1. Introduction and aims of guidelines.

The aims of the guidelines for nurse practitioners and clinicians in new referral breast clinics are to assist them manage patients who have been referred to the breast clinic via their GP/2 week waiting referral.

The guidelines have been agreed with the Breast Consultant Surgeons and Radiologists. They include advice on appropriate referral for investigations, when to discharge patients from the clinic and when to refer on to the Consultant surgeon for results and/or further treatment.

The nurse practitioner role has been introduced to help address the expected increase in demand for the referral of breast patients, which is due to the new two week wait targets for all patients with breast symptoms.

Men with axillary mass only should not be put in a breast symptomatic clinic.
Women with unilateral axillary symptoms of unknown origin only should be seen in a breast clinic.
A breast symptomatic clinic is for the investigation of symptoms arising from the breast/axilla region only – not upper abdomen, shoulder, upper arm, flank

Patients should have clinical examination first (clinical examination should take place before any biopsy procedure).
Clinical examination should be recorded using the 1-5 scale:
1 = normal
2 = benign
3 = uncertain
4 = suspicious
5 = malignant
It helps the imager if the site of concern is marked.

In order to allow the smooth running of a clinic it may be necessary to carry out XOA on the first few patients in the clinic e.g. the first three appointments in each clinic are given to women 50 or over for whom initial mammogram can be carried out.

Imaging findings are recorded as :
1 = normal
2 = benign
3 = indeterminate/probably benign
4 = suspicious of malignancy
5 = highly suspicious of malignancy

The radiologist may give an individual grade to each part of imaging but **ALL** reports should have a final overall imaging classification (IC =).

The final report is a verified report held on CRIS/PACS

2. Legal Liability Guideline Statement

Guidelines issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional' it is fully appropriate and justifiable - such decision to be fully recorded in the patient's notes.

3. Scope

The scope of the policy is to cover all Breast Nurse practitioners, Surgical and /radiology trainees and clinical assistants who work in the Surgical Directorate Breast Care Unit, new referral clinics.

All Nurse Practitioners, any trainees and Clinical Assistants who work in the new referral breast clinics will work within the guidelines for new referral clinics.
If there is any doubt over the interpretation of the guidelines the individual practitioner/ clinician must discuss this with the Breast Consultant Surgeon, in charge of that particular clinic. With regard to the Nurse Practitioners they will assume accountability for his/her own actions as per Nursing and Midwifery Council Guidelines (2008). (NMC).

REFERENCE: NURSING AND MIDWIFERY COUNCIL (2019) (NMC).
Code of professional conduct, London.

CLINICAL GUIDELINES

Clinically benign breast lump.

30 years to 26 years of age

Ultrasound = (US)

US = solid benign mass (Clinical Benign score = 2) :- Take fine needle aspirate cytology,
- Fulfils Stavros criteria for benign mass. And offer to telephone patient with
(Stavros criteria see appendix 2) results or see in clinic (Benign)

US = solid mass with any indeterminate features (Clinical score = 3) - US CORE BIOPSY

US = normal FNA freehand / or senior doctor/ consultant to review and if able to downgrade clinical findings to normal (clinical = 1) then no FNA required.

25 years and under FNA can be avoided as below.

Clinical Benign score = 2
Ultrasound- Fulfils Stavros criteria for benign mass.
(Stavros Criteria -: see appendix 2)
Lesion 29mm or under.

The patient must have no extenuating circumstances.

E.G BRCA patients, strong family history, previous full mantle radiotherapy.
Clinically the lump must be smooth and mobile with no associated skin changes.

Correlation between clinical examination = 2 + Ultrasound classification = 2

Between 31 and 35 years.

US = solid benign mass (2) - US OR CLINICAL CORE BIOPSY/ FNA

US = Solid mass (3-4 or over) - MAMMOGRAM, THEN CORE BIOPSY

US = normal - CLINICAL CORE BIOPSY/ FNA

US = Fat necrosis and history of trauma, lipoma – BIOPSY NOT REQUIRED (Clinical + US adequate to discharge)

(If tissue sample is deemed necessary, then CORE Biopsy as FNA not diagnostic).

40 years and over (with no past medical history of cysts)

Mammogram first, then if NAD discuss doing an ultrasound with radiologists.

If patient has had a mammogram in last 12 months, do not repeat the mammogram. If
patient has a past medical history of cysts and a mammogram in the last three years.
Send for US first.

Radiologically benign solid mass visible on US = US OR CLINICAL CORE BIOPSY/ FNA

Mammogram and US normal = CLINICAL CORE BIOPSY/ FNA

(Unless downgraded by consultant)

US = Fat necrosis and history of trauma = SAME AS 31-40 yrs.

