# NHS Wales Cancer Network

# Service Specification

## Specification for Hepato-Pancreato-Biliary surgery services for people resident in Wales

*May 2021*

*Version 1.0*

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This document underwent the following approvals.

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# Contents

## Statement

This document has been developed to inform the commissioning of Hepato-Pancreato-Biliary (HPB) surgery services.

In creating this document, the Wales Cancer Network has reviewed the requirements and standards of care that are expected to deliver this service.

## Disclaimer

Health Boards assume that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

The Wales Cancer Network disclaims any responsibility for damages arising out of the use or non-use of this document.

# 1. Introduction

This document has been developed as the recommended service specification to inform the delivery and commissioning of Hepato-Pancreato-Biliary (HPB) surgery services for people resident in Wales.

Whilst the responsibility for commissioning hepatobiliary surgery for cancer (primary and secondary) for south west, mid and south east Wales has been delegated to Welsh Health Specialised Services Committee (WHSSC), the responsibility for commissioning the remaining services has been retained by the Health Boards.

The service specification describes the scope of care provided by the HPB surgery service, which ranges from the surgical management of complex presentations of common diseases of the liver and pancreas, through to specialised management of cancers of the liver and pancreas.

## 1.1 Background

Diseases of the liver and pancreas often present with non-specific symptoms and signs (such as jaundice, pain and weight loss that can be attributed to pathology within either organ, and at other anatomical sites). While many common diseases affecting either organ can be safely managed in all general hospitals, there is an interface in complexity where escalation of treatment to identified tertiary centres offers better outcomes and more cost effective care.[1][2]

Following such a referral, it may be possible to transfer care back to the appropriate general hospital, but it may be necessary to offer all/most ongoing future care at the tertiary centre. Occasionally, where it is clinically appropriate, some aspects of tertiary care can be administered closer to the patient's home by the tertiary centre on an outreach hub and spoke basis, e.g. Chemotherapy.

The liver is a frequent site of primary malignancies or indeed secondary disease from other tumours in the body. The management of pancreatic cancer remains a challenge as a result of late diagnosis, often at an advanced stage. However treatment of cancers in both organs has advanced significantly over the last two decades with significant increases in the numbers of patients being offered potentially curative, but frequently complex, surgical procedures.

[1] The Impact of Increasing Hospital Volume on 90-Day Postoperative Outcomes Following Pancreaticoduodenectomy, 2017, Kagedan et al, Journal of Gastrointestinal Surgery

[2] Centralization of Pancreatic Surgery Improves Results: Review, 2020, Ahola et al, Scandinavian Journal of Surgery

### *Liver tumours*

There are around 300 new cases a year of primary liver cancer in Wales[3] The incidence of liver cancer has increased from 4 per 100,000 in 1993 to 10 per 100,000 in 2017. The increasing burden of metabolic and alcohol related liver disease indicates that the incidence of liver disease will continue to grow. It is more difficult to determine the numbers for metastases. There are around 90-95 resections being undertaken per annum for metastatic colorectal cancers in Wales, 10-15 for primary cancers, and 10-15 for other metastatic cancers. These numbers are likely to increase with better systemic cancer treatments in the coming years. Incidence is projected to rise by 38-40%[4].

There has been a tenfold increase in fatty liver disease over the last 20 years and the rate of increase also continues to rise. This is a significant risk factor for both HCC and Cholangiocarcinoma. These two areas will be the primary areas of focus for other treatments.

### *Primary cancers of the liver and biliary tree (hepatocellular carcinoma, intra hepatic Cholangiocarcinoma, intraductal or hilar cholangiocarcinoma and gallbladder cancers)*

Assessment of patients with suspected primary liver tumours involves a combination of imaging modalities, pathology services and specialised surgical and medical expertise. Complex imaging modalities may be required, e.g. liver magnetic resonance imaging (MRI) with special contrast agents, and careful case selection for these modalities is required to achieve optimal results.

