NHS England

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	E10/S(HSS)a
Service	Gestational Trophoblastic Disease (Choriocarcinoma - All Ages)
Commissioner Lead	
Provider Lead	
Period	12 Months
Date of Review	

ADOPTED

1. Population Needs

1.1 National/local context and evidence base

The UK Gestational Trophoblastic Disease (GTD) Service is an internationally renowned, multi-disciplinary team which provides both clinical and psychological care, for women diagnosed with GTD and specialist advice for health care professionals involved in giving care to this patient group.

GTD is a spectrum of rare pregnancy related disorders comprising the premalignant conditions of complete (CHM) and partial hydatidiform moles (PHM) through to the malignant invasive mole, choriocarcinoma and placental site trophoblastic tumour (PSTT). Sixty years ago, most women could expect to die of GTD. Fortunately this situation has been reversed by the progressive discovery of effective therapies and appropriate management protocols together with a very sensitive biomarker of the disease activity (human chorionic gonadotrophin; hCG).

The UK national GTD service was designated in 1984 and has played a leading international role in developing these therapies, management protocols and biomarker assays and currently cures more than 98% of affected women.

Evidence Base

- GTD is a rare disease so centralised care is necessary to ensure adequate skill

levels in the teams that manage it otherwise high cure rates cannot be achieved.

- Indeed, data from a recent survey for GTD survival in countries that do not have centralised care including the USA show considerably lower survival rates (Kohorn et al 2009 International Society for the Study of Trophoblastic Disease (ISSTD) conference Cochin and J Reprod Med 2013 in press).
- Similar improved survival results have been seen with other curable malignancies. Thus, testicular cancer cure rates have been shown to be significantly higher when the disease is managed in specialised centres than in district general hospitals (Harding et al Lancet 1999, 341, 999-1002)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	√
Domain 2	**Enhancing quality of life for people with long-term conditions**	√
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	√
Domain 4	**Ensuring people have a positive experience of care**	√
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	√

See appendix 2 but briefly:

Outcomes: Deaths as % of new cases

In addition to National Key Performance Indicators (KPI), e.g. waiting times, infection control etc; further service specific KPIs will monitor that:

- Counselling is offered to all patients during first course of chemotherapy;
- All patients have a named key worker on day of admission;
- Patient's GP is informed of admission within 24 hrs;
- All patients are issued with diary of treatment events on first discharge;
- Maximum 14 day turn around on histopathology specimens;
- Local to residence chemotherapy administration where feasible is established within three weeks of first admission

3. Scope

ADOPTED

3.1 Aims and objectives of service

- To provide centralised comprehensive health care for women with Gestational Trophoblastic Disease (GTD)
- To provide a world-class screening, diagnostic and treatment facility across the UK for the management of GTD, identifying and treating patients with malignant forms of GTD to achieve a cure rate ≥ 98% whilst minimising morbidity and psychological sequelae.
- To provide accurate (expert) diagnosis.
- To monitor GTD patients for relapse or new episodes of the disease
- To advise/teach nationally and internationally on the management of GTD
- To minimise complications (late effects) of treatment in this young fertile group of women
- To provide excellent patient experience.

3.2 Service description/care pathway

Women diagnosed with GTD, or where GTD is suspected, will be formally registered, using the official registration form, with one of the national screening centres. This will include the diagnosis of:

- Complete hydatidiform mole (classical type, androgenetic, no other foetal tissue)
- Partial hydatidiform mole (usually triploid, other foetal tissues present)
- Twin pregnancy with Complete or Partial hydatidiform mole
- Limited macroscopic or microscopic molar change judged to require follow-up
- Atypical placental site nodule.
- Referrals are also accepted in writing, or verbally in emergencies, for the diagnosis of:
- Choriocarcinoma
- Placental site trophoblastic tumour
- Persistently raised HCG of unknown cause

The provider will provide:

- A registration facility for molar pregnancies and other GTD events. • registration within 72 hours of referral receipt with written information sent to patient, GP and referring Gynaecologist at this point;
- Emergency telephone referral facility 24 hours a day, 7 days a week;
- A comprehensive monitoring facility including regular patient communication regarding results and progress;
- A comprehensive treatment facility including neurosurgical, thoracic, gynaecological, urological surgery, interventional radiology, radiotherapy, intensive care and high dose chemotherapy.
- Communications at each stage of the patient journey in accordance with the service information pathway. The provider will work with NHS England to ensure sufficient considerations are given to communications;
- A comprehensive discharge process;
- A disease specific hCG assay with maximum 48 hour turnaround of commented results;
- An efficient optimal patient pathway including a robust hCG monitoring protocol

ADOPTED

identifying those women “at risk”, with timely intervention and treatment;

- 24/7 access to clinical advice;
- a telephone advisory/ results service for patients and health professionals;
- Multi-disciplinary patient support including monthly drop-in sessions and a monthly support group;
- An internationally leading service and reference centre;
- GTD related education and support to patients and carers through information
- booklets, websites, telephone advisory service, drop-in sessions, and counselling;
- GTD related education and support to health professionals through annual study days, information sheets, telephone advisory service and websites;
- Central pathology review with expertise available to ensure a specialist pathological opinion within 14 days of receipt of appropriate materials;
- Genetic analysis; confirmation of pathological diagnosis and discrimination between gestational & non-gestational tumours as appropriate;
- Investigation of recurrent molar pregnancies;
- Annual audit of patient experience with an action plan on patient feedback;
- Patient inclusion in service design by consultation during structured drop-in sessions and annual surveys;
- Regular audit of provider assurance and governance processes.

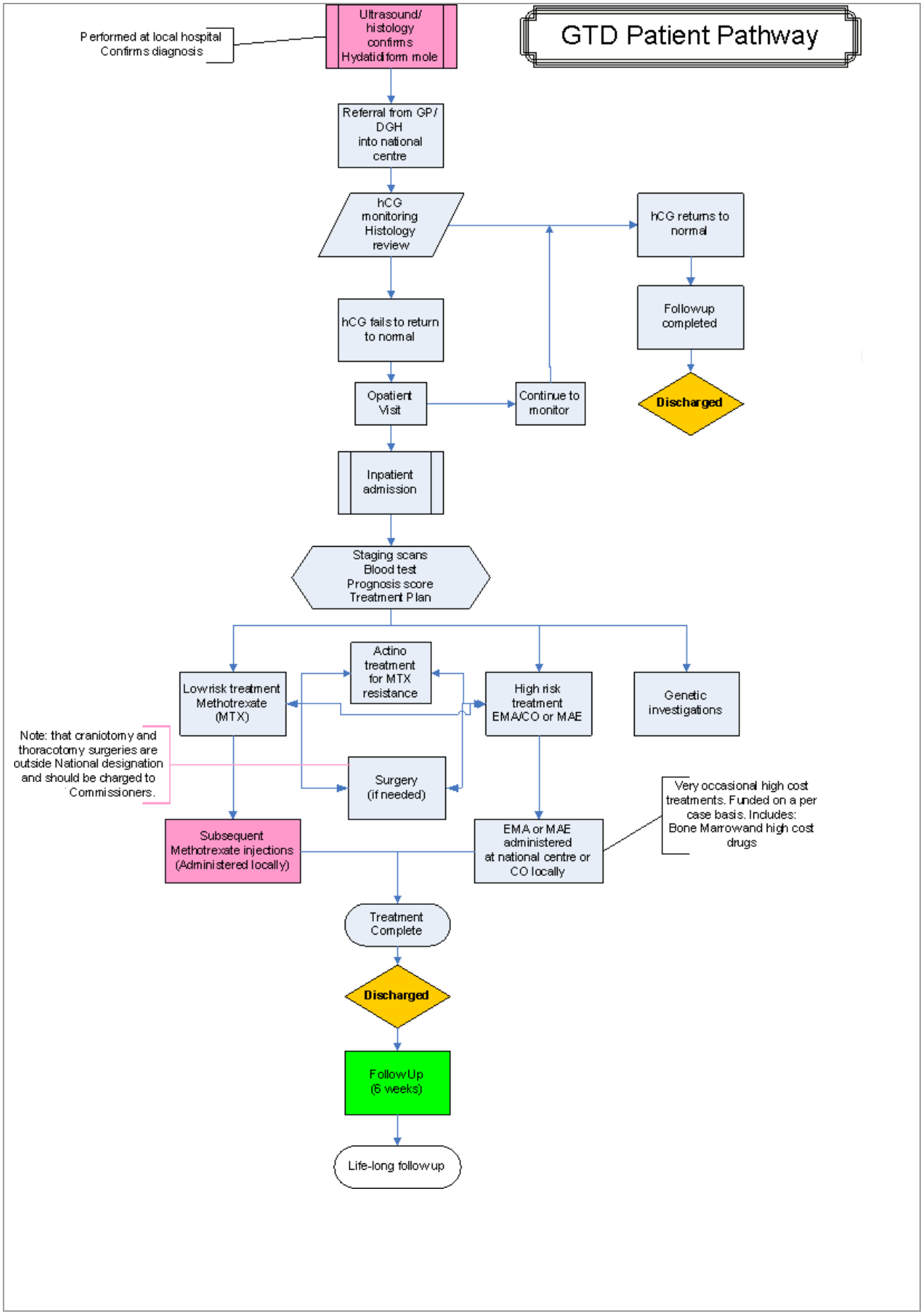
Risk management:

- Weekly multi-disciplinary team meetings to optimise clinical care and psychological support.
- National External Quality Assessment Scheme (NEQAS): to minimise analytical errors e.g. imprecision and bias. Monitored by daily Internal Quality Controls (IQC). All assays are registered, as required by Chemical Pathology Accreditation (CPA), with an appropriate NEQAS scheme;
- Cross-site (Charing Cross/Sheffield) meetings to harmonise service delivery;
- Datix (is a single incident reporting system for all incidents including accidents, complaints, claims and Patient Advice and Liaison Service (PALS) activities). Each incident is investigated and a report issued with remedial action if appropriate.

ADOPTED

Figure 1. The GTD service pathway

ADOPTED


GTD Patient Pathway
Performed at local hospital
Confirms diagnosis
Ultrasound/ histology confirms Hydatidiform mole
Referral from GP/ DGH into national centre
hCG monitoring Histology review
hCG returns to normal
Followup completed
Discharged
hCG fails to return to normal
Opatient Visit
Continue to monitor
Inpatient admission
Staging scans
Blood test
Prognosis score
Treatment Plan
Actino treatment for MTX resistance
Low risk treatment Methotrexate (MTX)
High risk treatment EMA/CO or MAE
Genetic investigations
Note: that craniotomy and thoracotomy surgeries are outside National designation and should be charged to Commissioners.
Surgery (if needed)
Subsequent Methotrexate injections (Administered locally)
EMA or MAE administered at national centre or CO locally
Very occasional high cost treatments. Funded on a per case basis. Includes: Bone Marrowand high cost drugs
Treatment Complete
Discharged
FollowUp (6 weeks)
Life-long followup

Service model, **Data Management , Audit and Governance**

The patient is sent information on molar pregnancy, a sample kit with instructions and information on the advisory and support services offered. These include a telephone advisory service, manned during office hours (30,000+ calls per annum), 24 hour emergency access to an on-call clinician & rapid access to counselling. Also, an invitation to attend a monthly drop-in session where they can meet other women suffering molar pregnancy, learn more about their condition, future pregnancies and have the opportunity for face to face contact with staff to discuss any personal concerns.

