Avon Somerset and Wiltshire Cancer Network Urological Cancer Clinical Care Guidelines

08-1A-207g	Network agreed guidelines for the management of kidney cancer
08-1A-208g	Network agreed guidelines for the management of bladder cancer
08-1A-209g	Network agreed guidelines for the management of prostate cancer
08-1A-210g	Network agreed guidelines for the management of T2, muscle invasive bladder cancer and organ-confined prostate cancer
08-1A-211g	Network/supra-network agreed guidelines for the management of testicular cancer - diagnosis and assessment
08-1A-212g	Network/supra-network agreed guidelines for the management of testicular cancer - referral to another team
08-1A-213g	Network/supra-network agreed guidelines for the management of testicular cancer - MDT discussion
08-1A-214g	Network/supra-network agreed guidelines for the management of testicular cancer - defining specialist/supra-network care
08-1A-215g	Network/supra-network agreed guidelines for the management of testicular cancer - referral of histology and radiology
08-1A-216g	Network/supra-network agreed guidelines for the management of penile cancer - diagnosis and assessment
08-1A-217g	Network/supra-network agreed guidelines for the management of penile cancer - defining specialist/supra-network care

July 2009

Avon, Somerset and Wiltshire NHS
Cancer Services

Reviewed July 2009

Mr Raj Persad on behalf of the ASWCS Urological Site Specialist Group

If you need further copies of this document please telephone ASWCS on 0117 900 2324

If you need this document in a different format please telephone ASWCS on 0117 900 2324

Contents

1 Background

This document outlines the clinical management guidelines for Urological Cancers, which includes: prostate, bladder, renal, testicular and penile cancers.

The Improving Outcomes Guidance for Urological Cancers was published in September 2002. The Network responded positively towards this IOG and proposed specialist teams for prostate, bladder, testicular and penile cancers, along with diagnostic and local care teams.

The Network Board has agreed the catchment populations for referral to each of the above teams. This should be a minimum of one million for specialist teams (unless there are locally agreed deviations from this target), two million for testicular cancer teams and four million for penile cancer teams. The Avon Somerset and Wiltshire Cancer Services (ASWCS) Network serves a population of 2.1 million and offers a supra-network service to both the Peninsula Network and the Three Counties Network.

2 NICE Referral Guidelines for Urological Cancer

2.1 General Recommendations

A patient who presents with symptoms or signs suggestive of urological cancer should be referred to a team specialising in the management of urological cancer, depending on local arrangements.

Referral for Suspected Cancer, a Clinical Practice Guideline. June 2005

http://www.nice.org.uk/nicemedia/pdf/CG027fullguideline.pdf

2.2 Specific Recommendations

2.2.1 Prostate Cancer

Patients presenting with symptoms suggesting prostate cancer should have a digital rectal examination (DRE) and prostate-specific antigen (PSA) test after counselling. Symptoms will be related to the lower urinary tract and may be inflammatory or obstructive.

Prostate cancer is also a possibility in male patients with any of the following unexplained symptoms:

- Erectile dysfunction;
- Haematuria;
- Lower back pain;
- Bone pain;
- Weight loss, especially in the elderly.

These patients should also be offered a DRE and a PSA test.

Urinary infection should be excluded before PSA testing, especially in men presenting with lower tract symptoms. The PSA test should be postponed for at least 1 month after treatment of a proven urinary infection.

If a hard, irregular prostate typical of a prostate carcinoma is felt on rectal examination, then the patient should be referred urgently. The PSA should be measured and the result should accompany the referral. Patients do not need urgent referral if the prostate is simply enlarged and the PSA is in the age-specific reference range.[1]

In a male patient with or without lower urinary tract symptoms and in whom the prostate is normal on DRE but the age-specific PSA is raised or rising, an urgent referral should be made. In those patients whose clinical state is compromised by other comorbidities, a discussion with the patient or carers and/or a specialist in urological cancer may be more appropriate.

Symptomatic patients with high PSA levels should be referred urgently.

If there is doubt about whether to refer an asymptomatic male with a borderline level of PSA, the PSA test should be repeated after an interval of one to three months. If the second test indicates that the PSA level is rising, the patient should be referred urgently.

2.2.2 Bladder and Renal Cancer

Male or female adult patients of any age who present with painless macroscopic haematuria should be referred urgently to a designated haematuria clinic.

In male or female patients with symptoms suggestive of a urinary infection who also present with macroscopic haematuria, investigations should be undertaken to diagnose and treat the infection before consideration of referral. If infection is not confirmed the patient should be referred urgently.

In all adult patients aged forty years and older who present with recurrent or persistent urinary tract infection associated with haematuria, an urgent referral should be made.

In patients under fifty years of age with microscopic haematuria, the urine should be tested for proteinuria and serum creatinine levels measured. Those with proteinurea or raised serum creatinine should be referred to a renal physician. If there is no proteinuria and serum creatinine is normal, a non-urgent referral to a urologist should be made.

In patients aged fifty years and older who are found to have unexplained microscopic haematuria, an urgent referral should be made.

Any patient with an abdominal mass identified clinically or on imaging that is thought to be arising from the urinary tract should be referred urgently.

[1] The age-specific cut-off PSA measurements recommended by the Prostate Cancer Risk Management Programme are as follows: aged 50−59 years ≥ 3.0 ng/ml; aged 60−69 years ≥ 4.0 ng/ml; aged 70 years and older ≥ 5.0 ng/ml. (Note that there are no age-specific reference ranges for men aged over 80 years. Nearly all men of this age have at least a focus of cancer in the prostate. Prostate cancer only needs to be diagnosed in this age group if it is likely to need palliative treatment.)

2.2.3 Testicular Cancer

Any patient with a swelling or mass in the body of the testis should be referred urgently.

An urgent ultrasound should be considered in men with a scrotal mass that does not transilluminate and/or when the body of the testis cannot be distinguished.

2.2.4 Penile Cancer

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 particularly, but can involve the skin of the penile shaft. Lumps within the corpora cavernosa not involving penile skin are usually not cancer but indicate Peyronie's disease, which does not require urgent referral.

3 Local Referral Guidelines for Urology Recommendations

Urgent suspected cancer referrals will be sent to the Trusts as detailed below by practices within each PCT.

Name of MDT/Host organisation	Referring PCT	Catchment Population 2009
North Bristol NHS Trust (NBT)	South Gloucester Bristol	261,300 100,000
Royal United Hospital Bath (RUH)	Bath and North East Somerset Wiltshire Somerset	178,300 158,952 55,000
Taunton and Somerset Hospital Trust (TST)	Somerset	356,066
Yeovil District Hospital NHS Foundation Trust (YDH)	Somerset	178,033
University Hospitals Bristol NHS Foundation Trust (UHB)	Bristol B&NES	325,100 19,554
Weston Area Health NHS Trust (WAHT)	North Somerset	213,600

4 Referral Guidelines for Specialist Urology MDT

The Specialist urology MDT for ASWCS is held weekly on Wednesday at 15.00 in the lecture theatre, Bristol Urological Institute, Southmead Hospital, Bristol. Minutes are appended for meetings over the last 18 months.

The MDT agrees appropriate treatment paths for all patients with cancer as defined in the Manual of Cancer Standards. The pathways along which particular patient subgroups are referred to and from the MDT are included below.

Cases for discussion are faxed to the MDT coordinator (Clare Wyatt) and outcomes from the MDT faxed back to local MDT coordinators within 24 hours.

Onward referral/action allocated to individual, currently on return to local hospital, but with MDT outcome copied to relevant e.g. oncologist.

Table defining patients for review at Specialist MDT (see also Tumour site guidelines).

Prostate Cancer	Bladder Cancer	Renal Cancer	Penile Cancer	Testicular Cancer
All organ confined, cancers (GI any T1-2) potentially curable by monotherapy	All T2/3 N0 M0 bladder cancers in patients fit for or wanting curative therapy	Complex renal tumours as defined by IOG - Nephron sparing and cryro partial cases, Vena caval involvement; laparoscopic cases have been discussed but as more surgeons become skilled in the procedure this is being undertaken as default for simple tumours.	All cases of penile cancer	All cases of testicular cancer are reviewed at a separate MDT
Tumours at high risk of local or lymph node disease on nomogram.	G3 Ta/1 cases either at presentation or after initial BCG course	Active surveillance patients		
Patients with recurrence after radical therapy.	All upper tract TCC	Patients with metastatic disease in whom nephrectomy prior to systemic therapy may be helpful		
Complex cases that have progressed for joint discussion.	Complex primary and secondary bladder tumours	Renal masses of uncertain diagnosis		

Testicular tumours are reviewed at a separate MDT as defined in the relevant guidelines.

4.1 Specialist MDT dates and timing

Review of 'rubberstamp' cases-organ confined prostate cancer.

1500-1600 Review of more complex cases.

1600-1630 (weeks 2,4) Guideline review/cancer site update/registrar presentation.

Network videoconferencing available.

4.2 Urology Multidisciplinary Team

There is one central specialist urological MDT within the Network, which meets every Wednesday afternoon at North Bristol Trust (Southmead Hospital) and is attended by key members from each of the Network referring Trusts. Taunton and Somerset Hospital, Royal United Hospital Bath and Yeovil District Hospital join via video link. The following table identifies the expected constitution of the centre MDT, which is self defined. Core membership will be determined by attendance, which is outlined in the standards:

"The MDT should meet weekly and record core members attendance, core members or their arranged cover should attend at least half of the meetings, members personal commitment is reflected in their attendance, not relying instead on their cover arrangements."

(Non- attendance at the central specialist MDT by a core team member will indicate that the member is not part of the specialist MDT and should therefore not be carrying out specialist urological cases).

MDT Member	Name	Organisation
Urologists	Ed Rowe	NBT
	David Gillatt	NBT
	Anthony Timoney	NBT
	Frank Keeley	NBT
	David Dickerson	WAHT/NBT
	Raj Persad	UH Bristol
	Mark Wright	UH Bristol
	Tim Whittlestone	UH Bristol
	Tim Porter	YDH
	Ru MacDonagh	TST
	Graham Howell	RUH
	John Macfarlane	RUH
	Rupert Beck	Swindon and Marlborough NHS Trust
Oncologists	Hugh Newman	RUH
	Paula Wilson	UH Bristol/BHOC
	Amit Bahl	UH Bristol/BHOC
	Serena Hilman	WAHT
	Mark Beresford	UH Bristol/BHOC
	John Graham	TST
Pathologists	John Oxley	NBT
	Chris Collins	UH Bristol
	Mohammed Sohail	UH Bristol
	Chandan Sen	NBT
Radiologists	Julian Kabala	UH Bristol
	Mike Thornton	NBT
	Andrew Mitchelmore	NBT
	Huw Roach	UH Bristol

Cancer Nurse Specialists	Miranda Benny	RUH
	Catherine Hurd	NBT
	Peter Gill	NBT
	Julia Hardwick	UH Bristol
Research Nurses	Karen Shelley	WAHT
	Sharon Tonkin	WAHT
	Helen Corderoy	NBT
MDT Co-ordinator	Clare Wyatt	NBT

5 Imaging Guidelines

NICE have produced a serious of Improving Outcomes Guidance (IOG) documents which are cancer disease site specific. They provide a framework for the consistent approach to the diagnosis, treatment and support of patients with suspected or confirmed cancer.

Compliance with IOG is tested through the process of External Peer Review. This is an audit process using standards (quality measures) defined in the Manual of Quality Measures (QMs). There are now specific QMs for radiology against which radiology departments will be externally audited at peer review.

In the newly revised Manual of QMs (May 2004), at a disease site-specific level, there is a requirement for network based site specialist groups (SSGs) to define:

- Imaging for diagnosis;
- Imaging for staging;
- Imaging for surveillance.

Both locally and nationally The Cancer Services Collaborative Improvement Project have identified that access to diagnostics (including radiology, pathology and endoscopy) represents the biggest bottleneck along the patient journey. Ironically, IOG recommendations have directly contributed to the problem. In the drive to achieve a networked/specialist approach to care, patients now frequently travel to hospitals around the ASWCS Network for different aspects of their overall care package. In common with other patients from other networks across the UK, patients are frequently investigated several times for the same thing in the different hospitals they attend on this journey. This causes unnecessary duplication of investigations contributing to the shortage of capacity. This common practice may also be at odds with recommendations set out in the IRMA regulations.

This guidance, proposed by the Network Imaging Group seeks to:

- Help SSGs, trusts, disease site multidisciplinary teams and the network to comply with IOG and QMs;
- Provide a framework for the consistent approach to diagnosis, staging and surveillance – end post code variations in practice;
- Assist radiology departments in controlling demand and manage capacity.

5.1 Haematuria

Diagnosis	Macroscopic	Renal US and plain film or CTU
	Microscopic – symptomatic (loin pain, frequency)	Flexible cystoscopy
	Without infection, age > 50 Yrs	IVU (if other investigations are normal). Consider CTU for persistent haematuria in over 50's.

5.2 Bladder Cancers

Staging	For patients deemed fit for radical surgery or other radical treatment	CT thorax abdomen and pelvis Bone scan – If clinically indicated
Surveillance		No routine imaging

5.3 Kidney Cancers

Diagnosis		US
Staging		CT thorax and abdomen MR – If IVC invasion seen on CT to clarify upper level
Surveillance	A. Post nephrectomy TCC B. Post nephrectomy Renal Cell Ca	A1. CT upper abdo and remaining kidney Perform at 6 months and at 3 years B1. CXR at 6/52 and 6/12 Then B2. CT abdomen at 1 year Then
Surveillance		B3. For T1 and T2: CXR 6 monthly for 3 years Then Yearly for 5 years B4. For T3 and T4 CXR and US 6 monthly for 3 years CT thorax and abdomen at 1 year and 3 years Then CXR yearly for 10 years B5. For partial nephrectomy CXR and US 6 monthly for 3 years and CT at 2 years Then CXR and US yearly for 10 years

5.4 Teratoma and Seminoma

Diagnosis		US
Staging		CT thorax abdomen and pelvis
Surveillance	A. TERATOMA: ONLY for patients who have a NEGATIVE pelvic staging CT B1. SEMINOMA: For patients who have received adjuvant treatment B2. SEMINOMA: For patients who have not received adjuvant treatment	A. CT chest and abdo Performed at 3, 6, 9, 12 and 24 months B1. CXR Performed 3 monthly for 1st year and then 6 monthly to 5 years B. B2. CT abdomen Performed at 3, 6, 9, 12 and 24 months

5.5 Prostate Cancer

Diagnosis	Only if fit for radical treatment or definite histological diagnosis needed	US TRUS (8-10 biopsies in 4 pots – minimum standard) (Gold standard = 8-12 biopsies in 8-12 pots)
staging	Radical treatment being considered and/or any of the following: • Gleeson 7 or above • PSA 10 or above • Bilateral disease or if ≥ 50% of biopsies taken are positive	MRI pelvis Bone scan
Surveillance		No routine imaging
Techniques	CT Abdomen +/- Pelvis MR Pelvis	• Oral and iv contrast • 10/10 axial scans, • 5/5 if multislice • Include liver • Image on lung, mediastinal and abdominal windows • Axial T1 and T2 5 mm whole pelvis • Axial T2 3 mm prostate • Coronal T2 3 mm prostate • Sagittal T2 4 mm whole pelvis

6 Pathology Guidelines

The network guidelines for the examination and reporting of urological cancer specimens take into account the following publications:

- Minimum datasets for histopathology reporting of urological cancers. The Royal College of Pathologists. www.rcpath.org or http://www.rcpath.org/index.asp?PageID=254;
- TNM classification of malignant tumours (6 edition). UICC (2002);
- WHO Classification of Tumours. Pathology and Genetics of tumours of the urinary system and male genital organs. IARC Press: Lyon 2004.

The Pathologist plays a central role in the diagnosis and staging of urological cancers. The information in their reports can help in the planning of future treatment of the patient.

All cancer cases should be reviewed by a cancer multi-disciplinary team, which has a Histopathologist as a core member. There should be a nominated lead pathologist for the service but all pathologists reporting urological cancer specimens should participate in the MDT meetings, in an appropriate EQA scheme and in local audit (including an assessment of consistency of reporting as appropriate to the site).

Specimens should be reported within an agreed time frame so as to allow appropriate clinical decision making at a planned MDT meeting.

Specimen Types:

- Prostate: Core biopsies, TURP chippings, radical prostatectomies.
- Bladder: Urine cytology, cystoscopic biopsies, cystectomies.
- Ureter: Cystoscopic biopsies, cytology, nephrouretectomy.
- Renal: Transcutaneous core biopsies, partial/complete nephrectomy.
- Testis: Testicular biopsies, orchidectomy.
- Penis: biopsy, partial/complete penectomies.

Specimen examination:

The local protocol for specimen examination should take into account national guidelines and should be regularly reviewed and updated by the lead pathologists in consultation with other pathologists who participate in the service delivery.

Grading and staging of urological tumours:

Tumour grading:

- Prostate: Gleason scores should be given for all cancers (apart from those undergoing hormone/radiotherapy treatment as the Gleason score has been shown to be unreliable);
- Bladder/Ureter: The recent WHO grading system has not been widely accepted and it is advisable to continue using the 1973 system (Grades 1-3) in combination with the new system (if local clinicians request this);
- Renal: Clear cell tumours – Fuhrmann grading system (Grades 1-4);
- Testis: No grading is used;

- Penis: Usually squamous cell carcinomas graded as well, moderate or poorly differentiated.

Tumour staging:

TNM classification of malignant tumours (6th edition).

Use of ancillary laboratory techniques:

All laboratories providing a pathology service in the network must have at least conditional CPA accreditation and ensure participation in an appropriate EQA programme, which demonstrates satisfactory laboratory performance.

A wide range of immunohistochemical markers are available within the network. Those which are often used in the reporting of urological tumours include:

- High molecular weight cytokeratin (for basal cell layer marking in prostatic biopsies);
- P506S/AMACR (a marker highlighting prostatic adenocarcinomas);
- PSA (used to confirm prostatic origin);
- EMA, vimentin, AE 1/3 CK7 and CD117 (classification of renal tumours);
- Electron microscopy is also useful in differentiating renal oncocytomas from eosinophilic renal cell carcinomas;
- Small biopsies sectioned at multiple levels should yield adequate numbers of spare sections to allow immunostaining of tumour if required;
- It is advisable to keep immunospares on levels of prostatic cores as small atypical foci may not be represented in all levels.

Audit

All pathologists reporting urological cancer specimens should participate in a relevant EQA scheme and local audits (including an assessment of consistency where more than one pathologist participates in service provision). The audits should include:

- Review of compliance with procedures for specimen examination and reporting.
- Completeness of minimum datasets.
- Diagnostic agreement/disagreement during review of cases for MDTs.
- Review of diagnostic consistency between pathologists using data from cases in EQA circulation or blind circulations.

The results of the audit process should be discussed with all pathologists who participate in service delivery.

Referral for review or specialist opinion:

NICE recommends that diagnostic biopsies are reviewed in the hospital where any definitive surgery is to be carried out.

Minimum dataset for reporting:

These are based on the minimum dataset for histopathology reports as published by the Royal College of Pathologists (http://www.rcpath.org/index.asp?PageID=254). These have recently been updated and the prostate datasets are due to be published shortly.

Appendix A: Prostate (published April 2000 due to be revised in 2009)
Suggested changes to prostate datasets:

Volume estimation in cores: It is desirable to comment on the volume of tumour in the core biopsies as well as the numbers of cores involved. There is a difference in management of a patient with four cores involved with only 10% as opposed to 80%. Whether the volume is expressed as a percentage or as a length of core involved is debatable and can be agreed between the clinician and pathologist.

Extraprostatic extension – the presence of tumour in fat or around a ganglion in a core biopsy indicates extracapsular extension and surgery would not be curative in these patients.

Seminal vesicle invasion – this is difficult to accurately assess as the ejaculatory ducts have similar epithelium but are intraprostatic.

Perineural invasion: The presence of this in core biopsies is debated and some clinicians will not perform nerve sparing surgery if this is present, though there is divided evidence on this.

Circumferential margin in radical prostatectomies: These can be split into inside (intraprostatic) and outside (extraprostatic) the capsule and have been shown to be different in terms of recurrence. Further oncological therapy is likely to separate these two margins.

