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Quality Assurance in Breast Cancer Screening Cytology: A Review of the Literature and a Report on the U.K. National Cytology Scheme

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The National Breast Screening Programme in the United Kingdom has had an external quality assessment (EQA) scheme for breast screening histopathology since 1990. Recently, it was decided, by the Cytology sub-group of the National Co-ordinating Committee for Breast Screening Pathology, to institute two forms of cytology quality assurance. An EQA scheme is planned with circulation of slides to pathologists, but this involves extra time and effort from the participants at a time when general pathology workloads are high. Because of this, a computer routine has been written to analyse the data already present within the National Breast Screening Computer Systems, to enable the calculation of sensitivity and specificity of fine needle aspiration, correlating the cytology results with subsequent histology or follow-up mammography for lesions where no biopsy is performed. This routine uses standardised terminology and calculations and, therefore, inter-unit comparisons can be made. Where problems are identified within a unit, the Quality Assurance team can investigate the cause and institute appropriate measures to correct the problem. This article details the procedures involved in this audit and reviews the literature, recalculating the parameters in a standard manner for a number of publications. The results of the cytology quality assurance routine from seven screening units in one health region in the U.K. are presented and the measures taken to improve the level of service are discussed.

Key words: female breast, fine needle aspiration cytology (FNA), quality assurance, breast screening, breast cancer, audit

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INTRODUCTION

EXTERNAL QUALITY ASSESSMENT (EQA) in cytology is generally performed by the circulation of slides which have a consensus opinion against which the performance of individual pathologists is tested. This is an artificial situation which, depending on the degree of nervousness of the individual pathologist, may be approached either as an examination or as a piece of routine work. In some situations, when workloads are heavy, EQA slide circulations can be seen as an imposition and may justifiably be given a lower priority than the routine workload. Many laboratories, however, perceive the benefits of participating in EQA schemes as an essential protection for the laboratory and a necessary step in laboratory accreditation.

In breast screening in the U.K., there has been an EQA scheme running in histological diagnosis since 1991. This slide circulation is anonymous and has been primarily concerned with testing the criteria published in the breast screening booklet *Pathology Reporting in Breast Cancer Screening* [1]. These circulations have been useful to ascertain the degree of consistency of histological diagnosis around the country.

In breast screening cytology practice in the U.K., a similar slide circulation scheme is planned, but there is another, less artificial, method of assessing the accuracy of the test in various units around the country. This involves the calculation of sensitivity and specificity of the test by comparison with the eventual histological diagnosis or, where no histology has been performed, with the subsequent clinical course of the woman. Because of the potential to calculate this automatically from the computer systems used for breast screening, a routine has been written to calculate the parameters of fine needle aspiration which are detailed in the U.K. breast screening document *Guidelines for Cytology* [2]. This method of auditing fine needle aspiration cytology has previously been proposed by Ciatto and colleagues [3] for use in the audit of stereotactic cytopathology in Italy.

One of the problems encountered in the literature relating to sensitivity and specificity of fine needle aspiration is the variable method of calculating the parameters which are used. Many publications do not give the detailed breakdown of the results necessary to allow standard calculations to be performed, making a direct comparison between the different studies difficult. Another problem is the fact that publications are generally written by enthusiasts in the particular field, and units performing badly are unlikely to publish figures, although even some of the published figures when recalculated are not as good as would be expected (see below). Different case mixes in some

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of the studies may be responsible for some, but not all, of the differences.

In a subsequent part of this review, a number of papers, where enough data are present to allow the parameters to be calculated to a reasonable degree of accuracy, have been assessed using the definitions used in the National Breast Screening Programme in the U.K. [2] (UK-NHSBSP). This form of analysis has been done before, to some extent, in previous articles by Vetrani and colleagues [4], Palombini and colleagues [5] and Giard and Hermans [6]. These publications have used various criteria for the parameters calculated.