Clinically benign lumps consistent with a lipoma or skin cyst (e.g. sebaceous cyst) may not require imaging or biopsy. If ultrasound is performed, and is either normal or consistent with lipoma or hamartoma, the lesion should be classified as clinically benign (2). A lesion typical of a lipoma on ultrasound does not require biopsy. (If 5cm or larger consider referral to Sarcoma team)

ULTRASOUND =CYST

Aspirate cyst. Discard aspirate (If not blood stained) and discharge patient unless:

a) **Residual clinical abnormality** i.e. cyst not the palpable abnormality- repeat US, if (US=1), do a freehand CORE or FNA, or consultant may wish to downgrade.
If residual US abnormality discuss management with radiologist

b) **Uniformly blood stained aspirate –** send aspirate for cytology and see/ring in results in 1 week for results.

For a and b review in consultant clinic in 1 week

c) **Intracystic filling defect** - US CORE BIOPSY or VACB

d) **Recurrent Individual Cyst** - Repeat US, aspirate and discard if simple cyst,

Send aspirate for cytology if the same cyst recurs

3 times in 3 months.

PATIENT FEELS LUMP- CLINICAL EXAMINATION NORMAL (P1)

If a patient can feel and point to a lump and clinical examination is normal then ULTRASOUND should be carried out.

US = normal – Discharge

US Abnormal – Manage according to US findings.

CLINICAL THICKENING OR INDETERMINATE LUMPS (P2-3).

Clinically symmetrical benign thickening – no imaging required.

Clinically asymmetrical localised thickening/lump :-
Manage as follows:-

40 years and over – Mammography and ultrasound. If mammography shows dense background pattern & US normal (score = 1) - clinical core biopsy with multiple passes.

Under 40 years – Ultrasound and if US=1 do clinical core biopsy with multiple passes, if U/S 3 mammography to be considered in 35-39y.o and core biopsy, if U/S 4-5 mammography to be carried out as well as a core biopsy.

All of above may firstly be discussed with the consultant to examine and potentially downgrade.

CLINICALLY SUSPICIOUS LUMPS (P4 or 5)

E.g. lump with associated tethering or other suspicious features.

<40 - Clinical examination, mammography + ultrasound
35-39 mammo +U/S
<35 consider mammography discuss with the radiologist

US Normal- clinical Core biopsy, if clinical core biopsy B1 discuss with consultant to downgrade or book for diagnostic surgery

US Abnormal- Ultrasound or clinical Core biopsy
ER status is routinely done by pathology.

Ultrasound the ipsilateral axilla in all patients with a clinically and/or radiologically suspicious/ malignant lump. If abnormal node is identified proceed to US FNA.

MULTIPLE LESIONS

If IC = 3, 4, 5 then at least two areas should be sampled to establish multifocality.
An FNA C5 is only acceptable when a B5 has been obtained from another focus and the C5 comes from a M4,5 or U4,5 lesion (i.e. for M3 or U3 a core biopsy is needed to prove cancer multifocality)

If IC = 2 for all lesions then a single biopsy can be carried out.

SKIN DIMPLING/ NIPPLE RETRACTION

Without palpable lump = Mammography + ultrasound. Follow guideline as per P4-5 above.

Discuss management with consultant surgeon if no abnormality on imaging.

PAGETS DISEASE/ NIPPLE ECZEMA

If suspicious of Paget's disease perform mammography (if under 40 years may consider mammography but discuss with radiologist) and perform nipple punch biopsy.

NIPPLE DISCHARGE

Investigate ONLY unilateral **spontaneous, single duct discharge**.

Nipple discharge smear specimens should not be sent for cytology routinely, since the results are unhelpful

Over 39 years – mammography to check for calcification +/- US to check for papilloma

Under 39 years – US to check for papilloma, discuss with radiologist if having microdochectomy. May consider mammography for 35-39, especially if microdochactomy is planned but discuss with radiology first. It helps the imager if the line of the discharging duct is marked.

Discuss with consultant if microdochectomy is indicated (persistent single duct discharge, copious enough to be present on any day) or follow-up.
Consider repeating mammography after microdochactomy in DCIS or invasive malignancy prior to performing further surgery.

PREGNANT OR BREAST FEEDING WOMEN

NOT FOR MAMMOGRAPHY – U/S only
If P4-5 discuss with radiologist.

In the presence of a palpable lump or suspicious thickening, if ultrasound is normal there should be a low threshold for undertaking clinical core biopsy.
Multiple cores should be taken.
REMEMBER TO INFORM THE PATHOLOGIST THE PATIENT IS PREGNANT/ BREAST FEEDING
FNA is not useful in breast feeding/pregnant women due to high rate of C3 equivocal / false results caused by pregnancy / lactational change.
If these demonstrate normal tissue or lactational change, review the patient in four to six weeks and repeat the cores if lump still present.
Discharge if 2 sets of cores are normal (consultant may wish to discuss at MDT if discharge appropriate)

UNFIT OR FRAIL WOMEN

Should have same investigations as fit women, unless unable to tolerate.
Suspicious lumps always need a core.
Histology results available in one week, but oestrogen receptors may not be available for two weeks.
Liase with the consultant, if referral to unfit/research clinic is appropriate and when to bring the patient back for results.

