REPORTING, RECORDING AND AUDITING B5 CORE BIOPSIES WITH NORMAL/BENIGN SURGERY

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BACKGROUND

1. With the use of larger core biopsies at assessment, there are an increasing number of cases where the whole lesion may be removed and subsequent histology from open surgical biopsy shows no evidence of cancer. This creates issues about patient support and also data recording. This document sets out guidance for these cases and covers the following aspects:

    - multidisciplinary review
    - patient handling and support
    - data recording and entry
    - audit

MULTIDISCIPLINARY REVIEW

2. All women who undergo needle tests should have their results reviewed by a breast screening multidisciplinary team (MDT) and management should be agreed in advance of any treatment.[1] Cases in which there is a B5 core biopsy followed by benign/normal surgical histology should be subject to review of the pathology specimens followed by review by the MDT **either** to confirm that the lesion was removed at initial biopsy and that the area of the breast corresponding to where the initial biopsy was taken is within the surgical specimen and that adequate surgical local excision is complete according to local protocol, **or**, where there is doubt about this, to agree on what the next steps should be prior to further review.

3. If the MDT fails to reach a conclusion, then further expert opinion should be sought as to whether the abnormality still remains. If there is doubt about the origin of either specimen, for example should there be legitimate concern about transposition or contamination of specimens, DNA testing to match the biopsy to the surgical specimen may be needed as a last resort. Where DNA testing is considered appropriate, patient consent must be sought and a sample of the patient's DNA obtained for comparison.

4. A C5 cytology result may also be followed by normal pathology at surgery. These cases should be managed in a manner consistent with that described for core biopsies.

5. The outcome of the pathology review and MDT discussion should be recorded on the multidisciplinary record of the National Breast Screening System (NBSS Release 8.1). Changes required to the NBSS record of the results should be noted and flagged as these could affect routine statistics.

6. Any proven error must also be recorded according to the trust and pathology department's error reporting and governance systems. A supplementary report should be issued by the reporting pathologist explaining the outcome so that the result becomes part of the pathology data at a given laboratory.

7. The outcome could be one of the following:

    - true removal at core biopsy
    - invasive component removed at core with DCIS only found at surgical excision
    - true positive at core biopsy – not removed at surgical excision
    - false positive core biopsy.

Appendix 1 shows data entry scenarios for the above cases.

7.1 True removal at core biopsy

True removal at core biopsy will be either B5a (counted in columns 12, 18, 25 and 27 of KC62 in the non-invasive/possibly microinvasive) or B5b (counted in columns 12, 18, 25, 34 (size not known) and 35 of KC62). It is anticipated that, following future approval by the Review of Central Returns (ROCR) process, the KC62 invasive size will be taken from the additional data held on the NBSS core biopsy (WBN) form or, if this is not present, from the mammography or ultrasound record, depending on the largest size. The size of the lesion measured from the core biopsy histological specimens can also be compared with the radiological size. True removal at core biopsy can be confirmed by checking the specimen to ensure that the biopsy site has been removed. If the pathology features of each specimen match as expected, and particularly if the core biopsy sample site and related track can be seen, then this would confirm removal. If they do not match, or if there is doubt, then a check should be made that the correct portion of the breast has been removed. Identification of the position of the core biopsy sample site is also important to confirm complete surgical excision with adequate surgical margins of the lesion. DNA testing may be necessary to ascertain whether the pathology sample and the excised tissue are from the same patient.

7.2 Invasive component removed at core with DCIS only found at surgical excision

If, at the pathology and subsequent MDT review, it is confirmed that the invasive component of a lesion was removed at core biopsy leaving only dutal carcinoma in situ (DCIS), then these women will be counted in columns 12, 18, 25, 34 (size not known) and 35 of KC62. The invasive cancer found at core biopsy is still counted in the number of invasive cancers detected but without an associated size. These data are entered onto NBSS according to the pathology form. Additional details can be recorded in the comments/additional information field. It is anticipated that following future approval by ROCR the KC62 invasive size will be taken from the additional data held on the NBSS core biopsy (WBN) form or, if this is not present, from the mammography or ultrasound record, depending on the largest size present.

7.3 True positive at core biopsy – not removed at surgical excision

The woman would follow the same procedure as a failed excision. If further surgery is undertaken which is then a true representation of the abnormality then these women will be counted in one of the columns 12, 18, 25, 29–35 of KC62. A biopsy and treatment form recording both sets of surgery will be recorded on NBSS. It is anticipated that following future approval by ROCR the KC62 invasive size will be taken from the additional data held on the NBSS core biopsy (WBN) form or, if this is not present, from the mammography or ultrasound record, depending on the largest size present.

7.4 False positive core biopsy

These rare events should be thoroughly investigated and audited (see paragraphs 11–13). All such women would be returned to three year recall and counted in either column 22 or 23 of KC62. An addendum to the original result record would need to be made. Any statistical reports should use the updated record.

PATIENT HANDLING AND SUPPORT

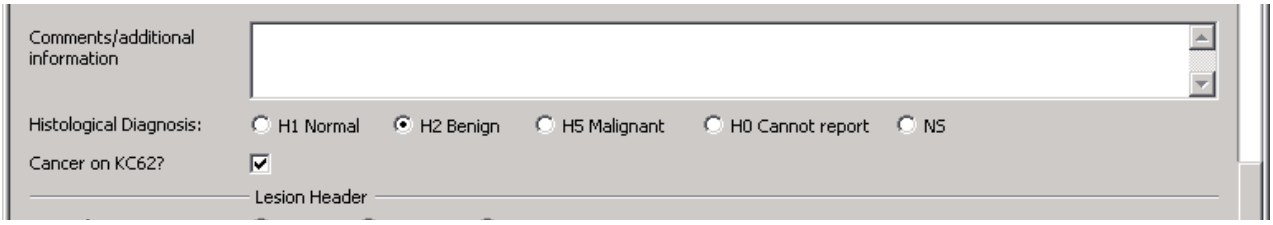
8. The NHS Cancer Screening Programme' advice on disclosure of audit results in cancer screening[2] may be helpful in devising local protocols. Access to a clinical nurse specialist in breast care is helpful to ensure

that these women are fully informed and supported throughout the process. Local protocols for patient management should be developed in parallel with each step in the review process. Care should be taken in ensuring that the waiting times standards for results are still adhered to.