MDT review of clinical cases and all imaging for suspected primary cancers should be undertaken at the HPB centre. Following discussion, some management may then occur locally. There will, however, be patients that need access to clinical and multi-disciplinary review at the HPB centre for a final decision on optimal treatment.

Suspected Cholangiocarcinomas may require specialist endoscopy such as ERCP (with or without direct Cholangioscopy) and/or interventional radiology such as due to their complexity in clinical management and work up for surgery.

### *Secondary liver tumours - colorectal, neuroendocrine and others*

Metastases to the liver from colorectal cancers are the most common tumours in the liver. Imaging, such as computed tomography (CT) and MRI, is performed in most district general hospitals, but decisions on surgery and interventional radiology will be taken by the tertiary centre multidisciplinary teams in line with NICE guidance on colorectal cancer

[3] WCISU Cancer Incidence in Wales Dashboard (accessed August 2020).

[4] Liver cancer statistics, Cancer Research UK, accessed August 2020

(CG131, 2011) and NICE quality standards for colorectal cancer (2012). Chemotherapy can be given locally according to National guidelines.

Neuroendocrine tumours (NET) require specialist imaging, particularly involving nuclear medicine and specialist pathology, which will be provided at the specialist centre through established neuroendocrine cancer pathways.

***Pancreatic tumours***
Pancreatic cancer refers to a malignant epithelial neoplasm of the pancreas. There were 487 new diagnoses of pancreatic cancer in Wales in 2017 (Cancerresearchuk.org) with a crude incidence rate of 15.8 per 100,000 population and similar rates seen in both sexes. Survival is poor with one-year relative survival estimates of around 25 per cent for both sexes. Pancreatic ductal adenocarcinoma is the most common type of pancreatic tumour, accounting for 90% of these malignancies. It arises within the exocrine component of the pancreas and is commonly referred to as "pancreatic cancer". The remaining 10% of malignant pancreatic tumours comprise pancreatic neuroendocrine tumours and cystic carcinomas. Cystic tumours of the pancreas may also be benign or premalignant.

The symptoms that lead to diagnosis of pancreatic tumours depend on the location, the size, and the tissue type of the tumour. They may include abdominal pain and jaundice (if the tumour compresses the bile duct). It is however common for pancreatic tumours to be completely devoid of symptoms in the early stages resulting in their late presentation often at an advanced stage.

***Pancreatic cystic tumours*** may be benign, premalignant or malignant. Fewer than half of these will be malignant and the management of cystic tumours is complex requiring careful assessment.

***Metastatic tumours to the pancreas*** are uncommon and account for a small proportion of all pancreatic malignancies e.g. renal cell carcinoma.

***Duodenal tumours including malignant and premalignant tumours***
These are rare tumours that affect the duodenum periampullary regions or the ampulla of vater.

***Pancreatic neuroendocrine tumours***
There is an increasing number of patients who present with primary pancreatic neuroendocrine tumours who require surgical resection.

***Periampullary tumours*** (of the ampulla, lower common bile duct, or duodenum) often present with similar symptoms and signs to pancreatic ductal adenocarcinoma; without careful histological evaluation the differential diagnosis of tumour type may be impossible. Periampullary

cancers are more often resectable than pancreatic ductal adenocarcinomas, so as many as half of all pancreatic resections are for these periampullary tumours.

With different types of tumours, diagnostic processes and management decisions are often complex. Specialist investigations such as endoscopic ultrasound for accurate staging, and diagnostics such as endoscopic guidance fine needle aspiration may be necessary. A careful multidisciplinary approach is therefore essential.

## 1.2 Aims and objectives

The aim of this service specification is to define the essential requirements and standard of care that tertiary services are required to meet in order to deliver HPB surgery services to people resident in Wales.

