

Greater Manchester, Cheshire, Lancashire & South Cumbria Supra Network Clinical Guidelines For Suspected and Confirmed Germ Cell Tumours of the Testis and other sites

Document Owner	Mr A Gulamhusein
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1 Background

The Christie NHS Foundation Trust in partnership with local trusts provide a supra-regional service for male genital cancers including penile cancer, prostate cancer, inguinoscrotal sarcoma and testis cancer. The service has seen a yearly increase in the number of new referrals over the last decade and has a national and international reputation for clinical management, and its research programme.

The Supraregional Testis Cancer MDT covers a population of approximately 7 million people.

2 Hospital Trusts Covered by this Policy

Blackpool Teaching Hospitals NHS Foundation Trust

Bolton NHS Foundation Trust

East Lancashire Hospitals NHS Trust

Lancashire Teaching Hospitals NHS Foundation Trust

Manchester University NHS Foundation Trust

Mid Cheshire Hospitals NHS Foundation Trust

Northern Care Alliance NHS Foundation Trust

Stockport NHS Foundation Trust

Tameside and Glossop Integrated Care NHS Foundation Trust

The Christie NHS Foundation Trust

University Hospitals of Morecambe Bay NHS Foundation Trust

Wrightington, Wigan and Leigh NHS Foundation Trust

3 Abbreviations and Definitions

Abbreviation	Expanded definition
AFP	Alpha-fetoprotein
AUC	Area Under the Curve
BEP	Bleomycin, Etoposide, Cisplatin chemotherapy regimen
β-HCG BHCG	/ Beta-human chorionic gonadotropin
CNS	Clinical Nurse Specialist
CT	Computed Tomography
CXR	Chest X-ray
DVT	Deep Vein Thrombosis
ECG	Electrocardiogram
EP	Etoposide + Cisplatin regimen
ESMO	European Society for Medical Oncology
FBC	Full Blood Count
FSE	Frozen Section Examination
FSH	Follicle-stimulating Hormone
GCT	Germ Cell Tumour
GCNIS	Germ Cell Neoplasia In Situ
GFR	Glomerular Filtration Rate
GP	General Practitioner
HCG	Human Chorionic Gonadotropin (total)
HIV	Human Immunodeficiency Virus
HNA	Holistic Needs Assessment
HTLV	Human T-cell Lymphotropic Virus
IGCCCCG	International Germ Cell Cancer Collaborative Group
ISUP	International Society of Urological Pathology
LDH	Lactate Dehydrogenase
LH	Luteinising Hormone
LN	Lymph Node
LVI	Lymphovascular Invasion
MDT / SnMDT	Multidisciplinary Team / Supraregional MDT
MRI	Magnetic Resonance Imaging
MUGA	Multigated Acquisition Scan
NSGCT	Non-seminomatous Germ Cell Tumour
PC-RPLND	Post-Chemotherapy Retroperitoneal Lymph Node Dissection
PET-CT	Positron Emission Tomography – Computed Tomography
PFT	Pulmonary Function Test(s)
PPV / NPV	Positive Predictive Value / Negative Predictive Value
PTTO	Percentage Testis Tumour Occupation
RPLND	Retroperitoneal Lymph Node Dissection
RMH staging	Royal Marsden Hospital staging system
RPLND	Retroperitoneal Lymph Node Dissection
SHBG	Sex Hormone Binding Globulin

STM	Small Testicular Mass
SnMDT	Testis Supraregional MDT hosted at The Christie NHS Foundation Trust (See Appendix A for operational documents)
TC	Testicular Cancer
TESE / onco-TESE	Testicular Sperm Extraction / Oncological Sperm Extraction
TIP	Paclitaxel, Ifosfamide, Cisplatin salvage regimen
TRISST	Trial of Imaging and Schedule in Seminoma Surveillance
TSS	Testis Sparing Surgery
TYA	Teenage and Young Adult (Oncology Service)
UICC TNM	Union for International Cancer Control TNM staging system
USS	Ultrasound Scan
AFP	Alpha-fetoprotein
AUC	Area Under the Curve (chemotherapy dosing parameter)
BEP	Bleomycin, Etoposide, Cisplatin chemotherapy regimen
β-HCG / BHCG	Beta-human chorionic gonadotropin
CNS	Clinical Nurse Specialist
CT	Computed Tomography

5 Introduction

Testicular cancer is a rare male genital malignancy with a high curative rate following surgery and adjuvant chemotherapy. Although some subtypes can grow rapidly, the majority can be treated following adequate staging and semen cryopreservation. A delay in referral for urological assessment can adversely affect the long-term outcome for the patient and the intensity of treatment.

5.1 Presenting Symptoms

Approximately 80-90% of patients will present with an enlarged testicle or mass in the testicle. This may be painless although 15% present with pain, sometimes described as a dragging sensation which can be associated with lower abdominal pain. In 97% of patients a mass is present on clinical examination. If this is clearly within the testis there is a high probability of an underlying testicular cancer.

A tender mass or enlargement persisting 10 days after starting antibiotics for a presumed infection requires imaging. A sudden development of a varicocele or hydrocele may also indicate an underlying testicular pathology. Gynaecomastia may be present in a small number of patients.

Back pain with weight loss and general systemic symptoms may be suggestive of metastatic disease.

A history of testicular maldescent is present in 10% of patients

6 Workup staging and diagnosis for newly suspected or diagnosed GCT testis

6.1 Overview

Below is an overview of the pathway.

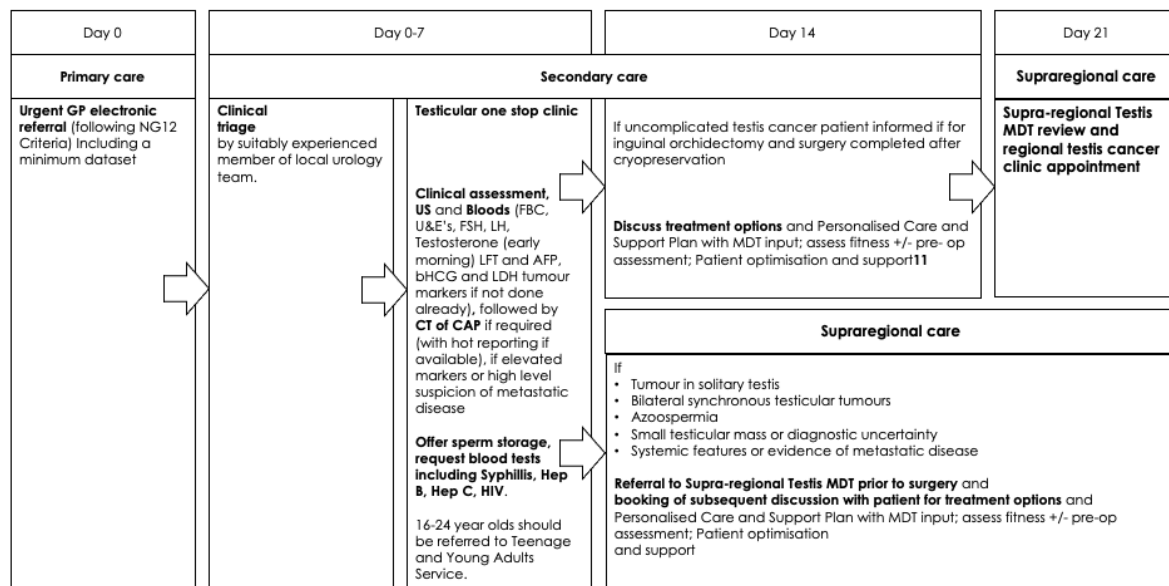


Figure 1 Summary of suggested best timed pathway for diagnostic pathway.

