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## **An audit to investigate the impact of false positive breast screening results and diagnostic work-up on re-engagement with subsequent routine screening**

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### Abstract

**Introduction:** Women attending breast screening may have suspicious mammographic findings that are subsequently found at assessment clinic to be normal (false positive, FP). A false positive diagnosis is not harmless, with short and long term negative psychosocial consequences reported. Women are at increased relative risk of breast cancer therefore their attendance at subsequent screening is essential.

**Aims:** To assess the impact of FP breast screening diagnosis and diagnostic work-up on re-attendance rates across four consecutive screening rounds at a typical breast screening centre.

**Method:** Diagnostic interventions and screening re-attendance rates at one prior and two consecutive rounds were analysed for women receiving a FP diagnosis between 2004-2006.

**Results:** 397 women (5.57%) were referred for further assessment, including 228 (57.43%) false positives. 34 eligible women failed to re-attend routine screening (+ 3 years), with 17 failing to re-attend subsequently (+ 6 years). 70.6% (24/34) of non-attenders had attended at least two screening rounds prior to FP assessment. 75% of FP women had an imaging-only assessment with 17.5% (30/171) failing to re-attend, and 25% received a biopsy, with 7% (4/57) failing to re-attend subsequently.

**Conclusion:** This study is unique as it follows FP women through four consecutive screening rounds. FP non-attendance rates were considerably lower compared to the general screening population, with diagnostic work-up having limited influence. FP non-attendance may appear insignificant in comparison to total screened population, but these women are at greater risk of subsequent cancer so should be actively encouraged to re-engage with the screening programme.

### Introduction

Breast cancer is the most common cancer in the UK, with a 1 in 8 lifetime risk of women developing the disease [1]. If breast cancer can be found at an early stage, prognosis is improved, and therefore eligible women in a range of countries are invited to have a mammogram examination within a breast screening programme every 1-3 years. In 2012 the NHS Breast Screening Programme extended the age range of women eligible for 3-yearly breast screening from 47 to 73 years [2].

5-9% of women attending routine mammography will have suspicious findings on their mammogram [3], necessitating referral to a breast cancer assessment clinic for further investigation. Following further assessment a significant proportion of these women will be given a 'normal' or 'benign' result, with no requirement for further treatment. This is considered to be a false positive (FP) result, with subsequent referral back into the screening programme (known as routine recall). A retrospective cohort study of 140,387 women identified that false positive women are at greater risk of cancer being detected at the next screen, interval cancer (cancers becoming symptomatic between the screening rounds), and larger cancers at presentation [3]. Von Euler-chelpin et al also identified an increased relative risk of breast cancer after a false-positive test which remained statistically significantly increased six or more years later, although technological improvements have reduced the size of excess risks [4]. Nonetheless both authors stress that it is essential that all false positive women are encouraged to re-attend for their next routine appointment.

A systematic review and meta-analysis by Brewer et al of over 340,000 attendances [5], later updated by Salz [6], identified that, within Europe, FP women are just as likely to re-attend routine screening 3 years later as those who had a 'normal' mammogram result. FP women in the USA are more likely to re-engage with the screening programme, and women in Canada less likely to re-engage [5.6]. Such differences are likely to reflect the variation in design of screening programmes and intervals, as well as differences in access to health care. While attendance at an assessment clinic is not the only factor to influence a woman's decision to participate in subsequent screening, a systematic review has demonstrated that the assessment clinic experience is intensely stressful, with increases in anxiety, worry and intrusive thoughts occurring in the short and medium term [7]. A more recent study [8] agreed that there were medium term (6 months) negative effects experienced by false positive women that were experienced at a similar level to women who had received a diagnosis of cancer. However when evaluated at three years after being declared free of cancer, these FP women still reported greater negative psychosocial consequences compared to women with normal screening findings [8]. This three year timeframe coincides with an invitation for the next routine screen within the UK – just receiving such an invitation has been shown to increase negative thoughts [9].

While some published literature suggests that the degree of diagnostic workup within an assessment clinic does not influence re-attendance rates [10], the Irish breast screening programme has identified that the more invasive the test, the less likely the client is to re-attend for subsequent screening [11]. The degree of diagnostic work-up may significantly affect the experience of the client and the nature of the staff-client interactions [12], with potential for anxious clients to receive information overload, insufficient information or even conflicting information.

This study aimed to identify the potential links between false positive diagnoses and diagnostic work-up on breast screening re-attendance rates at a typical breast screening unit in England. While previous studies have followed FP women for one screening round (3 years), this study aimed to correlate attendance both three years before the FP diagnosis, and then at two subsequent screening rounds (3 years and 6 years post FP diagnosis). The study received both ethical approval [11/NW/0741] and local R+D approval.

