Northern Ireland Cervical Screening Programme

Framework for the Audit of Invasive Cervical Cancers and Disclosure of Findings

Version 1.0

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Version control

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Contents

1 Introduction

This framework document provides guidance to Trusts on:

- reporting and reviewing invasive cervical cancers;
- categorisation of audit outcomes; and
- informing women of audit activities and disclosing audit findings.

The purpose of this document is to facilitate a consistent approach across Northern Ireland by which all newly diagnosed cases of invasive cervical cancer are reviewed and the results disclosed to the individual women concerned.

This document should be read in conjunction with the Public Health Agency (PHA) protocol for the audit of invasive cervical cancers[1] and forms part of a supporting audit toolkit.

All Trusts are expected to use this framework document and the wider toolkit to inform the development of local Trust protocols and procedures to deliver this audit and disclose findings as appropriate. This will be monitored through regional quality assurance activities, including the peer review visit programme for the cervical screening programme led by the PHA.

The pathways described in this document are informed by the policy used in Derby Teaching Hospitals NHS Foundation Trust[2], national guidance on applying duty of candour and disclosure of audit results in screening programmes[3], Public Health England toolkit on interval cancers and applying duty of candour[4], and from consultation workshops held with voluntary sector organisations and service representatives in June 2018.

The call/recall aspect of the patient experience will be examined and addressed separately to this audit. Where any issues are identified the Hospital Based Coordinator will be alerted.

2 Audit in the Cervical Screening Programme

The aim of the Northern Ireland Cervical Screening Programme (NICSP) is to reduce the incidence of and mortality from, invasive cervical cancer. This is achieved by offering regular cervical screening to eligible women so that conditions which otherwise might develop into cancer can be detected and treated before cancer develops.

Every screening programme will have false positive results (wrongly reported by the test as having the condition) and false negative results (wrongly reported by the test as not having the condition). While these have the potential to result in harm, such as over-diagnosis and treatment, unnecessary anxiety or a delayed diagnosis for a patient, they are not unexpected and are a feature of all screening programmes. In addition, cancer can develop between screening episodes. On balance, screening programmes should operate within agreed parameters so that they offer more benefit than harm to the screened population. All programmes work to minimise the number of false positive and false negative results.

It is good practice that all women who develop invasive cervical cancer should have their screening pathway reviewed. The purpose of the audit is to monitor the overall effectiveness of the screening programme, to identify areas of learning and highlight areas where further improvements can be made.

In addition, it is recognised that women diagnosed with cervical cancer will want to understand if something went wrong in their screening process and if a possible opportunity was missed to provide them with an earlier diagnosis or intervention.

While the majority of learning from this audit will be obtained at local Trust level through individual case review, analysis of data at regional level will look for recurring themes and trends over time.

The individual case review involves a review of the events and specimens in the ten years prior to diagnosis. This includes:

- a review of call/recall activities for the woman;

- a review of any cervical cytology screening tests from the 10 years prior to diagnosis;
- a review of colposcopy attendances; and
- a review of histology results.

In line with best practice, every Trust is expected to inform a woman diagnosed with an invasive cervical cancer that her screening history will be reviewed, and to offer appropriate feedback on the outcome of that review. This is set out in 'Guidance on applying Duty of Candour and disclosing audit results' within population screening programmes, published by Public Health England[3].

Significant patient safety issues identified during the course of an individual case review should be notified and managed according to existing regional and Trust serious adverse incident procedures[5].

3 Key Responsibilities/Duties

3.1 Hospital Based Programme Co-ordinator (HBPC)

The Hospital Based Programme Co-ordinator is responsible for ensuring all newly diagnosed cases of invasive cervical cancer within the Trust are audited in line with NICSP guidance.

Each Trust must have a nominated HBPC who will oversee the audit activity on their behalf. The HBPC may delegate specific coordinating tasks to other nominated individuals, but retains overall responsibility for the process. Where colposcopy and laboratory services are provided by different Trusts, agreement should be reached locally as to which Trust will undertake the HBPC role for the purpose of the audit and this should be clearly documented.