Pathology is requested for review. Patients found to be non-molar on review are discontinued from follow-up once normal hCG levels are achieved. If review confirms a third molar pregnancy patients are invited to the centre for a consultation with both a service consultant and consultant geneticist. The patient is offered further genetic investigation, advice and counselling regarding future pregnancy.

The referring consultant retains responsibility for the patient's on-going clinical care, with Patient's invited to call the specialist centre directly for on-going advice and interpretation of results. The specialist centre liaises closely with the local health care providers (GP/gynaecologist) during the monitoring period, with commented results and immediate alert to any problems arising. Patients are monitored every two weeks, with serum & urine hCG measurements until levels return to normal and then by urine samples only, every four weeks until follow-up is complete. Because of possible relapse with a future pregnancy, hCG samples are requested on two occasions after each future pregnancy.

For patient's requiring admission to the specialist centre, responsibility for their clinical management passes to the specialist centre oncology team. Patients are seen in the outpatient clinic by a consultant and Clinical Nurse Specialist. They undergo blood tests, pelvic ultrasound and chest x-ray to facilitate a prognostic score, determining if low or high risk chemotherapy is indicated. Some women will require further imaging. The initial admission is dependant on the patient medical status. The specialist centre liaises closely with the local health care providers (GP/gynaecologist/oncology team) for on-going care.
Following the initial admission, the centre endeavours to arrange on-going treatment(s) local to patient residence. During chemotherapy treatment the patient is seen at the national centres regularly the frequency depending on the nature and complexity of the treatment given.

Monitoring during treatment involves at least serum hCG analysis. When the patients are at home, this is done at the local hospital phlebotomy clinics or the GP practice and forwarded by the local laboratories to the centre for analysis using the pre-paid kits provided. The national providers will liaise closely with the local health care providers (GP/gynaecologist/oncology team). A full blood count (FBC), Liver (LFTs) and kidney function (U&Es) tests are also necessary prior to each course of chemotherapy.

Data management is handled through existing electronic systems at Charing Cross and Sheffield that have been tailored for automation of tumour marker surveillance, ease of clinical audit, activity reporting and to facilitate compliance with local and national governance. These systems are already supported by dedicated IT staff.

ADOPTED

Referral processes and sources

Referrals can be made by any doctor who has diagnosed the patient with a GTD event using a registration form for molar pregnancies (see Appendix 3) that is available:

- online at http://www.hmole-chorio.org.uk/clinicians_info_registration.html or by
- by directly contacting the Advisory services in London or Sheffield (Appendix 3) or by
- secure online registration system available at https://nww.h-mole.nhs.uk/.

Non molar referrals can be made by telephone, letter or email.

Discharge criteria and planning

Active discharge planning is commenced on admission or prior to elective admission as per provider discharge policy. GTT procedure Appendix 4
Tumour marker follow-up (hCG) is life-long for both low and high risk patients.

Patient-Centred Services

The patient is at the heart of the GTD service. Each patient is assigned a key worker, is offered counselling and where appropriate the necessary Teenage and Young Adult (TYA) support and paediatric support including play specialists. Clear communication with the patient and all associated teams within and external to the centre is essential and is the key to the service's successful operation.

Operational Delivery Network (ODN)

Regular satisfaction surveys of various aspects of the ODN are carried out in the GTD service including the patients, their GPs and referring gynaecologists so that improvements in the overall service are enabled. Over the years this has lead to the introduction of many patient driven changes to service delivery, information enhancement and improved patient experience.

3.3 Population covered

The service is accessible to all patients with GTD.

This is a UK service covering Scotland, Northern Ireland, England and Wales. Three centres have been designated for hCG monitoring and registration of new patients with GTD: Ninewells Hospital in Dundee for Scottish patients, Weston Park Hospital (Sheffield Teaching Hospitals NHS foundation Trust) in Sheffield for those women living in the north of England, central and north Wales and Charing Cross Hospital (Imperial College Healthcare NHS Trust) in London for all other regions. Treatment, if necessary, is given either in Sheffield for women in north England, central and north Wales or London for those in the rest of the UK.

