasia (CGIN), invasive disease and any other relevant pathology, as determined by the review panel, should be recorded, together with an indication of any particular difficulties in the interpretation of the case, eg severe diathermy artefact, epithelial stripping or poor orientation of the sample.
- The review should use standard NHSCSP/FIGO/RCPath terminology.[5,7–9]
- Once collected, the data must be sent to the QARC of the region of the initiating hospital. This will be via the HBPC of the hospital initiating the review. Demographic data will be collected as detailed on the cytology review form, and histology data as detailed on the RCPath minimum data format form.[7]
- Cases for which there is a lack of consensus between the reviewing pathologists, or which are perceived as difficult, are referred to the QARC for regional panel review.

3.6 Regional panels

The regional QARC will need access to an expert(s) or to a panel for cytology, histology and/or colposcopy review in the following circumstances:

- cases identified as problematic by the reviewers
- cases in which all samples are identified as negative or inadequate or borderline after local review.

All results should be notified to the HBPC in the initiating hospital by the QARC.

For cytology review, the panels should ideally consist of a minimum of three people. These would include a primary screener and/or a checker and a consultant pathologist and/or an advanced practitioner. They should independently review the cases submitted, and then review their own opinions against the original hospital based review. If this regional review identifies a case that is problematic, this needs to be noted and included in the report to the HBPC in the initiating hospital.

For histology review, the panel should consist of two consultant histopathologists who routinely report NHSCSP related material, at least one of whom regularly participates in the national gynaecological histopathology external quality assessment scheme. They should independently review the slides and then compare their opinions with the original hospital based review. If this regional review cannot reach consensus, this needs to be noted and included in the report to the HBPC in the initiating hospital.

The regional review process should be completed within one month of receipt of all the required material.

The regional panel opinion is recorded as the 'final' opinion in these reviewed cases. The regional panel view is conveyed to the HBPC in the initiating hospital, and all the other HBPCs involved, by the QARC. A final outcome of 'equivocal' is acceptable in cases where agreement cannot be reached even after regional review. The HBPC will communicate the review outcome to all other hospitals involved in the review.

Any hospital where an HBPC cannot be identified needs to consult the regional QARC to ensure clarity of communication.

Identifying details, such as the patient's name and NHS or hospital number, should be covered over so far as is possible without obscuring original detail in order to protect patient confidentiality before QARC review. Such details should **not** be permanently erased from the slides.

3.7 Reporting of review findings

The QARC will collate the information relating to the cervical screening history and complete the national data return for national analysis. This will include not only the slide review but also the colposcopy and screening history review.

The HBPC at all the sites involved in each case will receive a full screening history for each woman relevant to their site from the HBPC initiating the audit process when it has been completed. This can then be passed on to the individual clinicians involved (lead cytologist, lead histologist, lead colposcopist, PCT lead, call/recall lead) for information and could be used as a basis for discussion with the woman if she so wishes.

The report issued constitutes an NHSCSP audit review, not a legal review, and as such must be carefully discussed in this light.

The nationally collected data will allow annual data publication, and can be issued alongside other nationally collected data for regular analysis.

This may allow lessons about the NHSCSP at all points in the screening pathway to be identified, and so may lead to benefits that will help to improve the NHSCSP.

The purpose of this audit is to help to improve the NHSCSP. From an educational stance, this can be maximised within each department involved in the management of women in the programme by:

- discussion of the review results with all screening staff and any other health professional involved
- production of an annual report of the individual departmental experience, findings and any action points resulting (eg training, etc)
- production of an annual QARC/national report of the findings of the review, lessons learned and action points for the programme
- discussion at a local level (laboratory, PCT, colposcopists, etc) of findings, trends, etc.

All new cases of cervical cancer should be audited. All cases logged with the regional QARCs should be cross-checked against those registered with the cancer registries (see section 2.4).

3.8 Audit of treatment

An audit of the treatment of cervical cancer is being planned and guidance will be added following piloting. This will use essentially the same dataset as all other audits in the NHSCSP. In time, as information systems improve, it is envisaged that audit of cases of CIN 3 will be possible.

4. ANALYSIS

4.1 Evaluation

Women with cancer will be categorised into the following groups:

1. Screen detected cancer
2. Interval cancer
3. Lapsed attender
4. Never invited (subgroups by < 25, 25–64, 65+)
5. Never attended
6. Lost to follow up

Study of the different groups of women by the local QA teams will yield valuable information about where resources to improve the programme or correct deficiencies might best be directed. For example, those women who have never been invited but are however within the screening age group will need particular scrutiny by their local QA team to ascertain the reasons for their non-invitation, and study of those women who have never attended may assist in learning where activities to improve access to the programme might best be directed.

Further detail on these categories is given in Appendix 2.

4.2 Epidemiological audit

This audit will use the categories described above but will further sub-categorise those with a cytological history to consider:

1. Screen detected
   a. Cancer diagnosed at referral for colposcopy
   b. Cancer diagnosed after negative cytological follow up at colposcopy
   c. Persistent abnormality after treatment diagnosed at follow up cytology
2. Interval cancers
   a. Previously screened as recommended
   b. Not previously screened at recommended frequency
3. Lapsed attenders with previous negative cytology
   a. Previously screened as recommended
   b. Not previously screened at recommended frequency
4. Lost to follow up
   a. Abnormal cytology
   b. Referral indicated and not attended
   c. Follow up not attended after treatment for CIN

This will enable an evaluation to be made of the policies for follow up and for the age and frequency of invitation. It should be recognised, however, that the proportion of cases in each group reflects the screening coverage of the target population as well as the effectiveness of the screening programme. It is for this reason that the inclusion of controls is essential in the evaluation part of audit activities.