Notification of new cases of invasive cervical cancer to the HBPC should occur via an appropriately constituted Multidisciplinary Team (MDT) meeting.

The HBPC is responsible for:

- triggering the audit process and notifying the PHA of a new case;

- co-ordinating the completion of reviews by cytology, histology and colposcopy colleagues as appropriate;
- preparing a summary report of the case review findings for discussion at the MDT meeting;
- ensuring that an agreed audit outcome category is recorded for every case;
- submitting a complete, accurate and validated data return on each case to the PHA Information Officer within the agreed timescale;
- undertaking an annual Trust audit to demonstrate the disclosure process has been followed.

3.2 Trust Lead Cytopathologist

Co-ordinates the review of previous cytology and histopathology slides within the laboratory.

3.3 Trust Lead Colposcopist

Undertakes review of previous colposcopy appointments, or arranges for another accredited colposcopist to undertake the review of the case if they were involved in the original appointments.

3.4 Diagnosing Clinician

The clinician who makes the diagnosis is responsible for informing the woman that the audit will be carried out and, on agreement with the MDT, for subsequent disclosure of the audit findings.

3.5 PHA Cervical Screening Information Officer

The PHA Information Officer is responsible for:

- allocating study ID numbers
- obtaining screening call/recall history on individual cases from the Business Services Organisation
- collating all cases on the regional database for the audit of invasive cancers
- undertaking trend analysis at regional level

- preparing an annual regional report for the audit.

4 Informing Women of Audit Activities

Upon diagnosis, it is recommended that a cervical cancer *'Audit Disclosure Record Sheet'* is started and filed in the patient's notes (see supporting toolkit).

All women diagnosed with invasive cervical cancer must be given the information leaflet *'Reviewing your Cervical Screening History'* at the time of diagnosis. This leaflet explains that an audit will be undertaken, and why. It also explains that when the audit is completed, the findings will be made available to the patient.

It must be recorded on the *Audit Disclosure Record Sheet* that the leaflet has been given to the patient. It is good practice that at her next appointment, the patient's understanding of the process is checked – she should be asked if she has read the leaflet and is aware that a review is being done. Confirmation of this discussion should be documented in the patient's clinical notes and on the *Audit Disclosure Record Sheet*.

5 The Audit Process

5.1 Notification of cases

All new cases of invasive cervical cancer identified on histology should be discussed at an appropriately constituted MDT meeting. The Trust must ensure that there are mechanisms in place for the MDT to notify new cases to the HBPC who then triggers the audit process.

5.2 Study ID numbers and call/recall review

The HBPC notifies the PHA Information Officer of the new case. The PHA Information Officer assigns a study ID number to the case and obtains the screening history from the Open Exeter system. Information relating to invitation letters issued will be obtained via the Business Services Organisation screening office.

The PHA information officer populates the screening history on the audit dataset and then issues the template to the notifying HBPC for full completion.

If no previous screening history exists, the HBPC is asked to complete the diagnostic information only on the dataset.

It is expected that the diagnosing Trust will be the Trust responsible for the co-ordination of the audit. However, in circumstances where the patient's previous screening history or care crosses two or more Trusts, the notifying HBPC may wish to consider if another Trust is better placed to lead on the audit process. This should be discussed and agreed between Trusts. The PHA Information Officer must be advised if the responsible HBPC changes.

5.3 Cytology slide review

Any previous slides requiring review should be retrieved from archives, where available. In cases where slides were reported outside the diagnosing Trust, the HBPC will request the originating laboratory to initiate the slide review and send the results of the review to the HBPC.

Slide review should be undertaken in line with the NICSP audit protocol and the opinion of the reviewers recorded on the audit dataset.

