HTA Mammography Surveillance

Diagnostic Accuracy (review 2) data extraction form

Version 4 **May 2009**

Study id: **Extractor initials:** **Date:**

Study ids of linked reports:

Aim of study:

Types of participants:

☐ Women without detectable metastatic disease who have received breast conserving surgery for primary breast cancer

☐ Women without detectable metastatic disease who have received mastectomy for primary breast cancer

Test(s):

☐ Mammography
☐ GP follow up
☐ Self examination
☐ Self presentation (of symptoms)
☐ MRI
☐ Ultrasound
☐ Hospital clinician led examination
☐ Hospital nurse led examination

Outcomes reported:

☐ IBTR
☐ Test performance
☐ ***Adverse effects***
☐ Radiological or other operator expertise
☐ Interpretability/readability of tests
☐ Acceptability of tests

☐ MCBC
☐ Test performance
☐ ***Adverse effects***
☐ Radiological or other operator expertise
☐ Interpretability/readability of tests
☐ Acceptability of tests

Study design:

☐ ***RCT***
☐ Non-randomised comparative study with some participants receiving the index test, some receiving the comparator test and all receiving the reference standard
☐ ***Direct head-to-head with all participants receiving index test, comparator test and reference standard***
☐ ***Cohort with all participants receiving either the index test or comparator and reference standard***

Multicentre study? ☐ ***No*** ☐ ***Yes*** ***If yes, number of centres:*** Study start/end dates: Duration of study: Country: Source of funding: Additional information on study design:			
Inclusion criteria:			
Exclusion criteria:			
Characteristics of the participants			
	Group 1	***Group 2***	***All***
Enrolled			
[For RCTs – number randomised]			
Received tests			
Received reference standard			
[Post randomisation exclusions]			

Analysed			
Lost to follow-up			
No Age: Mean ***Median*** ***SD*** ***Range*** No. <50 No. 50 and over			
Menopausal status: No. premenopausal No. postmenopausal			
HRT Status: No. currently receiving HRT No. previously received HRT No. never received HRT			
Primary Treatment:			
No. received primary breast conserving surgery (WLE)			
No. received primary mastectomy			
No. reconstructed breast			
No. receiving treatment for primary breast cancer:			

Neoadjuvant radiotherapy Neoadjuvant chemotherapy Adjuvant radiotherapy Adjuvant chemotherapy Adjuvant tamoxifen /Endocrine Oopherectomy or ovarian ablation			
Additional patient information:			
Characteristics of the tests			
Index Test - Mammography Film ☐ Digital ☐			

Scoring system and positive test result defined as:

Details of interpreter/reader experience if reported:

Additional information on test (e.g. radiation dose, time taken, etc):

Comparator test:

- ☐ MRI
- ☐ Ultrasound

For the following comparators, a positive test result (e.g. lump identified by palpation) will initiate an imaging test prior to biopsy or Fine Needle Aspiration Cytology (FNAC). Please indicate whether a mammogram or other imaging test was conducted prior to biopsy/ FNAC for people with positive test results. Reported test performance (sensitivity/specificity) should reflect the comparator test and not the imaging test alone.

	Mammo/Other prior to biopsy/FNAC
☐ GP follow up	☐
☐ Self Examination	☐
☐ Self presentation (of symptoms)	☐
☐ Hospital Clinician led examination	☐
☐ Hospital Nurse led examination	☐

Positive test result defined as:

Details of operator experience if reported:

Additional information on comparator test:

Reference standard:

Positive Index/Comparator test results verified by:

- ☐ Histopathological assessment of biopsied tissue
- ☐ Fine Needle Aspiration Cytology

Negative Index/Comparator test results verified by:

- ☐ Subsequent testing within a 3 year follow up period

Length of follow-up time for verifying negative index/comparator test results:

How was tumour size determined?

How was tumour grade determined?

Additional information on reference standard:

Results

IBTR/MCBC Tumour Type

Please record the number of women with IBTR and/or MCBC

No of women with:	**No of women with:**
IBTR	MCBC

Please record the associated the number of women with the following for IBTR and/or MCBC:

IBTR – No of women with:	**MCBC – No of women with:**
DCIS	DCIS
LCIS	LCIS
Invasive	Invasive
Grade 1	Grade 1

Grade 2	Grade 2
Grade 3	Grade 3

If reported, please record the number of women with the following:

IBTR	MCBC
<u>Size</u>	<u>Size</u>
Not measurable	
Invasive tumor in mm (largest dimension of dominant invasive tumour focus)	
Whole size of tumor (invasive plus surrounding DCIS if DCIS extends > 1 mm beyond invasive)	
<u>Morphologic type</u> a. Ductal/no specific (ductal NST)	

b. Lobular

c. Other

Test performance ***(true and false positives and negatives)***   Record data for each level of analysis e.g. patient, all biopsies, e.g. Size, grade, DCIS, Invasive, etc on separate sheet(s) containing 2x2 tables
General information on IBTR/MCBC:
Adverse events associated with tests
General information on adverse events:

Adverse events reported	***Group 1*** ***no. of women with event and % of total women in group***	***Group 2*** no. of women with event and % of total women in group	***All*** no. of women with event and % of total women in study

Inter-observer agreement			
Scale used e.g. Kappa			*Notes*
Additional study information: