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1. Introduction and who this guidance applies to:

This guidance is designed to assist Gynaecological oncology surgeons, Cancer specialist nurses, Preoperative assessment nurses, Nuclear Medicine Physics team, Histopathologists, Gynaecological Oncology MDT, ward nurses and the theatre staff in managing patients who are undergoing vulval sentinel lymph nodes biopsy at University Hospital of Leicester NHS Trust.

Vulval cancer

Squamous cell cancer (SCC) of the vulva is a rare disease with an annual incidence of 2-3 per 100,000 women. The majority of patients with vulvar cancer have stage T1/2, N0/1, M0 tumours with extensions limited to the vulva (1,2). Standard treatment for these patients is surgical excision of the primary tumour with unilateral or bilateral inguofemoral lymphadenectomy with separate incisions. (See Appendix 1 for flowchart demonstrating investigation of a suspicious vulval lesion).

The excision of the primary tumour can be performed by radical vulvectomy, hemivulvectomy or wide local excision. This is dependent on the localisation of the primary tumour (whether it encroaches the midline or not) the size of the tumour and whether the tumour is unifocal or multifocal. The localisation of the tumour also determines whether a unilateral or bilateral inguofemoral lymphadenectomy by separate incisions is also performed. Adjuvant radiotherapy can also be indicated when there is evidence of metastases following pathological examination of lymph nodes. This may include where there is extra-nodal growth.

The efficacy of this treatment strategy is considered quite good with groin recurrence rates with negative nodes reported to be around 0.2% and with positive nodes 5-10% (3-6).

Why sentinel lymph node biopsy?

A sentinel node can be defined as any lymph node receiving drainage directly from the primary tumour. Only 10-20% of T1 and T2 vulvar cancer patient will have lymph node metastases which would require inguofemoral lymphadenectomy. The remaining majority of patients would likely find no benefit from lymphadenectomy but still be exposed to significant clinical morbidity from the procedure (3-6). These include:

- Compromised wound healing in post op period due to infection and formation of lymph cysts (20-30% of patients) (7-10).
- Lymphoedema in legs which increases risk of cellulitis (10-70% of patients) (7-10).

There are no reliable non-invasive methods to reliably detect inguofemoral lymph node metastases. Clinical palpation, MRI, CT and PET are not capable of discriminating between metastatic and normal lymph nodes (11-14). Ultrasound guided fine needle aspiration is able to detect enlarged inguofemoral lymph nodes metastases but cannot exclude microscopic metastases (15).

Sentinel node biopsy has been used extensively in other oncological specialities including in the management of breast cancer and melanoma.

Results of GROINSS-V study

Conclusions from GROINSS-V study

- For early-stage vulvar cancer following sentinel node biopsy only with a negative sentinel node
 - Low groin recurrence rate
 - Excellent 3-year survival
 - Minimal treatment related morbidity
- Patients with a positive sentinel node (indicative of metastases) should have additional groin treatment.

In the GROningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-V) a multicentre observational study on sentinel node detection using radioactive tracer and blue dye was performed in patients with T1/2 (< 4 cm) squamous cell cancer of the vulva. When the sentinel node was found to be negative at pathologic ultra-staging, inguinofemoral lymphadenectomy was omitted, and the patient was observed with follow-up for 2 years at intervals of every 2 months.

Groin recurrence rates were diagnosed in 6 patients who had unifocal vulvar disease and a negative sentinel node (2.3%; 95% CI, 0.6% to 5%) and a 3- year survival rates of 97% (95%CI, 91% to 99%). Short term morbidity was decreased in patients after sentinel node dissection only when compared with those who underwent inguinofemoral lymphadenectomy following positive sentinel node (wound breakdown in groin: 11.7% v 34.0%, respectively; P < .0001; and cellulitis: 4.5% v 21.3%, respectively; P < .0001). Long term morbidity was also less frequently observed after removal of only the sentinel node when compared to inguinofemoral lymphadenectomy (recurrent erysipelas: 0.4% v 16.2%, respectively; P < .0001; and lymphedema of the legs: 1.9% v 25.2%, respectively; P < .0001).

