NHS Breast Screening Programme
Reporting, classification and monitoring of interval cancers and cancers following previous assessment

August 2017

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

Public Health England exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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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 4 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.

www.gov.uk/phe/screening
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Executive summary

This guidance provides advice for services on:

- reporting, classification and monitoring of interval cancers
- how to carry out reviews for cancers that occur following a previous assessment

Interval cancers are cancers that are diagnosed in between screening episodes.

There are three reasons to report and monitor interval cancers.

1. To monitor rates of interval cancers in conjunction with rates of screen detected cancer to provide information on whole programme performance.
2. To support education and learning objectives for screening services and individuals. This helps improve the quality of the service provided to women.
3. So that women who have had an interval cancer can understand whether any abnormality was present on their previous films and if they wish to receive the information.

Use of interval cancer reports to monitor programme performance

Data from services on interval cancers can be used with the Screening History Information Management system (SHIM) and other data from the NHS Breast Screening Programme (NHSBSP) to calculate sensitivity and specificity for the screening programme. These data are monitored annually within the consolidated standards for breast screening. This allows comparison of NHSBSP to international standards of performance for these indicators.

The interval cancer manual (currently under revision) provides detailed guidance on definitions of types of interval cancer. This ensures consistent and accurate reporting so that trends and comparisons can be identified and made.

PHE commission annual reports on interval cancer rates to monitor national programme performance.

Use of interval cancer reviews for education and learning

Image review and the classification of interval cancers in a breast cancer screening programme are particularly valuable for their educational benefit to image readers. By viewing cases where the mammograms show very subtle changes of malignancy, readers have been able to improve their skills in detecting small breast cancers.
Breast cancers can also be diagnosed in women who have been assessed at the previous screening episode then returned to the normal 3 yearly routine recall protocol. These cancers may present in the interval between screens or at the next routine breast screening episode. Timely contemporaneous review of such cancers arising in women previously assessed can help determine whether national programme guidance has been followed at assessment. This document provides guidance on the use of a revised Previous Assessment Review Form (previously called Form 4) to undertake these reviews.

For educational purposes, all cancers that occur in between screens should be subject to image review even if they have occurred beyond 36 months. This may occur when the round length is greater than 36 months and the screening invitation has been delayed.

Information for women

This document should be read alongside the Guidance on applying Duty of Candour and disclosing audit results. This provides advice on how to share results of the audit with women should they wish to receive this information.

Breast screening and interval cancers

The breast screening programme is organised to detect cancers at an earlier stage than would present symptomatically so that treatment outcomes will be more successful. Interval cancers are an inevitable part of all breast cancer screening programmes, as not all cancers are detectable on mammography. In the NHSBSP some cancers are not detectable at screening and will grow to become visible on mammography or clinically detectable in the period between routine screens. In a very small number of cases, cancers are undetected due to reader misinterpretation.

The NHSBSP detects around 18,000 cancers annually. In addition about 6,000 women present with interval cancers each year in England. Of these women with interval cancers:

- around 4,800 (80%) had no cancer visible on previous screen, and it had grown to become detectable since that screen
- around 1,200 (20%) had a cancer which was not picked up at the previous screen. In most women the changes were subtle and would not be detectable by most image readers. In a minority of cases, the cancers were missed and on review readers could identify the cancer.
Reporting, classification and monitoring of interval cancers and cancers following previous assessment

Interval cancer definitions

A screening interval cancer is a breast cancer diagnosed in the interval between scheduled screening episodes in women who have been screened and issued with a normal screening result.

Interval cancers need to be monitored for 2 primary purposes.

1. Comparison of interval cancer rates against a reference population and to compare with other services nationally.

2. Educational and service improvement benefits.

Measuring and comparing rates of interval cancers

The NHSBSP requires all eligible women aged 50 to 70 to be invited for routine breast screening appointments at intervals of 36 months. In practice, women may be invited just before the age of 50 and they may be re-invited for a subsequent screen at either less or more than 36 months following their last screen. To ensure comparability between all screening services, there are strict rules when calculating rates of interval cancers.

