Best practice diagnostic guidelines for patients presenting with breast symptoms

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Presentation outline

Background and acknowledgements
Purpose of the guidelines
Process
Content
Discussion – throughout!
WHY DO WE NEED MORE GUIDELINES?!

“I’ll be happy to give you innovative thinking. What are the guidelines?”
To improve quality and experience – for patients and staff
Background

- 900 breast cancer diagnoses per week in UK
- hospital breast units under pressure
- expanding commitments
- diagnostic pathways have changed
- screening diagnostic guidelines have been updated
- benefits of making full use of all multidisciplinary team
Purpose

• Cover diagnosis of women referred by their GPs to hospital breast units for the assessment of breast symptoms
• Include all referrals regardless of whether cancer is suspected
• Deal specifically with process of triple assessment, up diagnosis
• Do not extend into management of diagnosed benign or malignant disease
• Primarily aimed at women with new symptoms
• Also apply to previous breast cancer patients with a new concern
• Audience: all health care professionals involved in the management of breast disease in hospitals and the community; patients; those who manage provision, commissioning and funding of services
To be used alongside existing detailed information and guidance:

- Association of Breast Surgery at BASO. *Surgical guidelines for the management of breast cancer*. 2009
- NHS Choices. www.nhs.uk

Process of development

• Multidisciplinary
• DH; CRS; Breakthrough Breast Cancer
• Review by professional groups
I. What are the main difficulties facing breast clinics in 2010?
Some Concerns

• Can you manage the overall quantity of referrals?
• Are you managing the 2 week wait for all?
• Can you sustain the quality of your service?
• How will you deal with screening expansion?
• Do you have digital mammography? – if not, is it planned?
• Do you have extended role practitioners in nursing and radiography? – if not is this planned?
• What will breast diagnostic services look like in 5 years time?
Content

1. Referral
2. Assessment
3. Multidisciplinary meeting
4. Quality Indicators
5. Algorithms
Referral

1. Referral from primary care to breast clinic
2. Lump, lumpiness, change in texture
3. Nipple symptoms
4. Breast pain
5. Axillary lump (in absence of clinical breast abnormality)
6. Communication
Assessment

1. One-stop assessment
2. Breast lump, lumpiness, change in texture
3. Nipple symptoms
4. Breast pain
5. Axillary lump
6. Women with breast implants
7. Breast lumps in men
2. How can new diagnostic guidelines help to address the difficulties facing breast units?
Some key messages

• Role of GPs
• Information, communication and support
• One stop assessment
• Clinical examination
  – by “a suitably trained member of the multidisciplinary team. This may be a nurse practitioner, radiographer, radiologist, breast clinician or surgeon”
• Imaging
  – Suitably trained; Digital; 40; MRI
• Biopsy (mainly image guided)
  – “Needle core biopsy is preferred rather than FNAC”
Breast pain

• “is a common symptom and if of short duration with no other clinical concern may be managed initially in a primary care setting

• When there are associated, or incidental, focal clinical signs in the breast (localised tenderness, nodularity, swelling or a lump) follow the lump imaging protocol (2.3). If infection or abscess is suspected an initial ultrasound scan should be performed and any fluid or pus aspirated and cultured.

• Breast pain alone is not an indication for imaging.”
X-ray mammography

• “is not indicated for the majority of patients aged < 40 years. Mammography should be provided in all women with proven malignancy even if < 40 years.
• X-ray mammography is used in the investigation of women aged = > 40 years with the addition of ultrasound when indicated.
• Mammography should include MLO and CC views of each breast. Digital mammography is preferred to film screen mammography, particularly for women aged < 50 years and those with dense breast tissue.”
Assessment of the axilla

• “Ultrasound of the axilla should be carried out in all patients when malignancy is expected.

• If lymph nodes showing abnormal morphology on ultrasound are found, needle sampling should be carried out under ultrasound guidance.

• Lymph node sampling may be performed using FNAC or needle core biopsy (published studies have shown no significant differences in sensitivity or specificity)”
Discussion of all who undergo triple assessment

• “All patients who undergo needle biopsy during assessment should be discussed.

