NHS England

Guidelines for the Management of Testicular Cancer

West Midlands Expert Advisory Group for Urological Cancer

West Midlands Clinical Networks and Clinical Senate

Coversheet for Network Expert Advisory Group Agreed Documentation

This sheet is to accompany all documentation agreed by the West Midlands Strategic Clinical Network Expert Advisory Groups. This will assist the Clinical Network to endorse the documentation and request implementation.

EAG name	Urological Cancer Expert Advisory Group	
Document Title	Guidelines for the Management of Testicular Cancer version 3.2	
Published date	December 2016	
Document Purpose	• The referral of patients presenting with symptoms suspicious of testicular cancer. • The management of patients with testicular cancer.	
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References		
Consultation Process	Guidelines drawn up as result of Urology workshop April 2016 with opportunity for comment via e-mail post workshop.	
Review Date (must be within three years)	December 2019	
Approval Signatures:	**EAG Chair** 	**Network Clinical Director** 

Guidelines for the Management of Testicular Cancer

Version History:

Version	Summary of change	Date Issued
Version 1.0	Approved Guidelines	May 2007
Draft 1.1	Amended by Mike Cullen after discussion at NSSG	June 2007
Draft 1.2	Network formatted by Clair McGarr	June 2007
Draft 1.3	With comments following circulation	July 2007
Draft 1.3	Endorsed by the Urology NSSG	July 2007
Version 2	Endorsed by the Governance Committee	September 2007
Draft 2.1	Discussed and updated by NSSG and sent to Mike Cullen to review and update	February 2010
2.2	With Mike Cullen's comments	13 April 2010
2.3	Reformatted by LB, for review by Alan Fergusson and Mike Cullen, Andrew Stanley and the Urology NSSG.	14 April 2010
2.4	With MC changes. Sent to the urology NSSG	14 April 2010
3.0	Updated with changes from Paul Hutton	Sept 2010
3.1	Updated with changes from Dr Emilio Porfiri and Paul Hutton	February 2016

Changes made since version 3.0

1. Adjuvant BEP chemotherapy for Stage 1 high and low risk now 1 course of BEP-165 (6.1)
2. NICE Suspected cancer guideline updated June 2015 (3.1)
3. Radiotherapy treatments updated (9.2)
4. Changes to follow up protocols as per EAU guidelines (12.6)
5. Updated orchidectomy guidelines (4.4)

1 Scope of the Guideline

This Guidance has been produced to support the following:

- The referral of patients presenting with symptoms suspicious of testicular cancer.
- The management of patients with testicular cancer.

2 Guideline Background

These guidelines are based on the NICE Suspected cancer: recognition and referral guidelines[1], Improving Outcomes for Urological Cancer – The Manual[2], and the European Association of Urology Clinical Guidelines[3]. They have been written by the supra-network service which consists of the urology and testicular cancer teams based at University Hospital Birmingham Foundation Trust (UHBFT),

Guideline Statements

3 Referral

3.1 Patients with suspected urological cancer should be referred from GPs to local urology units, urgently, according to the 2 week wait criteria[1] (outlined below):

a. Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for testicular cancer in men if they have a non‑painful enlargement or change in shape or texture of the testis.
b. Consider a direct access ultrasound scan for testicular cancer in men with unexplained or persistent testicular symptoms.

3.2 Referrals deemed inappropriate by consultant urologists will be notified to the referring GP and to the relevant PCT according to agreed protocols.

3.3 GPs will be notified of the diagnosis of cancer within 24 hours of the diagnosis being made, and will be kept informed of all aspects of the patients care at all times.

3.4 See appendix one for the referral form.

3.5 Referral for Family History Assessment.

3.5.1 Individuals (affected or unaffected with cancer) who have two or more relatives with testicular cancer at any age should be referred to the West Midlands Regional Clinical Genetics Unit, Birmingham Women's Hospital for risk assessment.