DATA RECORDING AND ENTRY

9. Where pathological size is not available, the size of the invasive lesion could be based on the largest diameter measured on any imaging modality (ultrasound or mammogram). Where the size of tumour is taken from imaging, the grade and type of cancer could be taken from the WBN specimen. Rarely, size data may be obtained from the core biopsy sample. Use of the imaging data to determine the pathological size must be confirmed at the multidisciplinary team meeting by the pathologist and radiologist. This decision must be recorded in the multidisciplinary team meeting minutes. In the future, these data may be acquired from the appropriate NBSS records during the KC62 processing.

10. Where a B5 (a or b) core biopsy is subsequently followed by normal/benign surgery, the core biopsy is entered as usual and a biopsy and treatment form generated. When the histopathology results from the surgery are entered, a 'cancer on KC62' box is checked. This ensures that the correct data are recorded on the KC62. Any additional information can be recorded in the comments/additional information box of NBSS.



For cases in paragraphs 7.2, 7.3 and 7.4, details are entered onto the NBSS computer system in accordance with the usual procedures for positive and negative results.

AUDIT

11. Quality assurance reference centres (QARCs) should undertake an annual audit of all cases of B5 biopsies with benign/normal surgery in their region. These should also be reviewed at each programme's three yearly quality assurance (QA) visit. An audit protocol is shown at Appendix 2.

12. It may be helpful to consider checking that the cores are similar to those x-rayed or the number of cores present is appropriate to the numbers recorded as taken and present in the blocks. All the laboratory procedures need to be checked to ensure that there has been no transposition of cores from different patients.

13. Reporting non-operative false positive incidents to the trust is part of clinical governance. Local trust procedures must be followed to log and record these rare events as a 'clinical incident' and each breast screening service should have a procedure in place providing clear details of how to handle these cases.

Details of each case, its subsequent discussion at the MDT and resulting action plan should also be documented and reported to the quality assurance reference centre. Documentary evidence of reporting and action plans should be copied to the QA team.

REFERENCES

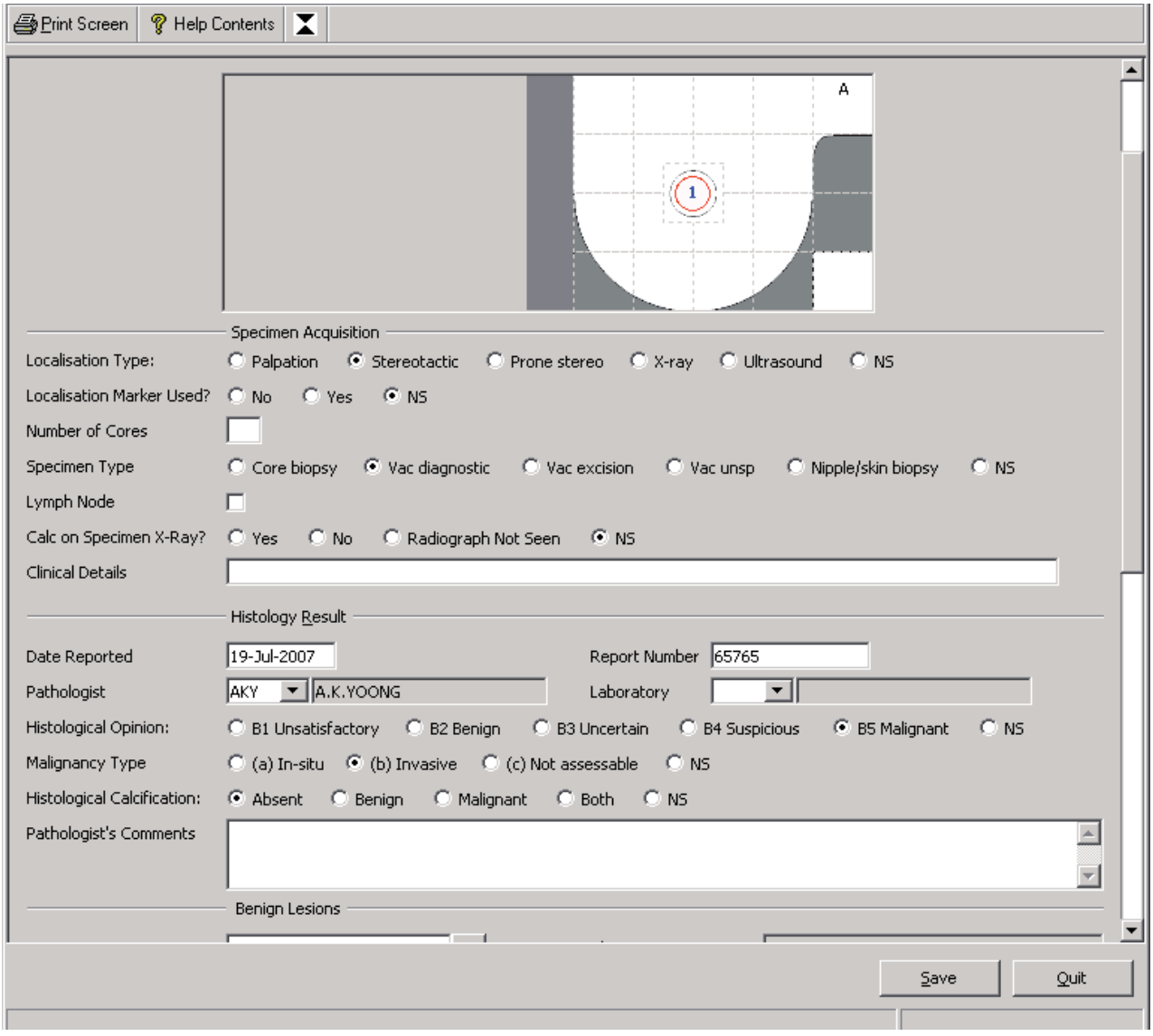
1. Wilson R, Liston J (eds). *Clinical Guidelines for Breast Cancer Screening and Assessment*, 2nd edn. Sheffield: NHS Cancer Screening Programmes, 2005 (NHSBSP Publication No 49).
2. Patnick J (ed). *Disclosure of Audit Results in Cancer Screening: Advice on Best Practice.* Sheffield: NHS Cancer Screening Programmes, 2006 (Cancer Screening Series No 3).