6.2 Patient group

Patients presenting with a new diagnosis of primary and/ or metastatic testis cancer/ mass

6.3 Inclusion criteria

- Male patient, testicular mass, 18 years of age and above
- Other suspicion of testicular cancer: gynecomastia with high serum B-HCG, raised AFP or LDH, metastatic disease in context of appropriate age group
- Female: primary ovarian germ cell tumour
- Refer pre op to SnMDT if small testicular mass <2cm **and** normal tumour markers or testicular mass with infertility.
- < 18 years of age: patient should be referred to paediatric services
- Primary non-germ cell cancer of testis
- Paratesticular (consider Christie Retroperitoneal/ Sarcoma MDT)

6.4 Initial investigations and work up prior to start of treatment

- All patients presenting with suspected testicular cancer should be referred urgently to the local urologist with a nominated role in cancer management and active involvement in local cancer MDT at the earliest opportunity.
- Two-week referral pathway should be used for patients with swelling in the body of the testis

6.5 Initial assessment

Bloods

- Tumour serum markers: Alpha-fetoprotein (AFP); beta-hCG; LDH (pre-operatively)
- Sperm storage requirements: Hepatitis B and C and HIV and HTLV 1 and 2 viral screen, Syphilis serology
- Hormone assessment; Early morning fasted testosterone, FSH, LH
- Full Blood Count (FBC), Renal profile, Bone Biochemistry and Liver function tests

Imaging

- Urgent bilateral USS testes (>10MHz). Document:
 - Lesion size in two dimensions
 - Vascularity
 - Solid and cystic components
 - Testis size or Percentage Testis Tumour Occupation (PTTO)
 - Location including side
 - Presence of microlithiasis (defined as borderline or pronounced; Borderline= 3-7 micro calcifications per transducer field , Pronounced >7 per transducer field.
- Staging CT chest abdomen pelvis with contrast if tumour confirmed on ultrasound
- MRI brain and Spine when multiple lung metastases or poor-prognosis IGCCCG risk group (especially with β -hCG values > 5,000 UI/L), or clinical symptoms

Fertility assessment

- Semen analysis and sperm banking if accepted

6.6 Expedite referral to the SnMDT without orchidectomy

In the following **Special Circumstances** referral should be made direct to sMDT core member at Lancashire (Lancashire Teaching Hospitals NHS FT) or Greater Manchester/Cheshire (The Christie NHS FT) without proceeding immediately to orchidectomy:

Surgical (for more information see section 8)

- Azoospermia
- Bilateral Testis tumours
- Small testis mass defined as <2cm and normal tumour markers
- Solitary testis

Oncology (for more information see section #)

- Non-gonadal germ cell tumour of (mediastinum, retroperitoneum, brain)
- Obvious metastatic disease
- Severe constitutional symptoms
- Very high tumour markers

6.7 Radical Orchidectomy

- Patients should be offered/counselled about testicular prosthesis insertion, and this should be recorded in the case notes.
- Patients undergoing testicular prosthesis insertion should receive a stat dose of antibiotic at surgery / induction
- Notify Teenage & Young Adult (TYA) MDT at primary treatment centre (Christie YOU) if 18-24 years
- Surgery should be performed within 31 days of referral (including non HSC205 referrals)
- DVT prophylaxis – either flowtron boots, TEDS and low molecular weight heparin should be administered and documented
- Where there is a clinical suspicion of testicular cancer then the preferred approach is a groin incision (not scrotal).
- Consider open inguinal biopsy of contra lateral testis if any of the following factors are present
 - History of cryptorchidism
 - Marked testicular atrophy (<12ml)
 - Age < 30 years
- The orchidectomy specimen should be placed in an adequate volume (at least 5:1) of formaldehyde fixative.
- The specimen should be bivalved through the rete testis and epididymis either in theatre or as soon as it arrives in the pathology department to allow proper fixation.
- Early referral after orchidectomy to SnMDT and SnMDT oncology representative for area (see Appendix A)

7 Special Circumstances

7.1 Solitary testis with suspected malignancy or bilateral synchronous tumours or contralateral atrophic testis

If a patient has a solitary testis with suspected malignancy or bilateral synchronous tumours, they should be discussed at the SnMDT prior to definitive surgery for consideration as to whether they are candidates for pre-operative chemotherapy or testis sparing surgery (TSS) (see figure 2). This may prevent hypogonadism and infertility in young men and preserve wellbeing.

7.2 Indeterminate Small Testis Masses (STM)

Higher resolution ultrasound scanning (USS) and broader indications for performing an USS of the scrotum has led to an increase in the number of indeterminate lesions being detected. Of lesions with small diameter virtually all < 3mm, 87% of those < 5mm and 70% < 10mm may be benign. A Small Testis Mass is defined as <2cm.

STM should be discussed at the sMDT with a specialist radiology review prior to surgical management. Depending on the degree of suspicion they may undergo surveillance or TSS with ultrasound guided excision and intraoperative frozen section by a SnMDT pathologist.

7.3 Testis Sparing Surgery (TSS)

7.3.1 Indications

TSS should be considered for:

- lesions in a solitary testis
- patients with an atrophic contralateral testis
- bilateral testis lesions
- STM with negative tumour markers

7.3.2 Summary Process

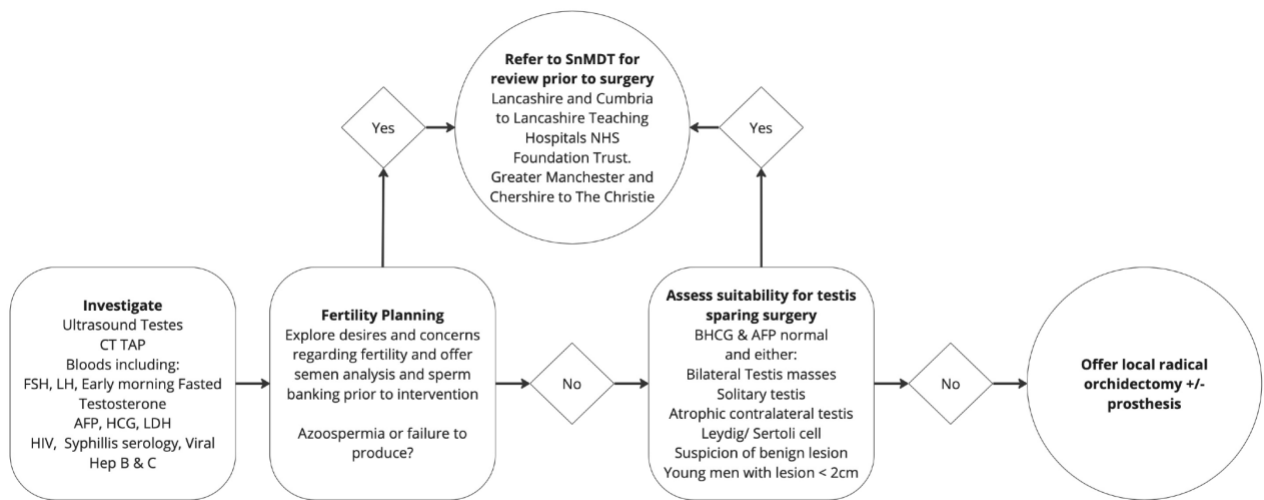


Figure 2 Summary pathway for patients with infertility and STM.

7.3.3 Prior to Testis Sparing Surgery

In cases of a history of GCT or indeterminate small testicular mass, patients should be made aware of the following issues regarding TSS practice:

- local recurrence rates have been reported up to 26.9%, when TC is present in the specimen and that TSS has implications for ongoing surveillance of the testis.
- patients should be informed about the role and impact of adjuvant radiotherapy when GCNIS is present, potential infertility, the need for hormonal supplementation despite parenchyma preservation and that occasional discordance between frozen section examination (FSE) and final pathology may lead to need for a delayed orchidectomy.
- There is a high risk of residual tumour following excision and patients should be warned that a completion orchidectomy may be advised following histological analysis.