REFERENCES

1. *IARC Handbook of Cancer Prevention*. No 10. *Cervical Cancer Screening*. IARC, 2005.
2. Sasieni P, Cuzick J, Farmery E. Accelerated decline in cervical cancer mortality in England and Wales. *The Lancet*, 1995, 346: 1566 [Letter].
3. *Cancer Statistics*. Cancer Research UK, 2006 (www.cancerresearchuk.org).
4. *Achievable Standards, Benchmarks for Reporting, and Criteria for Evaluating Cervical Cytopathology*. NHS Cancer Screening Programmes, 2000 (NHSCSP Publication No 1, second edition).
5. *FIGO Staging for Cervical Cancers* (www.figo.org/content/PDF/staging-booklet.pdf).
6. Luesley D and Leeson S (eds). *Colposcopy and Programme Management*. NHS Cancer Screening Programmes, 2004 (NHSCSP Publication No 20).
7. *Minimum Dataset for the Histopathological Reporting of Cervical Neoplasia*. RCPath, 2001 (www.rcpath.org/resources/pdf/datasetrecervicalcancer.pdf).
8. *Histopathology Reporting in Cervical Screening*. NHS Cancer Screening Programmes, 1999 (NHSCSP Publication No 10).
9. *Bench Aid for the Reporting of Cervical Histological Samples Associated with Abnormal Cervical Cytology or Colposcopic Examinations*. NHS Cancer Screening Programmes, 2003 (NHSCSP Publication No 16).

APPENDIX 1: NATIONAL AUDIT DATASET

A1.1 Common national database

The use of a common national database will facilitate the pooling of data from screening programmes across the country to allow epidemiological analysis. This is not a minimum national dataset (ie not all fields are essential); please refer to the coding guide for a list of essential fields.

A1.2 Access database

An electronic (Access) database is available on request and is provided with an explanatory manual. Please email nhscsp.audit@cancer.org.uk for a copy or for further details. The intention is that the electronic database will initially be used by QARCs to input the data collected by HBPCs.

A1.3 Data collection forms

HBPCs are expected to use the forms in this Appendix for data collection. Different forms are to be completed by different laboratories or clinics either by a specialist from the relevant area or by the person responsible for the collection of audit data. It is not necessary to complete all sections in the audit in order to submit data; however, sections A and B are essential.

A1.4 Coding guide

The coding guide for the national dataset provides an overview and explanation of the sections and fields that the audit aims to record. The last section lists the fields that are essential for audit purposes. The fields that are not mentioned are desirable, ie an effort should be made to collect the data but forms should be submitted even if there are some fields missing.

A1.5 Printable forms and coding guide

The data collection forms and coding guide listed below are included on the following pages. Printable copies of the forms as separate PDFs can be downloaded from the NHS Cancer Screening Programmes website (www.cancerscreening.nhs.uk). A copy of the coding guide can also be downloaded.

Data collection forms

Section A	Personal and cancer details
Section B	Cytology history
Section C	Colposcopy history
Section D	Histology history
Section E	Cytology review
Section F	Histology review
Section G	GP notes
Section H	HPV DNA testing

Coding guide

- Personal and cancer details
- Cytology history
- Colposcopy history
- Histology history and review
- Cytology review
- GP notes
- HPV DNA
- Essential fields

SECTION A. Personal and Cancer Details

PART A1. FOR LOCAL USE ONLY

Study ID

Surname _____ First Forename _____

Other Forename(s) _____ Surname at Birth/Maiden Name _____

NHS Number

GP Number

Address _____

_____

Postcode

----------(CUT HERE)----------

PART A1. FOR LOCAL, REGIONAL AND NATIONAL USE

Study ID

Date of Birth (D D M M Y Y Y Y)

Date First Registered with GP (date provided by Open Exeter and AJ-CRUK)

Index of Multiple Deprivation (derived from postcode by electronic database)

CASES ONLY

Date of Diagnosis (Date of Relevant Biopsy)

Stage of Tumour (FIGO)

Histology (Codes required for AJ-CRUK)
(S=Squamous A=Adeno B=Adeno-squamous, U=Undifferentiated, O=Other, X Unknown)

Screen Detected* (1=Yes 2=No)

Laboratory Code (where case was identified)

**Screen detected means that the discovery of cancer resulted originally from a woman having a routine screening test*

Treatment received -please tick one only

- ☐ None
- ☐ LLETZ/Cone Biopsy
- ☐ Trachelectomy
- ☐ Simple hysterectomy
- ☐ Radical hysterectomy
- ☐ Hysterectomy plus radiotherapy
- ☐ Hysterectomy plus chemotherapy
- ☐ Hysterectomy plus radiotherapy plus chemotherapy
- ☐ Radiotherapy only
- ☐ Chemotherapy only
- ☐ Radiotherapy plus chemotherapy

(End)

SECTION B CYTOLOGY

STUDY ID

Tick if **no cytology** was found

Please state **reason** for no cytology (see codes)

If **ceased** prior to diagnosis please give **reason** (see codes)

CYTOLOGY HISTORY (most recent first)