Appendix B: Bladder biopsy (revised Jan 2007)
Appendix C: Cystectomy (revised Jan 2007)
Appendix D: Adult kidney (revised Nov 2006)
Appendix E: Renal pelvis (revised Jan 2007)
Appendix F: Urethra (revised Jan 2007)
Appendix G: Testis (revised Oct 2007)
Appendix H: Penis (revised Nov 2006)

Appendix A: Prostate datasets – due to be revised in 2009

PROSTATE BIOPSY TUMOUR HISTOPATHOLOGY REPORT

Surname ..... Forenames ..... Date of birth ..... Sex.....

Hospital ..... Hospital No ..... NHS No .....

Date of request ..... Date of reporting..... Report No.....

Pathologist ..... Surgeon .....

PSA (if known) .....

TYPE OF SPECIMEN

Needle biopsy □ Number of cores sent .....

TURP □ Weight ..... g

HISTOLOGY

Adenocarcinoma present: Yes □ No □

High grade PIN present: Yes □ No □

Gleason score (largest %age first) .....

Number of chips containing tumour .....

For needle biopsy Right 1 Tumour present Yes □ No □

Right 2 Tumour present Yes □ No □

Right 3 Tumour present Yes □ No □

Left 1 Tumour present Yes □ No □

Left 2 Tumour present Yes □ No □

Left 3 Tumour present Yes □ No □

Invasion into seminal vesicle: Yes □ No □

Other histological features Acute inflammation □

Chronic inflammation □

Other tumour □ Please specify .....

PATHOLOGIST

Signature:..... Date:..... SNOMed codes:.....

RADICAL PROSTATECTOMY TUMOUR HISTOPATHOLOGY REPORT

Surname ..... Forenames ..... Date of birth ..... Sex.....

Hospital ..... Hospital No ..... NHS No .....

Date of request ..... Date of reporting..... Report No.....

Pathologist ..... Surgeon .....

GROSS DESCRIPTION

PSA (if known) .....

Weight ..... g Size ..... x ..... x ..... mm

HISTOLOGY

Adenocarcinoma present: Yes ☐ No ☐

Other tumour (including high grade PIN) .....

Gleason score .....

1 STAGING

Confined to prostate pT2 ☐ Extraprostatic extension pT3 ☐

Circumferential margin involved Yes ☐ No ☐

Apical margin involved Yes ☐ No ☐

Base margin involved Yes ☐ No ☐

Invasion of seminal vesicles Yes pT3b ☐ No ☐

Lymph nodes sent Yes ☐ No ☐

Lymph nodes contain tumour Yes ☐ No ☐

Other pathology.....

PATHOLOGIST

Signature:..... Date:..... SNOMed codes:.....

Appendix B: BLADDER BIOPSY TUMOUR HISTOPATHOLOGY REPORT

Surname ..... Forenames ..... Date of birth ..... Sex.....

Hospital ..... Hospital No ..... NHS No .....

Date of request .....Date of reporting..... Report No.....

Pathologist ..... Surgeon .....

Type of specimen: TURBT ☐ Biopsy ☐ Number of sites: .....

Histological type of tumour: Urothelial ☐ Squamous ☐ Adenocarcinoma ☐

Other ☐ specify.....

Growth pattern Papillary ☐

Invasive ☐

Flat in-situ only pTis ☐

Grade 1 ☐ 2 ☐ 3 ☐

Depth of invasion

Muscularis propria present: Yes ☐ No ☐

No invasion pTa ☐

Into lamina propria pT1 ☐

Into muscularis propria pT2a at least ☐

Flat in-situ Carcinoma in adjacent urothelium Yes ☐ No ☐

1.1 Biopsies of non-tumourous urothelium

Site	Benign	Epithelium absent	Atypical	CIS

Urothelial tumour extension into prostate: Yes ☐ No ☐

In urethra ☐ In prostatic ducts ☐ Stromal invasion ☐

Pathological Classification G..... pT.....

Pathologist:

Name ..... Signature .....
Date..../...../..... SNOMED T/M

APPENDIX C: URINARY BLADDER

Surname…… Forenames…… Date of birth…… Sex….
Hospital…… Hospital no…….. NHS no……..
Date of receipt…… Date of reporting…….…..... Report no…….
Pathologist…….. Surgeon……

2 NATURE OF SPECIMEN/PROCEDURE AND CORE MACROSCOPIC ITEMS

Biopsy ☐ **TURBT** ☐ **Diverticulectomy** ☐ **Partial cystectomy** ☐ **Radical cystectomy** ☐

Site(s) of biopsy or TURBT…….. **Tumour location……..**
Weight of TURBT……..(g) **Maximum tumour size ……(mm)**
Number of tumours……

Right obturator nodes **Yes** ☐ **No** ☐ **Left obturator nodes** **Yes** ☐ **No** ☐
Right pelvic nodes Yes ☐ No ☐ **Left pelvic nodes** **Yes** ☐ **No** ☐
Invasion into perivesical tissue (pT3b) **Yes** ☐ **No** ☐ **Cannot assess** ☐
Margins **N/A** ☐ **Negative** ☐ **Positive** ☐
Distance to the nearest margin ……(mm) **Site(s)……**

3 CORE MICROSCOPIC ITEMS

Tumour subtype(s) (one or more)

- **Urothelial carcinoma** ☐
- **Squamous carcinoma** ☐
- **Adenocarcinoma** ☐
- **Small cell carcinoma** ☐
- **Sarcomatoid carcinoma** ☐
- **Sarcoma** ☐
- **Other:** ☐

Please specify:……

For urothelial carcinomas:

WHO 1973		WHO 2004	
Grade 1	☐	**Low grade**	☐
Grade 2	☐		
		High grade	☐
Grade 3	☐		

Associated CIS Yes ☐ No ☐
Vascular invasion Yes ☐ No ☐

Carcinoma in situ only (pTis)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Non-invasive papillary tumour (pTa)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into lamina propria (pT1)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into inner half of muscle (pT2a)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into outer half of muscle (pT2b)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Microscopic invasion into perivesical tissue (pT3a)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into perivesical tissue confirmed	**Yes**	☐	**No**	☐	**Cannot assess** ☐

(pT3b) **(pTx)**

Invasion into prostate, uterus or vagina (pT4a) **Yes** ☐ **No** ☐ **Cannot assess (pTx)** ☐

Invasion into pelvic or abdominal wall (pT4b) **Yes** ☐ **No** ☐ **Cannot assess (pTx)** ☐

Margins **N/A** ☐ **Negative** ☐ **Positive** ☐

Distance to the nearest margin ……(mm) **Site(s)……**

Right nodes	**Total**	**No pos**	**ECS**		**Left nodes**	**Total**	**No pos**	**ECS**	
Obturator				**N/A** ☐	Obturator				**N/A** ☐
Pelvic				N/A ☐	Pelvic				N/A ☐
Other:				**N/A** ☐	**Other:**				**N/A** ☐
Please specify…….					**Please specify…….**				

pTNM stage: pT …… pN…… pM……. **SNOMED codes T…….. M…….**

Signature of pathologist…… Date……..……..

APPENDIX D. REPORTING PROFORMA FOR ADULT RENAL CARCINOMAS

Surname……………………… Forenames……………………… Date of birth………… Sex….
Hospital……………………… Hospital no…………………….. NHS no……………....
Date of receipt………………. Date of reporting……………..... Report no…………….
Pathologist……………………... Surgeon……………………….

Nature of specimen and core macroscopic items

Right kidney □ Left kidney □ Partial □ Radical □ Open □ Laparoscopic □
Adrenal present Yes □ No □ Adjacent organs present Yes □ No □
Nodal dissection Yes □ No □
Maximum tumour size ……………(mm) Tumour location…………………..
Invasion into the renal vein(s) or vena cava below the diaphragm
Yes □ No □ Cannot assess □
Invasion into the vena cava above the diaphragm Yes □ No □ Cannot assess □

Core microscopic items

Conventional (clear cell) □ Differentiation Grade 1 □
Papillary (chromophil) □ Grade 2 □
Chromophobe □ Grade 3 □
Collecting duct □ Grade 4 □ And sarcomatoid □
Unclassified □
Other: □ Coagulative tumour necrosis Yes □ No □
Tumour subtype
Please specify………………… Microvascular invasion Yes □ No □
Tumour 4cm or less, limited to the kidney (pT1a) □ No □ Cannot assess (pTx) □
Tumour 4.1 to 7cm, limited to the kidney (pT1b) □ No □ Cannot assess (pTx) □
Tumour more than 7cm, limited to the kidney (pT2) □ No □ Cannot assess (pTx) □
Direct invasion into perinephric fat (pT3a) □ No □ Cannot assess (pTx) □
Direct invasion into renal sinus fat (pT3a) □ No □ Cannot assess (pTx) □
Direct invasion into adrenal (pT3a) □ No □ Cannot assess (pTx) □
Confirmation of gross invasion into the renal vein or its segmental tributaries or the vena cava below the diaphragm (pT3b)
□ No □ Cannot assess (pTx) □
Confirmation of gross invasion into the vena cava above the diaphragm (pT3c) □ No □ Cannot assess (pTx) □
Direct invasion into Gerota's fascia (pT4) □ No □ Cannot assess (pTx) □
Margins Negative □ Positive □
Distance to the nearest margin ………(mm) Site(s)……………….
Nodes Total Number positive N/A □

pTNM stage: pT ……… pN……… pM…….

SNOMED codes

T……………….. M…………………
T……………….. M…………………

Signature of pathologist. …………………………. Date……………………..

APPENDIX E: RENAL PELVIS AND URETER

Surname…… Forenames…… Date of birth…… Sex….
Hospital…… Hospital no…….. NHS no……..
Date of receipt…… Date of reporting…….…..... Report no…….
Pathologist……..…….. Surgeon……..……

4 NATURE OF SPECIMEN/PROCEDURE AND CORE MACROSCOPIC ITEMS

Biopsy ☐ **Right ureter** ☐ **Left ureter** ☐ **Right nephroureterectomy** ☐ **Left nephroureterectomy** ☐

Site(s) of biopsy ……..

Tumour location ……..
Number of tumours……
Maximum tumour size ……(mm)

Nodes Yes ☐ **No** ☐

Please specify origin……

Margins N/A ☐ **Negative** ☐ **Positive** ☐

Distance to the nearest margin ……(mm)

Site(s)……

5 CORE MICROSCOPIC ITEMS

Tumour subtype(s) (one or more)

- **Urothelial carcinoma** ☐
- **Squamous carcinoma** ☐
- **Adenocarcinoma** ☐
- **Small cell carcinoma** ☐
- **Sarcomatoid carcinoma** ☐
- **Sarcoma** ☐
- **Other:** ☐

Please specify:……

For urothelial carcinomas:

WHO 1973		WHO 2004	
Grade 1	☐	**Low grade**	☐
Grade 2	☐		
		High grade	☐
Grade 3	☐		

Associated CIS Yes ☐ No ☐

Vascular invasion Yes ☐ No ☐

Carcinoma in situ only (pTis)	**Yes**	☐	**No**	☐	**Cannot assess(pTx)** ☐
Non-invasive papillary tumour (pTa)	**Yes**	☐	**No**	☐	**Cannot assess(pTx)** ☐
Invasion into subepithelial connective tissue (pT1)	**Yes**	☐	**No**	☐	**Cannot assess(pTx)** ☐
Invasion into muscularis (pT2)	**Yes**	☐	**No**	☐	**Cannot assess(pTx)** ☐
(Renal pelvis) Invasion into renal peripelvic fat or renal parenchyma (pT3)	**Yes**	☐	**No**	☐	**Cannot assess(pTx)** ☐

(Ureter) Invasion into periureteric fat (pT3) Yes ☐ No ☐ Cannot assess(pTx) ☐

Invasion into adjacent organs or through kidney to perinephric fat (pT4) Yes ☐ No ☐ Cannot assess(pTx) ☐

Margins N/A ☐ Negative ☐ Positive ☐
Distance to the nearest margin ……(mm) **Site(s)……**

Nodes N/A ☐ **Total** **No positive** **ECS** Yes ☐ No ☐

Origin:
pTNM stage: pT …… pN…… pM……. SNOMED codesT……..
M……Signature of pathologist……
Date……..

Appendix F: Reporting Proforma: Urethra

Surname…… **Forenames……..…** **Date of birth……**
Sex….
Hospital…… **Hospital no……...** **NHS no……....**
Date of receipt…… **Date of reporting……..…....** **Report no…….**
Pathologist……... **Surgeon……**

6 NATURE OF SPECIMEN/PROCEDURE AND CORE MACROSCOPIC ITEMS

Biopsy ☐ **TURT** ☐ **Diverticulectomy** ☐ **Urethrectomy** ☐
Site(s) of biopsy or TURT…….. **Tumour location……..**
Weight of TURT……(g) **Number of tumours……..**
Maximum tumour size ……(mm)

Nodes **Yes** ☐ **No** ☐
Please specify origin……

Margins **N/A** ☐ **Negative** ☐ **Distance to the nearest margin ……(mm)** **Positive** ☐ **Site(s)……**

7 CORE MICROSCOPIC ITEMS

Tumour subtype(s) (one or more)

- **Urothelial carcinoma** ☐
- **Squamous carcinoma** ☐
- **Adenocarcinoma** ☐
- **Small cell carcinoma** ☐
- **Sarcomatoid carcinoma** ☐
- **Sarcoma** ☐
- **Other:** ☐

Please specify:……

For urothelial carcinomas:

WHO 1973		WHO 2004	
Grade 1	☐	**Low grade**	☐
Grade 2	☐		
		High grade	☐
Grade 3	☐		

Associated CIS Yes ☐ No ☐

Vascular invasion Yes ☐ No ☐

Carcinoma in situ only (pTis, add pu or pd if prostatic urethral or ducts)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Non-invasive papillary tumour (pTa)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into subepithelial connective tissue (pT1)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into corpus spongiosum, prostate, periurethral muscle (pT2)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into corpus cavernosum, beyond prostatic capsule, anterior vagina, bladder neck (pT3)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐
Invasion into other adjacent organs (pT4)	**Yes**	☐	**No**	☐	**Cannot assess (pTx)** ☐

Margin **N/A** ☐ **Negative** ☐ **Positive** ☐

s

Distance to the nearest margin ……(mm) **Site(s)……**

Nodes **N/A** ☐ **Total** **No positive** **ECS** **Yes** ☐ **No** ☐

Origin:

pTNM stage: pT …… pN…… pM……. **SNOMED codes T…….. M…….**

Signature of pathologist…… Date……..……..

APPENDIX G: REPORTING PROFORMA FOR TESTICULAR CANCER

Surname……………………….Forenames……………………. Date of birth………… Sex….
Hospital………….…………… Hospital no…………………... NHS no……………....
Date of receipt……………..….Date of reporting…………..….... Report no…………….
Pathologist……….…………...Surgeon………………………

8 NATURE OF SPECIMEN/PROCEDURE AND CORE MACROSCOPIC ITEMS

Biopsy ☐ Right ☐ Left ☐ Orchidectomy ☐ Right ☐ Left ☐ Partial ☐ Retroperitoneal lymph node dissection ☐

Maximum tumour size ……………(mm) Tumour location …………………..
Nodes Yes ☐ No ☐
Please specify origin……………
Surgical margins Negative ☐ Positive ☐ Site(s)………………
Distance to the nearest margin …….(mm)

9 CORE MICROSCOPIC ITEMS

Tumour type/s (one or more)	**Germ cell tumour**	☐	**Non germ cell**	☐
	Classical seminoma	☐	Leydig cell tumour	☐
	Spermatocytic seminoma	☐	Sertoli cell tumour	☐
	Undifferentiated teratoma/embryonal carcinoma	☐	Undifferentiated sex cord/stromal	☐
	Yolk sac tumour	☐	Other	☐
	Malignant teratoma trophoblastic/choriocarcinoma	☐	Please specify:…………………………	
	Teratoma differentiated/teratoma	☐		
	Other	☐		
	Please specify:………………………………………			

No evidence of primary tumour (e.g. scar in testis, pT0)	Yes	☐	No	☐
Intratubular germ cell neoplasia only (pTis)	Yes	☐	No	☐
Tumour limited to testis/epididymis without vascular invasion, invasion of tunica albuginea but not vaginalis (pT1)	Yes	☐	No	☐
Tumour limited to testis/epididymis but tunica vaginalis involvement (pT2)	Yes	☐	No	☐
Tumour limited to testis/epididymis with vascular invasion (pT2)	Yes	☐	No	☐
Tumour invades spermatic cord with or without vascular invasion (pT3)	Yes	☐	No	☐
Tumour invades scrotum with or without vascular invasion (pT4)	Yes	☐	No	☐

Margins N/A ☐ Negative ☐ Positive ☐ Site(s)………………
Distance to the nearest margin …….(mm)

BTTP classification If seminoma, invasion into rete Yes ☐ No ☐
pTNM stage: pT ……… pN……… pM……. SNOMED codesT……M…………………
Signature of pathologist………………………………….. Date…………………………

APPENDIX G: Reporting proforma for Carcinomas of the Penis

Surname……Forenames……..… Date of birth…… Sex….
Hospital…….…… Hospital no……..... NHS no……....
Date of receipt……..……Date of reporting……..…..... Report no…….
Pathologist……..……...Surgeon…….……

10 NATURE OF SPECIMEN/PROCEDURE AND CORE MACROSCOPIC ITEMS

Biopsy ☐ Circumcision ☐ Wedge resection ☐ Glansectomy ☐ Partial penectomy ☐ Total penectomy ☐
Biopsy site(s):…… Other specimen type:……..
Node(s) (please specify):

Maximum tumour size ……(mm) Number of tumours:
Tumour location: Foreskin ☐ Sulcus ☐ Glans ☐ Shaft ☐ Multiple ☐

Margins N/A ☐ Negative ☐ Positive ☐
Distance to the nearest margin ……(mm)
Site(s)……

11 CORE MICROSCOPIC ITEMS

Tumour subtype	Squamous carcinoma, usual type	☐	Differentiation	Grade 1	☐
	Papillary squamous carcinoma	☐		Grade 2	☐
	Basaloid squamous carcinoma	☐		Grade 3	☐
	Warty squamous carcinoma	☐	Associated carcinoma in situ	Yes ☐	No ☐
	Verrucous squamous carcinoma	☐	Vascular invasion	Yes ☐	No ☐
	Sarcomatoid squamous carcinoma	☐	Margins clear	Yes ☐	No ☐
	Other: Please specify……	☐	If no, specify margins involved: ……..		

Carcinoma in situ only (pTis)	Yes ☐	No ☐	Cannot assess	☐
Invasion into lamina propria (pT1)	Yes ☐	No ☐	Cannot assess (pTx)	☐
Invasion into corpus spongiosum (pT2)	Yes ☐	No ☐	Cannot assess (pTx)	☐
Invasion into corpus cavernosum (pT2)	Yes ☐	No ☐	Cannot assess (pTx)	☐
Invasion into urethra or prostate (pT3)	Yes ☐	No ☐	Cannot assess (pTx)	☐
Invasion of adjacent organs (pT4)	Yes ☐	No ☐	Cannot assess (pTx)	☐

Node type, right	Total	No. positive	N/A	Node type, left	Total	No. positive	N/A
Sentinel/Cloquet's			☐	Sentinel/Cloquet's			☐

Superficial inguinal			☐	Superficial inguinal			☐
Deep inguinal			☐	Deep inguinal			☐
Pelvic			☐	Pelvic			☐

Extracapsular spread	Yes	☐	No	☐	N/A	☐

pTNM stage: pT …… pN…… pM……. SNOMED codes: T..…... M……

Signature of pathologist…… Date……..……..

7 Treatment and Follow Up Guidelines

7.1 Management of Prostate Cancer

7.1.1 Introduction

These guidelines are based on those produced by the European Association of Urology March 2007
http://www.uroweb.org/fileadmin/tx_eauguidelines/Prostate%20Cancer.pdf

Cancer of the prostate is now recognized as one of the principal medical problems facing the male population. In Europe, an estimated 2.6 million new cases of cancer are diagnosed each year. Prostate cancer constitutes about 11% of all male cancers in Europe, and accounts for 9% of all cancer deaths among men within the European Union.

By the time of diagnosis, only 55% of tumours are clinically localized in the absence of an organized screening programme. Even in modern series, 30–45% of patients with clinically localized disease are found to have extracapsular extension at pathological staging.

7.1.2 Diagnosis

Patients usually present with raised PSA or suspicious findings on rectal examination. Each urology department should provide rapid access prostate assessment clinics.

Ultrasound-guided transrectal prostate biopsies should be obtained using an 18G core biopsy under local anaesthesia with antibiotic prophylaxis.

A minimum of 10 cores should be taken unless the biopsies are being performed for confirmation in clinical T3-T4 disease. Occasionally treatment may be initiated without histological diagnosis in elderly patients with a high PSA and a clinically malignant prostate.

All tumour specimens will be handled and recorded according to the Royal College of Pathologists Minimum dataset for prostate Cancer histopathology reports, April 2000 incorporating the TNM staging 6 edition (2002).

7.1.3 MDT Discussion

All diagnoses of prostate cancer should be reviewed at the local MDT meeting. Patients with negative biopsies should be offered follow-up with PSA or repeat biopsy. Those with high grade PIN should have their histology reviewed at the local MDT and re-biopsy offered if PIN is confirmed.

The following cases should be referred to the Network MDT:

- All patients being considered for radical treatment;
- Local recurrence after radical therapy;
- Progression on active surveillance;
- Local MDT recommendation.

7.1.4 Staging Investigations

Prior to radical therapy staging investigations should be used selectively. Bony imaging is usually obtained with bone scanning, but MRI with complete vertebral strip is an alternative. Nodal imaging is performed either with CT or MRI. MRI scanning is used to evaluate local extent of disease. Imaging should be undertaken prior to radical therapy in the following circumstances:

- Gleason score 8-10 tumours;
- Gleason score 6 or 7 and PSA>20;
- Gleason score 7 and PSA <20; consider staging for high risk cases (primary Gleason pattern 4, clinical stage T2b, tertiary Gleason pattern 5).

Bony imaging should also be requested in patients with bone pain.

7.1.5 Radical Prostatectomy Team

David Gillatt, Consultant Urologist NBT.

Ed Rowe, Consultant Urologist NBT.

Jon McFarlane, Consultant Urologist RUH.

Graham Howell, Consultant Urologist RUH.

Tim Porter, Consultant Urologist YDH.

Ru McDonagh, Consultant Urologist TST.

Mark Wright, Consultant Urologist UH Bristol.

Raj Persad, Consultant Urologist UH Bristol.

7.1.6 Teams for Chemotherapy and Radiotherapy

Dr Amit Bahl Consultant Clinical Oncologist UHB

Dr John Graham, Consultant Clinical Oncologist TST

Dr Mark Beresford, Consultant Medical Oncologist, UH Bristol

Dr Serena Hillman, Consultant Oncologist, UH Bristol

Dr Paula Wilson, Consultant Clinical Oncologist, UH Bristol

Dr Hugh Newman, Consultant Clinical Oncologist, UH Bristol

Dr Olivera Frim, Consultant Oncologist, UH Bristol

Dr Mohini Varughese Consultant Oncologist TST

7.1.7 Treatment guidelines

Stage	Treatment	Comments
T1a	Watchful waiting	Standard treatment for well and moderately differentiated tumours with < 10-year life expectancy. In patients with > 10-year life expectancy, re-staging with TRUS and biopsy is advised
	Radical prostatectomy Radiotherapy	Options in young patients and those with poorly differentiated tumours

Stage	Treatment	Comments
	Brachytherapy	Increased chance of complications following TURP
	Hormonal	Not an option
T1b-T2b	Watchful waiting	Asymptomatic patients with well and moderately differentiated tumours and a life expectancy < 10 years. Patients who do not accept treatment-related complications
	Radical prostatectomy/ brachytherapy	Standard treatment for patients with life expectancy > 10 years who accept treatment-related complications
	Radiotherapy (including HDR boost)	Standard treatment for patients with a life expectancy > 10 years who accept treatment-related complications. Patients with contraindications for surgery. Unfit patients with 5-10 years of life expectancy and poorly differentiated tumours.
	Hormonal	Symptomatic patients unfit for curative treatment who need palliation of symptoms.
T3-T4	Watchful waiting	Option in asymptomatic patients with T3, well-differentiated and moderately differentiated tumours, and a life expectancy < 10 years
	Radical prostatectomy	Option for selected patients with T3a disease and life expectancy > 10 years
	Radiotherapy (including HDR boost)	T3 with > 5-10 years of life expectancy
	Hormonal	Symptomatic patients, extensive T3-T4, high PSA level (> 25 ng/mL), unfit patients
N+, M0	Watchful waiting	Asymptomatic patients. Patient driven. May have worse survival
	Radical prostatectomy Radiotherapy	Not a standard option
	Hormonal	Standard therapy
M+	Watchful waiting	May have worse survival/more complications than with immediate hormonal therapy
	Hormonal	Standard therapy

Point of contact for brachytherapy referrals

Mr John McFarlane RUH

Dr Amit Bahl UHB

7.1.8 Treatment options and counselling patients

For discussion of radical options patients will have the opportunity of seeing a surgeon from the core team (7.1.5) and an oncologist from the named list (7.1.6) and a clinical nurse specialist from within the 3 designated specialist teams – NBT, RUH and TST.

7.1.9 Active Surveillance

Suitable for any patient with localized prostate cancer considered suitable for radical treatment by the Network MDT. Most appropriate for Gleason 6, small volume disease, up to T2a, PSA <10.

Protocol

- Repeat PSA at least every 3 months during the first 2 years.
- Repeat prostate biopsies within the first 6 months to look for under-grading.
- Digital rectal examination annually.
- If the PSA doubling time is low, the interval of PSA testing can be increased to 6 monthly after 2 years.
- Consider re-biopsy if:
    - Sharp rise in PSA;
    - Change in clinical stage;
    - Patient develops symptoms suggestive of local or distant progression.
- Refer back to Network MDT for consideration of radical treatment if:
    - PSA rises above 10;
    - PSA doubling time is less than 2 years;
    - Increase in Gleason score or number of cores on re-biopsy;
    - Patient request for radical treatment.

7.1.10 Follow-up after treatment with curative intent

The measurement of PSA level is a cornerstone of follow-up after curative treatment. PSA recurrence nearly always precedes clinical recurrence, in some cases by many years.

Definition of PSA progression

Following Radical Prostatectomy, two consecutive values of 0.2 ng/ml or greater appear to represent an international consensus defining recurrent cancer. Following radiotherapy biochemical relapse is defined according to international guidelines (ASTRO guidance defines PSA >nadir +2.0 ng/ml as relapse post radiotherapy), It is essential to define PSA parameters for relapse for GPs when discharging the patient to their care.

PSA monitoring after radical prostatectomy

- PSA at 6 weeks post-op, thereafter:
    - PSA every 3-6 months for 2 years;
    - PSA every 6-12 months beyond 2 years.
- Outpatient follow-up until continence and potency satisfactory.
- Following a two year period remote (primary care) follow-up with PSA is acceptable.
- Consider regular outpatient review for Gleason grade 8-10 tumours where PSA might not be as reliable.

PSA monitoring after radiation therapy

The PSA level falls slowly after radiotherapy compared with radical prostatectomy. The optimal cut-off value for a favourable PSA nadir after radiotherapy is somewhat controversial. The interval before reaching the nadir PSA may be very long and can sometimes take up to 3 years or more.

Digital rectal examination (DRE)

It is very difficult to interpret the findings of DRE after curative therapy, especially after radiotherapy. A newly detected nodule should raise the suspicion of local disease recurrence.

Bone scintigraphy

Not recommended for the routine follow-up of asymptomatic patients. Indicated in patients with symptoms arising from the skeleton, since rarely metastatic disease may occur even if PSA is undetectable.

7.1.11 Management of PSA Relapse after Radical Prostatectomy

The first option is to consider the RADICALS trial for suitable patients.

- Refer to Network MDT to consider salvage radiotherapy if:
    - Definitive histology shows T3 tumour with positive surgical margins;
    - Detectable PSA immediately following surgery;
    - PSA >0.1 and 2 consecutive PSA rises;
    - Palpable biopsy-proven recurrence regardless of PSA.
- Repeat staging prior to salvage radiotherapy is not useful in most cases.
- Biopsy of the anastamosis is not recommended except in the rare situation of a suspected recurrence on DRE with no PSA rise.
- Expectant management is an option for patients with presumed local recurrence unfit for, or unwilling to undergo, radiation therapy.
- PSA recurrence indicative of systemic relapse is best treated by early ADT resulting in decreased frequency of clinical metastases.
- LHRH analogues/orchiectomy or bicalutamide at 150 mg/day can both be used when there is indication for hormonal therapy.

7.1.12 Management of PSA relapse after radiation therapy

Local recurrences may be treated by salvage radical prostatectomy in carefully selected patients. Cryosurgery and hormonal therapy are alternatives to be considered, depending on the original disease features. ADT is preferred in patients with presumed systemic relapse.

7.1.13 Hormonal Treatment

Patients suitable for hormonal treatment (as per EAU guidelines):

Antiandrogens	
Short-term therapy	To reduce “flare” except in cases of LH/RH antagonists
Non-steroidal anti-androgens	Monotherapy as an alternative to castration in locally advanced disease
Castration	
M1 symptomatic	To palliate symptoms and to reduce the risk of complications (spinal cord compression, pathological fractures, urethral obstruction, extra-skeletal metastasis)
M1 asymptomatic	Immediate castration to defer progression to a symptomatic stage and prevent serious progression-related complications
N+	Immediate castration to prolong progression-free and even overall survival
Locally advanced M0	Immediate castration to improve cancer-free survival
Locally advanced symptomatic	
Locally advanced asymptomatic	If unfit for local definitive treatment

7.1.14 Guidelines for follow-up after hormonal treatment

- Follow-up should be tailored for the individual patient, according to disease stage, symptoms, prognostic factors and the treatment given.
- In general patients should be evaluated at three and six months after initiating treatment. Tests should include serum PSA measurement, testosterone levels, DRE and evaluation of symptoms in order to assess treatment response and side-effects.
- In patients with stage M0 disease with a good treatment response, follow-up is scheduled every 6-12 months.
- In patients with stage M1 disease with a good treatment response, follow-up is scheduled every 3-6 months.
- Routine imaging in stable patients is not recommended.
- Remote follow-up is appropriate for stable patients as long as there is a mechanism in place for identification and re-referral of patients.

7.1.15 Second Line Hormone Treatment

Hormone resistant prostate cancer (HRPC) implies that disease progression occurs despite castration. Castration levels of testosterone should be documented to confirm adequate antiandrogen therapy and compliance. LH-RH analogues should be continued indefinitely.

Anti-androgens

Except in patients with non-castration testosterone levels, it remains difficult to predict which subset of individuals is most likely to respond to secondary hormonal strategies. Anti-androgens may produce a biochemical response in these patients.

Anti-androgen withdrawal syndrome

Approximately one-third of patients on CAB will show a biochemical response to oral antiandrogen withdrawal as indicated by a ≧ 50% PSA decrease.

No clear-cut recommendation can be made regarding the most effective drug for secondary hormonal manipulations since data from randomised trials are scarce.

Stilboestrol 1-3mg daily plus aspirin 75mg daily may produce a biochemical response.

Dexamethasone 0.5mg daily may be used as 3rd line hormonal therapy after MAB and anti-androgen withdrawal.

7.1.16 Guidelines for Cytotoxic Therapy in HRPC

As per NICE guidance:

- Potential benefits of cytotoxic therapy and expected side effects should be discussed with each individual patient;
- In patients with metastatic HRPCA, and who are candidates for cytotoxic therapy, docetaxel at 75 mg/m2 every 3 weeks, with prednisolone 5mg bd, for 6-10 cycles has shown a significant survival benefit, and should be considered in good PS patients.

7.1.17 Guidelines for Palliative Management of HRPC

As per NICE guidance:

- Patients with symptomatic and extensive osseous metastases cannot benefit from medical treatment with regard to prolongation of life;
- Management of these patients has to be directed at improvement of QoL and mainly pain reduction;
- Effective medical management with the highest efficacy and a low frequency of side effects represents the major goal;
- Zoledronic acid should be considered for pain relief when analgesics and palliative radiotherapy have not been successful, depending on the patient's renal function;
- Palliative treatments such as radionuclides, external beam radiotherapy, adequate use of analgesics should be considered early on in the management of painful osseous metastases;

- Men with extensive spinal bony metastases should have an MRI if they develop new spinal symptoms. Protocols for the management of malignant spinal cord compression should be followed.

7.1.18 Facilities and Services of Host Trusts

Radical prostatectomies are carried out in the Urology cancer centre in North Bristol Trust, the Taunton and Somerset NHS Trust, and the Royal United Hospital Bath NHS Trust.

The Services and facilities in North Bristol Trust are:

- Dedicated Urology outpatients department with access to specialist and core team members;
- Dedicated Urology wards;
- Dedicated Urology theatres;
- Urology oncology clinical nurse specialists;
- Lymphoedema service;
- Psychosexual counselling network.

The services and facilities in Taunton and Somerset NHS Trust are:

- All cases discussed at central specialist MDT;
- Dedicated urology outpatients department;
- Dedicated Urology ward;
- Urology clinical nurse specialists;
- Dedicated Prostate Cancer Clinic;
- Post operative unit and ICE clinic.

7.2 Management of Bladder Cancer

7.2.1 Introduction

The incidence of bladder carcinoma is rising in Western countries. Approximately 75-85% of patients present with disease confined to the mucosa (stage Ta-Tis) or submucosa (stage T1). The other 15-25% have muscle invasion or nodal disease (stages T2-T4, N+) at presentation. The management of superficial bladder cancer has become more complex, with urological opinion differing with regard to initial investigation, treatment and follow-up. The following guidelines entail our policy for all bladder tumour patients who are discussed at the regional MDT – meeting.

7.2.2 Classification

TNM Staging

The Tumor, Node, Metastases (TNM) 2002 classification approved by the Union International Contre le Cancer

(UICC, International Union Against Cancer) is widely accepted and set out below in Table 1.

Table 1: 2002 TNM classification of urinary bladder cancer (1)

T (Primary tumour)		
TX	Primary tumour cannot be assessed	
T0	No evidence of primary tumour	
Ta	Non-invasive papillary carcinoma	
Tis	Carcinoma *in situ* ('flat tumour')	
T1	Tumour invades subepithelial connective tissue	
T2	Tumour invades muscle	
	T2a	Tumour invades superficial muscle (inner half)
	T2b	Tumour invades deep muscle (outer half)
T3	Tumour invades perivesical tissue:	
	T3a	Microscopically
	T3b	Macroscopically (extravesical mass)
T4	Tumour invades any of the following: prostate, uterus, vagina, pelvic wall, abdominal wall	
	T4a	Tumour invades prostate, uterus or vagina
	T4b	Tumour invades pelvic wall or abdominal wal
N (Lymph nodes)		
NX	Regional lymph nodes cannot be assessed	
N0	No regional lymph node metastasis	
N1	Metatsasis in a single lymph node 2 cm or less in greatest dimension	
N2	Metastasis in a single lymph node more than 2 cm but not more than 5 cm in greatest dimension, or multiple lymph nodes, none more than 5 cm in greatest dimension	
N3	Metastasis in a lymph node more than 5 cm in greatest dimension	
M (Distant metastasis)		
MX	Distant metastasis cannot be assessed	
M0	No distant metastasis	
M1	Distant metastasis	

2.2 Histological grading

In addition, the histological classification of the World Health Organization (WHO) is generally applied throughout most of the world (Table 2).

Table 2: Histological grading of WHO and International Pathology Consensus Committee 1988 (2)

PTNM pathological classification	**The pT, pN, and pM categories correspond to the T, N, and M categories of the TNM classification**
G	**Histopathological grading**
GX	Grade of differentiation cannot be assessed
G1	Well differentiated
G2	Moderately differentiated
G3–4	Poorly differentiated/undifferentiated

7.2.3 Patients to be Discussed at Regional MDT - Meeting

The following patients will be discussed at the regional MDT meeting:

- High risk superficial bladder tumours which require conservative treatment and are staged M0:
- Multiple T1, G2, Ta, G2, any T1, any G3; and any Cis associated tumors.
- Muscle invasive or high-risk recurrent superficial bladder tumours (M0):
- T1, any G3 and any Cis associated tumors;
- Any ≥ T2 tumours.
- Non-responders to conservative treatment (M0);
- Relapse after bladder-sparing treatments (M0);
- Non-transitional cell carcinomas (M0).

7.2.4 Diagnosis

Mandatory evaluations

- Physical examination (including DRE and pelvic examination).
- Renal and bladder ultrasonography and/or IVP.
- Cystoscopy with description of the tumour.
- Urinary cytology.
- TUR with:
    - Biopsy of the underlying tissue;
    - Random biopsies in the presence of positive cytology, large or non-papillary tumour;
    - Biopsy of the prostatic urethra in cases of Tis or suspicion of it.

Additional evaluations in muscle invasive and high-risk recurrent superficial bladder tumours

- CT scan of chest, abdomen and pelvis.
- Bone scan if symptoms are present or alkaline phosphatase level is elevated.

7.2.5 Treatment

Treatment of high-risk superficial bladder tumours

- A Re-resection 4-6 weeks after the initial TUR.

If re-resection confirms initial stage and grade, no upstaging towards T2.

- A 6 week course of chemotherapy (4o mg MMC) followed by monthly instillations up to 6 months
- Alternatively a 6 week course of BCG, followed by a 3 week cycle at 3 months.
- Maintenance BCG schedule according to Lamm with 3 instillations at 3,6,12,18,24,30 and 36 months. (for at least 1 year).
- BCG treatment is mandatory in all cases with concomitant Cis.

Treatment of high-risk superficial bladder tumours' and muscle-invasive tumours

Cystectomy

If patients are considered fit for major surgery.

All cases of muscle invasive grade three TCC bladder should be considered for neo-adjuvant chemotherapy.

- Limited lymph node dissection.
- Preservation of the urethra if margins are negative (intraoperative frozen section).
- All types of urinary diversion are offered to the patient, depending on the fitness, age, general status and tumor localization (no neobladder if intraoperative frozen section of urethral margin positive).
- Patients will be seen in Joint Uro-oncology-Clinic and possible alternatives, including radiotherapy will be offered.
- Patients will be counselled by a surgeon from the core team, an oncologist from the named team and a clinical nurse specialist. They will be offered the opportunity to meet other patients who have already underwent either cystectomy with various types of diversion or radiotherapy.
- High risk cases post-cystectomy should be discussed at the regional MDT, and particularly those with node positive disease should be considered for adjuvant chemotherapy.

Teams for Cystectomy

Core Team

- Mr David Gillatt, Consultant Urologist NBT.
- Mr Ed Rowe, Consultant Urologist NBT.
- Mr Raj Persad, Consultant Urologist UHB.
- Mr Mark Wright, Consultant Urologist UHB.
- Mr Tim Whittlestone, Consultant Urologist UHB.

Extended Team

- Mr John Mc Farlane, Consultant Urologist RUH.
- Mr David Dickerson, Consultant Urologist WHAT.
- Mr Rupert Beck, Consultant Urologist Swindon and Marlborough NHS Trust.

Teams for Radiotherapy and Chemotherapy

Dr Amit Bahl Consultant Clinical Oncologist UHB

Dr John Graham, Consultant Clinical Oncologist TST

Dr Mark Beresford, Consultant Medical Oncologist, UH Bristol

Dr Serena Hillman, Consultant Oncologist, UH Bristol

Dr Paula Wilson, Consultant Clinical Oncologist, UH Bristol

Dr Hugh Newman, Consultant Clinical Oncologist, UH Bristol

Dr Olivera Frim, Consultant Oncologist, UH Bristol

Dr Mohini Varughese Consultant Oncologist TST

Radiotherapy

- Patients with adequate bladder capacity.
- Normal bladder function.
- No recurrent urinary tract infections.
- Previous inflammation or surgery of the true pelvis with consecutive adhesions.

Treatment

- Non-responders to conservative treatment.
- Relapse after bladder-sparing treatments.
- Non-transitional cell carcinomas.

Salvage Cystectomy if patients are considered to be fit for major surgery.

Treatment of Metastatic Disease

Chemotherapy.