Those with positive sentinel nodes underwent inguinofemoral lymphadenectomy. Disease-specific survival for patients with sentinel-node metastases larger than 2 mm was lower than for those with sentinel-node metastases 2 mm or smaller (69.5%vs 94.4%, p=0.001). The risk of non-sentinel-node metastases increases with size of sentinel-node metastasis. No size cut-off seems to exist below which chances of non-sentinel node metastases close to zero. Therefore, all patients with sentinel-node metastases should have additional groin treatment.

Patient selection

Inclusion criteria:

- Patients with biopsy confirmed squamous cell carcinoma
- Depth of invasion > 1 mm
- Unifocal primary lesion
- < 4 cm tumour size
- Peri-lesional injection of radioisotope possible
- Tumour should not encroach on urethra, vagina or anus.

- Clinically and radiologically negative inguofemoral lymph nodes (no suspicious nodes).

Exclusion criteria:

- Patients with squamous cells carcinoma, depth of invasion <1mm
- Primary lesion ≥ 4cm
- Multi-focal disease
- Clinically or radiologically positive inguofemoral lymph nodes.

Imaging

Imaging of the groin/pelvis is required for all patients. Options include:

- CT with intravenous (IV) contrast administration.
- MRI scan

Reporting of nodes <15mm should be described as unsuspecting unless there are any other concerning features which should be detailed at the discretion of the reporting radiologist.

See 'Figure 1' for guidance following imaging outcome.

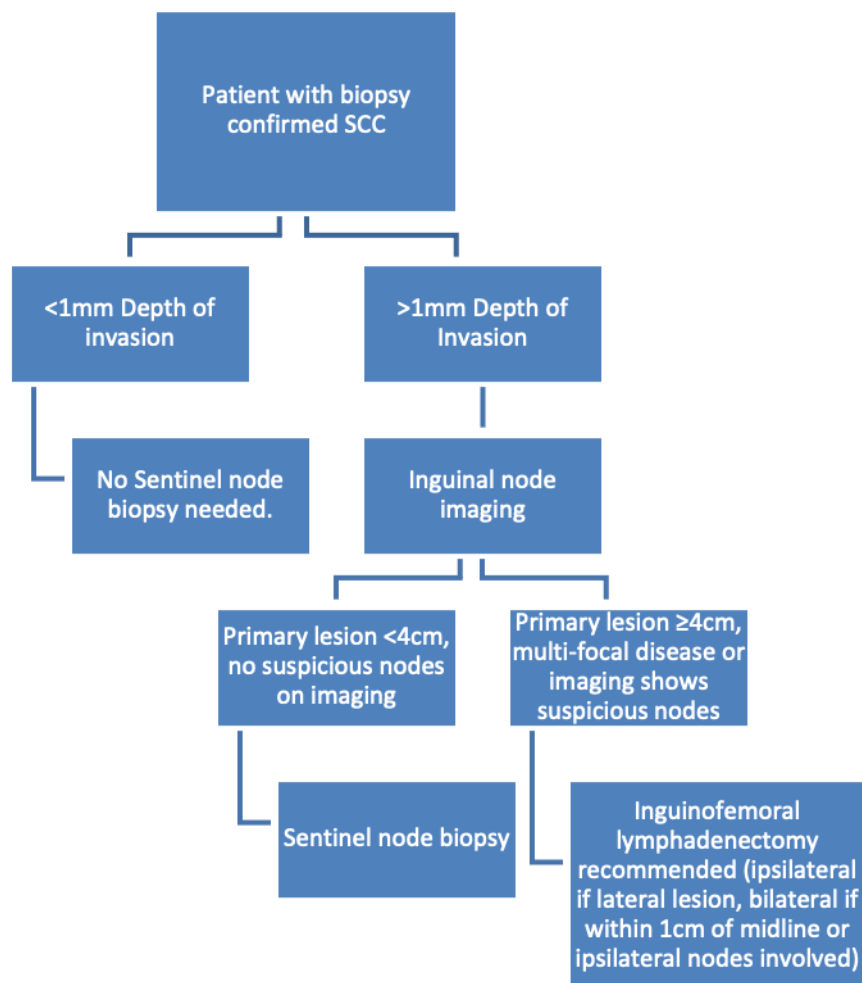


Figure 1: Decision-making aid following outcome of imaging.