APPENDIX 1

Data entry scenarios

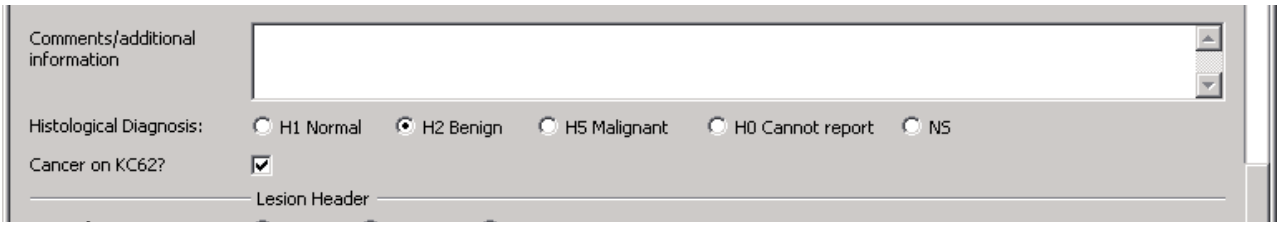
True removal at core biopsy

The core biopsy form is completed as usual:



The above example shows a diagnosis of B5b but equally this could be a B5a or c, or a FNA record with a C5 diagnosis.

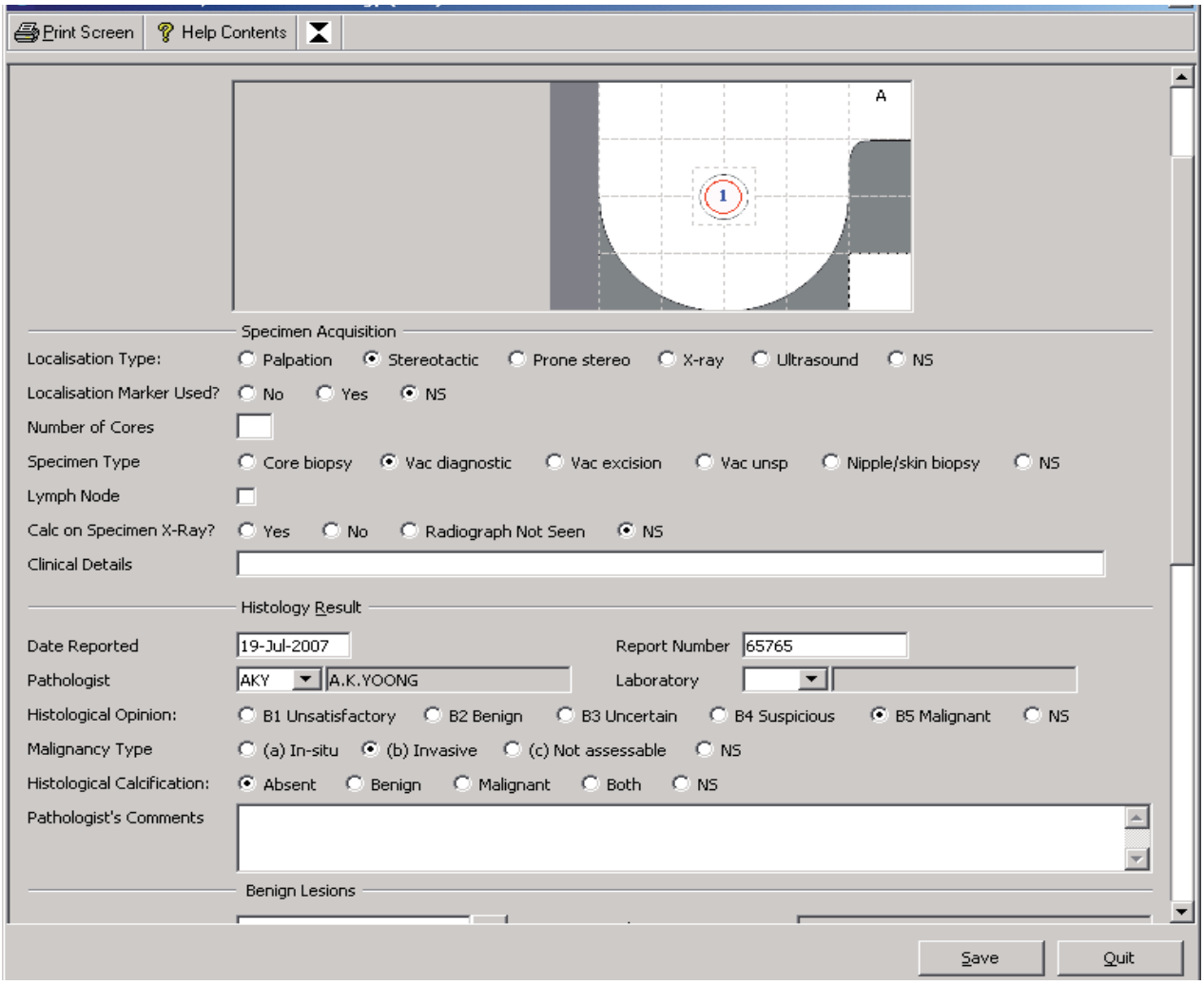
After the surgical procedure has been carried out the outcome is recorded on the NBSS biopsy and treatment form as a diagnosis of **H2 (histology benign)**, but the 'Cancer on KC62' box must be checked to enable correct recording of a cancer on the KC62:



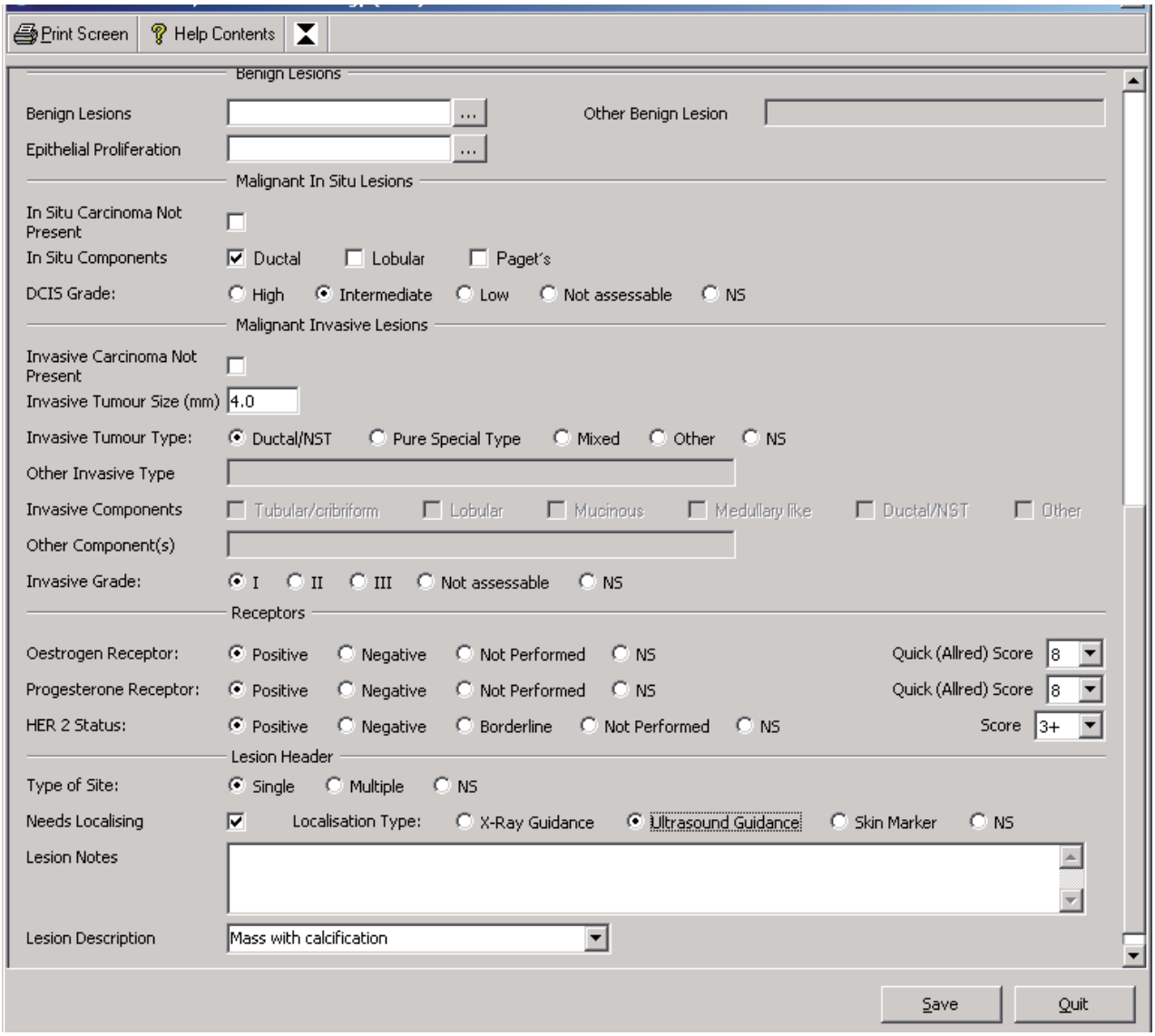
If the above box is not checked, then KC62 processing assumes the B5 core biopsy is a false positive and the woman is not recorded as a cancer on the KC62.

