



**West Yorkshire & Harrogate
Cancer Alliance**

**Guidelines for the Management and
Investigation of Biliary Cancers**

Version 1.0
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i Document Control

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1 Introduction

1.1 Purpose and scope of document

These guidelines are based on the National Improving Outcomes in Upper Gastro-intestinal Cancers guidance, and accompanying research evidence, with appropriate interpretation for our local service. The clinical guidelines cover the investigation and management of biliary cancer.

The guidelines will be reviewed every three years or sooner, if new guidance becomes available.

1.2 National Guidance for HPB Cancer

The 'Improving Outcomes in Upper Gastro-intestinal Cancers' document, produced by the National Guidance Steering Group in January 2001, highlights the following key recommendations:

- All hospitals which intend to provide services for patients with upper gastro-intestinal cancer should be fully involved in appropriate Cancer Alliances which include inter-linked Cancer Centres and Cancer Units. Each region should review proposals for these services, to ensure that proposed local arrangements reflect the recommendations in this guidance more accurately.
- There should be documented local referral policies for diagnostic services for suspected upper gastro-intestinal cancers. These should be jointly agreed between General Practitioners (GPs) in Primary Care Groups and Trusts, and appropriate specialists in local hospitals and cancer Units and Centres in each Cancer Alliance.
- Specialist treatment teams should be established at appropriate Cancer Centres or Units. Oesophago-gastric Cancer Teams should aim to draw patients from populations of more than one million; Pancreatic Cancer Teams should aim to draw patients from populations of two to four million.
- There should be clear documented policies for the referral of patients between hospitals, and for processed by which clinicians in local hospitals seek advice from specialist treatment teams about the management of individual patients for whom referral may not be appropriate.
- Palliative, Supportive and specialist care should be available to all who need it. This will require effective co-ordination and communication between primary care, social and voluntary services, local palliative care teams, hospital services and those who provide specialist advice and interventions.
- Monitoring systems using common data-sets should be established throughout each Cancer Alliance to audit patient management, key communications, referral processes and key outcomes of treatment.

1.3 Cholangiocarcinoma

Cholangiocarcinoma, a primary tumour of the biliary epithelium, accounts for 3% of all gastrointestinal malignancies, but has a dismal prognosis. Cholangiocarcinoma can occur at any location in the biliary tree, but is most commonly (60–70%) evident at the confluence of the hepatic ducts; this manifestation is termed ‘hilar cholangiocarcinoma’. Intrahepatic cholangiocarcinoma can occur anywhere within the liver. Hilar cholangiocarcinoma was first described in detail in 1965 by Gerald Klatskin and hence these tumours are often termed ‘Klatskin tumours’. More recently, the term ‘perihilar cholangiocarcinoma’ has been used to include both intra- and extrahepatic cholangiocarcinomas affecting the hepatic hilum as they are managed similarly. Perihilar cholangiocarcinoma (PHCCA) tends to present late for several reasons. The unobstructive lateral extension of the tumour combined with the detergent properties of bile result in the late occurrence of the complete obstruction of the bile duct, which causes jaundice, the most common form of presentation. This late presentation combined with the intimate relations of this tumour with the portal vein, hepatic arteries and liver make PHCCA a surgical challenge. Surgery remains the only curative therapy for patients with PHCCA, although chemotherapy and radiotherapy are sometimes useful as adjuncts to surgical resection or as palliative therapy.

Distal cholangiocarcinoma, affecting the lower common bile duct within the head of the pancreas, accounts for the majority of the remainder of cholangiocarcinomas. Investigation and treatment is similar to pancreatic cancer, although there is more evidence to support regional and para-aortic lymphadenectomy during surgical resection. Mid-duct cholangiocarcinoma is rare. Both usually present with jaundice.

Although some of these patients will benefit from radical treatment, most will require palliative interventions to minimise the impact of their symptoms and improve the quality of their life.

As the majority of patients have incurable disease at presentation, it is appropriate that palliative treatments are provided close to the patient’s home and family.

Referral

Patients fit for surgery with stage IV biliary cancer need to be referred to the Leeds Liver MDT via the MDT Co-ordinator, contact details below:

MDT Co-ordinator/ Data Manager for Upper GI/ HpB
3rd Floor Bexley Wing, St Institute of Oncology, Beckett Street, Leeds, LS9 7TF
Tel: 0113 2068750
Fax: 0113 2426496
Email: neil.wright5@nhs.net

The Liver MDT team will always communicate with the patient when the individual is in for treatment in Leeds. However the responsibility for communicating with all other patients remains with the referring local clinical team.

Follow-Up

Following resection all patients need to be followed up as per the Leeds protocol, which undergoes regular review. The CT scan and blood tests can be performed at the local hospital or in Leeds depending on patient choice, and development of shared care

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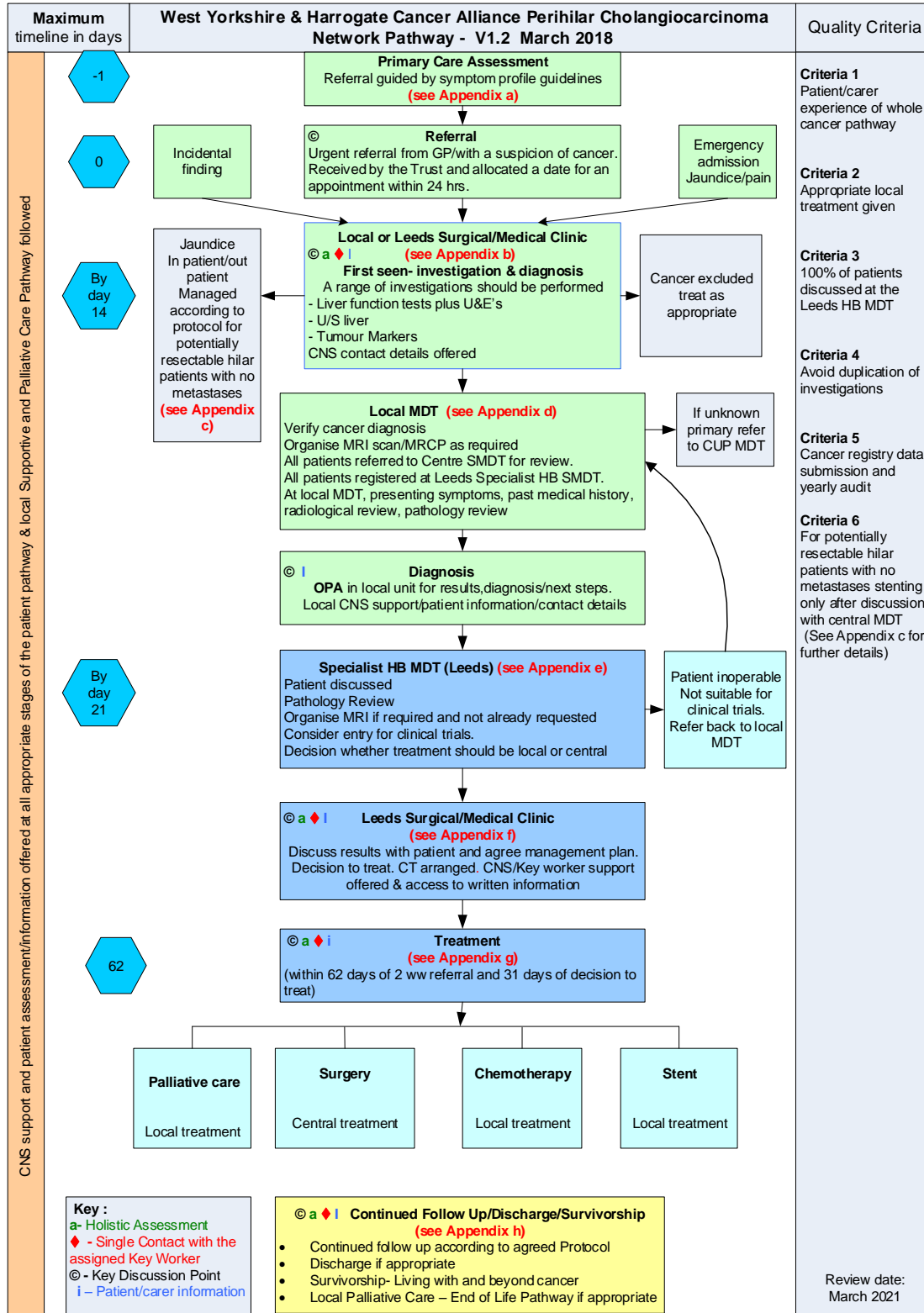
protocols. Most patients will then be seen in clinic in Leeds to discuss their results, especially if there is recurrent disease.