Sentinel node detection protocol

Which nodes should be biopsied?

If there is a lateral tumour: Sentinel node biopsy should be performed on the ipsilateral groin to the tumour site when imaging reports no suspicious nodes.

If there is a central tumour: The tumour margins cross the midline or within 1cm of midline: sentinel nodes should be identified in both groins.

Booking and Procedure

Step 1: Pre-op

- In clinic: Complete pink slip and prescribe Lidocaine-prilocaine 5% (EMLA cream) which the patients should bring with them for Step 1 of the procedure.
- Once the date has been confirmed: Complete the nuclear medicine request form (see Appendix 3) and email it to: Nuclear.Medicine@uhl-tr.nhs.uk cc: NMPhysics@uhl-tr.nhs.uk
- In Leicester we offer vulval SLNB on Wednesday and Fridays

On Wednesdays:

- Patient to attend the NM department in Glenfield Hospital at 10:00 and surgeon to be there at the same time to apply Lidocaine-prilocaine 5% EMLA cream and give the injections.
- NM department to upload SPECT-CT images on PACS.
- Transport will be arranged by the NM team for the patient to come back to Theatre arrivals area (TAA) at Leicester General Hospital (aiming to be there by 13:00).

On Fridays:

- Patient to attend the NM department in Leicester Royal Infirmary at 13:00 O'clock on Thursday (the day before) and the surgeon to be there at same time to apply Lidocaine-prilocaine 5% EMLA cream and give the injections.
- NM department to upload SPECT-CT images on PACS.
- The patient can go home following the imaging and to be told to come to Theatre Arrival Area (TAA) at Leicester General Hospital the next day (aiming to be there by 07:30 on the Friday morning).
- The procedure to be done first on the list.

NB: The timing of the injection of the radioisotope is very important. The radioactivity takes time to travel to the nodes, therefore a delay between injection and surgery is required. Operating too early or too late can cause unnecessary doses of radiation being administered to the patient.

- Theatre too early: not enough time for isotope to travel to node
- Theatre too late: not enough radiation to detect node

Step 2: On Wednesday morning or Thursday afternoon

- The doctor administering the injection must arrive 20 minutes prior to procedure and apply lidocaine-prilocaine 5% EMLA cream to the patient's vulva for pain relief.
- Inject 0.5ml 24-80MBq ^{99m}Tc Nanocolloid circumferentially **intradermally** on 4 locations around primary tumour (each location should receive 0.05ml of ^{99m}Tc Nanocolloid). Careful considerations should be taken to avoid spillage.
- Within 5 minutes of the injections, start imaging with 30 second frames over 20 minutes using the gamma camera with low energy high resolution collimator to produce anterior images.
- If no nodes are seen at the end of the first dynamic image, ask patient to mobilise for 15 minutes before repeating the dynamic image.
- Once the sentinel node has been visualised, no further dynamic imaging is required.
- SPECT imaging is performed with a CT scan for attenuation correction and localisation.
- Slices are created with depth measurements to give information about node location.

