Cervical screening: cytology reporting failsafe

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1. Introduction

This guidance aims to make sure that reasonable and effective failsafe measures are applied consistently across the NHS Cervical Screening Programme (NHSCSP) whilst avoiding unnecessary duplication of administrative effort. This version updates and replaces guidance from 2004.

Failsafe is a back-up mechanism which makes sure that if something goes wrong in the screening pathway processes are in place to identify what is going wrong and what action should follow to ensure a safe outcome.

The value of a screening programme is diminished if appropriate action is not always taken to make sure that the right people are invited to be screened, or if the right action is not taken to follow up those with abnormal test results. Failsafe processes are designed to prevent or reduce these risks and errors occurring.

Continued development of the National Health Applications and Infrastructure Services (NHAIS) software system used for the administration of NHSCSP call and recall has meant that reliable failsafe measures for routine call and recall are in place. However, additional failsafe measures by laboratories and colposcopy clinics are needed for women whose test results require referral for investigation or treatment in colposcopy.

2. The failsafe process

Failsafe processes make sure that as far as possible the cervical screening programme (CSP) takes the correct action following a cervical screening test, or that a valid reason for not taking that action is known and recorded. The effective monitoring of failsafe requires documentation of:

- the point at which a required screening activity is started
- the point at which it is concluded

This is usually via a failsafe systematic process and/or an IT system. In addition providers should have local protocols to ensure that all processes close within an appropriate timescale.

Opening a process

This is a trigger which indicates that a process requiring a failsafe control for an individual has started. For example a woman attends a cervical screening appointment and a sample is obtained by the sample taker.

Closing a process

This is an event or a stage of the screening pathway which signals the conclusion of a process requiring failsafe control for an individual. An example is the sending of a letter to notify a woman of her screening test result. There may be a number of events that can result in a particular process closing. For example a process opened as a result of a woman being directly referred to colposcopy for further investigation and possible treatment will be closed by a subsequent appropriate cervical biopsy, a screening sample booked onto the laboratory information system (LIMS) or correspondence sent to cytology from the colposcopy clinic advising the outcome of the appointment.

Making sure the process is closed

This is an additional check, usually on a group of individuals. It identifies any individual for whom a failsafe process remains open beyond a defined timescale. An example is a check by the laboratory to ensure all women directly referred to colposcopy have a valid outcome.

Most screening pathways will involve multiple failsafe processes at different levels of detail. For example a failsafe process to make sure that every woman requiring colposcopy receives direct referral can exist within a broader process making sure that call and recall notifies every woman of their screening result.


3. The role of the screening commissioner

NHS England (the commissioner of screening services) has responsibility on behalf of the Secretary of State for Health to commission and contract according to national regulations and guidance to ensure a safe, accessible and effective service. Cervical screening requires actions to pass safely and effectively between many different organisations. The commissioners will seek assurance that all stages of the screening process work well together. Commissioning for cervical screening, alongside other commissioning for screening programmes, has additional professional support from Public Health England (PHE) screening and immunisation teams (SITs).

4. Call and recall system

4.1 PCSE responsibilities for call and recall
NHS England is responsible for commissioning the call and recall system for the local delivery of cervical screening and for monitoring its effectiveness. The call and recall system is provided by Primary Care Support England (PCSE). The NHAS system software package records the screening history for women registered with a GP in England. The system provides a means of:

- sending, receiving and acting on prior notification lists of women due for a cervical screening test, which general practitioners (GPs) have updated to ensure women are not invited inappropriately
- inviting eligible women for cervical screening tests at the routine screening interval
- inviting women for an early repeat test before the routine screening interval
- sending women information to assist them make an informed choice about whether to participate in screening
- receiving, validating and confirming receipt immediately of screening results sent by the laboratory
- recording screening results
- informing women in writing of their screening results
- sending reminder letters to women if no test result has been entered on the system after the test due date
- providing non-responder notifications to the woman’s GP if no test result has been entered on the system after the test due date has passed and reminders have been sent
- operating a failsafe system which ensures that eligible women are invited for screening again even if no other action is recorded on the system
- operating a failsafe system which ensures that women referred to colposcopy are invited for a further cervical screening test at 12 months following the referral if no further results or outcome is entered on the system
- receiving and updating the system with next test due dates from discharge lists sent from colposcopy clinics, and querying with colposcopy any not meeting validation criteria

The sequence of notifications issued by the call and recall system is determined by action codes allocated by cytology laboratories to each test result.

A new call and recall IT system is due to replace the NHAS system in 2018.