- Gemcitabine/cisplatin and gemcitabine/ carboplatin are both used as up-front chemotherapy for metastatic disease depending on renal function and performance status. Median survival is 12-14 months.
- The palliative care team should be involved at an early stage.

7.2.6 Follow Up

Rationale for follow-up

Follow-up of patients with invasive bladder cancer after cystectomy and radiotherapy is recommended to detect local recurrence and distant metastases as early as possible to permit additional treatment when indicated and if possible. Such therapy may include salvage cystectomy, urethrectomy, nephro-ureterectomy and or systemic chemotherapy with and without secondary surgery for residual tumour. Moreover, side effects of urinary diversion should be recognized early on and corrected if possible.

Principles

Prognostic factors and type of intervention (cystectomy, radiotherapy) are relevant in determining the most efficient follow-up regimen. The pT and pN-stage are the most important prognostic factors and in addition risk factors such as pTis will guide the follow-up procedures.

Follow-up Procedures

Cystectomy

The first assessment is at three months postoperatively and includes:

- Physical examination;
- Serum creatinine;
- Urine analysis;
- CT Urogram or IVU;
- Chest-X-ray.

In case of unremarkable findings regular follow-up in intervals of 4 months are indicated. In case of pN+ additional regular CT scans and bone scintigraphy are necessary. PTis patients need regular assessment of the upper urinary tract. Barbotage cytology is recommended for the remaining urethra.

Radiotherapy

The first assessment is at three months post-radiotherapy and includes:

- Physical examination;
- CT scan of abdomen and pelvis;
- Cystoscopy.

The main interest during follow-up remains the bladder, because of the high local failure rate.

7.3 Guidelines for the Management of Kidney Cancer

7.3.1 ASWCS Urology SSG Working Group

Based on European Association of Urology guidelines 2007.

For review April 2011.

7.3.2 Renal Cell Cancer (RCC)

RCC is characterised by a constant rise in incidence over the last 50 years, with a predominance of men over women and an incidence peak in the 6th and 7th decade. There are no established risk factors and the current TNM system (UICC, 2002) is endorsed for staging purposes. Clinical signs and symptoms of RCC are becoming less frequent; incidental discovery already constitutes a majority of cases.

Diagnosis is established by ultrasound and abdominal CT. Assessment of distant metastases by chest x-ray or CT. Additional examinations such as bone scan are directed by symptoms. MRI can be helpful in assessing loco-regional extension.

Therapy of choice in organ-confined RCC is surgery. Radical tumornephrectomy is considered as a standard, although organ-sparing surgery is increasingly common. Efficacy and side effects of lymphadenectomy and inclusion/omission of ipsilateral adrenalectomy in selected cases is the matter of ongoing clinical research. In metastatic cases, nephrectomy should only be considered in the context of modern systemic immunotherapy and novel therapies.

Follow-up at regular intervals is recommended because certain cases of recurrences may be candidates for surgery and/or immunomodulating therapy.

Renal cell carcinoma (RCC) accounts for about 2% of all cancers, with a world-wide annual increase of 1.5 –5.9% . The mean age at the time of diagnosis is about 70 years and there is a predominance of men over women in the range of 1.5 – 3.1. The mortality from RCC is increasing parallel to trends in incidence.

World-wide mortality is expected to increase from 54,000 deaths in 1985 to 102,000 deaths in 2000. It may reach or even exceed that of bladder cancer in certain areas.

The increased incidence of RCC is primarily due to enhanced detection of tumours by expanded use of imaging techniques, such as ultrasound and computed tomography (CT). At present, 25 – 40% of clinically diagnosed RCC are found incidentally. A total of 25 – 30% of patients with RCC have overt metastases at initial presentation and, in addition, a substantial fraction of patients have subclinical metastases at that time explaining the hitherto unsatisfactory outcome of treatment . Survival is closely related to initial stage; 5-year survival is 50 – 90% for localised disease, decreasing to 0 – 13% for metastatic disease.

There are no generally accepted risk factors for RCC. There are some epidemiologic data indicating that a smoking habit, obesity or exposure to certain heavy metals such as cadmium may favour the development of RCCs.

7.3.3 Diagnosis

Clinical symptoms of RCC, such as haematuria, palpable tumour and flank pain, are becoming less frequent.

Asymptomatic tumours are more commonly diagnosed incidentally on investigation for other disease such as cholecystitis. Clinical examination has a limited role in diagnosing RCC, but it may be valuable in assessing co-morbidity. In case of haematuria, additional tumours of the genitourinary tract should be excluded.

The most commonly assessed laboratory parameters are:

- Haemoglobin and erythrocyte sedimentation rate: prognosis;
- Creatinine: overall kidney function;
- Alkaline phosphatase: liver metastasis, bone metastasis.

Serum calcium is frequently included in the preoperative assessment because of its association with paraneoplastic manifestation, which may have clinical implications.

The majority of tumours are identified by abdominal ultrasound performed for various reasons.

Standard diagnostic procedure is an abdominal CT-scan with and without contrast medium (usually with chest and pelvis at same time). It serves to document the diagnosis of RCC and provides information on the function and morphology of the contralateral kidney.

Additional diagnostic procedures, such as magnetic resonance imaging, angiography or fine needle biopsy may be considered in selected cases.

7.3.4 Staging Investigations

CT scan chest/abdo/pelvis (or MRI) should be used to assess primary tumour extension and provide information on venous involvement and on metastatic spread to loco-regional lymph nodes, adrenals, controlateral kidney, liver etc.

Specific angiographic modalities should be used to assess vena caval involvement if suspected, and to provide a “road map” in patients for nephron sparing surgery.

If indicated by signs and symptoms, other diagnostic procedures may be applied, such as bone scan, brain CT.

All new cases of renal cancer will be reviewed at the local MDT meeting. Any case of incident RCC may be referred to the Specialist MDT for review. This may include patients with significant comorbidity on whom active monitoring may be justified. Patients that must be referred to the specialist MDT for discussion include:

- All patients considered for nephron sparing surgery (defined below);
- Patients with metastatic disease considered for debulking nephrectomy;
- Resection of tumours in patients with hereditary RCC;
- Patients with bilateral disease;
- Patients to be considered for novel therapies (Cryotherapy/HIFU);
- Patients with organ confined disease not fit for nephrectomy but requiring palliative local treatment;

- Patients likely to require post op renal dialysis;
- Patients with urothelial and if known, pre op non renal cell kidney cancer;
- Patients for adjuvant therapy and or trial inclusion;
- Patients with recurrent disease suitable for further treatment;
- Patients with IVC involvement up to level of hepatic veins;
- Patients with IVC involvement above level of hepatic veins – these will be referred on to Supraregional centre (The Heath Hospital,Cardiff).

Specialist Nephrectomy Team: Surgical

Frank Keeley, Consultant Urologist NBT.

Mark Wright, Consultant Urologist UH Bristol.

David Gillatt, Consultant Urologist NBT.

Ed Rowe, Consultant Urologist NBT.

Tim Whittlestone, Consultant Urologist UH Bristol.

Anthony Timoney, Consultant Urologist NBT.

Treatment Guidelines

Only radical surgery offers a reasonable chance of curing the disease. The chances of cure by surgery most strongly depend on stage (primarily) and grade (secondarily) of the disease.

Standard operative procedure is a radical nephrectomy including Gerota's fascia. There is no evidence to favour a specific surgical approach. In selected cases of small (< 4 cm) peripheral lesions, an organ sparing approach may be considered. An increasing number of cases are being undertaken laparoscopically at sites in the region.

If surgery cannot eradicate all tumour deposits, tumour nephrectomy remains palliative therapy and should be considered in the context of multimodality treatment (e.g. in conjunction with immunotherapy or experimental therapies).

These cases should be identified at the local MDT and referred for discussion at the specialist meeting.

Certain cases, such as bilateral tumours, a solitary tumour-bearing kidney, multifocal lesions, renal insufficiency, or an occasional palliative situation, will require individual decisions not amenable to general guidelines (and be discussed at the specialist MDT).

Pathology Reporting

The reporting of specimens should follow the RC Path minimum dataset, preferably also the presence of microvascular invasion. This will incorporate TNM staging 6 edition (2002).

Traditionally RCC have been classified according to the nuclear or cellular morphology. New morphologic, cytogenetic and molecular studies make it possible to distinguish five types of carcinomas:

- Clear – cell: 60 – 85%;
- Chromophilic: 7 – 14%;
- Chromophobic: 4 – 10%;
- Oncocytic: 2 – 5%;
- Collecting duct: 1 – 2%.

Recent attempts have been made to generate a molecular classification.

7.3.5 Follow-Up

Rationale for follow up

Follow up of patients with RCC after surgical treatment is recommended to detect local recurrence and distant metastases as early as possible to permit additional treatment when indicated and if possible. Such therapy may include resection of pulmonary metastasis or local recurrences; certain cases may also be candidates for immunomodulating or novel small molecule therapy. With this background in mind, a regular postoperative follow up of patients with RCC is proposed.

Principles

Prognostic factors and the type of surgical intervention (radical vs. partial or nephron sparing surgery) are relevant in determining the most efficient follow up regimen. The most established prognostic factors are tumour stage according to the TNM system and presence of microvascular invasion. The Leibovich score gives an indication of prognosis and is determined by tumour size, stage, grade, nodal involvement and the presence or absence of necrosis.

Adjuvant therapy with tyrosine kinase inhibitors is currently under investigation. Patients at high risk of recurrence should be considered for entry into adjuvant therapy trials.

After nephron-sparing tumour resection (elective or mandatory indication), the local recurrence rate may vary between 0 and 10%. In a small proportion of patients with a genetic predisposition, a different follow-up procedure may be required.

The table below is a recommendation, not a protocol for follow up. Strict adherence to guidelines may not be appropriate for all patients. Factors including patient's co-morbidities and the willingness to pursue aggressive management in the event of recurrence may alter individual follow-up.

Tabulated follow up guidelines by tumour stage (assume N0M0):

STAGE (risk of recurrence)	VISIT	TEST	OPTION	RISK/ MEDIAN TIME RECURRENCE
All T baseline	Post op 4/6 weeks	Physical Exam		
		Creatinine		
		Hb		
			LFTs inc AlP	
		Baseline CT after nephron sparing surgery		
Low risk	Every 6 months for 1st year, then annually to 5 years	Clinical assessment		7% (75% of these occur in first 24 months) >50% pulmonary (others symptomatic)
		CXR		
		LFTs	Renal imaging	
Medium risk	Every 6 months for 3 years, then annually to 5 years	Clinical assessment	Renal imaging	20-30%, most within 30 months
		CXR		
		LFTs		
High risk	Every 6 months for 3 years, then annually to 5 years	Clinical assessment		40-55%, most within 18 months
		CXR		
		LFTs		
	6 and 12 months	CT chest and abdo		
	2 years		CT chest and abdo	

- **Low risk** – T1a ,Fuhrmann 1, non-collecting duct/medullary/sarcomatoid, no MVI . Leibovich Score 0-2.
- **Medium risk** T1/2, Fuhrmann any, non- collecting duct/medullary/ sarcomatoid. Leibovich Score 3-5.
- **High Risk** –T3/4, collecting duct/medullary/sarcomatoid. Leibovich Score 6-9.

7.3.6 Metastatic disease

Surgical options

Cytoreductive nephrectomy should be considered in patients with relatively low volume metastases prior to systemic treatment, with the aim of debulking the disease burden and potentially improving outcomes following drug therapy.

Palliative nephrectomy may also be considered in patients with more advanced metastatic disease with the aim of controlling local symptoms such as bleeding or pain.

Metastatectomy should be considered in the case of solitary (or few) metastases when the disease is slowly progressive and otherwise well-controlled, particularly for example if confined to one lobe of the lung. For patients with solitary brain metastases, consider neurosurgical intervention or stereotactic radiotherapy.

Systemic therapy

Sunitinib is approved for use as first line therapy in metastatic disease in patients with a good performance status (WHO 0 or 1).

The standard schedule is 50mg po daily for 4 weeks followed by 2 weeks rest. The 6-weekly cycles are continued to progression or intolerance. Doses can be reduced in increments of 12.5mg if poorly tolerated.

Common side effects include sore mouth, diarrhoea, fatigue, sore hands/feet, hypertension and thrombocytopaenia.

Interferon alpha is an option if patients are unsuitable or fail to tolerate sunitinib. Response rates are unimpressive and side effects are common (particularly fatigue, arthralgia and headaches).

There are several trials in advanced renal cncer and patients should be offered the opportunity to enter these at first line setting and subsequent settings.

Patients who progress after sunitinib should be considered for clinical trials of alternative targeted agents.

Radiotherapy

Palliative radiotherapy should be considered for painful bone metastases or to control local symptoms such as bleeding.

Mayo risk assessment

Tumour staging		
	1a	0
	1b	2
	2	3
	3-4	4

LN status		
	Nx	0
	N0	0
	N1	2
	N2	2

Tumour Size		
	<10	0
	>10	1

Nuclear grade		
	1	0
	2	0
	3	1
	4	3

Tumour Necrosis		
	No	0
	Yes	1

Total _____

Please circle		
	0-2	Low
	3-5	Intermediate
	>6	High

ECOG/ WHO performance status (0-4) _____

Is the patient fit, able and willing to undergo recommended follow-up regime? Y/N

Follow-up of renal tumour post nephrectomy – Low risk group

Months	3	6	12	18	24	30	36	48	60	Stop after 5 years
Dates										
Hx/PE			x		x		x	x	x	
Blood tests			x		x		x	x	x	
CXR			x		x		x	x	x	
CT abdomen					x			x		

Blood tests: FBC, U/E/Cr and LFT

Follow-up of renal tumour post nephrectomy – Intermediate risk group

Months	3	6	12	18	24	30	36	48	60	After 5th year, yrly follow-up with 2 yrly CT scan
Dates										
Hx/PE		x	x	x	x	x	x	x	x	
Blood tests		x	x	x	x	x	x	x	x	
CT chest*		x	x	x	x	x	x	x	x	
CT abdomen			x				x		x	

Blood tests : FBC, U/E/Cr and LFT
* CXR can alternate with CT chest after 3 years

Follow-up of renal tumour post nephrectomy – High risk group

Months	3	6	12	18	24	30	36	48	60	After 5th year, yrly follow-up with yrly CT scan
Dates										
Hx/PE		x	x	x	x	x	x	x	x	
Blood tests		x	x	x	x	x	x	x	x	
CT chest*		x	x	x	x	x	x	x	x	
CT abdomen		x	x	x	x		x	x	x	

Blood tests : FBC, U/E/Cr and LFT
* CXR can alternate with CT chest after 3 years

Follow-up of renal tumour post nephrectomy - pTxN+ or M+ group

Months	3	6	12	18	24	30	36	48	60	After 5th year, yrly follow-up with yrly CT scan
Dates										
Hx/PE	x	x	x	x	x		x	x	x	
Blood test	x	x	x	x	x		x	x	x	
CT chest*	x	x	x	x	x		x	x	x	
CT abdomen	x	x	x	x	x		x	x	x	

Blood tests : FBC, U/E/Cr and LFT
* CXR can alternate with CT chest after 3 years

7.4 Guidelines for the management of Male Patients with Germ Cell Tumours

7.4.1 Introduction

Testicular germ cell tumours are the most common cancer of young men with approximately 2000 new cases diagnosed each year in the U.K. In Bristol, around 100 new patients are seen each year. Testicular tumours are highly sensitive to treatment, with anticipated cure rates of over 95%. However, the small number of patients presenting with advanced (poor prognosis) disease continue to have modest survival with only 50 – 60% alive 5 years after diagnosis.

National guidelines (COIN guidelines 2000[1], Improving outcomes in urological cancer 2002[2]) provide recommendations for management of male patients with germ cell tumours and outline how care should be delivered. These guidelines form the basis for this document.

Development of a centralised service, serving a population of two to four million is recommended [2]. ASWCS network currently covers a population of 2.1 million. Bristol Haematology and Oncology Centre (BHOC) offer a regional germ cell tumour service providing a referral centre for Taunton, Yeovil, Bath and Weston as well as the Bristol area. The service is being developed to provide greater links with Three Counties and Peninsula Networks for specialist urological surgery for germ cell tumours in the South West is based at the Bristol Royal Infirmary and currently receives referrals from the following Networks:

ASWCS	2.1 million population
Three Counties Network	1.3 million population
Peninsula Network	1.6 million population

The service is also developing links with Female Germ Cell Specialists and Paediatrics.

7.4.2 Supranetwork Multi-Disciplinary Team Working

MDT: Supranetwork MDT for ASWCS Network – Friday 8.30AM Bristol Royal Infirmary.

The MDT is organised by Lucie Wheeler MDT Co-ordinator Tel: 0117 342 0603. Fax 0117 342 0652 e-mail: Lucie.Wheeler@UHBristol.nhs.uk

MDT Participants:

- Dr Jeremy Braybrooke (Consultant Medical Oncologist) **MDT lead**
- Dr Rob Jones (Consultant Medical Oncologist)
- Mrs Sue Brand (Germ Cell Clinical Nurse Specialist)
- Dr Julian Kabala (Consultant Radiologist)
- Mr Tim Whittlestone (Consultant Urological Surgeon)
- Dr Amit Bahl (Consultant Clinical Oncologist)
- Dr Chris Collins (Consultant Histopathologist)
- Dr Mohammed Sohail (Consultant Histopathologist)
- Ms Julia Hardwick (Uro-Oncology Clinical Nurse Specialist)
- Oncology and urology Specialist Registrars

All patients from ASWCS Network with newly diagnosed testicular tumours, residual disease or relapsed disease **must** be discussed along with those referred for consideration for Retroperitoneal Lymph Node Dissection (RPLND).

The following minimum information is normally required and will be requested by the MDT co-ordinator:

- Clinical details including tumour markers;
- CT scan chest / abdomen / pelvis;
- Pathology Report and histology slides for review.

All patients with recurrent disease will be discussed. Normally recurrent disease will be diagnosed and investigated (e.g. AFP, HCG, LDH and CT scan of chest, abdomen and pelvis) from the Network Testicular Cancer Clinic. If appropriate, biopsy will be arranged following the MDT. Imaging of patients with residual mass post chemotherapy will be reviewed and, if appropriate, patients will be referred for surgery.

Network Testicular cancer Clinic

Clinic: Friday morning at BHOC starting at 9.15am

Consultants: Dr Jeremy Braybrooke

Dr Susanna Alexander

Key Worker: Mrs Sue Brand

The clinic will see both new and follow up patients as well as those on treatment specific recommendations for follow up are listed in section 5. All new patients, and follow up patients with specific needs will be seen by the Germ Cell Clinical Nurse Specialist. Normally a specialist registrar in medical and/or clinical oncology will attend. The clinic provides good educational opportunities for management of patients with germ cell tumours.

Communication with Local and Diagnostic Teams

The MDT outcome proforma will be emailed back to the referring team with outcome and plans/recommendations. In addition, where patients are seen and assessed for supra-network treatment in the joint clinic a more detailed letter, copied to the General Practitioner, will follow the proforma.

Communication with referring Networks and General Practitioners

The MDT outcome proforma is emailed to the referring team within 24hours and available on the Bristol Cancer Registry. Where appropriate a detailed letter will follow the proforma with a copy sent to the patients General Practitioner.

Shared care Arrangements with Referring Networks

Shared care arrangements are mutually agreed on a case by case basis by the referring supranetwork teams, as stipulated in the supra-network MDT operational policy (Appendix Two)

Facilities for Patients

As the Supra-network centre for male patients with germ cell tumours the University Hospitals Bristol NHS Foundation Trust (UHB) is equipped and staffed appropriately to provide the following:

- Dedicated Testicular Cancer Clinic
- Dedicated Urology outpatients department with access to testicular specialist and core team members
- Dedicated Urology and Oncology wards
- Germ cell and Urology Clinical Nurse Specialists
- Dedicated Urology theatres
- Psychosexual counselling network

Waiting Times

The national milestone for testicular cancer is less than 31 days from urgent referral to treatment. In the UHB there are no waiting times for access to this service with patients fast tracked immediately and treated well within the national target for surgery, chemotherapy and radiotherapy.

Peer Review Measures (www.cQuins.nhs.uk)

Urology services are a mandatory assessment feature in the proposed peer review of 2009, although ASWCS had, in 2006, undertaken an in-house, externally audited review of all services. This review found no major issues relating to the delivery of clinical care.