Numerator: number of women eligible for screening presenting with an invasive interval cancer within 36 months of a previous screen

Denominator: total number of eligible women screened (within a screening year and interval cancers arising within 36 months of the specified period expressed as a rate per 1000 screened)

Women will have their final routine screening appointment between the ages of 68 and 70 if they have not been randomised to receive an additional screening invitation as part of the current age extension trial (AgeX). Any cancers diagnosed in the 36 months following their last screening episode are defined as an interval cancer and should be counted in the rates of interval cancers. For example: if a woman is screened routinely at age 70 and is not diagnosed with cancer, she will count as having an interval cancer if later diagnosed with cancer up to the age of 73, even though the programme would not routinely invite her at this age (if it is within 36 months of her previous screen).

1 *The numerator only counts women who have been screened and developed an interval cancer.

2 In circumstances where service rates are being compared, interval cancers may be calculated over a complete round of 3 years
Reporting, classification and monitoring of interval cancers and cancers following previous assessment

Monitoring interval cancers for educational and service improvement purposes

To learn from past and present performance, we need to identify and review as many women as possible diagnosed with an interval cancer.

The AgeX trial means that some women below the age of 50 or up to 73 years have breast screening. Screening slippage (where services do not screen all of their eligible population within 36 months of their previous screen) happens for a variety of reasons. This means that women can be diagnosed with cancer beyond 36 months from their previous screen even though they have not yet been invited for their next routine screening appointment.

To ensure that we examine all possible interval cancers we require the following:

- all women who have a cancer diagnosed within 40 months of their previous screen should be reviewed as an interval cancer case – this includes women who self-referred or were referred for screening by their GP
- interval cancers should be examined for all women screened (as part of the routine screening programme or AgeX trial), whatever their age at screening
- invasive and non-invasive cancers should be included in reviews

More detailed information on the analysis of interval cancers is in the interval cancer manual.

Radiological review of interval cancers

Image review and the classification of interval cancers in a breast cancer screening programme are particularly valuable for their educational benefit to image readers. By viewing cases where the mammograms show very subtle changes in malignancy, readers have been able to improve their skills in detecting small breast cancers.

Image reading review of interval cancers also provides helpful information for women diagnosed with breast cancer who request the results of the review of their previous images.

In all circumstances clinicians should follow disclosure of audit guidance. This includes applying duty of candour regulations where applicable.
Identification of interval cancers

Correctly identifying interval cancer cases is an important function of local services and the Screening Quality Assurance Service (SQAS). SHIM will also support this process. Services can increase the correct identification of interval cancers by identifying women who are:

- in the screening age group, have newly diagnosed breast cancer, and who are discussed at a symptomatic multidisciplinary team meeting
- or
- aged under 50 receiving high risk surveillance within the NHSBSP

Practical information on the process of collection of interval cancer data and categorisation of screening histories is given in detail in the interval cancer manual. This document is designed for screening services and SQAS use.

Recording interval cancers in screening services

Screening services must record all episodes of interval cancers on the national breast screening system (NBSS) in a timely way to allow adequate monitoring of service performance.

The screening service must create an interval episode on NBSS as soon as a potential interval cancer is identified. All imaging and pathology data relating to the interval cancer including radiological category (for example, ‘satisfactory’ or ‘unsatisfactory’) should be entered on NBSS within 6 months of the initial registration.

Women who have requested the results of an interval cancer review should receive them in a timely fashion. This should be within 4 months of the notification of the cancer to the service.\(^3\)

An interval cancer that occurs in a woman who has been previously assessed at breast screening should be reviewed by the service using the Previous Assessment Review Form (see below). This should be completed within 4 months of the symptomatic presentation.

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\(^3\) It is recognised that it will take time for services to clear backlogs of interval cancers and set up systems to review interval cancers routinely and in a timely fashion. It is expected that services will be able to meet this requirement by April 2019.
Undertaking local review of interval cancers

NHSBSP requirements for interval cancer review are that:

- a minimum of two reviewers should review the images
- the previous screening mammograms, with all prior images that were available at the time of screening, should be reviewed by the readers independently - this should be done without sight of the mammograms taken at diagnosis
- the presence of any abnormal mammographic sign or feature on the previous screening image should be recorded and the radiological level of suspicion for malignancy reported
- the diagnostic images should then be reviewed to confirm that any subtle or suspicious signs detected on the previous screening images match the site of the confirmed breast cancer on the diagnostic images
- there should be very few films that fall into the 'unsatisfactory' category - these are images where the appearance is obviously malignant and all readers reviewing the films agree that they would recall
- if the diagnostic symptomatic films are unavailable for review, these are regarded as unclassifiable and should be reported as such on NBSS