	Date test was taken (D D M M Y Y Y Y)	Result of test (see codes)	Action Code (see codes)	Source (see codes)
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Result Codes
1. Inadequate
2. Negative
3. Mild Dyskaryosis
4. Severe Dyskaryosis
5. ?invasive cancer
6. ?glandular neoplasia
7. Moderate dyskaryosis
8. Borderline dyskaryosis

Action Code
A. Routine Screening/Call/Recall
H. Result Recorded but no change in current action code
R. Early recall at interval specified by lab
S. Suspend recall pending referral

No Cytology Reason
1. Not on Exeter System
2. Invited but did not attend
3. Not yet called
4. Ceased
5. Unclear

If Ceased Reason
1. Age
2. Absence of cervix
3. Informed Choice
4. Other/ unknown

Source
(not provided by AJ-CRUK)
1. GP
2. Private
3. NHS Community Clinic
4. NHS Hospital (Colp)
5. GUM clinic
6. Other

(End)

SECTION C COLPOSCOPY

STUDY ID

COLPOSCOPY HISTORY (most recent first)

Number of colposcopic appointments, for cases, prior to diagnosis of invasive cancer.
Please enter 0 if number known to be zero. Cross out if unknown.

Date of Colp Appointment D D M M Y Y Y Y	Satisfactory Examination (or DNA)[1]	Colposcopist (see codes)	Colp Impression (see codes)	Surgical Procedure	Pathological Diagnosis	If Pregnant (# of weeks)[2]	Follow-up requested months[3]

[1] If patient DNAs multiple appointments, use boxes for appointments she did attend and list dates of missed appointments below.
[2] Leave blank if the woman is NOT pregnant, or write "NK" if NOT KNOWN.
[3] Leave blank if unknown. Write 99 if patient was discharged.

Satisfactory Examination
1. Yes
2. No
3. Not Recorded
4. DNA (Did not attend)

Colposcopist:
1. Consultant
2. Non-consultant (Registrar/SHO)
3. Nurse
4. Trainee

Colp Impression:
1. Normal
2. HPV only
3. Low Grade
4. High Grade
5. Invasive Cancer
6. Not Recorded

Surgical Procedure:
0. None
1. Punch Biopsy
2. LLETZ (loop)
3. Laserexcision/cone
4. Knife Cone
5. Laser Ablation
6. Cold Coagulation
7. Cryotherapy
8. Not Recorded

Pathological Diagnosis
(For details/decimals see colposcopy history on the coding guide)
0. Normal
X.Inadequate Biopsy
1.HPV Changes
2.CIN
3.CGIN
3.5 SMILE
4.Squamous Carcinoma
5.Adenocarcinoma
6. Adenosquamous
7. All other Cervical Malignancy
8.Benign lesions
9. Non-cervical Malignancy

(End)

SECTION D HISTOLOGY

STUDY ID

HISTOLOGY HISTORY

PART D1. CANCER DIAGNOSIS

Date of Specimen	Type of Specimen (see codes)	FIGO Stage (as recorded in histology notes)	Pathological Diagnosis (see codes)	Details
D D M M Y Y Y Y				

Number of histology specimens found for this woman. Cross out if NONE.

PART D2. PRE-DIAGNOSTIC SPECIMENS (generally colposcopic specimens) - (most recent first)

Date of Specimen	Type of Specimen (see codes)	Pathological Diagnosis (see codes)	Details	Clear Margins (Yes/No)
D D M M Y Y Y Y				

Type of Specimen
1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

Pathological Diagnosis
(For details/decimals see colposcopy history on the coding guide)
0. Normal
X.Inadequate Biopsy
1.HPV Changes
2.CIN
3.CGIN
3.5 SMILE
4.Squamous Carcinoma
5.Adenocarcinoma
6. Adenosquamous
7. All other Cervical Malignancy
8.Benign lesions
9. Non-cervical Malignancy

Details
Site for non-cervical cancer or type of other cervical malignancy.

FIGO Stage

1A	1B	2	3	4
1A1	1B1	2A	3A	4A
1A2	1B2	2B	3B	4B

(End)

CERVICAL SCREENING AUDIT **(USE ONE SHEET PER SLIDE)** SECTION E

SECTION E CYTOLOGY REVIEW

STUDY ID

PART E1. **ORIGINAL** SLIDE DETAILS

Lab Code	Slide ID	Date of Original Test (D D M M Y Y Y Y)	Test Type (see code)	Cytology Type (see codes)	Original Test Result	First Referral (Y/N)

PART E2. **REVIEW** RESULTS (please enter one line per reviewer. **START** with Local reviewers)

Reviewed at (1.Local/ 2.Regional level)	Type of Reviewer (see codes)	Date	Review Result (see code)	Factors likely to lead* to false **positive** results	Factors likely to lead* to false **negative** results

*Please enter as many factors as necessary. Leave blank if it does not apply

Result Codes
1. Inadequate
2. Negative
3. Mild Dyskaryosis
4. Severe dyskaryosis
5. ?invasive cancer
6. ? glandular neoplasia
7. Moderate dyskaryosis
8. Borderline dyskaryosis

Potential False Negatives
1. Small Cell Dysk
2. Pale Cell Dysk
3. Microbiopsies
4. Small Keratinized cells
5. Sparse Dysk(<200 cells)
6. Other (Specify)

Potential False Positive
A. Normal Endometrial Cells
B. Endometriosis/tubo-endo metaplasia
C. LUS Endometrial Sampling
D. Histiocytes
E. Follicular Lymphocytic cervicitis
F. IUCD Effect
G. Other (Specify)

Type of Reviewer
1. Screener
2. Checker
3. Advanced Practitioner
4. Consultant

Test Type
1. Routine Screening
2. Repeat (following abnormal)
3. Surveillance (following Colp)
4. Symptomatic
5. Colposcopy
6. Other

Cytology Type
1. Conventional
2. LBC (SurePath)
3. LBC (ThinPrep)
4. LBC (other)

(End)

CERVICAL SCREENING AUDIT **(ONE SHEET PER SPECIMEN)** SECTION F

SECTION F HISTOLOGY REVIEW PRE DIAGNOSTIC SPECIMEN

STUDY ID

PART F1. **ORIGINAL** SPECIMEN DETAILS

There is a separate form for cancer specimens (see F3 and F4)

In how many pieces was the specimen received ?