The objectives of this service specification are to:

- detail the specifications required to deliver surgical services for patients with HPB disease, resident in Wales, who require the specialised interventions provided by HPB surgery services
- specify the minimum standards of care for the delivery of HPB surgery services
- ensure equitable access to HPB surgery services for Welsh patients irrespective of geographical location.
- identify the minimum requirements that services must meet in order to provide services for Welsh patients
- improve outcomes for people with liver and pancreatic disease

### 1.2.1 The care pathway

There are three defined levels of care to manage HPB cancers:

- The diagnostic process
- Local care
- Specialist care

***The diagnostic process***

Local services should be available to meet the agreed standards adopted by NHS Wales for the Single Cancer Pathway (SCP). Patients should be referred in line with the SCP for primary cancers. There are currently no defined guidelines for the management of secondary cancer.

All patients who are diagnosed with HPB cancer (or suspected or having the disease) should be discussed and if the performance status is poor then the patient can be managed locally. If the performance status would allow all

patients without widespread metastatic disease should be referred to the HPB MDT for further evaluation. ERCP and such drainage procedures should be done after discussion with the tertiary centre, especially in patients with hilar cholangiocarcinoma and operable pancreatic cancers.

### *Local care*

The treatment and procedures classed as local care are:

- Palliative stenting.
- Palliative chemotherapy.
- Palliative and supportive care, not involving active, tumour shrinking or debulking therapy.
- Prehabilitation services should be available locally, although specialist advice and support may be required from the specialist centre.
- Procedures classed as local care may also be delivered under the care of a member(s) of the specialist team.

### *Specialist care*

Specialist care should only be delivered under the care of a member(s) of the specialist team.

The treatments and procedures classed as specialist care are:

- All resectional tumour surgery, whether with curative or palliative intent. In addition to being under the care of specialist team members, this should only be carried out in the host hospital of the specialist team. Following decision by the tertiary MDT a palliative surgical bypass could be performed locally if the necessary surgical skill is available.
- The following treatments, which should be delivered under the care of a member of the specialist team but the site of delivery is subject to agreement in the network's guidelines:
    - Chemo/radiotherapy.
    - Neoadjuvant treatment in selected cases
    - Stereotactic ablative radiotherapy (SABR)
    - Ablation
    - Transarterial chemoembolization (TACE)
    - Selective internal radiation therapy (SIRT)

The most common indication for liver resection is colorectal liver metastases. The population estimate for the need for liver resection in patients with colorectal cancer is around 5-6%.

The 2016[5] guidance states that each specialist team should aim to draw patients from a catchment area with a population of two to four million.

[5] The Provision of Services for Upper Gastrointestinal Surgery, 2016, The Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

Resections would be appropriate for about 15% of pancreatic tumours and 40-50% of malignant periampullary tumours[6]. At least 60% of the malignant tumours are likely to require biliary stents. The key to improving outcomes lies in ensuring that careful assessment and treatment of these patients allows for clinical needs to be identified and acted on by specialists in the various forms of management.

Many of these cancers are only diagnosed when they reach an advanced stage, as symptoms associated with early tumours are not specific to cancer. A key aim of the specialist HPB cancer service is to improve the quality of life of patients and minimise the impact of their symptoms. For the majority who do not undergo surgery, palliative and complementary treatments such as biliary stents, chemotherapy, radiotherapy or other endoscopic or radiological intervention to relieve symptoms are important. Palliative surgery is sometimes necessary.

## 1.3 Relationship with other documents

This document should be read in conjunction with the following documents:

- **WHSSC Commissioning Policy**
  - CP50a – Positron Emission Tomography (PET) Commissioning Policy
  - CP73 Hepatobiliary Cancer Surgery.
  - CP68 Transarterial Chemobolisation (TACE) Drug Eluting Doxyrubicin (DEBOX) for the Management of Unresectable, Metastatic Liver Disease.

