



Disclosure of cervical screening history review results and applying Duty of Candour

Contents

1. Cervical cancers
2. Role of cervical screening services
3. Informing women about their cervical screening history review
4. Review process
5. Being open and transparent
6. Women who do not want to know their results
7. When to apply Duty of Candour
8. Communicating the results of the screening history review to women
9. Applying local organisation policies
10. Appendix 1 – Patient information leaflet
11. Appendix 2 – Example of a response form
12. Appendix 3 – Process flowchart and suggested checklists for the cervical screening provider lead (CSPL) and disclosing clinician
13. Appendix 4 – Issues to consider when deciding how to classify an assessment/decision trees

Cervical cancers

The NHS Cervical Screening Programme (NHS CSP) aims to reduce the incidence of, and mortality from, invasive cervical cancer. It does this through a systematic, quality assured population-based screening programme for eligible women, so that abnormalities that might otherwise develop into invasive cancer can be identified and treated.

We offer women cervical screening every 3 years from age 24.5 to 49 and every 5 years from age 50 to 64. In England cervical screening currently prevents 70% of cervical cancer deaths. If everyone attended screening regularly, 83% could be prevented¹.

Screening is the process of identifying healthy people who may be at increased risk of a disease or condition.

Screening tests:

- cannot offer 100% sensitivity (ability of the test to correctly identify all true positives – those with the condition or disease)
- cannot offer 100% specificity (ability of the test to correctly identify all true negatives – those without the condition or disease).

In every screening programme there are false positives (wrongly reported by the test as having the condition) and false negatives (wrongly reported by the test as not having the condition).

In addition, the disease screened for, for example cancer, can occur between screening episodes.

Both false positive and false negative results can result in harm to an individual. However, these are not unexpected findings and are a feature of all screening programmes. More details on the overarching principles of applying Duty of Candour in screening programmes can be found in the document [“Guidance on applying Duty of Candour and disclosing audit results” 2016](#).

Review of all cases of cervical cancer, along with those women’s interactions with the screening programme, and comparing them with women who do not develop cervical cancer, is important.

The main purpose of the NHS CSP audit of invasive cervical cancer is to:

- support the continuous learning and development of health professionals involved in the programme
- monitor the effectiveness of the cervical screening programme by comparing the screening histories of women who develop cervical cancer with those who do not
- identify areas of good practice and indicate where improvements might be made to support evidence-based policy and practice

In order for the information to be reported consistently, all parties in the cervical screening programme must follow the same [national protocol for auditing cases of invasive cervical cancer](#).

The audit also allows women diagnosed with cervical cancer who have previously participated in the cervical screening programme to have information about what their screening history review found, if they wish to receive this.

Responsibilities of cervical screening services

Services delivering the NHS CSP have the responsibility to operate with effective disclosure, meeting all statutory requirements and adhering to guidance issued by the NHS CSP.

Organisations providing screening services take responsibility for undertaking nationally required audits of screening histories in a timely way and for offering screening participants disclosure of their audit results, in line with nationally published guidance and the screening service specifications.

The organisation's medical director takes overall responsibility for ensuring this guidance is followed.

The organisation's [cervical screening provider lead](#) (CSPL) is the person with operational responsibility for overseeing these activities.

The organisation which gives the woman her diagnosis of cervical cancer is responsible for offering her information about the screening history review and how she can receive the results if she wishes to have them.

This organisation is also responsible for having processes in place to ensure that the screening history review is completed in a timely manner:

- to allow women to be offered the results of the review of their cervical screening history at the earliest opportunity
- to allow services to identify learning points about cervical screening performance and alert services to any practice outside programme guidance which may need further investigation
- to facilitate an early response to information requests arising from disclosure of screening history reviews and Duty of Candour cases

Informing women about their cervical screening history review

The initial consultation when results of diagnosis are given is not an appropriate occasion to discuss the review in detail, unless the woman asks questions about her screening history. However, a general reference must be made that the review will be taking place. At this consultation an information leaflet and response form (Appendix 1 and 2) must be included in the documentation given to the woman for her to refer to at her own convenience.

The response form enables her to indicate that she has understood the content of the leaflet, and whether she would or would not like to know the outcome of her screening history review. The form is required so that a clear audit trail exists regarding the woman's wishes.