7.3.4 Surgical Description

- DVT prophylaxis – either flowtron boots, TEDS and low molecular weight heparin should be administered and documented
- Impalpable lesions in all cases need to undergo a further USS on the day of surgery either on table or a radiology departmental scan with marking of the patient to prevent the possibility of wrong side surgery.
- The preferred approach is a groin incision (not scrotal).
- In patients with synchronous bilateral tumours or in tumours in solitary testis two additional testicular biopsies should be taken to exclude GCNIS

- TSS should be offered together with FSE. FSE has shown to be reliable and highly concordant with final histopathology in expert hands, with a 99% and 96% of sensitivity and specificity respectively and 98% and 97% of PPV and NPV, respectively. FSE should only be performed by a member of the snMDT to ensure adequate exposure and maintenance of appropriate expertise
- The specimen should be placed in an adequate volume (at least 5:1) of formaldehyde fixative.

7.4 Azoospermia

Patients found to be azoospermic pre-operatively must be referred to the Testis Cancer SnMDT prior to surgery. These patients can be offered an oncoTESE on the day of cancer surgery. St Mary's reproductive unit will be contacted (via the andrology lab) in advance of the surgery to provide the relevant consent, transportation units and media. A surgical sperm retrieval can be performed from tubules adjacent to the tumour or from the contralateral testicle. Indeterminate lesions in azoospermic patients can be removed at the time of a microdissection TESE. These need to be discussed at the Testis Cancer SnMDT and the plan documented. Where the lesions are likely to be malignant based on imaging or tumour markers, surgery should be conducted by a core SnMDT member.

Post operative histopathology should be rediscussed at Testis Cancer SnMDT.

7.5 Histopathology

Mandatory pathological requirements based on recommendations of the International Society of Urological Pathology (ISUP) should be followed.

7.5.1 Staging

- Patients must be referred to the SnMDT with full staging (See figure 2)
- If cross sectional imaging is requested by the local team then it should include imaging of thorax abdomen and pelvis (CT preferable)
- Both the UICC TNM 7th ed and the RMH staging system will be used (See appendix B)
- Patients with metastatic disease will also be assessed according to the IGCCCG prognostic group (See appendix B)
- Patients with Stage I disease will be further classified for risk of relapse as per Warde et al. 2002 {Warde, 2002 #14} and Hoskin et al. 1986 {Hoskin, 1986 #16}
- Seminoma high risk features: size > 4cm; rete testis involvement and raised LDH
- Non-seminoma high risk features: Lymphovascular invasion, yolk sac and choriocarcinomatous elements

8 Post-Orchidectomy Care (local)

Following definitive management of the primary the patient should be seen by the operating team or a representative of.

The following investigations should be performed as standard

- Bloods including:
 - FBC & differential
 - U & E
 - LFT's (+gammaGT)
 - Baseline early morning fasted Testosterone
 - Tumour Markers- HCG, AFP, LDH, weekly until seen by oncology.
- CT scan of chest, abdomen and pelvis (if not performed pre-operatively)
 - The CT scan should be performed according to a defined protocol and should be reviewed by a Radiologist experienced in the interpretation of germ cell tumour patients' investigations. Any previous radiology should also be reviewed by this Radiologist

8.1.1 Additional Staging

- CNS staging (Gadolinium-enhanced MRI) is indicated in patients with > 20 lung metastases or HCG>20,000 (if not already performed)
- Bone Scan – may be considered in patients with metastatic seminoma or with symptoms consistent with skeletal disease

8.1.2 Patient information

The patient is offered information relating to their cancer in a timely and sensitive manner. This is the responsibility of the key worker, but other members of the team should also be involved in the process.

Patients will be offered information relating to:

- Diagnostic procedure
- Form of cancer (NSGCT, Seminoma)
- Local information regarding treatment options including chemotherapy and surgery
- Access to services offering psychological, social, spiritual/cultural and financial support if required
- Patient involvement and self-help groups if required
- Sperm storage (including contact arrangements specific to the sperm storage facilities available to teams' patients)
- Relevant clinical trials
- Holistic Needs Assessment

Information is given both verbally and in written format and where possible audio and visual supplements are supplied.

Where a patient does not understand or speak English, a Patient Advocate is booked or Language Line should be used, as appropriate.

8.1.3 Referral to SnMDT (For operational details regarding SnMDT please see appendix A)

- All patients undergoing orchidectomy for suspected malignancy should be referred to a core member of the SnMDT either at Lancashire Teaching Hospitals NHS Foundation Trust or The Christie NHS Foundation Trust (hosted at the Christie Hospital within 48 hours of surgery).
- Patients should be referred to a named member of the SnMDT (see contacts in Appendix A).
- All referrals to the Testis Cancer SnMDT meeting should be communicated via the Testis Cancer SnMDT Coordinator at The Christie NHS Foundation Trust and Lancashire Teaching Hospitals NHS FT. All appropriate imaging or location of such imaging should be sent to the coordinator along with pathological details, including location of pathology material and details of reporting pathologists.
- All referrals should be made to the MDT Coordinator by Monday 1700hrs prior to the SMDT meeting.

8.2 SnMDT meeting

- All new cases will be reviewed at least once at the snMDT meeting (The Christie NHS Foundation Trust, every Wednesday 1pm).
- Uncomplicated cases will normally be reviewed post-orchidectomy once staging and pathological review is complete to formulate the post-orchidectomy treatment plan
- The responsible clinician should complete the SnMDT request form and submit this to the MDT co-ordinator
- The responsible clinician (or a deputy who has physically assessed the patient) should attend the SnMDT meeting to discuss the patient.
- Attendance through video link is acceptable

8.3 Place of on-going further management

The following patients should be managed in the supraregional centre:

- Patients requiring post chemotherapy surgery (GCT 5)
- TYA patients 16 – 17 years 11 months should be managed at Primary Treatment Centre for TYA patients (The Christie NHS Foundation Trust Young Adolescent Unit)
- TYA patients 18 – 24 years 11 months should be offered unhindered access to PTC for TYAs

9 TESTIS: GCNIS

Patients diagnosed with GCNIS on biopsy of contralateral testis at time of orchidectomy

9.1 Inclusion criteria

- Histologically proven GCNIS

9.2 Exclusion Criteria

- None

9.3 Guidance.

- For patients with biopsy-proven GCNIS of the contralateral testis close surveillance is a suitable management. This should include regular self examination, 6 monthly US imaging and tumour marker checks. Radiotherapy or orchidectomy are alternative options in selected patients.

10 TESTIS: Active surveillance for Stage I GCT

10.1 Introduction/Background

Approximately 80% of patients with testicular cancer present with clinical stage I disease and if no further therapy is given approximately 20% of these will relapse over the next 5 years due to micro-metastatic disease that is clinically undetectable at the time of presentation. If high risk features are present in the pathologic assessment then the risk of relapse may be as high as 50%.

Management options include adjuvant therapy or follow-up without therapy with a view to chemotherapy for patients who relapse. Managed properly, long term disease specific survival is likely equivalent for either approach. Active surveillance is the term used to indicate a careful programme of intensive follow-up designed to detect relapse early and to ensure compliance with the follow-up requirements.

Advantages of active surveillance include reducing exposure to toxic therapy to only those who need it (i.e. those who relapse) and thereby avoiding late effects of therapy in many patients.

Disadvantages include burden of clinic visits on the patient and the hospital, and increased exposure to diagnostic radiation.