Lab Code	Specimen ID	Date of Original Specimen	Type of Specimen	Original Pathological Diagnosis (see codes)
		D D M M Y Y Y Y		Details

Biopsy Size (Length x Width x Depth) in mm ____ x ____ x ____

PART F2. HISTOLOGY **REVIEW** RESULTS (use one line per reviewer. **START** with Local reviewers)

Reviewed at (1. Local/ 2.Regional level)	Date	Review Pathological Diagnosis (see code)	Difficulties in interpretation
	D D M M Y Y Y Y	Details	

Type of Specimen
1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

Pathological Diagnosis
(For details/decimals see colposcopy history on the coding guide)
0. Normal
X.Inadequate Biopsy
1.HPV Changes
2.CIN
3.CGIN
3.5 SMILE
4.Squamous Carcinoma
5.Adenocarcinoma
6. Adenosquamous
7. All other Cervical Malignancy
8.Benign lesions
9. Non-cervical Malignancy

Difficulties in Interpretation
Open field. Some examples are:
Diathermy Artefact
Epithelial Stripping
Fragmented

Details
Site for non-cervical cancer or type of other cervical malignancy.

(continued)

CERVICAL SCREENING AUDIT **(ONE SHEET PER SPECIMEN)** SECTION F

SECTION F HISTOLOGY REVIEW CANCER REVIEW

STUDY ID

PART F3. CANCER SPECIMEN DETAILS

In how many pieces was the Specimen received ?

Lab Code	Specimen ID	Date of Original Specimen	Type of Specimen	FIGO Stage (see codes)	Original Pathological Diagnosis (see codes)
		D D M M Y Y Y Y			

Tumour Size (in mm)

Max Horizontal Dimension

Depth of Invasion

PART F4. CANCER REVIEW RESULTS (use one line per reviewer. START with the Local Reviewers)

Reviewed at (1. Local/ 2.Regional level)	Date	Review Pathological Diagnosis (see code)	Details	FIGO Stage (see codes)	Difficulties in interpretation
	D D M M Y Y Y Y				

Type of Specimen
1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

FIGO Stage
On review use 1B+ for all non-microinvasive cancers in which clinical staging is not possible.

Pathological Diagnosis
(For details/decimals see colposcopy history on the coding guide)
0. Normal
X.Inadequate Biopsy
1.HPV Changes
2.CIN
3.CGIN
3.5 SMILE
4.Squamous Carcinoma
5.Adenocarcinoma
6. Adenosquamous
7. All other Cervical Malignancy
8.Benign lesions
9. Non-cervical Malignancy

Difficulties in Interpretation
Open field. Some examples are:
Diathermy Artefact
Epithelial Stripping
Fragmented

Details
Site for non-cervical cancer, type of other cervical malignancy or extra information not covered by the Pathological Diagnosis codes.

(End)

SECTION G GP NOTES

STUDY ID

Please tick if no correspondence was found. Cross out if the GP records were not searched.

PART G1. CORRESPONDENCE

D D M M Y Y Y Y	SENT FROM	SENT TO	Action/Contents

PART G2. SPECIAL PERIOD/EVENT

FROM D D M M Y Y Y Y	TO D D M M Y Y Y Y	Reasons for Special Period

Other relevant information

Sent From/To
1. GP
2. Patient
3. Cytology Lab
4. Histology Lab
5. Gynaecologist
6. PCT
7. Private Doctor

Action/Contents
1. Referral
2. Discharge
3. Invitation
4. Complaint
5. Opted for private care
6. Postpone
7. Opted out of recall
8. Other (please specify)

Reasons for Special Period
1. Pregnant
2. Abroad
3. Hospitalized
4. Hysterectomy
5. Other (please specify)

(End)

SECTION H HPV DNA TESTING

STUDY ID

This section applies only to women who have had an HPV test the result of which might have impacted on the clinical management. If HPV testing becomes routine this information will be recorded in section B.

Date of Sample D D M M Y Y Y Y	Result (+/-)	Type of Test (e.g. HC-II, GP5+/6+)	Name of Study (e.g. HART, Triage pilot, ARTISTIC, TOMBOLA)	Other Details (Threshold (if non-standard), HPV types, Context (dual testing, triage))

(End)

Personal and Cancer Details

Postcode It is essential that postcode is recorded in full. Postcodes are available from www.royalmail.com. The postcode will be used to obtain an Index of Multiple Deprivation for each woman.

Index of Multiple Deprivation

The index can be obtained by typing the Postcode into the appropriate space in the Access database, the database will automatically return the corresponding Index. This index is calculated by the Office of the Deputy Prime Minister, it is based on geographical areas (Super Output Areas) each of which includes approximately 1,500 residents. The index is ranked and the percentile is recorded.

Study ID Study ID is 14 characters long and is assigned automatically by AJ-CRUK (Exeter) at the same time that the controls are assigned to the case.

It has the following format TES/QT2/CCYY/NNNX, where

- TES = HA cipher
- QT2 = Q code of Case/Control as at the date of diagnosis
- CCYY = the year of the case's diagnosis
- NNN = a sequence number for the Qcode and year of diagnosis
- X = the Case/Control type identifier. If:
    - X = 1 – indicates a Case
    - X = 2 – indicates a GP Control
    - X = 3 – indicates a District Control
    - X = 4 – an Adjusted Screened Control
    - X = 5 – an Abnormal Control
    - X = 6 – an Unadjusted Screened Control.

Dates All dates are of the form DD MM YYYY (eg. May 7, 1992 becomes 07 05 1992)
If only the year is available then leave the day and month blank.
(Most of the dates can be obtained from Open Exeter or AJ-CRUK)

Stage The FIGO staging should be used. 1A, 1A1, 1A2, 1B, 1B1, 1B2, 2, 2A, 2B, 3A, 3B, 4A, 4B. Convert Roman numerals to Arabic numerals. E.g. IIIb becomes 3B. Micro-invasive (1A) should be recorded by the laboratory.
NOTE: valid stage codes for AJ-CRUK are: 1A, IN,1B, 2, 2A, 2B, 3A, 3B, 4A, 4B, X.
"X" should be used for unknown stage and "IN" if the tumour is known to be worse than micro-invasive, but the stage is not available (this can also be labeled as "1B+")

Histology (this coding must be used in order to run Exeter AJ-CRUK and should only be used in reference to this output)

S. Squamous
A. Adeno
B. Adeno-squamous
U.Undifferentiated
O. Other
X Unknown

CYTOLOGY HISTORY

No Cytology

1. Not on Exeter System
2. Invited but did not attend
3. Not yet called
4. Ceased
5. Unclear

Ceased

1. Age
2. Absence of cervix
3. Informed Choice
4. Other/ unknown

Result

Where there is a conflict between the result recorded on Exeter and the one in the laboratory records, use the latter. Leave blank if the sample was only used for HPV DNA testing.
Use standard codes:

1. Inadequate
2. Negative
3. Mild dyskaryosis
4. Severe dyskaryosis
5. ?invasive cancer
6. ? glandular neoplasia
7. Moderate dyskaryosis
8. Borderline dyskaryosis

Action Code

A. Routine screening/ Call/ Recall
H. Result recorded but no change in current action code
R. Early recall at interval specified by lab
S. Suspend recall pending referral

Cytology Source (this field is not provided by AJ-CRUK)

1. GP
2. Private
3. NHS Community Clinic
4. NHS Hospital (including colposcopy clinics)
5. GUM Clinic

COLPOSCOPY HISTORY

Please give details of all known relevant colposcopy appointments prior to diagnosis date.

Satisfactory Examination

Defined as able to see the squamocolumnar junction

1. Yes
2. No
3. Not Recorded
4. DNA (did not attend)

Colposcopist

1. Consultant
2. Non-Consultant (Registrar/SHO)
3. Nurse
4. Trainee

Colposcopic/Surgical Procedure

0. None
1. Punch Biopsy
2. LLETZ (loop)
3. Laser excision/Cone
4. Knife Cone
5. Laser Ablation
6. Cold Coagulation
7. Cryotherapy
8. Not Recorded

Colposcopic Impression

1. Normal
2. HPV Only
3. Low Grade
4. High Grade
5. Invasive cancer
6. Not recorded

Pregnant

Leave blank if the woman is NOT pregnant. Write "NK" if NOT KNOWN.

Follow-up

Leave blank if unknown. Write 99 if patient was discharged

Pathological Diagnosis Codes

0. Normal (include cervicitis, infection)
X Inadequate Biopsy
1. HPV Changes only
2. CIN - not otherwise specified
- 2.1 CIN 1
- 2.2 CIN 2
- 2.3 CIN 3

3. CGIN- not otherwise specified
- 3.1 Low grade CGIN (include early invasive & glandular dysplasia)
- 3.2 High grade CGIN
- 3.5 SMILE (Stratified Mucin-producing Intraepithelial Lesions)

4. Invasive Squamous Carcinoma- not otherwise specified
- 4.1 Keratinizing
- 4.2 Non-Keratinizing
- 4.3 Basaloid
- 4.4 Verrucous
- 4.5 Warty
- 4.6 Papillary
- 4.7 Lymphoepithelioma-like

5. Adenocarcinoma of Cervix – not otherwise specified
- 5.1 Mucinous (5.11 Endocervical, 5.12 Intestinal, 5.13 Signet-ring cell, 5.14 Minimal deviation, 5.15 Villoglandular)
- 5.2 Endometriod
- 5.3 Clear cell
- 5.4 Serous
- 5.5 Mesonephric

6. Adenosquamous Carcinoma - not otherwise specified
- 6.1 Glassy cell carcinoma variant

7. All other Cervical Malignancy (please specify)
8. Benign squamous cell lesions (include condyloma, papilloma, polyp)
- 8.1 Benign glandular lesions (include mullerian, polyp)
- 8.2 Non-cervical Atypia

9. Non-cervical Malignancy (include secondary tumours)

HISTOLOGY HISTORY AND REVIEW

Type of Specimen

1. Punch Biopsy
2. Polyp
3. LLETZ (loop)
4. Laser excision/cone
5. Knife Cone
6. Trachelectomy
7. Hysterectomy
8. Other complete cervical excisions

Pathological Diagnosis Codes

(see under Colposcopy History)

Details

Site for non-cervical cancer or type of other cervical cancer.
Any extra information not covered by the Pathological Diagnosis codes.

