



**West Yorkshire & Harrogate
Cancer Alliance**

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

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ii Information Reader Box

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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 liver 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 Hepatocellular Carcinoma

HCC remains one of the commonest malignant diseases in the world but it has not previously been a leading cause of death in the Western world. HCC causes approximately 1500 deaths per year in the United Kingdom. However, there is now conclusive evidence from the USA and a strong suggestion from the UK that HCC is becoming a more common cancer, primarily due to the hepatitis C (HCV) epidemic. HCC is unusual among human cancers in that the aetiological agent responsible is usually readily identifiable. The prevalence of HCC worldwide parallels that of viral hepatitis and the majority of cases are associated with hepatitis B and C. Alcohol, genetic haemochromatosis and rarely primary biliary cirrhosis (PBC) are associated. The high rates of migration to the UK from areas with high levels of hepatitis B and C are likely to lead to an increase in incidence of HCC.

Some of these patients will benefit from radical treatment (usually surgery but more recently also ablation), which may offer the hope of cure; 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.

1.4 Cholangiocarcinoma

Cholangiocarcinoma, a primary tumour of the biliary epithelium, accounts for 3% of all gastrointestinal malignancies, but its incidence is increasing. 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 may 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, radiotherapy and photodynamic therapy are sometimes useful as adjuncts to surgical resection or as palliative therapy.

Distal cholangiocarcinoma, affecting the lower common bile duct within the head, if 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. This is dealt with in the document on Biliary Cancer.

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.

1.5 Metastatic liver cancer

Although the most common indication for hepatic resection in the UK is liver metastases from colorectal cancer, and there are increasing numbers of patients undergoing surgery for liver metastases from other cancers (including breast, renal, neuroendocrine, GIST, malignant melanoma and renal carcinomas), the role of liver resection is considered in guidelines relevant to the primary tumours. It is, however, appropriate to include a brief review here for ease of referral.

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.

1.6 Colorectal Liver Metastases

Referral

Patients fit for surgery with stage IV colorectal 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

Cases that should be referred include:

- Patient with liver only / liver with limited extra-hepatic disease
- Patients presenting *de novo* in stage 4
- Patients with potentially resectable liver and lung metastases

The referral should include histology of the primary if available and historic cross sectional imaging of liver and lungs. This will help diagnose potential metastases. Usually CT is adequate and the Liver MDT will advise or arrange MRI of the liver, ideally before commencement of chemotherapy. It is the responsibility of the referring centre to ensure that access of imaging and pathology specimens is straightforward. It is not usually necessary to perform a liver tumour biopsy – this is only needed in rare cases.

New treatment strategies

There is an increasing role for pre-operative portal vein embolization and multi-stage surgical strategies (two stage liver surgery and ALPPS – **A**ssociated **L**iver **P**artition and **P**ortal vein ligation for **S**taged hepatectomy) and also consideration for a liver first approach (liver surgery before primary colorectal surgery) in cases where decisions about liver surgery are borderline.

Communication

The Leeds MDT communicates decisions through real-time electronic recording of the MDT meetings and issuing of minutes.

The Liver MDT 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.