In addition, some figures are presented from all the screening units in one Health Region in the U.K., using the direct printout of the computer routine now resident in the breast screening computer system. By using standardised statistics, a comparison can easily be made between units, and areas of difficulty in some units can be addressed by education and improvement in techniques.

DATA COLLECTION AND RECORDING

The computer system used by the Breast Screening Service operating in most units in the country is a MUMPS based system, either running on a DEC PDP11 computer or under the UNIX operating system on IBM compatible computers. Women invited for screening are identified through the Family Health Services Register and their details are downloaded from this computerised Register by a direct link to the screening computer. After a list has been checked by the General Practitioner looking after the women, the Breast Screening System makes automatic appointments for eligible women, and the results of screening are entered on to their record. The system contains all the details of assessment, and cytology results are entered on to the system in a standard format using the categories:

C1 - Inadequate
C2 - Benign
C3 - Atypia probably benign
C4 - Suspicious of malignancy
C5 - Malignant.

Histology is also recorded on the system in the format specified in the publication *Pathology Reporting in Breast Cancer Screening* [1]. From these data, the computer can calculate the parameters below for the Cytology Quality Assurance routine (CQA). The figures produced by the CQA statistics package can be used to identify areas where the process would benefit from an initiative to improve the diagnostic performance of the technique. It should, however, be noted that, for statistical analysis to be of maximum use, statistics related to small numbers of cases (less than 200) should be interpreted with caution.

DEFINITIONS

The definitions given below are the definitions used by the U.K. Breast Screening Programme for the assessment of fine needle aspiration [2]. It is intentional that inadequate and suspicious results have been included in the calculations of sensitivity and specificity as the objective is to assess the whole process of performing the test rather than just the effectiveness of the cytological diagnosis. Cytologists wishing to evaluate their statistics purely to see their own accuracy in diagnosis may wish to calculate the figures slightly differently.

The precise definitions used for the calculation of the various parameters are given in the UK-NHSBSP document *Guidelines for Cytology* [2] which is summarised in *Cytopathology* [7].

Absolute sensitivity

This statistic gives the proportion of cancers diagnosed as malignant (C5) by cytology. The recommended minimum value of this parameter is 60%. It will interrelate with the inadequate and suspicious rates, and will give an indication of the number of tumours which can potentially be treated by a one-stage operation.

Complete sensitivity

This is a measure of the number of tumours in which an abnormal cytological appearance has been recognised. It includes all tumours which have been called malignant (C5), suspicious (C4) or atypical (C3), and will correlate with the inadequate and false negative rates. The recommended minimum value is 80%.

Specificity (biopsied cases only)

This is an indirect measure of the degree to which the cytology is being used to determine therapy. The parameter is calculated by the proportion of histologically benign biopsied cases on which the cytology was said to be benign (C2). A high percentage here will mean that the surgical team may not be basing therapeutic decisions on the cytological findings and hence indicates a lack of trust in the technique. No minimum or maximum value for this parameter has been specified. The parameter includes inadequate results, and if there are a large number of these then the figure may still be low where confidence in the technique is low. It should, therefore, be interpreted alongside the inadequate rate.

Specificity (full)

This is the percentage of benign cases (biopsied or reviewed with no evidence of cancer and hence assumed benign) on which a benign cytological diagnosis (C2) has been made. The suggested minimum value is 60%. The figure, unlike many in the literature, includes inadequate results in the analysis and hence figures such as 99% as are seen in some publications will not occur. High, inadequate and/or suspicious rates will reduce this figure.

Positive predictive value of a malignant diagnosis (C5)

This figure is a measure of the cytological accuracy of diagnosis. The suggested minimum value is 95%. This would be a low figure for a symptomatic practice, but the possibility of aspirating an area of atypical hyperplasia or an unusual lesion which would not usually be seen symptomatically means that the figure may be lower in screening series containing a high number of impalpable lesions.