Concern about recurrence need to be referred back to the Liver MDT, so that further management plans can be discussed.

Patients who have chemotherapy first before liver surgery may need to be referred back to the liver MDT so that operability can be assessed, although this is usually done directly through the clinics.

2 Clinical Pathways for Biliary Cancer

2.1 Clinical Pathways for Perihilar Cholangiocarcinoma



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Appendix

West Yorkshire & Harrogate Cancer Alliance Perihilar Cholangiocarcinoma Pathway

Pathway Details/Supporting Information

Title	Perihilar Cholangiocarcinoma Pathway
Author & Owner	West Yorkshire & Harrogate Cancer Alliance

Version Control		
Version/ Draft	Date	Revision summary
Version 1.0	April 2012	Original published
Version 1.1	April 2014	Include reference to CUP MDT and patient rehabilitation
Version 1.2	September 2018	Updated to reflect new ownership of the WY&H Cancer Alliance

a) Pre-referral

The majority of biliary cancers present via the following clinical routes:-

- Acute admission with jaundice/pain
- Urgent outpatient GP referral with jaundice/abnormal LFT's/weight loss
- Unsuspected finding on cross-sectional imaging for another indication
- Referral from a secondary care consultant

An urgent referral should be made for patients presenting with either:

- Unexplained upper abdominal pain and weight loss, with or without back pain
- Upper abdominal mass
- Jaundice/abnormal LFTs

It is important that an urgent abdominal ultrasound is requested by the referring clinician at the same time. The USS request should be marked as urgent fast track referral.

- GP to discuss information to date with the patient and forward with the referral
- GP to discuss implications of the referral – 2ww +/- Straight to Test
- GP should ensure 2ww guidelines are followed and include specific information as requested – i.e. blood results – Liver function tests, U&E's, USS result or date of scan

b) First seen at local/Leeds surgical or medical clinic

A range of investigations should be performed:

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- Liver function tests
 - U/S liver
 - Tumour Markers – usually CEA and CA19-9
- For presentation at the centre MDT meeting a patient history and examination to assess clinical extent of disease, co-morbid disease(s) and overall fitness should be recorded.
 - Ideally, the clinical assessment and diagnostic investigations should take place at the same visit.
 - The patient will be informed of the diagnosis and introduced to the Clinical Nurse Specialist based in their locality whenever possible.
 - The General Practitioner will be informed within 24 hours that the patient has been given their diagnosis.
 - After explanation of the condition the patient's understanding will be assessed and their willingness to undergo further investigation and treatments will be recorded.
 - The patient will be informed that their case will be discussed by a group of health care professionals in a specialist multidisciplinary team meeting (by way of gaining implied consent to divulge their clinical details to a group of health care professionals).
 - All patients will require a CT scan for staging hepatobiliary cancer.
 - The scans will be performed in the patient's locality in accordance with local Imaging Guidelines.
 - The CT scan performed should at least include a triple phase upper abdominal CT scan.
 - The scans will be promptly sent (electronically) to the designated Clinician in the specified specialist team for each hospital for review in accordance with the protocol for review of radiology.
 - Non 2ww referrals can be upgraded by consultant if suspicion of cancer
 - Diagnostic and staging tests to be co-ordinated to reduce delays and the number of hospital visits, appropriate information sent to the patient
 - Letter for GP
 - OPA arranged if required
 - Non-malignant diagnosis discharged back to GP or further management planned

c) Stenting

For Hilar patients who are potentially resectable with no metastases and are fit the following protocol should be followed:

- Diagnosis to be recorded on PPM
- **Not to be stented prior to SMDT discussion or if urgent then discussion with a hepatobiliary surgeon in Leeds to decide on the best approach.**
- For clearly unresectable tumours (clear evidence of metastases or discussion with Leeds surgical team) then palliative options should be explored urgently, including ERCP/PTC/combined approaches.
- Local Consultant to contact the HPB team at Leeds on the following telephone number/fax:

Tel: 0113 2068750

Fax: 0113 2426496

Email: neil.wright5@nhs.net

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- The Leeds team will discuss the patient with local Consultant (within 24 hours) once the information has been passed on by the MDT Co-ordinator.
- The Leeds team would be happy to review the CT images outside the MDT in order to facilitate a quick decision
- Most patients won't have resectable disease so it is right that they should be managed in their local hospital

d) Local Diagnostic MDT discussion

The membership of each diagnostic / local care team for HPB Cancer should include: A designated Lead Clinician; one or more clinicians specialising in gastroenterology; Histopathologist; Radiologist with expertise in cross-sectional imaging and a Clinical Nurse Specialist. Input from a medical/clinical oncologist may also be helpful.

The role of each diagnostic / local care team is to provide a rapid diagnostic service for patients with possible or suspected biliary cancer; action rapid and appropriate referrals for patients found to have cancer; liaise with primary care teams and specialist care teams as required and cooperate with appropriate data collection and audit.

The diagnostic / local care team will aim to refer all their patients with biliary cancer for review at the Centre Specialist MDT (Leeds HPB SMDT/ West Yorkshire SMDT) meeting in line with the Hilar & Intrahepatic Cholangiocarcinoma Pathway.

If unknown primary refer to appropriate Cancer of Unknown Primary (CUP) MDT

e) The role and function of the Centre MDT meeting

The Specialist Hepatobiliary Team is a multidisciplinary group, which provides a service for nearly (4-5 million) population both within and outside the West Yorkshire & Harrogate Cancer Alliance. The aim of the Specialist Hepatobiliary MDT is to ensure a co-ordinated and multi-professional approach to diagnosis, treatment planning and care provision for patients diagnosed with a suspected or definite cancer, ensuring timely communication with the appropriate agencies.