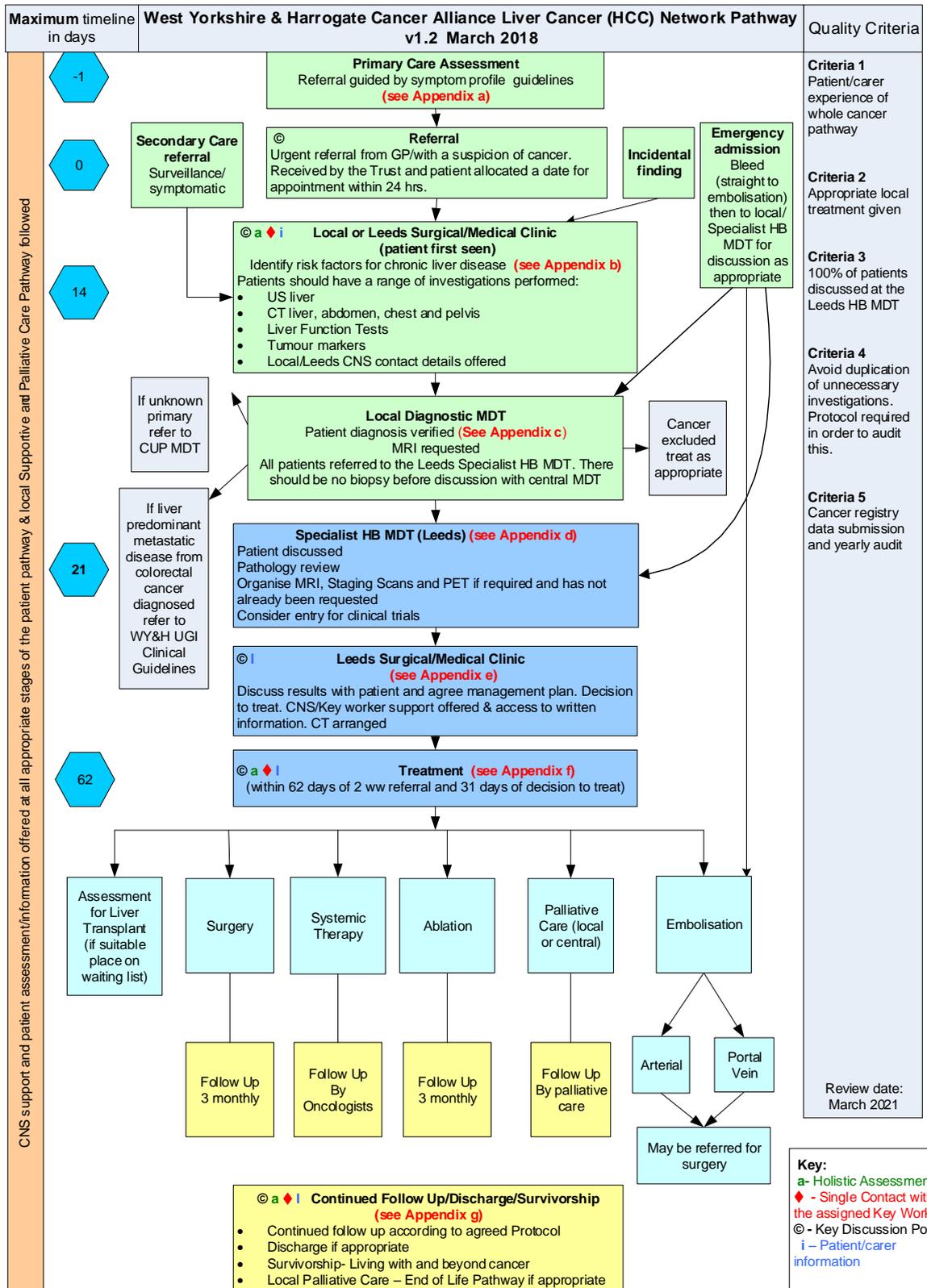
Follow-Up

Increasingly, patients are undergoing chemotherapy before liver resection for metastases. Ideally, this is a decision that should be made by discussion with the Leeds Liver MDT. Good quality baseline scans before commencement of chemotherapy can be crucial to subsequent decisions regarding liver resection surgery. Patients who have chemotherapy first before liver surgery need to be referred back to the liver MDT so that operability can be assessed.

Following liver resection all patients need to be followed up as per the Leeds protocols, which undergo regular review. The regular follow up CT scan and blood tests can be performed at the local hospital or in Leeds depending on patient choice. Most patients will then be seen in clinic in Leeds to discuss their results, particularly if there are concerns about recurrent disease. Share care protocols are currently under review.

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

1.7 Clinical Pathway for Liver Cancer



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Appendix

West Yorkshire & Harrogate Cancer Alliance Liver Cancer Pathway Pathway Details/Supporting Information

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|---------------------------|---|
| Title | Liver Cancer (Hepatocellular Carcinoma) Pathway |
| Author & Owner | West Yorkshire & Harrogate Cancer Alliance |

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| Version 1.0 | April 2012 | Original published |
| Version 1.1 | April 2014 | Include reference to CUP MDT, patient rehabilitation plus liver predominant metastatic disease from colorectal cancer |
| Version 2.2 | March 2018 | Updated to reflect the new ownership of the WY&H Cancer Alliance |

a) Pre-referral

The majority of Liver (Hepatocellular carcinoma -HCC) cancers present via the following clinical routes:-

The vast majority of patients with Liver (Hepatocellular carcinoma – HCC) cancers will come from secondary care ‘screening’ or ‘follow up’ or:

- 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/surveillance

Three potential symptoms are:

- Progressive liver function deterioration
- Progressive unintentional weight loss
- Epigastric mass

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.