4.2 Early repeat tests

The call and recall system provides a failsafe for women recommended for an early repeat test. Laboratory failsafe is not required.

Call and recall generates the following notifications if no test result is entered onto the system after a defined number of weeks following the invitation. The time periods are:

- 18 weeks after invitation - a first reminder (early repeat) letter to the woman
- 32 weeks after invitation - a non-responder notification to the GP
- 12 months from previous test due date - another next test due date is set

The call and recall system also provides validation checks as an additional safeguard for women who have had a recent abnormal result to prevent an inappropriate immediate return to routine recall (see section 4.3).

4.3 Validation checks

The call and recall system validates all test results entered onto the system to ensure that:

- the result and action codes allocated by the laboratory form a valid code combination
- women who require more than one follow up test after an abnormal result are not returned to routine recall prematurely


Some women will require 2 or more normal tests after an abnormal screening test result before they can be returned to routine recall. A normal test result is any combination of cytology and HPV test results that can validly have a routine recall action (see appendix 2 (https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe) part 3). This will include borderline and low-grade cytology provided that the associated HPV test result is negative.

Women who cannot be returned to routine recall at their next normal test are those whose most recent adequate NHS test was one of the following result code combinations:

3R, 8R or 9R
4S, 49S, 4US or 4QS
5S, 59S, 5US or 5QS
6S, 69S, 6US or 6QS
7S, 79S, 7US or 7QS
Colposcopy outcomes are not recorded on the call and recall system. The system will therefore only enforce the minimum requirement for follow up based on the most favourable possible colposcopy outcome for any given screening test result. In all cases a maximum of 2 consecutive normal results will be required before a woman can be returned to routine recall. In practice this means that a routine recall action (code A) can be recorded in conjunction with a woman’s second normal test result, so that her subsequent next test due date will be set at the routine recall interval.

A laboratory must always check that a routine recall recommendation is appropriate with reference to a woman’s screening history before issuing an A-coded result. It is important to note that the call and recall system cannot be relied upon to identify inappropriate recommendations for routine recall in all cases. If a woman was referred for colposcopy after a screening result not subject to validation and requires non-routine recall (for example B9S leading to untreated CIN1), the system will accept a routine recall-coded normal result at her next test if one is provided by the laboratory. Similarly, if a woman under follow-up after treatment for CGIN requires 3 or more consecutive normal tests, the system may accept a routine recall-coded normal result at her first or second subsequent test if one is provided by the laboratory, dependent upon the immediately preceding screening test result.

The call and recall system will, in accordance with established practice, allow an immediate return to recall when a normal test result is entered for a woman whose most recent abnormal test (regardless of cytological classification) was taken more than 5 years earlier.

The call and recall system will apply the validation rules to all test results including those from women who are on a non-standard screening pathway (such as women whose pathway began under a superseded screening protocol). This will include women who had a borderline or low-grade abnormal test result without a referral for colposcopy prior to the implementation of HPV triage and test of cure. Such women should have at least 3 consecutive cytology negative tests before routine recall, unless a follow up test was normal that included a negative HPV result. The system will no longer prevent a return to routine recall on the second normal result.

If the system rejects a test result because it has failed validation checks then the call and recall department should notify the laboratory immediately in writing and ask for the test result to be reviewed and resent.

4.4 Women who move address

A woman retains her next test due date even if she moves to a different part of England. Arrangements for women who move to other parts of the UK will depend on local agreements. If the woman registers with another GP in a different area her screening history will follow her so she will still receive relevant and timely invitations, reminders and result letters. If the woman has not registered with another GP, correspondence will continue to go to her previous address.

4.5 Women who request screening results to be sent to an alternative address

When a woman requests that her cervical screening results go to an alternative address the arrangement will only apply to that single screening episode. Future call and recall letters and results letters will then default back to her home address. The call and recall system provides failsafe measures by returning women to recall if they have not attended for an early repeat test or have been suspended from recall.

In these circumstances, it is the responsibility of the GP (or clinician responsible for requesting the test) to ensure that alternative arrangements are made to give the woman her test result, and to ensure she is referred for investigation or treatment if recommended. The GP (or responsible clinician) must ensure that the woman understands that by requesting that her results go to an alternative address she takes on the responsibility for collecting her test result and for responding to any recommendation for further tests or investigations. She must also understand that the arrangement is for that screening episode only.

