Somerset, Wiltshire, Avon and Gloucestershire (SWAG) Cancer Services

Urology Cancer Network Clinical Advisory Group

Clinical Guidelines

July 2023

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VERSION CONTROL

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VERSION	DATE ISSUED	SUMMARY OF CHANGE	OWNER'S NAME
Draft 0.1	13th March 2015	Renal Cancer Update	Multiple SSG members
Draft 0.2	20th May 2015	Bladder Cancer Update	Ed Rowe
Draft 0.3	26th May 2015	Penile Cancer Update	David Dickerson
Draft 0.4	14th June 2015	Prostate Cancer Update	Multiple SSG members
1.0	30th June 2015	Finalised	SWAG Urology SSG
1.1	May 2017	Biennial review	SWAG Urology SSG
1.2	12th May 2017	Revision of local to regional MDT referral details for renal and bladder cancer patients (sections 2.2 and 3.3)	J McFarlane
1.3	15th May 2017	Addition of the services provided by Gloucestershire Hospitals. Amendment of sections 3.6.1, 4.4, 4.10.3	L Poulton
1.4	27th June 2017	Update of pathology guidelines	J Oxley
1.5	30th June 2017	Addition of Appendix 5. Amendment of 2.3.2. Imaging guideline update. Finalised.	H Dunderdale
1.6	23rd October 2017	Addition to Section 4.8, page 21: Pelvic radiotherapy guidelines	E Gray
1.7	31st May 2019	Biennial review and rebranding from Site Specific Group to Clinical Advisory Group	H Dunderdale
1.8	28th June 2019	Finalised	H Dunderdale
1.9	9th October 2019	3.5 Amendment of recommendation for CT Thorax for NMIBC to MIBC only	Ratified via CAG, J Phull, L Poulton
2.0	June 2021	Update of penile cancer guidelines	A Manjunath
2.1	April 2023	Update of EAU guidelines Addition of Indications for PET CT for Prostate Cancer	H Dunderdale A Challapalli
2.2	6th July 2023	Removal of signature table in line with sign off by the SWAG Cancer Alliance Lead. Reduction of document to links to National guidance with regional exceptions	H Dunderdale

Urological Cancer Clinical Advisory Group Clinical Guidelines Contents

1. Introduction

The following guidelines pertain to the local management of urological malignancies for the Somerset, Wiltshire, Avon and Gloucestershire (SWAG) Network Urology Oncology Clinical Advisory Group (CAG).

The CAG refers to the National Institute for Health and Care Excellence (NICE) and the European Association of Urology (EAU) (2023):

https://www.nice.org.uk/guidance
EAU Guidelines - Uroweb

Primary care clinicians should refer to the NICE guidelines *Suspected Cancer: recognition and management of suspected cancer in children, young people and adults* (2021) for the signs and symptoms relevant when referring to urology oncology services. Further details on the two week wait referral process can be found in the CAG constitution and within these clinical guidelines.

The guidelines should be reviewed alongside three other key documents for the CAG: the Constitution, Annual Report and the Work Programme. The Urology CAG Constitution provides an overview of how the CAG operates, outlining its general working processes, the patient referral pathways and the guidelines to which the CAG adheres. The Annual Report reflects the period of activity for the CAG from the previous year. It contains a summary of the activity of the Urology CAG for this period, measured against several key performance indicators that have been outlined in the National Cancer Peer Review Programme. The Work Programme summarises the key areas for growth, development and improvement of the CAG over the next financial year (and beyond where appropriate). All four documents should be reviewed together to give a full overview of the CAG, its performance and future plans.

The CAG is committed to offering all eligible patients entry into clinical trials where available. Consent to provide tissue for research purposes will also be sought wherever appropriate.

2. Clinical Guidelines

Clinical Guidelines	Measure	Source	Link
Renal Cell Carcinoma	B14/S/ks-16-005	European Association of Urology	EAU-Guidelines-on-Renal-Cell-Carcinoma-2023.pdf (d56bochluxqnz.cloudfront.net)
Non-Muscle Invasive Bladder Cancer	B14/S/gu-16-006	European Association of Urology	EAU Non Muscle Invasive Bladder Cancer
Muscle Invasive Metastatic Bladder Cancer	B14/S/gu-16-006	European Association of Urology	EAU Muscle Invasive and Metastatic Bladder Cancer
Bladder Cancer		NICE	NICE Bladder Cancer
Bladder Cancer		SWAG	CT Kidneys, Ureter and Bladder (KUB) will replace CT Urogram for visible haematuria in patients ≥50 to reduce the risks associated with radiation exposure
Prostate Cancer	B14/S/gu-16-006	European Association of Urology	EAU Prostate Cancer
Prostate Cancer	B14/S/gu-16-006	NICE	NICE Prostate Cancer
Testicular Cancer	B14/S/c-16-005	SWAG	SWAG Website
Pathology		Royal College of Pathologists	Cancer datasets and tissue pathways (rcpath.org) Tissue pathways for exfoliative cytology and fine needle aspiration cytology TNM classification of malignant tumours – 8th Edition WHO Classification of Tumours
Radiology		Royal College of Radiologists	The Royal College of Radiologists (rcr.ac.uk)
Systemic Anti-Cancer Therapy (SACT)		SWAG	Protocols Archive - SWAG Cancer Alliance

3. Clinical Guidelines for Penile Cancer Including supra-network information (B14/S/b-16-006)

3.1 Introduction

The NICE Improving Outcomes Guidance on Urological Cancers recommends that all new cases of carcinoma of the penis should be reviewed by a specialist penile cancer team and that men who require organ conserving treatment, reconstruction or node clearance surgery are managed by the supra-network team each providing care for a population of 4 million or more. In ASWCS this team is established in North Bristol Trust Southmead site and currently receives referrals from the following Networks:

- SWAG 2.1 million population
- Three Counties Network 1.3 million population
- Peninsula Network 1.7 million population

Local teams around the Network may carry out diagnostic procedures including biopsy or circumcision. Following discussion at the supra-regional MDT local teams may carry out penile surgery without penile reconstruction under the guidance of the MDT if patients are too frail to travel.