The cancer types discussed at the MDT include:

- Colorectal liver metastases
- Hilar Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma
- Hepatocellular Cancer
- Benign Liver Tumours
- Non colorectal liver metastases where appropriate

The Specialist Hepatobiliary MDT meeting is held on a weekly basis on a Friday 8am-11:30am. The meeting takes place in MDT meeting room 2 on level 7, Bexley Wing, St. James' University Hospital. Details of patients for discussion at the meeting must be submitted by 5pm on the previous Tuesday by the clinicians using the MDT proforma to:

Neil Wright- MDT Coordinator

Tel: 0113 2068750

Fax: 0113 2426496

Email: neil.wright5@nhs.net

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Should a patient require a treatment decision prior to the next meeting, the patient should be discussed with an appropriate core member outside of the MDT meeting. The patient will be discussed retrospectively at the next meeting.

Patients for discussion fall into 3 categories:

1. All new cancers - where a definite diagnosis is confirmed and treatment plans drawn up (including review after neoadjuvant therapies);
2. Relevant post-surgery histopathology - to discuss the appropriateness of adjuvant treatment or surgical follow-up;
3. Recurrent or progression of cancer - to plan further treatment or best supportive care and any complex case requiring multidisciplinary review.

The membership of the Specialist HPB MDT meeting includes: A designated Lead Clinician; Consultant HPB and Transplant Surgeons; Consultant Medical Oncologist, Consultant Clinical Oncologist, Consultant Radiologist, Consultant Interventionist Radiologist, Consultant Histopathologist, Consultant Hepatologist, Consultant Palliative Care Physician; Clinical Nurse Specialist, MDT Co-ordinator.

The Centre SMDT will assist in creating strong and supportive links with each diagnostic / local care team. The Centre SMDT will appoint a Lead Clinician who will take an active role in the coordination of Hepatobiliary cancer services provided by the Cancer Alliance as a whole.

The Centre SMDT will ensure robust and timely feedback to diagnostic / local care teams and will be willing to audit the established communication systems regularly.

Central oncology representation is provided at the MDT for advice regarding chemotherapy and radiotherapy.

Relationship between the Leeds HPB SMDT & the West Yorkshire SMDT based in Bradford

The following points establish the relationship between the two SMDTs, which ensures a robust high quality equitable service for patients within the Cancer Alliance with liver cancer (Ideally treatment decision should be made in the Leeds Specialist MDT. Care and treatment can be shared).

- Patients considered potentially suitable for radical (curative) treatment by surgery will be referred to the Leeds HPB SMDT
- Patients whose non-radical treatment can be delivered within West Yorkshire, including those discussed at the Leeds HPB SMDT but where it is decided that radical treatment will not be pursued will remain in the governance of the West Yorkshire SMDT.
- Post-surgical patients from West Yorkshire who need to be considered for adjuvant therapy will be transferred back to the West Yorkshire SMDT for assessment once post-operative histology has been discussed at the Leeds HPB SMDT. This will be facilitated by the MDT co-ordinators on each site.
- For patients from West Yorkshire requiring interventional biliary endoscopy and /or interventional biliary radiology this will take place in the West Yorkshire hospitals.

- Regular collaboration/audit between the two SMDTs will ensure equitable treatment of all patients with liver cancer within the Cancer Alliance.
- A Consultant MDT member from Bradford is a core member of the Leeds SMDT.

Further investigations/completion of staging

- Patient meets CNS, contact details given (Key Worker) and supported through further tests / staging
- Further imaging as directed by Centre SMDT
- When MRI is required for further staging this will be reported and reviewed at the Centre SMDT by the respective specialist radiology services in Leeds.
- Referral for PET CT should be in accordance with the local PET CT Guidelines 2007
- Patient given a fully booked appointment for after the MDT to discuss their management plan.
- Patient details and question submitted for MDT discussion
GP informed of the cancer diagnosis less than 24 hours following the discussion with the patient

f) Decision to Treat/Best Supportive Care/Rehabilitation

- Patient seen to discuss their treatment options supported by the HPB / site specific CNS.
- A record of consultation available if required, specific information and holistic assessment carried out
- Surgery date given, Pre-treatment assessment arranged or Radiotherapy / Chemotherapy planning starts
- If patient is age appropriate (16 – 24) refer patient to the Teenager and Young Adult (TYA) MDT at Leeds as described in the Humber Vale & Coast and West Yorkshire & Harrogate Cancer Alliance TYA with cancer pathway
- Assisted conception /fertility issues discussed and refer to Reproductive Medicine Unit at Leeds if appropriate
- Referral to Specialist Palliative team as appropriate (palliative care representative at the MDT meeting)
- Participation in clinical trials encouraged
- Best supportive and rehabilitative care needs assessed and actioned according to patient's rehabilitation requirements.

g) First definitive treatment

- Commencement of systemic therapy
- Biliary stenting if this is the only treatment planned
- Biliary stenting as part of the preoperative preparation and possible portal vein embolisation
- Surgery based on the best principles of enhanced recovery
- Decision at MDT for best supportive care

h) Follow-up – discharge

Guidelines have been agreed between the central MDT and the referring units and will be according to local Guidelines.

- Post-operatively, patients will be seen reviewed regularly in line with the MDT's follow up imaging protocol.
- Non-surgical oncology patients will have regular follow-up until treatment is no longer appropriate.
- Where appropriate, the patient may be referred to the Community Palliative Care Team.

2.2 Patient Information

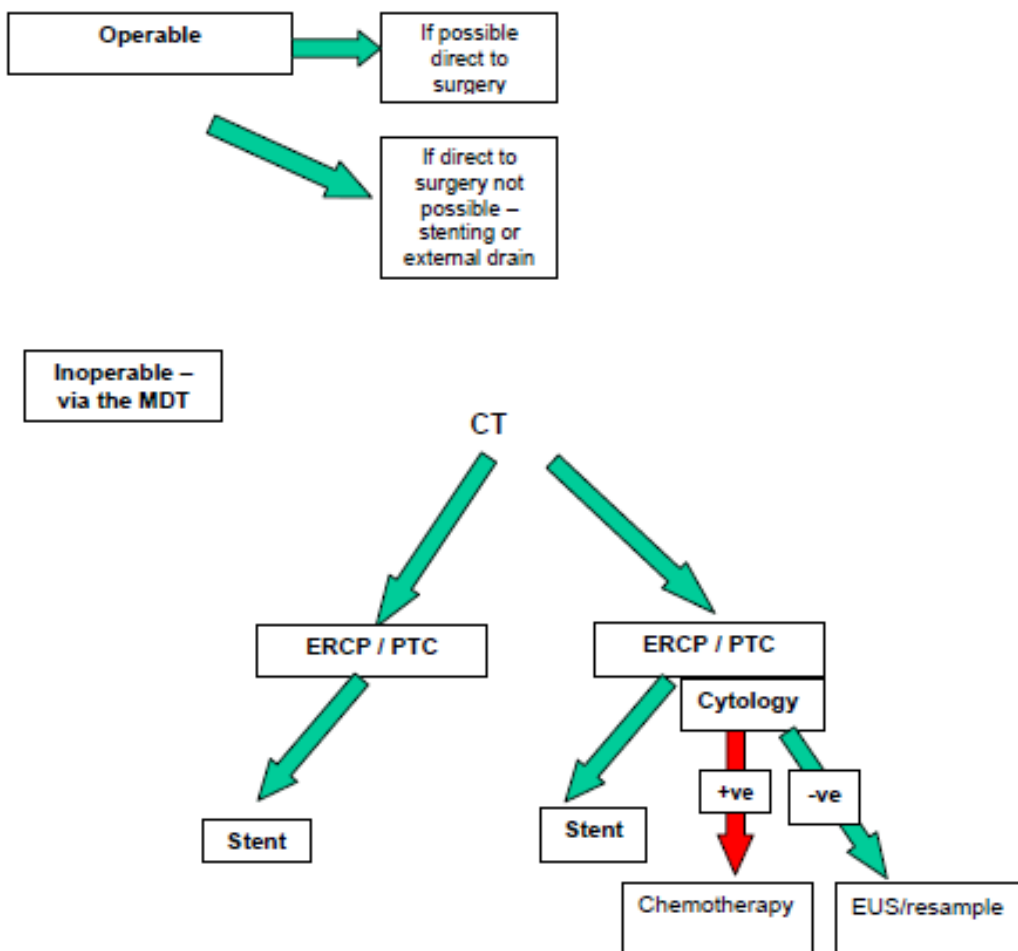
Clinical teams offer all newly diagnosed cancer patients information specific to their site, treatment and relevant to their individual need. Patients can also access NHS choices for an information prescription and clinical teams will offer help to do this, if required.