- **NICE Guidance and Clinical Knowledge Summaries**
  - Improving supportive and palliative care for adults with cancer - NICE(2004)
  - Referral guidelines for suspected cancer – NICE clinical guideline 27 (2005)
  - Quality standard for end of life care for adults – NICE (2011)
  - Quality standard for patient experience in adult NHS services – NICE (2012)
  - NICE (2009) Hepatocellular carcinoma (advanced and metastatic) - sorafenib (first line), NICE Appraisal
  - CG32 - NICE Guidance on nutrition support in adults (2006)
  - NG180 - NICE Guidance on Perioperative care (2020)

[6] The provision of services for upper gastrointestinal surgery, The Association of Upper Gastrointestinal Surgeons (AUGIS), 2016

  - NG85 – NICE Guidelines Pancreatic Cancer in adults diagnosis and management (2018)

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding
  - Review of Upper Gastrointestinal Cancer services – South Wales Report, July 2017, Wales Cancer Network
  - Consolidated Rules for Managing Cancer Waiting Times, Welsh Government
  - National Optimal pathways for Oesophageal, Gastric, Pancreatic and Primary Liver Cancers
  - National Standards for Acute Oncology Services, June 2016, Wales Cancer Network
  - National Standards for Rehabilitation of Adult Cancer Patients, 2010, Welsh Government
  - Single Cancer Pathway Point of Suspicion Definitions, December 2018
  - Key workers for cancer patients (WHC 2014/001), 2014, Welsh Government
  - Palliative and end of life care delivery plan, 2017, Welsh Government
  - The Provision of Services for Upper Gastrointestinal Surgery, 2016, AUGIS

- **Relevant NHS England policies**
  - NHS England Improving Quality, 2013. National Peer Review Programme HPB Cancer Measures.
  - Improving Outcomes in Upper Gastro-intestinal Cancer – The Manual, January 2001, NHS Executive
  - B11/S/a Cancer: Oesophageal and Gastric (Adult) Service Specification

## 1.4 National and international service guidance

The following are national and international guidance from which this service specification has been drawn. However, it is important that detailed interventions for cancer patients across the patient pathway should be specifically approved for support before mandating implementation in Wales.

- National Standards for Rehabilitation of Adult Cancer Patients, 2010, Welsh Assembly Government
- Cancer rehabilitation pathways. Macmillan Cancer Support.[7]

[7] These guidelines have not been formally adopted at the time of publication

- Prehabilitation for people with cancer, 2019, Macmillan Cancer Support[8]
- The provision of services for upper gastrointestinal surgery, The Association of Upper Gastrointestinal Surgeons (AUGIS), 2016
- UK Guidelines for the management of patients with pancreatic cancer, periampullary and ampullary cancers (2005) - currently being updated in 2011-2012
- Association of Upper Gastrointestinal Surgeons, 2010. Guidance on minimum surgeon volumes.
- Association of Upper Gastrointestinal Surgeons, 2011. The Provision of Services for Upper GI Surgery.
- ESPEN guidelines on nutrition in cancer patients - https://www.espen.info/wp/wordpress/wp-content/uploads/2016/11/ESPEN-cancer-guidelines-2016-final-published.pdf
- ESPEN guideline: Clinical nutrition in surgery - https://www.espen.org/files/ESPEN-guideline_Clinical-nutrition-in-surgery.pdfESPEN expert group recommendations for action against cancer related malnutrition - https://www.espen.org/files/ESPEN-Guidelines/PIIS0261561417302285.pdf

[8] These guidelines have not been formally adopted at the time of publication

# 2. Service delivery

The aim of this service specification is to define the criteria that HPB surgery services are required to meet in order to provide specialist treatment and care for adults with agreed HPB diseases for people resident in Wales. Health Boards will commission HPB surgery services in accordance with the criteria outlined in this document.

The aim of the service is to provide specialist surgical treatment and care for adults with agreed HPB diseases, as set out below, in accordance with the best available evidence or, in the absence of evidence, in line with best practice / consensus clinical opinion.