• Patients in whom there is a discrepancy between the clinical findings and imaging should be discussed in order to decide whether further investigation should be undertaken.”
5. Algorithm A. Assessment: Lump/Lumpiness

Clinical Assessment

P1

Imaging
mammo if = > 40 years
(see text for detail)

< 40 years

Imaging 1
N.B if clinical P4/P5 then clinical review + CB if clinical concern persists

Imaging 2
cyst

Offer aspiration

Imaging 2
solid*

Imaging 3

Imaging 4/5

consider x-ray mammography for patients < 40 years
(see text for detail)

P2/P3/P4/P5
(P1 if persistent concern from patient)

IMAGING
• Ultrasound
• Mammogram (if = > 40 years)
(see text for detail)

Needle biopsy
MDM discussion
Ensure concordance between clinical, imaging and biopsy findings.

B1/B2
if clinical/irrraging concern persists

B3/B4
Non concordance of clinical, imaging, biopsy

Consider
• repeat CB
• VACB
• diagnostic excision

B5 Plan treatment

Discharge

Key:
P1-P5: Clinical examination score.
Imaging1-Imaging5: Imaging score (conclusion following mammogram and ultrasound).
CB: Core biopsy.
B1-B5: Histopathology interpretation.
VACE: Vacuum assisted core biopsy.
Mammo: Mammogram.
Im2 solid* biopsy not necessary for solid lesions with typical ultrasound features of a fibroadenoma < 25 years, fat necrosis, intrammary lymph node, lipoma.
Appendix A: Example of information for patient leaflet

- Why have I been referred to a breast clinic? What should I do now?
- How long will I have to wait for my appointment?
- Do I need to tell the clinic anything before my appointment?
- Do I need to make any special preparations before attending the clinic?
- Can I bring someone with me to the clinic?
Appendix A: Example of information for patient leaflet

- How do I get to the clinic?
- Will I be able to reclaim my travel expenses from attending the clinic?
- When should I arrive at the clinic?
- How long will I be at the clinic?
- Who will I see at the clinic?
- What tests will I need?
- When will I get my results?
- What if I want more information?
Appendix B: Example, pre-clinic patient questionnaire

- Age / occupation / number of children / allergies
- Have you had any serious illnesses in the past?
- Are you taking any drugs regularly?
- Have you had any breast problems in the past?
- Have you noticed any lumps or other changes in your breasts recently?
Appendix B: Example, pre-clinic patient questionnaire

• Is there a history of (breast / ovarian / colon / rectum) cancer in your family?
• Are you currently using the contraceptive pill?
• Are you currently pregnant?
• Have you ever taken Hormone Replacement Therapy?
• Have you had a hysterectomy?
3. How can we test them and measure their impact?
## Quality indicators

<table>
<thead>
<tr>
<th>National requirement:</th>
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</table>
| **Q11** | **Referral/Access**  
All patients with breast symptoms referred to a specialist are seen within two weeks of referral. *(operational standard = 93%)* |

<table>
<thead>
<tr>
<th>Developmental markers of quality:</th>
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</thead>
</table>
| **Q12** | **Delayed Diagnosis Cancers**  
Less than 1% of new symptomatic cancers per annum are diagnosed between 3 and 12 months after triple assessment. *(marker of quality = 99%)* |
| **Q13** | **Cancer Diagnosis**  
All patients with symptomatic invasive cancer receive the diagnosis within 5 working days of initial assessment. *(marker of quality = TBA)* |
| **Q14** | **Physical Examination**  
All patients should have a physical examination and the level of suspicion for malignancy should be recorded using the P1-5 scale. *(marker of quality = 95%)* |
| **Q15** | **Ultrasound**  
X-ray mammography is not indicated for the majority of patients aged less than 40 and ultrasound imaging is the method of choice. *(marker of quality = TBA)* |
| **Q16** | **Imaging**  
For patients having ultrasound and/or X-ray imaging, the level of suspicion for malignancy should be recorded using the U1-5 and R/M1-5 scales. *(marker of quality = 95%)* |
| **Q17** | **Fine Needle Aspiration Cytology [FNAC]**  
Needle core biopsy is preferred rather than FNAC for lesions suspicious of cancer. *(marker of quality = 95%)* |
| **Q18** | **Needle Biopsy**  
For patients having needle core biopsy and/or fine needle aspiration cytology (FNAC), the level of suspicion for malignancy should be recorded using the C1-5 and B1-5 scales. *(marker of quality = 95%)* |
| **Q19** | **Triple Assessment**  
All patients 'requiring' Triple Assessment (clinical, imaging, and needle biopsy) have this performed at their first visit. *(marker of quality = 95%)* |
| **Q10** | **Imaging Under 40 Years**  
All patients aged <40 years with ultrasound features categorized as U4-U5 should undergo X-ray mammography. *(marker of quality = 95%)* |
## Appendix C. Quality indicators and their measurement