3.2 Named Supra network Team

Name	Title	Trust
Mr David Dickerson (Lead)	Consultant Urologist	Weston Area Health NHS Trust and North Bristol NHS Trust
Mr Aditya Manjunath	Consultant Urologist	North Bristol NHS Trust
Dr Jon Oxley (Pathology Lead)	Consultant Histopathologist	North Bristol NHS Trust
Dr Mark Thornton (Radiology Lead)	Consultant Radiologist	North Bristol NHS Trust
Dr Paul Mccoubrie	Consultant Radiologist	North Bristol NHS Trust
Dr Ali Vosough	Consultant Radiologist	North Bristol NHS Trust
Dr Janice Ash-Miles	Consultant Radiologist	North Bristol NHS Trust
Prof Amit Bahl	Consultant Oncologist	University Hospitals Bristol NHS Foundation Trust
Dr Amar Challapalli	Consultant Oncologist	University Hospitals Bristol NHS Foundation Trust
Laura Anstee	Uro-Oncology Nurse Specialist	North Bristol NHS Trust
Zoe Waller	MDT Co-Ordinator	North Bristol NHS Trust
Charlotte Kemp	Lead MDT Co-Ordinator	North Bristol NHS Trust

3.3 Referral criteria

An urgent referral should be made for any patient presenting with symptoms or signs of penile cancer. These include progressive ulceration or a mass in the glans or prepuce with associated symptoms such as bleeding or purulent discharge. Primary penile shaft skin lesions are rare but should also be referred. If the patient presents

with a clinically obvious penile cancer, it is not always necessary to biopsy the tumour as definitive surgery can be both diagnostic and therapeutic. In the case of a clinically obvious penile tumour the supra network team will accept direct referral prior to biopsy. In addition, if there is uncertainty about the extent of the tumour due to phimosis, it is best to avoid circumcision and undertake a dorsal slit and biopsy of the lesion.

3.4 Multi-Disciplinary Team Meetings (MDT/MDM)

The supra-regional penile cancer MDT meets weekly in Southmead Hospital every Wednesday afternoon, with attendance from urology surgeons and a full complement of other key MDT members, including oncologists, pathologists, radiologists and specialist nurses etc. All new cases of penile cancer should be referred and will be discussed at the next available MDT meeting. This will include any pathology and/or imaging from referring hospitals. Currently the supra network penile cancer team discuss approximately 50-70 new cases per year.

3.5 Communication with local and diagnostic teams

The MDT outcome will be sent back to the referring team with the outcome with management plans and/or recommendations. A detailed letter will also be sent to the referring clinician and GP following the MDT discussion. For new patients requiring assessment in Southmead an outpatient appointment will be made following the MDT. The patient will need to be made aware of the diagnosis (if not already) by the referring team.

It is intended that there will be an opportunity on an annual basis for the supra network team to meet with members of the referring teams who wish to discuss and feedback on issues relating to the supra network pathways.

3.6 Local specialist teams for counselling and carrying out non-supra- network procedures/treatments

Referring teams may wish to initiate discussion about the treatment options recommended by the MDT prior to the patient's appointment at Southmead Hospital. However, if clinicians feel unfamiliar with the contemporary management of penile cancer then patients will in any case receive detailed discussion at their outpatient visit.

In rare instances where, for example, a patient is too frail to travel, the MDT may recommend a procedure carried out by the referring team locally. This would only be penile surgery for local control; 'toilet' surgery and only if the referring department felt able to do so. In exceptional circumstances it may be possible for the supra network surgeons to attend the patient's local hospital to assist or perform the surgery.

The extended team not present at weekly supra-network MDT meetings includes North Bristol NHS Trust plastic surgeons, vascular surgeons, a lymphoedema specialist service, psychosexual counselling service and palliative care service.

3.7 Core team members to present options to patients

The core team members from the supra-network penile cancer team who will present the options for surgery, chemotherapy or radiotherapy and other options are:

- David Dickerson (Surgeon)
- Aditya Manjunath (Surgeon)
- Amit Bahl (Oncologist)
- Amarnath Challapalli (Oncologist)
- Laura Anstee (CNS).

The patients who will require counselling on options from the core team members will be seen in clinic at Southmead Hospital, North Bristol Trust or Bristol Haematology and Oncology Centre. The sites which will deliver a radiotherapy and chemotherapy service are the Bristol Haematology and Chemotherapy Service in Bristol, Cheltenham Oncology Centre (GHNHSFT) and the Royal United Hospital in Bath. Chemotherapy only can be delivered in Weston Area Health Trust and Taunton and Somerset NHS Trust. The Peninsula network is also able to deliver chemotherapy and radiotherapy across a number of sites. Where possible and if appropriate, the supra-network MDT oncologists will refer patients to their local oncology service for chemotherapy and/or radiotherapy.

3.8 Facilities for patients

The supra-network centre for penile cancer at Southmead Hospital is equipped and staffed appropriately to provide the following:

- Dedicated Urology outpatients department with access to penile specialist team members
- Dedicated Urology wards
- Dedicated Urology theatres
- Urology oncology clinical nurse specialists
- Referral to local and regional Lymphoedema services
- Psychosexual counselling service
- Dedicated research team to facilitate patient involvement in penile cancer trials.

3.9 Waiting times position

Currently, there is a weekly penile cancer MDT meeting and all referrals are reviewed at the next MDT after receipt of the referral and relevant pathology specimens and imaging. These will be discussed and patients will be offered an appointment in the clinic after the MDT for assessment and to discuss and arrange supra network care.

The supra network surgeons have a total of 7 operating lists in a 2 week cycle at Southmead Hospital where penile cancer surgery can be performed. Dynamic sentinel node sampling in conjunction with nuclear medicine is performed every Monday. Patients will be offered a date for surgery within national cancer waiting times standards, unless patients request a later date (if clinically acceptable).

3.10 Guidelines on Staging of Penile Cancer

3.10.1 Introduction

For all tumours diagnosed after 1st January 2018 staging of penile cancer should now follow the TNM8 classification as outlined below:
In the case of multiple tumours, the tumour with the highest T category should be classified and the multiplicity or number of tumours should be indicated in parentheses, e.g. pT2 (m) or pT2 (5).

The new WHO classification uses only grades 1–3 in Squamous Cell Carcinoma. The grade given is that of the highest grade area of tumour seen irrespective of the percentage of tumour. Sarcomatoid differentiation should also be reported separately.

Use of the category Tx is to be avoided and the designation T… at least is preferable if full staging is not possible because of the nature of the specimen (e.g. small incision biopsies) or the presence of positive margins.

TNM 8 removes the need to substage penile tumours into T2a and T2b as tumours involving the Corpus Cavernosum are now T3. Urethral involvement is no longer regarded as a defining feature of staging. Inguinal lymph node metastasis with extracapsular extension is categorised as pN3 recognising the significant adverse effect of extracapsular spread on prognosis. Retroperitoneal lymph node metastases are classified as extra-regional nodal and therefore distant metastases which corresponds to the clinical course of the disease.