3.5.2 The individuals will be assessed and managed using the West Midlands Family Cancer Strategy guidelines. Further details about the strategy are available at www.bwnft.nhs.uk/healthcare-professional/clinical-genetics-service/cancer-referral-guidelines

4 Diagnosis and Staging

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

4.2 90% of cancers can be confirmed with ultrasound. Occasionally a mass cannot be clearly categorised as either benign or malignant on USS. The options for the management of this small group of patients include follow-up scanning or surgery. On the rare occasion that the diagnosis is in doubt, representative samples may be sent for frozen section[4]

4.3 An FNA or percutaneous biopsy **should not be carried out** under any circumstances.

4.4 When a cancer is diagnosed on ultrasound:

4.4.1 Blood should be taken prior to surgery for tumour markers (AFP, HCG) and LDH.

4.4.2 An Urgent CT of chest, abdomen and pelvis should be booked.

4.4.3 Surgery (orchidectomy) should be offered, and can be carried out at the cancer unit except:

a. When the tumour is apparently in the patient's only testis or there are bilateral tumours. In these cases partial testicular preservation may be possible.
b. When there are clear signs or symptoms of metastatic germ cell cancer (generally unwell, have multiple lung metastases, AFP above >1000ng/ml, HCG> 5000iu/ml, or renal obstruction).
c. when there is a small non-palpable mass <50% testicle volume on USS for consideration of partial orchidectomy (with cold clamping/frozen section/ 3 quarterly biopsies (EAU 2016)
d. reduced androgen function

All these groups should be referred immediately to the specialist MDT.

4.4.4 All patients should be offered the insertion of prosthesis at the time of primary surgery.
4.4.5 Histology slides should be sent to UHBFT for review at the time of referral to the lead pathologist for testicular cancer.

5 Management of Testicular Cancer – All Patients.

5.1 Initial treatment is usually with radical orchidectomy (but see 4.4.3 above), and the local urology team should perform this.
5.2 All patients with proven urological malignancy will be discussed by an MDT. Normally this will be the local MDT in the first instance, and the overall responsibility for the patient's management rests with the local MDT until referral has been agreed.
5.3 Once diagnosis is confirmed or strongly suspected the patient should be referred to the regional testicular tumour team at UHBFT for discussion at the UHBFT Specialist Testicular MDT, and for treatment planning.
5.4 All non-surgical treatment of these patients is led by the specialist team at UHBFT.
5.5 In limited circumstances there may be a requirement for shared care:
a. Children under the age of 16 with teratoma are treated at the Children's Hospital.
b. Patients aged between 16 and 25 that require inpatient treatment are offered a bed on the young persons unit.
c. Older patients and those that prefer not to be treated on the young persons unit are admitted to the 5 day treatment unit for inpatient care.
5.6 Where relevant, patients should be offered sperm banking regardless of treatment plan.
5.7 At 12 months following treatment all patients should be offered sperm analysis to determine the need for continued storage of their sperm samples.
5.8.1 Consideration of testosterone replacement therapy to all anorchic patients or hypo-orchic patients

6 Management of non-seminomatous germ cell and combined (mixed) seminoma plus non-seminomatous tumours - Stage 1 (see section 9 for seminoma stage 1)

6.1 High risk patients (that is those with lymphovascular space invasion [LVS] on histology). These are those with an increased risk of recurrence; that is > 45% chance of relapse on surveillance only.

Stage 1 adjuvant treatment for High risk patients:

a. One cycle of adjuvant BEP165 chemotherapy in high risk, stage 1 non-seminomatous germ cell tumours of the testis (NSGCTT) should be offered to all these patients.
b. Active surveillance providing patients are willing and able to comply with follow up policy.

6.2 For Low Risk

Patients with stage I disease without LVS invasion factors management options include:

a. Surveillance is recommended if the patient is willing and able to comply. It should be undertaken in **Regional Testicular Tumour Centre** (UHBFT) according to schedule shown below (12.6.1).
b. In patients not willing (or suitable) to undergo surveillance adjuvant chemotherapy with BEP-165 x 1 cycle is recommended[3]

On surveillance their risk of recurrence is 15 – 20%. This is reduced to 2-3% with adjuvant chemotherapy.