FIGO Stage

(if you are carrying out HISTOLOGY REVIEW please use 1B+ for non micro-invasive cancers where clinical staging is necessary)

1A	1B	2	3	4
1A1	1B1	2A	3A	4A
1A2	1B2	2B	3B	4B

Difficulties in Interpretation

This is an open field. Some examples of possible difficulties encountered are:
Diathermy Artefact, Epithelial Stripping or Fragmented

CYTOLOGY REVIEW

Test Type

1. Routine Screening
2. Repeat (following abnormal)
3. Surveillance (following colp)
4. Symptomatic
5. Colposcopy
6. Other

Cytology Type

(This field should be filled in by the first reviewer)

1. Conventional
2. LBC (SurePath)
3. LBC (ThinPrep)
4. LBC (other)

Type of Reviewer

1. Screener
2. Checker
3. Advanced Practitioner
4. Consultant

Factors that contribute to Potential False Negatives

1. Small Cell Dyskaryosis
2. Pale Cell Dyskaryosis
3. Microbiopsies
4. Small Keratinized Cell
5. Sparse Dyskaryosis (<200 abnormal cells)
6. Other (specify)

Factors that contribute to Potential False Positives

A. Normal Endometrial Cells
B. Endometriosis/tubo-endo metaplasia
C. Lower uterine segment (LUS) Endometrial Sampling
D. Histiocytes
E. Follicular Lymphocytic cervicitis
F. IUCD Effect
G. Other (Specify)

GP NOTES

Sent From/To

1. GP
2. Patient
3. Cytology laboratory
4. Histology laboratory
5. Gynaecologist
6. PCT
7. Private Doctor
8. Other (specify)

Action/Contents

1. Referral
2. Discharge
3. Invitation
4. Complaint
5. Opted for private care
6. Postpone
7. Opted out of recall
8. Other (please specify)

Reasons for Special Period

1. Pregnant
2. Abroad
3. Hospitalized
4. Hysterectomy
5. Other (please specify)

HPV DNA

This section applies only to women who have had an HPV test the result of which might have impacted on the clinical management. If HPV testing becomes routine this information will be recorded in section B.

Essential Fields

Study ID required for all sections

SECTION A & A1
Personal and Cancer Details

- NHS Number
- Date of Birth
- Date of Diagnosis
- Stage of Tumour (FIGO)
- Histology

SECTION B
Cytology

- No cytology found
- Date test was taken
- Result of Test

SECTION C
Colposcopy

- Number of colposcopic appointments
- Date of colposcopy
- Satisfactory Examination or DNA
- Surgical Procedure

SECTION D1
Histology Cancer Diagnosis

- Date of Specimen
- FIGO Stage
- Pathological Diagnosis

SECTION D2
Specimen History

- Date of Specimen
- Type of Specimen
- Pathological Diagnosis
- Clear Margins

SECTION E Cytology Review
E1. Original slide

- Slide ID
- Date of Original Test
- Cytology Type
- Original Test Result

E2. Review Results

- Reviewed at
- Review result

SECTION F Histology Review
F1. Original Specimen

- Specimen ID
- Date of Original Specimen

F2. Review Results

- Review Pathological Diagnosis

F3. Cancer Original Specimen

- Specimen ID
- Date of Original Specimen

F4. Cancer Review Results

- Review Pathological Diagnosis

SECTION G
GP Notes

Although Section G is not essential, if you attempt to collect data, all fields are required

SECTION H
HPV DNA Testing

- Date of Sample
- Result

APPENDIX 2: CERVICAL CANCER CATEGORISATION

A2.1 Categories of cervical cancer

1. Screen detected	Detected after a diagnostic process that began with a cytology test taken up to three months before the test due date or up to six months after the test was due
2. Interval cancer	Detected in the interval between test due dates with the previous episode having been closed with no diagnosis of cancer
3. Lapsed attender	Cancer detected in a woman who had previously been screened at least once, whose last result was negative and who had not attended when last invited (up to six months after the test was due) **and** who was less than 70 years old (ie less than five years above the upper age limit for invitation)
4. Never invited	Woman who has never been tested nor sent an invitation for screening (subgroups by <25, 25–64, 65+)
5. Never attended	Woman who has never been tested but who has been invited for screening
6. Lost to follow up	Woman in whom either colposcopy or repeat smear was indicated, but who never received any follow up

Notes

1. Categories 2–6 ignore any cytology taken as part of the diagnostic process.

2. The screening invitation must be sent by the NHAIS system or its dispatch must be verified by checking with the woman's GP whether the practice sends its own invitations.

3. Cancers in women who are under follow up after colposcopy and treatment should be categorised according to their test status, eg was their cancer detected when they responded to an invitation to follow up (category 1) or did they fail to attend when invited (category 6)?

4. The test due date will be affected by the woman's screening status immediately before being diagnosed with cervical cancer (routine, early recall/suspended, post-treatment).