Positive predictive value of a suspicious diagnosis (C4)

This is a measure of the ability of the pathologist to be able to categorise difficult smears into the probably malignant category. There is no target figure for this, but experience so far suggests that approximately 70–80% of the smears called suspicious (C4) turn out to be malignant.

Positive predictive value of an atypical diagnosis (C3)

This is a measure of how often a pathologist identifies malignancy when there are only subtle signs such as occasional atypical cells or heaping up of hyperplastic-appearing epithelium in an otherwise benign appearing slide. There is no target value for this, but current practice suggests a value of approximately 20%. If this figure is low, radiologists may choose to regard a lesion as

worthy of follow-up unless the radiological features are suspicious or malignant. Tubular carcinoma, lobular carcinoma and cribriform *in situ* lesions are the commonest malignancies to fall into this category.

False negative rate

This measures the percentage of cancers either misinterpreted as benign (C2) or not sampled accurately by the technique. It excludes inadequate specimens which are assessed separately below. Current practice in experienced units suggests that the figure can be as low as 4%. This false negative rate, however, means that radiologically malignant or suspicious lesions cannot be ignored. A high value for this parameter would suggest either a high miss rate on aspiration or a tendency of the pathologist to not recognise subtle signs of well-differentiated malignancies such as tubular, lobular or cribriform carcinomas and may lead to a delay in diagnosis. The target value for this parameter is less than 5%.

False positive rate

This is a measure of overdiagnosis and should be less than 1%. All cases should be reviewed carefully to determine where the abnormal cells came from as it is possible that the relevant lesion has not been removed.

Inadequate rate

This is the proportion of specimens where insufficient material (C1) was aspirated to enable a diagnosis to be made. It is a measure of the accuracy of aspiration and, although partially dependent on the characteristics of the lesion aspirated, it is the easiest to rectify by limiting aspiration to experienced operators and by training. A value above 20% in this parameter suggests that action needs to be taken as the efficiency of the technique is not optimal. Experienced aspirators can achieve values of less than 10%, and values as low as 5% have been reported. Some papers treat all inadequate specimens as benign, but this is not recommended in impalpable screening lesions as the reporting pathologist cannot know that a lesion has been accurately sampled.

Inadequate rate from cancers

This is a very important measure and if this is high then measures to improve the aspiration technique should be instituted. There is no target value as yet for this, but experience suggests that values as low as 3% can be achieved by the best units.

Suspicious rate

This is the percentage of results which are felt to be suspicious of malignancy or are atypical (C4 or C3). Although suspicious (C4) results are useful for the team to plan whether it is necessary to operate or not, they are less useful to determine treatment. Results of atypia (C3) are even less useful. They really add little to the management and, unless the positive predictive value of this parameter is high, the team may be justified in an early review of a radiological abnormality rather than biopsy unless the abnormality is sufficiently worrying radiologically to require biopsy in its own right. The recommended maximum value of this parameter is 20%, but it should be realised that if both the suspicious and inadequate rates are high then the effectiveness of the technique will be very limited.

Other reports

The CQA report (Figure 1) can be analysed by aspirator, pathologist, radiological appearance or location, but these are intended for internal unit quality control where a problem has been identified in the general statistics, or research only. Some results from this for one breast screening unit are included below in the tables related to different methods of aspiration. It should be noted that, when the statistics are split into a number of different categories, then the numbers may be too small for accurate statistical evaluation of the process, and in this case the figures must be interpreted with caution.

MINIMUM STANDARDS PROPOSED FOR THE U.K. BREAST SCREENING PROGRAMME

Absolute sensitivity	>60%
Complete sensitivity	>80%
Specificity	>60% (including non-biopsied cases)
Positive predictive value (C5)	>95%
False negative rate	<5%
False positive rate	<1%
Inadequate rate	<25%
Suspicious rate	<20%

INTERPRETATION OF RESULTS

The figures produced by the Cytology QA routine will obviously depend on aspiration techniques and the experience and care of the aspirator [8], and can vary widely between units depending on expertise. It is undeniable that, where pathologists are involved in taking aspirates and controlling the adequacy of aspiration, the figures are much improved [5, 9, 10].