3.10.2 Tumours of the penis and foreskin

Primary tumour (T)

TX Primary tumour cannot be assessed
T0 No evidence of primary tumour
Tis Carcinoma in situ – Note terminology changed to penile intraepithelial neoplasia (PeIN –see later)
Ta* Non-invasive localised squamous cell carcinoma*
T1a Tumour invades subepithelial connective tissue** without lymphovascular invasion or perineural invasion and is not poorly differentiated (i.e. grade 3 or sarcomatoid)
T1b Tumour invades subepithelial connective tissue** with lymphovascular invasion or perineural invasion or is poorly differentiated
T2 Tumour invades corpus spongiosum with or without invasion of the urethra
T3 Tumour invades corpus cavernosum
T4 Tumour invades other adjacent structures

*Including verrucous carcinoma. The authors view is that the category Ta is to be used with care as these tumours are exceptionally rare and are not evidence based
**Glans: Tumour invades lamina propria.
Foreskin: Tumour invades dermis, lamina propria or dartos fascia.
Shaft: Tumour invades connective tissue between epidermis and corpora and regardless of location

3.10.3 Regional lymph nodes (N)

Clinical stage definition

cNX Regional lymph nodes cannot be assessed
cN0 No palpable or visibly enlarged inguinal lymph nodes
cN1 Palpable mobile unilateral inguinal lymph node
cN2 Palpable mobile multiple or bilateral inguinal lymph nodes
cN3 Palpable fixed inguinal nodal mass or pelvic lymphadenopathy, unilateral or bilateral

Pathologic stage definition

pNX Regional lymph nodes cannot be assessed
pN0 No regional lymph node metastasis
pN1 Metastasis in up to two regional lymph nodes

pN2 Metastases in three or more unilateral lymph nodes or bilateral inguinal lymph nodes
pN3 Extranodal extension of lymph node metastasis or pelvic lymph node(s), unilateral or bilateral

Distant metastasis (M)

M0 No distant metastasis (clinical category only)
M1 Distant metastasis – includes lymph node metastasis outside of the true pelvis in addition to visceral or bone sites

Anatomic stage/prognostic groups

Stage	**T**	**N**	**M**
0	Tis	N0	M0
	Ta	N0	M0
I	T1a	N0	M0
IIA	T1b	N0	M0
	T2	N0	M0
IIB	T3	N0	M0
IIIA	T1–3	N1	M0
IIIB	T1–3	N2	M0
IV	T4	Any N	M0
	Any T	N3	M0
	Any T	Any N	M1

3.10.4 Tumours of the male distal urethra

Tumours of the male distal urethra are predominantly squamous cell carcinoma (SCC). They demonstrate a similar pattern of behaviour to primary penile SCC including metastasis to the inguinal nodes in a stepwise fashion.
TNM classification applies to urethral cancer as a whole without separation of the male distal urethral tumours. It should be noted that the N categories differ considerably between urethral and penile tumours and extranodal spread is not a feature of the urethral N staging (i.e. there is no N3 category).

3.10.5 Primary tumour (T)

Urethra (male and female)

TX Primary tumour cannot be assessed
T0 No evidence of primary tumour
Ta* Non-invasive papillary, polypoid or verrucous carcinoma*
Tis Carcinoma in situ (PeIN)** or urothelial carcinoma in situ
T1 Tumour invades subepithelial connective tissue
T2 Tumour invades any of the following: corpus spongiosum, prostate or periurethral muscle
T3 Tumour invades any of the following: corpus cavernosum, beyond prostatic capsule, anterior vagina or bladder neck (extraprostatic extension)
T4 Tumour invades other adjacent organs (invasion of the bladder)

*The dataset authors' view is that the use of this category for verrucous carcinoma is to be avoided as it is not evidence based. This category includes non-invasive urothelial carcinomas but these are very rare in the distal urethra.
**The dataset authors recommend the use of the same terminology (PeIN) for squamous precancerous lesions of the distal urethra as in the penis.

3.10.6 Regional lymph nodes (N)

NX Regional lymph nodes cannot be assessed
N0 No regional lymph node metastasis
N1 Single regional lymph node metastasis in the inguinal region or true pelvis [perivesical, obturator, internal (hypogastric) and external iliac], or presacral lymph node
N2 Multiple regional lymph node metastasis in the inguinal region or true pelvis [perivesical, obturator, internal (hypogastric) and external iliac], or presacral lymph node

3.10.7 Distant metastasis (M)

M0 No distant metastasis*
M1 Distant metastasis

*This is a clinical category, not to be used in pathological reporting.

Table 3.10.8 Risk stratification of invasive penile cancer by grade and stage

Low Risk	Intermediate Risk	High Risk
G1pT1	G2pT1	G2pT2/pT3
		G3pT1 G3pT2 G3pT3
		All pT4 tumours

3.10.9 Premalignant penile lesions

Terminology describing the histological appearance of non-invasive penile cancer has changed with all cases grouped under the umbrella term of penile intraepithelial neoplasia (PeIN); either undifferentiated (uPeIN) or differentiated (dPeIN). This replaces previous terms such as carcinoma in situ (CIS) and eponymous names such as Bowen's disease. Undifferentiated PeIN has a higher correlation with HPV positivity which confers a better prognosis. Terminology change is recognised by the World Health Organisation (WHO). The diagnosis of PeIN is a histological one. Men with persistent red patches or maculopapular penile lesions should be offered a penile biopsy to rule out PeIN.

3.10.10 Primary Lesion

Detailed physical examination of the penis noting the size, nature and position of the primary tumour, if this is possible. A biopsy of the lesion is advisable when the diagnosis is unclear or in the presence of advanced disease (in cases where there is a tight phimosis a dorsal slit may be necessary to perform this*). Circumcision should be avoided in the presence of phimosis as outcomes of further surgery, in particular, organ sparing surgery with reconstruction can be compromised by skin loss*. Cytological scrapings are usually inadequate and under-stage the disease. The role of imaging the primary tumour is debatable. Routine penile MRI scanning is not essential; most tumours can be locally staged with clinical examination. Penile MRI scan should be reserved for cases where there is doubt about the ability to safely perform organ sparing surgery (OSS) or in morbidly obese/buried penis patients. If penile MRI is performed, it is only of value when done under artificial erection. There is no role for ultrasound of the penis.

