NHS Screening Programmes

Guidance on applying Duty of Candour and disclosing audit results

Incorporating disclosure of audit guidance and adapted from ‘Disclosure of audit results in cancer screening: advice on best practice 2006’

Version 1.0/ September 2016

Public Health England leads the NHS Screening Programmes
About Public Health England

Public Health England (PHE) exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

PHE Screening, Floor 2, Zone B, Skipton House, 80 London Road, London SE1 6LH
www.gov.uk/topic/population-screening-programmes
Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk

For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

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## Guidance on applying Duty of Candour and disclosing audit results

### Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>About Public Health England</td>
<td>2</td>
</tr>
<tr>
<td>About PHE Screening</td>
<td>2</td>
</tr>
<tr>
<td>Purpose</td>
<td>4</td>
</tr>
<tr>
<td>NHS screening programmes</td>
<td>5</td>
</tr>
<tr>
<td>Duty of candour</td>
<td>6</td>
</tr>
<tr>
<td>Supporting a culture of openness and transparency in NHS screening programmes</td>
<td>8</td>
</tr>
<tr>
<td>Using audit to distinguish limitations of screening from <em>something going wrong</em></td>
<td>9</td>
</tr>
<tr>
<td>When to apply duty of candour in screening programmes</td>
<td>10</td>
</tr>
<tr>
<td>How to disclose audit results</td>
<td>11</td>
</tr>
<tr>
<td>Appendix A: medico-legal aspects</td>
<td>15</td>
</tr>
<tr>
<td>Appendix B: example of process for disclosing audit results in NHS Breast screening programme</td>
<td>17</td>
</tr>
<tr>
<td>Appendix C: Interval cancers explained in the NHS Breast screening programme: notes for professionals and patients</td>
<td>18</td>
</tr>
<tr>
<td>Appendix D: safety incidents in NHS screening programmes</td>
<td>21</td>
</tr>
<tr>
<td>Appendix E: references</td>
<td>22</td>
</tr>
</tbody>
</table>
Purpose

The aim of this publication is to advise providers and commissioners of NHS screening programmes on best practice in providing information to individuals when they receive a diagnosis for a screened condition (positive diagnosis)1 after a screening result that was reported as normal (negative).

It advises organisations how to:

- ensure they are open and transparent with users of screening programmes
- ensure compliance with duty of candour regulations in these circumstances
- disclose results of audits undertaken following a diagnosis for a screened condition (positive) after a screening result that was reported as normal (negative)

PHE, the organisation responsible for the NHS screening programmes, has produced this guidance working with clinical colleagues: the Care Quality Commission (CQC) and the Independent Cancer Patients’ Voice (ICPV)

Many of the examples in this publication are from the NHS Breast screening programme (NHSBSP). This is because most queries about the application of duty of candour regulations in screening programmes have come from clinicians working in the NHSBSP. We will do further work following publication to collect examples from other NHS screening programmes and develop tools and training materials. These will be shared through other routes such as the PHE Screening blog.

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1 In this document, screened or diagnosed ‘positive’ means the screening result was abnormal or the target condition was detected. Screened or diagnosed ‘negative’ means the result was normal or the target condition was not detected.
NHS screening programmes

The screening programmes covered by this guidance are:

- NHS Abdominal aortic aneurysm screening programme
- NHS Bowel cancer screening programme
- NHS Breast screening programme
- NHS Cervical screening programme
- NHS Diabetic eye screening programme
- NHS Fetal anomaly screening programme
- NHS Infectious diseases in pregnancy screening programme
- NHS Sickle cell and Thalassaemia screening programme
- NHS Newborn and infant physical examination screening programme
- NHS Newborn blood spot screening programme
- NHS Newborn hearing screening programme

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.

Screening programmes should operate within agreed parameters so they offer more benefit than harm to the screened population, at a reasonable cost to the NHS.
Duty of candour

The intention of the duty of candour legislation is to ensure that providers are open and transparent with people who use services. It sets out some specific requirements providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

The approach of being open and transparent should be no different in NHS screening programmes. However, because of the nature of screening programmes, sometimes it can be hard for screening services to know how to distinguish between a false negative/false positive that has occurred because of the limitations of screening and a false negative/false positive that has occurred because something has gone wrong.

Duty of candour regulations

Duty of candour regulations apply as soon as reasonably practicable after the screening service has become aware that a notifiable safety incident has occurred.