The figures are interrelated and strategy to improve one figure will affect others—thus if an attempt is made to reduce the inadequate rate, this will often increase the number of suspicious reports; attempts to improve the sensitivity are likely to increase the false positive rate; attempts to improve the specificity will increase the false negative rate and so on. In addition, attempts to reduce the benign biopsy rate by not performing a biopsy on the majority of lesions called "benign" on cytology will reduce the biopsy specificity which is based on benign histology results rather than on all aspirated cases. The biopsy specificity can be used as a surrogate measure of how much the unit surgeon trusts the cytology results. The more the cytology results are used to determine treatment, the lower this value should be. A high proportion of impalpable cases aspirated in any series is likely to make the figures worse as there is more chance of missing a small area of microcalcification, leading to a false negative or inadequate result, and more likelihood of aspirating atypical hyperplasia, radial scars and tubular carcinoma, leading to a high level of suspicious or atypical reports. In screening with aspiration of impalpable lesions, the results are likely to reveal lower values than those achieved in the symptomatic setting. It is important to keep the number of atypical (C3) reports as low as possible without compromising the detection of subtle signs of malignancy. Where the positive predictive value of a C3 diagnosis is low then the clinician may be justified in follow-up of a lesion which has a low index of suspicion radiologically to avoid unnecessary benign biopsies. Laboratories do vary in their positive predictive value (PPV) for C3 diagnosis and the value of this parameter for the individual laboratory should be taken into account in making a clinical decision on these cases.

CYTOLOGY QA STANDARD REPORT

TOTAL CASES SCREENED IN PERIOD.....
TOTAL ASSESSED.....
TOTAL FNA PERFORMED.....

	C5 Cytology Malignant	C4 Cytology Suspicious	C3 Cytology Atypia	C2 Cytology Benign	C1 Cytology Inadequate	Total
Histology malignant	BOX 1	BOX 2	BOX 3	BOX 4	BOX 5	BOX 6
Invasive	BOX 7	BOX 8	BOX 9	BOX 10	BOX 11	BOX 12
Non-invasive	BOX 13	BOX 14	BOX 15	BOX 16	BOX 17	BOX 18
Histology Benign	BOX 19	BOX 20	BOX 21	BOX 22	BOX 23	BOX 24
No histology	BOX 25	BOX 26	BOX 27	BOX 28	BOX 29	BOX 30
Total C results	BOX 31	BOX 32	BOX 33	BOX 34	BOX 35	BOX 36

Figure 1. Each box (numbered 1–36) is calculated from the numbers of FNA with a C code (C1, C2 etc.) cross referenced with the worst histology diagnosis. The table and calculations (see below) are produced for all FNA tests (headed All tests) and also for all patients (headed All patients) where, if two FNA records are present for one breast, the highest C number is taken.

The sensitivities and specificities in percentages for each of the categories in the cytology document are then calculated from the above table. (Numbers correspond to box numbers in the above table).

1. **Absolute sensitivity =** $\frac{(\text{Box1} + \text{Box25})}{\text{Box6} + \text{Box25}} \times 100.$

(This assumes that all unbiopsied C5 results are carcinoma and are treated with primary chemotherapy or hormonal therapy.)

2. **Complete sensitivity =** $\frac{\text{Box1} + \text{Box2} + \text{Box3} + \text{Box25}}{\text{Box6} + \text{Box25}} \times 100.$

3. **Specificity (biopsy cases only) =** $\frac{\text{Box22}}{\text{Box24}} \times 100.$

4. **Specificity (full) =** $\frac{(\text{Box22} + \text{Box28})}{\text{Box24} + \text{Box27} + \text{Box28} + \text{Box29}} \times 100.$

(This assumes that all cases of atypia (C3) which are not biopsied are benign.)