3.10.11 Assessment of regional lymph nodes

Careful palpation of both groins for the detection of enlarged lymph nodes must be part of the initial physical examination of patients with penile cancer.

a) Impalpable nodes (Clinically negative, cN0)

In intermediate and high risk penile tumours (G2pT1 or greater) the risk of micro-metastatic disease in the inguinal nodes is at least 20%. Current imaging techniques are unreliable in in detecting micro-metastatic disease. Further diagnostic management of patients with impalpable lymph nodes should be guided by risk stratification of the primary penile tumour. Local stage, tumour grade and lymphovascular invasion are risk factors for predicting the likelihood of lymph node metastases.

Invasive lymph node staging in the form of Dynamic Sentinel Node Biopsy (DSNB) or Modified Inguinal Lymph Node Dissection (mILND) should be considered in patients at intermediate or high risk of lymphatic spread.

b) Palpable nodes (Clinically positive, cN+)

Palpable inguinal lymph nodes are highly suspicious for the presence of lymph node metastases. Physical examination should note the number of palpable nodes on each side and whether these are fixed or mobile. Image guided FNA or core biopsy of palpable nodes may provide additional information to support Radical Inguinal Lymph Node Dissection (rILND). Further inguinal imaging, however, does not alter management and is usually not required.

A staging CT Chest/Abdomen and Pelvis scan should be performed in order to assess the pelvic lymph nodes and for distant metastases. 18FDG-PET/CT has been reported to have a high sensitivity of 88-100% with a specificity of 98-100% for confirming metastatic nodes in patients with palpable inguinal lymph nodes (8,11). Although data does not currently support the widespread use of PET/CT scanning.

3.11 Guidelines on the Treatment of Penile Cancer

3.11.1 Treatment of non invasive disease (PeIN)

PeIN can be managed in a number of ways. PeIN of the foreskin is best managed by circumcision. PeIN of the glans penis can be managed by topical chemotherapy, laser treatment or surgical excision.
Small areas of PeIN on the glans or shaft skin of 2cm or less can be managed with topical treatment. Recommended first line treatment is with topical 5FU; the recommended treatment regime is alternate day application for 28 days and stop. Toxicity and adverse events of 5FU are relatively low but the efficacy is limited. Complete responses have been reported in up to 50% of cases of PeIN. Second line topical treatment is Imiquimod, an immunomodulator. Limited data exists for its use in PeIN however in data from 48 patients a 62.5% complete response was observed (6). Due to the high rate of persistence and/or recurrence, close and long-term surveillance of such patients is required. Topical treatment should only be considered in those men able to undergo close follow up. There is no data to support the repeated use of topical treatments if they fail.

Laser treatment, Photodynamic therapy and Moh's micrographic surgery can be used for PeIN. Studies report small numbers with short follow up. The main disadvantage of the laser and photodynamic therapy is the lack of histological tissue. In addition, since approximately 20% of patients with PeIN have underlying invasive disease, these treatments would be inadequate in these cases.

Alternatively, wide local excision, partial or total glans resurfacing can be offered as a primary treatment modality for PeIN, and as a secondary treatment in case of treatment failure with topical chemotherapy or laser therapy. For disease greater than 2cm in diameter surgical excision is recommended. Total glans resurfacing is a surgical technique which consists of complete dissection of the glanular epithelium off the underlying corpus spongiosum with covering by a split skin graft. With glans resurfacing for presumed non-invasive disease, up to 20% of patients are found to have superficial invasive disease and may therefore require further treatment.

3.11.2 Treatment of the Primary tumour

The aims of the treatment of the primary penile cancer lesion are complete tumour removal with as much organ preservation as possible, while radicality of the treatment should not be compromised. A local recurrence in itself has little influence on long-term survival so that organ preservation strategies are justified.

Penile preservation is superior in maintaining urinary and sexual function as well as having psychological benefit. This should be offered as the primary treatment modality to men with localised penile cancer if appropriate. However, there are no randomized studies comparing organ-preserving, radical surgery and ablative treatments. Large published series of organ sparing surgery have shown oncological safety.

There is limited data on functional outcomes in penile cancer surgery and sexual/urinary function PROM's are unvalidated in this group of patients. *Evidence Level 3 or less.*

Pre-treatment histological diagnosis is essential if considering non-surgical treatment. In clinically obvious tumours, primary surgery may be offered without prior histological diagnosis.

The treatment of the primary tumour and that of the regional nodes can be done as staged procedures if deemed to beneficial to the patient. In both cases, it is essential to remove all malignant tissue with negative surgical margins. Patients will be counselled about all relevant treatment modalities. There is a variety of local treatment modalities for small and localized penile cancer including excisional surgery, external beam radiotherapy, brachytherapy and laser ablation which are used to treat localized invasive disease. As previously stated, no randomised data is available comparing these treatment modalities.

3.11.3 Treatment of invasive disease confined to the glans (Ta/T1)

For small and localized invasive lesions penile preserving treatment is recommended. Prior to non-surgical treatment modalities, it is mandatory to obtain histopathological diagnosis by biopsy. Patients should be circumcised before considering non-surgical treatment modalities. *For tumours confined to the prepuce, radical circumcision alone may be curative* if negative surgical margins are confirmed by definitive histology. For all surgical treatment options, the intra-operative assessment of surgical margins by frozen section can be considered as tumour-positive margins can lead to local recurrence.

Wide local excision, partial or total glans resurfacing with skin graft reconstruction should be considered provided negative surgical margins can be achieved in Ta/T1 tumours of the glans. This preserves penile length and provides better functional outcomes.

Total removal of the glans (glanectomy) and prepuce with our without simultaneous glans reconstruction does have the lowest recurrence rate among the treatment modalities for penile tumours confined to the glans (2-10%). Negative surgical margins are imperative when using penile-conserving treatments and a margin of >1mm is considered oncologically safe. Treatment choice should depend on tumour size, histology including stage and grade, localization especially relative to the meatus, as well as patient preference given the lack of randomised data. Glans reconstruction should be discussed with all patients but may only be appropriate for those who are sexually active and fit enough to undergo the more complex surgery and post-operative care.

3.11.4 Treatment of invasive disease confined to the corpus spongiosum/glans/urethra (T2)

Total glansectomy, with or without glans reconstruction (partial thickness skin graft resurfacing of the corporal heads) is recommended. Glans reconstruction should be discussed with all patients but may only be appropriate for those who are sexually active and fit enough to undergo the more complex surgery and post-operative care. Radiotherapy is also an option however there is no randomised data comparing treatment modalities.

Intraoperative conversion to distal corporectomy/partial penectomy may be required to achieve oncological clearance and patients having glansectomy should be consented for this. Intraoperative frozen section may be required to assist decision making.