The National Centre for the Physics of Mammography (NCCPM) is currently working on mechanisms to share interval cancer images to provide greater uniformity in the radiological classification of interval cancers in the future.
Classifying screening interval cancers

All interval cancers should be classified into the following categories:

<table>
<thead>
<tr>
<th>Category</th>
<th>Radiological</th>
<th>Action warranted</th>
<th>DOA/ DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Satisfactory</td>
<td>Normal or benign mammographic features</td>
<td>No reason to recall</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td><strong>2</strong> Satisfactory, with learning points</td>
<td>Seen with hindsight, difficult to perceive.</td>
<td>May provide learning Not all readers would recall</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td></td>
<td>Not obviously malignant.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3</strong> Unsatisfactory</td>
<td>Appearance is obviously malignant</td>
<td>Should have been recalled All readers reviewing the films agree that they would recall*</td>
<td>Classify as a notifiable safety incident under Duty of Candour process</td>
</tr>
</tbody>
</table>

*Films in this category should have obvious lesions. If there is any disagreement or it is felt that this is only obvious with hindsight they should be placed in the category of ‘satisfactory with learning points’.
Figure 1: classification of interval cancers

1. Identify interval cancer
2. Confirm diagnosis/obtain all pathology reports
3. Obtain diagnostic mammograms
4. Review and classify screening images
5. No diagnostic mammograms available
   - Satisfactory – apply disclosure of audit
   - Satisfactory with learning points – apply disclosure of audit
   - Unsatisfactory – apply duty of candour
6. Discuss with patient: refer to disclosure of audit and/or Duty of Candour

Discuss with patient: refer to disclosure of audit and/or Duty of Candour
Cancers following assessment

Assessment cancers are breast cancers diagnosed in women who have been assessed and returned to routine screening following their previous breast screening appointment.

This includes both interval and screen-detected cancers which have been assessed at the previous screening episode.

Assessment cancers include all cancers regardless of where in the breast they occur and includes those cancers occurring in the opposite breast to the side on which assessment took place.

Ipsilateral assessment cancers are further classified into:

- a cancer on the same side as previously assessed
- a cancer on the same side AND at the same site as previously assessed

The local service should review all assessment cancers (including those that occur after 36 months and up to 40 months after their previous screen).

Breast cancers diagnosed in follow up non-attenders (women who were either recalled for assessment or placed on short term recall at the previous screening episode, but failed to attend) are defined as interval cancers in assessment non-attenders.

Assessment cancers occurring in the opposite breast that are interval cancers should be reviewed according to the interval cancer review protocol above.

Review of same side assessments

The review protocol for both interval and screen detected cancers that occur following assessment is described in the Previous Assessment Review Form (previously called Form 4). Use of this form will help produce consistency and objectivity in the review process.

However well assessment is conducted in a screening programme, cancers will occasionally occur at the same site as that previously assessed, either presenting as interval cancers or screen detected at the next screening appointment. Audit and review of these cases is essential for education, ongoing service improvement, and to establish and monitor the background rate of such events.
As these are known cancer cases, reviewers should be aware that hindsight can bias the review and this should be acknowledged when categorising assessment cancers.

When previous assessment was at the same site as the subsequent cancer diagnosis, it does not necessarily mean that the previous assessment was flawed. Audit has shown that on review, the majority of such cases had undergone adequate assessment.

**Undertaking local review of same side assessment cancers**

The NHSBSP requirements for a review are that:

- the review of the previous assessment episode and current diagnostic images should be undertaken by two practitioners (such as a radiologist, breast clinician or radiographic consultant practitioner)
- the review should be undertaken on the most recent assessment episode in the last 3 years
- the individual involved with the previous assessment should not undertake the review, but should be made aware of the outcome
- the following information should be available:
  - original screening images
  - all documentation from assessment
  - all additional views and/or ultrasound images from assessment
  - documentation of multidisciplinary team opinion
  - symptomatic images and/or ultrasound
  - pathology reports

**Completing a Previous Assessment Review Form**

The Previous Assessment Review Form (previously called Form 4) should be completed in all cases where a cancer has been diagnosed on the same side following a previous assessment attendance. This includes:

- interval cancers
- screen detected (when the woman is diagnosed with cancer at the next routine screening appointment)
- when the woman is on short term recall
When completing a Previous Assessment Review Form, consider the following points.