Step 3: On Wednesday afternoon or Friday morning

- Following induction of anaesthesia, inject a total of 1-2mls of Patent blue dye intradermally into the same 4 locations around the primary tumour. This needs to be done 10 minutes prior to the excision of the nodes.
- Use the handheld gamma-ray detection probe to confirm the area of greatest activity in the groin and to determine background activity.
- Make a small skin incision and excise the sentinel node. Use the gamma-ray detector and blue stained lymph vessels to guide this dissection.
- If identification of sentinel node is not distinguishable due to high background radioactivity, consider removing the primary tumour first. This will reduce the radiation background allowing for early detection of the sentinel nodes.
- After removal of the sentinel nodes, re-examine the biopsy bed for radioactivity. If this is higher than 10% of the first excised lymph node reading, further dissection is required to search for additional sentinel nodes.
- After completing sentinel node dissection, the surgeon may consider marking the deepest point of dissection by placing a haemostatic clip.
- Pathology request forms should state: 'sentinel node biopsy for ultra-staging'.
- Describe the node whether it was Hot & Blue, Hot only or Blue Only.
- Keep a record of these readings: Background, Greatest node reading and the Biopsy bed reading.

Setup, apparatus and materials

Apparatus and Materials

- Lidocaine-prilocaine 5% EMLA cream.
- The radioisotope (^{99m}Tc Nanocolloid) is prepared each morning in the radiopharmacy department at Leicester Royal Infirmary.
- An individual dose is drawn up and injected into the appropriate site.

The activity of the injection should be 10MBq at the time of surgery:

- 24MBq in the morning for surgery that afternoon
- 80MBq in the afternoon for surgery the following morning
- 2mls of Patent blue-V dye
- A gamma probe is used to detect radioactivity in the nodes (*see Appendix 3*).

Gamma Probe Setup

- Probes are very fragile and should be handled with care. Please ensure that they are set up correctly before cases start.
- Probes from one unit may not always work with another. Please contact Nuclear Medicine if changes to the probes need to be made.
- Connect the probe to the box before switching on. The probe should be automatically detected.
- When switching off, please turn off power button and mains supply before disconnecting leads.
- After removing the sheath used on the probe during surgery, please clean the probe with a Trigene (or equivalent) wipe before returning it to the case. Monitor the probe to ensure it is not contaminated.
- *See Appendix 3 for pictures and instructions of gamma probe or visit <https://www.britec.net/europrobe-3.2-systems.html> for further information.*

Risks and Side Effects

^{99m}Tc-labelled nanocolloid

- Observe closely but monitoring of observations, biochemical or haematological parameters is not required.

Patent Blue-V dye

- Allergy.
- Urine will be stained blue temporarily.

Radiation exposure for staff

- Exposure to radiation is extremely low but scrubbed staff will need monitoring (see Contamination and Monitoring).
- Pregnant staff members should be advised not to participate in procedures described in this protocol.

Contamination and Monitoring

Contamination occurs when people/objects physically come into contact with radioactive materials and may become radioactive themselves. It is extremely important to monitor anything that may have been contaminated to prevent spread of radioactivity.

An item is considered contaminated if it exceeds the level of background radioactivity on monitoring. Background radiation is normally 5-10 counts per second on monitoring.

- Possible sources of radioactivity: surgical site, excised lymph nodes, waste, bodily fluids.
- Possible recipients of contamination: staff, objects/instruments in theatre.

Who and what should be monitored?

- Scrubbed staff: ensure hands (after removal of gloves) and bottom of shoes are monitored.
- Waste bags (including linen)
- Surgical instruments and sharps waste
- Operating table and floor surrounding/any areas which may have been contaminated by blood or dropped tissue.

How to monitor?

- Use radiation monitor.
- Prior to use, ensure the battery check is complete and the needle is pointing to the green area.
- If battery check fails, please replace batteries with 6*AA or 1*PP3
- The monitor is most sensitive to a radiation source directly in front of it. Move the monitor slowly around the area being checked but without touching the item/area.
- Note that 'hot' (radioactive items) which may inadvertently have been placed in a linen bag may not show up strongly on the monitor.

What to do if there is contamination?