Network Measures

The following relevant peer review measures will be self assessed in July 2009. The measures and compliance are outlined below.

08-1A-211g Diagnosis and assessment.

08-1A-212g Referral for treatment to another team – is met through the ongoing development of this document.

08-1A-213g MDT discussion – see paragraph 2 above.

08-1A-214g Defining specialist care for the network – see section 7.4.5 below.

08-1A-215g Referral of Histology and Radiology.

Dr Mohammed Sohail/Dr Christopher Collins at the Bristol Royal Infirmary will review histopathology slides. Histopathology slides and report will be requested by the MDT Co-ordinator to send to Dr Mohammed Sohail at the department of histopathology at the BRI. Tissue blocks may also be required in some cases for further work. After review in the MDT the slides will be returned to the referring hospital. Most Radiology is available on Webpacs and accessible by Dr Julian Kabala, where this is not possible a CD will be requested and sent to the Bristol Royal Infirmary FAO Lucie Wheeler and she will arrange for this to be uploaded.

Supra-Network MDT Measures

The supranetwork team at the BHOC will evidence measures **08-2G-301 – 08-2G-339** inclusive. This document will form part of the evidence to meet some measures.

It is anticipated that the germ cell cancer supra-network team will comply with all of the current measures. However, where non-compliance is observed, the mechanism for resolution will be through the Network Site Specialist Group at its next immediate meeting, in collaboration with the Network Testicular Cancer Service Team and Network management team.

7.4.3 Network Site Specialist Group Meetings

The ASWCS Site Specialist Group for Urology meets quarterly, after the Network Specialist MDT on Wednesday afternoons at the Bristol Urological Institute at Southmead Hospital, Bristol.

All six Acute Trusts have representation at the meeting. There are also members of the Network Testicular Cancer Service and Network management team and consistent user representation.

The core membership is as Appendix One. Additional mailing list contacts are also available on request.

7.4.4 Initial Diagnosis and Referral

Most patients will present to the local urological team with a testicular lump. Responsibilities of the local team include:

- Clinical diagnosis including testicular ultra-sound;
- Pre-operative tumour markers (AFP, HCG, LDH) and weekly post-operative markers;
- Radical inguinal Orchidectomy with availability of testicular prostheses, this is to be offered to all patients;
- Initial histological diagnosis and organisation of an urgent CT scan of chest, abdomen and pelvis.

This must be performed within two weeks of surgery.

- Availability of the following patient information:
    - 'Information for men with Testicular cancer' (Document Management System UHB)
    - Cancer Backup booklet 'Testicular Cancer'
    - Contact details of Germ Cell Clinical Nurse Specialist (Key Worker)
- Referral to the Network Testicular Cancer Service (NTCS) must be made **within 24 hours of surgery**
- All referrals are to be made using the Network Testicular Cancer Service MDT Referral Form in accordance to the guidance and Supra-network MDT Operational policy **(Appendix three)**.

7.4.5 Treatment Guidelines and Specialist Care

Level of Evidence for Practice.

Level	Source and characteristics of evidence
IA	Meta-analysis of randomised controlled trials (RCT) and review of RCT
IB	At least one RCT
IIA	At least one well designed controlled study without randomisation
IIB	At least one well designed quasi experimental study
III	Well designed non experimental descriptive studies
IV	Expert committee report, opinions/clinical experience of respected authority

All patients diagnosed within ASWCS will receive chemotherapy treatment and follow-up in the Bristol Haematology and Oncology Centre. Radiotherapy can, by arrangement, be administered in Bath or Taunton. The named contacts are:

Dr Hugh Newman RUH

Dr John Graham TST

Post treatment follow-up will revert back to BHOC. For those patients referred from The Peninsula and Three Counties Networks treatment to be agreed on an individual patient basis.

Classification: TNM Testis	
pTis	Intratubular
pT1	Testis and epididymis, no vascular/lymphatic invasion
pT2	Testis and epididymis with vascular/lymphatic invasion or tunica vaginalis
pT3	Spermatic cord
pT4	Scrotum
N1	<2 cm
pN1	≤2 cm and ≤5 nodes
N2	>2 to 5 cm
pN2	>2 cm or >5 Nodes or extra nodal extension
N3	>5 cm
pN3	>5 cm
M1a	Non-regional lymph nodes or lung
M1b	Other sites

The most widely used prognostic classification for metastatic disease is that proposed by the International Germ Cell Consensus Classification [3].

Teratoma (NSGCT)	Seminoma
Good prognosis	
Testis/ retro-peritoneal primary; no non-pulmonary visceral metastases and AFP < 1000 ng/ml + HCG < 5000 iU/l + LDH < 1.5 x ULN	Any primary site; no non-pulmonary visceral metastases and Normal AFP + Any HCG + Any LDH
Intermediate prognosis	
Testis / retro-peritoneal primary; no non-pulmonary visceral metastases and any of	Any primary site; non-pulmonary visceral metastases and

Teratoma (NSGCT)	Seminoma
AFP > 1000 and < 10 000 ng/ml HCG > 5000 and < 50 0000 iU/l LDH > 1.5 x ULN and < 10 x ULN	Normal AFP + Any HCG + Any LDH

Poor prognosis	
Mediastinal primary or non-pulmonary visceral metastases and / or any of AFP > 10 000 ng/ml HCG > 50 000 iU/l LDH > 10 x normal	

Management of patients Receiving Chemotherapy

Prior to chemotherapy all patients have:

- **Clinical review prior to each cycle of chemotherapy;**
- **Tumour markers** (AFP, HCG, LDH). Repeat weekly in patients with metastatic disease whilst on chemotherapy;
- **Full blood count and biochemical profile including Ca 2+, Mg2+;**
- **CXR.** This should be repeated after 2 cycles of bleomycin containing chemotherapy;
- **CT** scan of chest, abdomen and pelvis. Repeat after 2 cycles for patients with intermediate or poor prognosis and after 3 cycles for good prognosis disease. Poor and Intermediate prognosis metastatic patients should have a baseline CT brain;
- **Audiogram** (before 1 cycle and then if clinically indicated);
- Calculated **creatinine clearance** (before each cycle). EDTA clearance should be arranged for intermediate/poor prognosis patients or if calculated creatinine clearance <60ml/min;
- **Pulmonary function tests** (bleomycin containing schedules only) to include FEV1/FVC and transfer factor (before 1st cycle and then if clinically indicated. For patients with intermediate or poor prognosis disease PFT's should be repeated after 2 cycles). An absolute drop of >20% in transfer factor, new respiratory symptoms or changes on CXR must be discussed with the consultant before proceeding with further bleomycin;
- **Sperm Storage** must be discussed with all patients prior to chemotherapy. Referrals should be made to Bristol Centre for Reproductive Medicine according to the Standard Operating Procedure, UHBristol.

Patient to be given and information leaflets:

- Virology Screening for Sperm Storage;
- Patient information leaflet from BCRM;
- Cancer Backup booklet Men and Fertility;
- Map of Southmead Hospital and Free Parking Permit;
- Patients will be asked to consent to HIV, Hepatitis B, Hepatitis C and Syphilis testing. Procedure will be carried out according to Standard Operating Procedure and Algorithum (Appendix Four).

- There is increasing evidence that men who have received chemotherapy for testicular cancer are at increased risk of Heart Disease later in life [34, 35]. We therefore, will be carrying out the following on all men who attend to ascertain the potential risks:

  - **Baseline, at two years and five years and at discharge**

    Male Hormone Profile.

    Full blood count, biochemical profile and Lipids.

    Weight and BMI.

    BP and ECG.

  - **First Line Treatment**

  - **Classical Seminoma**

    No residual disease post surgery i.e. normal tumour markers and normal CT scan:

    Risk of relapse is 15 – 20% over 3 years, reduced to 3 –5% by adjuvant therapy. Adverse predictive factors are tumour >4 cm and/or invasion of rete testis. Late relapses up to 5 years are rarely seen.

    Recommended

    Carboplatin x 1 cycle AUC 7 based on EDTA clearance (use absolute value uncorrected for surface area) [5]. Evidence Level IB Check reference publication Oliver et al Lancet 2005: 366: 293 – 300.

    Or

    Radiotherapy 20Gy in 10 fractions to para-aortic nodes. If there is a history of previous pelvic or scrotal surgery, including inguinal hernia repair, the ipsilateral pelvic nodes should also be irradiated with a dog leg field (usually 20Gy in 10 fractions) [4]. Vasectomy is not an indication for pelvic node irradiation. Evidence Level IB.

    Or

    TRISST MRC TE24 – Trial of Imaging and Schedule in Seminoma Testis(Version 2.0 5th December 2008).

Surveillance has not been routine practice in the UK but could be considered for patients at lower risk of recurrence i.e. tumour < 4cm and no invasion of rete testis [6]. Where appropriate these patients should be offered the TE24 trial Evidence level IIA.

- **Para-aortic lymphadenopathy < 3cm maximum diameter and treatable in a single radiotherapy field**

  Recommended

  Radiotherapy to para-aortic nodes. Usually 30 Gy in 15 fractions followed by boost 5Gy in 3 fractions. [7]. Evidence level IV.

- **Para-aortic lymphadenopathy > 3cm or metastatic disease:**

  Recommended:

  3 day BEP500 x 3 cycles (cisplatin 100mg/m2, etoposide 500mg/m2, bleomycin 30mg d 2, 8, 15). Total bleomycin dose 270 mg [8]. Evidence level IB.

  Or

  3 day EP500 x 4 cycles (cisplatin 100mg/m2 and etoposide 500mg/m2) [9]. Evidence level IB.

  There is no direct evidence that the addition of bleomycin improves outcome for patients with pure seminoma [1] (Evidence level IV) and should normally be omitted for patients >40 years, those with impaired renal function or pre-existing lung disease because of the increased risk of pulmonary toxicity.

- **Non-Seminomatous Germ Cell Tumour**

  No residual disease post surgery i.e. normal post-operative markers and normal CT scan.

  No evidence of vascular or lymphatic invasion.

  Risk of recurrence around 10 - 20% in first 2 years [10] Evidence level IB.

  Recommended:

  Active surveillance providing patients are able to comply with follow up policy (see section 6) [7]. Evidence level IV. CT scan of chest, abdomen and pelvis at 3 and 12 months. Evidence level IB.

- **Vascular or Lymphatic Invasion.**

  Risk of recurrence without treatment is 45 - 50% within first 2 years. This is reduced to 3% with chemotherapy [11]. Evidence level IIB.

  Recommended:

  Active surveillance providing patients are able and willing to comply with follow up policy. Evidence level IV.

  Or

  3 day BEP360 x 2 cycles (cisplatin 100mg/m^2, etoposide 360mg/m^2, bleomycin 30mg d 2, 8, 15). Total bleomycin dose = 180mg [11]. Evidence level IIA.

  European consensus guidelines [7](Evidence level IV) recommend consideration for 2 cycles of adjuvant BEP chemotherapy. There is concern about psychological distress for patients on surveillance. However, over 90% of patients who relapse on surveillance will be cured with 3 cycles of BEP chemotherapy. The potential long-term risks from chemotherapy (e.g. cardiovascular disease, second malignancy) must therefore be discussed with patients before proceeding with adjuvant chemotherapy.

- **Good Prognosis Metastatic**

  Recommended:

  3 day BEP500 x 3 cycles (cisplatin 100mg/m^2, etoposide 500mg/m^2, bleomycin 30mg d 2, 8, 15). Total bleomycin dose 270 mg [8]. Evidence level IB.

  Omission of bleomycin [12] (Evidence level III) should be considered if:

  - > 40 years of age;
  - Creatinine clearance <80ml/min;
  - Pre-existing lung disease.

  Alternatives:

  If bleomycin is omitted:

  3 day EP500 x 4 cycles (Cisplatin 100mg/m^2 and etoposide 500mg/m^2) [9]. Evidence level IB.

  In patients with poor performance status or where there are specific concerns about potential toxicity BEP500 or EP500 can be administered over 5 days.

  Post Chemotherapy: CT scan at 4 weeks to assess response after 3/4 cycles. CT scan to be reviewed at MDT. If residual mass post treatment discuss surgical resection (see below).

- **Intermediate Prognosis Metastatic**

  To date, no randomised trial has demonstrated a convincing survival advantage compared to 5-day BEP500 for intermediate or poor prognosis NSGCT. 3-day BEP500 has been shown to be equivalent to 5-day BEP500 for good prognosis metastatic disease but has not been evaluated in intermediate or poor prognosis disease and cannot be routinely recommended in this setting.

  Recommended:

  5-day BEP500 x 4 cycles (cisplatin 100mg/m^2, etoposide 500mg/m^2, bleomycin 30mg d 2, 8, 15). Total bleomycin dose 360mg [1, 14-18]. Evidence level IB

  Omission of bleomycin [12] (Evidence level III) should be considered if:

  - > 40 years of age;
  - Creatinine clearance <80ml/min;
  - Pre-existing lung disease.

- Alternatives:

  If bleomycin is omitted:

  3 day EP500 x 4 cycles (Cisplatin 100mg/m^2 and etoposide 500mg/m^2) [9]. Evidence level IB

  Poor Prognosis Metastatic

  Recommended:

  MRC TE23 Randomised phase II trial of intensive induction chemotherapy (CBOP/BEP) and standard BEP chemotherapy in poor prognosis male germ cell tumours

  Or

  5-day BEP500 x 4 cycles (cisplatin 100mg/m^2, etoposide 500mg/m^2, bleomycin 30mg d 2, 8, 15). Total bleomycin dose 360mg [1, 14-18]. Evidence level IB

  Or

  CBOP-BEP [19]. Evidence level IIA. Schedule is:

  CBOP for 6 weeks:

  Cisplatin 100mg/m^2 wk 1 and 3; 40mg/m^2 wk 2 and 4

  Carboplatin AUC 3 wk 2 and 4

  Vincristine 1.4mg/m^2 (max. 2mg) weekly for 6 wks

  Bleomycin 75mg as 5-day infusion wks 2 and 4; 15mg weekly on all other weeks including during BEP. Total bleomycin dose 345mg.

Then 3 x BEP with 5 day schedule of etoposide 100mg/m^2/day and cisplatin 20mg/m^2/day.

Surgery/Radiotherapy for Residual Disease:

Seminoma

Surgical resection is not routinely recommended. For patients with a residual mass > 3cm PET-CT scan should be performed [20,21].. If PET negative then repeat scan in 3 months and review at MDT. If PET positive discuss at MDT and consider surgical resection or, if inoperable radiotherapy. Evidence level IIB.

Non-Seminoma

Any patients with a residual mass > 1cm post chemotherapy (including mediastinal disease, pulmonary metastases) should be discussed at the MDT and considered for surgery [7,22]. Evidence level IIA. Normally surgery is only appropriate if tumour markers have stabilised and complete excision is considered to be technically possible.

Residual mass may contain viable tumour, differentiated teratoma or fibrosis/necrosis. The role of further salvage chemotherapy, for patients with incomplete excision and undifferentiated tumour in the resection specimen is uncertain but should be considered [7]. Evidence level IV. Studies suggest that “adjuvant” treatment may improve progression free survival but not necessarily overall survival [23]. Evidence level III.

Surgical Teams:

Retroperitoneal Lymph Node Dissection:

Mr Tim Whittlestone Consultant Urological Surgeon
Bristol Royal Infirmary Tel: 0117 342 3884
MDT Coordinator Lucie Wheeler
Tel: 0117 342 0603

Thoracic disease:
Mr Tim Batchelor Consultant Thoracic Surgeon
Bristol Royal Infirmary Tel: 0117 342 4214 Fax 0117 342 3522
Lung MDT Coordinator Carrie Trott
Tel: 0117 342 0617

Liver Metastases:
Ms Meg Finch-Jones Consultant Hepatobiliary Surgeon
Bristol Royal Infirmary 0117 342 3055 Fax 0117 342 3339
Ian Pope Consultant Hepatobiliary Surgeon
Bristol Royal Infirmary 0117 342 4654 fax as above.
Hepatobiliary MDT Coordinator Serena Hodges and Tracy Goolam-Hossen
Tel: 0117 342 0624

- **Second Line Treatment**

Options for patients with relapsed disease include chemotherapy, surgery or radiotherapy. In general, patients with late relapse of NSGCT (> 2 years) are more likely to be chemotherapy resistant and, where possible, should be considered for immediate surgical resection [7] (Evidence level IV).

There is no accepted standard chemotherapy schedule for relapsed disease. Typical salvage treatments have included VIP (vinblastine or etoposide, ifosfamide and cisplatin), TIP (paclitaxel, ifosfamide and cisplatin) and high dose therapy [24-30]. Currently the recommendation in Bristol is:

TIP x 4 (5-day schedule of paclitaxel 175mg/m2, cisplatin 100mg/m2, ifosfamide 5g/m2) [30](MRC TIP). Evidence level IIB. CT chest, abdomen and pelvis should be performed after 2 cycles and 4 cycles and reviewed at the MDT.

High dose chemotherapy with autologous stem cell support:

This may be considered for responding patients who had a short disease free interval following first line treatment. As yet there is no evidence from randomised trials for superiority over standard dose treatment [29]. Evidence level IB. However, a number of non-randomised trials have reported approximately a 10% improvement in survival using high dose chemotherapy [25, 28]. Evidence level IIB. When considered, patients would normally have a peripheral stem cell harvest following the 2nd or 3rd cycle of TIP with high dose therapy following 4 cycles of TIP. The haematology consultants manage patients during high dose treatment and stem cell support.

Refer to: Dr David Marks Consultant in Haematology
Tel: 0117 342 8523

Dr Steve Robinson Consultant in Haematology
Tel: 0117 342 8817

Third and subsequent lines of treatment

Treatment in this situation is normally palliative. Possible schedules that can be used include gemcitabine – oxaliplatin [31], gemcitabine [32], or oral etoposide [33]. Level of evidence IIA. Where available, patients should be considered for appropriate clinical trials.

7.4.6 Follow up policy

Seminoma Surveillance (Patient to be offered TE24 surveillance study)

Year 1	3 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 6 months and 1 Year
Year 2	3 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 6 months and 1 Year **Late Effects as a control**
Year 3	4 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 1 Year
Year 4	6 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 1 Year
Year 5	6 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 1 Year **Late Effects as a control**
Year 6	Annual Tumour Markers, Clinical Examination and CXR
Year 7	Annual Tumour Markers, Clinical Examination and CXR
Year 8	Annual Tumour Markers, Clinical Examination and CXR
Year 9	Annual Tumour Markers, Clinical Examination and CXR
Year 10	Annual Tumour Markers, Clinical Examination and CXR **Late Effects as a control and Discharge**

Seminoma Post Adjuvant Carboplatin and Post Para-aortic Radiotherapy

Year 1	3 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 1 Year
Year 2	4 Monthly Tumour Markers, Clinical Examination and CXR: CT scan at 1 Year **Late Effects**
Year 3	6 Monthly Tumour Markers, Clinical Examination and CXR
Year 4	6 Monthly Tumour Markers, Clinical Examination and CXR
Year 5	Annual Tumour Markers, Clinical Examination and CT scan at 1 Year **Late Effects**
Year 6	Annual Tumour Markers, Clinical Examination and CXR
Year 7	Annual Tumour Markers, Clinical Examination and CXR
Year 8	Annual Tumour Markers, Clinical Examination and CXR
Year 9	Annual Tumour Markers, Clinical Examination and CXR
Year 10	Annual Tumour Markers, Clinical Examination and CXR **Late Effects and Discharge**

Non Seminomatous Germ Cell Tumours (NSGCT) Active Surveillance

Year 1 and	Monthly Tumour Markers, 2 Monthly Clinical Examination CXR CT Scan C/A/P at 3 months and 1 year.
Year 2	2 Monthly Tumour Markers, 4 monthly Clinical Examination and CXR **Late effects as a control**
Year 3	3 Monthly Tumour Markers, 6 monthly Clinical Examination and CXR
Year 4	6 monthly Tumour Markers, Clinical Examination and CXR
Year 5	Annual Tumour Markers, Clinical Examination and CXR **Late effects as a control and Discharge**

Non Seminomatous Germ Cell Tumours (NSGCT) Post Adjuvant chemotherapy

Year 1	Appointment 4-6 weeks post chemotherapy then: 3 Monthly Tumour Markers, Clinical Examination and CXR: CT Scan at 1 year
Year 2	4 Monthly Tumour Markers, Clinical Examination and CXR **Late effects**
Year 3	6 Monthly Tumour Markers, Clinical Examination and CXR
Year 4	6 Monthly Tumour Markers, Clinical Examination and CXR
Year 5	Annual Tumour Markers, Clinical Examination and CXR **Late Effects**
Year 6	Annual Tumour Markers, Clinical Examination and CXR
Year 7	Annual Tumour Markers, Clinical Examination and CXR
Year 8	Annual Tumour Markers, Clinical Examination and CXR
Year 9	Annual Tumour Markers, Clinical Examination and CXR
Year 10	Annual Tumour Markers, Clinical Examination and CXR **Late effects and Discharge**

Non Seminomatous Germ Cell Tumours (NSGCT) and Seminoma Metastatic Disease

Year 1	4 – 6 week post treatment then: 2 monthly Tumour Markers, Clinical Examination and CXR **CT residual disease according to MDT decision.**
Year 2	4 monthly Tumour Markers, Clinical Examination and CXR **Late effects**
Year 3	6 Monthly Tumour Markers, Clinical Examination and CXR
Year 4	6 Monthly (Tumour Markers, Clinical Examination and CXR
Year 5	Annual Tumour Markers, Clinical Examination and CXR **Late effects**
Year 6	Annual Tumour Markers, Clinical Examination and CXR
Year 7	Annual Tumour Markers, Clinical Examination and CXR
Year 8	Annual Tumour Markers, Clinical Examination and CXR
Year 9	Annual Tumour Markers, Clinical Examination and CXR
Year 10	Annual Tumour Markers, Clinical Examination and CXR **Late effects and Discharge**

Do Not Discharge if Residual Mass.