1. The site assessed at the initial assessment and the site where cancer is diagnosed at the time of diagnosis should be clearly marked on the pictograms. A decision is then made regarding whether this is the same or a different site within the breast.

2. If the cancer has been diagnosed at the same site, then the case should be carefully reviewed using the Previous Assessment Review Form to document whether each aspect of the assessment was carried out according to expected processes and met national guidance on breast cancer screening assessment or not.

3. If the cancer has been diagnosed at a different site to the previous assessment, the question on the form ‘Was this cancer at the same site?’ should be answered ‘No’. The rest of the form may then be left blank. The local service should still submit the form to SQAS.

4. If there is any aspect of assessment that is felt to be imperfect, the reviewer(s) need to consider whether this is a slight difference to what they would have done/expected. In this circumstance it should be classified as ‘satisfactory with learning points’. (appendix A)

5. If all reviewers agree that there was a CLEAR failure either to follow guidance, or in the interpretation or investigations or multidisciplinary team decision-making, this should be classified as ‘unsatisfactory’.

6. If there is insufficient information to be sure about an aspect of a previous assessment this should be accurately recorded as ‘don’t know’ or ‘uncertain’. The reason why this is unclear may be important also, for example is there is poor or inadequate documentation of what has been done/not done at assessment. Even if the information available is incomplete a decision should be made to the best of the reviewers’ ability as to whether the assessment was satisfactory or not.

7. All Previous Assessment Review Forms should give an outcome of the review for same side, same site reviews. This should be either:
   - satisfactory assessment
   - satisfactory assessment with learning points
   - unsatisfactory assessment
Classifying same side, same site assessment cancers

<table>
<thead>
<tr>
<th>Category</th>
<th>Assessment process – guidance followed</th>
<th>Assessment process – interpretation/poorly performed</th>
<th>Action</th>
<th>DOA/ DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Satisfactory</td>
<td>Guidance followed</td>
<td>Assessment investigation and procedures carried out to a good standard.</td>
<td>Nil</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td>2 Satisfactory – with learning points</td>
<td>Minor deviation from guidance</td>
<td>Some assessors might have interpreted or carried out procedures in a different way that might have resulted in the cancer being detected.</td>
<td>May provide learning</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td>3 Unsatisfactory</td>
<td>Clear failure to follow guidance</td>
<td>On review all assessors would have interpreted the findings differently or performed the procedure to a higher standard*</td>
<td>Learning required and possible re-training</td>
<td>Classify as notifiable safety incident under Duty of Candour process</td>
</tr>
</tbody>
</table>
Reporting, classification and monitoring of interval cancers and cancers following previous assessment

After completion of assessment forms

All (including those that are same side, different site) Previous Assessment Review Forms should:

- be saved securely (and scanned electronically) by the screening service
- be sent to the local SQAS as soon as possible, and no longer than 4 months after the symptomatic presentation

Local services should ensure that:

- reviews with the finding of satisfactory or satisfactory with learning points are subject to disclosure of audit (see section on disclosure of audit and duty of candour)
- reviews with the finding of ‘unsatisfactory assessment’ are subject to Duty of Candour guidance. The appropriate locally agreed procedures within the Trust should be undertaken immediately when such a case is identified.

Local SQAS will:

- review and record the results of all Previous Assessment Review Forms
- assist as and when requested by a Service/Trust with the further review or investigation of any unsatisfactory assessment case(s)
- collate all cases and include in the Annual Data Day Review conducted by the complete SQAS team
- review in the 3-yearly QA visit for radiology (ref QA visits)
Disclosure of audit results and applying Duty of Candour

Guidance on applying Duty of Candour is available which details best practice in providing information to individuals when they receive a positive diagnosis after a screening result that was reported as negative (normal).

Figures 2 and 3 below shows the process which should be followed to enable disclosing outcomes of audit or duty of candour by screening services.

Figure 2: Classification of previously assessed screen detected cancers and application of DOC
Figure 3: Classification of interval cancers and application of DOC

Interval cancer identified: Retrieve pathology and diagnostic films

Not previously assessed

Radiological review and classification

Previously assessed - review assessment using assessment review form

Assessment different site / side

Satisfactory or satisfactory with learning points

Disclosure of Audit

Unsatisfactory

Assessment same site as cancer

Satisfactory assessment or satisfactory with learning points

Duty of Candour

Unsatisfactory assessment

Disclosure of Audit

Duty of Candour

Duty of Candour
Appendix 1: Previous assessment review form NHSBSP

| Previous Assessment Review Form NHSBSP | Screening Service: 
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: ...</td>
<td>Screening number: ...</td>
</tr>
</tbody>
</table>

Assessment Details
Date of assessment: 
Responsible assessor: 

Feature: 
Size: mm
Outcome: RR STR Refer

Diagnosis Details
Date of diagnosis: 
Route of diagnosis: screening/symptomatic
Feature: 
Size: mm

Is the cancer at the same site as the previous assessment? No (treat as interval cancer if diagnosed between screens)
Please circle: yes/no

---

<table>
<thead>
<tr>
<th>REVIEW OF PREVIOUS ASSESSMENT</th>
<th>Year/No</th>
<th>Guidance followed?</th>
<th>Interpretation Correct?</th>
<th>Anything else that should have been done?</th>
<th>Overall comments and any learning points about this assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the correct area assessed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were additional views performed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was ultrasound done?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical examination?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was a biopsy performed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDT discussion of the case?</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Was the case reviewed by a second assessor?</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

If the Cancer is at SAME site as the previous assessment:
Was the previous assessment? :

A: Satisfactory
B: Satisfactory, with learning points: some assessors might have acted slightly differently such that the cancer might have been detected.
C: Unsatisfactory
   i) Assessment not of area recalled at screening
   ii) Further tests should have been done
   iii) Tests that were done, were not performed according to guidelines or were misinterpreted
   iv) Incorrect MDT decision

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<table>
<thead>
<tr>
<th>Outcome of Review</th>
<th>Tick Box</th>
</tr>
</thead>
<tbody>
<tr>
<td>Different site assessed</td>
<td></td>
</tr>
<tr>
<td>Same site: Satisfactory assessment</td>
<td></td>
</tr>
<tr>
<td>Same site: Satisfactory assessment with learning points</td>
<td></td>
</tr>
<tr>
<td>Same site: Unsatisfactory assessment (see guidance)</td>
<td></td>
</tr>
<tr>
<td>Is further review of practice required?</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

Date of review: 
Date copied to SQAS: 
Review performed by: 
Actioned by: 

(Disclosure of audit if requested by client if outcome is satisfactory with or without learning points, duty of candour guidance applies if unsatisfactory assessment)
Appendix 2: Suggested examples/questions in reaching a decision to classify assessment

Was the area recalled the area that was assessed or not?
- Was the area recalled clearly marked at film reading to aid the assessor?
- Did the assessing clinician assess the correct site?

Were additional views performed for a soft tissue abnormality?
- If so, were they of the correct site and of appropriate quality?
- Were these correctly interpreted?

Ultrasound – is there documentation to indicate that the correct site of the breast was scanned?
- For example a lesion only seen over the pectoral muscle on oblique view may lie in the upper inner breast.
- Was definite correlation between the mammographic feature and the ultrasound shown?

Clinical abnormality such as possible tethering or a lump?
- Did a suitably qualified clinician examine the woman and was appropriate imaging conducted, such as ultrasound?

Biopsy – was this performed with the correct technique and of the correct area?
- Examples might include nodular breast pattern or one more prominent /dominant nodule recalled

If biopsy was ultrasound guided:
- was a clip placed and post procedure images taken to ensure the correct nodule was sampled, or was stereo biopsy used for biopsy guidance?

If an asymmetrical density has not been explained:
- was stereo biopsy performed?

MDT – was decision-making at MDT robust? For example:
- a new and radiologically indeterminate 15mm cluster of calcifications sampled by stereo guidance, but no calcification was seen on specimen x-ray and a B2, benign, core biopsy result was accepted by the MDTM. Sampling in this scenario is inadequate and 2nd line vacuum-assisted biopsy is indicated.
- if histology at MDTM does not appear to correlate with the mammographic feature described, was a further biopsy advised/performed?