In relation to a health service body, ‘notifiable safety incident’ means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in:

- the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
- severe harm, moderate harm or prolonged psychological harm to the service user

In relation to a registered person who is not a health service body (clinician), ‘notifiable safety incident’ means any unintended or unexpected incident that in the reasonable opinion of a health care professional appears to have resulted in:

- the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition
- an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days
- changes to the structure of the service user’s body
- the service user experiencing prolonged pain or prolonged psychological harm, or
- the shortening of the life expectancy of the service user
 Guidance on applying Duty of Candour and disclosing audit results

Or, requires treatment by a health care professional in order to prevent:

- the death of the service user, or
- any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned above

If the answer is yes to any of the indicators outlined above then duty of candour applies.

How does duty of candour apply to NHS screening programmes?

There are circumstances when a person who has been screened may experience severe or moderate harm. This may be because:

- the condition screened for has not been detected and it is not treated early enough to improve the outcome for the patient – examples can include breast cancer, fetal anomaly and abdominal aortic aneurism
- the person with or without the target condition is harmed by the procedure for detecting the condition – examples include loss of a fetus due to amniocentesis and death from bowel rupture following colonoscopy
- they experience psychological harm from being told they are screen positive (or screen negative) and then finding out that their true result is different

These are recognised harms of a screening programme and are therefore not ‘unexpected’ if the programme is operating within agreed standards.

Therefore, when these events occur they should not be automatically treated as notifiable safety incidents.

However, when a patient has come to either moderate or serious harm in a screening programme a review (audit) should be carried out to understand why this has occurred. If the audit reveals something has gone wrong in the screening process, then this should be treated as a notifiable safety incident and duty of candour regulations will apply.

Notifiable incidents should be managed in accordance with ‘Managing safety incidents in NHS screening programmes’ (PHE 2015) and ‘The serious incident framework’ (NHS England 2015).
Supporting a culture of openness and transparency in NHS screening programmes

People who are invited for screening should be aware of the potential harms as well as the potential benefits of being screened. Screening services should provide people with the information they need, in formats they understand, in order to make informed decisions about whether to take up the offer of screening.

This information should include the fact that the screening programme may sometimes fail to pick up the condition or the risk factor.

When a person is diagnosed with a condition or disease after a negative screening result, the screening service should let them know that it will review (audit) why this has happened. If the person wants to know the findings of this review, then the screening service should provide that information. This approach will help ensure the organisation is open and transparent.

The value of audits

The screening pathway involves a number of steps: invitation, sample taking, examination (carrying out the screening ‘test’) and reporting, results, intervention and diagnosis. At any one or more of these steps there may be suboptimal provision or an existing abnormality may not have been identified despite an effective programme.

Audit helps to identify potential problems at any one or more of these steps. It also helps improve the whole process for patients in the future. Without audit, the opportunity to learn vital lessons from individual cases would be lost.

In many cases audits will not find that something has gone wrong. Disclosing the results of audits to patients, regardless of their findings, shows that an organisation is being open and transparent.
Using audit to distinguish limitations of screening from *something going wrong*

Audits should review the specific part of the pathway where an error may have occurred that could have contributed to a patient being seriously or moderately harmed. This is most often the screening test (for example, ultrasound, grading of images, mammography, cytology) or the diagnostic element of the pathway (for example, amniocentesis, breast screening assessment, colposcopy, colonoscopy or histology).

Where an error may have occurred in the screening test or diagnostic part of the screening pathway, the review should explicitly consider and document:

- was the process for undertaking the screen or diagnosis correctly carried out according to NHS screening guidance?
- is the programme operating to national standards and the national specification?

If the answer to either of these questions is no, then the audit review should:

- document that there has been a failure in screening process (handle in accordance with ‘Managing safety incidents in NHS screening programmes’ (PHE 2015) iii and ‘The serious incident framework’ (NHS England 2015) iv
- specifically consider whether the failure to follow process has (or could have in the reasonable opinion of a health care professional) contributed to the person being seriously or moderately harmed

The audit should then consider whether or not staff carrying out the screening or diagnostic test did so to a standard that most staff could be expected to achieve. If the conclusion is that most staff would not have made a similar error of interpretation and that this error led to serious or moderate harm, then this should be documented as an error due to interpretation performance below an expected standard.

Therefore, if the audit finds that there was either a process failure and/or if interpretation performance fell below an expected standard, and this contributed to serious or moderate harm to the screened person, then *something has gone wrong*. This should then be recorded as a notifiable safety incident and duty of candour regulations should be followed, including the offer of an apology.
When to apply duty of candour in screening programmes

Positive diagnosis, following negative screen

Conduct review of case (audit)

Something has gone wrong and someone has been harmed

Notifiable Safety Incident

Duty of Candour regulations apply

Nothing has gone wrong

Disclose audit results according to patient wishes
How to disclose audit results

This section advises how to disclose information after an audit of screened cases where there has been an unexpected affected result or diagnosis. It is in addition to any local policies, protocols or guidelines. It is not intended to replace or supersede them.