## Methodology

The screening re-attendance rates for false positive (FP) women attending a typical breast screening unit over a 3 year period (2004-2006) were analysed via a retrospective study. This period was selected for data collection to enable follow up of these women through two further screening rounds (additional 6 years) with the later women being invited to their second screen in 2012. All women called back to assessment following routine screening attendance were reviewed. Those women who went on to be referred to a breast surgeon for further investigations and treatment were discounted and only those who were referred back to routine screening (FP) were considered further.

For all eligible FP women attending an assessment clinic (2004-2006), the diagnostic tests that they underwent were noted and correlated with subsequent screening attendance. Diagnostic tests received within the assessment clinic visit were categorised as either imaging-only (mammograms and ultrasound) or biopsies.

The audit data was collated into the following categories:

- a) Number of women referred to assessment clinic between 1<sup>st</sup> April 2004 and 31<sup>st</sup> March 2007
- b) Number of women designated as 'normal' following assessment (FP)
- c) Assessment clinic interventions received by FP women
- d) Number of eligible women who returned for subsequent routine screening three years later and of those women failing to re-attend the number who returned for routine screening six years later
- e) Number of FP women failing to re-attend 3 years later who had previously attended for breast screening before their false positive assessment

## Results

Following invitations to attend a breast screening appointment, the attendance rates at the study centre were 70.2% (2007); 72.67% (2008); 70.93% (2009). The breast screening unit screened a total of 7124 women during the 3 year period.

The audit considered women called back to assessment in 2004-6 and the subsequent screening re-attendance in 2007-9 and again in 2010-12. 397 women were referred for further assessment, equating to an overall 5.57% assessment referral rate. Within the three year period (2004-6), a total of 228 women (57.43%) who had been referred for further assessment were subsequently referred back to routine recall. These women were categorised as False Positive (FP) results (see Table 1).

The 228 FP women were tracked to identify subsequent re-engagement with routine screening mammography three years later. In total 25.89% (n=59) of false positive women failed to re-attend their subsequent screening round in 2007-9. It should be noted, however, that not all the women with false positive results, were eligible for subsequent routine recall for various reasons including being under consultant care (n=5), over 70 years of age (n=19) or moved away from the screening area (n=1).

Of those women eligible for subsequent screening 14.91% (n=34) did not re-attend the following (+ 3 years) screening round. Of these 34 women, 79.41% (n=27) did not attend for screening six years later. It should again be noted, however, that not all women were eligible for subsequent routine recall for various reasons including deceased (n=3), under consultant care (n=2), over 70 years (n=8) and moved away from screening area (n=4). See Table 2 and Figure 1.

The eligible women who failed to attend for subsequent screening were investigated to identify whether they had previously engaged with the screening programme (attending at least one screening round prior to their false positive assessment in 2004-6). The majority of the non-attenders at subsequent screening (24/34; 70.6%) had attended at least one screening round prior to their false positive result. See Table 3.

75% of the 228 FP women (n=171) had received an imaging-only assessment before being referred back to routine screening. 22.81% women (n=52) had received interventions including a stereo taxis breast biopsy, and just 2.19% of FP women (n=5) had received an ultrasound breast biopsy before being referred back to routine screening (see Table 4). The numbers of eligible women failing to re-attend were correlated with the type of intervention they had received (Table 5). 17.5% (30/171) of women having imaging-only interventions failed to re-attend three years later, while 7% (4/57) of women having biopsy interventions (SBB + UBB) failed to re-attend.

## **Discussion**

This research centred in a typical breast screening unit has attempted to identify whether women who have received a false positive result are more or less likely to attend for subsequent screening. This unit is a medium sized screening unit serving a largely socially deprived, mixed ethnicity population in the North West of England. In the three year period under observation, 5.57% of women were referred for further assessment, which is within recommended referral benchmarks of the NHS Breast Screening Programme [13;14].

Of the 397 women referred for further assessment between the years 2004-6, 57.43% (n=228) received a false positive diagnosis and were referred back into the routine screening programme. This compares to a recent smaller-scale UK audit (6 month timeframe) with findings of 77.5% [15]. The number of referrals to assessment and false positive results appears to be relatively stable over the three years in the study centre.

The audit has identified that over the three year period, 34 (14.91%) false positive eligible women failed to re-attend when invited to their subsequent routine screening appointment. This is not dissimilar to a previous audit which identified 13% of eligible false positive women not attending for subsequent screening [15]. However no national benchmarks exist with which to compare directly the 'FP failure to re-attend' rates in this study. Breast screening population cohorts are fluid and inconsistent (older women leaving the programme and young women joining), so the NHSBSP (2010) standards focus on attendance rather than re-attendance, requiring attendance rates of more than 70% [14]. The attendance rates at the study centre comply with these standards for each of the study cohorts.