All patients should be offered access to an appropriate clinical nurse specialist. Support should be offered to patients from a specialist dietitian with knowledge and skills in gastrointestinal disease, oncology, type 3c diabetes and surgical experience. Local prehabilitation services should be available to optimise patients prior to treatment and rehabilitation services for post treatment recovery.

***Primary cancers of the liver and biliary tree (hepatocellular carcinoma, intra hepatic Cholangiocarcinoma, intraductal or hilar cholangiocarcinoma and gallbladder cancers).***

Assessment of patients with suspected primary liver tumours involves a combination of imaging modalities, pathology services, Allied Health Professional (AHP) services, and specialised surgical and medical expertise. Complex imaging modalities may be required, e.g. liver MRI with special contrast agents, and careful case selection for these modalities is required to achieve optimal result. This is best done by a HPB centre, although the patient may not necessarily need to travel to the centre as long as data on imaging, pathology and clinical state are sent to the centre for multidisciplinary team assessment. Treatment for patients with primary cancers of the liver and biliary tree is provided at HPB centres. Treatment options include:

- surgical management (curative resections, palliative bypass surgery or liver transplantation in selected cases)
- interventional radiological management (radiofrequency ablation, microwave ablation, transarterial chemoembolisation (TACE), transarterial embolisation (TAE) and selective internal radiation therapy (SIRT))
- Stereotactic Ablative Radiotherapy (SABR) or Stereotactic Body Radiation Therapy (SBRT)
- endoscopic stenting and other endoscopic therapies of biliary tumours
- Systemic anticancer therapies including chemotherapy, immunotherapy and multikinase inhibitors

- palliative endoscopic stenting is provided by many district general hospitals based on agreed protocols
- Percutaneous Transhepatic Cholangiography (PTC) or Spyglass for the diagnosis, active management and palliation for hilar cholangiocarcinoma
- national or local cancer networks

The treatment of liver cancers is limited by performance status and the degree of underlying liver disease. Effective prehabilitation, optimisation of the patient and medical management of liver disease can improve quality of life and liver function, allowing a greater range of treatment options including potentially curative interventions.

***Secondary liver tumours - colorectal, neuroendocrine***

Colorectal cancer (CRC) secondary tumours in the liver are one of the most common liver tumours. Imaging, using computerized tomography (CT) and magnetic resonance imaging (MRI), is performed in most district general hospitals, but decisions on surgery and interventional radiology will be taken by the HPB centre multidisciplinary teams in line with NICE Guidance on Colorectal Cancer (CG131, 2011) and NICE Quality Standards for colorectal cancer (2012). Chemotherapy can be given locally according to cancer network guidelines. Neuroendocrine tumours (NET) require specialist imaging, particularly involving nuclear medicine and specialist pathology, which will be provided at the specialist centre.

***Non-cancer related hepatobiliary surgery***

Apart from routine cholecystectomy, virtually all hepatobiliary surgery is a specialised service. Non-cancer related hepatobiliary surgery includes complex stone disease and emergency cover for liver trauma and bile duct injury (traumatic or iatrogenic).

Liver trauma (including iatrogenic bile duct injury) presents at district general hospitals as an emergency and initial stabilization may take place there, before discussion of the case with a HPB centre. Transfer to a HPB centre is usually required for further imaging and a decision on surgery or interventional radiology. Where the liver injury is part of multi-organ trauma it is likely to be dealt with by the designated major trauma centre, which, if not coterminous with the liver centre, will liaise with the HPB centre depending on the severity of the case.

***Pancreatic cancer including duodenal cancers, neuroendocrine tumours and cystic neoplasms***

HPB surgery centres provide a multi-disciplinary approach which involves surgical, medical, endocrine, AHP, pathology and interventional endoscopy and radiology services. Complex imaging modalities may be required, e.g. CT, positron emission tomography (PET), MRI with special contrast agents and endoscopic ultrasound scanning. Choice of modality is carried out by a

multi-disciplinary team assessment at the pancreatic centre. The patient does not need to attend the centre in person as long as data on imaging, pathology and clinical state has been forwarded to the centre.

