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Version History:

Version	Date	Author	Reason/Change
V1.0	Aug 2014	THCGAP	Change of header and reference to joint hospital version
V2.0	Jun 2015	THCGAP	JPUH has a policy and now will not be using joint guideline
V3.0	Jul 2016	Authors	NNUH document only reviewed flowchart updated
V4.0	Aug 2019	Dr Arne Juette	Audit criteria amended, key people amended and staff selection updated
V5.0	Mar 2023	Rebecca Bond	Bi-annual Review. Terms in Glossary updated and Equality table completed.
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Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
None	Not applicable

Distribution Control

The authors have drafted this guideline in consultation with the Director of Breast Screening and members of the multi-disciplinary team (MDT) at the Operational Policy Meeting on 14 May 2013.

During the development process, the guideline had been circulated for comment to: Consultant Radiologists, Consultant Breast Surgeons, Consultant Pathologists and Consultant Oncologists.

This version has been endorsed by the Clinical Guidelines Assessment Panel

This version was reviewed in March 2023 by Rebecca Bond and only minor changes were made.

Distribution

Clinical Director of Breast Imaging – paper copy to be held in Guidelines and Procedures manual. Trust Intranet.

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

Erika Denton, Consultant Radiologist, Breast Imaging Vicki Ames, Consultant Radiologist, Breast Imaging Samyukta Boddu, Consultant Radiologist, Breast Imaging David Newman, Consultant Radiologist, Breast Imaging Kelvin Tan, Consultant Radiologist, Breast Imaging Claudia Woodward, Consultant Radiologist, Breast Imaging Tina Lucie-Smith, Consultant Radiographer, Breast Imaging

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g., changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a strategy/policy/non-clinical procedure/clinical procedure/standard operating procedure/clinical guideline/non-clinical guideline/protocol (please mark which type is applicable) applicable to (Integrated Care System, Acute Collaborative, individual Trust); please refer to local Trust's procedural documents for further guidance, as noted in Section 5.

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Quick reference guide for breast cancer patients undergoing preoperative axillary LN assessment

1. Introduction

1.1. Rationale

In patients with invasive breast cancer, the presence of axillary lymph node (ALN) metastases is an important predictor of survival ¹. It also determines the need for adjuvant chemotherapy and/or hormonal therapy ². It is well established that clinical examination of the axillary lymph nodes is not a good indicator of the presence or absence of lymph node metastases in breast cancer ³.

Axillary lymph node dissection is the accepted method of removing abnormal axillary lymph nodes for local control but also to obtain histological evidence of lymph node involvement. Unfortunately, ALN is associated with significant morbidity (6), and so it is desirable to minimize axillary surgery. In women without preoperative evidence of axillary metastases, sentinel lymph node biopsy (SLN) is now standard practice as the method to sample axillary nodes with less morbidity than ALN. In some women this process (initial SLN followed by ALN) means they require 2 or even 3 surgical procedures before completing their treatment. In order to reduce the number of axillary operations, methods have been sought to obtain as much information about the axillary nodes pre-operatively as possible.

The morphology of the axillary lymph nodes on ultrasound in combination with ultrasound guided needle sampling of the nodes has been shown to be useful in assisting in the safe reduction of axillary surgical procedures in these patients ⁷.

This guideline outlines the use of axillary ultrasound in the breast cancer diagnosis pathway.

1.2. Objective

To set down an agreed approach required in axillary ultrasound assessment of patients with newly diagnosed primary breast cancer, to standardise practice.

1.3. Scope

This document applies to Consultant Radiologists, Consultant Radiographers, Breast Surgeons, breast cancer patients with lymph node involvement.

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
MDT	Multi-Disciplinary Team
ALN	Axillary Lymph Node
SLN	Sentinel Lymph Node
FNA	Fine Needle Aspiration
WBA	Workplace Based Assessments

2. Responsibilities

The details of each member of staff working to this guideline must be retained on a 'live' departmental register (Appendix 1) held within the Breast Imaging Department. It is the department's responsibility to keep the register up to date.