3.11.5 Treatment of disease invading the corpora cavernosa (T3)

Larger distal tumours involving the glans and extension in to the corporal heads can be managed with penile preserving surgery in most cases. Frozen section analysis of the margins of the resection can be used. *Partial amputation with a tumour-free margin +/- reconstruction is standard treatment*. A surgical margin of >1 mm is considered safe but patients should remain under close follow-up. Radiotherapy is an option. Sexual and urinary outcomes are expectedly worse after partial amputation than less radical surgery.

3.11.6 Treatment of locally advanced disease invading adjacent structures (T4)

These are relatively rare (Europe 5%, Brazil 13%) (6). Total penectomy with perineal urethrostomy is standard surgical treatment for some T3 and all T4 tumours. In more advanced disease (T4) neoadjuvant chemotherapy may be considered, followed by surgery in responders as in the treatment of patients with fixed enlarged inguinal nodes. Otherwise, palliative chemotherapy or palliative radiotherapy may be an option. Palliative total penectomy is occasionally performed for symptom control in advanced disease.

3.11.7 Local recurrence after organ-conserving surgery

Local recurrence occurs in 2-10% after wide local excision, glans resurfacing and glansectomy. A second organ-conserving procedure can be performed if clinically and radiologically, oncological clearance can be achieved. For large or high stage recurrence, partial or total amputation will be required. In patients undergoing total/subtotal amputation a total phallic reconstruction may be offered with referral to a centre undertaking this surgery.

3.11.8 Management of the Regional Nodes

The development of lymphatic metastases in penile cancer follows some anatomic rules. The inguinal and the pelvic lymph nodes are the regional drainage system of the penis. The superficial and deep inguinal lymph nodes are thereby the first regional nodal group reached by lymphatic metastatic spread (Daseler's zones). Spread to the inguinal lymph nodes can be uni- or bilateral from any primary penile cancer.

A single photon emission computed tomography (SPECT) study in penile cancer patients reported that all inguinal sentinel nodes were located in the superior and central inguinal zones, with most found in the medial superior zone. No lymphatic drainage was observed from the penis to the two inferior regions of the groin, and no direct drainage to the pelvic nodes was visualized. These findings confirm earlier studies. The second regional lymph node groups are the ipsilateral pelvic lymph nodes. Pelvic nodal disease does not seem to occur without ipsilateral inguinal lymph node metastasis, and cross-over metastatic spread from one inguinal side to the contralateral pelvic side has never been reported in penile cancer. Further metastatic lymph node spread from the pelvic nodes to para aortic and para caval nodes is outside the regional lymph node drainage system of the penis, and is therefore classified as systemic metastatic disease.

The management of regional lymph nodes is decisive for long-term patient survival. Cure can be achieved in metastatic disease confined to the regional lymph nodes. Lymphadenectomy is the treatment of choice for patients with inguinal lymph node metastases but multimodal treatment combining surgery and chemoradiotherapy is often indicated.

Management of the regional lymph nodes should be stage-dependent:

In clinically node-negative patients (cN0), there is a definite risk of micro-metastatic lymph node involvement in about 20% of cases which is related to local tumour stage and grade

- In clinically positive (palpable) lymph nodes (cN1/cN2), metastatic disease is highly likely and no time should be wasted on antibiotic treatment before surgical treatment
- With fixed inguinal lymph nodes (cN3), multimodal treatment by neoadjuvant chemotherapy and surgery may be indicated
- Capsular penetration leading to extranodal extension (ECS) in lymph node metastasis even if present in only one node carries a high risk of progression and is classified as pN3 which also requires multimodal treatment.

3.11.9 Management of patients with clinically normal (impalpable) inguinal lymph nodes (cN0)

Risk stratification for the management of patients with clinically normal lymph nodes depends on stage, grade and the presence or absence of lymphovascular invasion in the primary tumour.

Tumours with low risk of metastatic disease are those with superficial penile cancer (pTa, pTis) and low grade pT1 tumours represent a heterogeneous risk group: they can be considered low-risk if they are well differentiated (pT1G1), otherwise they represent an intermediate-risk group (pT1G2) or must be considered high risk (pT1G3) together with all higher stages.

Patients with intermediate or high risk penile tumour and cN0 inguinal nodes have at least a 20% risk of harbouring micro-metastatic disease in the inguinal nodes.

Several studies have shown that early inguinal lymphadenectomy in clinically node-negative patients is far superior concerning long-term patient survival compared to therapeutic lymphadenectomy when regional nodal recurrence occurs. One prospective study comparing bilateral lymphadenectomy, radiotherapy and surveillance in clinically node-negative patients reported that 5-year overall survival was significantly better with inguinal lymphadenectomy compared to immediate inguinal radiotherapy or that observed with a surveillance strategy (74% vs 66% and 63%, respectively).

a) Surveillance (Ta Gl, Tl Gl lesions)

Surveillance for the management of regional lymph nodes carries the risk of regional recurrence arising later from existing micrometastatic disease. Patient survival is over 90% with early lymphadenectomy and below 40% with lymphadenectomy for regional recurrence later. This definite risk must be taken into account when considering surveillance and the patient should be informed about this. Surveillance can only be recommended in patients with pTis and pTa penile cancer, and with the appropriate caveats in pT1G1 tumours. A prerequisite for surveillance is good patient information and compliance.

Patients who are advised or elect surveillance are followed up two to three monthly for the first year, four monthly for the second year and six monthly for the third year. Surveillance includes physical examination and ultrasound or CT/MRI examination with or without fine needle aspiration of the groins. The sensitivity of radiological tests in surveillance is relatively poor but could be used in those men whose groins are difficult to examine e.g in obesity.

b) Invasive nodal staging

Staging of the inguinal lymph nodes in cN0 penile cancer requires an invasive procedure since all imaging techniques (ultrasound, CT, MRI) are unreliable in excluding small and micro-metastatic lymph node involvement. While CT criteria other than size have been defined for the retrospective detection of lymph node metastases, these have not been validated prospectively. Nomograms are unreliable as their ability to predict the likelihood of lymph node involvement does not exceed 80%. Fine needle aspiration cytology does not reliably exclude micrometastatic disease (low specificity). Therefore, the pathological risk factors have to be used to stratify node-negative patients.

There are two invasive diagnostic procedures whose efficacy is evidence-based: modified inguinal lymphadenectomy and dynamic sentinel-node biopsy. Both are at present standard approaches for the invasive diagnosis of inguinal lymph nodes in node-negative patients.