If she wishes, the woman can return the response form at this point for inclusion in her notes. However, she will be contacted again once the results of her review are ready and, if she prefers, can complete and return the response form then.

Review process

All women should be offered the results of the review of their screening history, unless they have no previous screening history or their most recent history is more than 10 years prior to diagnosis, in which case old samples will have been destroyed.

A suggested flowchart and checklists for the CSPL and disclosing clinician for the management of the review process within the diagnosing organisation, and disclosure of the review results can be found at Appendix 3.

The review and disclosure process should be completed within a maximum period of 12 months from diagnosis, with the CSPL providing an update to the colposcopy multidisciplinary team meeting (MDT) on progress at 6 months, if the case is not already complete. At the MDT where the final review results are discussed and the case assessed, the lead colposcopist should nominate an appropriately trained clinician (see section below on communicating the results of the screening history review to women) to offer disclosure to the woman.

When other organisations are involved in the woman's treatment, the CSPL is responsible for communicating with them to find out when her treatment is complete. This will be facilitated by agreeing and documenting a set of contacts between the organisations involved. Disclosure of the review result must be offered by the organisation where the woman received her diagnosis rather than the treating organisation, where these are different. In rare circumstances where the woman requests disclosure from her treating organisation instead, both organisations involved in the woman's care must work collaboratively to ensure that this is facilitated. It is essential that disclosure discussions are always undertaken by individuals with detailed knowledge of the NHS CSP and who have undertaken appropriate disclosure training.

Should any issues come to light during the review which could indicate a potential screening incident, the Screening Quality Assurance Service (SQAS) must be informed immediately so that appropriate advice can be given in line with [national guidelines on the management of potential screening incidents](#).

An annual audit of the offer of disclosure of the review outcomes to patients must be carried out by the CSPL to ensure that there is full implementation of national guidance and that there is equal treatment of all women diagnosed with cervical cancer.

Where a woman is being treated privately, a cervical screening history review must still take place if she has been screened or treated within the NHS CSP in the previous 10 years. Occasionally patients may be diagnosed and/or treated in the UK, but outside of England, whilst elements of their screening history may be held in England and may be needed to contribute to disclosure. In these cases, specific arrangements will need to be agreed on a case by case basis and advice should be sought from SQAS.

Being open and transparent

Once results of the screening history review are available, if the woman has not already returned her response form she must be contacted promptly using her preferred method of communication.

Communicating the offer of results is a 2-stage process. The service should initially determine whether or not the woman wishes to know the results of her screening history review.

She must be sent:

- a letter informing her that the review results are available and contact details of the relevant nurse specialist should she wish to discuss the offer of disclosure before making a decision
- the information leaflet
- the response form and a request to complete and return it

If the woman has not responded within 3 months of the letter being sent, it can be assumed that she does not wish to know the results of her review.

If she responds to say she does wish to receive the results of her review, a further communication should be sent depending on the outcome of the review results:

Letter A (nothing found)

Thank you for returning your form indicating that you would like to receive the results of your screening history review. Your review did not identify any problems with your care. If you would like to discuss this further, either by telephone or in person, please contact the nurse specialist to arrange this.

Letter B (findings to discuss)

Thank you for returning your form indicating that you would like to receive the results of your screening history review. We would like to invite you to a meeting to discuss the findings.

This letter must not include any details regarding the review findings, but it must include:

- the offer for the woman to bring her partner, family member or a friend if desired
- contact details of a nurse specialist or other suitable individual to arrange the review
- details of the clinician who will meet with the woman on request
- the offer to send the results of the review in writing if preferred

If the woman responds to say she does not want her results at present and requests a reminder in 6 months' time, the disclosing clinician must inform the CSPL and ensure that a reminder offer letter is sent to her at the right time.

Women who do not want to know their results

Where women do not wish to receive the results from the review of their screening history, they must be told that they can change their mind at any point and that if they subsequently choose to know the results, they can contact their consultant, or their GP (if they have been discharged), to make the necessary arrangements. The GP should be informed of their decision and the process to follow, which is to notify the relevant organisation should the patient change their mind in future.

When to apply Duty of Candour

In a very small number of cases, once the results of the review are known, Duty of Candour will apply.