Invasive component removed at core with DCIS only found at surgical excision

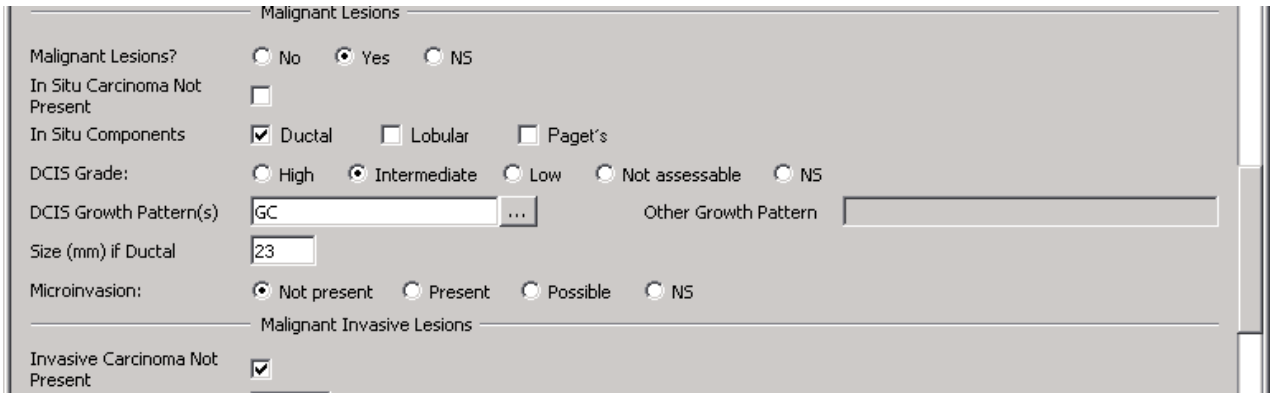
The core biopsy form is completed as usual showing the B5b diagnosis.



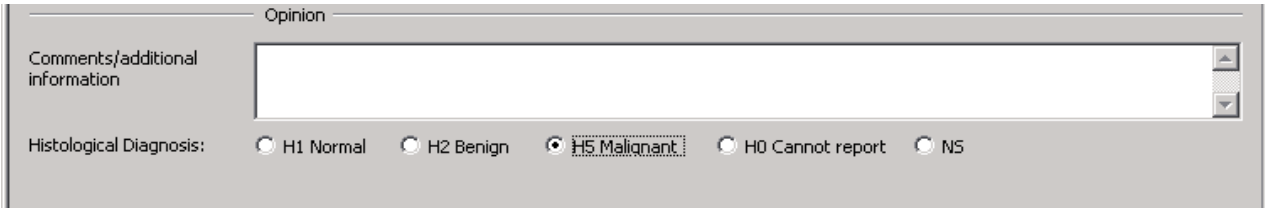
Additional optional data from the core pathology report can be recorded on the NBSS WBN record:



After the surgical procedure has been carried out the outcome is recorded on the NBSS biopsy and treatment form as a diagnosis of **H5** with the appropriate non-invasive pathology details completed.



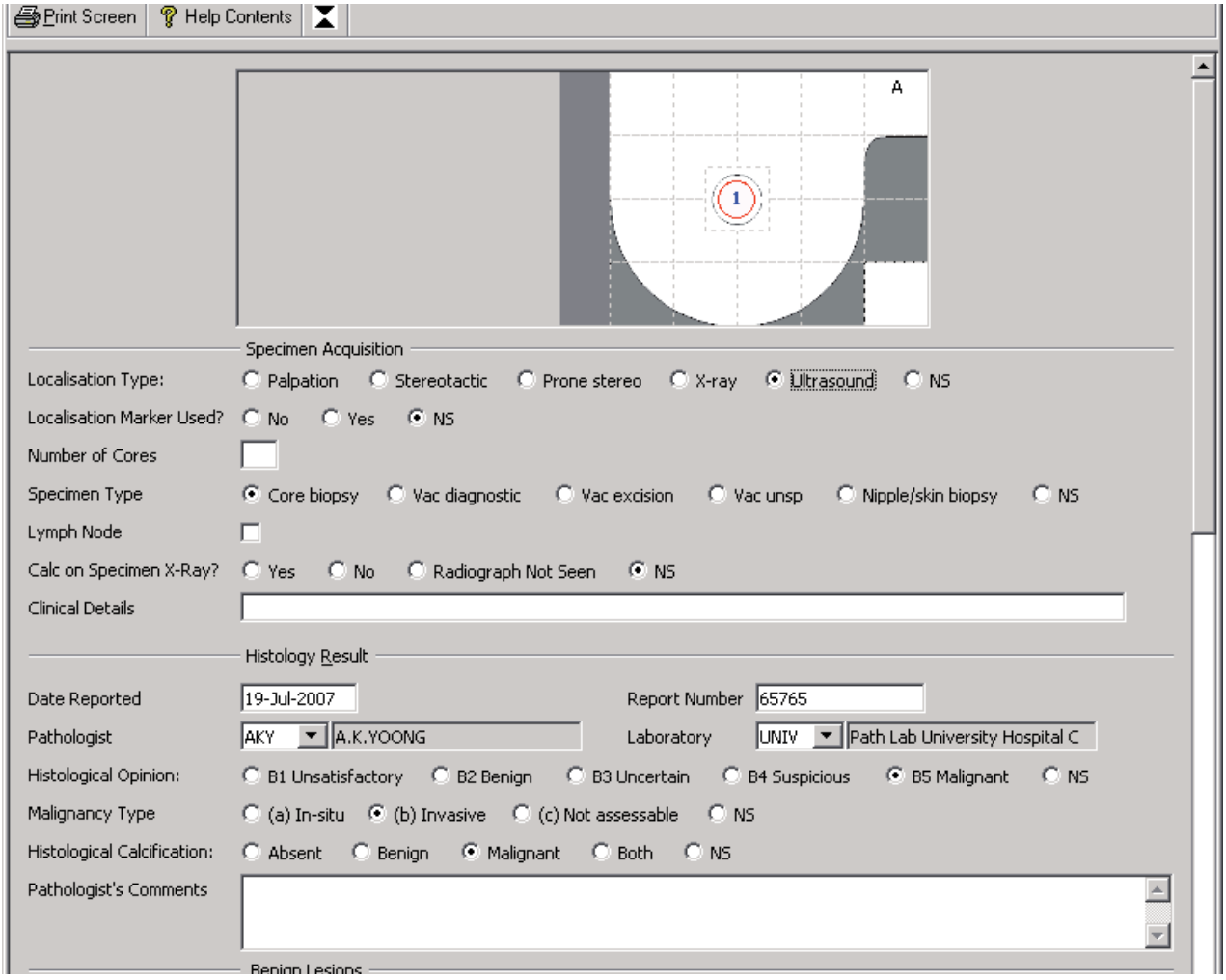
The diagnosis of H5 is recorded as usual as shown below:

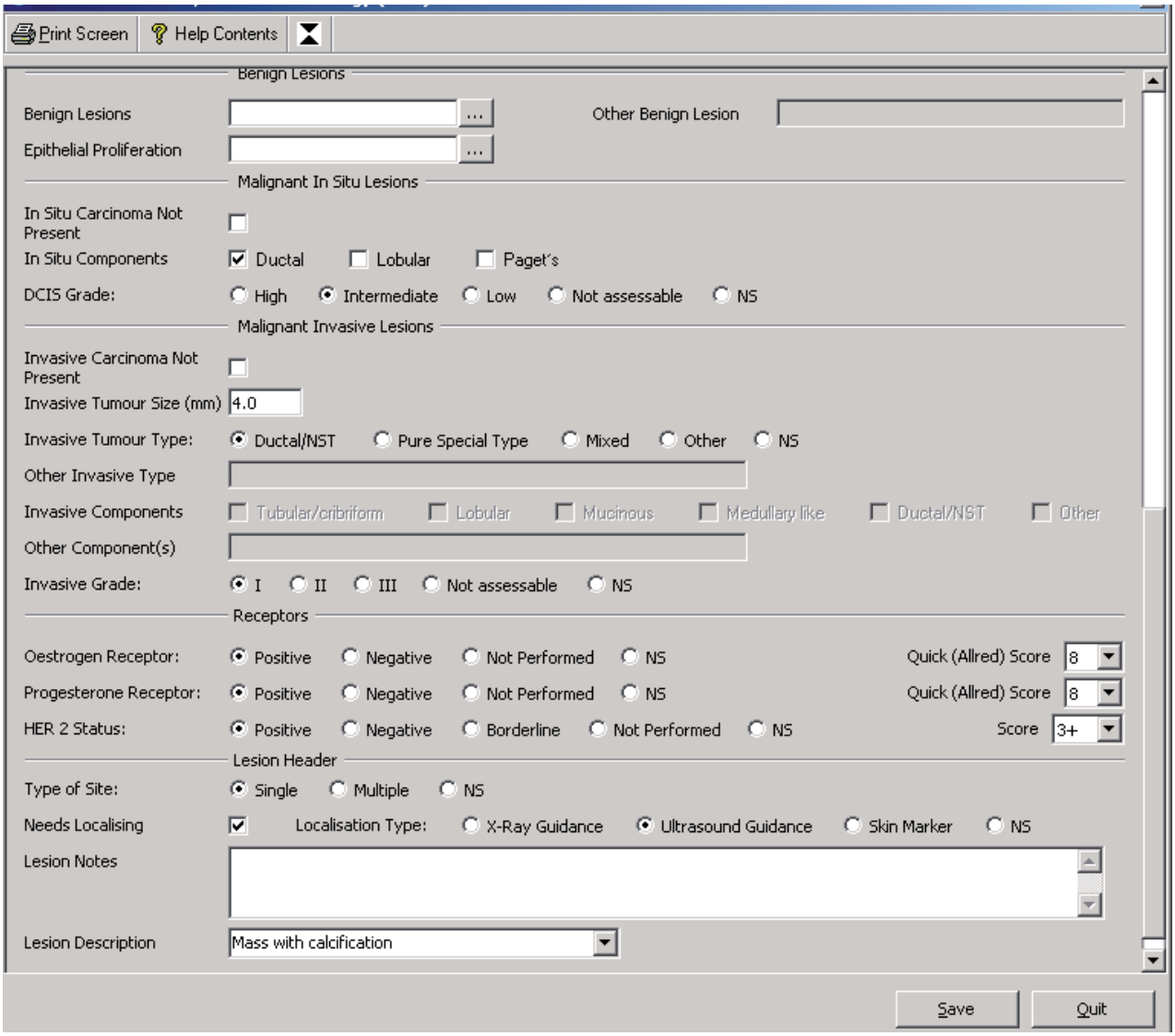


The woman will be recorded as an invasive cancer on the KC62 (columns 12, 18, 25 and 34 (size not known). See paragraph 7.2 of the report. KC62 processing may be changed in future to include the core biopsy pathology and/or imaging size automatically in these cases.

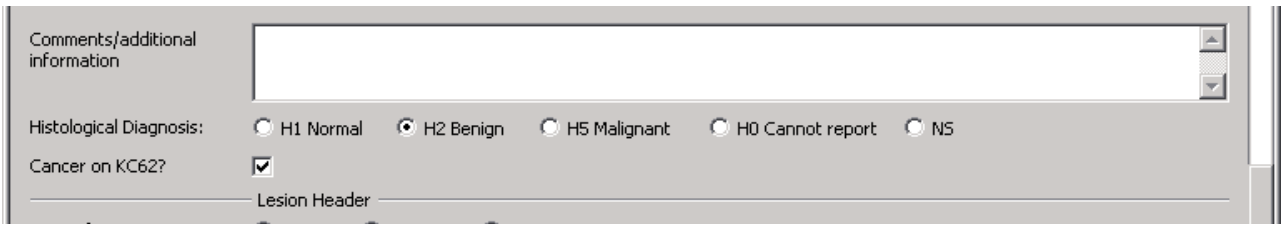
True positive at core biopsy – not removed at surgical excision

The core biopsy report is recorded as usual.