Active surveillance in non-seminoma is much assisted by the likelihood that relapse will be detected first through monitoring of tumour serum markers. In seminoma, tumour serum markers are often not present and therefore there is more reliance on diagnostic imaging. In seminoma, relapse after 2 years is not infrequently seen and this means that diagnostic imaging must be continued longer than is usually thought necessary in non-seminoma

10.2 Patient Group

Active surveillance is currently considered the optimal management option for patients with the following characteristics:

Germ cell tumour of testis

Non-seminoma histology or mixed seminoma + non-seminoma confirmed on expert review or pure classical seminoma
Stage 1 confirmed by radiology review at Christie
Willing and able to comply with visit schedule

10.3 Initial investigations

- Full clerking
- Staging and work-up complete (see TESTIS 1a)
-

10.4 Non-seminoma and mixed histology germ cell tumour (as per ESMO guidelines)

10.4.1 Visit Schedule

- Year 1: tumour markers 4 times, CXR 2 times, MR/CT abdo pelvis 2 times
- Year 2: tumour markers 4 times, CXR 2 times, MR/CT abdo pelvis at 24 months
- Year 3: tumour markers 2 times, CXR 1 time if LVI, MR/CT abdo pelvis once at 36 months
- Year 4 & 5: tumour markers 1-2 times, CXR once at 60 months if LVI, MR/CT abdo pelvis once at 60 months
- After year 5: further management according to survivorship care plan
-

10.5 Seminoma (as per TRISST)

10.5.1 Visit schedule

- Every 3 months years 1 – 2
- Every 4 months years 3
- Then 6 monthly to 5 years
- Annually years 5 – 10 then discharge

10.5.2 Screening at each clinic

- Directed H&P (including LN, abdomen and testis)
- Blood draw for serum tumour markers AFT, b-HCG and LDH

10.5.3 Routine MRI scans

- MRI abdomen
- MRI at 6 months, 18 months and 36 months.
- CXR at all visits until 6 years.

11 TESTIS: Stage I Seminoma

Surveillance (schedule as per 11.5, TRISST study protocol is standard of care)

Adjuvant carboplatin single cycle AUC 7 should be discussed with patients who have risk factors (tumour size >4cm and stromal rete testis invasion)
Adjuvant radiotherapy only to be offered in exceptional cases.

11.1 Routine clinic visit schedule post adjuvant chemo (as per ESMO guidelines)

- Year 1: tumour markers 2 times, MR/CT abdo pelvis 2 times
- Year 2: tumour markers 2 times, MR/CT abdo pelvis 2 times
- Year 3: Tumour markers 2 times, MR/CT abdo pelvis once at 36 months
- Year 4 & 5: Tumour markers once, MR/CT abdo pelvis once at 60 months
- After 5 years: further management according to survivorship care plan

12 TESTIS: Stage I NSGCT

Surveillance is standard of care.

Patients with LVI , embryonal carcinoma and choriocarcinoma, have a high risk of relapse and should be offered 'preferably' BEP x1

Robotic RPLND considered in specific cases, namely patients with post pubertal teratoma with a somatic malignant component in orchidectomy specimen or where patients are unwilling to accept surveillance/not suitable for chemotherapy.

12.1 Routine clinic visit schedule (as per ESMO guidelines)

- Year 1: tumour markers 4 times; chest X-ray 2 times; abdominopelvic MRI/CT 2 times
- Year 2: tumour markers 4 times; chest X-ray 2 times; abdominopelvic MRI/CT at 24 months (plus an additional CT at 18 months if LVI+)
- Year 3: tumour markers 2 times; chest X-ray once if LVI+; abdominopelvic MRI/CT once at 36 months
- Year 4 & 5: tumour markers 1–2 times; chest X-ray at 60 months if LVI+; abdominopelvic MRI/CT once at 60 months
- After 5 years: further management according to survivorship care plan

13 TESTIS: Stage IIA/B seminoma

Patients with retroperitoneal LNs <2cm and normal markers: consider repeat staging CT TAP 6-8 weeks.

If persistent nodes and markers remain normal, can offer robotic RPLND (modified template with nerve sparing) in the context of a prospective cohort series

MDT discussion with post op path regarding surveillance versus adjuvant chemotherapy (eg 1x carboplatin AUC 7) if viable disease

Chemotherapy remains a standard option (3x BEP or 4x EP)

Radiotherapy remains an alternative

14 First Line Chemotherapy with BEP for metastatic GCT

Chemotherapy with 3x BEP or 4x EP is the standard of care for good prognosis. For Intermediate and poor prognosis 4x BEP are recommended.

Carboplatin AUC 10 is an alternative in patients with low volume metastatic disease, or where there has been previous treatment eg for a contralateral metastatic GCT on a case by case basis and data collection is paramount as part of a cohort group

14.1 Patient group

This regimen is usually used for patients with metastatic primary germ cell testicular cancer and primary extra-gonadal germ cell tumours (mediastinal or retroperitoneal) and for patients with primary ovarian germ cell cancer.

14.2 Inclusion criteria

- Histologically proven germ cell tumours of testis (seminoma or non-seminoma) N+ or M+, good, intermediate or poor prognosis
- **OR** Histologically proven extra-gonadal germ cell tumour (mediastinal or retroperitoneal)
- **OR** Any widespread malignancy with high B-HCG with or without histology particularly in a younger male patient
- **OR** selected patients with metastatic malignancy of unknown origin, undifferentiated with elevated AFP and no other cause for this found (e.g. Hepatocellular carcinoma) after discussion in the snMDT meeting

14.3 Exclusion Criteria

- Severe pre-existing renal impairment (GFR < 40 ml/min)

14.4 Initial investigations and work up prior to start of chemotherapy

- Regime for BEP as on Alliance chemotherapy algorithms.

14.4.1 Work-up

- Routine biochemistry, haematology (inc coagulation), CXR, ECG
- PFT (if to have bleomycin)
- GFR by isotope estimation, 24 hr urine collection for creatinine clearance or calculated GFR using Cockcroft-Gault formula
- Audiometry
- Offer semen storage (requires HepB, HepC and HIV status)
- ECHO or MUGA only if clinically indicated
- Patient information sheet
- Counsel patient regarding risks of chemotherapy and 24 hour telephone advice service.
- Informed Consent Form

14.5 Specific concerns for Drugs and Doses

- Consideration of **omitting** bleomycin will be given in the following circumstances:
- Patient over the age of 40 years
- Heavy smoking history
- Co-morbid pulmonary conditions
- Pure seminoma (optional, at physician's discretion)
- GFR < 40

14.5.1 Cycle length

- 21 days

14.5.2 Number of cycles

14.5.3 BEP

Good prognosis group: 3 cycles

Intermediate and poor prognosis: 4 cycles

14.5.4 EP

4 cycles will be given if bleomycin is omitted

14.6 On treatment assessments and dose modifications as per local guidelines at LTHTR and Christie (links)

Consider thromboprophylaxis in high risk patients

14.6.1 Tumour response assessment

- No routine in-treatment response assessment by CT scan – only if concern regarding tumour progression (new symptoms or marker rise)

14.7 Dose modifications & Toxicity

According to regime at treating centre protocols

14.8 Follow-up

14.8.1 Routine clinic visit schedule

- Year 1: tumour markers 4 times; chest X-ray 1–2 times; abdominopelvic MRI/CT 1–2 times; thorax CT 1–2 times (if pulmonary metastases at diagnosis)
- Year 2: tumour markers 4 times; chest X-ray once; abdominopelvic MRI/CT at 24 months; thorax CT at 24 months (if pulmonary metastases at diagnosis)
- Year 3: tumour markers; chest X-ray once; abdominopelvic MRI/CT once at 36 months; thorax CT once at 60 months (if pulmonary metastases at diagnosis)
- Year 4 & 5: tumour markers ± doctor visit 2 times; chest X-ray once; abdominopelvic MRI/CT once at 60 months; thorax CT once at 60 months (if pulmonary metastases at diagnosis)
- After 5 years: further management according to survivorship care plan (if teratoma in residual disease, follow-up continues)

14.8.2 CT abnormalities

- Seminoma: most will resolve spontaneously, re-scan after interval. Cases where post chemotherapy residual masses > 3 cm should be reviewed at snMDT meeting
- NSGCT: All cases with post-chemotherapy residual masses will be discussed at the snMDT meeting for consideration of RPLND or thoracotomy for resection of lung metastases etc. Post-chemo masses ≤ 1 cm will not usually be considered for resection but those >1 cm will. Each case will be assessed individually taking into account the characteristics, location and multiplicity of their disease. Restaging imaging should ideally be performed 3-4 weeks after the beginning of the last cycle of chemotherapy. Surgery if clearly indicated should ideally with 6-8 weeks after the last chemotherapy cycle.
- PET CT should be performed in patients with seminoma and post chemo masses >3cm, if highly PET avid can be considered for surgery.