The HBPC must notify the PHA Information Officer of any slide that requires external review, as per the criteria set out in the NICSP protocol. The PHA will select the external review panel and inform the HBPC. It is the responsibility of the HBPC to make arrangements for the transport of the slide to the review panel. The external review will be undertaken in line with the NICSP audit protocol. The results of the external review should be returned by the panel directly to the HBPC who will record it in the audit dataset.

5.4 Histology review

A record of cervical histology results from the 10 years preceding diagnosis is collated. Samples should be reviewed in line with the NICSP audit protocol and the findings documented on the audit dataset.

5.5 Review of colposcopy and gynaecological management

This is undertaken by the lead Consultant Colposcopist, or another accredited Colposcopist if the lead participated in the management of the woman. The review should be undertaken in line with NICSP audit protocol and the findings documented on the audit dataset.

6 Defining Audit Outcomes

Once all sections of the dataset have been completed, the HBPC will prepare a summary of the audit findings (see audit toolkit). This should be used to inform the case discussion at the multidisciplinary team (MDT) meeting.

The screening pathway involves a number of steps: invitation, sample taking, reporting of the screening test, colposcopy investigation, diagnosis and intervention. The audit discussion should review the pathway to consider if any process or interpretation issues at screening possibly impacted on the outcomes for the patient.

Key Questions

Process	• Was the process carried out according to national/ regional screening guidance? • Is the service operating to national/regional standards?
Interpretation	• Did staff carrying out the screening or diagnostic test do so to a standard that most staff could be expected to achieve?
Impact	• Did a process failure or suboptimal interpretation of a test contribute to a delay in diagnosis or treatment that resulted in serious or moderate harm to the patient.

An appropriate audit outcome category should be agreed by the MDT and assigned to every case (Table 1). It is recognised that each case will be unique and will need to be considered on an individual basis.

Table 1: Audit Outcome Categories for Invasive Cervical Cancer

Category	Description
Category 1: Satisfactory review	No untoward findings.
Category 2: Satisfactory review with learning points	False negative cases or minor process or management shortcomings, but considered to be within the limitations of the screening programme
Category 3: Unsatisfactory review	False negative cases or significant process or management shortcomings that constitute a patient safety incident.

Cases assigned a Category 3 outcome should be considered a notifiable patient safety incident and therefore regional and Trust governance procedures apply[5].

At the MDT meeting, discussion should also identify any areas for local or regional learning and service improvement.

Following the MDT meeting, the HBPC will submit a completed dataset on each case to the PHA Information Officer, for the purpose of the case contributing to the regional audit trend analysis.

7 Disclosure of Audit Findings

There is a requirement on all professional healthcare staff to be open and transparent with patients. The General Medical Council and Nursing and Midwifery Council have published joint guidance on professional duty of candour[6]. This has been taken further with duty of candour legislation introduced elsewhere in the UK for healthcare organisations. This sets out specific requirements when things go wrong with care and treatment, including informing patients about the incident, providing reasonable support, providing truthful information and an apology when

things go wrong. These principles should be equally applied to screening programmes and any audit processes.

Once the audit data collection is complete, the summary report prepared by the HBPC should be discussed by the MDT and an appropriate outcomes category and disclosure pathway agreed. Consideration should be given where a patient has indicated that they do not want to know the findings of the audit. In such cases, it should be made clear to the woman that she can change her mind at any time. Otherwise, the following approach should be followed:

- Where there are no untoward findings (Category 1) the patient should be written to or told this at her next appointment with her Consultant.
- Where the audit shows that her care/treatment could have been different but was within the acceptable limitations of the screening programme (Category 2), the patient should be informed in writing or at her next appointment. Some clinicians may wish to offer these patients an appointment to discuss this in further detail.
- Where significant findings were identified to suggest that the woman's care/treatment should have been different (Category 3) then she should be written to, advising that the results of the audit are now available and offered an appointment to discuss these with her Consultant.

Trust protocols should clarify who has responsibility for issuing the letters on audit findings to women.