- Contact the Nuclear Medicine Physics team in the first instance and then the Radiation Protection Advisor if necessary.
 - Nuclear Medicine Physics team: Ext: 16331,15166, 12935 email: NMPphysics@uhl-tr.nhs.uk
 - Radiation Protection Advisor: Ext: 16750
 - Nuclear Medicine: Ext: 13850, 15627

Histopathology

Definitions of nodal involvement:

The size of the metastases in the lymph node affects the stage allocated. These are defined as:

- Macrometastasis: >2 mm pN1
- Micrometastasis: >0.2 mm to </=2mm pN1 mi
- Individual Tumour Cells (microscopic clusters and single cells) </= 0.2mm pN0 (i+)

Macroscopy:

- Number, site and number of nodes involved by metastatic tumour should be reported.
- Examine lymph node and adherent fat.
- Lymph nodes up to 2 mm are embedded whole.
- Lymph nodes 2-4 mm in size are bisected and both halves submitted.
- Nodes that are 4 mm or more in largest dimension should be sliced at 2 mm intervals.
- A block index must be maintained.

Ultrastaging:

- Indicated when initial H/E staining of the lymph node does not identify metastatic disease.

- Cut four sections at 200µ intervals through the block and staining one section each with H/E and pancytokeratin stain (AE1/AE3 antibody).
- Retain one at each level in case of technical difficulties with H/E or IHC staining.

Extranodal extension:

- Report extension outside lymph node as it is an independent predictor of poorer survival and is included in FIGO and TMN staging.

Surgical Treatment Protocol

Treatment of the primary tumour

Treatment is radical local excision of the primary tumour in combination with sentinel node biopsy.

Sentinel Node Result	Action
Negative	No further treatment required
Positive	<p>Consideration should be given to completion lymphadenectomy of both groins</p> <p>Unilateral Lymphadenectomy is an option in clearly lateral vulval tumour (medial margin of the tumour > 1cm from the midline and no signs of a sentinel node on the contralateral side, and a metastatic sentinel node on the ipsilateral side</p>
Sentinel nodes cannot be identified ('method failure')	Inguinofemoral lymphadenectomy recommended

Inguinofemoral lymphadenectomy

- Separate incisions for the lymphadenectomy are made parallel to the inguinal ligament and then the node-bearing fat pad is removed.
- The extent of the dissection is the inguinal ligament cephalad, the adductor longus muscle medially and the sartorius muscle inferolaterally.
- After opening of the cribiform fascia all node-bearing fatty tissue medially from the femoral vein was removed as well.

Post-operative period, radiotherapy and follow-up

Patients can stay in general bays and do not need to be in side-rooms.

The optimal follow-up protocol for detecting groin recurrence in cases of negative SLNB has not yet been established. Inguinofemoral lymphadenectomy and radiotherapy may be effective in cases of recurrence following negative SNLB. Recurrence risk is greatest in the first two years and follow-up should be tailored to

detect metastases at an early stage. Ultrasound is the more effective at detecting lymph nodes metastases.

Postoperative Complications:

Lymphoedema, Lymphocyst and Lymphocele collection are relatively rare following groin sentinel lymph node biopsy compared to full groin lymphadenectomy.

Lymphoceles are abnormal lymphatic fluid collections without epithelial lining that form as a result of disruption of lymphatic channels during the surgical procedure. The fluid is typically straw-coloured with creatinine concentration closely approximating serum levels. They can result in considerable morbidity with significant swelling, pain and sepsis.

The oblique groin incision is thought to be less traumatic to the lymphatic channels and can be a preventative strategy in high-risk patients. Another way to reduce the incidence is meticulously ligating crossing lymphatic channels in the field of dissection.