- Modified inguinal lymphadenectomy (mILND) is the surgical approach defined by a limited template whereby the superficial inguinal lymph nodes from at least the central and both superior Daseler's zones are removed bilaterally and the greater saphenous vein is left in place
- Dynamic sentinel node biopsy (DSNB) is a technique based on the assumption that primary lymphatic drainage from a penile cancer goes to only one inguinal lymph node on each side which may however be in different locations based on individual anatomy.
- With both methods of invasive regional lymph node staging in cN0 patients, missing existing micrometastatic disease will lead to later regional recurrence with a dramatic deterioration in long-term survival. In experienced centres the sensitivity and specificity of DSNB is 94-97%. The false-negative rate of mILND is not known.
- The small risk of a false-negative result and its implications for the prognosis should be explained to the patient regardless of the method of invasive staging. If lymph node metastasis is found with either method, an ipsilateral completion radical inguinal lymphadenectomy is indicated.
- Patients should be considered for invasive lymph node staging based on their risk status. Patients in whom FNA, biopsy and/or dynamic sentinel lymph node study are positive should undergo ipsilateral radical inguinal node dissection.

3.11.10 Management of patients with palpable inguinal nodes (cN1/cN2)

With uni- or bilateral palpable inguinal lymph nodes (cN1/cN2), the likelihood is very high that metastatic lymph node disease is present. Therefore, the old clinical advice that antibiotic treatment should be given for several weeks because such lymph node enlargement might be related to infection no longer holds true. Instead, no time should be wasted with such unnecessary delays and appropriate oncological diagnosis and treatment should be undertaken before further metastatic spread occurs. In clinically doubtful cases, ultrasound-guided fine needle aspiration cytology is an option.

With palpably enlarged inguinal lymph nodes, additional staging investigations are not useful. Imaging by ultrasound, CT or MRI does not provide additional information about the inguinal lymph nodes except in very obese patients. However, CT or MRI can provide information about the pelvic nodal status. PET/CT can identify additional metastases in lymph-node positive patients. Dynamic sentinel node biopsy is not reliable in patients with palpably enlarged and suspicious inguinal lymph nodes and should not be used.

Patients in whom any of the investigative tests are histologically positive should have a radical inguinal node dissection.

Radical inguinal lymphadenectomy

In clinically lymph-node positive patients, surgical staging by inguinal lymphadenectomy is indicated. Intraoperative frozen sections may be used to confirm lymph node metastasis in which case an ipsilateral radical inguinal lymphadenectomy is required.

Radical inguinal lymphadenectomy carries a significant morbidity related to problems of lymph drainage from the legs and wound healing. Early and intermediate post-operative problems are dealt with earlier and a shorter length of stay occurs with utilisation of the Hospital at Home service. Morbidity can be as high as 70% in those with increased BMI and Sartorius muscle transposition. Skeletalising the femoral vessels is thought to be unnecessary with little to no lymph nodes present there. This has resulted in lower requirement for sartorius transposition. Therapeutic radical inguinal lymphadenectomy can be life-saving but it may be underused for fear of associated morbidity and is therefore carried out in the supra-regional centre.

Additional measures counteracting postoperative lymphatic stasis and leakage such as stockings, inguinal pressure dressings or vacuum suction as well as prophylactic antibiotics can reduce postoperative morbidity. In advanced cases, reconstructive surgery may be necessary for primary wound closure.

The feasibility of performing laparoscopic and/or robotic-assisted inguinal lymphadenectomy has been reported by several groups. Early reports suggest a reduction in wound problems but lymphoedema and other complications are unchanged.

3.11.11 Management of patients with fixed inguinal nodes (cN3)

The presence of metastatic disease in these cases is beyond doubt. Additional diagnostic measures do not alter the immediate management but staging by thoracic, abdominal and pelvic CT scan is indicated in order to assess the presence of further pelvic nodal disease and systemic metastatic disease.

In clinically unequivocal cases, histological verification by biopsy is not required. In rare cases with reasonable doubt, an excisional or core needle biopsy may be done.

These patients have a poor prognosis and are unlikely to be cured by surgery alone. Upfront surgery is often not possible. Surgery alone is non-curative and also usually quite destructive with the need for myo-cutaneous flap reconstruction. Multimodal treatment with neoadjuvant chemotherapy followed by radical lymphadenectomy in clinically responsive cases is recommended. In patients deemed unsuitable for radical lymphadenectomy, radiotherapy is an option. There is no head to head data to compare these two treatment methods. Responders to neoadjuvant chemotherapy with post-chemotherapy surgery have been reported to achieve long-term survival in 37% of cases. In some cases, there may be individualized reasons for upfront surgery followed by adjuvant treatment. Non responders to chemotherapy may be offered palliative radiotherapy to reduce the complications of fungation; in particular femoral blowout.

3.11.12 Management of patients after complete pathological inguinal node staging (pN+)

a) pN1 Disease

Patients with up to two positive nodes without extra-capsular extension should then be kept on surveillance. It is recommended that these patients have an initial staging CT Thorax/abdomen and pelvis and 1 surveillance scan at 6 months post inguinal lymphadenectomy. Subsequently clinical surveillance is adequate (see below). 5 year survival in pN1 disease is >75%.

b) pN2 Disease

Patients with 3 or more unilateral or bilateral positive inguinal nodes without extracapsular extension (ECS) are staged pN2. These patients should undergo an initial staging CT Thorax/abdomen and pelvis and be offered minimally invasive (robotic) pelvic lymph node dissection unless contraindicated. These patients should also be offered adjuvant chemotherapy +/- radiotherapy with 5FU, Cisplatin + Taxane (TPF). Adjuvant chemotherapy can improve disease free survival in pN2 and pN3 patients by up to 25% over surgery alone. 5 year survival in pN2 disease is around 60%.

c) pN3 Disease (Inguinal Nodes)

Patients with extracapsular spread (ECS) regardless of the number of lymph nodes involved are staged pN3. In addition those with radiological evidence of pelvic node involvement is considered pN3. These patients should be have an initial staging CT Thorax/Abdomen and Pelvis. They should be offered minimally invasive (robotic) pelvic lymph node dissection unless contraindicated. These patients should also be offered adjuvant chemotherapy +/- radiotherapy with 5FU, Cisplatin + Taxane (TPF). 5 year survival in pN3 disease is around 35%.

3.11.13 Management of pelvic lymph nodes

Patients with radiological and/or pathological evidence of pelvic node involvement have a worse prognosis compared to patients with only inguinal nodal metastases.

In a study of 142 node positive patients the significant risk factors for pelvic nodal metastasis are the number of positive inguinal nodes (cut-off 3), the diameter of inguinal metastatic nodes (cut-off 30 mm) and the presence of extra nodal extension. The proportion of pelvic nodal metastases was 0% in cases without any of these risk factors, and 57.1% when all three risk factors were present.