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- 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, USS result or date of scan

b) First seen at local/Leeds surgical medical clinic

Identify risk factors for chronic liver disease e.g.

- Alcohol history
 - Hepatitis status
 - Haemochromatosis history
- 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 Liver 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) Local Diagnostic MDT discussion

The membership of each diagnostic / local care team for Liver 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

The role of each diagnostic / local care team for Liver Cancer is to provide a rapid diagnostic service for patients with possible, or suspected liver cancer; action rapid and

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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 liver cancer for review at the Centre SMDT (Leeds HPB SMDT/ West Yorkshire SMDT) meeting in line with the Hepatocellular Carcinoma Cancer Pathway

Any patient with unknown primary will be referred to the appropriate Cancer of Unknown Primary (CUP) MDT.

If liver predominant metastatic disease from colorectal cancer diagnosed refer to the Cancer Alliance Liver and Colorectal Cancer Clinical Guidelines.

d) The role and function of the Centre MDT meeting

The Specialist Hepatobiliary Team is a multidisciplinary group, which provides a service for a 4-5 million population both within and outside the 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

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;

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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

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- When MRI is required for further staging this will be reported and reviewed at the Centre SMDT by the respective specialist radiology/*gastroenterology* services in Leeds.
- 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

e) Decision to Treat/Best Supportive Care/Rehabilitation

- Patient seen to discuss their treatment options supported by the HPB / oncology 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 WYH& and HC&V 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.

f) First definitive treatment

- Commencement of systemic therapy
- Surgery
- Ablation (Radiofrequency ablation or Microwave ablation or IRE)
- Embolisation (either TACE or PVE)
- Radiotherapy (SABR/SBRT)
- Assessment for Liver Transplant
- Decision at MDT for best supportive care

g) Follow-up – discharge

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

- 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.

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1.8 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.

2 Management of Liver Metastases

The management of liver metastases from colorectal cancer continues to develop, with improving peri-operative outcomes associated with better patient preparation and safer surgery. New approaches continue to develop, including selective use of neoadjuvant and adjuvant chemotherapies. There is an increasing role for pre-operative portal vein embolization and multi-stage surgical strategies (two stage liver surgery and ALPPS – **A**ssociated **L**iver **P**artition and **P**ortal vein ligation for **S**taged hepatectomy) and also consideration for a liver first approach (liver surgery before primary colorectal surgery) in cases where decisions about liver surgery are borderline. Classical guidelines for inoperability are no longer useful. Resection margin data suggests that 1mm clearance is adequate. Re-resection is also of benefit. Having said that, many patients continue to present with inoperable disease. Although neoadjuvant chemotherapy may enable resection in some cases this is by no means a general rule. Patient co-morbidities and extra-hepatic disease may also prevent resection of liver metastases.

Staging by CT chest, abdomen and pelvis along with liver MRI is the most usual method of staging. There is an increasing role for PET-CT but this is not yet widespread. Biopsy is not usually recommended before surgery.

Liver surgery may be carried out laparoscopically in an increasing number of cases and the role of robotic surgery is being evaluated. The advantage of these methods is shorter recovery times and there does not appear to be an oncologic disadvantage.

Current data suggests that 5 year survival is on the range of 40 to 60%, with up to 30% of patients surviving 10 years following liver resection, although it is increasingly recognised that many are living with recurrent disease. Approximately 20-25% of patients should be disease free and therefore most likely cured by 10 years.

Follow up is important as re-resection is often possible if liver only recurrence develops and lung metastasectomy has also been shown to be worthwhile. For patients developing widespread recurrence, there is often a role for palliative chemotherapy. Decisions are most usually made in conjunction with the local colorectal MDT.

3 Surgery and Other Curative Options for Hepatocellular Carcinoma

3.1 Surgery – Hepatic resection and liver transplantation

The only treatments that are capable of providing cure for HCC are hepatic resection, ablation and liver transplantation. Ablation is currently only applicable to very small tumours (less than 2 cm diameter) and it is used infrequently but technologies continue to improve. Despite the lack of high grade evidence from randomised trials for either resection or transplantation, the results of these treatments provide 5-year survival rates of up to 70% in selected patients.