Patients with primary tumours are often referred to the pancreatic centre prior to biliary drainage commencing, depending on local network guidelines. Thereafter, treatment options at the pancreatic centre include:

- endoscopic ultrasound for cytological confirmation and staging surgical management (curative resections, palliative bypass surgery, and specialist palliative interventions e.g. neurolysis)
- oncology
- biliary drainage by interventional radiological management, e.g. endoscopic or percutaneous drainage (if not previously achieved), biopsy.

***Benign pancreatic disease including acute and chronic pancreatitis***

Benign pancreatic disease includes acute and chronic pancreatitis of varying aetiologies and varying severities and with various complications. In addition, cystic lesions of the pancreas, strictures of the pancreatic duct and stricturing and spasm of the sphincter of Oddi would normally be considered part of pancreatic disease. Optimal care for benign pancreatic conditions is best provided within a clinical network with the local hospital managing the patient until specialist intervention is required.

Surgery and interventional endoscopy/radiology for benign pancreatic conditions may be provided at the HPB centre; such cases are usually elective. Medical management by the local hospital is on a multi-disciplinary basis involving gastroenterological/endoscopic, endocrine, nutritional, analgesic and critical care services. In cases of severe pancreatitis, a 'hub and spoke' arrangement will be established between the HPB centre and the local hospital, with transfer of patients to the HPB centre at times of definitive intervention.

The majority of patients with pancreatic trauma, including those with transection of the gland or associated duodenal injury, cannot be managed by a local hospital and will be transferred to the HPB centre.

In order to maximise the health outcomes and quality of life for the patient, and to ensure ready and timely access to appropriate supportive care for patients, their relatives and carers. The service will be delivered through a HPB multi-disciplinary team.

The specialist HPB service will serve a population base for between two to four million, formally agreed by commissioners.

The service is required to agree the following areas with the Wales Cancer Network:

- Service configuration and population coverage
- Referral criteria, clinical protocols and network policies and treatment pathways

## 2.1 Service Objectives

The overall objectives of the services are to:

- provide an exemplary and comprehensive service for all referred patients with suspected HPB cancers and benign conditions
- identify those individuals at high risk of developing HPB cancers and to develop a clear plan for monitoring them.
- ensure radiological, pathological and diagnostic facilities are available in order to effectively diagnose, classify and stage the condition prior to planning treatment.
- advise on and undertake investigations to determine whether the patient is appropriate for radical or palliative treatment and to provide high quality surgical treatment for patients with HPB cancers including interventional radiological and endoscopic procedures.
- ensure high quality supportive care and treatment for those patients not suitable for curative therapies.
- carry out effective monitoring of patients to ensure that clinical treatment is safe and effective.
- provide care to promote the optimal functioning and quality of life for each individual patient.
- provide appropriate follow-up and surveillance after definitive treatment.
- ensure that all aspects of the service are delivered as safely as possible, conform to national standards and published clinical guidelines and are monitored through audits.
- provide care with a patient and family-centred focus to minimise the unpleasant experience of the illness.
- ensure that every patient with suspected or confirmed cancer is seen or discussed with the specialist MDT.
- support health boards to manage patients with HPB cancers whenever it is safe to do so and clinically appropriate.
- provide high quality information for patients, families and carers in appropriate and accessible formats and media.
- ensure there is accurate and timely information given to the patient's primary care team.
- ensure that there is involvement of service users and carers in all aspects of the service.
- ensure there is a commitment to continual service improvement.
- ensure compliance with peer review recommendations
- identify individuals at risk of HPB and related tumours and provide appropriate genetic counselling and screening.
- provide equity of access to high quality research and clinical trials