3.4 Any acceptance and exclusion criteria and thresholds

The criteria for registration/referral acceptance are either pathological confirmation of GTD or clinical suspicion of GTD in the absence of pathological evidence. Referrals are accepted from consultant gynaecologists, GPs or any clinician who suspects a diagnosis of GTD following discussion with the specialist centre. Patients physically

ADOPTED

seen by the service include those identified:

- By the monitoring process as requiring further treatment
- As placental site or epitheliod trophoblastic tumours or choriocarcinomas
- With persistently raised and/or unexplained elevated hCG levels
- As having multiple molar pregnancies
- With atypical placental site nodules

Patients identified for intervention through the hCG monitoring protocol will meet one or more of the following criteria:

- Serum hCG > 20, 000 IU/L at >4 weeks post evacuation
- Rising hCG i.e. 2 consecutive rising serum samples
- HCG plateau i.e. 3 consecutive serum samples not rising or falling significantly
- Heavy haemorrhage and/or severe abdominal pain
- HCG still abnormal at 6 months post evacuation

There is no exclusion criteria providing patients reside within the areas covered by the UK scheme.

3.5 Interdependencies with other services/providers

i) Co-located Services

The effective running of the GTD service requires effective teamwork between a number of departments within the hospital including, gynaecology, histopathology, radiology, thoraco-abdominal surgery, liver surgery, neurosurgery, intensive care, psychiatry, palliative care/pain control, paediatrics and a high dose transplantation centre. Within the hospital the service is supported by a full range of ancillary services, including a comprehensive translating service, designated clinical nurse specialist, counselling specialist, paediatric play specialists, accommodation facilities for relatives, TYA services and the various other support services including a Maggie's Centre are available. The Sheffield centre is the regional TYA centre and Charing Cross is a designated TYA unit with all necessary links in place for TYA services across the country.

ii) Interdependent Services

Externally, good relationships have been built between the national centres, patient's GPs and other oncology units to deliver the centrally designated treatment close to the patient's home. There are protocols in place for chemotherapy to be administered in many local oncology units. Whilst patients are receiving treatment locally, the direction and prescription of their clinical care remains with the national centre at all times.

iii) Related Services

The following local outside services may be engaged either before referral, during shared care treatment or after completion of therapy: Gynaecology, Oncology, Radiology, GP, Phlebotomy (tumour marker monitoring), TYA principle treatment centres (PTC), psychiatric, fertility and social workers.

ADOPTED

iv) Data Submission: Monthly activity reports. Annual workload analysis.

Referring centres: All obstetric and gynaecology units, gynae/onc centres and any other NHS facility where the diagnosis of GTD is suspected

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

See Appendix 2

All clinical services, including treatment protocols must be in accordance with appropriate clinical guidelines and National Standards e.g. NICE/ NCAT(National Cancer Action Team), Nursing & Midwifery Council: National Standard of Conduct, Performance & Ethics for Nurses & Midwives, acute oncology, safe-guarding children and TYA(Teenage & Young Adults).

All medical laboratory services (e.g. hCG analysis) must be provided in an appropriately regulated environment, operated according to nationally accepted quality standards(UK-NEQAS-United Kingdom National External Quality Assessment Service) and have Clinical Pathology Accreditation (CPA).

The two national centres have considerable expertise in developing high standards of clinical care / maintaining databases of patients with GTD where fertility preservation is important. Moreover, Charing Cross has the world's largest experience with GTD and has an international reputation for establishing new standards of care in this area.

Potential aspirational standards for the next year will include development of:

- Shorter follow-up protocols
- An application for i-phone and android phones to provide patients and their doctors with easily accessible information about GTD and its therapy.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable CQUIN goals (See Schedule 4 Part E)

The GTD service is a highly specialised service and the quality standard goals will be determined by the two national centres in dialogue with the commissioners.