7 Management of metastatic malignant teratoma (stage 2 and above):

7.1 Poor prognosis factors include:

a. Mediastinal primary or
b. Non-pulmonary visceral metastases (NPVM) or
c. AFP>10,000 ng/L or
d. HCG>50,000 iu/L or
e. LDH >10 x upper limit of normal

Treatment
The primary treatment will be 4 cycles BEP/EP (5 day regimen) plus interval Bleomycin, followed by reassessment after 4 cycles. Depending on outcome, proceed to 2 further cycles, elective surgery or no further action.

7.2 Intermediate prognosis:

Testicular or retro-peritoneal primary, no NPVM and:
a. *AFP >1000 + <10 000 or*
b. *HCG > 5000 + < 50 000 or*
c. LDH > 1.5 x upper limit of normal + < *10 x upper limit of normal.*

Treatment
The primary treatment will be 3-4 cycles BEP/EP (BEP-165) plus interval Bleomycin, followed by reassessment. Depending on outcome, proceed to 2 further cycles, elective surgery or no further action.

7.3 Good Prognosis

Testicular or retro-peritoneal primary, no NPVM and:
a. AFP <1,000 ng/L **and**
b. HCG <5,000 iu/L **and**
c. LDH <1.5 x upper limit of normal

Treatment
The primary treatment will be 3 cycles BEP (BEP-165)

8 **Post Chemotherapy Residual Disease in non-seminomatous germ cell tumours**
Surgical resection of residual para aortic nodes after chemotherapy is mandatory in all patients with a residual mass is ≥ 1cm in the short axis on CT imaging. These patients should be discussed at the Specialist MDT and referred to the Lead Consultant Urologist/Retroperitoneal surgeon.

9 **Seminoma Stage 1**

Surveillance, adjuvant chemotherapy or radiotherapy are all options for stage 1 Seminoma.

15-20% of Stage 1 seminomas will recur on surveillance.

Treatment with either chemotherapy or radiotherapy results in a reduction in recurrence rate from 15-20% to less than 3-4%.

9.1 Chemotherapy.

Patients should be offered a single cycle of carboplatin AUC7 (based on EDTA Clearance)

9.2 Radiotherapy

9.2.1 A few patients, for whom chemotherapy is inappropriate or who decline it, may be offered 20 Gy/10# / over 2 weeks.

9.2.2 **Localisation**
a. Patient supine
b. Intravenous urogram used to localise the kidneys.

9.2.3 **Clinical Target Volume (CTV)**
As a guide, outline the aorta from 1cm inferior to the aortic bifurcation to 1 cm superior to the right renal artery or, 1.5 cm superior to the left renal artery, whichever point lies more inferiorly.

The aorta should be expanded 2.5cm laterally and posteriorly, excluding overlapping vertebral bodies, and 2.1cm anteriorly4. The bowel, bone, kidneys and

muscle should then be edited out. This expansion has been shown to incorporate 99% of nodes.

9.2.4 **Planning Target Volume (PTV)**

PTV1: CTV1 + 5mm

10 **Seminoma Stage IIa and IIb**

Radiotherapy may be appropriate if RT volume permits curative doses, if not, chemotherapy with cisplatin and etoposide (EP 165 x 3) should be offered.

CTV1: As per stage I with regards to the superior border however, limit the inferior border of the extended field to the cranial rim of the acetabulum as proposed by Classen et al. as it covers all pelvic nodes but not inguinal nodes.

PTV1: As per Stage I above.
GTV2: All macroscopic disease should be outlined as GTV2. Where appropriate use Fused CT/PET.
CTV2 = GTV2 + 2cm circumferential margin5
PTV2 = CTV2+5mm
If PTV2 is outside of PTV1, PTV1 should be expanded to include PTV2

Stage IIA Seminoma/Recurrent Disease (NSGCT where RT appropriate)

Additional 10Gy in 5 fractions (total dose to PTV2 30y in 15 fractions)[7]

Stage IIB Seminoma/Recurrent Disease

Additional 16Gy/8 Fractions (total dose to PTV2 36 Gy in 18 Fractions)[7]