3 Management of Perihilar Cholangiocarcinoma

Management of perihilar cholangiocarcinoma continues to evolve. Surgery offer the only chance for cure, with survival rates determined by R0/R1 status at resection, lymph node involvement and tumour differentiation. The flow chart below summarises current pathways.

The recognised clinical pathways follow IOG guidelines as illustrated in the following flow chart. The initial diagnostic pathway is common to all pancreato-biliary cancers.

a) Proximal (Hilar) Cholangiocarcinoma Pathway



Radiological diagnosis: CT and MRI are the backbone of diagnosis and both are helpful in determining operability, often limited by vascular involvement. PET-CT is widely used to look for occult extra-hepatic disease. Staging laparoscopy is used to check for peritoneal metastases as a routine.

Histological diagnosis: It is not always possible to obtain an accurate diagnosis before surgery: international series continue to report 8-12% negative histopathology post-operatively due to the recognition of risks of spread by invasive biopsy techniques. New technologies

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continue to be introduced. ERCP brushings are helpful if positive. Percutaneous and EUS biopsy are not recommended if surgery with curative intent is a possibility because of the risk of peritoneal spread. Spyglass biopsy can be helpful and does not appear to carry this risk. All methods may be used if a decision had been made for palliative therapies alone.

Biliary drainage: It is recognised that cholangiocarcinoma surgery results in jaundiced patients are poor. Pre-operative biliary drainage is therefore routine unless the patient is not jaundiced. ERCP is preferred over PTC for biliary drainage whenever possible, again due to the documented risks of peritoneal and pleural spread via PTC drains. Drainage of the planned future liver remnant is preferred so it is important to discuss the case early with the HPB surgical team or through the SMDT meeting. Drainage of the rest of the liver is only needed in cases of sepsis.

Portal vein embolisation (PVE): It is recognised that cholangiocarcinoma surgery patients have fared badly in the past due to a high rate of post-operative liver failure. This has been related to many factors but not least the radical nature of the surgery and the often small future liver remnant (FLR). In recent years, PVE has been used more extensively to enlarge the FLR with the result that peri-operative mortality has fallen significantly.

Surgical resection: It is recognised that cholangiocarcinoma surgery needs to be more radical than most liver surgery due to the usual involvement of major vascular structures. As such, experience is limited to a few individuals within specialist liver units, including Leeds. The Leeds team has an international reputation for dealing with peri-hilar cholangiocarcinoma. Principles for surgery are based on: regional lymphadenectomy, portal vein and hepatic artery resection and reconstruction if appropriate, liver resection to encompass all regions supplied by involved vasculature or infiltrated ducts and caudate lobectomy with en bloc resection of the external biliary tree, and biliary reconstruction.

Adjuvant chemotherapy: Following on from the BILCAP Trial, patients are currently offered Capecitabine following surgery.

Palliative chemotherapy: If surgery is not possible, then first line therapy is most often gemcitabine with cis-platin and this should be delivered locally.

4 Radiology/Endoscopic Intervention

4.1 Radiology

4.1.1 Initial Imaging

Imaging guidelines for patients suspected of having biliary tract cancer

A. Investigation of patients with jaundice:

- Trans-abdominal ultrasound (BSG grade level of evidence “B”)*

Outcome:

- Dilated ducts - Probable malignant obstruction Urgent staging CT and urgent referral to centre sMDT via core team clinician
- Dilated ducts - choledocholithiasis Therapeutic ERCP
- Dilated ducts - indeterminate cause MRCP if probable malignant obstruction either complete staging with MR or CT.
- No obstruction - Medical Management

4.1.2 Staging CT (BSG grade level of evidence “B”)*

Technique: Arterial phase and portal venous acquisitions through the thorax, pancreas and liver obtained – collimation dependent upon specification of available CT scanner, ideally maximal slice thickness - arterial phase 3mm / portal venous phase 5mm.

4.1.3 Action to be taken following CT

All patients with suspected pancreatic carcinoma and with obstructive jaundice for which no cause can be found should be referred through to the Centre SMDT via a core team clinician.

Ideally, the CT with any other imaging with appropriate clinical details should be available for soft copy review at least 24 hours prior to the MDT. Failing this, hard copy will be reviewed.

Outcome:

- Operable – offer patient surgery if appropriate ideally prior to stenting
- Operable but requires stent to treat jaundice or temporise whilst other medical conditions assessed/treated
- Unresectable – obtain histology or cytology if at all possible (BSG grade level of evidence “C”). Palliative options determined including stent / chemotherapy / radiotherapy etc.
- Indeterminate resectability or the nature or cause of obstruction unclear – either EUS (+/- biopsy) or MR following discussion of the individual merits of each case.

Imaging should proceed as rapidly as possible. The initial referral for ultrasound should be treated as urgent - the cumulative effect of delays along the pathway is almost certain to result in progressive jaundice which may limit or force therapeutic options and may adversely affect outcome.

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Patients presenting with non-specific symptoms will generally be identified at CT, and should be referred directly to the MDT following this.

Percutaneous biopsy should be avoided in potentially resectable cases even if the character of the lesion is in doubt. Percutaneous biopsy may prejudice outcome.
EUS guided biopsy may be indicated in selected cases following SMDT review.