The process of disclosure of audit should be built around an individual’s needs. Health literacy should be taken into account when explaining what has happened and when using written material to support discussions. Some individuals with certain disabilities or those with mental health issues may lack capacity and be subject to the Mental Capacity Act\(^2\). Provision should be made for advocates, key workers or carers in to be included in relevant discussions.

Clinicians should read and ensure they understand the audit results and information relating to the individual patient before the interview.

It is important to follow the process below which takes into account the psychological needs of patients and outlines the basic medico-legal requirements in such circumstances. A disclosure process is separate from and does not preclude or replace the complaints process or medico-legal processes.

Appendix 1 provides further information on medico-legal aspects of disclosure. The process for disclosing audit results in the breast screening programme is illustrated in Appendix 2.

Informing the patient or their family\(^3\) that an audit has been undertaken

It is recommended that when a patient or family attends the first appointment to receive a positive diagnosis following a negative screening result, they are informed (written rather than verbal information may be most appropriate at this stage):

- that the screening programme routinely reviews all previous screening results
- if they would like to discuss these findings at any time, they should inform their clinician responsible for the treatment or intervention

It is good practice to repeat this information at later appointments and include this in all written information given to patients.


\(^3\) In some circumstances this may include other individuals such as the legal guardian of an affected baby
The clinician responsible for the treatment or intervention should always respect a patient’s wish to decline information at any time. The patient may change their mind at any point during or after treatment. Letting patients and family know that this decision will be routinely reviewed a year after diagnosis can allow patients time to consider how they wish to deal with information from an audit.

Where an audit has been undertaken and the results show that a diagnosis or treatment intervention could possibly have been made at an earlier stage in the screening pathway, the patient should be made aware of the audit and offered the opportunity to discuss their screening history and the result of the audit.

Who should disclose the information?

Ideally, the clinician responsible for the treatment or intervention should be the one to undertake the discussion with the patient’s key worker/specialist nurse where applicable.

There will be instances where the clinician responsible for the treatment or intervention is employed by a different organisation to the one where the screening episode took place. In these circumstances it is important that clear agreement is reached between the organisations about how the information is given and by whom.

Both organisations should document this agreement and share the outcome of any discussions with the patient about the findings of the audit and action taken.

When should the information be given?

It is important that clinicians are flexible and any information disclosure occurs at a time suited to the patient’s needs.

The provider of the service where the diagnosis is made is responsible for ensuring:

- the screening service is aware of the diagnosis
- the result of the subsequent audit is locally documented, once known

The optimum time for the audit result to be offered can then be identified during the patient’s treatment journey.

The best time for information disclosure is likely to become clear during or after treatment, by which time a rapport may have built up between the patient and the clinician responsible for the treatment or intervention.
Guidance on applying Duty of Candour and disclosing audit results

It may be appropriate that such discussions happen after treatment has finished unless the patient requests information about their screening history during conversations about their care.

The offer of audit disclosure will also be included in the patient information and by the key worker (where applicable) during the patient journey.

In screening programmes, the time and method for communicating with individuals may be affected by local circumstances and the context of the individual case. If a decision is taken to delay communication because of individual and/or population needs, the clinician should clearly document the reasons.

How should the information be given?

The patient should be given the opportunity for a friend, relative, carer or advocate to be present at the discussion.

At the disclosure interview the clinician should:

- check the patient’s understanding of why he or she has asked for the information
- find out how much the patient wants to know
- discuss the relevant reports and their implications
- allow the patient time to voice his or her comments and concerns

The results of the audit should form the basis of the discussion and the clinician should allow themselves enough time to prepare. A scripted interview is not recommended but clinicians may find it helpful to prepare in advance a list of points to cover in the course of the meeting. If the discussion is not undertaken by the radiologist/screen interpreting lead it may be helpful to discuss the audit findings with them in advance of the meeting with the patient.

Before offering explanations, it is important to check the patient’s understanding and find out what they need/want to know about their screening history. The results should be used to guide the discussion and the amount of information given at this stage. Clinicians should give patients time to voice any comments or concerns about their care. There should also be time for the clinician to respond, checking the patients understanding and whether further information/explanation is wanted or required.
If patients decline information

It is important to respect the patient’s wishes if they decline the offer. The clinician should make it clear that the individual can request the information at a future date should they change their mind. If the patient changes their mind following discharge from treatment they should be informed that they can either contact their screening service or their GP, who can make the necessary arrangements.