When comparing the re-attendance rates for the FP women in this study (85.1%) with the attendance rates in the general screening population over the same three year period (circa 71%), the FP re-attendance rates appear favourable. A meta-analysis of over 340,000 attendances [5;6] identified that European FP women are just as likely to re-attend routine screening as those who had a 'normal' mammogram result. The European results were based upon a number of studies in the UK, France, Norway and Denmark, which showed significant variation in attendance results per region, with a French study reporting an attendance rate consistently under 44% [6]. It is therefore more appropriate to compare the results of our study with other UK studies, but many of these studies were published at least a decade ago, based upon early screening rounds. Later rounds, such as those on which this research is based, may have different characteristics due to increased participant familiarity and acceptance of the screening programme, and the effects of increased positive and negative media coverage. A small-scale audit demonstrated no significant difference between non-attendance in the false positive group and non-attendance in the 'normal' screening population [15], but these conclusions are similarly flawed as they are not comparing like-for-like study populations.

Our study is unique in following FP women through two future attendances, as well as one prior attendance. 34 FP eligible women failed to attend 3 years later, and 27 of these eligible women failed to re-attend 6 years later. The majority of the FP non-attenders (24/34 70.6%) had attended at least one screening round prior to their false positive results. This is concerning because these women

could be considered 'habitual' attenders, having attended at least two breast screening rounds. Without interrogating these false positive women directly, it is impossible to state that a 'negative' assessment clinic experience influenced their decision to no longer engage with the screening programme, but this must be a consideration. Previous literature has suggested that assessment clinic attendance can be a 'distressing' experience [7;12], although a recent study on 'intent to re-attend' suggested that a positive assessment clinic experience could improve confidence in the breast screening programme [16]. However even three years following FP diagnosis, women are still likely to experience greater negative psychosocial consequences than women with a normal diagnosis [8], so this heightened anxiety is likely to influence decision-making upon receiving the screening invitation.

Over a three year period, 34 false positive women failing to re-engage with the screening programme does not seem high when one considers the thousands of clients that any one unit engages with in any one year. However there is evidence to suggest that these false positive women are at greater excess risk of future breast cancer [3;4;11], so it is imperative that all false positive women are encouraged by their units to re-attend for their next routine appointment.

In this study 75% of the false positive women referred to the assessment clinic received an imaging-only intervention. The numbers referred for breast biopsy are compliant with NHSBSP (2010) guidance which states that approximately 1% of women screened will undergo a needle biopsy [14]. Those women undergoing breast biopsy procedures in this study were more likely to return to future screening than those undergoing minimally invasive assessment (17.5% compared to 7%). While caution should be shown because numbers of women in each category are small, this local finding is in opposition to the findings of the large-scale Fitzpatrick et al study (biopsy candidates less likely to attend) [11] and Signeurin et al (no effect of diagnostic work-up on attendance) [10]. We propose that although biopsy procedures are potentially more distressing and require a longer anxious wait for results, this delay in receiving results may in fact work in the woman's favour, offering them more time to consider their situation, seek support from family members, and ask pertinent questions of health care staff at their follow-up visit one week later. This 'continuum of care' may leave women with a positive perception of the breast screening unit.

## **Conclusion**

In this study, the re-attendance rates for the FP women are considerably higher than attendance rates in the general screening population over the same three year period, though this is not a like-for-like comparison. The percentage of false positive women failing to re-attend for subsequent screening was similar to other published literature. The majority of the eligible women failing to re-attend for subsequent screening had previously engaged well with the screening programme. Even though 'FP failure to re-attend' numbers form a very small proportion of the screening population, it is imperative for screening units to understand their own local situation, because false positive women are known to be in a higher risk group for cancer and re-engagement with the screening programme is vital.