*BSG grade level of evidence

“B” = well conducted clinical studies but no randomised controlled trials

“C” = respected opinion but absence of applicable good quality clinical studies

TNM Staging

TNM Staging of intrahepatic bile duct cancer			
Primary tumour (T)			
TX	Primary tumour cannot be assessed		
T0	No evidence of primary tumour		
Tis	Carcinoma in situ (intraductal tumour)		
T1	Solitary tumour with vascular invasion		
T1a	Solitary tumour ≤ 5cm without vascular invasion		
T1b	Solitary tumour > 5cm without vascular invasion		
T2	Solitary tumour with intrahepatic invasion or multiple tumours, with or without vascular invasion		
T3	Tumour perforating the visceral peritoneum		
T4	Tumour involving local extrahepatic structures by direct invasion		
	<u>Note:</u> <ul style="list-style-type: none"> Tumour growth patterns (mass forming versus periductal) are no longer part of staging criteria but should still be reported 		
Regional lymph nodes (N)			
NX	Regional lymph nodes cannot be assessed		
N0	No regional lymph node metastasis		
N1	Regional lymph node metastasis		
	<u>Notes:</u> <ul style="list-style-type: none"> Regional lymph nodes depend on tumour site For left sided lesions, regional nodes include inferior phrenic, hilar and gastrohepatic lymph nodes For right sided lesions, regional nodes include hilar, periduodenal and peripancreatic lymph nodes 		
Distant metastasis (M)			
M0	No distant metastasis		
M1	Distant metastasis		
Stage grouping			
Stage 0	Tis	N0	M0
Stage IA	T1a	N0	M0
Stage IB	T1b	N0	M0
Stage IIA	T2	N0	M0
Stage IIIA	T3	N0	M0
Stage IIIB	T4	N0	M0
	any T	N1	M0
Stage IV	any T	any N	M1
From AJCC Cancer Staging Manual 8th Edition, 2018			

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TABLE 5: TNM staging of gallbladder cancer

Primary tumor (T)			
TX		Primary tumor cannot be assessed	
T0		No evidence of primary tumor	
Tis		Carcinoma in situ	
T1		Tumor invades lamina propria or muscular layer	
	T1a	Tumor invades lamina propria	
	T1b	Tumor invades muscular layer	
T2		Tumor invades perimuscular connective tissue; no extension beyond serosa or into liver	
T3		Tumor perforates the serosa (visceral peritoneum) and/or directly invades the liver and/or one other adjacent organ or structure, such as the stomach, duodenum, colon, pancreas, omentum, or extrahepatic bile ducts	
T4		Tumor invades main portal vein or hepatic artery or invades two or more extrahepatic organs or structures	
Regional lymph nodes (N)			
NX		Regional lymph nodes cannot be assessed	
N0		No regional lymph node metastasis	
N1		Metastases to nodes along the cystic duct, common bile duct, hepatic artery, and/or portal vein	
N2		Metastases to periaortic, pericaval, superior mesentery artery and/or celiac artery lymph nodes	
Distant metastasis (M)			
M0		No distant metastasis	
M1		Distant metastasis	
Stage grouping			
Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage IIIA	T3	N0	M0
Stage IIIB	T1–3	N1	M0
Stage IVA	T4	N0–1	M0
Stage IVB	Any T	N2	M0
	Any T	Any N	M1

From Edge SB, Byrd DR, Compton CC, et al (eds): AJCC Cancer Staging Manual, 7th ed. New York, Springer, 2010.

4.2 Endoscopic Intervention

4.2.1 Biliary Drainage in patients with biliary tract cancers

Patients who present with obstructive jaundice due to perihilar cholangiocarcinoma may require biliary drainage. These patients fall into one of two groups – those who require biliary drainage as a palliative measure and those who may require biliary drainage pre-operatively.

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Patients should ideally have the staging CT and MRI with MRCP performed before any attempted biliary drainage so that they can be stratified into the correct group.

4.2.2 Palliative Treatment

Endoscopic insertion of a metal endoprosthesis into the bile duct is the main stay of palliative treatment of jaundice from biliary cancers. If endoscopic insertion fails then PTC drainage and possibly stenting may be appropriate.

In those patients in whom endoscopic access is not possible, arrangements should be made for the patient to have a percutaneous transhepatic biliary drainage (PTBD) and stent insertion. If an ERCP has been performed where contrast has been injected into an undrained system, referral for PTBD must be made immediately. In some cases this may require transfer to another hospital. Whilst arrangements for transfer are being made, the patient should remain on antibiotics and careful attention should be paid to the fluid balance as these patients are at high risk of developing pre-renal failure.

Some patients who have palliative stent placement for relief of obstructive jaundice will subsequently develop stent occlusion requiring stent exchange. Patients and their relatives should be informed of this possibility. Arrangements for managing this complication must be clear to both cancer centre and cancer unit.

4.2.3 Pre-operative Biliary Drainage

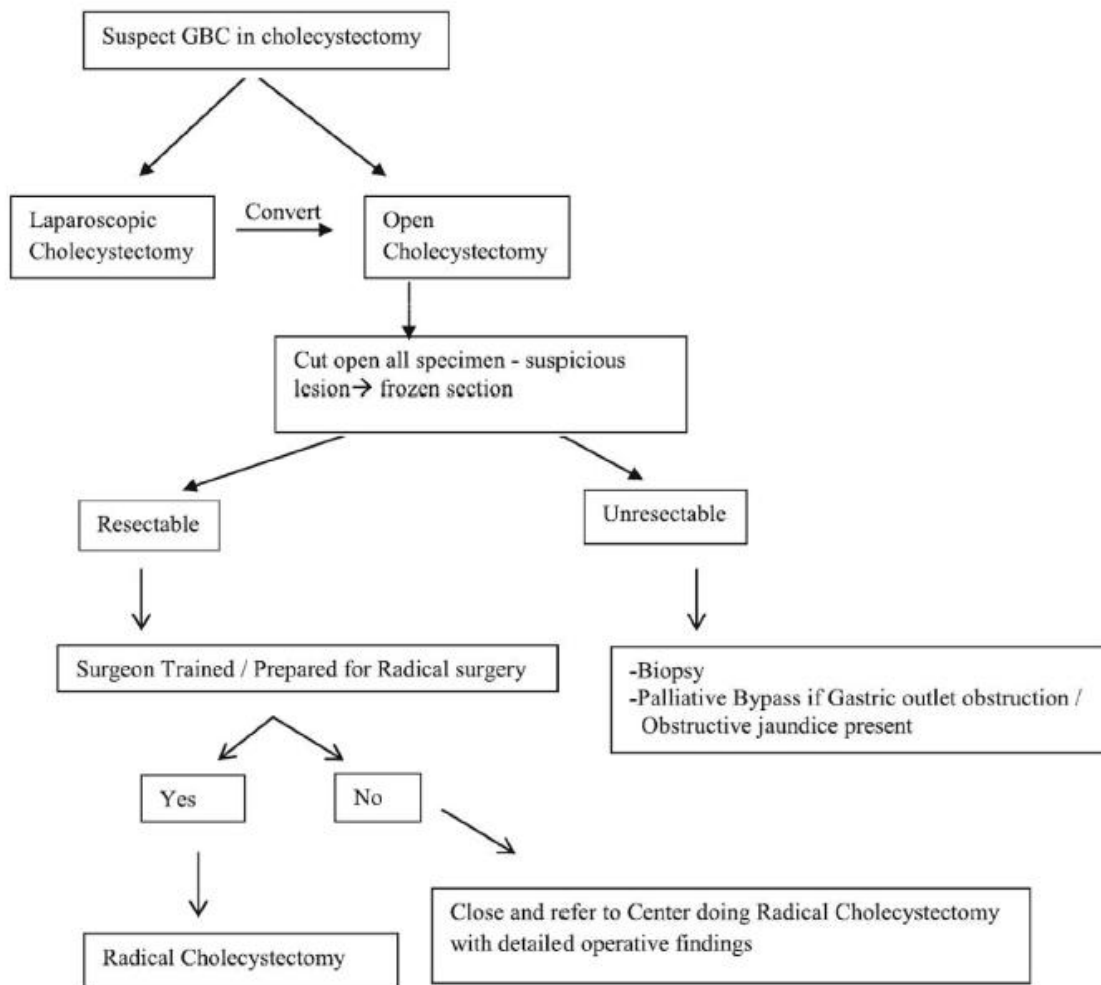
Surgical outcomes are significantly improved by resolution of jaundice preoperatively. Recent data suggests that the correct approach is endoscopic biliary stent insertion into the ducts draining the planned future liver remnant at surgery. It is therefore appropriate to discuss these cases urgently with the Leeds team at an early stage. PTC drainage in biliary tract cancer is associated with poorer outcomes with surgery due to tumour seeding and this should be avoided unless endoscopic drainage fails.