14.8.3 Late effects monitoring

- Repeat PFT; audiometry and Creatinine clearance one year of completing chemotherapy.
- Fertility and gonadal function. Screen for gonadal failure if complaining of symptoms (excessive tiredness, loss of libido, impotence) FSH, LH, Testosterone, SHBG. Refer to endocrinology if hormone replacement indicated. Refer for semen analysis and IVF if required. Screen for neuropathy, hypertension, minimise cardiovascular risk factors, monitor for pulmonary toxicity, and signs of second malignancy. Counsel on self examination of contralateral testis and risk to sons.

15 RPLND for post-chemotherapy residual disease in metastatic GCT

RPLND in the North West UK will generally be performed at the supraregional center – The Christie Hospital. Where supplementary surgery is required (e.g. vascular replacement, hepatic / pancreatic / duodenal resection, intracranial residual tumours etc) surgery may be performed at The Christie with support from relevant surgical teams (e.g. from the Thoracic surgical centre at UHSM) or at relevant surgical centre with support from the Christie team as deemed most appropriate.

The standard protocol in the UK is to carry out Retroperitoneal Lymph Node Dissection (RPLND) for residual post chemotherapy masses in NSGCT. If a major remission has occurred after chemotherapy and it is considered that a reasonable prospect for complete remission to occur with further resolution a further period of observation may be justified. If the testicular primary tumour has not been removed, this should be done at the time of the resection of residual masses.

15.1 Seminoma

More than 90% of seminoma patients will have fibrotic residual tissue after post-chemotherapy partial remission (PR) with normal markers (M-). Even if the residual tumour is > 3 cm in greatest transverse diameter, the probability of viable malignant tissue is < 20%. Hence, CT surveillance is treatment of choice in most patients with residual masses in seminoma. A PET CT is indicated for patients with residual mass >3cm.

Because of the fibrotic reaction, the complete resection of residual masses of seminomatous tumours is more demanding compared to non-seminoma and, thus, the morbidity of this procedure is higher.

In pure seminoma, retroperitoneal tumour resection (post-chemotherapy retroperitoneal lymph node dissection, PC-RPLND) is only indicated in patients with residual tumour progression after chemotherapy with marker normalisation where there is a suspicion of residual non-seminoma elements.

15.2 Non-Seminoma

In patients with NSGCT in the primary tumour and a residual mass post chemotherapy (greater than 1 cm) and marker normalisation, surgical resection (RPLND) is indicated except in specific circumstances (see above). Overall, following BEP induction chemotherapy approx 10% of the residual masses contain viable cancer, 50% contain mature teratoma and 40% contain necrotic – fibrotic tissue. In this group of patients with residual masses - the “growing teratoma syndrome” is a significant future risk.

In general, all non-seminoma elements have the potential to de-differentiate to active teratoma, sarcoma or other aggressive malignancies and, thus, PC-RPLND in non-seminoma patients is mostly indicated. The de-differentiation to teratoma or sarcoma is chemoresistant and this type of disease may be

surgically curable. Only patients with a complete remission after CT restaging may be treated with surveillance only.

Persistently elevated markers after salvage chemotherapy (two different cisplatin containing regimens) is not a contraindication for surgery. The prognosis in these patients can be poor. However, complete surgical resection of residual disease provides long-term cure in up to 47% of patients. Poor prognostic parameters in these patients are multiple sites of residual disease and/or incomplete resections.

In patients with lower disease burden, nerve sparing techniques should be adopted by use of surgical templates. The German testis cancer group found 8% of patients with vital cancer or teratoma outside the residual mass within the surgical template and this compared favourably with US groups undertaking full bilateral RPLND. The side effects following template approaches are significantly lower. Hence, the standard treatment at The Christie is to carry out a right or left sided template dissection when the disease burden is confined to the nodal landing sites of the ipsi-lateral testis. Even in PC-RPLND, preservation of sympathetic nerves for antegrade ejaculation is possible. However, in nearly all published series patients have been selected to undergo a nerve-sparing PC-RPLND (e.g. unilateral disease only, low volume residual tumour) and therefore it follows that when there is more extensive disease the patients should undergo a full bilateral non nerve sparing procedure. Prior to surgery patients must be counselled fully about surgical risk and in particular, the risk of loss of ejaculatory function. In full bilateral PC-RPLND this will approach 100%.

If residual tumour is present in the retroperitoneum as well as in the lungs, primary resection of the retroperitoneal disease is recommended as long as the volume of the pulmonary disease does not exceed the volume of the retroperitoneal disease. If the retroperitoneal disease shows necrotic tissue only, the same histology in other sites can only be expected in 70%. Thus, patients with fibrosis in the post RPLND specimen who have residual thoracic disease should be considered for resection of the thoracic lesions. However, if there are bilateral thoracic masses and after the first resection, the histology shows fibrosis, the second thoracic resection is not necessary as there is virtually 100% concordance with the presence of fibrosis on the opposite side.

After a complete resection of teratomatous tissue, no adjuvant treatment is necessary. Even with a complete resection of vital undifferentiated tumour there is no evidence that adjuvant conventional chemotherapy is beneficial.

Patients with a late relapse of testis cancer (> 2 years after complete remission) represent a subgroup of patients with a very poor prognosis. In 80% of these tumours, chemoresistant carcinoma is to be found. Hence, with chemotherapy only most patients will not survive and the long term survivors of late relapse are patients in whom it is possible to carry out a complete resection of all visible disease.

15.3 Surgical aspects of PC-RPLND

Resection of bone metastases

Bone metastases at diagnosis are an unusual finding (approximately 5% of poor-prognosis non-seminoma patients). It is an even rarer phenomenon in seminoma. Resection should be considered when possible but decisions regarding post-chemotherapy surgery should be taken on an individual basis and by a multi-disciplinary surgical team specialising in this type of ultra-complex intervention.

Consideration may be given to post-operative radiation: positive long-term outcome has been reported with this combined approach

Resections in primary mediastinal non-seminoma

There is a high rate of residual and often chemo-refractory cancer in patients with residual lesions post-chemotherapy (1, 2). Therefore, surgery is an important and integral part in the post-chemotherapy management of primary mediastinal non-seminoma. Residual lesions must be radically resected whenever feasible following completion of first-line chemotherapy, sometimes even in the presence of positive and even increasing markers

15.4 Patient group

- Patients with confirmed histological diagnosis of germ cell cancer metastatic to retroperitoneal LN, with post chemotherapy residual masses and where pathology is non seminoma. Pure seminoma residual mass is not managed surgically.

15.5 Inclusion criteria

- Histologically germ cell tumours of the testis NSGCT
- Expert review of histology by nominated germ cell histopathologist
- Post chemo residual masses > 1cm
- Mature teratoma in orchidectomy specimen where nodal disease is thought to be due to mature teratoma rather than immature elements (eg marker negative and cystic mass) and patient is chemotherapy naive.