The specific objectives of the HPB Surgery Service are to:

- provide complex tertiary elective and emergency HPB surgery in line with the 2016 AUGIS document (the provision of services for Upper Gastrointestinal Surgery) and the nationally designated trauma centre network (2012). This includes meeting the standards for:-
    - treating patients according to protocols as curative or life extending treatments.
    - reduction of operative morbidity and mortality.
    - development and production of appropriate patient and carer information.
    - entry of patients to clinical trials and collection of national clinical trial data.
    - provision of appropriately staffed and robust consultant surgical rotas to provide 24/7 cover for specialised HPB surgery patients, in line with the minimum population requirements of the NICE IOG.
- provide 24/7 emergency HPB surgery cover for the designated Major Trauma Networks and Major Trauma Centres.
- operate a service consisting of a network of outlying hospitals feeding into a HPB centre providing specialist care for a population of two to four million.
- ensure that for suspected and confirmed HPB cancers
    - the centre will work with the units to enable first line diagnostic and palliative services for non resectable patients to be provided locally
    - more complex imaging will be provided in the centre.

Patients with clearly inoperable cancers (metastatic) and or poor performance status can be managed locally. All patients with HCC and operable or potentially operable liver and pancreatic cancers should be referred to the tertiary centre MDT. Reference should be made to the National Optimal Pathway for pancreatic and Primary Liver Cancers.

The HPB team is constituted according to NICE 2001 IOG for Upper Gastrointestinal Cancers:

- ensure that for acute pancreatitis:
    - the HPB centre will provide a specialist service.
    - patients with confirmed severe acute pancreatitis, according to modified Atlanta criteria, (approximately 100 per million population per year) will have their details an imaging uploaded to the specialist centre from where advice will be given through a benign pancreatic multidisciplinary team
    - transfer of patients to the specialist centre will be for specific interventions (operative, radiological and/or endoscopic) according to pre-agreed criteria. Interventions for pancreatic necrosis including necrosectomy and pseudocyst treatment (approx. 20 per million per year) will be carried out at the HPB

centre (where facilities and expertise for minimally invasive and endoscopic therapy will be available)

- ensure that for chronic pancreatitis
    - patients will be transferred to the HPB centre for management of specific complications including biliary obstruction, duodenal obstruction, painful obstructive pancreatitis. Interventions will be carried out at the centre.
    - hereditary pancreatitis patients will be managed by the centre.

## 2.2 Access criteria

This service is for people aged 18 and over, with confirmed or suspected HPB cancer, and non-cancer conditions requiring specialised intervention and management, as outlined within this specification. Referrals of people under the age of 18 will be considered on a case by case basis.

## 2.3 Patient referrals

Patients are referred from general practitioners, hospital consultant for medical or surgical assessment and management of specialised hepatobiliary diseases or conditions, including:

- Primary tumours of the liver and biliary tree
- secondary liver tumours
- non-cancer related complex hepatobiliary surgery
- pancreatic, periampullary and duodenal neoplasms
- benign pancreatic disease including acute and chronic pancreatitis
- portal hypertension related procedures

Once referred the patient will be assessed by a specialist multidisciplinary team. The service must manage all referrals within the cancer referral to treatment waiting time thresholds. In order to meet the 62 day waiting time standard on the Single Cancer[9] Pathway, rapid referral from the local Upper Gastro Intestinal MDT and rapid decision making by the tertiary MDTs is essential.

[9] The Single Cancer Pathway specifies that patients should receive cancer diagnostic tests and start their treatment within 62 days from the very first point at which cancer might be suspected.