5. **Positive predictive value (C5 diagnosis) =** $\frac{\text{Box31} - \text{Box19}}{\text{Box31}} \times 100.$

6. **Positive predictive value (C4 diagnosis) =** $\frac{\text{Box32} - \text{Box26} - \text{Box20}}{\text{Box32} - \text{Box26}} \times 100.$

7. **Positive predictive value (C3 diagnosis) =** $\frac{\text{Box3}}{\text{Box33}} \times 100.$

8. **False negative rate =** $\frac{\text{Box4}}{\text{Box6} + \text{Box25}} \times 100.$

(This EXCLUDES inadequate results.)

9. **False positive rate =** $\frac{\text{Box19}}{\text{Box6} + \text{Box25}} \times 100.$

10. **Inadequate rate =** $\frac{\text{Box35}}{\text{Box36}} \times 100.$

11. **Inadequate rate from cancers =** $\frac{\text{Box5}}{\text{Box6} + \text{Box25}} \times 100.$

12. **Suspicious rate =** $\frac{\text{Box32} + \text{Box33}}{\text{Box36}} \times 100.$

It is recognised that the specificities are approximate and will be more accurate the longer the date range of the analysis is from the date printed. All lesions falling into box 26 (suspicious lesions which have not been biopsied) are flagged for investigation by the unit.

ANALYSIS OF RESULTS IN THE LITERATURE ACCORDING TO THE ABOVE DEFINITIONS

Many units have published figures of sensitivity and specificity of fine needle aspiration of palpable lesions in symptomatic practice, and have clearly shown that there is a difference in both these measures depending on the experience and care of the aspirator [8]. In units where the cytologist takes the aspirates and checks adequacy, sometimes giving an instant diagnosis [9, 10], sensitivity and specificity are better with many fewer inadequate aspirates. Other units have used laboratory scientists to check the adequacy of aspirates. Some units even use ultrasound or mammographically guided aspiration in palpable lesions where there is an inadequate aspirate to ensure that aspiration has been performed from the lesion. Many of the papers in the literature relate to palpable lesions only and may have better results than series relating to screen detected lesions owing to the larger size of the lesions detected and the greater diagnostic problems encountered with screen detected lesions. These problems relate to the difficulties in diagnosis of well differentiated carcinomas, such as tubular and *in situ* cribriform cancer, and the problems in differentiating radial scars from tubular carcinoma on cytology. Data have been re-calculated from results given in the papers and represented as far as possible according to the definitions above.

Symptomatic cases

The figures for a series of symptomatic cases in the literature are presented in Table 1. Series containing fewer than 200 cases have not been included as the statistics are less robust on small numbers of cases.

Data from stereotactic aspiration

The figures from reported series in the literature using stereotaxis are presented in Table 2. Although the figures have been compared with the standards set by the UK-NHSBSP [2], it should be remembered that these standards are for a mixed group of screening patients and that cases requiring stereotaxis are by nature more difficult. Even so, the results compare favourably to some of the symptomatic papers quoted in Table 1.

Data from ultrasound aspiration

The figures from reported series of ultrasound guided aspiration are given in Table 3. In general, this method appears to give the best results of all the published series.

Data from fenestrated plate X-ray guided aspiration

The figures for fenestrated or perforated plate aspiration are given in Table 4. Although the figures published in the literature are poor in terms of inadequate rate, a number of anecdotal series, not yet published, suggest that, in careful hands, this technique can be almost as good as stereotaxis (Manson JC, personal communication; Warren R, personal communication).

