An Update on Interval Cancers and Duty of Candour

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BSBR November 2016
• Current interval cancer process
• The CQC and Duty of Candour
• Classification of interval cancers
• Classification of previously assessed cancers
• A practical guide on finding an interval
What is an interval cancer?

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

<table>
<thead>
<tr>
<th></th>
<th>0-24 months</th>
<th>25-36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of invasive cancers per 1000 women screened</td>
<td>1.2</td>
<td>1.4</td>
</tr>
</tbody>
</table>
Classification

- Identify
- Confirm
- Retrieve imaging, etc

Interval cancer review

- False negative assessment
- Formal audit of assessment

No imaging - unclassifiable

1. Normal/benign
2. Uncertain
3. Suspicious

QA Guidelines for Breast Cancer Screening Radiology
NHSBSP Pub 59, 2011

- Audit all interval cancers and offer results to women
- Ascertain what information individuals want
- Minimise distress for professionals
- Advice on when and how to communicate
• Current interval cancer process
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Communication and candour

Duty of Candour:

CQC regulation 20 published April 2015 in response to Francis report

- Must act in open and transparent way
- Must tell users as soon as practicable about notifiable safety incidents and investigation
- Must apologise

- Evidence that open communication reduces risk of litigation
Problem

• Many trusts do not understand that interval cancers are inevitable in screening and are applying DOC to all intervals

• Published 5 10 2016
Guidance on applying Duty of Candour and disclosing audit results

- Joint work between PHE, CQC and screening representatives: all screening programmes covered
- Advises trusts on applying DOC when an individual is found to have a condition after a normal screen (e.g., breast interval cancers).
- Explains that screening tests not 100% accurate so will have false negatives and false positives: should not automatically trigger DOC
Possible harm related to screening such as abnormal diagnosis after normal screening result (false negative), complication of screening test or false positive diagnosis

Audit of screening test

Something has gone wrong

Possible harm not unexpected, screening operating within expected parameters

Audit:

Was guidance followed (eg for assessment)?

Is the program operating to national standards?

Did an individual(s) make an error that most staff would not make?

DoC

DoA
Interval cancer
pictogram
NHS BSP
• Current interval cancer process
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## Interval classification: update with DOC

<table>
<thead>
<tr>
<th>Category</th>
<th>Radiological</th>
<th>Action warranted</th>
<th>DOA/ DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Normal or benign mammographic features</td>
<td>No reason to recall</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td>2</td>
<td>Seen with hindsight, difficult to perceive, not clearly malignant</td>
<td>May provide learning Not all readers would recall</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td>3</td>
<td>Appearance clearly suggests malignancy</td>
<td>Should have been recalled All reasonable readers would have recalled</td>
<td>Classify as notifiable safety incident under Duty of Candour process</td>
</tr>
</tbody>
</table>
Classification of interval cancers and application of DOC

Interval cancer identified: Retrieve pathology and diagnostic films

Not previously assessed

Radiological review and classification

- Category 1 or 2
- Category 3

Previously assessed

- Review assessment using Form 4

Assessment

- Different site / side
  - Satisfactory assessment
  - Unsatisfactory assessment
- Same site as cancer
  - Disclosure of Audit
  - Duty of Candour

Duty of Candour

Disclosure of Audit
• Current interval cancer process
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Previously assessed cancers

• An important group as may indicate weakness in assessment process
• Burns report recommended audit
• Expected ‘normal’ published rate same site cancers (false negative assessments FNA) 1:200: some cancers will not be detectable despite satisfactory assessment
• London audit same site cancers shows those detected at next screening round 6x as numerous as those presenting as interval cancers *
• Use ‘Form 4 ‘ to review all women presenting with cancer after assessment, through next round screening, short term recall or as intervals

*Louise Willkinson personal communication
## Classification: previously assessed women

<table>
<thead>
<tr>
<th>Category</th>
<th>Assessment process – Guidance followed</th>
<th>Assessment process – Interpretation/poorly performed</th>
<th>Action warranted</th>
<th>DOA/ DOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>Satisfactory – learning possible</td>
<td>Minor deviation from guidance</td>
<td>Some assessors might have interpreted or carried out procedures in a different way that would have resulted in the cancer being detected.</td>
<td>May provide learning</td>
<td>Disclosure of audit</td>
</tr>
<tr>
<td>Unsatisfactory</td>
<td>Clear failure to follow guidance</td>
<td>All reasonable 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>
Classification of previously assessed screen detected cancers and application of DOC

Not previously assessed

Screen detected cancer: no further process necessary

Previously assessed
  – review assessment using Form 4

Assessment different site / side
  - Satisfactory assessment
    - Disclosure of Audit
  - Unsatisfactory assessment
    - Duty of Candour

Assessment same site as cancer = FNA
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Process for disclosing audit / DOC in NHSBSP

Cancer diagnosis
Symptomatic service

Given diagnosis
Screening history checked
Given info re screening review & national BC diagnosis leaflet

Screening unit informed

Patient has had previous screens
Screening and diagnostic unit exchange films

Screening unit review and categorise interval cancer

Screening unit inform diagnostic unit of result

Patient has discussion with screening unit
Post discussion summary shared with patient and treating clinician

Patient accepts result
Discussion with clinician
Offer of further discussion with screening unit
Conversation documented

Treatment

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 she changes mind

Do not initiate discussion prior to review of case by screening unit

Screening unit review and categorise interval cancer

Screening unit inform diagnostic unit of result

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Conclusion

• Interval cancers are an important measure of the quality of screening
• New guidance describes application of Duty of Candour to screening programmes
• Updated classification interval cancers to indicate which trigger DOC is being developed
• Updated classification and review of previously assessed women with subsequent screened detected or interval cancers will allow audit assessment quality (New Form 4)