A discussion regarding whether or not Duty of Candour applies should take place at the colposcopy MDT of the diagnosing organisation where the results of the review of screening history are presented. The MDT should consider whether the review results for each discipline (cytology, histology and colposcopy - see Appendix 4) are categorised as:

- Satisfactory
- Satisfactory with learning points
- Unsatisfactory

Cases identified as 'Satisfactory' or 'Satisfactory with learning points' would not be classified as a Duty of Candour cases. The findings must, however, be disclosed to the woman if she has asked for disclosure of her review results.

Duty of Candour will apply to cases with an assessment of 'Unsatisfactory', and for these cases the organisation must follow its Duty of Candour policy. In cases where Duty of Candour applies but the woman has indicated by returning the response form that she does not wish to know the results of her review, this decision must be respected.

In cases where Duty of Candour applies but the woman has not returned her response form, a second communication should be sent. If she still does not respond, organisational policies on Duty of Candour should be followed.

Communicating the results of the screening history review to women

Women who request an appointment to discuss the outcome of their personal screening history review must be seen in a timely way. Only a clinician who has appropriate counselling skills and training in Duty of Candour, and has completed the e-learning on disclosure (as a minimum once online) should undertake these meetings.

An appropriate time (60 to 90 minutes is suggested) must be set aside to undertake the consultation so that the woman has the time she requires. This cannot be rushed and must include some time at the end of the consultation for reflection and writing up notes and the summary letter to the woman and her GP. The meeting must take place in confidential, comfortable surroundings with no interruptions.

Clinicians must include the following points at the consultation with the woman, whether or not Duty of Candour applies.

To aid effective communication:

1. The patient should be invited to express her concerns and raise any questions she may have
2. The effectiveness and limitations of the screening programme described in the information leaflet should be discussed
3. There should be an open discussion about whether the cancer could have been prevented from developing or found earlier
4. The clinician may be asked about the impact on prognosis where a delay in diagnosis was evident. This is a complex area and should not be speculated upon in this consultation unless there is a degree of certainty or the clinician has particular expertise in this specialist area
5. The discussion should concentrate on the clinical aspects of the woman's care and it is not appropriate to discuss any possible litigation which may or may not already have commenced. Litigation issues must be handled separately according to organisation protocols
6. Patients who wish to complain or seek advice on litigation should be given information on how to proceed via the Patient Advisory Liaison

Service (PALs) and be informed of the organisation's complaints procedure

7. Clinicians are encouraged to include apologies where appropriate.
8. The clinician should explain what will happen as a result of the collection of information from the review and how it will help improve the learning and education of staff and overall performance of the programme
9. Clinicians should discuss the possibility of accessing further counselling and support if the patient requires it
10. After the interview, the clinician should document the discussion and send an outline of it to the patient, her GP and the treating clinician for their notes
11. The clinician should end the meeting with the offer of a follow-up telephone call at the woman's convenience

Applying local organisation policies

All organisations providing cervical screening services must have a policy outlining how the necessary screening history review following a cervical cancer diagnosis is carried out. There must also be a local protocol in place outlining how the process of the review is managed within the organisation, including how the results of the review are offered to the individual women concerned.

These policies must be developed and agreed by the organisation's multi-disciplinary cervical screening business meeting, chaired by the CSPL, and approved through local organisational processes. They must be consistent across the organisation, regardless of whether aspects of screening are carried out on different sites (as the same policy should operate in all hospitals within a single organisation). The policies must follow the relevant NHS CSP guidance documents. Text included within this guidance may be used to form the basis of local organisation policies.

All organisations must have policies to deal with incident management and applying Duty of Candour. These must be followed in conjunction with NHS CSP guidance. It is suggested that all situations where the outcome of the screening history review is "satisfactory with learning points" and "unsatisfactory" are recorded on organisational reporting systems.

If a legal question arises or legal teams request medical records, the organisation's legal team should be approached for advice.

References

1. Castanon, A and others (2017). By how much could screening by primary human papillomavirus testing reduce cervical cancer incidence in England? *Journal of Medical Screening* vol. 24, (2) 110-112.