RESULTS FROM NORTH THAMES (EAST)

In this analysis, the routine has been run for a specified time period (1991–1993) in each of the seven screening units in North

Table 1. Data from published symptomatic series

No. of cases	AS	CS	SBx	SPE	C5PPV	C4PPV	C3PPV	Fls−	Fls+	INA	INCA	Sus	Ref
240	65	94	36	**60**	100	32	7	**6**	0	0.4	0	**39**	11
257	**41**	88	65	71	100	52	18	3	0	14	9	16	12
219	71	84	89	91	97	85	—	**14**	**2**	7	2	3	13
678	86	92	69	73	98	—	8	5	1	16	3	9	14
321	68	84	51	55	100	40	8	**14**	0	4	1	**34**	15
581	92	96	91	77	99	62	—	2	0.4	11	2	9	4
594	72	87	*	70	100	58	—	**5.3**	0	22	7.9	6.4	16
674	91	96	*	83	100	53	—	3.0	0	2.5	1.4	6.7	5
350	**60**	**74**	*	69	97.4	100	—	**21**	**1.6**	**25.7**	4.8	2.6	17
1283	70	83	*	**57**	99.6	62.4	—	7	0.3	21.3	10	11	8
1731	67	84	*	**42**	100	90.5	—	4.6	0	14	11	17	18
247	72	90	*	86	100	79	—	0.8	0	8.9	9.3	12	19
318	72	85	*	78	99.3	62.5	—	**10**	0.5	6.6	4.7	12.6	20
683	71	83	*	74	100	69.2	—	**7.7**	0	16	9.3	7.6	21
3548	**55**	**79**	*	**56**	98.2	68.8	12.3	**8.2**	**1.0**	**34.0**	13.3	6.4	22
1183	**51**	**65**	*	**57**	98.9	76.3	—	**12.6**	0.6	**31.7**	22	8.2	23
365	77	88	*	66	100	61.5	—	4.2	0	21.4	7.7	7.1	24
3545	65	89	*	88	100	84	50	**9.5**	0	8.8	1.1	4.2	25
2077	77	91	*	80	99.9	69.3	—	**5.2**	0.1	8.0	3.1	11	26
2670	89	91	*	89	99.8	45.3	—	3.7	0.2	5.1	5.2	3.6	27
334	**38**	**70**	*	**58**	**90.5**	41	—	**18**	**4**	**30**	12	11.7	28
239	70	**70**	*	73	96.2	0	—	**6.8**	**2.7**	24.7	23.3	0.4	29
294	83	93	*	77	100	—	25	3.3	0	12.6	3.3	8.2	30
985	86	93	56	67	99.6	80	11	3.1	0.3	20.6	4.1	6.0	31
1002	85	95	84	94	100	80	—	2.6	0	3.5	2.4	5.0	10
1145	**47**	83	54	69	100	76	17	**10.7**	0	12.8	6.0	**20.8**	32
1995	92	96	88	92	99.8	78	—	2.7	0.2	4.1	0.9	3.1	33

AS, absolute sensitivity; CS, complete sensitivity; SBx, biopsy specificity; SPE, specificity; C5PPV, C4PPV, C3PPV, positive predictive value of a C5, C4 and C3 diagnosis, respectively; Fls−, false negative rate; Fls+, false positive rate; INA, inadequate rate; INCA, inadequate rate from cancer bearing breasts; Sus, suspicious rate.* Proportion of biopsied cases not stated. Figures falling outside the NHSBSP standard are in **bold type**.

Table 2. Data from published stereotactic series

No. of cases	AS	CS	SBx	SPE	C5PPV	C4PPV	C3PPV	Fls−	Fls+	INA	INCA	Sus	Ref
567*	**55**	**74**	*	**57**	99.6	79	58	**19.6**	0.2	8.6	6.3	**21**	34
219	75	94	43	**56**	100	73	22	0	0	**26**	6.3	13.2	35
114	**40**	93	*	78	100	88	13	0	0	13	6.7	14	36
100*	**57**	90	*	77	100	100	20	**10**	0	0	0	**26**	37
218	**60**	**77**	63	76	100	72	—	**14.9**	0	16.5	8.1	8.3	38
528	73	95	*	80	**95.4**	45	9.1	3.5	**3.5**	10.2	1.2	9.7	39
250	**42**	**69**	12	**52**	100	61	—	**11.3**	0	**35.2**	19.4	12.3	40
150	70	85	59	73	100	67	—	**11.1**	0	16.0	3.7	8.0	41
187	85	98	*	74	100	42	—	2.5	0	16.6	0	6.4	42
356	65	89	29	63	97.6	81	20	**6.5**	**1.6**	14.6	4.9	19.1	43