Advances in diagnostic, anaesthetic, and surgical techniques have led to significant reductions in perioperative morbidity and mortality such that resection is now an important arm in the multidisciplinary approach to HCC.

3.2 (i) Selecting patients for resection

Resection is the only curative treatment option for patients with HCC developing in a liver without background liver disease and for patients with fibrolamellar variant of HCC. In patients with fibrosis or cirrhosis, resection should be considered for patients with good synthetic liver function. Irrespective of the presence or absence of cirrhosis, the median perioperative mortality rate for papers quoting either 30-day or in-hospital mortality has been a median of 4.7% with a range from 0 to 21.1%, with lower rates seen in series with larger volumes irrespective of underlying liver disease. Hepatic resection is indicated when all the tumour nodules can be resected with negative margins leaving behind a functioning liver parenchyma of at least 25-50% depending on the quality of remnant parenchyma. Absolute contraindications for resection include extra hepatic disease, tumour thrombus extending into inferior vena cava or main portal vein to the level of the superior mesenteric vein, and poor functional status of remnant liver parenchyma.

Preoperative assessment

Preoperative assessment includes assessment of the extent of tumour, functional status of the liver, volumetry of the remnant liver, degree of portal hypertension and architecture of the remnant liver parenchyma.

Tumour Assessment:

There are no absolute contraindications for resection based on size, multicentricity, presence of satellite nodules, local vascular invasion, history of previous rupture and bleeding and the levels of alpha-fetoprotein.

Functional Status of the liver:

Evaluation of the liver function is more important in patients with underlying chronic liver disease. In patients with fibrosis and/or cirrhosis, the Child-Pugh (also known as Child-Turcotte-Pugh) score is a reliable semi-quantitative means of classifying patients into risk based on presence or absence of ascites and encephalopathy, and measurement of albumin, bilirubin and prothrombin time. Resection of any extent is contraindicated in patients with a Child-Pugh C score, and selected patients with a Child-Pugh B score are suitable candidates for minor segmental or nonsegmental resections. Patients with a Child-Pugh A

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score can usually undergo liver resection with acceptable morbidity and mortality rates. Further stratification of Child-Pugh A score patients based on degree of portal hypertension will enable selection for major resections in this group. The Model for End stage Liver Disease (MELD) score has recently been shown to predict the development of postoperative liver failure after hepatectomy for patients with cirrhosis undergoing resection of HCC, with a preoperative score of ≥ 11 being associated with a poor outcome. This needs further validation and comparisons with Child-Pugh score in prospective studies.

Various quantitative tests based on hepatic clearance of a substrate injected have been used for a more accurate functional assessment of the liver. Indocyanine Green (ICG) is the most popular and is a standard test in the algorithm for functional assessment in majority of far eastern centres. ICG retention at 15 minutes (ICG R) is the most widely used parameter and the normal value is $<10\%$. Major resection is contraindicated even in patients with Child-Pugh A status if ICG R is $>20\%$.

Volumetry of the remnant liver:

Patients with normal underlying parenchyma will tolerate liver resections with remnant volumes of about 25% with acceptable morbidity and mortality rates. However patients with abnormal liver parenchyma in form of fibrosis or cirrhosis would tolerate only limited resections. It has been proposed by several groups that the safe limit for future liver remnant in this group of patients with Child-Pugh A score would be about 40%. This limit has been extended to 50% if the ICG R is abnormal (10-20%) or in presence of portal hypertension.

Patients needing major resections in form of right hepatectomy or more will often benefit from preoperative portal vein embolisation (PVE) to increase the remnant liver parenchyma. Absence of liver regeneration after PVE would be a relative contraindication to proceed to liver resection. Combining transcatheter arterial chemoembolisation (TACE) with PVE has shown to be advantageous in form more complete tumour necrosis, more regeneration and higher 5 year survival by some groups. The future liver remnant (FLR) may be measured by three dimensional computed tomography volumetry or using a mathematical formula relating liver volume to body surface area.