### Developmental markers of quality:

<table>
<thead>
<tr>
<th>No.</th>
<th>Quality Indicator (QI)</th>
<th>Data Source</th>
<th>Comment</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>QI1</td>
<td>Referral/Access</td>
<td>Cancer Waiting Times data</td>
<td>QI1 – Monitored at national level in the Cancer Waiting Times targets as the 2 week wait target 'Time from GP referral' to 'date first seen'. The QI would be monitored by referral type (urgent [U], non urgent [NU]), gender, age and socio-economic status (SES) to look at effect of new 2 week for all policy to see where feedback can be provided to GPs on inappropriate referrals.</td>
<td>1.1</td>
</tr>
<tr>
<td>QI2</td>
<td>Diagnosis Delayed Cancers</td>
<td>CWT, HES/CDS, CR data, NCDS</td>
<td>QI2 - Monitor time from assessment clinic attendance i.e. 'date first seen' to when clinic result is received and physical examination results [P1-P5], x-ray results [X1-X5], needle biopsy results [B1-B5] receipt. CR results for neck, chest and abdomen.</td>
<td>2.1</td>
</tr>
<tr>
<td>QI3</td>
<td>C2G history</td>
<td>Cancer Waiting Times data</td>
<td>QI3</td>
<td>2.1</td>
</tr>
<tr>
<td>QI4a</td>
<td>Physical Examination</td>
<td></td>
<td>QI4a - Would also look at physical examination sensitivity i.e. proportion of patients</td>
<td>2.1A</td>
</tr>
<tr>
<td>QI4b</td>
<td>Physical Examination</td>
<td></td>
<td></td>
<td>2.8</td>
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<tbody>
<tr>
<td>1</td>
<td>Date of breast clinical/physical examination</td>
<td>dd/mm/yyyy</td>
<td>Outpatient appointment at assessment clinic</td>
</tr>
<tr>
<td>2</td>
<td>Hospital of breast clinical/physical examination</td>
<td>Org code</td>
<td>Organisation code (code of provider)</td>
</tr>
<tr>
<td>3</td>
<td>Result of breast clinical/physical examination</td>
<td>P1, P2, P3, P4, P5</td>
<td>Normal, Benign, Uncertain, Suspicious, Malignant</td>
</tr>
<tr>
<td>4</td>
<td>Date of ultrasound of the axilla</td>
<td>U1, U2, U3, U4, U5</td>
<td>Normal, Benign, Indeterminate/probably benign, Suspicious of malignancy, Highly suspicious of malignancy</td>
</tr>
<tr>
<td>5</td>
<td>Hospital of ultrasound of the axilla</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Results of ultrasound of the axilla</td>
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**Section: Pathology**

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<tr>
<td>13</td>
<td>Date breast FNAC sample taken</td>
<td>dd/mm/yyyy</td>
<td>Already included in NCDS</td>
</tr>
<tr>
<td>14</td>
<td>Hospital of breast FNAC</td>
<td></td>
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<td>15</td>
<td>Pathologist reporting breast FNAC</td>
<td></td>
<td></td>
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<tr>
<td>16</td>
<td>Results of breast cytology fine needle aspiration cytology (FNAC)</td>
<td>C1, C2, C3, C4, C5</td>
<td>Inadequate/unsatisfactory specimen, No evidence of malignancy, Probably benign, Suspicious of malignancy, Malignant</td>
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<td>17</td>
<td>Date breast core biopsy taken</td>
<td>dd/mm/yyyy</td>
<td>Already included in NCDS</td>
</tr>
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<td>18</td>
<td>Hospital of breast core biopsy</td>
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<tr>
<td>19</td>
<td>Pathologist reporting breast core biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Results of breast core biopsy</td>
<td>B1, B2, B3, B4, B5, B5a, B5b</td>
<td>Unsatisfactory / normal tissue, Benign, Uncertain malignant potential, Suspicious, Malignant, In situ, Invasive</td>
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**Section: Diagnosis and imaging**

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Discussion