There is no direct lymphatic drainage from penile tumours to the pelvic lymph nodes, therefore pelvic lymph node dissection is not indicated if there is no involvement of inguinal nodes on that side, i.e there is no crossover from the groin to the contralateral pelvis.

For small volume disease on CT scan and those with pN2/pN3 inguinal node disease and normal pelvic nodes on CT scan consideration should be given for complete pelvic node dissection followed by adjuvant chemo-radiotherapy. Unless contraindicated, minimally invasive pelvic node dissection should be the gold standard. For patients with large volume disease at presentation, prognosis is very poor with a close to 0% three year survival. Surgery is optional and consideration should be given for primary chemo-radiotherapy.
Pelvic lymphadenectomy may be performed simultaneously or as a secondary procedure following definitive histology. If bilateral pelvic node dissection is indicated, it should be performed with a minimally invasive approach otherwise open surgery can be through a midline suprapubic extraperitoneal incision. It is important to avoid unnecessary delay if these procedures are indicated.

3.11.14 Management of lymph node recurrence

Patients with regional (inguinal or pelvic node) recurrence should be treated in the same way as patients with primary cN1, cN2 or cN3 disease. Patients with regional recurrence following negative invasive staging by DSNB or modified inguinal lymphadenectomy already have a disordered inguinal lymphatic drainage anatomy and must be considered at a high risk of irregular metastatic progression. Patients with inguinal nodal recurrence after therapeutic radical inguinal lymphadenectomy have been reported to have a 5-year cancer specific survival of 16%. *There is no evidence for the best management in such cases but multimodal treatment with neoadjuvant and/or adjuvant chemotherapy after radical lymph node surgery is advised.*

3.11.15 Delayed Presentation of metastatic inguinal nodes

In this situation ipsilateral radical inguinal node dissection is appropriate (assuming unilateral presentation). Assessment of the contra-lateral groin is sensible by DSNB but is usually not involved. Subsequent management depends on the pathological nodal stage.

3.11.16 Metastatic Disease (M+)

Palliative chemotherapy can be helpful to slow the progression of metastatic disease. There is no specific regime which is generally recognized. Cisplatin and 5 FU are used, though use of newer chemotherapy agents is being considered. Pulmonary metastases are the commonest site and chest CT should be offered in following up high-risk patients.

3.11.17 Clinical Trials

Two national and international trials are currently active/in development in Penile Cancer:
InPACT – Multicentre international randomised control trial evaluating the treatment of men with clinically positive inguinal node metastases. Patients are randomised to surgery or neoadjuvant chemotherapy with subsequent further randomisation possible in to InPACT Pelvis. The supra-regional penile cancer centre is due to join this trial.

1. Cemiplimab in Advanced SCC of the penis – Phase II trial of standard of care chemotherapy in combination with immunotherapy (cemiplimab) in locally advanced or metastatic penile cancer.

3.12 Follow-up

A post-surgical follow-up appointment will be offered at two to three weeks to check on progress, discuss the definitive histology and to plan further treatment. Due to the geographical distance from some referral centres to Bristol, patients may be offered follow up at their local hospital provided the local Urologists are happy to provide this.

The highest risk of local and regional recurrence is in the first 18 months and therefore follow up during this period will be at the penile cancer centre.

Table 12.1 -Follow up of patients with PeIN by treatment modality

Year	Topical /Ablative treatment only	Surgery	Surgery plus topical treatment
1	3 monthly	3 monthly	3 monthly
2	6 monthly	6 monthly	6 monthly
3	Discharge if recurrence free to self-examination	Discharge if recurrence free to self-examination	Annually to year 5

Table 12.2 -Follow up of invasive penile SCC patients with N0 disease

Year	Low Risk (G1pT1)	Intermediate Risk (G2pT1)	High Risk (all G3 and all pT2, pT3 and pT4)
1	3 monthly	3 monthly	3 monthly
2	6 monthly	4 monthly	3 monthly
3	Discharge to self examination	6 monthly	4-6 monthly
4		Annually	6 monthly
5+		Discharge to self examination	Annually to 10 years

Table 12.3 – Follow up of patients with Node positive disease

Year	pN1	pN2	pN3
1	3 monthly	3 monthly	3 monthly
2	4 monthly	3 monthly	3 monthly
3	6 monthly	6 monthly	4 monthly
4	As per risk category of primary tumour (see above)	6 monthly	6 monthly
5+		Annually	Annually

Table 12.4 – CT Chest/Abdomen/Pelvis scan follow up of Node positive patients following completion of treatment

Year	pN1	pN2	pN3
1	6 months only	3 months 6 months 12 months	3 months 6 months 12 months
2	-	24 months	18 months 24 months
3	-	-	36 months
4	-	-	-
5+	-	-	-

3.13 Operational policy for the Penile Cancer Supra- network Multidisciplinary Team (B14/S/b-16-006)

Background

This operational policy has been written to ensure that all members of the network/supra-network are aware of the purpose and organisation of the Supra-network Penile Cancer MDT and the scope of services offered by the multidisciplinary team at Southmead Hospital.

The document has been written in accordance with the national manual of Cancer Services standards and aims to encourage best practice in the management of patients with penile cancer.

Aims of the Operational Policy:

The aims are to ensure that all MDT members have a policy of agreed standards and process to provide quality care.

The objectives of the MDT are:

- To ensure that designated specialists work effectively together in teams such that decisions regarding all aspects of patient care for individual patients are based on review, discussion and agreement by the MDT
- To ensure that all decisions regarding operational policies are multidisciplinary decisions

- To ensure that care is given according to recognised guidelines and targets (including guidelines for onward referrals) with appropriate information being collected to inform clinical decision-making and to support clinical governance/audit
- To ensure that mechanisms are in place to support recruitment of eligible patients into clinical trials, subject to patients giving fully informed consent.