Degree of portal hypertension:

Assessment of the degree of portal hypertension has acquired significance since Bruix and colleagues demonstrated the importance of hepatic venous pressure gradient (HVPG) in predicting post hepatectomy decompensation. HVPG of >10 mm Hg has also been shown to be an adverse prognostic factor for long-term survival. Non-invasive assessment of portal hypertension is more commonly used. Various parameters assessed include splenomegaly, hypersplenism especially thrombocytopenia, and presence of varices on endoscopy or cross sectional imaging. In general, platelet counts of less than $100 \times 10^9 /L$ should be considered a contraindication for major hepatectomy.

Architecture of remnant liver parenchyma:

Preoperative biopsy of remnant liver parenchyma has been advocated by some groups in the preoperative assessment. However there was no correlation demonstrated between the degree of architecture disruption and the rate of liver regeneration or postoperative complications. In addition, the invasive nature of this investigation makes it difficult to justify its routine usage in patients known to have cirrhosis or fibrosis. Presence of inflammatory infiltrates has been shown to predict poor outcome following liver resection. However marked serum transaminitis is a reliable predictor of hepatitis on histology and by itself can be used as a predictor for post hepatectomy complications. Recently, the use of a fibroscan has become more routine.

3.3 (ii) Selecting patients for liver transplantation

Early results for liver transplantation for HCC were poor, with 5 year survival figures well below 50%, mainly due to tumour recurrence. It is now clear that this was the result of poor selection of patients for transplantation. It is well established that patients with single lesions of 5cm diameter or up to five lesions of less than 3cm in the absence of vascular invasion as defined by imaging, have an almost zero recurrence rate for the HCC and the prognosis after transplantation is the same as for a similar underlying liver disease without HCC.

The criteria for selection to the transplant list for cases with HCC has recently been revised and current UK guidelines from May 2008 advise the following:

1. Radiological assessment should include both multidetector (MD) CT and MRI with size being assessed by the widest dimensions on either scan.
2. A lesion (for the purposes of counting numbers) will require to be identified as an arterialised focal abnormality with portal phase washout on MDCT or Gd enhanced MR. Other lesions are considered indeterminate.
3. Tumour rupture and an AFP > 10,000 iu/l are absolute contraindications to transplantation, as are extrahepatic spread and macroscopic vascular invasion.
4. The following are criteria for listing for transplantation;
 - a single lesion < 5 cms diameter or
 - up to 5 lesions all < 3 cms
 - single lesion > 5 cms < 7 cms diameter where there has been no evidence of tumour progression (volume increase by <20%; no extrahepatic spread; no new nodule formation) over a 6 month period. Locoregional +/- chemotherapy may be given during that time. Their waiting list place may be considered from the time of their first staging scan.
5. Locoregional therapy should be considered for all transplant list cases.
6. Cases outwith current proposed selection criteria will not be selectable on to the transplant list after their tumour has been downsized by surgical or loco-regional treatments.

3.4 Ablative therapy

A number of non-surgical therapies are in clinical use for HCC, percutaneous ablative therapies are well described initially using ethanol injection. Radiofrequency ablation (RFA) is a newer technique, where high frequency ultrasound probes are placed into a liver mass, usually under ultrasound control. Series show that tumour necrosis can be produced and that morbidity and mortality are low for both techniques.

(i) Percutaneous ethanol injection (PEI)

Although percutaneous ethanol injection has not been subjected to randomised controlled trials there is a considerable literature on its use in HCC. In large series, complete response rates of 75% in tumours less than 3cm in diameter have been reported, with 5 year survival rates of between 35% and 75%. Treatment of larger and multiple lesions is possible, often requiring repeated sessions and a general anaesthetic, but recurrence occurs in more than 50% at one year and only 10% of 3 to 4cm lesions were completely ablated. Treatment is technically very difficult in lesions affecting the posterior segments of the liver. Complications are uncommon, but seeding in the needle tract occurs in 3% and serious bile duct injury in 1%.