Repeat CT scan after completion of surgery.

7.4.7 References

1. Guidelines on the management of adult testicular cancer. Clinical Oncology, 2000. 12(5): p. 173-210.
2. Improving Outcomes in Urological Cancer. NICE, 2002.
3. International Germ Cell Consensus Classification: a prognostic factor-based staging system for metastatic germ cell cancers. International Germ Cell Cancer Collaborative Group. J Clin Oncol, 1997. 15(2): p. 594-603.
4. Jones, W.G., et al., Randomized trial of 30 versus 20 Gy in the Adjuvant treatment of Stage 1 testicular seminoma: A report on Medical Research Council Trial TE18, European Organisation for the Research and Treatment of Cancer Trial 30942 (ISRCTN18525328). J Clin Oncol, 2005. 23(6): p. 1200-08
5. Oliver, R.T., et al., Radiotherapy versus single-dose carboplatin in adjuvant treatment of stage 1 seminoma: a randomised trial. Lancet, 2005. 366: p. 293-300
6. Warde, P., et al., Prognostic factors for relapse in stage I seminoma managed by surveillance: a pooled analysis. J Clin Oncol, 2002. 20(22): p. 4448-52.
7. Schmoll, H.J., et al., European consensus on diagnosis and treatment of germ cell cancer: a report of the European Germ Cell Consensus Group (EGCCCG). Ann Oncol, 2004. 15:p. 1377-99

8. de Wit, R., et al., Equivalence of three or four cycles of bleomycin, etoposide, and cisplatin chemotherapy and of a 3- or 5-day schedule in good-prognosis germ cell cancer: a randomized study of the European Organization for Research and Treatment of Cancer Genitourinary Tract Cancer Cooperative Group and the Medical Research Council. J Clin Oncol, 2001. 19(6): p. 1629-40.

9. de Wit, R., et al., Importance of bleomycin in combination chemotherapy for good prognosis testicular nonseminoma: a randomized study of the European Organization for Research and Treatment of Cancer Genitourinary Tract Cancer Cooperative Group. J Clin Oncol, 1997. 15(5): p 1837-43

10. Albers, P., et al., Risk factors for relapse in clinical stage I nonseminomatous testicular germ cell tumours: results of the German Testicular Cancer Study Group trial. J Clin Oncol, 2003. 21: p1505-12

11. Cullen, M.H., et al., Short-course adjuvant chemotherapy in high-risk stage I nonseminomatous germ cell tumors of the testis: a Medical Research Council report. J Clin Oncol, 1996. 14(4): p. 1106-13.

12. O'Sullivan, J.M., et al., Predicting the risk of bleomycin lung toxicity in patients with germ cell tumours. Ann Oncol, 2003. 14: p91-96

13. de Wit, R., et al., Management of intermediate-prognosis germ-cell cancer: results of a phase I/II study of Taxol-BEP. Int J Cancer,1999. 83(6): p. 831-3.

14. Bajorin, D.F., et al., Two-drug therapy in patients with metastatic germ cell tumors. Cancer, 1991. 67(1): p. 28-32.

15. de Wit, R., et al., Four cycles of BEP versus an alternating regime of PVB and BEP in patients with poor-prognosis metastatic t esticular non-seminoma; a randomised study of the EORTC Genitourinary Tract Cancer Cooperative Group. Br J Cancer, 1995. 71(6): p. 1311-4.

16. Kaye, S.B., et al., Intensive induction-sequential chemotherapy with BOP/VIP-B compared with treatment with BEP/EP for poor-prognosis metastatic nonseminomatous germ cell tumor: a Randomized Medical Research Council/European Organization for Research and Treatment of Cancer study. J Clin Oncol, 1998. 16(2): p. 692-701.

17. Nichols, C.R., et al., Randomized comparison of cisplatin and etoposide and either bleomycin or ifosfamide in treatment of advanced disseminated germ cell tumors: an Eastern Cooperative Oncology Group, Southwest Oncology Group, and Cancer and Leukemia Group B Study. J Clin Oncol, 1998. 16(4): p. 1287-93.

18. de Wit, R., et al., Four cycles of BEP vs four cycles of VIP in patients with intermediate-prognosis metastatic testicular non-seminoma: a randomized study of the EORTC Genitourinary Tract Cancer Cooperative Group. European Organization for Research and Treatment of Cancer. Br J Cancer, 1998. 78(6): p. 828-32.

19. Christian, J.A., et al., Intensive induction chemotherapy with CBOP/BEP in patients with poor prognosis germ cell tumors. J Clin Oncol, 2003. 21(5): p. 871-7.

20. De Santis, M., et al., Predictive Impact of 2-18Fluoro-2-deoxy-d-glucons positron emission tomography for residual post chemotherapy massess in patients with bulky seminoma. J Clin Oncol, 2001. 19(17): p. 3740-4

21. Ganjoo, K.N., et al., Positron Emission Tomography scans in the evaluation of postchemotherapy residual masses in patients with seminoma. J Clin Oncol, 1999. 17 (11): p. 3457-60

22. Aprikian, A.G., et al., Resection of post-chemotherapy residual masses and limited retroperitoneal lymphadenectomy in patients with metastatic testicular non-seminomatous germ cell tumours. Cancer, 1994. 74: p. 1329-1334

23. Fizazi, K., et al., Viable malignant cells after primary chemotherapy for disseminated nonseminomatous germ cell tumors: prognostic factors and role of postsurgery chemotherapy--results from an international study group. J Clin Oncol, 2001. 19(10): p. 2647-57.

24. Loehrer, P.J., Sr., et al., Vinblastine plus ifosfamide plus cisplatin as initial salvage therapy in recurrent germ cell tumor. J Clin Oncol, 1998. 16(7): p. 2500-4.

25. Bokemeyer, C., et al., First-line high-dose chemotherapy compared with standard-dose PEB/VIP chemotherapy in patients with advanced germ cell tumors: A multivariate and matched-pair analysis. J Clin Oncol, 1999. 17(11): p. 3450-6.

26. Motzer, R.J., et al., Paclitaxel, ifosfamide, and cisplatin second-line therapy for patients with relapsed testicular germ cell cancer. J Clin Oncol, 2000. 18(12): p. 2413-8.

27. Rick, O., et al., Salvage treatment with paclitaxel, ifosfamide, and cisplatin plus high-dose carboplatin, etoposide, and thiotepa followed by autologous stem-cell rescue in patients with relapsed or refractory germ cell cancer. J Clin Oncol, 2001. 19(1): p. 81-8.

28. Beyer, J., et al., High dose versus conventional dose chemotherapy as first salvage treatment in patients with non-seminomatous germ cell tumours: a matched pair analysis. Ann Oncol, 2002. 13:p. 599-605.

29. Pico, J.L., et al., A randomised trial of high-dose chemotherapy in the salvage treatment of patients failing first line platinum chemotherapy for advanced germ cell tumours. Ann Oncol, 2005. 16: p. 1152-9.

30. Mead, G.M., et al., A phase II trial of TIP (paclitaxel, ifosfamide and cisplatin given as second-line (post BEP) salvage chemotherapy for patients with metastatic germ cell cancer. British Journal Cancer, 2005. 93(2): p. 178-84.

31. Kollmannsberger, C., et al., Combination chemotherapy with gemcitabine plus oxaliplatin in patients with intensively pre-treated or refractory germ cell cancer; A study of the German Testicular

Cancer Study Group. Journal of Clinical Oncology, 2004. 22 (1): p. 108-14.

32. Bokemeyer, C., et al., Gemcitabine in patients with relapsed or cisplatin refractory testicular cancer. Journal of Clinical Oncology, 1999. 17(2): p. 512-6.

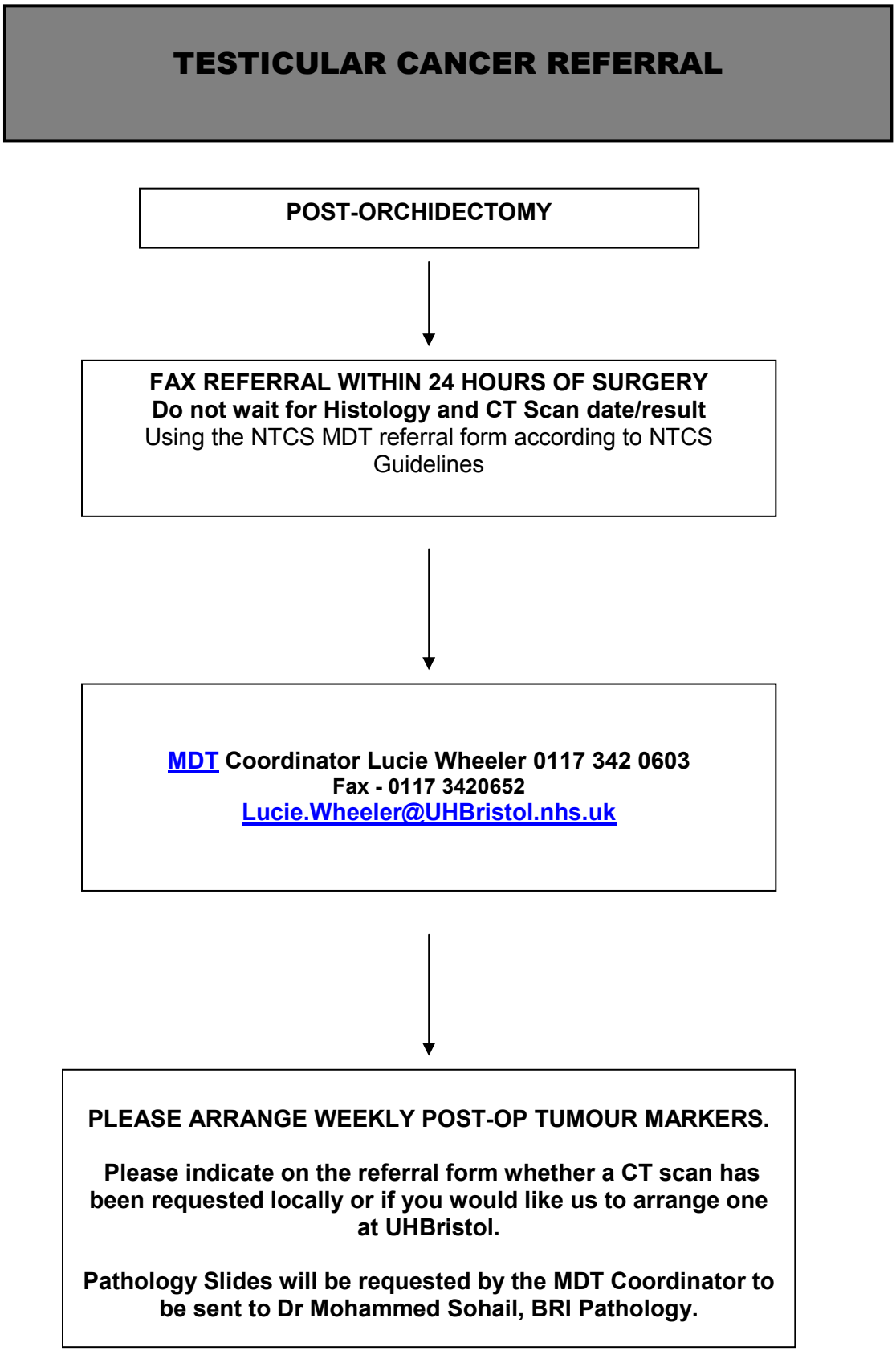
33. Miller, J.C., et al., Phase II study of daily oral etoposide in refractory germ cell tumours. Semin Oncol, 1990: p. 36-9.

34 van den Belt-Dusebout Alexandra W et al Treatment-Specific Risks of Second Malignancies and Cardiovascular Disease in 5-Year Survivors of Testicular Cancer. Journal of Clinical Oncology, 2007: 25 (28) p. 4370-4378

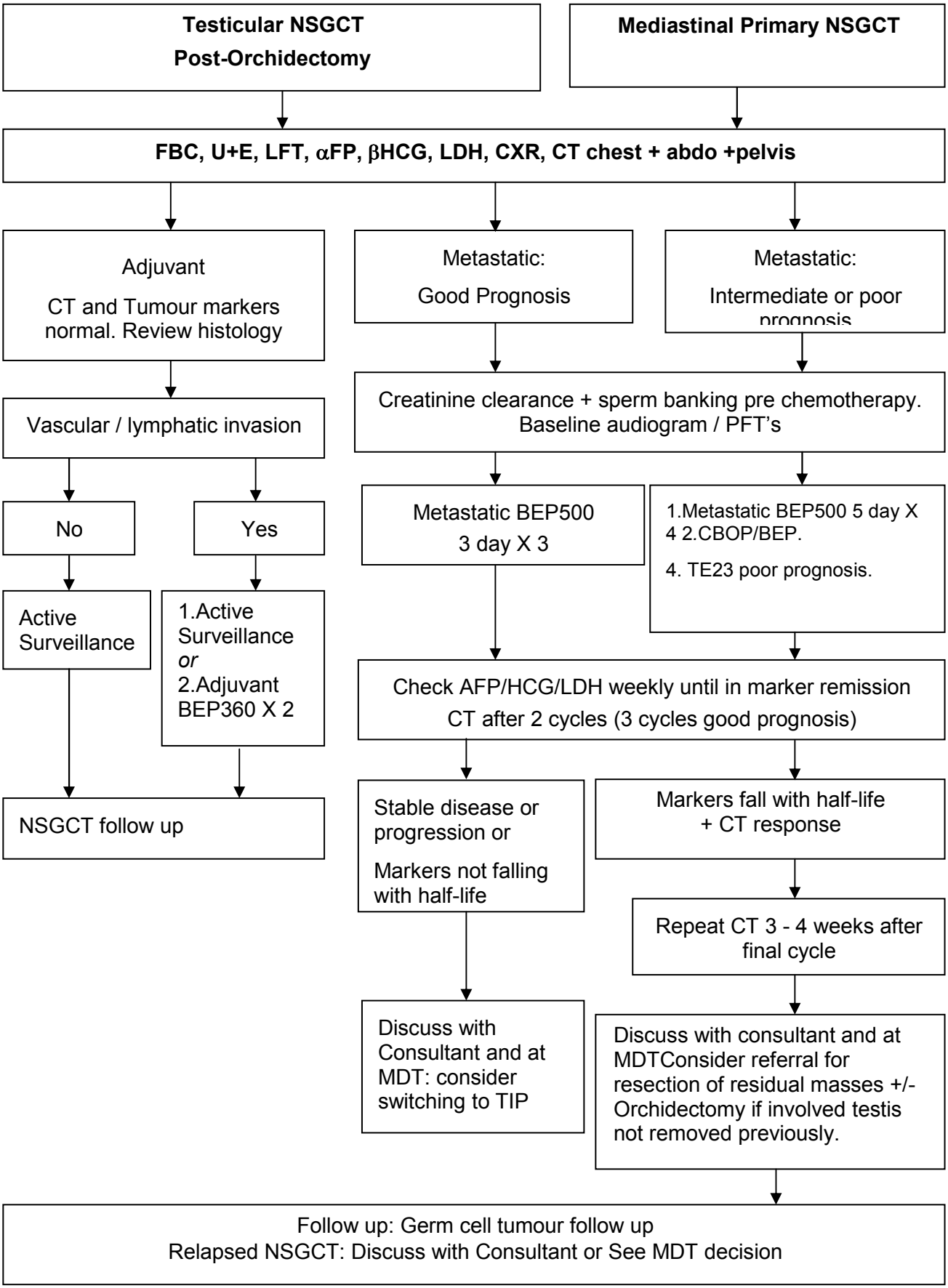
35 Nuver Janine et al the Metabolic Syndrome and Distubances in Hormaone Levels in Long-Term Survivors of Disseminated Testicular Cancer, Journal of Clinical Oncology, 2005 23 (16) p 3718-3724

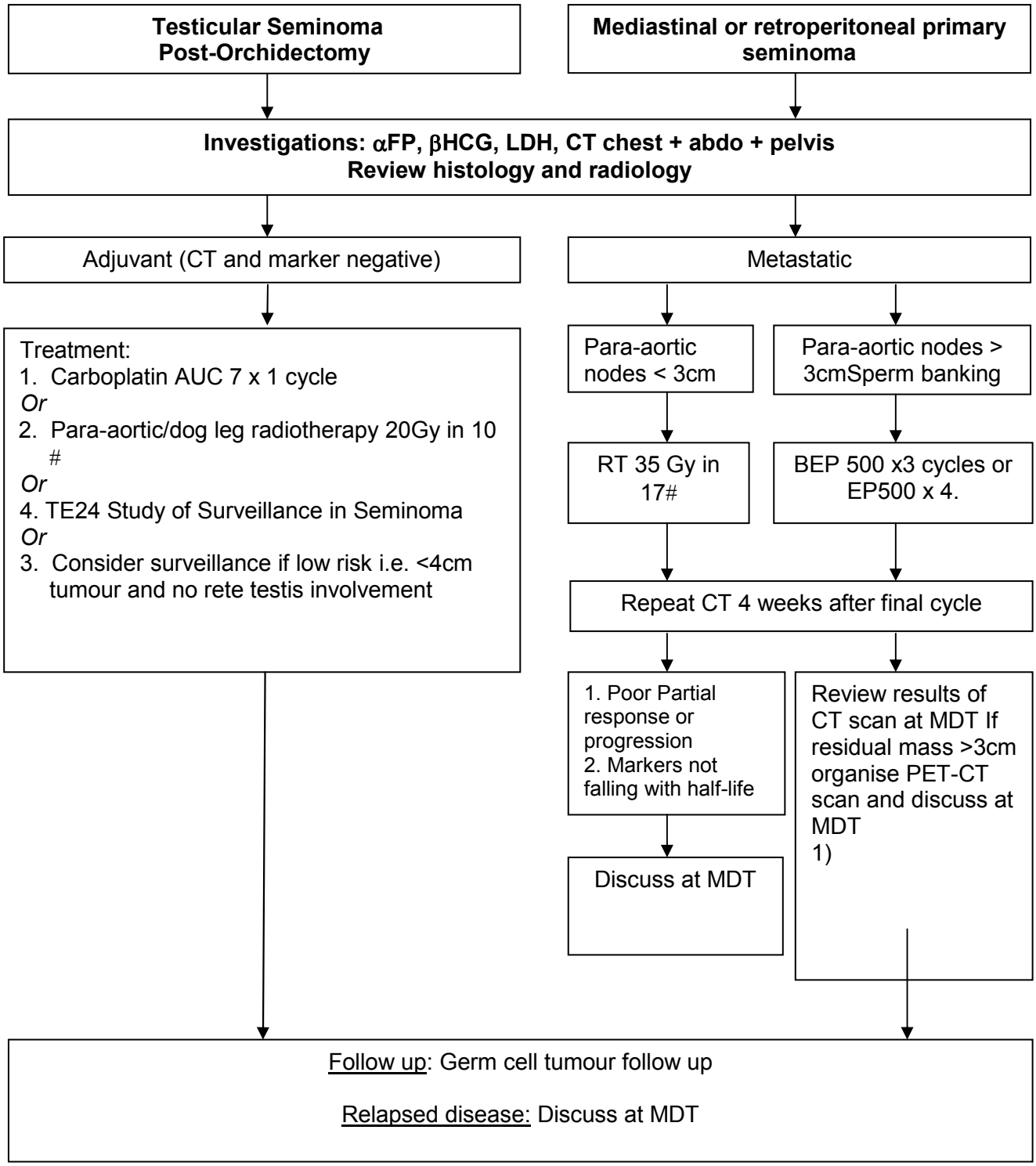
36 Van As N J et al. evidence-based pragmatic guidelines for the follow-up of testicular cancer: optimising the detection of relapse, British Journal of Cancer, 2008. 98 p 1894-1902

