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Position Statement on Breast Pain

Background

Over the past decade referrals of women to breast cancer diagnostic clinics (also known as "one-stop clinics" (OSCs)) have grown by almost 100%[1], a rise which has not been mirrored by an increase in breast cancer diagnoses, which have increased by 14%[2]. This was highlighted in the recent breast Getting it Right First Time (GIRFT) report[3]. To deal with the upsurge in referral numbers many units are undertaking extra OSC in evenings or weekends[4] but despite best efforts up to 51% of breast units are now failing to see patients within the 2 week target standard[5].

Drivers behind the increased referral numbers

The increase in referral numbers is multifactorial in aetiology but does suggest that there are many women referred to breast cancer diagnostic clinics who could be better served outside of the OSC and avoid the inevitable anxiety of referral to a 'breast cancer clinic'.

Women with breast pain constitute up to 41% of attendees in OSC.[6,7] The incidence of breast cancer in women with breast pain only symptoms (no lumps, nipple or skin symptoms) is 0.4%, as reported both in the largest consecutive series of women attending a symptomatic breast clinic[8] (and in the most recent literature review.[9]) This figure is half the number seen in asymptomatic women invited to the national breast screening programme (0.8%).

NHS England has also stated that "Based on NG12, in the absence of associated red flag symptoms, i.e. lump or skin changes, breast pain alone is not a symptom of cancer and should not be automatically referred on an urgent cancer pathway."[9]

Despite these publications, many women perceive that breast pain is associated with an increased risk of breast cancer. At the same time, some General Practitioners are concerned regarding their potential risk if they do not refer a woman, particularly if the patient is voicing concern regarding a cancer diagnosis. Hence referrals of women with breast pain are a significant contributor to the workload in OSCs.

Better care for women with breast pain

The Association of Breast Surgery (ABS) believes that women with breast pain require and deserve management by skilled clinicians, who can address the presenting complaint of breast pain and manage this appropriately. Time is also needed to give advice on the management of symptoms and address patient concerns, which is difficult in a pressured OSC.

The OSC is not the appropriate place to see patients with breast pain only as it is a service designed to diagnose breast cancer. Referral to a cancer diagnostic clinic not only increases anxiety inappropriately, but also leads to excess imaging in contravention of NICE and Royal College of Radiology guidance. Within a busy OSC, with its focus on diagnosing cancer, the necessary time required to reassure and inform women about breast pain and symptom control is limited. The very problem with which the patient is referred is not effectively addressed.

Better care for all women with breast symptoms

As noted above, a significantly increased number of patients referred to the OSC has resulted in delays in being seen for all women, including those with red-flag symptoms of breast cancer such as breast lumps. This is highly unsatisfactory for these women and their healthcare professionals. An alternative high quality, safe and effective pathway for women with breast pain only outside of the OSC will allow greater capacity for rapid review of women with red-flag symptoms (breast cancer incidence 5-6%) within the OSC.

ABS Working with NHS England on the Faster Diagnosis Breast Pathway

We are currently working with NHS England on the breast pathway for the new Faster Diagnosis Standard. We have made all these points and hope that the new pathway will recommend stratification of new patient breast referrals to allow best use of the scarce one stop clinic resource. This should also allow for more appropriate bespoke care for patients with breast pain and other breast presenting symptoms

Breast Services have found local solutions

A number of breast services have developed their own local solutions involving assessment of women with breast pain outside of OSCs, freeing up capacity within these clinics for women with true red-flag symptoms.

Many different models will exist across the NHS and ABS is in the process of collecting information

on the various pathways currently being used across the country, and ABS is currently collating examples of these pathways.

Two examples are provided here (see appendix). The East Midlands model has been used in a larger number of patients and has published evaluation data.

No innovation without evaluation

All units who have developed new assessment pathways for women referred with breast pain are reminded of their obligation to evaluate the new pathways to ensure safety, effectiveness and patient satisfaction. ABS has developed guidance on the introduction of new techniques and devices and a 'traffic light system' by which to judge these new techniques, the same principles apply to the introduction of new pathways for patient management.

At this time different pathways have been evaluated in different ways, have been applied to different numbers of patients, and have different amounts of presented and published evaluation. It is incumbent upon you to take this in to account when introducing new pathways (see ABS traffic light document).