(ii) Radiofrequency ablation (RFA)

Radiofrequency ablation of HCC uses a high frequency ultrasound probe placed into the tumour mass, usually percutaneously. High frequency ultrasound generates heat at the probe tip which can destroy tissue. A single probe can destroy lesions of up to 3cm and a multiple tipped probe has been used to target lesions up to 6cm in diameter. In a single series of 149 tumour nodules treated either percutaneously or at open operation, with an average tumour diameter of 3.5 cm, the local recurrence rate at 19 months was 3.6% with all nodules showing initial complete ablation. Distant metastases or a second tumour developed in 46%. Larger tumours can be treated by radiofrequency ablation, the largest series is 126 HCC greater than 3cm in diameter. Complete necrosis was produced in 47% (132) but there is a significantly higher local recurrence or incomplete ablation rate in lesions larger than 3cm treated by RFA.

A comparison of 112 patients treated by PEI or RFA showed that 47 out of 52 treated by RFA had complete tumour necrosis with a median of 1.2 treatment sessions versus 48 out of 60 having complete ablation by alcohol injection with 4.8 sessions required. The authors suggested that radiofrequency ablation was more effective but also had a higher complication rate. Three small-scale randomised clinical studies comparing RFA with PEI in patients with early stage HCC each suggest that radiofrequency ablation yields better clinical outcomes and it is now widely accepted as primary ablative therapy. RFA can probably be regarded as curative therapy for small (<2cm) lesions but lesions above 2cm have a significant local recurrence rate.

(iii) Microwave ablation (MWA)

Microwave ablation is now generally recognised to be improved technology, particularly for tumours >2cm and it is associated with lower local recurrence rates than RFA, so MWA is increasingly being used today.

(iv) Irreversible electroporation (IRE)

Irreversible electroporation (IRE, or NTIRE for non-thermal irreversible electroporation) is a soft tissue ablation technique using ultra short but strong electrical fields to create permanent and hence lethal nanopores in the cell membrane, to disrupt the cellular homeostasis. IRE is a relatively new technology and results are not widely published. It is applicable for small tumours close to vital vascular and biliary structures

Embolisation/chemoembolization

Chemoembolisation has been widely used as primary therapy for inoperable HCC. The literature is difficult to interpret and to compare as the techniques used differ substantially and the patient groups treated are frequently those with very advanced disease where the risk of therapy as well as potential benefits may be greatest.

Initial interest in radiological techniques producing tumour devascularisation developed in the 1970s. There is good evidence that it is effective at reducing tumour size and treating pain or bleeding from HCC. In all of the six initial randomised controlled trials of chemoembolisation as primary treatment for HCC none show any increase in survival, although tumour shrinkage was seen. These trials all included patients with predominantly large tumours and severe underlying liver disease, which may have masked any beneficial effect. There is evidence from non-controlled series that small HCC are more likely to respond to chemoembolisation. This has been confirmed in a trial of repeated chemoembolisation using lipiodol and doxorubicin versus arterial embolization without chemotherapy in patients with small tumours and good liver function. In the 38 patients treated with chemoembolisation

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survival was 63% at 2 years versus 50% (n=34) in the embolisation group and 27% (n=35) in the untreated arm. This study establishes the role of chemoembolisation in the treatment of HCC but it will only be applicable to a relatively small group of patients: 903 patients were screened for the trial to enrol 112. This has been confirmed in a further randomised trial which included patients with more advanced HCC. Side effects of chemoembolisation are those of the chemotherapeutic agent used (usually Doxorubicin) in addition to the complications of the arterial embolisation, pain, fever, hepatic decompensation and rarely infarction of organs other than the liver. Serious complications occur in 3-5% of treated patients. A small number of studies have combined ethanol injection with chemoembolisation and a single large randomised trial has now confirmed that tumours of 3-5cm have better survival given combined chemoembolisation and RFA than either therapy alone. It has been suggested that this combination therapy for this selected group of patients should be the standard of care.

Chemoembolisation should always be performed at specialist centres performing sufficient numbers of these procedures to demonstrate competence. Chemoembolisation should be performed with antibiotic prophylaxis and under conditions of adequate hydration. The efficacy of drug-eluting beads is still under investigation and until further data are available, these agents should only be used at specialist research centres.

SABR (SBRT)

Indications for liver SABR:

As part of NHS England's Commissioning through Evaluation process, SABR can be considered for patients with oligometastatic liver disease or primary hepatocellular carcinoma who fulfil the criteria below.