A2.2 National Cancer Dataset, Version 4.0 Issue date 11.08.03

C1	Diagnostic route (screening status)	Indicates the patient's route to diagnosis	1. Cancers detected by the national screening programme (category 1 above) 2. Interval cancers occurring in patients screened by a national screening programme (category 2 above) 3. Other cancers (categories 3–6 above) 9. Not known (default)

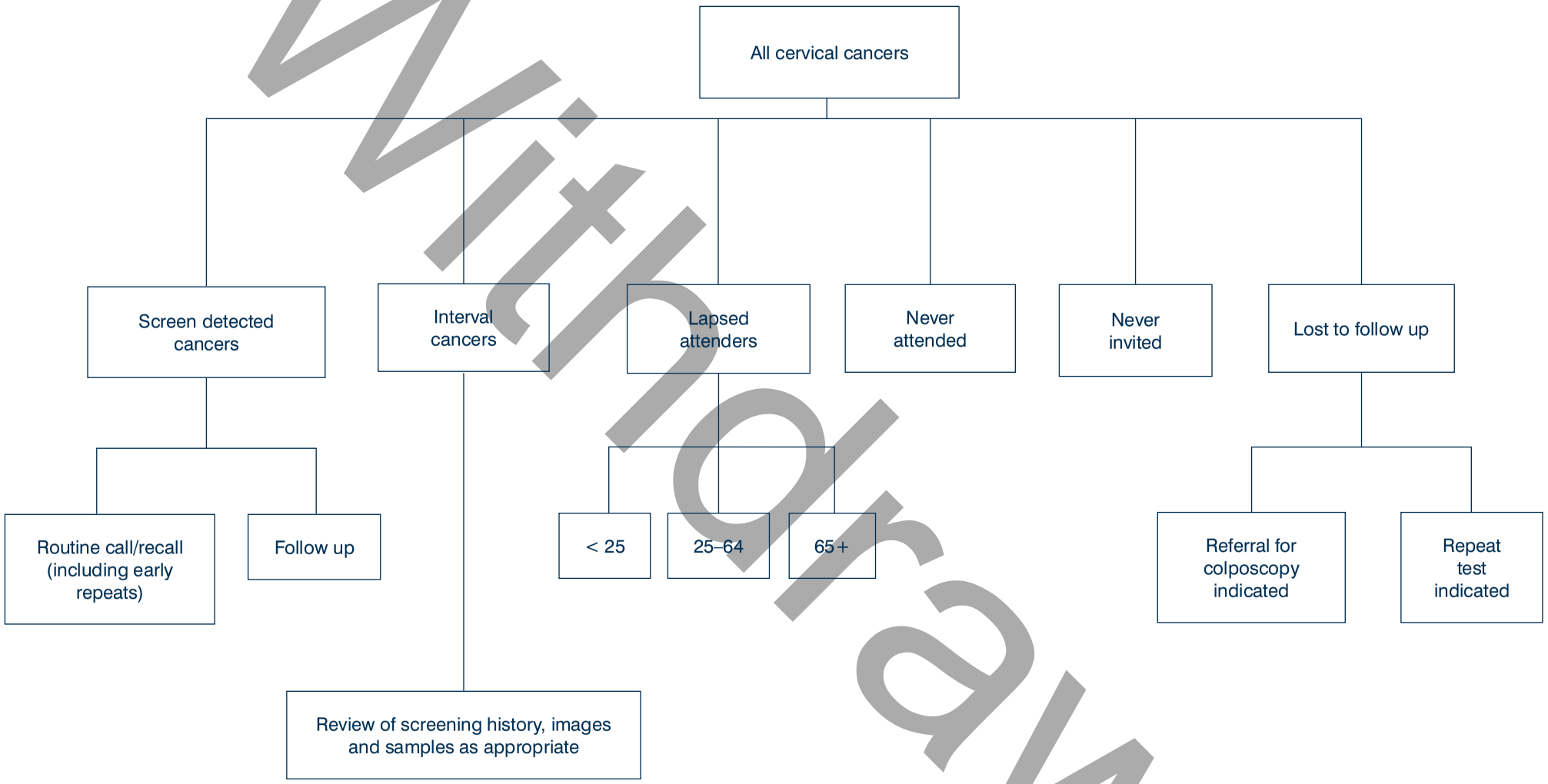

Figure A2.1 Categorisation of cervical cancers.

APPENDIX 3: DIFFICULTIES IN THE IDENTIFICATION OF DYSKARYOSIS

A3.1 Potential false negative results

It is relatively easy to recognise the classic form of severe dyskaryosis in which the dissociated cells have high nuclear–cytoplasmic ratios and hyperchromatic nuclei with irregularly dispersed chromatin. There are, however, several other cytological patterns indicating the presence of CIN 2/3 that are less easy to recognise and may lead to false negative cytology reports. The following sections draw attention to the main patterns which screeners, biomedical scientists and pathologists should recognise as potential problems.

A3.1.1 Small cell severe dyskaryosis

Small severely dyskaryotic cells may be only the same size as a neutrophil polymorph or even smaller. They sometimes have regular nuclear membranes, in which case their correct recognition depends on the appreciation of abnormal, irregularly clumped or speckled chromatin patterns. Nucleoli are usually, but not invariably, inconspicuous. Such cells may be mistaken for histiocytes, lymphocytes, endometrial cells or immature metaplastic cells. The key to recognising these cells is the characteristic nuclear chromatin pattern in association with a high nuclear–cytoplasmic ratio, despite the small size of the cells. Careful searching may reveal cells with keratinisation, confirming their squamous cell type. Many samples with small cell severe dyskaryosis will also include dyskaryotic cells of lesser grade which are obviously squamous in type. The observation of a continuum of cytological features from unequivocal mild or moderate squamous dyskaryosis into a small cell population may help the confident identification of small cell severe dyskaryosis.