There are no established guidelines for Lymphocele management; It can be sometimes difficult to manage due to high recurrence rate. Management strategies include conservative, repeated percutaneous drainage, marsupialisation, percutaneous image-guided lymphatic ligation (PILL procedure) and sclerotherapy (Common sclerosing agents are: tetracycline, bleomycin, absolute alcohol). Conservative management is usually the first line of treatment for asymptomatic lymphocele. Percutaneous drainage is usually considered if infected or the patient is very symptomatic. However, the recurrence rate is as high as 60% and the risk of infection increases with every treatment. The PILL procedure, while considered percutaneous, requires a small incision with insertion of a clip applicator to occlude leaking lymphatic channels under fluoroscopic guidance using lymphangiography. Sclerotherapy is an effective treatment strategy for resistant large lymphoceles. The type of sclerosing agent that is used seems mostly based on the treating physicians' preferences. Few data exist on the available treatments and consensus is therefore lacking on the best type, dosage and length of administration of sclerosing agent. Hence, there are no established guidelines or protocols for the use of sclerosing agents.

2. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Compliance with the standards of the vulval sentinel lymph node biopsy guidance	Auditing and monitoring of all health and safety and/or clinical incidents Datix and investigated	Gynaecological oncology department	Annually	multi-disciplinary team

3. Education & Training

None

4. Supporting References

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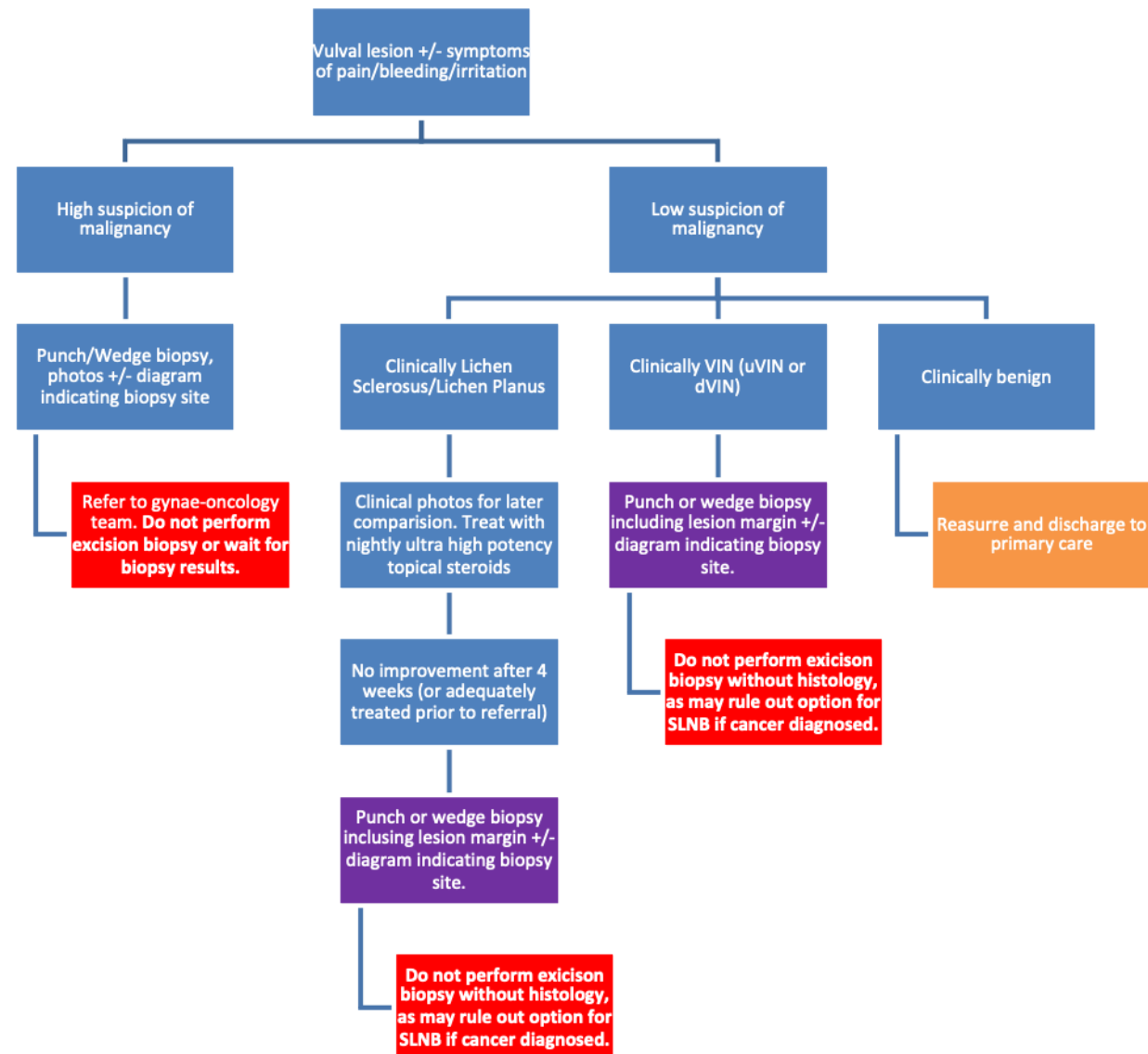
5. Key Words