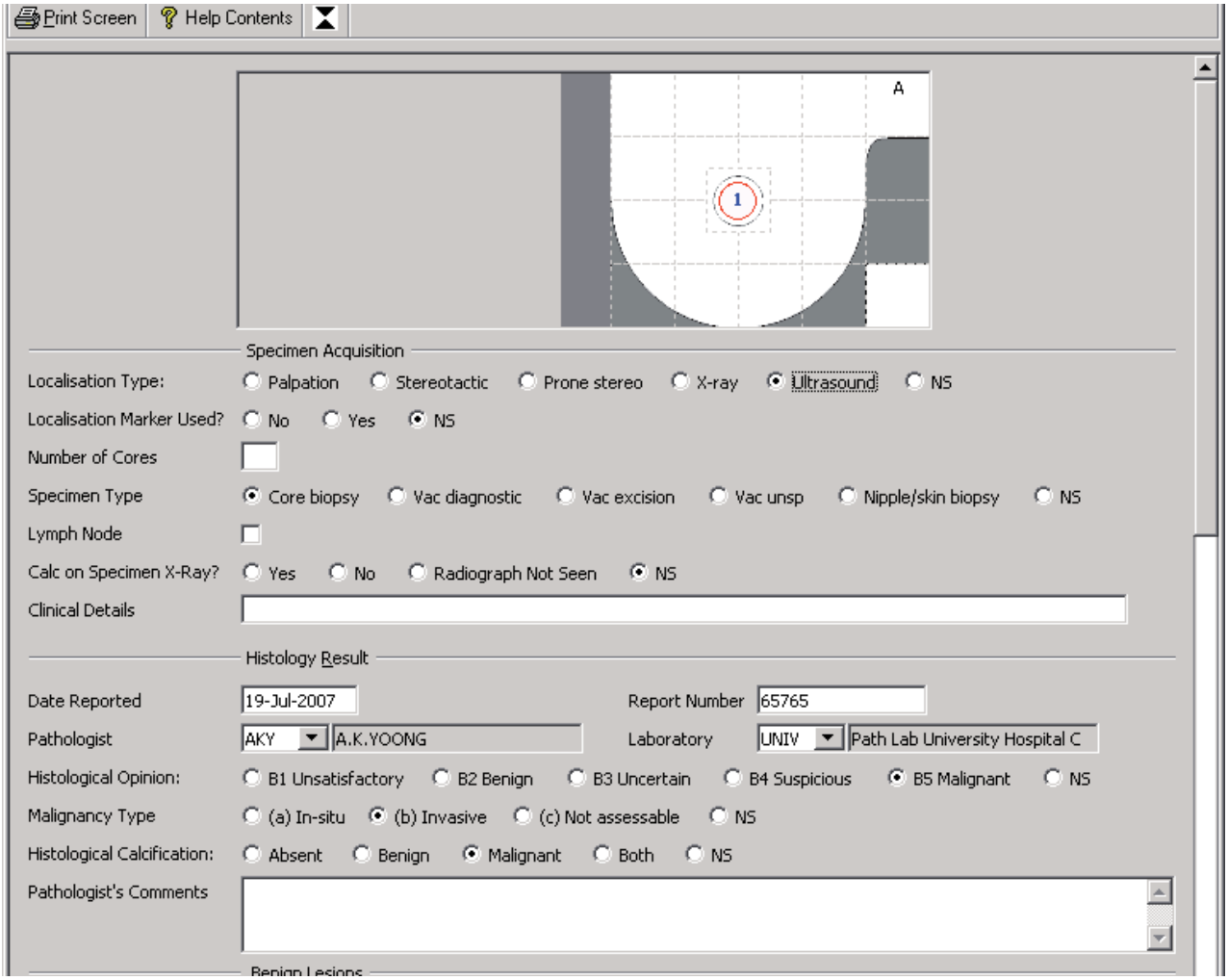
However at surgical excision no malignancy is found. After confirmation, the cancer on KC62 box can be checked as shown below:



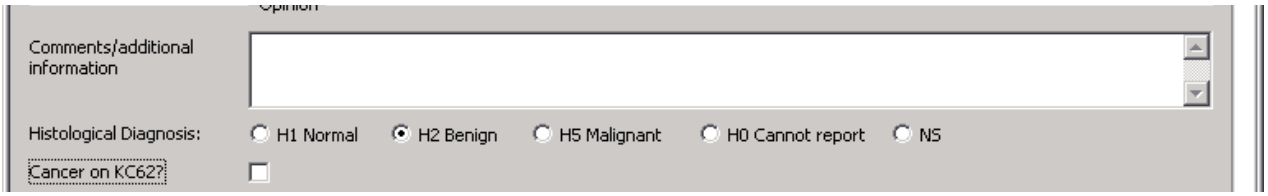
The woman will be recorded on the KC62 in columns 12, 18, 25 and 27–35, depending on whether the core biopsy result was a B5a or B5b. Any subsequent surgery where malignant pathology is reported should be entered onto an **additional** NBSS biopsy and treatment record.

False positive core biopsy

The core biopsy report is recorded on the NBSS system as reported.