5 Management of Gallbladder Cancer

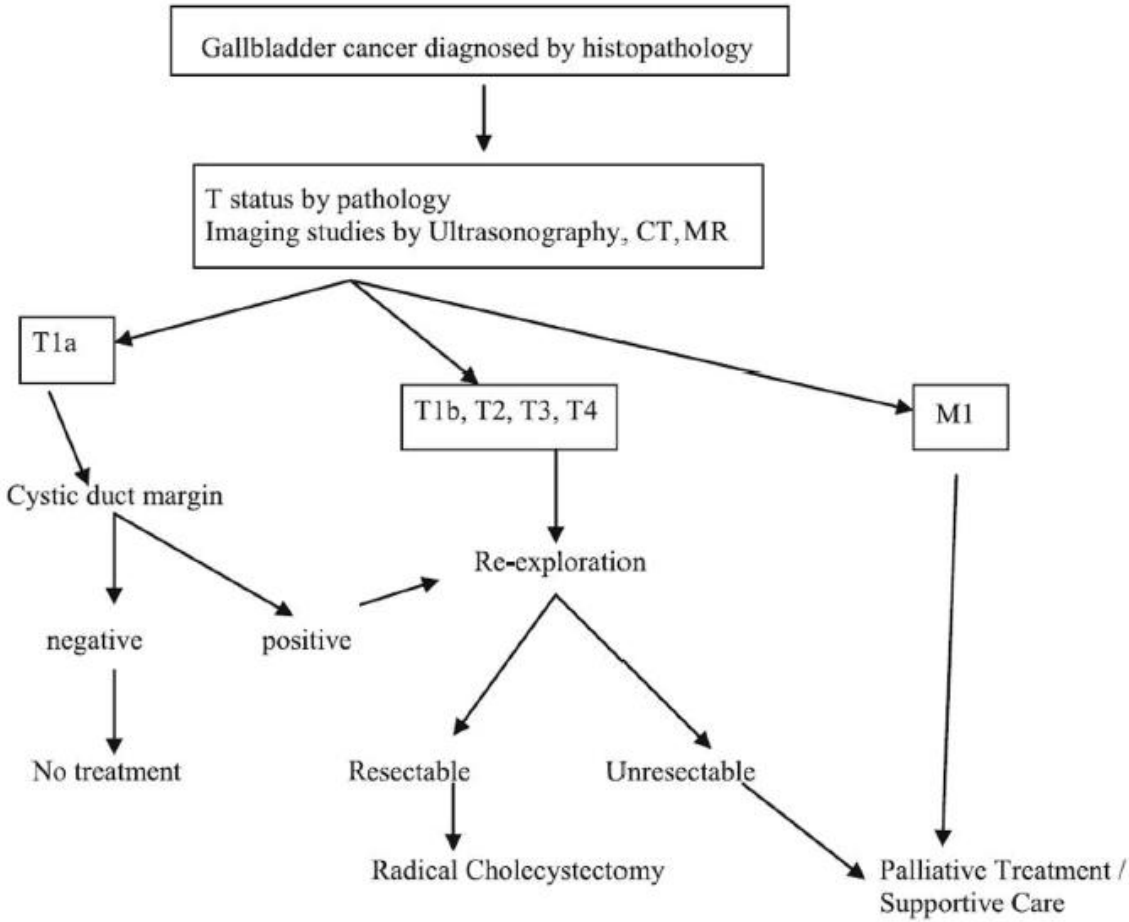
Gallbladder cancer is increasingly recognised within the UK's aging population and as a result of immigration. Treatment protocols clearly are continuing to evolve.

Cholecystectomy is thought to be curative for dysplasia and carcinoma-in-situ but this can be a difficult diagnosis and the Leeds SMDT is happy to review cases of incidental gallbladder "cancer" found at cholecystectomy.

The treatment algorithm below summarises current thoughts on what to do if a gallbladder cancer is suspected at surgery:



The treatment algorithm below summarises current thoughts on what to do if a gallbladder cancer is confirmed after cholecystectomy:

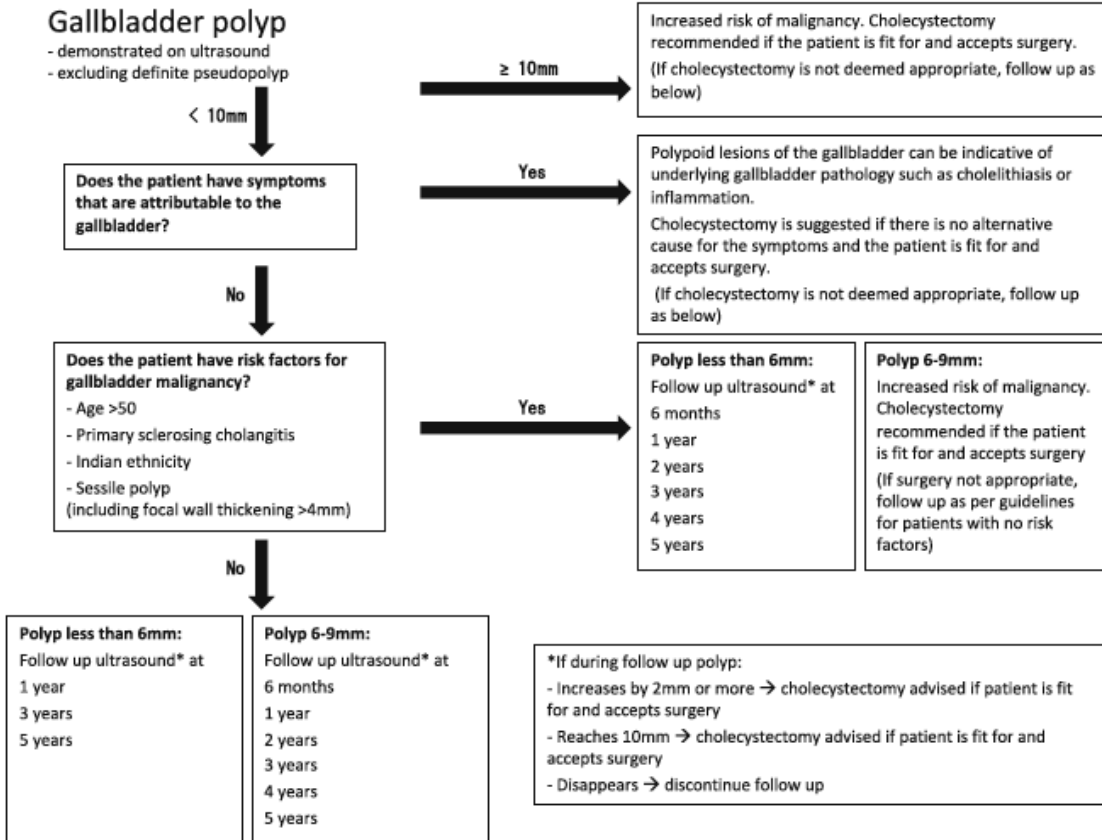


These flow charts are from:

A. Cavallaro et al / International Journal of Surgery 12 (2014) S108–S119

Management of gallbladder polyps:

This is more controversial as there are no defined universally accepted guidelines. A recent European review (Wiles R et al, European radiology 2017; 27: 3856) suggested the following:



6 Non-Surgical Oncology

6.1 Adjuvant Chemotherapy

Following on from the BILCAP Trial the current consensus on the role of adjuvant chemotherapy for biliary tract cancer is to offer Capecitabine.

6.1.1 Intra-hepatic / Extra-hepatic cholangiocarcinoma and Gallbladder adenocarcinoma

Following on from the BILCAP Trial the current consensus on the role of adjuvant chemotherapy for biliary tract cancer is to offer Capecitabine.

6.1.2 Recommendation:

1. Patients should be encouraged to enter clinical trials if available
2. Outwith a clinical trial, the standard approach would be Capecitabine and then surgical follow up.

6.2 Palliative Chemotherapy and Radiotherapy

6.2.1 Cholangiocarcinoma and Gallbladder Adenocarcinoma

Gallbladder carcinoma appears to have a greater response to chemotherapy than cholangiocarcinoma. Phase II studies using gemcitabine, cisplatin, capecitabine and other agents (singly or combinations of) have shown response rates in the range of 20 – 50%. These trials will undoubtedly have a selection bias in terms of fitter, less advanced patients. A recent meta-analysis of trials of chemotherapy in biliary tract cancers (Br J Cancer. 2007 Mar 26; 96(6):896-902) suggests that gallbladder cancers respond better to chemotherapy than cholangiocarcinomas although (most likely due to the natural history of the disease) have a shorter overall survival. In addition it suggests that chemotherapy regimens with gemcitabine and platinum give better tumour control and response rates.

The results of the NCRN ABC01 study (a randomised phase II) comparing gemcitabine and gemcitabine+ cisplatin showed that there was a greater tumour control rate (58 vs 76%) and time to progression (5.5 vs 8 months) for the combination chemotherapy. The ABC-02 study comparing the same regimens in a phase III study with overall survival as the primary endpoint has just closed.

Radiotherapy for Cholangiocarcinoma

This indication is not covered under Commissioning through Evaluation and therefore SABR is currently not available for patients within the NHS outside a clinical trial.

The ABC07 trial is open to recruitment in Leeds - for patients with medically or technically inoperable intra and extra hepatic cholangiocarcinoma. This trial is randomizing patients with stable or responding disease after initial chemotherapy to standard

chemotherapy x 8cycles in total, or to 6 cycles chemo in total and then SABR (1:2 randomisation).

Inclusion criteria:

- histologically confirmed
- max tumour diameter 12cm
- adequate biliary drainage, adequate baseline bloodwork
- PS 0-1
- no metastatic disease, no tumour extension into GI luminal tissues
- no previous abdominal radiotherapy or SIRT

Palliative radiotherapy:

For patients with bulky liver mets, and significant tumour related pain, a single fraction of palliative radiotherapy to the liver can be considered for pain relief. Palliative radiotherapy can also be considered for other areas of symptomatic metastatic disease, e.g. painful bone metastases.

Recommendations:

Patients with inoperable locally advanced or disseminated gallbladder carcinoma or cholangiocarcinoma should be considered for inclusion in national or local tumour specific clinical trials if available. These include trials of chemotherapy, photodynamic therapy etc.

In the absence of tumour specific clinical trials patients with gallbladder adenocarcinoma or cholangiocarcinoma who are fit enough to consider palliative chemotherapy (e.g. (a) sufficient physiological condition – ECOG PS 0 – 2, (b) sufficient bone marrow, renal and hepatic function e.g. neutrophil count > 1.0; platelets > 100; GFR > 50ml/min; bilirubin < 2 x ULN, (c) no evidence of rapid deterioration in clinical condition i.e. life expectancy > 12 weeks) may be considered for chemotherapy off study.

Although no standard regimen exists, the use of combination gemcitabine / cisplatin or single agent gemcitabine should be discussed with patients.

7 Palliative & End of Life Care

7.1 Definitions

This section has been updated in May 2017

Palliative care is part of supportive care. It embraces many elements of supportive care.

Palliative & End of life care is care that helps all those with advanced, progressive, incurable illness to live as well as possible until they die. It enables the supportive and palliative care needs of both patient and family to be identified and met throughout the last year(s) of life and into bereavement. It includes management of pain and other symptoms and provision of psychological, social, spiritual and practical support.

The Department of Health (2008) definition of end of life care states that it includes:

- Adults with advanced, progressive, incurable illness (e.g. advanced cancer, heart failure, COPD, stroke, chronic neurological conditions, dementia);
- Care given in all settings (e.g. home, acute hospital, ambulance, residential/nursing care home, hospice, community hospital, prison);
- Care given in the last year(s) of life
- Patients, carers and family members (including bereavement care).

End of Life Strategy, Department of Health 2008
National Council for Palliative Care Services 2006

7.2 Who Provides Palliative / End of Life Care?

Palliative / end of life care is provided by two distinct categories of health and social care professionals:

- All health care and social care professionals providing the day-to-day care to patients and carers in any care setting
- Those who specialize in palliative care (consultants in palliative medicine and clinical nurse specialists in palliative care, for example) who care for palliative care patients who have complex needs

Those providing day-to-day care should be able to:

- Assess the care needs of each patient and their families across the domains of physical, psychological, social spiritual and information needs
- Meet those needs within the limits of their knowledge, skills, competence in palliative care
- Know when to seek advice from or refer to specialist palliative care services

Training and education in the skills required for palliative / end of life care should be available to and undertaken by all health and social care professionals.

The national strategy *Ambitions for Palliative and End of Life Care 2015-2020* sets out the vision to improve end of life care through partnership and collaborative action between organisations at local level throughout England.

More information can be found at: <http://endoflifecareambitions.org.uk/>

For more information about local improvements, frameworks, tools to support best practice please contact your local End of Life Care Lead or Specialist Palliative Care Team.