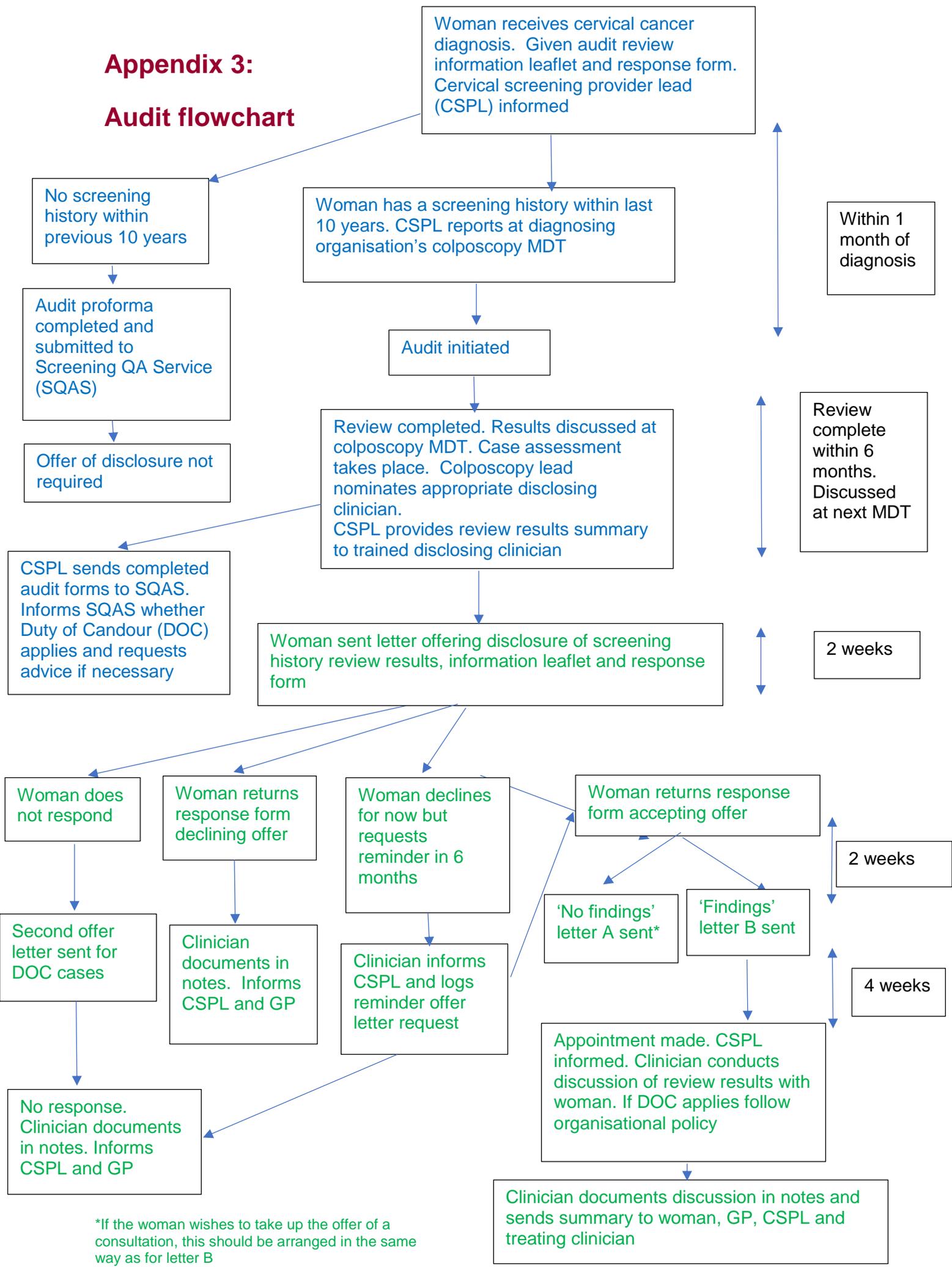
Appendix 1 – Example patient information leaflet

Consultation with patients undertaken separately

Appendix 2 – Example response form

Consultation with patients undertaken separately

Appendix 3: Audit flowchart



*If the woman wishes to take up the offer of a consultation, this should be arranged in the same way as for letter B

Suggested CSPL and disclosing clinician checklists

CSPL checklist:

- CSPL informed of cancer diagnosis
- CSPL logs case and tables discussion at colposcopy MDT
- audit of invasive cervical cancer initiated and relevant parties contacted
- liaison with relevant contact at treating organisation, if applicable
- Audit completed
- CSPL presents results at colposcopy MDT and decision made regarding the classification of the case, including whether Duty of Candour applies
- agreement made at MDT regarding who will be the disclosing clinician
- inform treating organisation that review is complete and what the review found
- CSPL finalises summary report, incorporating MDT assessment and sends to disclosing clinician
- CSPL sends completed audit to SQAS
- should the audit uncover a possible screening incident CSPL to inform SQAS at earliest opportunity
- track to make sure that the disclosure offer letter is sent by the diagnosing organisation's clinical team and that the treating organisation is informed that disclosure has been offered
- include any local outcomes and learning in the CSPL's annual report. This report will be discussed at the local programme board once it has been approved by the organisation, enabling outcomes and learning to be captured by SQAS
- carry out annual audit of offers of disclosure to women diagnosed with cervical cancer

Checklist for disclosing clinician:

- review summary report provided by CSPL
- arrange for offer of disclosure letter and response form to be sent to patient
- log if no patient response and ensure CSPL, treating organisation and GP are informed
- log if patient wants reminder in 6 months' time, inform CSPL and ensure reminder offer letter sent in 6 months
- if Duty of Candour applies, and no response to first letter, arrange for a second offer letter to be sent
- if patient wishes to have disclosure, arrange for appropriate disclosure letter to be sent (no findings - letter A, findings - letter B)
- arrange for a timely appointment to be made if requested by patient
- arrange appropriately trained nursing support for the appointment
- arrange for a suitable room to be booked and a translator to be available if needed
- offer woman a follow up call to take place after the appointment in case she has further questions
- send summary of disclosure meeting to woman, her GP, CSPL and treating organisation

Appendix 4

Issues to consider when deciding how to classify a screening history

Cervical cytology slide reviews

Any cytology slide review undertaken in line with requirements set out in NHS Cervical Screening Programme guidance is for education and audit purposes. It is not undertaken as a medico-legal review, which is a different approach and would be done to a different set of standards.

All slides reviewed for the [invasive cervical cancer audit](#) must be categorised into 1 of the 3 categories below. Cases considered to be Unsatisfactory must be agreed as such by at least 2 senior members of staff qualified in that area of clinical practice and actively working in the NHS Cervical Screening Programme who meet the standards set out for the programme.

Satisfactory - on review previous cytology report(s) agreed with.

Satisfactory with Learning Points - abnormalities present but seen only on review and seen with hindsight and full knowledge that this is a cancer case. This will include cases known to be difficult to perceive or identify or are cases that are not clearly abnormal. Whilst many of these cases are identified at screening some are not. These cases may provide for learning for the programme as they are likely to be an unavoidable error.

The satisfactory with learning points category would be cases that evidence indicates are at the limit of detection by cytology screening staff and would include:

- low abnormal cell numbers (less than 50 cells in a liquid-based cytology sample)
- hyperchromatic crowded groups (HCGs)
- small cell dyskaryosis
- pale cell dyskaryosis
- bland cell dyskaryosis
- small cell severe dyskaryosis
- small keratinised cells
- glandular abnormalities of low number and/or subtle architectural/cytological changes
- poorly preserved abnormal cells
- borderline changes on review in the absence of any definite dyskaryotic changes

In some cases there may be combination of these features.