However it is important when recording the surgical pathology on the biopsy and treatment form that the 'Cancer on KC62' box is **not checked**. This will ensure that the woman is recorded in column 22 or 23 of the KC62 and **not** recorded as a cancer.



APPENDIX 2

Audit of B5 core biopsy with normal/benign surgery

Background

A B5 core biopsy could be followed by a benign or normal surgical outcome in the following circumstances:

1 all the cancer was removed by the core biopsy
2 false positive core biopsy
3 failed excision initially; lesion removed at subsequent attempt.

For the purposes of this guidance, only the first two circumstances are considered. The third circumstance should also be audited separately against the NHSBSP minimum standard regarding the number of operations (90% of women with single lesion should be treated by one operation).

Aim

To investigate all cases where a positive core biopsy is followed by a normal or benign final surgical outcome.

Frequency

This audit must be undertaken on an annual basis by the QARC. The audit should be undertaken after the KC62 and BASO audits as all data queries should, at this point, have been resolved. The outcome of the audit should be sent to the national office by 31 March each year and submitted to a national review of these data co-ordinated by the NHSBSP QA Coordinating Group for Surgeons in Breast Cancer Screening.

Method

1 A Crystal report (to be developed) should be run and all relevant cases identified (it may be possible to collect other data items through this mechanism though this will delay the undertaking of this audit).
2 If not already done, all cases should be reviewed by the multidisciplinary team and the relevant record on NBSS updated (once available).
3 The data items shown on the Excel spreadsheet should be collected and returned to the QARC for analysis. Guidance on the acceptable answers within the audit is given in the audit spreadsheet. Where the *other* classification for surgical pathology is chosen, details on the exact pathological outcome should be given in the *Comments* column. A copy of the Excel spreadsheet is available on the NHS Cancer Screening Programmes' website www.cancerscreening.nhs.uk
4 If a process other than those listed has been employed to ascertain if there has been a mix up in specimens, this information should be included in the *Comments* column.
5 The option '*other*' under MDM classification should be used for cases which remain under surveillance or where a definitive consensus classification cannot be reached. Details of this should be included in the *Comments* column.

6 Data should be reported on a regional level to the national office.
7 A copy of the completed spreadsheet with all identifiers removed and replaced by a breast screening service anonymous reference code (will identify where one breast screening unit had more than one case) should be sent to the NHSBSP National Surgical Group for review and analysis of the data.
8 The audit loop should be closed through the publication of a report which will be circulated to the breast screening services.

Audit of B5 Results with Normal/Benign Surgery 200X - 200X									
SX No	Screening Round	Radiological Appearance	Radiological Opinion	Clinical Opinion	Ultrasound opinion	No of Attempts	1st Non op procedure	Date of first non op procedure	

table continued on next page

Guidance used	WBN/FNA result	2nd Non op procedure	Date of 2nd non op procedure	Guidance used	WBN/FNA result	3rd Non op procedure	Date of 3rd non op procedure	Guidance used	WBN/FNA result	No of Operations	Operation types

Weight of specimen (gm's)	Number of nodes removed	Details of Final Surgical Pathological Diagnosis	Was a mix up of specimens considered?	Process for investigating if there was a mix up of specimens?	Was the case sent for external review by another laboratory	Date of MDM to review case	Date women told final MDM decision	MDM classification	Comments

Key		
Screening Round	Prevalent Screen	P
	Incident Screen	I
Radiological Appearance	Asymmetric Density	ASD
	Radial Scar/Stromal Distortion	STD
	Spiculated Mass	SPM
	Ill-defined Mass	IDM
	Well defined mass	WDM
	Calcification	MCN
Mammographic Opinion	Normal	R1
	Benign	R2
	Uncertain	R3
	Suspicious	R4
	Malignant	R5
Clinical Opinion	Normal	P1
	Benign	P2
	Uncertain	P3
	Suspicious	P4
	Malignant	P5
Ultrasound Opinion	Normal	U1
	Benign	U2
	Uncertain	U3
	Suspicious	U4
	Malignant	U5
Non op procedure	Core biopsy	WBN
	Cytology	FNAC
	Vacuum assisted biopsy	VAB
	VAB & prone table	PT-VAB
Guidance used	x-ray	XR
	digital stereo	DS
	analogue stereo	AS
	Ultrasound	US
	None (palpation)	P
Operation Type	Excision biopsy	EXB
	Breast conserving surgery	WLE
	Breast conserving surgery & axillary node procedure	WLE AND
	Mastectomy	Mx
	Mastectomy & axillary node procedure	MX AND
No. of nodes removed	None	0
	Give actual number	

Details of final surgical pathology	microglandular adenosis	MGA
	radial scar / complex sclerosing lesion	RS
	papillomas	PAP
	epithelial hyperplasia / columnar cell change	EPH
	pseudoangiomatous stromal hyperplasia	PASH
	granular cell tumour	GCT
	benign phylodes tumour	BPT
	fibromatosis	FM
	nodular fasciitis	NF
	Other	O
Was a mix up of specimens considered?	Yes	Y
	No	N
	Unknown	UK
Process for investigating if there was a mix up of specimens?	Correlation of no of cores taken with no examined by pathologist	CNC
	Comparing tissue in parafin block with specimen x-ray	PBSXR
	Comparing the general appearance of tissue in core with the excision	GATCE
	DNA testing	DNA
	Other (please specify)	O
Case sent for external review	Yes	Y
	No	N
	Unknown	UK
MDM Classification	True removal (1.1)	R
	Invasive component removed at core DCIS only on surgury(1.2)	IR
	False positive core biopsy(1.4)	FP
	True positive at core biopsy(1.3)	TP
	Other	O
Comments		
	Can use this column to describe why there were delays in the process	