If the patient or their family has indicated previously that they do not wish to know the results of the audit and this has been documented, including cases where the result of the audit has led to a notifiable safety incident, then the organisation is not required to write to the patient with an apology.

Record keeping

The results of the discussion should be clearly documented by the clinician in the patient’s hospital record. A record of the discussion should also be sent to the GP and the patient.

Access to further information/resources

A number of provider organisations offer training in breaking bad news which clinicians may wish to access.

Local guidelines and protocols should be adhered to.

Explaining to a patient or their family why their condition was not detected can be complex. Use of visual aids such as a pictogram (Appendix 3) to explain the occurrence of interval cancers in breast screening can support these conversations.

The Nursing and Midwifery Council, in conjunction with the General Medical Council, have produced the following helpful guidance: Openness and honesty when things go wrong: the professional duty of candour.
Appendix A: medico-legal aspects

The advice in this section focuses on the communication of the results of audit undertaken for education and improvement of the service rather than the prevention of claims for damages.

What does the law expect of clinicians?

Under normal conditions the law expects no more of those caring for patients than that they perform as may be reasonably expected of members of their profession.

Clinicians may be concerned that by being open and transparent when communicating news of a reporting discrepancy, patients may regard the disclosure as an admission of error. From a medico-legal perspective such conclusions may not be justified.

Patients or relatives who indicate they wish to complain or seek legal redress should be given information about how they may proceed.

What do clinicians need to know?

Patient information is confidential. In most instances it may be shared between trust staff only in relation to the management of a patient’s treatment.

Points to consider when conducting a disclosure interview

Steps can be taken to reduce the likelihood of complaints and claims. It is important to understand the likely issues and to deal with them sensitively. When talking to patients about disclosure of audit findings, the quality of the explanation is crucial and must be detailed.

Complaints or claims are less likely if patients perceive that the process which led to the interview is transparent and they receive an apology or expression of sympathy for their present position.

Apologies and explanations, as opposed to admissions of liability, are encouraged. The NHS Litigation Authority (NHSLA) Circular 02/02 Apologies and Explanations provides guidance on this issue.

Issues of consent to audit and confidentiality in respect of patient data should be addressed during the disclosure interview.
It is important to note that the law judges standards according to the year in which the sample was taken. Therefore, improvements in screening technique will not result in a retrospective finding of liability.

Denials of liability can be as unhelpful as admissions of liability, while a lack of definite advice may lead to allegations of stalling for time or fudging the issue. A consistent approach is required which sets out the issues objectively.

If a legal question is raised or access to records is requested the clinician should refer to local trust policy and check with the trust’s legal team. Providers should be able to demonstrate they have undertaken due diligence in assessing how the duty of candour applies to each serious incident and seek legal advice where necessary.

**Advising patients**

Patients should be advised that:

- no matter how closely the review panel tries to reproduce the original screening conditions, the conditions of a review are different – the fact that a review includes records of a patient known to have a serious condition, such as cancer, will heighten vigilance and increase reports of abnormality
- finding discrepancies on review does not imply that the same findings should have been made under routine conditions
- hindsight has a significant impact on the interpretation of images
- screening tests work within agreed parameters of sensitivity and specificity and cannot detect 100% of abnormalities at the time of screening
- in a number of screening programmes, such as fetal anomaly ultrasound, cervical and breast screening, the result is based on interpretation of appearances on a scan, slide or mammogram in circumstances where the boundary between normality and abnormality is not firmly drawn – this may result in debate between experts as to the appropriate classification of the sample or the interpretation of the image
- the patient should be given the option to see another clinician for a second opinion should they wish

**Further sources of information**

Where requested, patients should be given the contact details for the trust’s Patient Advisory Liaison Service (PALS) and be informed about the trust’s complaint procedure.

The following associations may also be of use to the patient: Citizens Advice and AVMA (Action Against Medical Accidents).
Appendix B: example of process for disclosing audit results in NHS Breast screening programme

You should only give feedback when full results of the audit review process are available. Feedback should be given in accordance with this guidance. Otherwise harm could be caused.