For 2013/14 the GTD service will propose to:

- Audit length of hCG surveillance required following uterine evacuation of a molar

ADOPTED

pregnancy to determine shortest, safest length thus reducing costs and enhancing the patient experience.

- Re-evaluate the impact of high dose chemotherapy to determine whether we should continue this high cost intervention in selected patients

6. Location of Provider Premises

The Provider's Premises are located at:

- Imperial College Healthcare NHS Trust (Charing Cross Hospital) London
- Sheffield Teaching Hospital NHS Foundation Trust (Weston park Hospital)

7. Individual Service User Placement

The provision of high dose chemotherapy and other services required in selected patients will be managed on a per patient basis.

ADOPTED

Appendix One

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Deaths	< 2% overall	Deaths as a percentage of all new cases	Audit to evaluate causation and change in practice
Domain 2: Enhancing the quality of life of people with long-term conditions			
Maximising fertility rates post chemotherapy	> 80%	Proportion of patients who are attempting pregnancy after chemotherapy that are succeeding, assessed through questionaires/telephone interview	Audit to evaluate causation and change in practice where feasible
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Counselling offered to all patients	>98%	Proportion of patients offered counselling	Audit to evaluate causation and remedial action
Domain 4: Ensuring that people have a positive experience of care			
All patients to have a named key worker on day of admission	> 98%	Proportion of patients who were assigned a named key worker on day of admission	Audit to evaluate causation and remedial action
Patient's GP is informed of admission within 24 h of admission	> 95%	% patient's GPs informed in this time frame	Audit to evaluate causation and remedial action
All patients to see consultant on day or within 24 h of admission	>98%	% patients who saw consultant within 24 h admission	Audit to evaluate causation and remedial action
Establishing local chemotherapy / shared care within three weeks of first admission	> 90%	% of patients achieving this where appropriate	Audit to evaluate causation and remedial action
Annual patient survey	100% offered survey	% patients achieving this	Audit to evaluate causation and remedial action
All patients on chemo offered patient diary on 1st discharge	>98%	% patients achieving this	Audit to evaluate causation and remedial action

ADOPTED

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Compliance with all relevant national KPIs including infection control and waiting times	As per national KPIs	As per national KPIs	As per national KPIs
Maximum 14 day turn around time on histopathological specimens	> 90%	% of total GTD pathology specimens not reported in this time	Audit to evaluate causation and remedial action

ADOPTED

Appendix Two

Contact numbers.

Charing Cross Hospital Advisory Line
Dee Short, Sabrina Casalboni or Karina Catalano
Tel: 020-33111409
Email: hmole-chorio@imperial.nhs.uk

and for emergencies out of hours: Professor Michael Seckl and Dr Philip Savage
available on call via the Charing Cross Hospital switchboard:
Tel 020-3311-1234

Weston Park Hospital Trophoblastic Service
Jane Cook, Annie Hills, Sarah Gillet, Kam Singh, Dr Matt Winter, Profs Robert Coleman & John Tidy
Tel: 0114 2265205
Email: trophoblastic@sth.nhs.uk

and for emergencies out of hours: Dr Matt Winter, Prof Robert Coleman, Prof John Tidy,
or Medical Oncology Consultant On call
via Weston Park Hospital switchboard
Tel: 0114 2265000

REGISTRATION FORM FOR PATIENTS HAVING HYDATIDIFORM MOLE

Registration is now ONLINE. Go to https://www.h-mole.nhs.uk/ If online registration is not possible this form may be used.
Please send to one of the Centres shown overleaf. Receipt will be acknowledged. 2013

REFERRING CONSULTANT
CONSULTANT
GMC Number
HOSPITAL
ADDRESS

POSTCODE
TEL:
FAX:

PATIENT IDENTITY / AFFIX LABEL
SURNAME
FIRST NAMES
DoB Hospital No.
NHS No
ADDRESS

POSTCODE
Telephone:
ETHNIC ORIGIN
UNDERSTANDS ENGLISH? YES / NO / LITTLE
MOTHER TONGUE/1st LANGUAGE?