		PTV36		**PTV30**		**PTV20**	
% Volume	**% Dose**	Dose Required	Dose Achieved	Dose Required	Dose Achieved	Dose Required	Dose Achieved
99%	**>90%**	35.64 Gy		18 Gy27Gy		18 Gy	
95%	**>95%**	34.2 Gy		19 Gy28.5Gy		19 Gy	
50%	**=100%**	36 Gy		20 Gy30Gy		20 Gy	
5%	**<105%**	37.8 Gy		21 Gy31.5Gy		21 Gy	
2%	**<110%**	39.6 Gy		22 Gy30.6Gy		22 Gy	

Dose Constraints OAR

OAR	Ideal in 2Gy/fraction	Absolute	Achieved	Priority
Spinal Cord PRV	30Gy in 2Gy # (max. point)	38		
Kidneys	Bilateral whole organ Mean Dose < 15-18Gy Both kidneys: V_{12}<55% V_{20}<32% V_{28}<20%			
Liver	V_{30}Gy<50% V_{10}<68% Mean dose<30Gy			
Bowel Bag	V_{15}Gy <830cc V_{25}Gy <650cc			
Small bowel loop	V_{15}Gy <120cc			

Organs at Risk

All organs at risk within and in close proximity to the planning target volume will be contoured.
OAR include; Both Kidneys, Liver, Spinal Cord and Bowel.

Gaps

RCR guidelines suggest a maximum of 5 days may be missed for long course treatments. Patients can be hyper-fractionated to account for missed fractions due to; bank holidays, service days, breakdown or illness for up to a dose limit of an additional 2.7Gy per day.

11 Seminoma stage III / IV / bulk disease

4 cycles cisplatin + etoposide (EP 165) should be offered.

12 Follow-up and recurrent disease.

12.1 In testis tumours the aims of follow-up are:

a. To detect relapse as early as possible in all stages
b. To detect an asynchronous contra lateral carcinoma of the testis in an early phase.
c. To encourage healthy lifestyles, particularly important is smoking cessation counselling.

12.2 Different treatment policies are available for Stage I and low-volume of metastatic disease (resulting in the same survival but different recurrence rate), in those

stages the intensity of the follow-up should be determined by the rate and timing of relapse (see tables in 12.5 below). Shared care may be appropriate in some circumstances.

12.3 Whether in early or advanced stages follow-up attendances should include:

a. Enquiry concerning testicular self-examination (TSE), and advice to report any concerns promptly, not necessarily waiting for next scheduled appointment.
b. Physical examination is only required routinely in symptomatic patients, those who are concerned about an abnormality on TSE or those where investigations raise concerns.
c. Serum Tumour Markers determination (AFP, beta-hCG and LDH),
d. Chest, Abdominal and pelvic CT (see schedules in 12.5 below).
e. Post chemotherapy semen analysis at 12 months or at other times if requested and indicated.
f. Brain CT or MRI in case of neurological symptoms and bone scan in case of suspicious bone pain.

12.4 Surveillance should continue for 5 years for non-seminoma and seminoma.

12.5 Patients who have been recruited into a clinical trial will be followed up as defined in the protocol.

12.6 Follow-up schedules

12.6.1 Five year minimum Follow-up Stage 1 non-seminoma germ cell tumour Surveillance

Procedure	Year 1	Year 2	Year 3	Year 4	Year 5
Patient self-examination reminder	4 times	4 times	4 times	Once/year	Once/year
LH, FSH, Testosterone	twice (3 and 12 months)	If indicated	If indicated	If indicated	If indicated
Tumour markers	4 times	4 times	4 times	Once/year	Once/year
Chest X-ray	Twice	Twice	Twice	Twice	Twice
CT scan abdomen and pelvis	twice (3 and 12 months)	Once (24 months)	Once (36 months)	none	none

12.6.2 Five year minimum follow-up schedule post adjuvant chemotherapy for Stage 1 non seminoma germ cell tumour

Procedure	Year 1	Year 2	Year 3	Year 4 and 5
Patient self-examination reminder	4 times	4 times	4 times	Once/year
Tumour markers	4 times	4 times	4 times	Once/year [a]
FBC, UE's	Once	Once	If indicated	If indicated
LH, FSH, Testosterone	Twice (3 and 12 months)	Once	If indicated	If indicated
Chest X ray	Twice	Twice	Twice	-
CT scan abdomen and pelvis	Once (twelve months)	Once	Once	If indicated