1. Cancer diagnosis
   - Symptomatic service
2. Given diagnosis
   - Screening history checked
   - Given information regarding screening review and national breast cancer diagnosis leaflet
3. Treatment
4. At patient’s request OR at suitable point after initial treatment discussion regarding offer of results of review:
   - Patient declines results, including possible missed cancer result
     - Decision recorded
     - Offer of result at later date if patient changes their mind
   - Patient receives result
     - Discussion with clinician (who should ensure they have prepared for the interview)
     - Offer of further discussion with screening service
     - Conversation documented
5. Patient has had previous screens
   - Screening and diagnostic service exchange films
6. Screening service informed
7. Screening service reviews and categorises interval cancer
8. Screening service informs diagnostic service of findings

Text in black relates to symptomatic elements. Text in red relates to screening elements.
Appendix C: Interval cancers explained in the NHS Breast Screening Programme: notes for professionals and patients

Of 1,000 women screened for breast cancer:

- eight are diagnosed with cancer
- 992 have a normal result, of whom around three will develop an interval cancer

An interval cancer is a breast cancer found during the three years after a normal result and before the next screening appointment. In England, each year approximately 6,000 women will develop an interval cancer.

The diagram on page 20 shows why interval cancers can occur. It also highlights how professionals and organisations can be open and transparent.

If a woman develops an interval cancer the screening programme should:

- review the previous screening mammograms
- compare the previous mammograms to those taken at the time of diagnosis
- give information to the woman (if she wishes) to explain the findings
- use the experience to learn and improve

Of the 6,000 women with interval cancers each year in England:

- around 4,800 (80%) will have developed cancer between screening appointments - this means there was no sign of cancer at the previous screen
- around 1,200 (20%) had a cancer which was not picked up at their previous screen (false negatives)

When a cancer was not picked up at the previous screen (false negative) this is usually because the cancer changes were hard to see and would only be seen with hindsight.

In a small number of cases, other screeners think the changes should have been picked up. These are notifiable safety incidents. Services should follow the statutory requirements of duty of candour. Any such incident should be investigated so lessons can be learnt and a formal apology offered to the woman.
Notes for professionals

Review teams in breast screening units currently classify interval cancers into categories one, two or three to support learning and development. However, a national survey showed screening units vary in the way they do this. In some units this classification may have significant overlap with the decision about which interval cancers should fall within the remits of a notifiable safety incident, but this is not the case for all units.

Local review teams should therefore reach a clearly documented decision as to which cases should be considered notifiable safety incidents. For instance when review shows there has been a general service failure or inadequate assessment processes.

Further work is being done to ensure a clearer and more consistent approach to classification of interval cancers.
ALL INTERVAL CANCERS

NHS Breast Screening Programme: Interval cancers explained
An interval cancer is an invasive cancer diagnosed within the 3-year period after a normal result. Interval cancers occur in around 3 of every 1,000 women screened.

Out of every 1,000 women screened for breast cancer:

- 8 are diagnosed with cancer
- 992 have a normal result, of which 3 are interval cancers

For every 100 interval cancers that are reviewed

- 80 women had a normal screening mammogram. The cancer could not have been detected at their most recent screen (true negative). These women should have the findings communicated to them according to guidance *. Taking this approach, organisations can ensure they are operating in an open and transparent manner. No other action is required.

- 13 women have cancers that most screeners would not have detected. Only subtle changes can be seen on the screening mammogram (false negative). These women should have the findings communicated to them according to guidance *. Taking this approach, organisations can ensure they are operating in an open and transparent manner. No other action is required.

- 7 women have cancers that most screeners would have detected on the screening mammogram (also false negatives). These are notifiable safety incidents and a formal apology in accordance with Duty of Candour regulations should be followed.

All interval cancers should be reviewed/audited
Appendix D: safety incidents in NHS screening programmes

The guidance on screening safety incidents applies to all organisations that provide NHS screening programmes in England whether an NHS trust, NHS foundation trust, general practitioner or private provider.

The guidance details the accountabilities for reporting, investigating and managing incidents in NHS screening programmes. It covers the management of safety concerns, safety incidents and serious incidents. It is written for staff working in local NHS funded screening services, organisations that host screening services, commissioners of screening, Public Health England (PHE) screening and immunisation teams, the screening quality assurance service (SQAS), national screening programme teams, PHE regions and centres and local authority directors of public health.
Appendix E: references

i CQC Regulation 20: Duty of candour 2015
Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare

www.legislation.gov.uk/ukdsi/2014/9780111117613

iii PHE. Managing safety incidents in NHS Screening Programme. 2015

iv NHS England Serious Incident framework 2015
www.england.nhs.uk/patientsafety/serious-incident/

v NHSLA Letter to Trusts 02/03 Explanations and Apologies www.nhsla.com

vi Openness and honesty when things go wrong: the professional duty of candour.
General Medical Council / Nursing and Midwifery Council. June 2015