When a disclosure meeting is required, the MDT should agree who is best placed to meet with the patient. This should take account of the nature and complexity of the issues to be discussed and the need to involve the Trust's clinical governance team. The meeting should always be led by an individual the patient already has a relationship with, and consideration should be given as to who will provide support to the patient during the meeting. Full and open disclosure must be given to all patients at a disclosure meeting.

The following approach should be considered for the disclosure meeting:

- Check the patient's understanding of the audit
- Ascertain how much information she wishes to know
- Discuss the relevant reports and implications
- Invite her to voice any concerns or ask any questions
- Offer an appropriate apology
- Explain the Trust's complaints procedure

The patient must be helped to understand the reasons for any missed abnormality, suboptimal processes or management, and where appropriate the limitations of the screening programme. Providing a contact point for any follow up questions should also be considered.

The disclosure meeting should be documented in the patient's notes and on the *Audit Disclosure Record Sheet*. The patient's GP must be informed of the details discussed at the disclosure meeting.

If a patient chooses not to take up the offer of a disclosure meeting at this time, it must be made clear to her that she has the right to change her mind at any point in the future.

A copy of the completed *Audit Disclosure Record Sheet* should be sent to the HBPC for filing with the case review records and for the purpose of the Trust's annual audit of disclosure processes.

8 Timescale for completion

As a diagnosis of cancer is already a traumatic situation for any patient, it is important that they are given clear expectations up front of the timescale for completion of audit and the findings being made available.

All audits of cervical cancer should be completed within a maximum of 6 months of the diagnosis of cancer. However, it is expected that most cases can be completed

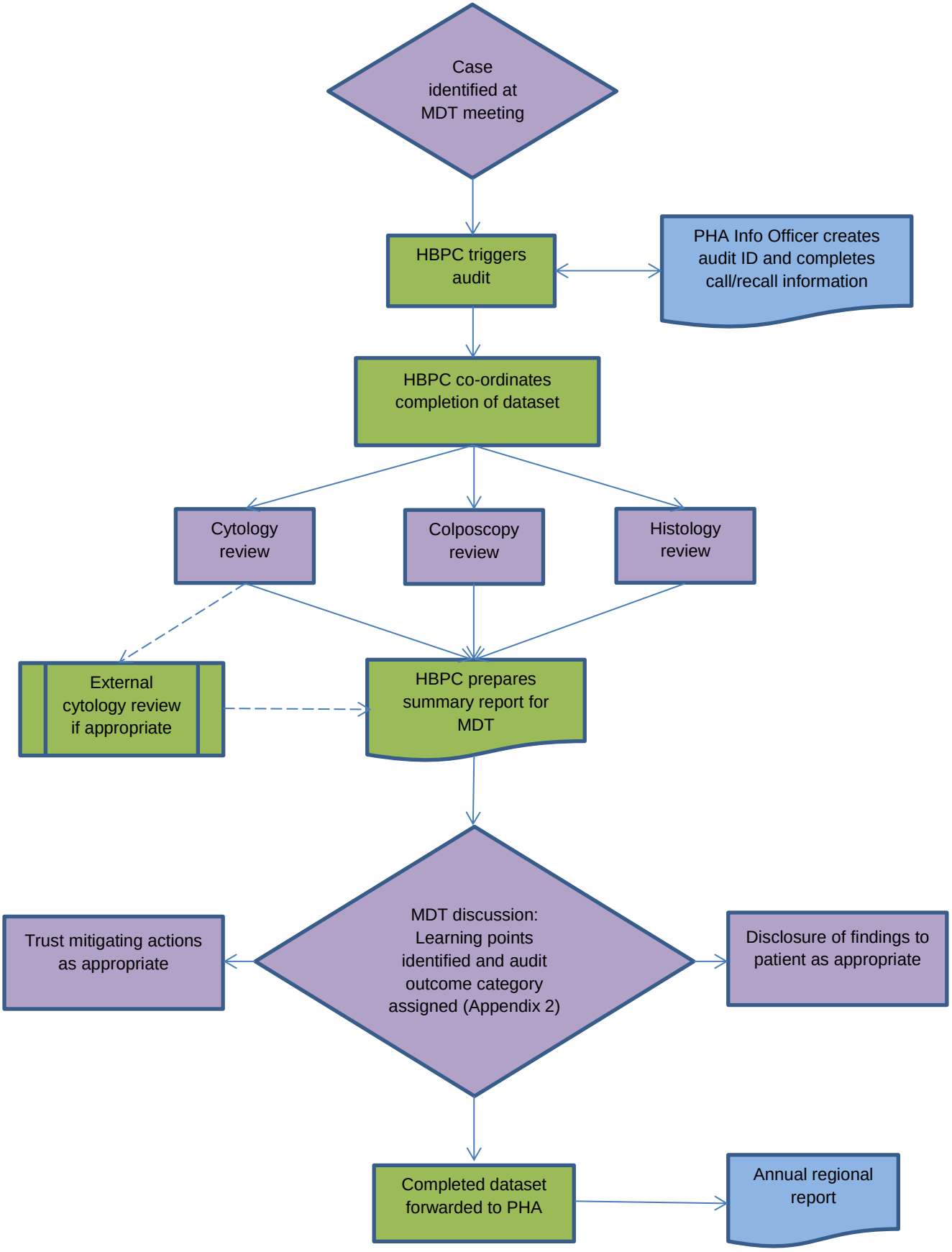
well within this timescale and outcomes communicated to patients in a timely manner.