AS, absolute sensitivity; CS, complete sensitivity; SBx, biopsy specificity; SPE, specificity; C5PPV, C4PPV, C3PPV, positive predictive value of a C5, C4 and C3 diagnosis, respectively; Fls−, false negative rate; Fls+, false positive rate; INA, inadequate rate; INCA, inadequate rate from cancer bearing breasts; Sus, suspicious rate. * Biopsied cases only. Figures falling outside the NHSBSP standard are in **bold type**.

Table 3. Published series of ultrasound guided aspiration

No. of cases	AS	CS	SBx	SPE	C5PPV	C4PPV	C3PPV	Fls−	Fls+	INA	INCA	Sus	Ref
120	81	97	57	71	100	83	—	3.1	0	21	0	5	41
1301	75	96	64	94	100	56	—	3.6†	0	2.1	0†	7.1	44
110	92	100	*	94	97	100	—	0	**2.6**	2.7	0	2.7	45
190	89	98	36	74	100	75	10	2.5	0	9.5	0	10	43

AS, absolute sensitivity; CS, complete sensitivity; SBx, biopsy specificity; SPE, specificity; C5PPV, C4PPV, C3PPV, positive predictive value of a C5, C4 and C3 diagnosis, respectively; Fls−, false negative rate; Fls+, false positive rate; INA, inadequate rate; INCA, inadequate rate from cancer bearing breasts; Sus, suspicious rate; † includes atypical cysts. * Biopsied cases only. Figures falling outside the NHSBSP standard are in **bold type**.

Table 4. Published series of fenestrated/perforated plate aspiration

No. of cases	AS	CS	SBx	SPE	C5PPV	C4PPV	C3PPV	Fls−	Fls+	INA	INCA	Sus	Ref
229	71	**79**	*	**48**	100	27	10	4.2	0	**37.6**	16.7	9.2	46
215	71	**79**	45	**51**	100	38	11	4.2	0	**35.8**	16.7	7.9	47
215	**59**	**68**	15	**38**	100	50	—	2.4†	0	**54†**	29	3.7	48
100	85	95	*	63	100	—	8.7	**5**	0	9	0	**23**	49
81	65	100	22	64	100	80	25	0	0	19.8	0	17.3	43

AS, absolute sensitivity; CS, complete sensitivity; SBx, biopsy specificity; SPE, specificity; C5PPV, C4PPV, C3PPV, positive predictive value of a C5, C4 and C3 diagnosis, respectively; Fls−, false negative rate; Fls+, false positive rate; INA, inadequate rate; INCA, inadequate rate from cancer bearing breasts; Sus, suspicious rate. * Biopsied cases only. † The definition of inadequate in this paper is not standard and includes some cases which would be regarded as benign under the NHSBSP definitions. Figures falling outside the NHSBSP standard are in **bold type**.

Thames (East), North-East London and Essex, U.K. The comparison between units for the various parameters can be seen in Table 5. The figures are also assessed against the standards set for the screening programme in the cytology guidelines. Analysis of the results shows that there are small differences between units, but that generally units are performing to the standards set, or better.