Gamma prob, ^{99m}Tc, Patent Blue, Vulvectomy, Vulval cancer

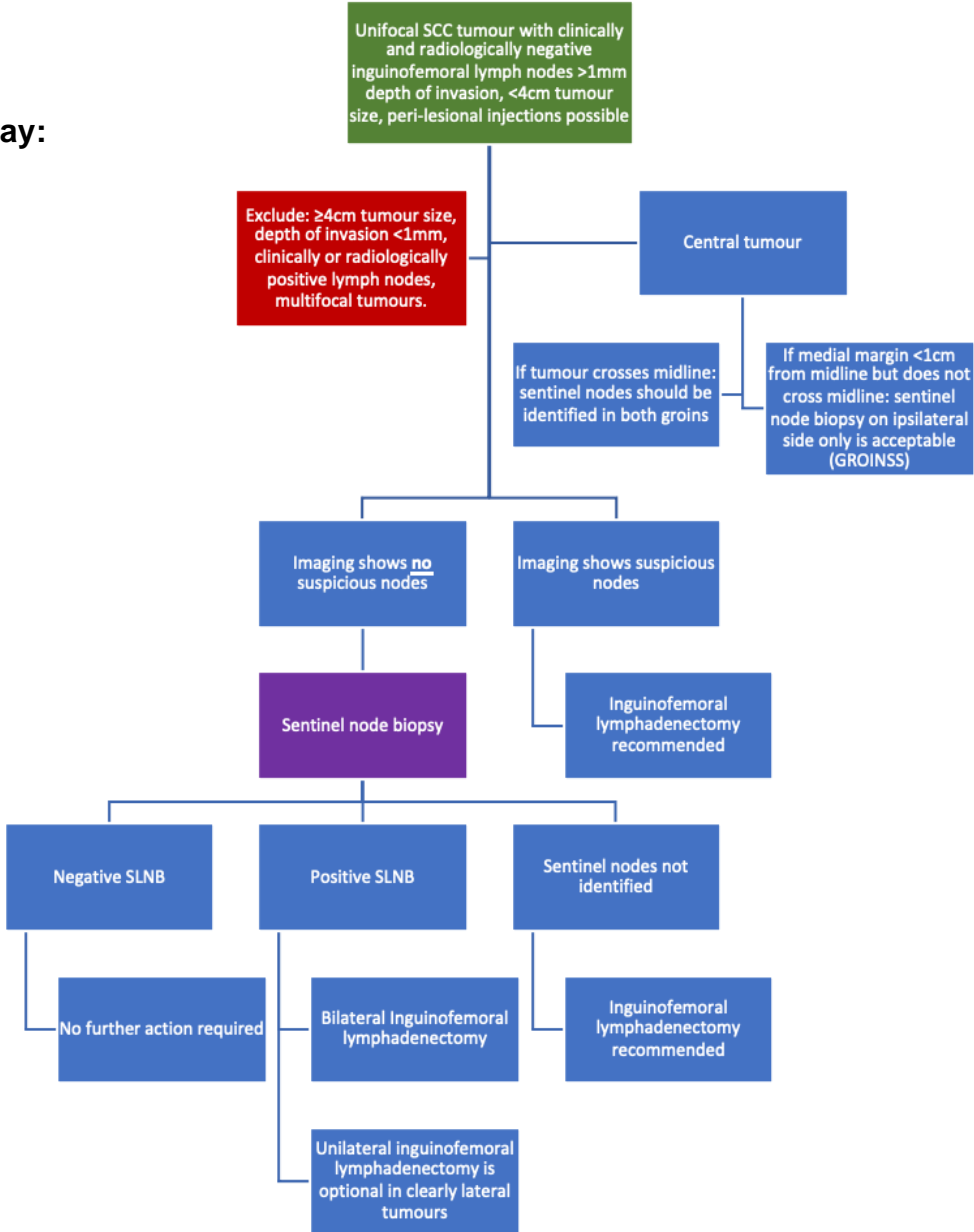
The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs. As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