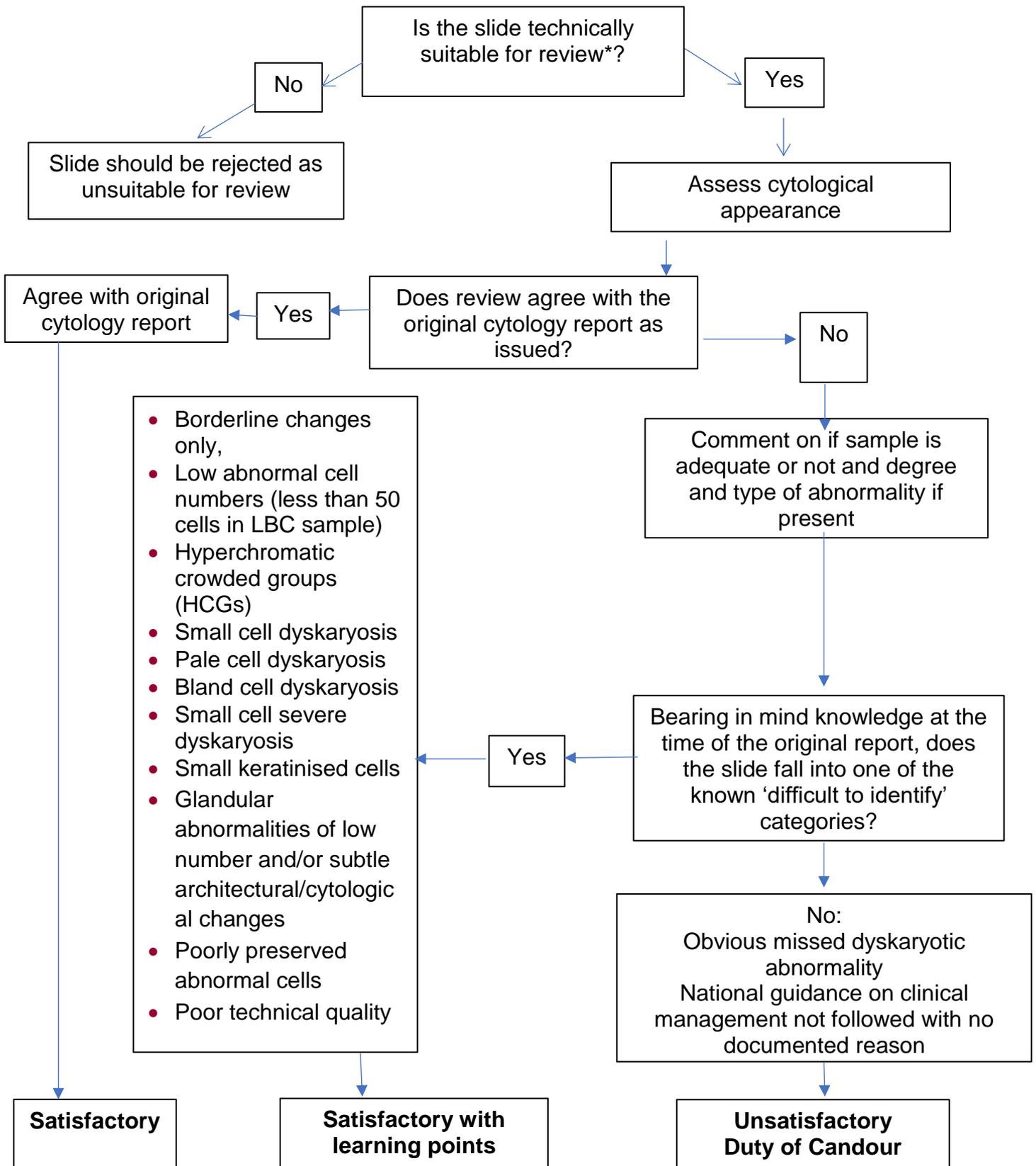
Cases where in hindsight the slide is considered likely to have been of poor technical quality at the time of initial reporting (taking into account technical deterioration

judged to have occurred due to storage over time since the slide was prepared) should be considered as Satisfactory with Learning Points.

Unsatisfactory - on review the appearances are obvious and the cytology should have been reported as requiring further action. These are cases that competent screeners and reporting staff would have identified and as such an avoidable error of the cervical screening programme. The performance of all staff is closely monitored within the NSHCSP and any identified issue does not necessarily reflect on the individual's skills or abilities.

Cases not managed according to national guidance without adequate explanation, for example a negative cytology result following treatment required an HPV test to be carried out and this was not done.

Duty of Candour: cervical screening cytology slide reviews



* Slides may become technically inadequate for use, for example, broken slide, faded staining, suffer “dry back” of mountant with age (as slides are kept for 10 years), air bubbles and do not reflect necessarily on the technical quality of the slide at the time of the original reporting, but which would materially affect a review process.

Cervical histology slide reviews

Any histology slide review undertaken in line with requirements set out in NHS Cervical Screening Programme guidance is for education and audit purposes. It is not undertaken as a medico-legal review, which is a different approach and would be done to a different set of standards.

All specimens reviewed for the [invasive cervical cancer audit](#) must be categorised into 1 of the 3 categories below. Cases considered to be Unsatisfactory must be agreed as such by at least 2 senior histopathologists actively reporting cervical histology for the NHS Cervical Screening Programme who meet the standards set out for the programme.