15.6 Exclusion Criteria

- Elevated aFP or BHCG (such cases may be offered surgery on a case by case basis after discussion in SnMDT meeting)
- Prior abdominal radiotherapy (relative contra-indication)
- Severe co-morbidity which would lead to unacceptable operative risk
- Unresectable metastatic disease at other sites (relative contra-indication)

15.7 Initial investigations and work up prior to start of treatment

- Complete re-staging within 3 months of surgery date
- CT scan chest abdo pelvis
- Tumour serum markers (aFP, bHCG, LDH)

- Standard pre-operative work up
- MAG3 Radioisotope renogram (selected cases)

15.8 Patient information

Patient will be counselled on risk of:

- Operative complications: bleeding, injury to surrounding structures, multivisceral resection
- Post-operative complications: infection, lymphocele formation, chylous leak, retrograde ejaculation and thromboembolic events.

15.9 Treatment planning, delivery, validation etc

- Final response assessment by CT should be no sooner than 6 weeks after last dose of chemotherapy
- RPLND should be performed within 8 weeks of the decision to operate
- Thoracic surgery (if required) should be performed within 3 months of end of chemotherapy

15.10 Histopathological handling & reporting Post Chemotherapy specimens

- Must be as per guidance.

16 Post Chemotherapy Orchidectomy

- If orchidectomy has not already been performed this can be done prior to the RPLND when clinically indicated.
- The orchidectomy may be performed by either the patients local Urologist or the Christie Urology team as appropriate and after discussion with the patient.

16.1.1 SnMDT review

- Cases will be reviewed pre-operatively at the SnMDT meeting
- Cases will also be discussed at the SnMDT meeting post-operatively once they have recovered from their surgery and pathology reports are available.

16.1.2 Where no immature elements are seen

The patient has a high chance of long term relapse free survival and requires no further therapy (chemotherapy or radiotherapy) and should be offered clinical follow-up (see below)

16.1.3 Where immature elements are seen

The chance of long term relapse free survival is low and further treatment needs to be considered. Options include:

1. Expectant management with salvage chemotherapy delayed until clinical relapse (marker or CT scan confirmed)
2. Immediate salvage chemotherapy

16.1.4 Oncology follow-up

Follow up will be directed at screening for relapse and managing any on-going medical issues from oncological therapies given.

17 Salvage therapy for relapsed metastatic GCT after first line chemo: TIP Regimen

17.1 Patient group

This regimen is for patients with metastatic primary germ cell testicular cancer and primary extra-gonadal germ cell tumours (mediastinal or retroperitoneal) and for patients with primary ovarian germ cell cancer who have relapsed after initial chemotherapy with BEP.

17.2 Use in second line

TIP is an internationally recognised option for use in second line i.e. for relapse following BEP chemotherapy. This is its main indication

17.3 Use in first line

TIP may be considered as the preferred chemotherapy regimen in first line for patients where there are concerns regarding the use of Bleomycin. In this case, the options are either to use EP(5) or consideration may be given to using TIP (however this is not standard first line treatment). Situations where Bleomycin may be contra-indicated include significant pre-existing pulmonary co-morbidity; wide spread pulmonary metastases; intercurrent pulmonary infection or haemorrhage

17.4 Exclusion Criteria

- Severe pre-existing renal impairment (GFR < 50 ml/min)

17.5 Initial investigations and work up prior to start of chemotherapy

17.5.1 Diagnostic review

- All histology must be reviewed by nominated network histopathologists for GCT

17.5.2 Staging

- As per Testis 1a

17.5.3 Work-up

- Routine biochemistry, haematology (inc coagulation), CXR, ECG
- GFR by isotope estimation, 24 hr urine collection for creatinine clearance or calculated GFR using Cockcroft-Gault formula

Audiometry (optional)

- Offer semen storage (requires HepB, HepC and HIV status if not done at time of first line treatment)
- ECHO or MUGA only if clinically indicated
- Patient information sheet
- Counsel patient regarding risks of chemotherapy and 24 hour telephone advice service.
- Informed Consent Form

17.6 End of treatment assessments

17.6.1 Tumour Assessment

CT scans of chest, abdomen and pelvis with iv and oral contrast will be performed between 3-4 weeks after day 1 of the last cycle of chemotherapy

17.7 High dose chemotherapy

Consideration should be given to consolidating good response in salvage chemotherapy with high dose chemotherapy usually using the CarboPEC regimen. This would be most suitable for patients who have a good response to salvage chemo and are marker negative.

17.8 Follow-up

17.8.1 Routine clinic visit schedule

- q3/12 for 1st year
- q4/12 in year 2
- q6/12 in yrs 3-5
- then either discharge to GP or annually to year 10

17.8.2 Relapse monitoring

- Examine remaining testis, lymph nodes, chest, abdomen
- CXR and markers each visit

17.8.3 CT abnormalities

- All cases with significant (> 1 cm) post-chemotherapy residual masses will be presented at the snMDT meeting for consideration of surgical resection.
- Patients with seminoma and post-chemotherapy residual masses should have PET if residual mass > 3 cm

17.8.4 Late effects monitoring

- Repeat PFT ; audiometry and GFR within one year of completing chemotherapy.
- Fertility and gonadal function. Screen for gonadal failure if complaining of symptoms (excessive tiredness, loss of libido, impotence) FSH, LH, Testosterone, SHBG. Refer to endocrinology if hormone replacement indicated. Refer for semen analysis and IVF if required. Screen for neuropathy, hypertension, minimise cardiovascular risk factors, monitor for pulmonary toxicity, and signs of second malignancy. Counsel on self examination of contralateral testis and risk to sons.

18 Palliative chemotherapy for relapsed metastatic GCT after salvage chemotherapy

18.1 Patient group

This regimen is for patients with metastatic primary germ cell testicular cancer and primary extra-gonadal germ cell tumours (mediastinal or retroperitoneal) and for patients with primary ovarian germ cell cancer who have relapsed after two platinum containing regimens (usually BEP and TIP) and are considered refractory to curative therapy.

18.2 Inclusion criteria

- Histologically proven germ cell tumours of testis (seminoma or non-seminoma) N+ or M+, good, intermediate or poor prognosis
- **OR** Histologically proven extra-gonadal germ cell tumour (mediastinal or retroperitoneal)
- **OR** Any widespread malignancy with high B-HCG with or without histology particularly in a younger male patient
- Previous chemotherapy two previous lines of platinum containing chemotherapy

18.3 Exclusion Criteria

- Severe pre-existing renal impairment (GFR < 50 ml/min)

18.4 Anticipated benefit

This is non-curative therapy will approx 35 % chance of patient benefit with temporary partial response which may be associated with improved quality of life and modest improvement in survival

18.5 Expected toxicity

- Neurotoxicity: peripheral neuropathy

- Myelosuppression
- Fatigue
- Flu-like symptoms

18.6 Initial investigations and work up prior to start of chemotherapy

18.6.1 Diagnostic review

- All histology must be reviewed by nominated network histopathologists for GCT

18.6.2 Staging

- As per Testis 1a

18.6.3 Work-up

- See previous

18.7 Drugs and Doses

- Must be as per guidance & clinician's discretion.

18.8 On treatment assessments

18.8.1 Tumour response assessment

- Response assessment is advised every 9 weeks

18.9 End of treatment assessments

18.9.1 Tumour Assessment

CT scans of chest, abdomen and pelvis with iv and oral contrast will be performed between 3-4 weeks after day 1 of the last cycle of chemotherapy

18.10 Follow-up

Patients will be followed up indefinitely in the expectation of tumour progression and palliative care

19 High dose chemotherapy for GCT

19.1 Patient group

The use of high dose (bone marrow ablative) chemotherapy for patients with germ cell cancer is controversial. A recently published analysis reviewed 1,984 patients with GCTs who experienced progression after at least three cisplatin-based cycles and were treated with either cisplatin-based CDCT or carboplatin-based HDCT chemotherapy at 38 centers or groups worldwide. Of 1,984 patients, 1,594 (80%) were eligible, and among the eligible patients, 1,435 (90%) could reliably be classified into one of the following five prognostic categories based on prior prognostic classification: very low (n = 76), low (n = 257), intermediate (n = 646), high (n = 351), and very high risk (n = 105). Within

each of the five categories, the progression-free survival (PFS) and overall survival (OS) after CDCT and HDCT were compared using the Cox model adjusted for significant distributional differences between important variables. The results showed that overall, 773 patients received CDCT, and 821 patients received HDCT. Both treatment modalities were used with similar frequencies within each prognostic category. The hazard ratio for PFS was 0.44 (95% CI, 0.39 to 0.51) stratified on prognostic category, and the hazard ratio for OS was 0.65 (95% CI, 0.56 to 0.75), favoring HDCT. These results were consistent within each prognostic category except among low-risk patients, for whom similar OS was observed between the two treatment groups. In conclusion, this retrospective analysis suggests a benefit from HDCT given as intensification of first salvage treatment in male patients with GCTs.