3. Processes to be followed – Broad recommendations

Every newly diagnosed primary breast cancer patient has axillary lymph node assessment with ultrasound.

Morphologically normal lymph nodes will usually require further assessment with SLN as they may still contain histological evidence of disease.

Indeterminate or abnormal looking nodes require needle assessment with fine needle aspiration (FNA) or core biopsy to differentiate benign from malignant disease.

All findings will be discussed at the multidisciplinary team meeting (MDT) before surgery or other treatments are undertaken.

4. Training & Competencies

All axillary ultrasound assessments are to be performed by a Breast Radiologist or Breast Consultant Radiographer, all of whom are trained in breast and axillary ultrasound with needle biopsy.

Alternatively, the ultrasound assessment is performed under appropriate delegation by an adequately trained Advanced Practitioner, Breast Imaging Fellow, or Radiology ST. The fitness of these members of staff to carry out the axillary ultrasound is assessed via Workplace Based Assessments (WBA).

5. Related Documents

Not applicable

6. References

- 1. Kinne DW. Surgical management of stage I and stage II breast cancer. Cancer 1990; 66 (6 suppl):1373-7.
- 2. Jatoi I. Management of the axilla in primary breast cancer. Surg Clin North Am 1999; 79:1061-73.
- 3. <u>Valente SA</u>, <u>Levine GM</u>, <u>Silverstein MJ</u>, <u>Rayhanabad JA</u>, <u>Weng-Grumley JG</u>, <u>Ji L</u>, <u>Holmes DR</u>, <u>Sposto R</u>, <u>Sener SF</u>. Accuracy of predicting axillary lymph node positivity by physical examination, mammography, ultrasonography, and magnetic resonance imaging. <u>Ann Surg Oncol.</u> 2012 Jun;19 (6):1825-30.
- 4. Yarnold J. Early and locally advanced breast cancer: diagnosis and treatment National Institute for Health and Clinical Excellence guideline 2009. Clin Oncol(R Coll Radiol). 2009 Apr; 21(3):159-60..
- 5. Alfahad et al. An Audit of Preoperative Ultrasound Assessment of the Axilla in Breast Cancer in a Large Regional Centre. NNUH 2012.
- 6. Schijven et al. Comparison of morbidity between axillary lymph node dissection and sentinel node biopsy. Eur J Surg Oncol 2003, 29; 341-350
- 7. Houssami et al. Pre-operative ultrasound guided needle biopsy of axillary nodes in invasive breast cancer: a meta-analysis of its accuracy and utility in staging the axilla. Ann. Surg.. 2011, 254 (2); 243-251

7. Audit of the process

To ensure that this guideline is compliant with the above standards, the following monitoring processes will be undertaken:

There is a commitment to audit the axillary ultrasound outcome against surgical and pathological data at regular intervals determined by the clinical team.

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Imaging outcome against surgical and path data	Data audit	Breast Radiologists	Radiology Governance	Annually

The audit results are to be discussed at Breast Imaging and Radiology governance meetings to review the results and recommendations for further action. Then sent to the Clinical Director who will ensure that the actions and recommendations are suitable and sufficient.

8. Appendices

Appendix 1 - Departmental Record of Signatories

This is the departmental list of all those who have read and agreed to act within the parameters of this guideline. Each individual has kept a signed copy of the guideline for his / herself.

Print Name	Signature	Date (dd/mm/yyyy)

9. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Radiology	Department	Breast Imaging
Name of person completing form	Rebecca Bond	Date	24/03/2023

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	No impact	No impact	No impact	No
Pregnancy & Maternity	No impact	No impact	No impact	No
Disability	No impact	No impact	No impact	No
Religion and beliefs	No impact	No impact	No impact	No
Sex	No impact	No impact	No impact	No
Gender reassignment	No impact	No impact	No impact	No
Sexual Orientation	No impact	No impact	No impact	No
Age	No impact	No impact	No impact	No
Marriage & Civil Partnership	No impact	No impact	No impact	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?		No impact		

• A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty

• Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service

• The policy or function/service is assessed to be of high significance

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.