Satisfactory - on review, the original pathology report is agreed with, and no material differences are found that would have affected management at the time of the original report

Satisfactory, with learning points – on review, there are minor differences or learning points that would not have materially affected the report and management at the time of the original report, but which are of educational value.

This would include issues such as:

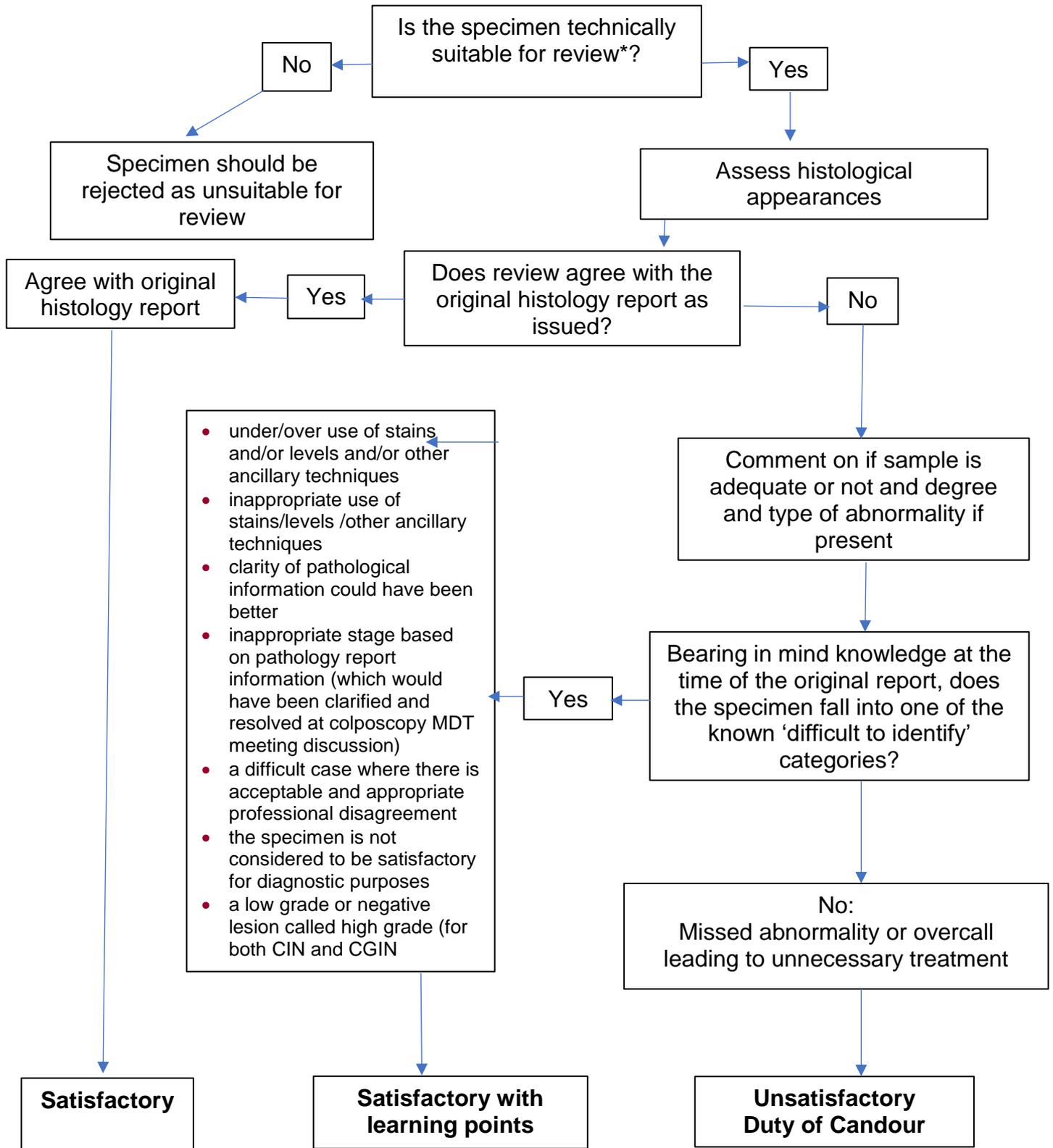
- under/over use of stains and/or levels and/or other ancillary techniques
- inappropriate use of stains/levels /other ancillary techniques
- clarity of pathological information could have been better
- inappropriate stage based on pathology report information (which would have been clarified and resolved at colposcopy multi-disciplinary team (MDT) meeting discussion)
- a difficult case where there is acceptable and appropriate professional disagreement
- the specimen is not considered to be satisfactory for diagnostic purposes, for example does not contain appropriate tissue
- a low grade or negative lesion called high grade (for both cervical intraepithelial neoplasia (CIN) and cervical glandular intraepithelial neoplasia (CGIN))