A3.1.2 Pale dyskaryosis

Dyskaryotic nuclei are not necessarily hyperchromatic, and dyskaryosis may be seen in deceptively hypochromatic nuclei from all grades of CIN and even invasive squamous cell carcinoma. Pale dyskaryosis is often seen in samples mixed with cells showing more classic or hyperchromatic dyskaryosis; however, when this occurs as the predominant or only type in a sample, its recognition may be particularly difficult. Careful attention to the chromatin pattern, as described above, should allow recognition of this subtype.

A3.1.3 CIN 3 'microbiopsies' and CIN 2 and 3 infiltrating crypts

Severe dyskaryosis may be seen in sheets or three dimensional aggregates of cells which frequently appear crowded and hyperchromatic, and such aggregates are recognised as a common cause of errors of interpretation (as opposed to detection). They may easily be mistaken for endocervical cells. Diagnostic clues to the presence of severe dyskaryosis include disorderly cell arrangements with loss of polarity or chaotic architecture, mitotic figures (especially if numerous or abnormal) and a coarse, dark chromatin pattern. The last may be particularly difficult to evaluate in three dimensional clusters, and careful attention to the nuclear chromatin and nuclear–cytoplasmic ratio of cells at the edge of the group, especially if single non-overlapped nuclei can be seen, should help in interpretation. Aggregates of small severely dyskaryotic cells, especially if also showing pale dyskaryosis, may be very difficult to interpret. They may appear to

be deceptively orderly; columnar cells may be seen in small cell CIN 3 lesions and the aggregates may even on occasions have a border of low columnar cells. It is very unusual for CIN lesions to present in cervical samples as only cell aggregates without any single dyskaryotic cells, and the observation of dyskaryosis elsewhere in the sample may assist in interpretation. If a confident conclusion cannot be reached, it may be necessary to use the borderline category for reporting, and this is one situation where it may be justifiable for this report to warrant immediate referral for colposcopy.

Severe, and less frequently moderate, dyskaryosis may be intimately associated with endocervical cells in such a way that the cell group may be considered to be entirely glandular. This feature is sometimes taken to indicate crypt infiltration by CIN 2/3. Groups of this type with a columnar edge of apparently normal endocervical cells in places are occasionally seen and present a particular diagnostic pitfall. High power examination of individual nuclei should reveal the characteristics of dyskaryosis in some of the cells. The characteristic architectural features of glandular neoplasia are not seen in these groups.

A3.1.4 Small keratinised cells

Small keratinised dyskaryotic cells may be difficult to recognise in atrophic samples, particularly in association with inflammation. If in doubt, an early repeat sample after topical estrogen treatment may be justified, as dyskaryotic cells are often much easier to recognise in a more mature pattern sample.

A3.1.5 Sparse dyskaryotic cells

Sparse severely dyskaryotic cells may be difficult to grade and may be misinterpreted as mild dyskaryosis or borderline nuclear change. The degree of dyskaryosis shown by abnormal cells should not be downgraded because of their scarcity in a sample.

A3.2 Potential false positive results

False positive results for samples reported as severe dyskaryosis are unusual. They are more common in samples reported as moderate dyskaryosis or glandular neoplasia in which the abnormal nuclear changes may be less obvious. The following conditions and cell changes occasionally give rise to false positive results.

A3.2.1 Normal endometrial cells

Normal shed endometrial cells may be mistaken for small dyskaryotic squamous cells. Careful attention to clinical data, date of last menstrual period in relation to the sample, intrauterine contraceptive device use or sex hormone therapy and to the sample appearances and cell detail will usually enable correct identification of such cells to be made.

A3.2.2 Endometriosis and tuboendometrioid metaplasia

Endometriosis and tubal or tuboendometrioid metaplasia may occur spontaneously in the cervix, and are likely to occur much more frequently after cone biopsy and other operative procedures. Endometrial stromal cells may mimic dyskaryotic squamous cells, and large combined glandular and stromal or glandular cell groups are more likely to be mistaken for abnormal endocervical cell groups. It should be noted that the nuclei of endometrial and tubal epithelial cells may normally appear to be pseudostratified.

A3.2.3 Lower uterine segment (LUS) endometrium

Endometrial material may be sampled directly, possibly because of shortening of the endocervical canal after treatment but more frequently when endocervical brushes, or other sampling devices for improved endocervical sampling, are used. Such material may include glandular and stromal cells, and often includes 'microbiopsies' of endometrial tissue. The recognition of such large biphasic groups is important in the identification of LUS endometrium; if both glandular and stromal cells can be identified in the same cell group, the endometrium is extremely unlikely to be neoplastic. LUS endometrium may respond to hormones, and mitotic activity may be seen in the stromal or epithelial components.

A3.2.4 Histiocytes

Histiocytes are normally easily recognisable but, especially when they become degenerate, they may show granular or dense chromatin and dense cytoplasm, closely mimicking the appearance of severe squamous dyskaryosis of small cell type. Occasionally, usually in late menstrual samples, the cytoplasm of histiocytes may become eosinophilic, resembling keratinisation.

A3.2.5 Follicular lymphocytic cervicitis

This condition may occasionally be misinterpreted as severe dyskaryosis or as endometrial cells. Attention to the typically coarse but evenly clumped chromatin and the presence of tingible body macrophages should determine the correct diagnosis.