One can, however, see from the results that unit 6 has a low sensitivity and high specificity, with a high PPV, and also a high PPV for suspicious and atypical diagnoses. The very high false negative rate in this unit appears to have led to a delay in diagnosis in a proportion of cancers. Ciatto and associates [3] infer that this statistical profile suggests that the unit should verify the accuracy of sampling. In fact, the Quality Assurance Unit in North Thames (East) is undertaking a review of the false negative diagnoses in this unit to assess whether these are likely to be aspiration misses or false diagnoses. This review will be followed by practical help in training in aspiration technique or in diagnostic criteria. Preliminary review suggests a certain amount of inaccuracy in localisation combined with poor smear quality with a heavy overlay of blood, making reading of the slides difficult.

Table 5. Results from North Thames (East) screening units

No. of cases	AS	CS	SBx	SPE	C5PPV	C4PPV	C3PPV	Fls−	Fls+	INA	INCA	Sus	SO no.
561	77	93	35	72	98.8	82.9	14.6	3.8	**1.0**	10.9	2.9	14.3	1
745	66	89	32	55	100	74.0	26.7	**6.2**	0	**29.4**	4.6	11.3	2
489	70	89	27	78	99.1	70.6	17.1	3.1	0.6	8.0	8.1	15.5	3
149	62	85	42	63	100	100	30.8	0	0	22.4	15.5	15.1	4
419	64	86	15	**59**	99.1	85.7	29.2	4.7	0.6	22	9.4	15.0	5
414	**40**	81	55	80	100	95.0	56.0	**14.6**	0	11.7	4.9	15.1	6
283	69	91	20	61	96.6	75.0	18.2	3.2	**2.4**	10.6	5.6	**23.3**	7
3060	64	88	32	67	99.1	83.3	27.5	**5.1**	0.65	16.4	6.5	15.7	Mn

AS, absolute sensitivity; CS, complete sensitivity; SBx, biopsy specificity; SPE, specificity; C5PPV, C4PPV, C3PPV, positive predictive value of a C5, C4 and C3 diagnosis, respectively; Fls−, false negative rate; Fls+, false positive rate; INA, inadequate rate; INCA, inadequate rate from cancer bearing breasts; Sus, suspicious rate, SO no., Screening Office number; Mn, Mean results for the Region. Figures falling outside the NHSBSP standard are in **bold type**. These figures are for all screening cases regardless of the mode of aspiration.

It is important to investigate the causes of discrepant results carefully. A casual look at the figures would suggest that unit 7 has a high false positive rate due to misdiagnosis, but the false positive cases in this unit are not the result of a single reading pathologist. In fact, two of the three cases were read by the same pathologist as unit 3 and, owing to the relative numbers of cases involved, amalgamation of the figures for the two units leads to the figure for false positive diagnosis falling close to the recommended values. Review of the figures from unit 7 in 6 months time has been instituted. Preliminary results indicate that one of the false positive cases was due to a data entry error, but have highlighted an increase in the suspicious rate with no further false positive cases. This may be due to an early overswing of diagnostic cautiousness after the bad experience of a false positive diagnosis. Further investigation is proceeding.

It is also interesting to note that the inadequate rate may not necessarily reflect the skill of the radiologist in aspiration. The high inadequate rate in unit 2 is not accompanied by a high inadequate rate from cases which subsequently turn out to be cancers on biopsy or radiological review. This suggests that this unit is following a policy of aspirating lesions which are generally thought radiologically to be benign, but the cytology is being used to provide additional evidence of benignity for lesions which are regarded as low risk radiologically. The high inadequate rate from cancers in unit 4 may indicate an aspiration technique problem, but this is a small unit and the figures are not borne out by the false negative rate. Further figures are expected this year. This experience suggests that a better assessment may be obtained by using the inadequate rate from lesions which subsequently turn out to be cancer as the standard rather than the total inadequate rate.

CONCLUSION

An extensive audit of the parameters tested in the United Kingdom NHS Breast Screening Programme cytology quality assurance routine demonstrates that the analysis of sensitivity and specificity, along with the other rates discussed above, is a highly effective method for judging the quality of fine needle aspiration cytology in any given screening unit. Problems in units can be identified by this method and corrective action can be instituted.

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