5. Failsafe in primary care

5.1 GPs providing cervical screening services

GPs that provide cervical screening services in accordance with the GMS contract are responsible for:

- making sure that the woman is provided with the necessary information and advice to assist her in making an informed choice about whether to participate
- respecting the wishes of women who wish to be ceased from screening, supporting them in making their decision, and notifying the call and recall service where necessary
- acting on non-responder notifications for women who have not responded to an invitation for a routine test or early repeat test
- inviting women who have not responded to their centrally produced invitation and reminder letters (sending a third invitation)
- making sure that women no longer eligible for screening (due to absence of cervix) are notified to the call and recall service promptly
- reviewing prior notification lists from call and recall services and revising accordingly
- making arrangements for taking an appropriate cervical screening sample in line with programme guidance and according to the woman’s circumstances
- arranging for a woman to be informed of her test result (1)
- discussing the test result in person with the woman if required for cases of high-grade dyskaryosis/invasive squamous carcinoma or glandular neoplasia of endocervical type
- giving a woman her test result in person where an urgent referral is required for glandular neoplasia (non-cervical)
ensuring that arrangements are made for women who fall outside the call and recall system to receive their test results
making sure that the test result is known and followed up appropriately
for intersex individuals with a cervix, female to male transgender (trans) men, and for individuals who identify as male but require cervical screening, the GP should take responsibility for the screening process and notify the laboratory that the results should be returned to the practice directly and not the call and recall service
referring a woman for further investigation and treatment where necessary (for example, a woman needing colposcopy who has moved from another area, or a woman who has been discharged following a previous non-attendance at colposcopy) (2)
acting on the non-responder notification from the colposcopy clinic for women who have not attended for colposcopy
cooperating promptly with failsafe enquiries from the laboratory about a woman who requires further investigation and treatment (3)

(1) Although it remains the responsibility of the GP to make sure women are informed of their test result, this function is provided automatically by the call and recall service once a valid result or action code is received.

(2) All laboratories operate a direct referral system for colposcopy in conjunction with their local colposcopy clinics. In areas using this system, the GP still has a responsibility to make sure that colposcopy has taken place.

(3) It should be noted that failure by providers to respond to failsafe enquiries should be considered as a clinical governance issue.

5.2 GPs opting out of cervical screening services

Under the GMS contract, some GPs may choose not to provide cervical screening services for their registered population. NHS England has the responsibility for commissioning cervical screening for this population.

5.3 Other clinicians responsible for requesting a cervical screening test

Cervical screening services may be provided in other settings including community clinics, out of hours clinics and genito-urinary medicine (GUM) clinics. Clinicians responsible for requesting cervical screening tests are responsible for:

- ensuring that the woman is provided with the necessary information and advice to assist her in making an informed choice about whether to participate
- making arrangements for taking an appropriate cervical screening sample in line with programme guidance (1)
- arranging for the woman to be informed of her test result
- arranging for the woman’s GP to be notified of the test result
- ensuring that there is a mechanism in place so that the test result is followed up appropriately (2)
- ensuring the woman receives colposcopy for further investigation and treatment where necessary, where the clinician has responsibility for the woman’s clinical care for example in a GUM clinic, or where the clinician is providing a cervical screening service because the woman’s GP has opted out
- cooperating with failsafe enquiries about a woman who requires further investigation and treatment (3)

Where another health care provider rather than the woman’s GP provides cervical screening, the provider should have clearly documented and agreed roles and responsibilities in place to ensure that:

- women are followed up appropriately
- a record of the woman’s screening history is maintained
- adequate failsafe provision is in place

5.4 Further responsibilities of sample takers

In addition to the responsibilities outlined in sections above, sample takers are responsible for:

- maintaining a register of tests taken
- checking that a test result has been received from the laboratory for every sample taken, within an appropriate timeframe
- ensuring all samples are repeated/taken at the correct interval
- ensuring the screening history of all newly registered women at the GP practice is reviewed prior to taking a sample, to ensure samples are taken appropriately
- ensuring that when a test sample has been rejected by a laboratory (see Guidance for acceptance of cervical screening samples in laboratories (https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories)) the woman is informed and advised regarding repeat testing where appropriate

6. Laboratory failsafe

6.1 Role of the cytology laboratory

Cytology laboratories are responsible for:

- transferring test results and recommendations for management to the call and recall system using standard result and action codes
- notifying the sample taker and GP or responsible clinician of test results and recommendations for management
operating a direct referral system for women who need a referral to colposcopy; this will include daily communication with each colposcopy clinic
informing GPs and responsible clinicians about women who require referral for colposcopy
ensuring that histology results are collated with cytology results


The guidance applies to samples from both primary care and gynaecology clinics. All test results which are subject to laboratory failsafe have an action code S (‘suspend from recall’). Laboratory failsafe procedures should operate during the period of suspension from recall (a maximum of 12 months). The call and recall system provides a final failsafe by returning the woman to recall after a maximum period of 12 months from the date that the test result.