Of the two models in the appendix; both models have presented audit data of initial pilot results. The East Midlands model has also published their pilot data in a peer reviewed journal and have presented confirmatory data from Derbyshire and are funded/supported by EM Academic Health Science Network and EM Cancer Alliance to audit implementation across the whole of the East Midlands in 2021-22.

Obtaining the best evidence - research

In parallel to the above, ABS has convened a breast pain working group under the auspices of the Academic and Research Committee to consider the available published evidence and develop research ideas to improve the evidence base. Research is a vital part of the ongoing consideration of optimal management of women with breast pain.

Obtaining the Best Evidence - evaluation

It is recognised that conducting the research and analysing the data will take some time whilst the pressures on the OSC are current and significant.

ABS are working with the iBRA-NET Research Network and are seeking to set up a platform evaluation study whereby anyone who is setting up and piloting a new pathway for breast pain can

collect standard data for evaluation. Standard data collection allows comparison of the different pathways being set up. The new pathways can be compared with current/historical practice of seeing patients in the one stop clinic.

This will be an evaluation of practices, which allows relatively speedy set up, pragmatic assessment and data collection of very large numbers of patients. The platform study design allows for the addition of multiple pathways for evaluation as and when they arise.

The first step is to obtain data on the number of different pathways, which are currently being used across the country. You will have recently had a request for this and many thanks to those of you who have already sent in your breast pain pathways to the Clinical Practice and Standards Committee.

ABS proposes that all breast services that have developed or are developing new assessment pathways for women with breast pain become part of a combined iBRA-NET collective and enter data for patients on their pathway. This will allow rapid accumulation of outcome data and prompt cross fertilisation of best practice.

Summary

1. Women with breast pain are not best served by current referral pathways, which can raise anxiety but fail to offer the opportunity to address underlying concerns and symptom management.
2. ABS are working with NHS England and Breast Cancer charities to develop more appropriate pathways out-with the one stop clinic.
3. New pathways should be evaluated assiduously with standard data collection via an iBRA-NET evaluation study.
4. ABS will continue to promote and facilitate collection of best evidence as part of the iBRA-NET mastalgia group and the Breast Pain Working Group

Appendix – Two examples of models of care currently in use for breast pain

1. **East Midlands Model:** a breast pain clinic run by an experienced clinician assesses women with breast pain in a community facility. This breast pain clinic receives referrals of breast pain only from primary care, clinical examination is carried out by an experienced clinician and there is an objective, reproducible familial breast cancer risk assessment appropriate for primary care and as mandated by NICE guidance CG164. The latter is based on evidence from a literature review and pilot implementation data which report that between 11%-35% of women with 'breast pain only' give a family history of breast cancer.[11] The risk assessment provides mutual security for the patient, the clinician and the service provider (i.e. CCG/ICS). Onward referral to Secondary Care Familial Cancer Services for those identified at moderate / high risk and/or referral to OSC, for those found to have another symptom, are carried out as appropriate. This model is being audited through collection of a core dataset by all centres/areas implementing it. This pathway has also been highlighted in the breast GIRFT report[12]

2. **Manchester Model:** all breast pain referrals are reviewed by advanced nurse practitioners (ANPs). Those referrals mentioning breast pain alone with no associated breast symptoms (for example, but not limited to, breast lumps, nipple complaints, women with a previous history of any breast surgery) are triaged out of OSC into a telephone-based breast pain clinic run by ANPs, who undertake the telephone consultation using a breast unit multidisciplinary team approved standard operating procedure. During consultation patients identified as having symptoms, other than breast pain alone, are redirected to the next immediately available OSC for clinical evaluation and imaging as indicated. Women with breast pain alone receive advice regarding the aetiology and management of their symptoms and are also sent a personalised letter summarising the same, which includes a link to a UK based breast surgeon's YouTube video on breast pain.
   Unless they have had mammography within the previous 6 months, all women above 40y are referred for mammography in accordance with Royal College of Radiologist guidance[4]. If mammographic abnormalities are identified then the patient is directed to the next immediately available OSC. Patients receive a text message inviting participation in a survey to gain their feedback following the telephone consultation. Furthermore, women assessed via the telephone consultation service are tracked (using NHS numbers) over the subsequent 12 months to see if there are any return referrals to our breast service during this time. This provides one important indicator of effectiveness of the service.

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