OBSTETRIC HISTORY
Number of live births:
Date of evacuation of hydatidiform mole:
Date of last menstrual period prior to evac:
Gestational age: Uterine size:
Classification of mole(note 4):
Site of mole: Uterine Ectopic
Repeat D&C? YES / NO Date/s
Comment.
Family history of H.Mole? YES / NO

GP NAME
ADDRESS

POSTCODE
Telephone:

EVENTS LEADING TO DIAGNOSIS (Please ring and number sequence of events)

PV bleeding	Histology report	Missed miscarriage	Foetal abnormality
Ultrasound	Large for dates	Incomplete miscarriage	Ectopic pregnancy
Recurrent bleeding-following abortion	Small for dates ^hCG	Termination	Evacuation of uterus

OTHER (please describe in separate letter if preferred)

METHOD(S) OF EVACUATI0N (Please ring as appropriate)

Spontaneous	Curettage	Hysterotomy	Prostaglandins/Analogue
Suction evacuation	Syntocinon	Hysterectomy	Mifepristone

OTHER (please specify)

WAS DIAGNOSIS SUSPECTED PRIOR TO EVACUATION? YES / NO

Please confirm that the need for follow-up has been discussed with the patient, that the procedure has been explained to her and that she has consented to her data being held on computer. Please ask her to notify us of any change of address.

Signed Name Pathologist
Consultant or Registrar Date Hospital site.
GMC Number Path.Lab.No.

********PLEASE ATTACH A COPY OF THE HISTOLOGY REPORT********

Appendix 3

Imperial discharge procedure for Gestational Trophoblastic Tumours

Low risk. Within 48 hours of admission:

- Organise the administration of the methotrexate (MTX) injections local to patient residence. Contact the GP to discuss, fax the referral letter, protocol and the three subsequent treatment schedules. If the GP unable to administer, contact the local oncology unit and refer to an appropriate oncologist, then fax the referral letter and treatment schedules. Provide information on methotrexate administration
- Order three courses of MTX and folinic acid tablets from pharmacy to be prepared as a To Take Away (TTA)
- Educate the patient on the safe storage and transport of drugs

Prior to discharge:

- Arrange six week out-patient appointment (OPA), give copy of letter, treatment schedules, spillage kit, purple sharps in and any other TTA's to patient
- Arrange for patient to see the clinical co-ordinator the day before discharge to collect blood test instructions for once or twice weekly hCG testing, and a letter requesting full blood count (FBC) and urea & electrolyte's (U&E's) test to be done the day before each cycle of treatment using local phlebotomy provision
- Give advice (verbal and written) on contraception, caution in the sun, alcohol consumption and exercise
- Ensure appropriate transport arrangements are in place
- Minimal/no vaginal bleeding
- Adequate storage facilities identified for methotrexate and other drugs

Upon completion of treatment:

- Arrange a six week follow-up OPA with repeat pelvic ultrasound (if required) (and chest
- X ray if lung metastases identified on pre treatment CXR)
- Give advice (verbal & written) on long term hCG monitoring, future pregnancy advice and any other issues raised
- Post six week clinical check-up
- Discharge from clinic to continue postal follow-up of hCG

High risk:

- Organise the administration of the CO infusions local to patient residence. Contact the local oncology unit to discuss and refer to an appropriate oncologist, fax the referral letter and protocol;
- Ensure all take away drugs are available;
- Educate the patient on the safe storage and use of prescribed drugs;
- Arrange a two week out-patient appointment
- Ensure appropriate transport arrangements are in place.
- Give written information, including copies of patient letters on the above including discharge after in-patient stay.

ADOPTED