12.6.3 Five year minimum follow up protocol for testicular seminoma: Stage 1 Post-Adjuvant chemotherapy, Radiotherapy or Surveillance

Procedure	Year 1	Year 2	Year 3-4	Year 5
Patient self-examination reminder	Three times	Three times	Twice	Once
Tumour markers	Three times	Three times	Twice	Once
FBC, UE's	Once	Once	Once	If indicated
LH, FSH, Testosterone	Once	Once	Once	If indicated
Chest X-ray	Twice	Twice	Once	Once
CT abdomen and pelvis	Twice (6 and 12 months)	Once (24 months)	Once (36 months)	Once (60 months)

12.6.4 Five year minimum follow up for NSGCTT and Seminoma >stage 1 CR post chemotherapy + / - RPLND

Procedure	Year 1	Year 2	Year 3	Year 4	Year 5
Patient self-examination reminder	Four times	Four times	Three times	Twice	Twice
Tumour markers	Four times	Four times	Three times	Twice	Twice
FBC, UE's	Twice	Once	If indicated	If indicated	If indicated
LH, FSH, Testosterone	Once	Once	Once	If indicated	If indicated
Chest X-ray	Four times	Four times	Once	Once	Once
CT scan abdomen and pelvis*†	Twice (6 and 12 months)	Twice (18 and 24 months)	Once	Once	
CT Chest‡	Once/year	Once/year	Once	Once	
Brain CT§	Once/year	Once/year	Once/year		

* An abdominal CT must be performed at least annually if teratoma is found in the retroperitoneum

† If post chemotherapy evaluation in a seminoma patient shows any mass >3cm, the appropriate CT should be repeated 2 and 4 months later to ensure that the mass is continuing to regress. If available, FDG-PET/CT can be performed

‡ A chest CT is indicated if abnormality is detected on plain radiography chest and after pulmonary resection

§ In patients with headaches, focal neurological findings or any central nervous system symptoms

12.6.5 Seven year follow up for Residual Radiological abnormalities Post-chemotherapy + / - Surgery / RT

Procedures	Year 1	Year 2	Year 3	Year 4	Year 5	Years 6-7
Patient self-examination reminder	Bimonthly	Four times	Twice	Twice	Twice	Once yearly
Tumour markers	Bimonthly	Four times	Three times	Twice	Twice	Once yearly
FBC, UE's	Twice	Once	Once	Once	Once	If indicated
LH, FSH. Testosterone	Twice	Once	If indicated	If indicated	If indicated	If indicated
Chest X-ray	Once	If indicated	If indicated	If indicated	Once	If indicated
CT scan chest, abdomen and pelvis	Three	Twice	Once	Once	If indicated	If indicated

13 Recurrence

13.1 Recurrence following primary treatment of stage 1 germ cell cancers is curable in the vast majority of cases and management is generally with chemotherapy in the first instance. Referral to the regional testicular tumour centre is required in all cases.

13.2 Recurrence following treatment of metastatic disease is also treated with curative intent with chemotherapy (e.g. TIP), surgery or radiotherapy alone, or in combination. Referral to the Regional Testicular Tumour Centre is required in all cases.

13.3 Contralateral tumours

The risk of a second contralateral tumour is about 1%. Management varies enormously between individuals based on prospects and wishes for maintaining fertility and an endogenous androgen source whilst maximising the chance of cure. Radical orchidectomy is usually, but not invariably required. Urgent referral to the Regional Testicular Tumour Centre prior to orchidectomy is required to discuss options for individualised care.

14 Patient Information and Counselling

14.1 All patients, and with their consent, their partners will be given access to appropriate written information during their investigation and treatment, and on diagnosis will be given the opportunity to discuss their management with a clinical nurse specialist who is a member of the relevant MDT. The patient should have a method of access to the regional testicular tumour team at all times.