Oligometastatic disease (liver alone or liver plus other sites)

- histologically proven primary
- up to 3 lesions (but max 3 disease sites, e.g. 2 liver and 1 lung met) – ALL areas of disease needed to be treated with a form of ablative therapy
- liver met(s) max 5cm diameter
- CPA liver function, adequate baseline bloodwork
- Discussion at Liver MDT
- unsuitable for surgery, or patient declines surgical resection
- Synchronous mets from CRC allowed, for other primaries: 6 months disease free interval
- PS ≤2
- no active hepatitis or prior abdominal radiotherapy

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).

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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 HCC or liver metastases, 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.

3.5 Systemic therapy for HCC

Based on two prospective randomised trials, one undertaken in Europe and one in Asia, sorafenib, an oral multikinase inhibitor has now become the standard of care for patients with advanced HCC for whom no potential curative option is available. To date, benefit has only been convincingly shown in patients with good liver function (Child-Pugh grade A) and good performance status, where the improvement in median survival is between two and three months, representing a hazard ratio of between 0.6 and 0.7. Treatment with sorafenib is usually continued until there is radiological or symptomatic evidence of disease progression. Treatment is usually well-tolerated, the most common side-effects being the hand foot skin reaction and diarrhoea which occur in about 10% of cases.

Cytotoxic chemotherapy has response rates of around 10-15% (for example, doxorubicin or the combination of doxorubicin and cisplatin) and these agents can be used in HCC in situations where tumour progression has been seen with sorafenib, recognising that treatment should not be pursued unless there is clear evidence of response in terms of serological changes (AFP falls), tumour size reduction (on radiological grounds) or symptomatic improvement. There is a need for trials of combinations of sorafenib and conventional chemotherapy.

4 Non-Surgical Oncology

4.1 Adjuvant Chemotherapy

There is no current evidence that adjuvant chemotherapy has a role for hepatocellular carcinoma.

Adjuvant chemotherapy with Capecitabine has been recommended for patients undergoing surgery for cholangiocarcinoma, based on the outcome of the BILCAP trial. There is also emerging evidence that neoadjuvant therapy may be of benefit, particularly a combination of Gemcitabine and Cis-platin for borderline operable/inoperable intrahepatic cholangiocarcinoma, but this needs further study.

The role of adjuvant chemotherapy following resection of colorectal liver metastases is well established in patients who are “chemo-naïve” but less so for patients who have undergone chemotherapy in the past. Decisions are usually made in conjunction with the local colorectal MDTs.

4.2 Palliative Chemotherapy

4.2.1 Hepatocellular Carcinoma

Patients with advanced hepatocellular carcinoma who are not candidates for treatment with liver directed therapies (e.g. chemoembolisation, RFA, resection etc.) may be considered for palliative systemic chemotherapy. Until recently there has been no good randomised data that establishes the benefit of systemic chemotherapy over best supportive care in this group of patients. Response rates to single agent therapy have in general tended to be below 20%.

The recently published results of the SHARP study showed that treatment with Sorafenib (in patients with HCC and no worse than Child-Pugh A liver impairment) brought about a median improvement in survival of 3 months over patients receiving placebo (N Engl J Med. 2008 Jul 24; 359(4):378-90). There was a similar improvement in time to progression although objective responses were not different. Sorafenib has been licensed for use in HCC although not NICE reviewed as yet.

The use of Tamoxifen has been shown in two large randomised trials and a Cochrane review to be no better than placebo. The use of Octreotide has not been shown to be better than placebo.

Recommendations:

Patients with advanced hepatocellular carcinoma who are fit enough to consider systemic chemotherapy (physiological parameters as follows; – ECOG PS 0 – 2; sufficient bone marrow, renal and hepatic function e.g. neutrophil count > 1.0; platelets > 100; GFR > 50ml/min; bilirubin < 1.5 x ULN) and who are keen to consider palliative chemotherapy should if possible be encouraged to participate in local or national clinical trials. This includes consideration of early phase clinical trials through the Early Trials Clinic at St James’s Hospital.

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5 Palliative & End of Life Care

5.1 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

5.2 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.

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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.

5.3 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.

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

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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.

5.4 Further Links and Information

Contact the local Specialist Palliative Care Team for further information

5.5 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 |
| | Fax | 01274 215660 |
| Marie Cure Hospice (Bradford) | Tel | 01274 337000 |

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| | | |
|---|-----|--------------|
| | 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://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

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|--|-----|--------------|
| 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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