9 Monitoring Compliance and Effectiveness

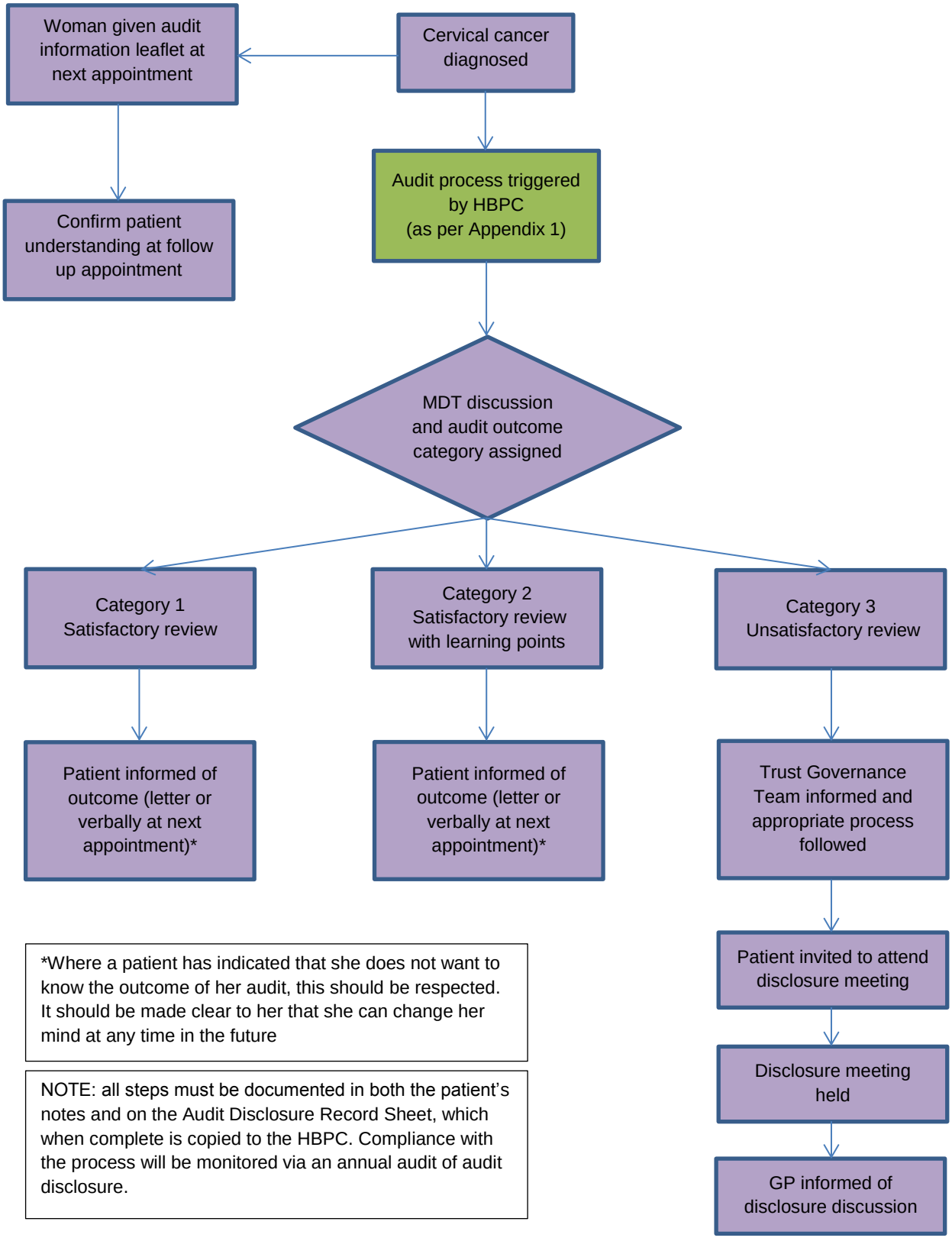
Each Trust is expected to undertake an annual audit of their compliance with the audit and disclosure pathways.