14.2 Access to psychological support will be available if required. All patients should undergo a Holistic Needs Assessment and onward referral as required.

15 Palliative Care

Palliative care services will be made available to all patients as deemed appropriate by the MDT.

16 Clinical Trials

16.1 Wherever possible, patients who are eligible should be offered the opportunity to participate in National Institute for Health Research portfolio clinical trials and other well designed studies.

16.2 Where a study is only open at one Trust in the Network, patients should be referred for trial entry.

16.3 Teratoma:

a. National Institute for Health Research: Feasibility of a guided workbook intervention for cancer patients (recruiting)

16.4 Seminoma:

a. National Institute for Health Research: Feasibility of a guided workbook intervention for cancer patients (recruiting)

17 Monitoring of the Guideline

18 References

1 NICE 2015. Suspected cancer: recognition and referral. (www.nice.org.uk/guidance/ng12),

2 NICE, 2002. Improving Outcomes in Urological Cancers - The Manual. (www.nice.org.uk)

3 European Association of Urology, 2015. Guidelines on Testicular Cancer (www.uroweb.org/wp-content/uploads/EAU-Guidelines-Testicular-Cancer-2015-v2.pdfwww.uroweb.org).

4. Classen J, Schmidberger H, Meisner C, et al. Radiotherapy for stages IIA/B testicular seminoma: final report of a prospective multicenter clinical trial. JClin Oncol 2003;21:1101–6.

7 Authors

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Appendix 1

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URGENT REFERRAL FOR SUSPECTED UROLOGICAL CANCER (Version 2.0)

If you wish to include an accompanying letter, please do so. **On completion please FAX to the number below.**

These forms should only be used for suspected cancer and in conjunction with the NICE Referral Guidelines for Suspected Cancer, June 2005

Patient Details		**GP Details (inc Fax Number)**
Surname Forename D.O.B. Gender Address Postcode Telephone NHS No Hospital No Interpreter Y / N First Language		Fax No: **Date of Decision to Refer** **Date of Referral**

Suspected cancer: **Prostate** ☐ PSA value _____ng/ml	**Symptoms:** Hard irregular prostate on DRE ☐ Significant symptoms (inc. symptoms of metastases) and raised PSA ☐ Raised age-related PSA ☐
Age related cut-off measurements : 50-59 > 3.0 ng/ml ; 60-69 > 4.0 ng/ml; 70-80 > 5.0ng/ml *Elderly patients (over 80yrs) or those with significant co-morbidity do not require urgent referral for mildly elevated PSA in the absence of symptoms. PSA measurements are NOT valid in the presence of urinary tract infection and need to be repeated once the infection has resolved.*	
Bladder or Renal ☐	**Symptoms:** PAINLESS macroscopic haematuria (any age) ☐ Haematuria associated with PERSISTENT UTI (over 40) ☐ Unexplained microscopic haematuria (over 50) ☐ Palpable renal mass or solid renal mass on U/S scan ☐
Testicular ☐	**Symptoms:** Swelling / mass in BODY of testicle ☐
Penile ☐	**Symptoms:** Ulceration / mass in the glans or the prepuce ☐

Clinical Details: History/Examination/Investigations……..……..…….

Medication ...……

For Hospital Use

Appointment Date Clinic Attending

Was the referral appropriate Yes No (if no please give reason)

UROLOGY CLINICS WITH RAPID ACCESS FACILITIES

Hospital	Tel	Fax
City	**0121 507 5805**	**0121 507 5075**
Good Hope	**0121 424 7476**	**0121 7376**
Heart of England	**0121 424 5000**	**0121 424 5001**
Queen Elizabeth (UHBFT)	**0121 627 2485**	**0121 460 5800**
Walsall Manor	**01922 721172 ext 6876 or 7227**	**01922 656773**
Sandwell	**0121 507 3834**	**0121 507 3723**

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. (No 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 pa treatment.)

Appendix 2: Algorithm for the Management of Testicular Germ Cell Neoplasms by Histopathology, Stage and IGCCC Grouping