19.2 Inclusion criteria

- Histologically proven germ cell cancer any site
- AND
- Confirmed relapse on markers or imaging after first line chemotherapy
- AND
- Demonstrated evidence of chemosensitive disease as shown by complete or good partial response on markers and imaging to a standard second line regimen
- AND
- Renal and liver function within acceptable parameters

19.3 Exclusion Criteria

- Evidence of progressive tumour growth despite re-induction chemotherapy
- Rising markers
- New or growing metastases on imaging
-

19.4 Initial investigations and work up prior to start of chemotherapy

19.4.1 Diagnostic review

- All histology must be reviewed by nominated network histopathologists for GCT

19.4.2 Staging

- As per Testis 1a

19.4.3 Work-up

- See previous

19.5 Drugs and Doses

- CarboPEC regimen as per guidance
-

19.6 Follow-up

Patients will be followed up indefinitely in the expectation of tumour progression and palliative care

20 "Desperation surgery"

Desperation surgery refers to surgery in patients with resectable disease after salvage chemotherapy in whom no further chemotherapy with curative-intent is available. Long-term survival may be achieved in highly selected patients. Viable cancer or teratoma with somatic-type malignant transformation is more frequent after "desperation surgery" this type of tumour is usually chemo-resistant.

21 Appendix A Testis SnMDT

21.1 The Testis Cancer SnMDT at The Christie NHS Foundation Trust

The multidisciplinary team brings together expertise in surgery, oncology, pathology, radiology.

Core members of the SNMDT are listed in Appendix A and have responsibility to manage patients with suspected testis cancer and indeterminate testis lesions.

The aim of the MDT is to ensure the highest standard of care for testicular cancer patients and ensure that the management is discussed and agreed. It is also a forum to discuss complex cases, indeterminate testis lesions, testis sparing surgery, concomitant surgical sperm retrieval due to azoospermia and the management of intra-abdominal/inguinal testicles.

21.2 Time and Frequency of the Testis Cancer SnMDT Meeting

The Testis Cancer SnMDT is held on a weekly basis on Wednesday between 1300hrs and 1330hrs via videoconference hosted by The Christie NHS Foundation Trust, Manchester, UK

21.3 Attendance at SnMDT Meeting

The meeting is attended by all core members. If core members are unable to be present, their designated cover should attend. The contributions from pathology, radiology are provided by different team members in a meeting.

21.4 External visitors

Provision may be made for non SnMDT clinicians and healthcare professionals to attend the SnMDT on an adhoc basis to present individual cases. This can be done either face to face or virtually. Individuals wishing to attend should email the SnMDT lead and MDT co-ordinator 1 week in advance (see table 2.5). Admittance is at the discretion of the SnMDT lead.

21.5 SnMDT Testis Membership

Name	Role	Core	Cover
<i>21.6 Surgical Oncology</i>			
Prof. NW Clarke	Consultant Urological Surgeon and joint MDT Lead	Yes	
Mr A Gulamhusein (Chair)	Consultant Urological Surgeon and deputy MDT Lead	Yes	
Mr J Oates	Consultant Urological Surgeon	Yes	
Mr T Lee	Consultant Urological Surgeon	Yes	
Mr VAC Ramani	Consultant Urological Surgeon	Yes	
Prof. V K Sangar	Consultant Urological Surgeon	Yes	
Mr A S Parnham	Consultant Urological Surgeon	Yes	
<i>21.7 Medical & Clinical Oncology</i>			
Dr A Lee	Consultant Medical Oncologist and Joint MDT lead	Yes	
Prof A Birtle	Consultant Clinical Oncologist	Yes	
Dr C Mitchell	Consultant Clinical Oncologist	Yes	
Dr J Logue	Consultant Clinical Oncologist	Yes	
Dr J Wylie	Consultant Clinical Oncologist	Yes	
Dr O Parikh (manages Stage 1 disease for east Lancashire with support from core members of snMDT)	Consultant Clinical Oncologist	No	
<i>21.8 Radiology</i>			
Dr J Bell	Consultant Radiologist	Yes	
Dr P Najran	Consultant Radiologist	Yes	
Dr S Tenant	Consultant Radiologist	Yes	
Dr Y Jain	Consultant Radiologist	Yes	

21.9 Histopathology			
Dr P Oliveira	Consultant Pathologist	Yes	
Dr R Salama	Consultant Pathologist	Yes	
Dr S Verma	Consultant Pathologist	Yes	
21.10 CNS			
Ms M Bell	Macmillan Specialist Nurse	Yes	
Ms C Petterson	Macmillan Specialist Nurse	Yes	
Mr S Booth	Macmillan Specialist Nurse	Yes	
Ms S Capper	Macmillan Specialist Nurse	Yes	
Ms J Booker	Macmillan Specialist Nurse	Yes	
Ms S Yates	Macmillan Specialist Nurse	Yes	
Ms L Atkinson	Macmillan Specialist Nurse	Yes	
21.11 MDT Co-ordinators			
Shannon Bartlett			

21.12 Lead Clinician Role and Responsibilities

The Lead Clinician for the MDT is Mr Aziz Gulamhusein

Responsibilities of the snMDT lead(s) are to:

- Develop and review clinical practice standards, policies and protocols
- Ensure that the objectives of the MDT are met and for the development of the MDT and its activities
- Ensure that designated specialists work effectively together such that decisions regarding all aspects of diagnosis, treatment and care of individual patients and decisions regarding the team's operational policies are multidisciplinary decisions
- Ensure that care is given according to recognised guidelines (including those 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 the MDT meeting and team meet peer review quality measures
- Ensure attendance levels of core members and cover are maintained, in line with quality measures
- Ensure that the target of 100% of cancer patients discussed at the MDT is met, each patient discussed has a clear treatment plan and that the meeting runs to time
- Provide a link to Greater Manchester Cancer Alliance either by attendance at meetings or by nominating another MDT member to attend on their behalf
- Lead on or nominate a lead for service improvement
- Lead on the development of a research programme and recruitment to clinical trials
- Ensure Public and Patient involvement in the ongoing research programme
- Organise and chair an annual meeting examining the function of the 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 MDT's activities are audited, and results documented
- In the absence of the Lead Clinician a nominated deputy will lead the MDT
- Ensure that the outcomes of the meeting are clearly recorded and clinically validated, and that appropriate data collection is supported
- Ensure the target of communicating MDT outcomes to primary care is met
- Hold the presenting clinician responsible for carrying out any action plan e.g. contact the patient, arranging for further tests
- Have overall Governance responsibility for all areas of practice
- Ensure that all core members of the team who have direct clinical contact with patients apply for and attend the National Advanced Communications skills training course

21.13 SnMDT Core members responsibilities

- All core team members who have direct clinical contact with patients should have attended the national advanced communications skills course.
- All core members undertaking cancer surgery must attend 80% of the MDT meetings and 100% with cover.
- Actively engage in audit and research
- Actively engage and facilitate yearly review of SnMDT guidelines