6.2 Cytology laboratory failsafe system

The lead pathologist for the service is responsible for ensuring that a laboratory failsafe system is in place.

The cytology laboratory must:

- keep a record of all test results which are subject to laboratory failsafe
- ensure that the womans GP (or responsible clinician) is notified of test results which require urgent referral
- send the GP (or responsible clinician) sufficient and timely information to respond to queries from women about their urgent referrals (this may be covered by existing result notification in which case the laboratory is not required to phone or fax the GP)
- record colposcopy attendance and outcome (as defined in the KC61), such as histology results following tests which are subject to laboratory failsafe
- initiate failsafe enquiries to the womans GP (or responsible clinician) if no colposcopy attendance or outcome is notified to the laboratory
- keep a record of all failsafe enquiries (including letters, phone calls, e-mails)
- send the GP (or responsible clinician) a closure letter when laboratory failsafe enquiries have been made and actions are closed
- audit the laboratory failsafe procedures on an annual basis

6.3 Direct referral

The laboratory must have an internal audit system in place to ensure that all direct referrals have been made in a timely fashion to the appropriate colposcopy unit.

The laboratory must have a system to make sure that the appropriate colposcopy units have received all referrals. The colposcopy unit must confirm to the laboratory that they have received the referrals. This also includes both parties confirming if there were no referrals sent or received on a particular day.

The referral arrangements for women needing investigation following a result of non-cervical glandular neoplasia are not within the remit of the cervical screening programme. However it is important that a system is in place for the safe hand-over of these women to the appropriate service. It is also good practice to ensure that an outcome is received from these referrals to support cervical cytology staff education and training, and to ensure there were no histological findings that involved the cervix. If local direct referral policies exclude any urgent referral cases (such as non-cervical glandular neoplasia) there is still a requirement for individual notification of these results to the GP.

6.4 Laboratory failsafe enquiries

Having access to histology and ideally colposcopy databases at all providers where biopsies are reported is crucial for a centralised cytology laboratory referring women to a number of different colposcopy clinics. This will reduce the number of failsafe enquiries the cytology laboratory has to perform for those:

- who have not attended
- who have attended but not had a biopsy

6.4.1 Laboratory failsafe enquiries for women urgently referred with results of high-grade dyskaryosis/invasive squamous carcinoma or glandular neoplasia of endocervical type

If the cytology laboratory has no information about the colposcopy or histological outcome after 6 weeks, failsafe enquiries should be made to the multi-disciplinary team (MDT) or colposcopy clinic and the histology laboratory, then the GP (or responsible clinician) depending on the response. Enquiries are made in writing and a record kept of these and the responses. Example template letters are provided in appendix 1 and appendix 2 (https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe)
6.4.2 Laboratory failsafe enquiries for non-urgent referrals and women referred with results of high-grade dyskaryosis (moderate or severe)

This section describes failsafe arrangements for all screening referrals not included in 6.4.1 above.

If the cytology laboratory has no information about the colposcopy or histological outcome after an agreed interval (normally 3 months from the date of the test result, but this may depend on local colposcopy waiting times), failsafe enquiries should be made to the colposcopy clinic and the histology laboratory, then the GP (or responsible clinician) depending on the response. Enquiries are made in writing and a record kept of these and the responses. Example template letters are provided in appendix 3 and appendix 4 (https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe).

A single enquiry in writing is sufficient. If there is no response, the laboratory should check that the enquiry has been received. Failure to respond to a failsafe enquiry is a clinical governance issue which the laboratory should raise with the provider and relevant SIT.

6.5 Closure of laboratory failsafe

If the woman has attended colposcopy or is removed from the NHANs system, the laboratory failsafe can be closed. Otherwise the laboratory should keep failsafe enquiries open for women who do not attend colposcopy for at least 6 months (or 12 months if the woman is known to be pregnant) after the date of the test result.

If the woman does not attend, responsibility for taking any further action rests with the GP (or responsible clinician) who is managing the care of the woman’s individual circumstances. The laboratory should inform the GP or responsible clinician that no further failsafe action will be taken by the laboratory (failsafe closure letter).