CONTACT AND REVIEW DETAILS			
SOP Lead (Name and Title) Ayisha Ashmore ST4 Obstetrics and Gynaecology Trainee, Aemn Ismail Consultant Gynaecological Oncology Surgeon		Executive Lead Chief Medical Officer	
Details of Changes made during review:			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
July 2023	1	Gynaecology Governance Committee	New document



Appendix 1: Investigation Suspicious Vulval Lesion:



Appendix 2: Patient Pathway:



Appendix 3: Nuclear Medicine Request Form:

	University Hospitals of Leicester Medical Physics Department										
Imaging and Medical Physics CBU Nuclear Medicine Section											
Glenfield Hospital (0116) 256 3850	Leicester General Hospital (0116) 258 4579	Leicester Royal Infirmary (0116) 258 5627									
NUCLEAR MEDICINE REQUEST											
Unit No.....NHS/PP Surname.....M/F First Name..... Address..... D.O.B..... Patient's Phone No(s)..... Ward/Clinic..... Clinic return date..... Consultant..... Practice/Hospital:..... Referral type: Primary diagnostic <input type="checkbox"/> Follow-up <input type="checkbox"/> Surveillance <input type="checkbox"/> Planned <input type="checkbox"/> Research <input type="checkbox"/> Urgency: Routine <input type="checkbox"/> Clinically Urgent <input type="checkbox"/> Please give specific reason:.....	Please indicate any pathway patient is on: RTT <input type="checkbox"/> Cancer 62 day <input type="checkbox"/> Other: Breach date: Patient Weight.....kg In patients: Trolley / Chair / O ₂ Out patients: Ambulance/Car required? Yes / No Infection Control Risk? Yes / No Could patient be pregnant? Yes / No Is the patient breastfeeding? Yes / No Known allergies? Latex Yes / No Other (please list)										
INVESTIGATION REQUIRED:											
Clinical details (including reasons for the test):											
Signature..... Print name..... Date.....											
Job title..... Bleep.....											
Radioiodine Therapy Therapy prescription..... MBq Changes in medication required: Changes to standard restrictions:	Trial patients: Trial name: Study investigator: Patient ID number: Consent obtained? <input type="checkbox"/> Written information given? <input type="checkbox"/>										
OFFICE USE ONLY											
CRIS number Previous NM scans	<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <th colspan="3">Appointment date and time</th> </tr> <tr> <td style="width: 33%;">App 1</td> <td style="width: 33%;">App 2</td> <td style="width: 33%;">App 3</td> </tr> <tr> <td style="height: 40px;"></td> <td></td> <td></td> </tr> </table>		Appointment date and time			App 1	App 2	App 3			
Appointment date and time											
App 1	App 2	App 3									
MPNMNM0268 Version 1.0 Issued Sept 2013											

Appendix 4: Gamma probe set up:



Gamma Probe – Set up