7.4.8 Testicular Cancer Flow Diagram



7.4.9 Non Seminomatous Germ Cell Tumour (NSGCT) Flow Sheet




Testicular Seminoma Post-Orchidectomy
Mediastinal or retroperitoneal primary seminoma
Investigations: αFP, βHCG, LDH, CT chest + abdo + pelvis
Review histology and radiology
Adjuvant (CT and marker negative)
Metastatic
Treatment:
1. Carboplatin AUC 7 x 1 cycle
Or
2. Para-aortic/dog leg radiotherapy 20Gy in 10 #
Or
4. TE24 Study of Surveillance in Seminoma
Or
3. Consider surveillance if low risk i.e. <4cm tumour and no rete testis involvement
Para-aortic nodes < 3cm
Para-aortic nodes > 3cmSperm banking
RT 35 Gy in 17#
BEP 500 x3 cycles or EP500 x 4.
Repeat CT 4 weeks after final cycle
1. Poor Partial response or progression
2. Markers not falling with half-life
Discuss at MDT
Review results of CT scan at MDT If residual mass >3cm organise PET-CT scan and discuss at MDT
1)
Follow up: Germ cell tumour follow up
Relapsed disease: Discuss at MDT

7.4.11 Appendix One

Network Site Specialist Group Membership

MDT Member	Name	Organisation
Urologists	Ed Rowe	NBT
	David Gillatt	NBT
	Anthony Timoney	NBT
	Frank Keeley	NBT
	David Dickerson	WAHT/NBT
	Raj Persad (Chair)	UH Bristol
	Mark Wright	UH Bristol
	Tim Whittlestone	UH Bristol
	Tim Porter	YDH
	Ru MacDonagh	TST
	Graham Howell	RUH
	John Macfarlane	RUH
	Chris Gallegos	RUH
	Rupert Beck	Swindon and Marlborough NHS Trust
Oncologists	Hugh Newman	RUH
	Paula Wilson	UH Bristol/BHOC
	Amit Bahl (Vice Chair)	UH Bristol/BHOC
	Serena Hilman	WAHT
	Mark Beresford	UH Bristol/BHOC
	John Graham	TST
	Rob Jones	UHB/BHOC
	Jeremy Braybrooke	UHB/BHOC
Pathologists	John Oxley	NBT
	Chris Collins	UH Bristol
	Mohammed Sohail	UH Bristol
	Chandan Sen	NBT
Radiologists	Julian Kabala	UH Bristol
	Mike Thornton	NBT
	Andrew Mitchelmore	NBT
	Huw Roach	UH Bristol
Clinical Nurse Specialists	Miranda Benny	RUH

MDT Member	Name	Organisation
	Catherine Hurd Peter Gill Julia Hardwick Sue Brand (Germ Cell)	NBT NBT UH Bristol UH Bristol
Research Nurses	Karen Shelley Sharon Tonkin Helen Corderoy	WAHT WAHT NBT
MDT Co-ordinator	Clare Wyatt	NBT
User Representative	Frank Rhodes	
User Representative	Michael Gamblin	
Network Lead Manager	Patricia McLarnon	ASWCS
2nd Network Lead Manager	Mary Barnes	ASWCS
Administrator	Sarah Clacey	ASWCS

7.4.12 Appendix Two

Network Testicular Cancer Service

Bristol Haematology and Oncology Centre

MDT Referral Form

<table>
<tr><td colspan="3">Referring Trust:

Referring Clinician:

Urology CNS and contact:

NHS Number:</td><td colspan="4">Patient Details:
Surname:
Forename(s):
Address:

Gender Male / Female
DOB:
Patients telephone Number:</td></tr>
<tr><td colspan="3" rowspan="2">USS Date and Result.
(Please include side of tumour, please tick)</td><td colspan="4"></td></tr>
<tr><td>Right</td><td></td><td>Left</td><td></td></tr>
<tr><td colspan="3">Date of Orchidectomy</td><td colspan="4"></td></tr>
<tr><td colspan="3">Prosthesis offered</td><td>Yes</td><td></td><td>No</td><td></td></tr>
<tr><td colspan="3">Prosthesis placed</td><td>Yes</td><td></td><td>No</td><td></td></tr>
<tr><td>Tumour Markers</td><td colspan="2">AFP</td><td colspan="2">HCG</td><td colspan="2">LDH</td></tr>
<tr><td>Pre – Operative</td><td colspan="2"></td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">Staging CT Scan (within 2 weeks of surgery)</td><td colspan="4">Date:</td></tr>
<tr><td colspan="3">Patient Information given (please tick)
(Information for Men Diagnosed with Testicular Cancer) available on DMS (UHB)</td><td>Yes</td><td></td><td>No</td><td></td></tr>
<tr><td colspan="3">Key Worker Details given</td><td>Yes</td><td></td><td>No</td><td></td></tr>
<tr><td colspan="7">Additional Clinical Information:</td></tr>
<tr><td colspan="7">Please note the Network Testicular MDT is held on Fridays at 8.30am
The cut off for New Patient referrals is Wednesday at 14:00, any received after this time will be added to the next available MDT.
Please Fax/email this referral to:
Lucie Wheeler Urology and Testicular MDT Co-ordinator
Lucie.wheeler@UHBristol.nhs.uk / Fax - 0117 3420652 / Tel – 0117 3420603</td></tr>
</table>

7.4.13 Appendix Three

Network Testicular Cancer Service.

Bristol Haematology and Oncology Centre.

MDT Referral Guidance.

These guidelines have been written to help the process of referral to the Network Testicular Cancer Service MDT. If you have any questions regarding these guidelines or the process please contact one of the team.

On confirmation of a tumour by testicular USS then:

- Surgery to be arranged at local hospital;
- Tumour Markers to be taken. (AFP, LDH and HCG);
- Staging CT Scan (Chest, abdomen and pelvis) to be arranged.

  (**Within 2 weeks of surgery**).

The CT Scan can be performed Pre Orchidectomy but should not delay treatment.

Referral to Oncologist with 24 hours of surgery

Markers – AFP, LDH and HCG should be taken on the day of Surgery (if not previously taken).

Please arrange for patient to have weekly post operative tumour markers.

Clinical Nurse Specialist (CNS)

Sue Brand Germ Cell CNS will be notified of new patient referrals and offer support and advice.

Contact details

Dr J Braybrooke, Consultant Medical Oncologist.

0117 923 0000 via BRI switchboard if urgent.

Dr R Jones, Consultant Medical Oncologist.

0117 923 0000 via BRI switchboard if urgent

Sue Brand, Germ Cell Clinical Nurse Specialist.

(Available Tues, Thurs and Friday)

0117 342 3472 or mobile 07827082328

Bleep 5147 via 9230000

Lucie Wheeler, MDT Co-ordinator. 0117 342 0603.

Sue Gray, Secretary 0117 342 2418.

Urgent Referrals

Please contact Dr Braybrooke/Dr Jones direct via BRI switchboard

7.5 Guidelines on the Management of Penile Cancer Including supra-network information

7.5.1 Introduction

The NICE Improving Outcomes Guidance on Urological Cancers recommend that all new cases of carcinoma of the penis should be reviewed by a specialist penile cancer team and that men who are likely to require organ conserving treatment, reconstruction or node clearance surgery are managed by a 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;

ASWCS	2.1 million population
Three Counties Network	1.3 million population
Peninsula Network	1.7 million population

Local teams around the Network carry out diagnostic procedures including biopsy or circumcision and may treat penile cancer with surgery without penile reconstruction or lymph node resection.

7.5.2 Named Supranetwork Team

Name	Title	Trust
Core Team		
Mr David Dickerson	Consultant Urologist	Weston Area Health NHS Trust
Mr Ed Rowe	Consultant Urologist	North Bristol Trust
Mr Tim Porter	Consultant Urologist	Taunton & Somerset Trust
Clare Wyatt	MDT Co-ordinator	North Bristol Trust
Dr Jon Oxley	Histopathologist	North Bristol Trust
Dr Mark Thornton	Radiologist	North Bristol Trust
Dr Amit Bahl	Oncologist	University Hospitals Bristol NHS Foundation Trust
Dr Mark Beresford	Oncologist	University Hospitals Bristol NHS Foundation Trust
Dr Serena Hilman	Oncologist	Weston Area Health NHS Trust
Dr Andrew Mitchelmore	Radiologist	North Bristol Trust
Sr Catherine Hurd, Mr Peter Gill, Sr Sharon Tonkin	Uro-oncology nurse specialist	North Bristol Trust, Weston Area Health NHS Trust

Extended team		
Mr Tim Burge Mr Alan Kay Mr John Palmer	Plastic Surgeon Plastic Surgeon Plastic Surgeon	North Bristol Trust North Bristol Trust Royal Devon and Exeter
Dr Giles Dunnel Dr David DeBerker	Consultant Dermatologist Consultant Dermatologist	North Bristol Trust
Host Centre Consultant	Consultant in Palliative care	
TBC	Psycho-sexual Counselor	

7.5.3 Multi-Disciplinary Team Meetings (MDT/MDM)

The ASWCS Network uro-oncology MDT has been meeting weekly in Southmead Hospital every Wednesday afternoon with attendance from all the urology clinicians from the six Acute Trusts around the Network and a full complement of other key MDT members including oncologists, pathologists, radiologists specialist nurses etc.

There are 25-30 Network cases discussed at this meeting (100% of appropriate cancer diagnosis) every week with approximately 30 new penile cases discussed per year in a supra-network setting.

Communication with local and diagnostic teams

The MDT outcome proforma will be faxed back to the referring team with outcome and plans/recommendations. In addition, where patients are seen and assessed for supranetwork treatment in the joint clinic, a more detailed letter copied to the GP will follow the proforma.

It is intended that there will be an opportunity on an annual basis for the supranetwork team to meet with those members of the referring teams who deal with penile cancer to discuss and feedback on issues relating to diagnosis, workup, management, outcome, and operation of the Network as well as audit of patients referred.

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

The Network have agreed a list of specialist teams for the Network who may counsel patients in order for them to select their primary treatment option from curative surgery, curative radiotherapy or other options.

Trust	Surgeon(s)	Oncologist
NBT	David Dickerson/Ed Rowe	Amit Bahl
UHB	Tim Whittlestone	Hugh Newman, Amit Bahl, Mark Beresford
YDH	Christopher Parker, Tim Porter	
RUH	Christopher Gallegos, Graham Howell	Hugh Newman, Amit Bahl
TST	Ruaraidh, MacDonagh, Tim Porter	John Graham
WAHT	David Dickerson	Serena Hilman

Core team members to present options to patients

The core team members from the supranetwork penile cancer team who will present the options for curative surgery, curative radiotherapy or other options are:

- David Dickerson (Surgeon);
- Amit Bahl (Oncologist);
- Catherine Hurd (CNS).

The patients who will require counseling on options from the core team members will be seen at the joint clinic at the specialist Urology Centre in North Bristol Trust.

The sites which will deliver a radiotherapy and chemotherapy service are The Bristol Hematology and Chemotherapy Service in Bristol and the Royal United Hospital in Bath. Chemotherapy only, can be delivered in Weston Area Health Trust and Taunton and Somerset NHS Trust.

Communication with referring Networks and General Practitioners

The MDT outcome proforma is faxed back to the referring team within 24hrs. Where appropriate a detailed letter will follow the proforma with a copy sent to the patients General Practitioner.

Shared Care arrangements with referring Networks

Shared care arrangements are mutually agreed on a case by case basis by the referring and supra-Network teams, and as outlined under 1.9 diagnosis and assessment below.

Facilities for patients

As the Supra-Network centre for penile cancers Southmead Hospital is equipped and staffed appropriately to provide the following:

- Dedicated Urology outpatients department with access to penile specialist and core team members;
- Dedicated Urology wards;

- Dedicated Urology theatres;
- Urology oncology clinical nurse specialists;
- Lymphoedema service.

Waiting times position

Currently there is a weekly core member MDT meeting and all referrals are reviewed in the next MDT after receipt of the referral. Relevant histology specimens and imaging will be discussed, and, where necessary, patients will be offered an appointment in the joint clinic after the MDT for assessment and to discuss and arrange supranetwork care. Treatment recommendations will be made to the referring MDT where treatment can be carried out locally.

There is a weekly operating list at South mead Hospital to accommodate appropriate cases and the aim is to offer a date for surgery within national cancer waiting times standards, especially when the clinical situation requires more urgent intervention, unless patients request a later date (if clinically acceptable).

7.5.4 Network Site Specialist Group Meetings

The ASWCS Site Specialist Group for Urology meets quarterly, after the Network Specialist MDT on Wednesday afternoons at the Bristol Urological Institute at Southmead Hospital, Bristol.

All six Acute Trusts have representation at the meeting. There are also members of the Network management team and consistent user representation.

Diagnosis and assessment

Patients should be referred under the two-week rule to their local urology department for initial diagnosis and assessment and each new case should be reviewed by the supranetwork MDT. Following referral the network MDT will review all pathology.

Those cases likely to require organ preserving treatment, reconstruction, node clearance surgery or complex adjuvant therapy should be assessed and where appropriate treated by this team.

Other forms of treatment (partial or total penectomy, radiotherapy, or chemotherapy) may be carried out by other (local referring) specialist urological cancer teams which do not specialise in penile cancer but the penile cancer supranetwork MDT which reviews the case and makes treatment recommendations remains responsible for the overall management of the case.

7.5.5 Guidelines on Diagnosis of Penile Cancer

Primary Lesion

Detailed physical examination of the penis noting the size, nature and position of the primary tumour, if this is possible. A deep biopsy of the lesion is mandatory and in cases where there is a tight phimosis a dorsal slit may be necessary to perform this. Cytological scrapings are usually inadequate and under-stage the disease. Ultrasound and MRI scanning of the penis have been used for staging but the role has not been fully established and should be considered optional.

Regional Nodes

Physical examination of the inguinal nodes will categorize people into clinically positive (palpable nodes) and clinically negative (impalpable nodes). In the case of clinically positive groin nodes fine needle aspiration or preferably ultrasound guided fine needle aspiration is recommended. A CT scan of the chest, abdomen and pelvis is recommended. If the aspiration is negative and there is still a high index of suspicion, open biopsy of the lymph node should be considered.

7.5.6 Guidelines on Treatment of Penile Cancer

Treatment of the Primary Lesion

Stage TiS (carcinoma in situ)

Lesions on the penile shaft skin are most commonly Bowen's disease or bowenoid papulosis. These lesions can be excised with a small margin of surrounding penile skin and patients should be advised on regular follow up. If the foreskin and glans are otherwise normal, circumcision is optional.

Erythroplasia of Queryat is a red velvety lesion on the glans and/or inner prepuce. This has a higher incidence of conversion to invasive disease and should be managed differently. A circumcision is recommended. Careful examination of the glans with 5% acetic acid staining together with deep biopsy is recommended. Inspection of the distal urethra is recommended. Primary treatment should include a course of a topical chemotherapy agent such as 5 Fluro Uracil, Bleomycin or Imiquimod. Incomplete responders could be offered a second course of chemotherapy or laser vapourization or total glans resurfacing with partial thickness skin. Close follow up is recommended.

Ta (verrucous carcinoma)

A penile preserving treatment is recommended. These include circumcision if the lesion is solely on the prepuce. For lesions on the glans wide local excision for smaller lesions or total glans resurfacing or glansectomy for larger lesions is recommended.

TI lesions

TI lesions of the prepuce only can be treated by a circumcision and close follow up. TI lesions of the glans are managed with a penile preserving surgical procedure such as wide local excision with or without grafting or glansectomy and skin grafting. Radiotherapy is an option that may be considered for organ preservation.

T2/T3 lesions

Larger distal tumours invading the glans and/or corporal heads can be managed with penile preserving surgery in most cases. Frozen section analysis of the margins of the resection are mandatory. Either glansectomy and skin graft reconstruction or glansectomy and distal corporectomy and reconstruction are recommended. For large proximal shaft tumours, consideration should be given to penile preservation. In selected cases partial amputation and delayed phalloplasty should be considered. If penile preservation is not considered possible, radical penectomy with perineal urethrostomy is recommended. Radiotherapy is an alternative alternative treatment where organ preservation is desired.

T4 lesions

Radical penectomy and formation of perineal urethrostomy is usually the only option. In selected cases down staging with neoadjuvant chemotherapy should be considered. Depending on the patient's performance status and co-morbidities chemotherapy and/or radiotherapy maybe an option.

7.5.7 Management of the Regional Nodes

Clinically Negative at Presentation

Ta GI, TI GI lesions Patients are observed

≥TI G2 lesions, T2-4, Any T stage with vascular invasion, Any G3

Patients should be considered for modified radical inguinal node dissection based on their risk status. Patients who are advised or elect surveillance are followed up two monthly for the first year, three monthly for the second year and four monthly for the third year. Surveillance includes physical examination and ultrasound or MRI examination with or without fine needle aspiration of the groins

Patients in whom MRI, ultrasound, FNA and/or dynamic sentinel lymph node study are positive undergo modified radical inguinal node dissection.

Clinically Positive at Presentation

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

N1 Disease

Patients with a single positive node without extra-capsular extension should then be kept on surveillance. The role of CT/MRI scanning in follow up is currently being evaluated.

N2 Disease

Patients with a single positive node with extra-capsular extension should be offered adjuvant radiotherapy to the ipsilateral groin. Patients with multiple or bilateral superficial nodes should be considered for bilateral pelvic node dissection or adjuvant radiotherapy to the involved groin and pelvic sidewall. Chemotherapy should ideally be considered within a clinical trial (although currently none is open for recruitment).

N3 Disease

In unilateral disease ipsilateral pelvic node dissection coupled with adjuvant radiotherapy to the groin and pelvis is recommended, chemotherapy should be considered as for N2 disease.

Positive Pelvic Nodes

For small volume disease consideration should be given for complete pelvic node dissection followed by adjuvant radiotherapy and chemotherapy. For patients with large volume disease at presentation, surgery is optional and consideration should be given for primary radio-chemotherapy. Again, ideally, chemotherapy should be offered within the context of a clinical trial.

Fixed or Fungating Inguinal Nodes

Careful assessment should be made before a final decision. Sometimes it is possible to down-stage patients with chemotherapy and sometimes with the help of a vascular surgeon or plastic surgeon it is possible to remove nodes. However, in truly inoperable situations palliative radiotherapy or chemo-ratdiotherapy would be appropriate.

Delayed Presentation of Positive Groin Nodes

In this situation ipsilateral modified inguinal node dissection is appropriate. Assessment of the contra-lateral groin is sensible but is usually not involved. The same subsequent management depends on the number of nodes affected.