Unsatisfactory - on review, significant differences are identified that would have affected patient management at the time of the original report. These would fall under Duty of Candour.

These would include:

- a high grade lesion called low grade or negative (for both CIN and CGIN)
- missed invasive cancer (of any size/type/stage)
- undercall of an invasive lesion as not invasive
- overcall of a non-invasive lesion as invasive
- incorrect tumour classification that would have resulted in different management, for example, sarcoma, lymphoma, missed small cell carcinoma, non-identification of metastatic disease

Duty of Candour: cervical screening histology slide reviews



* Slides may become technically inadequate for use, for example, broken slide, faded staining, suffer "dry back" of mountant with age (as slides are kept for 10 years), air bubbles and do not reflect necessarily on the technical quality of the slide at the time of the original reporting, but which would materially affect a review process.

Colposcopy management reviews

Any colposcopy review undertaken in line with requirements set out in NHS Cervical Screening Programme guidance is for education and audit purposes. It is not undertaken as a medico-legal review, which is a different approach and would be done to a different set of standards.

All colposcopy attendances reviewed for the [invasive cervical cancer audit](#) must be categorised into 1 of the 3 categories below. Cases considered to be Unsatisfactory must be agreed as such by at least 2 senior colposcopists actively working in the NHS Cervical Screening Programme who meet the standards set out for the programme.

Satisfactory - on review, the colposcopy management and related documentation is fully in line with national guidance in place at the time, and no material differences are found that would have affected management

Satisfactory with Learning Points - this would include issues such as:

- incomplete documentation
- cases where management was in line with national guidance but with the benefit of hindsight could have been improved, for example
 - not undertaking treatment in a poor attender with a high grade referral
 - not considering repeat excisional treatment first follow up after treatment with previous incomplete excision of high grade and squamo-columnar junction not seen
 - surveillance option chosen over immediate treatment
 - inadequate depth of treatment without clear excision margins and without adequate explanation
 - case meets criteria for discussion at colposcopy MDT meeting but was not discussed
 - multiple pieces of tissue excised during treatment without explanation

Unsatisfactory - on review, significant differences are identified that would have affected patient management at the time of the attendance. These would fall under Duty of Candour.

These would include:

- high grade cytology referral with no biopsy taken without appropriate reason recorded
- treatment indicated based on cytology referral or colposcopic findings but not carried out and no reason or colposcopy MDT discussion recorded
- ablative treatment for CIN/CGIN undertaken without a biopsy being taken in advance
- failure to follow up and issue appointment at the appropriate interval, for example, pregnant patients or those requiring future colposcopic follow up
- clinical management plan not carried out and no reason recorded
- confirmed CGIN with incomplete excision margins not offered re-excision
- inappropriate discharge to routine recall

- failure to follow national guidance with no explanation and no discussion at colposcopy MDT
- cancer diagnosed within 12 months of colposcopy assessment and cancer stage such that it is judged to have probably been present at colposcopy

Duty of Candour Application

All assessments are considered in the context of an individual being diagnosed with cervical cancer.

An individual's screening history can involve any or all of a combination of cervical cytology, cervical histology and colposcopy attendances. Each must be given a classification of Satisfactory, Satisfactory with Learning Points or Unsatisfactory.

Classifications of Satisfactory or Satisfactory with Learning Points do not fulfill the definition of harm that requires the Duty of Candour process to be followed. However, they are disclosed if the individual has requested feedback as part of the routine disclosure of audit process.

Cases identified as Unsatisfactory fulfill the definition of moderate or severe harm and therefore are classified as a notifiable safety incident. The Duty of Candour process is followed in these circumstances.

The classification of each element of the screening history must be disclosed when discussing with individuals, whether or not Duty of Candour applies.