21.14 SnMDT Coordinator Responsibilities

- Facilitate and co-ordinate the functions of the SMDT meetings
- Ensure that appropriate patients are discussed at SMDT meetings
- Help with the introduction and changes to proformas used to ensure that all patients are discussed and that outcomes of discussions are recorded and reviewed
- Ensure that patients' diagnoses, investigations and management plans are completed and added to the patients notes
- Manage systems that inform GP's of the patient's diagnosis, decisions made at out-patient appointments and at other times where key events occur
- Work with staff to ensure all patients have a booked first appointment, investigation and procedure and record details of patients coming via a different route
- Work with key SMDT members to identify areas where targets are not achieved and undertake process mapping to identify bottlenecks
- Undertake demand and capacity studies where appropriate
- Report any changes to SMDTs monthly
- Data collection and recording of data for peer review including new referrals and referring hospitals and waiting times to be seen in clinic and time to surgery.
- Manage the systems according to guidelines, monitoring milestones and submitting the required report in the given format and required times
- Keep a comprehensive diary of all team meetings
- Record the attendance at the SMDT meetings
- Ensure, along with the SMDT lead clinician, that MDT proformas are updated with details of discussions occurring during the SMDT meeting including an action plan such that they form minutes of each discussion which are available to all members of the team and are sent to involved clinicians outside the SnMDT by e-mail and hard copy
- Be instrumental in the development of databases to capture patient information and report this information to the clinicians on a weekly basis
- Inform lead cancer manager of waiting times for patients when these breach or are close to exceeding appropriate targets
- Ensure lists of patients to be discussed at meetings are prepared and distributed in advance of the SMDT meeting
- Ensure that all correspondence, notes, imaging, clinical photographs, results, etc. are available for the SMDT meetings

- Assist in capturing cancer data on all patients and assist in the development of systems to complement the cancer audit system
- Ensure members or their deputies are advised of meetings and any changes of date, venue, etc.
- The Testis MDT Coordinator ensures that the list of patients to be discussed at each MDT is up-to-date and complete.
- The Testis MDT Coordinator will email the list of patients to be discussed to all MDT members on Thursday prior to the meeting
- The Testis MDT Coordinator will ensure that the rooms are organised and prepared in advance for the meeting with appropriate technical link ups
- The Testis MDT Coordinators will ensure that the MDT decision is documented in an appropriate way. The final verified and signed minutes are re-distributed to all core team members.

21.15 How the MDT meeting outcome is documented

Every patient discussed at the Testicular cancer MDT meeting will have the decision and outcome of the meeting documented in the form of an individual treatment plan. This should form part of each patient's notes and uploaded to CWP.

Following the MDT meeting, the Testis MDT Coordinator liaises with the CNS and minutes of the meeting are confirmed. The proforma are then checked and signed by the chair of the MDT.

When patients are being re-presented at the MDT the original Proforma should be used and updated to ensure the full history and details of previous discussions and treatments are available.

The following information must appear on the form: -

- Identity of patient – Hospital number, date of birth and NHS number.
- Date of MDT meeting
- Diagnosis, type of testicular cancer and staging
- Tumour markers Pre-Op, Post-Op & current markers should be listed on the proforma
- For Stage I patients: Record the tumour size and if there is Rete Invasion and document the presence or absence of vascular invasion.
- Management to date
- Previous MDT decisions
- Whether clinical trial is appropriate
- The MDT treatment planning decision i.e. to which modalities of specialist or local care they are to be referred to for consideration
- Holistic needs: formal assessment not noted on the form as “HNA” but patient's preferences / needs and specific problems are annotated in the discussion.

21.16 Communication of Testicular Cancer MDT outcome with patient and GP

After discussion at the MDT meeting, the recommended treatment plan will be discussed with the patient at the following outpatient clinic or when agreed by telephone with the patient. All patients are offered a written record of this consultation in the form of a copy of the letter that is sent to their GP.

21.17 Diagnosis Communication with GP

Patients referred to the Testicular MDT will have had their diagnosis made at the unit prior to the MDT meeting discussion.

21.18 Permanent record of consultation

In addition to the above information, patients are sent a permanent record of their consultation (via a copy of the letter to their GP) unless they opt out of this. The letter will have the patient's diagnosis, treatment options and/or plan and relevant follow-up arrangements.

22 Appendix B - Staging

pT	
pTx	Cannot be assessed (no orchidectomy)
pT0	No evidence tumour (Azopardi nodule)
pTis	“Carcinoma in situ” Note that the terminology has since been changed by WHO in 2016 to Germ cell neoplasia in situ GCNIS. This was also previously called intratubular germ cell neoplasia, unclassified type (IGCNU) and testicular intraepithelial neoplasia (TIN)
pT1	Limited to testis and epididymis, No vascular or lymphatic invasion. May invade into tunica albuginea but not tunica vaginalis
pT2	Limited to testis and epididymis with vascular or lymphatic invasion or extending through tunica albuginea into tunica vaginalis
pT3	Tumour invades spermatic cord with or without lymphatic / vascular invasion
pT4	Tumour invades scrotum with or without lymphatic / vascular invasion
N	
Nx	Cannot be assessed
N0	No regional lymph node metastasis
N1	LN mass < 2 cm or multiple small LN
N2	LN mass 2 – 5 cm or multiple LN none more than 5 cm
N3	LN mass > 5cm
M	
Mx	Distant metastases cannot be assessed
M0	No distant metastases
M1	Distant metastases present
M1a	Non-regional nodal or lung metastases
M1b	Distant metastases other than non-regional nodal or pulmonary metastases
S Tumour markers	
SX	Marker studies not available or not performed
S0	Marker studies within normal limits
S1	LDH < 1.5 x ULN and hCG < 5000 and AFP < 1000
S2	LDH 1.5 – 10 x ULN or hCG 5000 – 50,000 or AFP 1000 – 10,000
S3	LDH > 10 x ULN or hCG > 50,000 or AFP > 10,000

I	No evidence of disease outside the testis
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IM	As above but with persistently raised tumour markers (i.e. post op)
II	Infradiaphragmatic nodal involvement
IIA	Maximum diameter < 2 cm
IIB	Maximum diameter 2-5 cm
IIC	Maximum diameter > 5-10 cm
IID	Maximum diameter > 10 cm
III	Supra and infradiaphragmatic node involvement Abdominal nodes A, B, C, as above Mediastinal nodes M + Neck nodes N +
IV	Extralymphatic metastases Abdominal nodes A, B, C, as above Mediastinal or neck nodes as for stage 3
Lungs:	
L1	< 3 metastases
L2	Multiple metastases < 2 cm maximum diameter
L3	Multiple metastases > 2 cm in diameter
H+	Liver involvement
	Other sites specified

Teratoma (NSGCT)	Seminoma
Good prognosis (Latest version acknowledges subdivision but no current clinical treatment impact)	
Testis/retroperitoneal primary; no non-pulmonary visceral metastases;	Any primary site; no non-pulmonary visceral metastases;
AFP < 1000 ng/ml; HCG < 5000 IU/l; and LDH < 1.5 x upper limit of normal.	Normal AFP; any HCG; any LDH
56% of teratomas: 5-year survival 92%	90% of seminomas: 5-year survival 86%
Intermediate prognosis	
Testis/retroperitoneal primary; no non-pulmonary visceral metastases	Any primary site; non-pulmonary visceral metastases
AFP > 1000 and < 10,000 ng/ml; HCG > 5000 and < 50000 IU/l; LDH > 1.5 x normal < 10 normal.	Normal AFP; any HCG; any LDH
28% of teratomas: 5-year survival 80%	10% of seminomas: 5-year survival 73%.
Poor prognosis	
Mediastinal primary or non-pulmonary visceral metastases AFP >	No patients in this group

10,000 ng/L and/or HCG > 50,000 IU/L and/or LDH > 10 normal	
16% of teratomas: 5-year survival 48%	-