Metastatic Disease

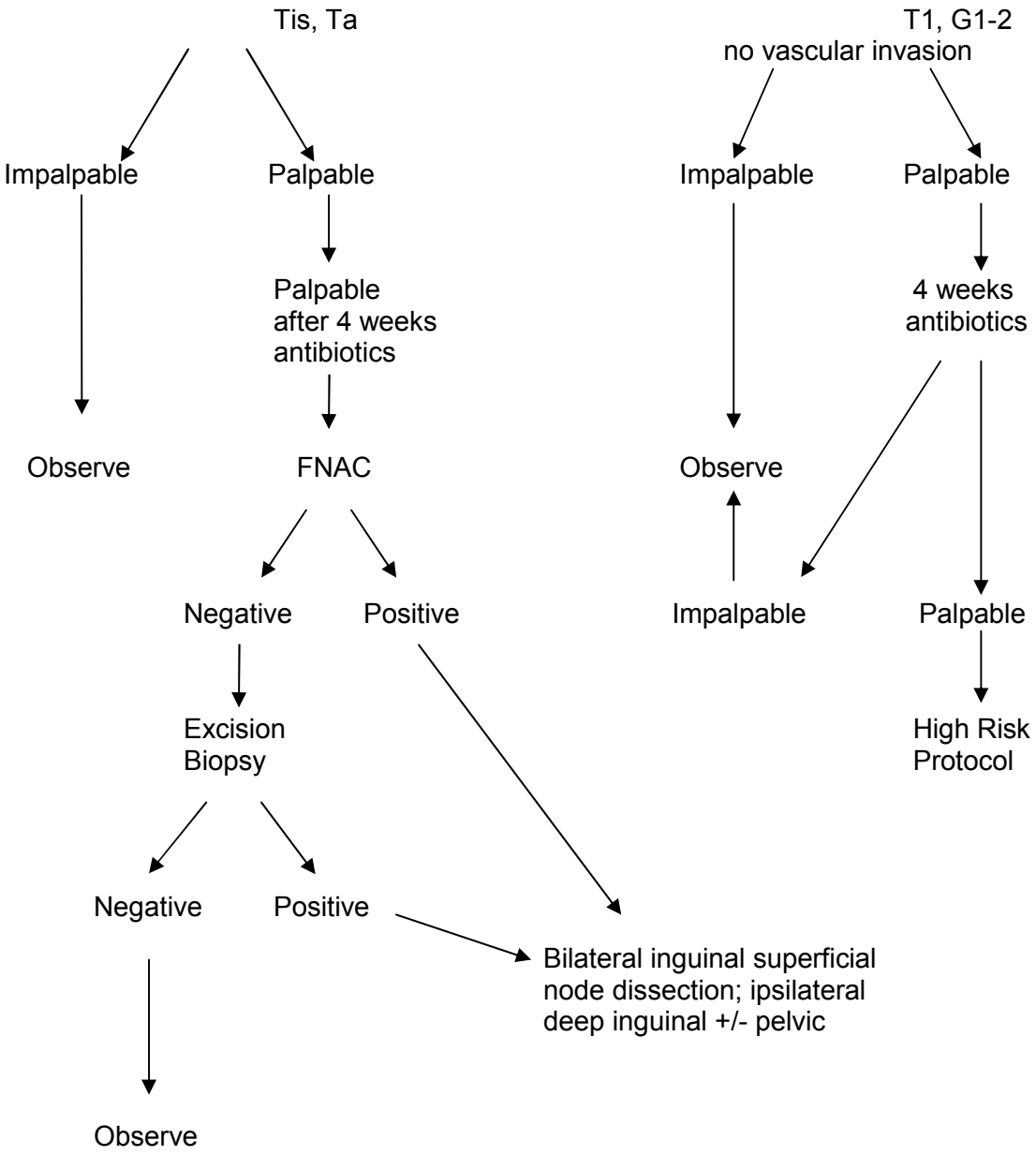
Palliative chemotherapy can be helpful to slow the progression of metastatic disease. There is no specific regime, which is generally recognized Cis-platinum and 5 Fluro-urocil are used though use of newer chemotherapy agents is being considered. Pulmonary metastases are the commonest site and chest CT should be offered in following up high-risk patients. The most common site for metastases is in the chest and the chest CT scan is probably the best way to evaluate this.

7.5.8 Trials

Currently there are no trials in penile cancer running at the Bristol Haematology and Oncology Centre.

The local lymph nodes may be managed on the basis of stratification into low and high-risk groups as indicated in the tables below:

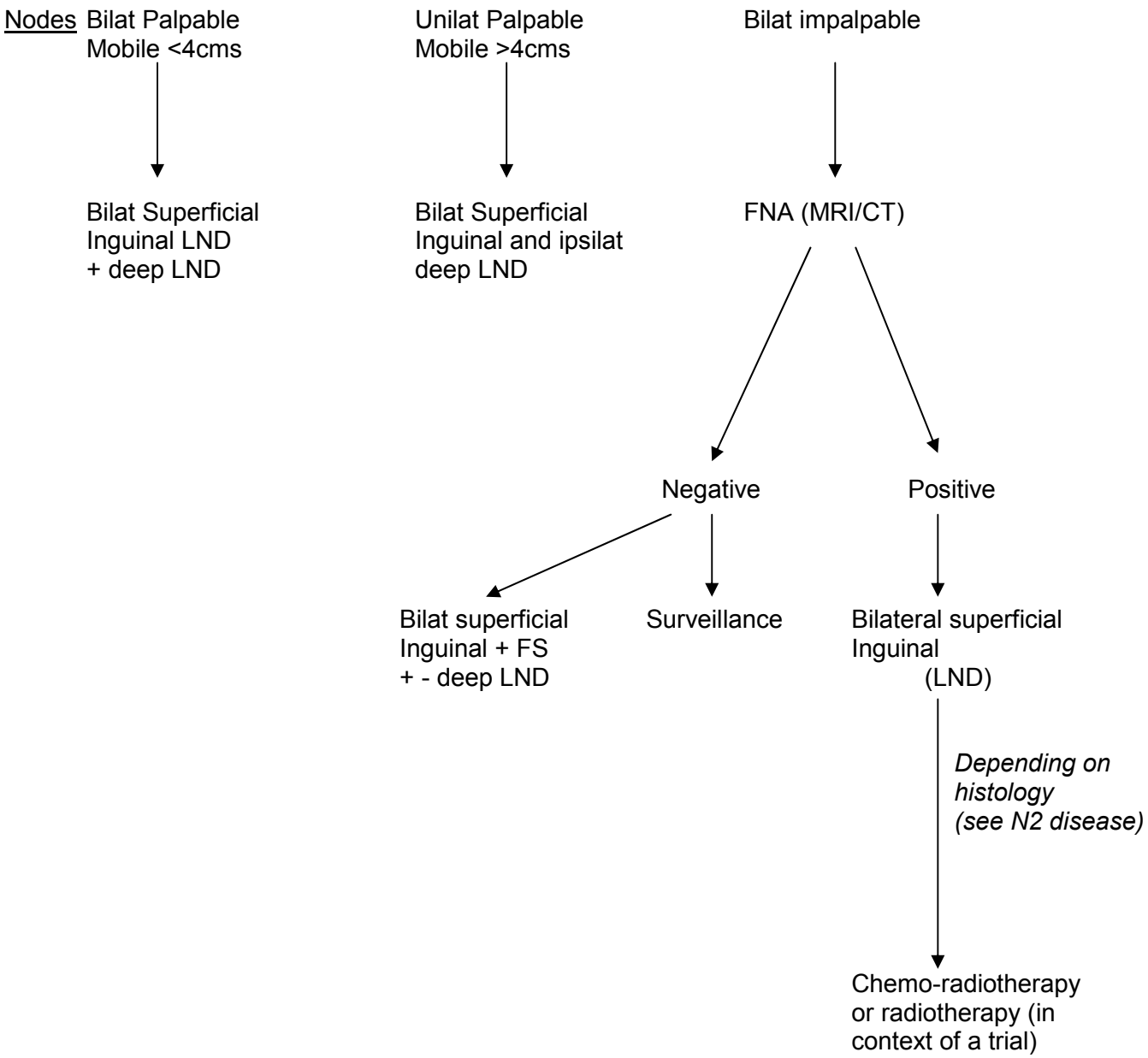
Low Risk Group



High Risk Group

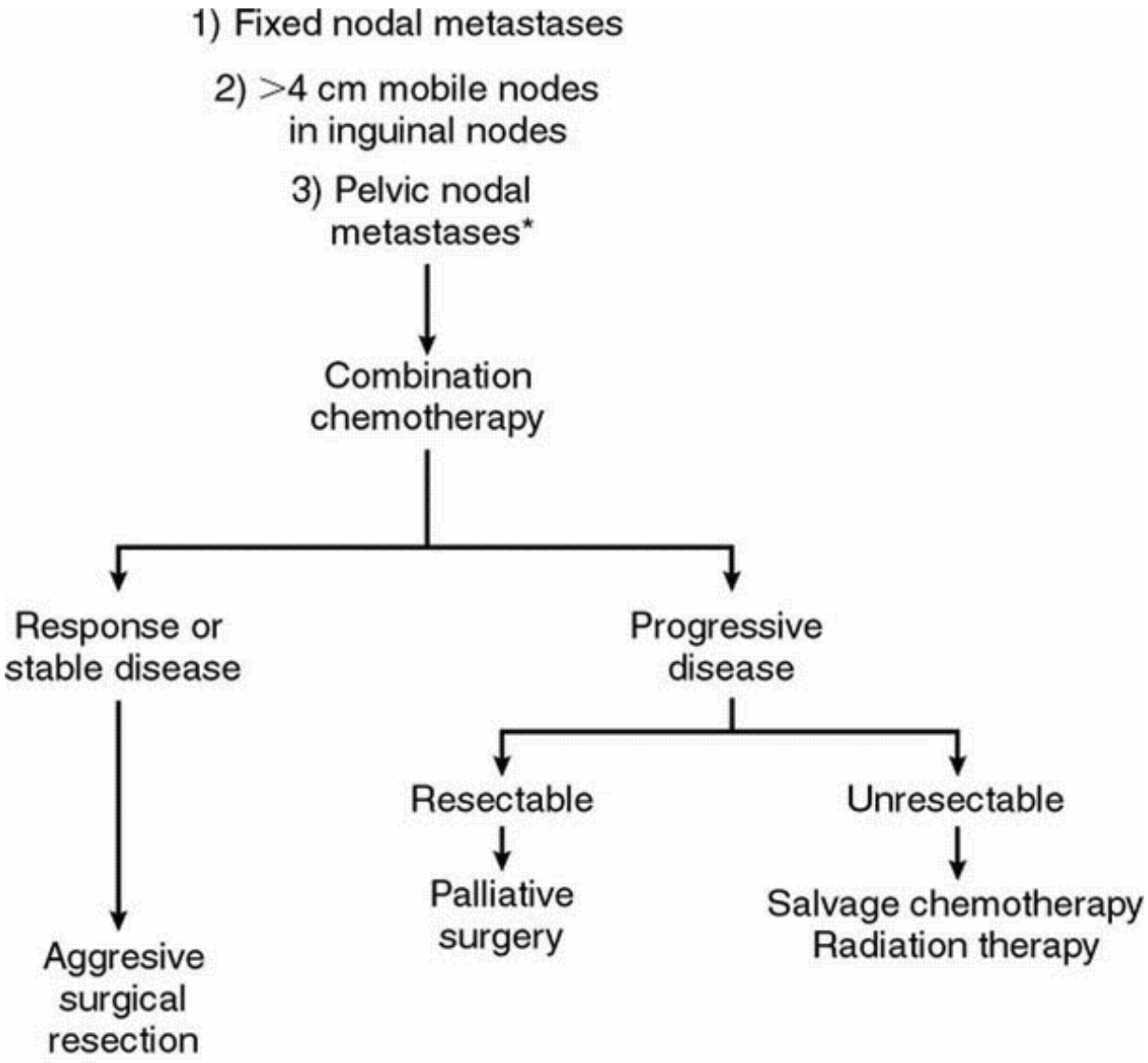
T2-4

Any T stage with vascular invasion
Any Grade 3



Bulky Adenopathy and Fixed Nodal mass

Survival in this patient cohort is related to completely eradicating extensive disease. This task is difficult to achieve with surgery, chemotherapy, or radiotherapy alone.



*Subsequent to preoperative imaging studies.

7.5.9 Follow-up

A post surgical follow-up appointment may be offered at two to three weeks to check on progress, discuss the definitive histology and to plan further treatment.

Subsequent follow-up regime dependent on risk of developing lymph node metastases:

YEAR	Low Risk Group • Tis, Ta • T1 G1-2 with no vascular invasion	High Risk Group Any G3 T2-3 Vascular invasion
1 and 2	3 months	2 months
3	4 months	3 months
4	6 months	6 months
5+	Annually	Annually

September 2005

7.5.10 Appendix Two - Operational policy for the Penile Cancer Supra-network Multidisciplinary Team

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 patient care of 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 entry 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 ASWCS network and centre MDT providing care for all cases of penile ca. from the local catchment as well as for the network and supra-network and currently receives referrals from the following Networks;

ASWCS	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 of 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 recognised 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 meeting and team meet Peer Review Quality Measures
- Ensure that target of 100% of new penile cancer patients are discussed at the MDT meeting is met.
- 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 target 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 (SPC) / Supra-Network MDT meets weekly in Southmead Hospital / BUI every Wednesday afternoon with recorded attendance of the core/extended team members and urology clinicians from the 6 other Trusts around the Network and other key MDT members including oncologists, pathologists, radiologists specialist nurses etc. Core members or their deputies should achieve > 50% 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 (proforma fax sheet.)

There are 25-30 Network cases discussed at this meeting every week with approximately 30 new penile cases discussed per year.

Referral of patients to MDT

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

- Faxed proforma to MDT co-ordinator (contact details, copy of proforma);
- Direct referral to core members of SPCMDT (letter, telephone).

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 TWW arrangements.

All new cases of penile cancer, recurrent disease, patients with Lymph node metastasis or those with high risk of lymph node metastasis should be discussed at the MDT.

All relevant scans/x-rays and Pathology slides should be reviewed at the MDT and management/follow up recommendations made as per agreed network guidelines, and where supra-network treatment is planned, the relevant scans/x-rays will be forwarded to the admission point.

Once decided, the management plan/outcome is fast tracked back to referringTeam/Centre/Specialist (proforma fax back followed by letter.)

Where appropriate (i.e. supra-network care/assessment likely or necessary, e.g. Stage 1 penile cancer, recurrence or LN disease) the patient will be offered an either Joint Clinic appointment or meeting with any member of the MDT to be assessed and/or to discuss and arrange further diagnostic tests/treatment.

Surgical procedures designated as requiring supranetwork care will be carried out on the North Bristol Trust Southmead Hospital site and patients

will be offered a choice of elective admission or treatment (out patient) dates at the consultation at which treatment is decided.

Where appropriate, patients may be referred to neighboring or remote supranetworks or specialist centres (e.g. total penile reconstruction or where core member is unable to provide specific treatment timeously due to leave illness etc. to Mr David Ralph(London) or Mr Aivar Bracka(Midlands) as per agreed referral guidelines.

Patient Information

The MDT will develop and provide written information to patients including:

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

and will develop Template info sheet/booklet for use throughout the Supra-network.

Network Guidelines and Audit

The MDT (supra-network) will meet annually to discuss/ develop/approve/agree:

- Guidelines (Network) 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) including cancer wait times and to be carried out by all MDT's (for Penile Cancer Site) in the Network;
- The audited total number of annual penile cancer referrals and surgical procedures by individual surgeon will be reported and minuted at the AGM.

Service Improvement

MDT Lead is responsible for including service improvement into MDT function and 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.

8 Patient Involvement and Information

The ASWCS network is committed to the development of a patient centred care. With this in mind the ASWCS User Involvement Group has produced a series of policy documents aiming to contribute to improved patient and carer experience.

8.1 Principles of Effective Patient Involvement and Information

The following summarises the level of service that people affected by cancer should expect. This is based on the service model of the NICE Supportive and Palliative Care Guidance.

People affected by cancer should be involved in decisions about their care and treatment. They should always be able to express their views or worries about their treatment and care.

People affected by cancer can expect their health team to communicate clearly with them. They should feel confident that the doctors, nurses and other health staff caring for them are honest and sensitive when talking to them, and explain things in a way they understand.

People affected by cancer should be told where they can get help and advice. The name and contact details of a key worker should be given to them so that they can get in touch if they need any information or advice.

People affected by cancer should be offered as much information as they want. Clinical Nurse Specialists have an important role to play in explaining the clinical care and treatment, while the information specialists at the Information and Support Centres (where available) can provide information about the impact of living with Cancer.

Health professionals looking after service users should be aware that your needs are not only physical and medical. They should ask you about the kind of practical and social support they may need as well and put them in touch with people and local organisations who can help.

Health staff should be aware that some people want emotional and spiritual support, and help them to find it - if that is what they want.

Service users should also be offered help living with the effects of cancer and its treatment.

Health and social care staff should ensure that families and friends are asked about their needs, particularly at crucial times such as diagnosis or bereavement, and get all the emotional and practical support they need.

People affected by cancer should expect a speedy response at times of greatest need.

Preferences about where and how someone wants die should be respected.

People affected by cancer should be offered an opportunity to get involved in making cancer services better; for example by being put in touch with the ASWCS User Involvement Group.

8.2 Communicating Significant News

The following section summarises the main points of the ASWCS Communicating Significant News Policy. The whole guidance is available online at http://www.aswcs.nhs.uk/supportivecare/bbnindex.htm

The User Involvement Group has also produced a leaflet summarising this policy. The leaflet has been distributed to all key MDT members.

8.2.1 Before a first cancer related appointment

The information and support needs of patients and their carers need to be addressed at what could be a stressful time.

An appointment letter should be accompanied by a leaflet explaining why the patient has been referred by his/ her GP. The letter can also suggest that the patient can bring with him/her a member of his/ her family or a significant other.

8.2.2 Breaking Bad News – confirming a diagnosis

A cancer diagnosis should be communicated honestly to the patient with the minimum of delay.

This information should be communicated in a comfortable quiet area with privacy and without interruption, ideally in the company of a close relative or a significant other, if this is the patient's preference.

Patient dignity is also important, and the aim is that the patient should be fully dressed.

The number of people present should be kept to a minimum, although it is suggested that a specialist nurse should be present.

Health professionals should also make sure that they introduce themselves at the start of the consultation.

Health professionals should also respect the wish of the patient if he/ or she does not wish to be told bad news. Further opportunities for discussion should be planned according to patient's wishes.

It must be remembered that screen, cubicle walls and curtains surrounding bed are not soundproof.

Exceptions may be made when patient care may be affected i.e. Intensive Care Unit- High Dependency Unit (ICU-HDU), recovery post anaesthesia and emergencies.

Information should be delivered in a way and a format that the patient can understand. Special attention should be paid to these needs of people with learning, memory or other sensory disabilities.

Patients should be given information to help make an informed decision on their treatment options. This should include written and verbal information on the cancer type, diagnostic procedures, treatment options, effects and side effects, possible outcomes, post treatment options.

Patients should also be given an option to receive a patient held record/ diary if they so wish (either the Teamwork file or cancer specific patient held diaries that have been developed locally).

Patients should have an opportunity to review what has been said during the consultation and also ask further questions.

Breaking Bad News Training should be made available to all staff who have contact with cancer patients.

8.3 Holistic Needs Assessment Guidance

The Measure 1E-502 of the Manual of National Cancer Measures (2004), stipulates that the Network Partnership Group should develop a Holistic Needs Assessment Guidance addressing the needs of people affected by cancer. The terms holistic includes a number of different needs – physical, psychological, social, spiritual information and carers' needs.

A Network Workshop was held in Bath in November 2004 which was attended by a wide range of health care professionals, the voluntary sector, service users and carers. During the course of the Workshop all participants were asked to consider what they perceived to be essential core components of a holistic needs assessment at the following key points during the patient pathway:

- Pre Diagnosis – including GP referral;
- Diagnosis;
- Treatment;
- Post treatment or living with cancer;
- End of Life.

The Network Holistic Needs Assessment Framework aims to give prompts for needs that should be assessed throughout the cancer journey. This could be either user led, focusing on health and well being, or professionally led. The workshop participants were in agreement that local solutions could be found providing that all the core principles as detailed in the guidance were met and that information was easily transferable should users move around the Network and duplication of assessment did not take place.

The full guidance is available online at
http://www.aswcs.nhs.uk/supportivecare/holistic.htm