If the woman is known to have moved address or is no longer registered with the GP, the laboratory can identify the new GP from the call and recall system if she is still in the laboratory catchment area, and forward the failsafe enquiry. If the woman moves away from the area covered by the laboratory the laboratory will be unable to continue follow up. In this case the failsafe can be closed. In these circumstances, PCSE is responsible for making enquiries and the transfer of screening records.

6.6 Cases where follow-up cannot be established

As part of the annual audit of the laboratory failsafe system, laboratories should keep a record of all women for whom colposcopy attendance and outcome (as per KC61) could not be established.

The cytology laboratory should provide a quarterly summary report to the SIT, who commission and performance manage the programme, and the cervical screening provider lead(s) (CSPL) (formerly known as hospital based programme coordinator) linked to the cytology laboratory. The report should detail the findings of failsafe actions for all women referred to colposcopy. No patient identifiable data (PID) information is required in this report.

The purpose of the report is to assure public health commissioning teams that all appropriate failsafe actions have been taken. Commissioners can also use this information to monitor the performance of the local service and identify practices, geographical areas or groups of women in order to target screening initiatives.

The summary report should include:

- the number of women subject to failsafe in the time period covered by the report, for each colposcopy clinic in each provider
- the number of women who attended their colposcopy appointment, for each colposcopy clinic
- the outcome of failsafe enquiries for those women who did not attend, for each colposcopy clinic include reasons such as:
  - pregnancy
  - temporarily moved away
  - permanently moved away
  - undergoing treatment for a condition where colposcopy would be clinically inappropriate
  - no longer registered with a GP
  - death
  - woman has declined further investigation
  - reason not known
  - number of instances of no response to a failsafe enquiry by GP or colposcopy clinic

7. Colposcopy clinics

7.1 Referrals for colposcopy

Responsibility for referring a woman for colposcopy rests with the GP (or responsible clinician), irrespective of direct referral arrangements that are in place. Following direct referral the responsibility for failsafe moves to the colposcopy unit. If the woman attends for colposcopy, the colposcopist to whom she is referred becomes responsible for her treatment, arranging any further follow-up and informing the laboratory and the GP (or responsible clinician) of the outcome.
If a woman declines her appointment and chooses to attend a different colposcopy unit (NHS or private) the colposcopy unit that received
the initial referral should document this to ensure they are able to respond to failsafe enquiries. Some colposcopy units will pass on the
referral to the alternative provider; however it remains the responsibility of the GP to ensure that the referral has been made.

7.2 Outcomes of colposcopy

Colposcopy clinics must have a system for notifying laboratories of colposcopy attendance and the results (such as histology results). This
includes the results from colposcopy procedures carried out under general anaesthetic. They must also notify the GP (or responsible
clinician).

7.3 Responsibilities for failsafe

The lead colposcopist for the service has responsibility for ensuring that a colposcopy failsafe system is in place.

Colposcopy clinics must:

- confirm receipt of all referrals sent by the laboratory on a daily basis (or confirm no referrals received)
- have an auditable system to ensure an appointment is allocated to all referrals received
- send invitation letters or appointments to women directly referred for colposcopy
- have a system to ensure women can have their appointment rebooked for a more suitable time
- send a letter to all women who do not attend for their appointment advising how they can be re-referred to colposcopy
- send a non-responder notification to the GP (or responsible clinician) and the laboratory if a woman does not attend a first
  appointment for colposcopy
- send a non-responder notification to the GP (or responsible clinician) and the laboratory if a woman does not attend a follow-up
  appointment for colposcopy
- have systems in place to ensure a result is received for all cytology or histology specimens taken in colposcopy
- send a clinician-validated template (see appendix F in NHS Cervical Screening call/recall: guide to administrative good practice
  women discharged from the colposcopy clinic to the call and recall service and the laboratory
- inform the woman and her GP (or responsible clinician) of the future management plan for all women, make the appropriate
  arrangements for further colposcopy appointments where indicated (including MDT discussion and agreed outcome) or onward
  referral, and ensure the GP is aware that they will be responsible for future follow up for women who are being discharged
- respond to failsafe enquiries by laboratories
- have a system in place to ensure women deferring appointments are re-invited at the correct interval
- perform a continuous audit (and produce audit reports) of referrals received against outcome to ensure all are women are accounted
  for

The CSPL should address any failure to respond to laboratory failsafe enquiries as a clinical governance issue.

8. Cervical screening provider leads

CSPLs may be based in any discipline within the organisation that provides a service to the NHSCSP. They are responsible for ensuring
that documented failsafe arrangements (as indicated in this guidance) are in place, and audited regularly, for the cervical screening
programme activities carried out by the provider or organisation.