One aspect of care is to discuss with individuals, if they wish, their preferences regarding the type of care they would wish to receive and where they wish to be cared for in case they lose capacity or are unable to express a preference in the future. This is the process of Advance Care Planning (ACP).

An ACP discussion might include:

- the individual's concerns and wishes,
- their important values or personal goals for care,
- their understanding about their illness and prognosis,
- their preferences and wishes for types of care or treatment that may be beneficial in the future and the availability of these.

Such discussions can also inform shared decision-making regarding treatments with palliative intent. Local arrangements for recording this information for each individual patient will differ. Many services are developing/have developed Electronic Palliative Care Co-ordination Systems (EPaCCS) where by this information can be shared across professionals and settings (e.g. on SystmOne). Contact your local specialist palliative care team for more information.

7.3 Specialist Palliative Care

Is provided by specialist multidisciplinary palliative care teams in services or units whose core specialty is palliative care (for example hospices, community or hospital palliative care teams). The specialist teams should include palliative medicine consultants and palliative care nurse specialists together with a range of expertise provided by physiotherapists, occupational therapists, dieticians, pharmacists, social workers and those able to give spiritual and psychological support.

Eligibility for referral to specialist palliative care services is based on patient need not diagnosis. The agreed criteria for referral are as follows:

1. The patient has active, progressive and usually advanced disease for which the prognosis is limited (although it may be several years) and the focus of care is quality of life.
2. The patient has unresolved complex needs that cannot be met by the caring team, for example:
 - Uncontrolled or complicated symptoms (e.g. symptoms not adequately controlled within 48 hours by the referring team, or sooner if causing overwhelming distress).
 - Complex psychological/emotional difficulties.
 - Complex social or family issues.
 - Difficult decision making about appropriate future care.

Patients fulfilling these criteria should be referred to and assessed by a member of the specialist palliative care team.

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The subsequent care package will be dependent on this assessment and should be made in agreement with the patient, carer(s) and referring team. It is not appropriate for specialist palliative care services to be committed to patients by professionals outside these services. Equally, specialist services should ensure that the assessment process is accessible and responsive to patients in need.

The level of specialist palliative care support required may fluctuate. Shared care of patients between the specialist palliative care professionals and the referring team (for hospital patients) or the primary care team (for patients at home / care home) is usually appropriate. Timely and effective communication is essential in these situations. For these patients advice from specialist palliative care services on a 24 hour basis should be available in all care settings.

Sometimes the specialist palliative care consultant and team may take the lead role in patient care, usually in a specialist in-patient unit (hospice) or designated specialist palliative care beds.

Referral systems for specialist palliative care services vary in different areas. They should be clear to all local referring consultants and primary care teams.

7.4 Further Links and Information

Contact the local Specialist Palliative Care Team for further information

7.5 Directory of West Yorkshire & Harrogate Cancer Alliance Specialist Palliative Care Services

The Directory has been checked and updated in May 2017

Bradford, Airedale, Wharfedale and Craven
 Bradford Teaching Hospitals NHS Foundation Trust
 Airedale NHS Foundation Trust
 NHS Bradford, Airedale, Wharfedale and Craven
 Website: www.palliativecare.bradford.nhs.uk

Airedale General Hospital Palliative Care Team	Tel	01535 292184 01535 295016
	Fax	01535 295036
Sue Ryder Care – Manorlands Hospice (Oxenhope)	Tel	01535 642308
	Fax	01535 642902
Bradford Teaching Hospitals Palliative Care Team	Tel	01274 364035
	Fax	01274 366851
Bradford Community Palliative Care Team	Tel	01274 323511

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	Fax	01274 215660
Marie Cure Hospice (Bradford)	Tel	01274 337000
	Fax	01274 337095
Out of Hours Advice via on-call Palliative Medicine Consultant via Marie Curie Hospice / Manorlands Hospice	Tel	01274 337000
	Tel	01535 642308

Calderdale and Huddersfield

Calderdale & Huddersfield NHS Foundation Trust

NHS Calderdale

NHS Kirklees

Web: <http://www.cht.nhs.uk/services/clinical-services/palliative-and-end-of-life-care/specialist-palliative-care/>

Calderdale Royal Hospital & Huddersfield Royal Infirmary Palliative Care Team	Tel	01484 342965
	Fax	none
Calderdale Community Palliative Care Team Left message to confirm fax	Tel	01422 310874
	Fax	01422 378425
Overgate Hospice	Tel	01422 379151
	Fax	01422 384210
Kirkwood Hospice and Community Palliative Care Team	Tel	01484 557906
	Fax	01484 557918
Out of Hours Advice via Hospices	Tel	01422 379151 01484 557900

Harrogate and District

Harrogate NHS Foundation Trust

NHS North Yorkshire and York

Website: [https:// https://www.hdft.nhs.uk/services/palliative-care/](https://www.hdft.nhs.uk/services/palliative-care/)

Harrogate Hospital and Community Palliative Care Team	Tel	01423 553464
	Fax	01423 555763
St Michael's Hospice	Tel	01423 872658
	Fax	01423 815454
Out of Hours Advice via Hospice	Tel	01423 879687

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Leeds**Leeds Palliative Care**Website: www.leedspalliativecare.co.uk

Leeds Teaching Hospitals NHS Trust Specialist Palliative Care Team	Tel	0113 2064563
	Fax	0113 2064863
Sue Ryder Care - Wheatfields Hospice and Community Palliative Care Team (West Leeds)	Tel	0113 2787249
	Fax	0113 2302778
St Gemma's Hospice and Community Palliative Care Team (East Leeds)	Tel	0113 2185500
	Fax	0113 2185524
Out of Hours Advice via SJUH Switchboard	Tel	0113 2433144

Mid Yorkshire

Mid Yorkshire Hospitals NHS Trust

NHS Wakefield District

Kirklees PCT

Website: <https://www.midyorks.nhs.uk/palliative-care1>

Dewsbury Hospital and Community Palliative Care Team	Tel	01924 816052
	Fax	01924 543883
Dewsbury Day Support and Drop-in (Rosewood Centre)	Tel	01924 512039
Mid Yorkshire Hospitals NHS Trust Palliative Care Team	Tel	01924 543801
	Fax	01924 543883
Pontefract Community Palliative Care Team (Prince of Wales Hospice)	Tel	01977 781456
	Fax	01977 796209
Prince of Wales Hospice (Pontefract)	Tel	01977 708 868
	Fax	01977 600097
Wakefield Hospice	Tel	01924 331400
	Fax	01924 362769
Out of Hours Advice via Pinderfields Hospital Switchboard	Tel	01924 541000

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York

York Hospitals NHS Foundation Trust
NHS North Yorkshire and York

https://www.yorkhospitals.nhs.uk/our_services/az_of_services/palliative_care/

York Hospital Palliative Care Team both correct	Tel	01904 725835
	Fax	01904 726440
Community Palliative Care Team	Tel	01904 724476
	Fax	01904 777049
St Leonard's Hospice	Tel	01904 708553
	Fax	01904 704337
Out of Hours Advice via Hospice	Tel	01904 708553

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