This will be monitored at annual quality assurance data review meetings for cytology and colposcopy with the PHA and the respective Regional QA Leads.

Appendix 1: Audit Pathway



Appendix 2: Patient Information and Audit Disclosure Pathway



*Where a patient has indicated that she does not want to know the outcome of her audit, this should be respected. It should be made clear to her that she can change her mind at any time in the future

NOTE: all steps must be documented in both the patient's notes and on the Audit Disclosure Record Sheet, which when complete is copied to the HBPC. Compliance with the process will be monitored via an annual audit of audit disclosure.

Appendix 3: Audit Toolkit

The Toolkit to support this Framework document includes the following:

- The protocol for undertaking the review
- Patient Information Resources
    - leaflet - *'Reviewing your Cervical Screening History'*
    - Frequently asked questions
- Audit Disclosure Record Sheet
- Audit dataset

The latest versions of each item will be available at www.cancerscreening.hscni.net

References

[1] Protocol for the Audit of Invasive Cervical Cancers. Northern Ireland Cervical Screening Programme, Public Health Agency, December 2014.

[2] Policy for Clinical Audit of new cases of Invasive Cervical Cancer and Disclosure of Results (v 3). Derby Teaching Hospitals NHS Foundation Trust, September 2015.

[3] Guidance on applying Duty of Candour and disclosing audit results. (version 1.0) NHS Screening Programmes, Public Health England, September 2016. https://www.gov.uk/government/publications/nhs-screening-programmes-duty-of-candour

[4] Breast Screening: Interval cancers and duty of candour toolkit. Public Health England, Updated March 2018. https://www.gov.uk/government/publications/breast-screening-interval-cancers-and-duty-of-candour-toolkit/interval-cancers-and-applying-duty-of-candour

[5] Procedure for the Reporting and Follow up of Serious Adverse Incidents (version 1.1). Health and Social Care Board, November 2016.

[6] Openness and Honesty when things go wrong: the professional duty of candour. General Medical Council/Nursing and Midwifery Council. June 2015. https://www.gmc-uk.org/-/media/documents/openness-and-honesty-when-things-go-wrong--the-professional-duty-of-cand pdf-61540594.pdf