BREAST PAIN

Breast pain alone (in the absence of any clinically indeterminate/worrying findings) IS NOT an indication for imaging. However in UHL imaging should be offered to women over the age of 70 who present with FOCAL breast pain.

Normal clinical examination but focal breast pain = mammogram if over 70

Bilateral diffuse breast pain with normal clinical- No imaging required.
If investigations normal = give breast pain advice and written information.

OTHER RELEVANT INFORMATION

Radiologists should carry out biopsies of any impalpable lesions and lesions in women with implants.
Clinicians/Breast Nurse Practitioner should refer to the consultant to perform a free hand biopsies on any clinically suspicious lesions (mass, nipple change) where imaging is normal.
Consultant can carry out freehand biopsies of palpable masses of adequate size when they feel comfortable that they can obtain a representative sample.
It is up to the radiologists to determine what, if any, further investigation of incidental imaging findings should be carried out in the absence of any relevant clinical findings (as per screening).In the case of an incidental imaging finding please discuss further with radiology prior to further communication with the patient.
Repeat sampling of U4/U5 graded axillary lymph nodes should be carried out if the pathology is B1 or C1.
For primary breast abscesses follow the Breast Abscess Protocol 2019.

MANAGING THE RESULT

Only selected cases in which FNA needle biopsy has been performed will be discussed at a multidisciplinary meeting. (MDT)

BENIGN LUMPS

US = Benign solid mass

B2 pathology concordant with a mass-DISCHARGE
If patient wishes to have excision, discuss with the surgeon responsible in clinic.
(fibroadenoma, lymph node or other).

B1 or B2 pathology not concordant with a mass (e.g. fibrocystic change)
Arrange for repeat ultrasound core (consider VACB if small lesion difficult to core).
If repeat core = B1 – **Discharge**

SOLID LESIONS greater than 30mm on US

B2 pathology – arrange surgical excision unless hamartoma/ lipoma/PASH.

For B1, B3, B4, B5 pathology see above.

For indications for VACB – see Appendix 1

NIPPLE DISCHARGE

If spontaneous single duct, sufficiently copious discharge persists for 3 months or more, offer choice of a review in 3 months and then consider microductemy

RESULTS CLINIC

US = INDETERMINATE SOLID MASS (U3)

B1 pathology

Arrange for repeat US core biopsy or VACB/E. If repeat core = B2 accept, if B1 discuss at

MDT

B2 Pathology – Discharge if less than 30mm in size.

B3 pathology

Where there is a B3 report including radial scar, papillary lesion and mucocele like lesion with no atypia, following discussion at the MDT the patient can be offered the choice of VACB excision if technically suitable, or diagnostic surgery. If VACB excision of the abnormality shows no atypia the patient can be advised that there is an extremely low risk of malignancy and that further surgical excision is not required.

B4 Pathology

Repeat core or VACB biopsy and Discuss at MDT and decide if to repeat core or VACB.

B5 Pathology
Following MDM Discussion

Staging investigations as appropriate and treatment planning

CLINICALLY MALIGNANT LESIONS (5)
Following MDM Discussion
(If B5 result given pre MDM the patient should be made aware that the plan may change following MDM discussion.

B5 pathology
Staging investigations and treatment planning

B1, B2, B3, B4

Repeat core biopsy or VACB (see above for B3 lesions).
Surgical biopsy is mandatory for a B3, B4 lesion if VACB not appropriate.
(UHL NHS Breast Unit Protocol for VACB)

3. Education and Training

All Breast Nurse Practitioners working autonomously in the clinics, following these guidelines will have completed the in-house and external university module with sign off of competence from the ANP Education Lead, in breast examination, history taking and radiology non-medical refer training.

4. Monitoring Compliance

What will be measured to monitor compliance
Breast Examination concordance, and appropriate imaging and biopsy requests

How will compliance be monitored?

Breast examination and imaging referral concordance, standards set and audited

Monitoring Lead
Lead Advanced Clinical Practitioner and ANP Education Lead

Frequency
When breast staff change or themes of inconcordance with examination or referral for imaging noted in MDT

Reporting Arrangments
Breast Board meeting – monthly

5 **Supporting References**

UHL Breast Unit Protocol – 2019 including breast abscess protocol

Accountability for Registerd Nurses NMC 2018. NMC London

6. Key Word

Breast and New Referral Clinic#

Contact and Review Details

Guideline Lead – Jill Hardman- Smith – Lead Macmillan Advanced Clinical Practitioner in Breast Care

Lead MSS and SS Lead – Mr Simon Pilgrim – Breast and onco-plastic Surgeon

Details of changes – Update of current practice and in line with Trust COVID gudiance