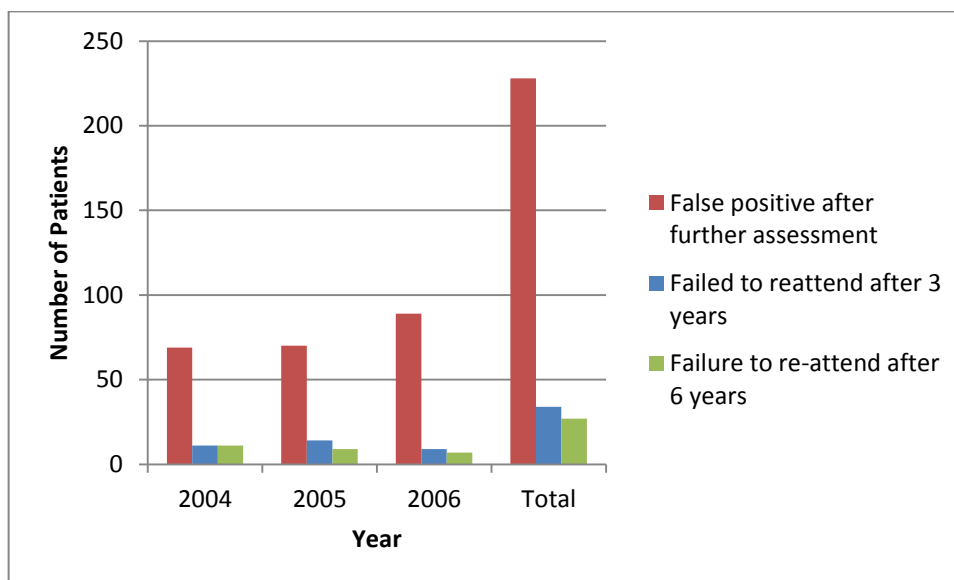
While actual numbers were too small to make definite conclusions, the degree of diagnostic work-up did have some influence on re-attendance rates, with women receiving biopsies more likely to re-attend for subsequent screening. It is possible that the higher level of communication and the longer continuum of care afforded to these women has some beneficial effects regarding their perception of the wider breast screening programme. The authors hypothesise that this continuing care model would be beneficial for all clients attending the assessment clinic, regardless of diagnostic work-up, and further qualitative research is underway at the study centre to identify whether a continuum of care could be afforded by an enhanced radiographer role.

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**Figure 1 Chart demonstrating the numbers of false positive women who failed to re-attend at 3 years and 6 years.**



**Table 1 Screening Unit Activity: Number of women screened, referred for assessment and subsequently categorised as false positive**

	2004	2005	2006	Total
No. women screened annually	2595	2266	2263	<b>7124</b>
No. screened women referred for further assessment	115	145	137	<b>397</b>
Assessment referral rate (%)	4.43	6.40	6.05	<b>5.57</b>
No. women with a false positive diagnosis	69	70	89	<b>228</b>
Percentage (%) of assessed women classified false positive	60.00	48.28	64.96	<b>57.43</b>

**Table 2 Number of eligible false positive women failing to re-attend after 3 years and after 6 years**

	2007	2008	2009	Total
No. FP women failing to attend (+ 3 years)	11	14	9	<b>34</b>
Non-attendance (%) (+ 3 years)	15.94	20.00	10.11	<b>14.91</b>
Attendance (%) (+3 years)	84.06	80.00	89.89	<b>85.09</b>

No. FP women failing to attend at 2 subsequent screening rounds (+ 3 and +6 years)	11	9	7	<b>27</b>
Percentage women not attending at +3 years also not attending at 6 years (%)	100.00	64.29	77.78	<b>79.41</b>

**Table 3 Previous attendance history of false positive women who failed to re-attend at 3 years**

	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Total</b>
No. False Positive women	69	70	89	<b>228</b>
No. FP women who did not attend after 3 years	11	14	9	<b>34</b>
No. FP women not attending at 3 years who had previously attended at least one round	9	11	4	<b>24</b>
Percentage who had previously attended	81.82	78.57	44.44	<b>70.59</b>

**Table 4 Interventions received by false positive women**

	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Total</b>
mammography targeted projections or ultrasound (imaging only)	44	55	72	<b>171</b>
Imaging only %	63.77	78.57	80.90	<b>75.00</b>
stereo taxis breast biopsy (SBB)	22	10	20	<b>52</b>
SBB %	31.88	14.29	22.47	<b>22.81</b>
ultrasound breast biopsy (UBB)	2	0	3	<b>5</b>
UBB %	2.90	0.00	3.37	<b>2.19</b>

**Table 5 Assessment clinic interventions received by subsequent FP non-attenders**

	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>Total</b>
mammography targeted projections or ultrasound (imaging-only)	44	55	72	<b>171</b>
Number of non-re-attendance after 3 years (imaging-only)	7	14	9	<b>30</b>
Percentage of non-re-attendance after 3 years (imaging-only)	15.91	25.45	12.50	<b>17.54</b>
stereo taxis breast biopsy (SBB)	22	10	20	<b>52</b>
Number of non-re-attendance after 3 years (SBB)	4	0	0	<b>4</b>
Percentage of non-re-attendance after 3 years (SBB)	18.18	0.00	0.00	<b>7.69</b>
ultrasound breast biopsy (UBB)	2	0	3	<b>5</b>
Number of non-re-attendance after 3 years (UBB)	0	0	0	<b>0</b>
Percentage of non-re-attendance after 3 years (UBB)	0.00	0.00	0.00	<b>0.00</b>