Membership and responsibilities

The Supra-Network Penile Cancer MDT is based at North Bristol Trust Southmead Hospital Network Cancer Centre and is incorporated into the SWAG network and centre MDT, providing care for all cases of penile cancer from the local catchment as well as for the network and supra-network and currently receives referrals from the following Networks:

- SWAG 2.1 million population
- Three Counties Network 1.3 million population
- Peninsula Network 1.7 million population

MDT Lead Clinician

Lead Clinician for the Supra-network Penile Cancer MDT will, within the constraints of the resources available, endeavour to:

- Ensure the objectives of MDT working (as laid out in Manual for Cancer Service Standards) are met
- Ensure that designated specialists work effectively together in teams such that decisions regarding all aspects of diagnosis, treatment and care of individual patients and decisions regarding the team's operational policies are multi-disciplinary decisions
- Ensure that care is given according to recognized guidelines (including guidelines for onward referrals) with appropriate information being collected to inform clinical decision-making and to support clinical governance/audit
- Ensure mechanisms are in place to support entry of eligible patients into clinical trials, subject to patients giving fully informed consent
- Take overall responsibility for ensuring that MDT meetings and team meet Peer Review Quality Measures
- Ensure that target of 100% is met for new penile cancer patients to be discussed at the MDT meeting
- Provide link to NSSG, either by attendance at meetings or by nominating another MDT member to attend
- Lead on, or nominate lead for service improvement
- Organise and chair annual meeting examining functioning of team and reviewing operational policies, and collate any activities that are required to ensure optimal functioning of the team (e.g. training for team members)
- Ensure that the outcomes of the meeting are clearly recorded and clinically validated and the appropriate data collection is supported
- Ensure targets of communicating MDT outcomes to referring team/clinician are met
- The development and co-ordination of the Supra-network Penile Cancer MDT and its activities. (Including the organisation of an annual meeting to review operational polices and team functionality, ensuring team attendance at meetings and maintaining effective multi-disciplinary working and decision-making processes)

- Ensure the MDT's activities are audited, case review is undertaken and the results documented.

Meetings

- The Specialist Penile Cancer / Supra-Network MDT meets weekly in Southmead Hospital every Wednesday afternoon with recorded attendance of the core and other key MDT members including oncologists, pathologists, radiologists, specialist nurses etc
- Core members or their deputies should achieve > 70% attendance
- The MDT will be represented by a team member at > two thirds of the NSSG meetings
- Attendance at MDT meetings will be audited annually and presented at the MDT AGM
- A record of the patients discussed, the source of the referral and the outcome of the discussion/treatment plan are kept and the outcome will be communicated to the referring clinician/team.

Currently the supra-network MDT discusses between 50-70 new penile cancer cases per year.

Referral of patients to MDT

Referrals from within the Local Network and the Supra-network are made via:

- Faxed/Email proforma to MDT co-ordinator (contact details, copy of proforma)
- Direct referrals to core members of MDT (letter, telephone, email) are discussed at next scheduled MDT Meeting. Relevant radiological investigations and pathology specimens should accompany or follow the referral to enable full review
- Two week wait referrals are not usually received directly by the supra- network MDT, however new suspected penile cancer referrals to the host centre are offered appointments and seen in accordance with the host centre's 2WW arrangements
- All new cases of penile cancer, recurrent disease, patients with lymph node metastasis or those with high risk of lymph node metastasis and surveillance imaging will be discussed at the MDT
- All relevant scans/x-rays and Pathology slides will be reviewed at the MDT and management/follow up recommendations made as per network guidelines
- Once decided, the management plan and outcome is fast tracked back to referring team/specialist/centre (proforma fax/email followed by letter)
- The patient will be offered an urgent outpatient appointment with a core member of the MDT to be assessed and arrange further management
- Surgical procedures will be carried out on the North Bristol Trust Southmead Hospital site unless the MDT deems it suitable that surgery could be carried out at the referring centre.
- Patients requiring primary chemotherapy/radiotherapy will be offered an Oncology appointment at their local Oncology centre by way of a referral letter to the local penile cancer oncologist
- Patients may be referred to specialist centres for total phallic reconstruction or where a core member is unable to provide specific treatment at the due time. Total phallic reconstruction is carried out at University College Hospital, London.

Patient Information

All patients meet with a member of the CNS team at the time of their outpatient appointment.
The MDT provides written information to patients including:

- Disease specific and treatment specific information
- Contact information (patient self-help groups, key worker, hospital, access to MDT).

For tertiary referral patients requiring surgery, every effort is made for them to have a pre-op assessment at the same time as their outpatient appointment.

Network Guidelines and Audit

The supra-network MDT will meet annually to discuss, develop, agree and approve:

- Supra-network guidelines including follow-up protocols
- Referral guidelines i.e. networks and supranetwork roles (i.e. who can do what, and the named referring teams) and referral to another team
- Minimum Data Set and who collects which portion (clerical - target times and clinical). Currently the supra-network MDT uses the dataset (incorporated into the MDT proforma) as agreed and used by the NSSG
- Audit projects and feedback from completed audits (minuted)
- The audited total number of annual penile cancer referrals, waiting times and surgical procedures by individual surgeons will be reported and minuted at the AGM.

Service Improvement

- MDT Lead is responsible for service improvement into MDT function and reporting to the AGM
- Process mapping covering key stages of the patient journey will be carried out annually and an action plan for service improvement produced for agreement and action by the MDT and NSSG service improvement leads
- Where necessary the service improvement lead will instigate a capacity/demand study to substantiate the service improvement action plan.

4. Appendices:

4.1 Appendix 1

Indications for PET/CT in Prostate cancer

PSMA is considered the first line PET tracer however the limited availability in the UK is recognised and choline/ fluciclovine may be used as an alternative as documented below:

PSMA PET/CT

Note most of the literature to date is based on 68Ga-labelled PSMA tracers, but some using 18F PSMA.

Biochemical Relapse post radical Prostatectomy

Offer PSMA PET in patients with biochemical recurrence after radical prostatectomy (PSA ≥0.2ng/mL) and if the results will influence subsequent treatment decisions.

Biochemical Relapse post radical prostatectomy & prostate bed radiotherapy

Offer PSMA PET in patients with biochemical recurrence (PSA ≥0.2ng/ml) after surgery and salvage radiotherapy where there is intent for further salvage therapy (e.g. SABR).

Biochemical Relapse post radical radiotherapy

Offer PSMA PET in patients with biochemical recurrence after radical radiotherapy/brachytherapy (PSA nadir + 2ng/ml) in patients fit for salvage local therapy (salvage prostatectomy). Note multi-parametric prostate MRI should be performed for local staging if PSMA PET shows no metastatic disease.

Non-metastatic castrate resistant prostate cancer (nmCRPC)

PSMA PET is not recommended routinely in patients with nmCRPC *as the clinical benefit and impact on management in detecting metastases with PSMA PET remains unclear.*

Metastatic Prostate Cancer

Patients being considered for 177 Lutetium-labelled PSMA-ligand therapy a PSMA PET should be performed. Consider paired FDG PET to optimise patient selection.

Staging in High risk Prostate cancer

Consider PSMA PET in selected patients with equivocal lesions on baseline conventional staging investigations where management will be directly influenced by the PSMA result or if there is a high clinical suspicion of occult metastatic disease and PSMA PET felt warranted at MDT.

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