The HPB Service comprises three distinct MDTs. The referral categories for these MDTs are as follows:

| | |
|---|---|
| **Tertiary Hepatobiliary MDT** | Referrals are accepted by any qualified doctor from the specialist hepatobiliary service where the patient has confirmed:<br>• primary cancers of the liver (excluding hepatocellular carcinomas) and biliary tree<br>• secondary liver tumours<br>• non-cancer related complex hepatobiliary surgery |
| **Tertiary Hepatocellular MDT** | Referrals are accepted by any qualified doctor from the specialist HCC service where the patient has confirmed or suspected Primary Hepatocellular Cancer of the Liver |
| **Tertiary Pancreatic MDT** | Referrals are accepted by any qualified doctor from the specialist pancreatic cancer service where the patient has confirmed or suspected pancreatic cancer or related cancers including:<br>• Pancreatic cancer.<br>• Duodenal cancer.<br>• Bile duct cancer in the lower or mid-bile duct.<br>• Pancreatic cystic lesions.<br>• Pancreatic and duodenal neuroendocrine cancer.<br>• Pancreatic and duodenal premalignant tumours/polyps. |

A dedicated pancreas protocol CT and full staging CT are essential and must be performed by the upper gastro-intestinal diagnostic team at the local district general hospital.

Patients can be referred directly to the tertiary centre from primary care, Emergency Department (ED) or secondary care. To avoid delay in making the diagnosis, appropriate Single Cancer Pathway investigations should be instigated.

***Asymptomatic individuals at risk of the disease***

Individuals with a strong family history (two or more first-degree relatives) of pancreatic cancer may present to a clinical genetics department or to

their general practitioner where a full family history will be taken in an attempt to classify the risk.
Individuals with familial adenomatous polyposis (FAP) should be part of a local surveillance program to identify duodenal polyps. If duodenal polyps are identified, the HPB unit should be informed and there should be a policy for referral related to the classification of the polyposis (e.g. the Spigelman Classification).

Individuals with fatty liver or known cirrhosis should be on surveillance programmes for early identification of HCC.

Patients with any indeterminate liver masses and complex liver cysts should be referred to the HPB centre.

### 2.3.1 Population

The service is accessible to all patients with confirmed or suspected HPB cancer regardless of sex, race, or gender. Services will require staff to attend mandatory training on equality and diversity and the facilities provided offer appropriate disabled access for patients, family and carers. When required, the services will use translators and printed information available in multiple languages.

Services have a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, and religion and disability equality legislation.

## 2.4 Service description

Services must achieve specific quality standards and measures. The provider must also meet the standards as set out below.

### 2.4.1 HPB Surgery Services

HPB surgery services must meet the following criteria:

***Person centred care***

- All Health Boards should provide a key worker to patients on high suspicion of cancer and expedite pathways as quickly as possible from the date of suspicion.
- Patients will be allocated a key worker around the time of diagnosis, if not before. This role should fulfil the criteria of the current key worker specification.

- Each patient should be offered a holistic needs assessment (HNA) and care plan at identified intervals during their cancer pathway, from diagnosis to first definitive treatment. HNA should also be offered at subsequent points during further treatment and/or palliative care. HNAs should be used to inform and develop a formal care plan which is shared with the patient and their care providers across care sectors. The key worker should ensure the results of patients' HNA are taken into account in the MDT decision making.
- Each patient should have their multi-professional rehabilitation needs considered (prehabilitation) before, during and after treatment. These include nutrition, physical and emotional needs. Referral to Allied Health Professionals (AHP) services should be made in a timely manner in order to meet these needs, as local to the patient as possible. This complies with the National Rehabilitation Standards for Wales[10].
- Patients should be provided with information and given access to resources that adequately describe the diagnostic and staging interventions, particularly endoscopy.
- Patients should have access to appropriate specialists and healthcare professionals to discuss all their potential treatment options.

### *Transition across local and tertiary services*

- Transitions between local and tertiary services should be planned, to ensure that they are continuous, seamless and efficient. Clear communication between professionals is essential at these points.
- The HPB surgery service must be able to access information from all of the participating Health Boards and clinicians and vice versa.
- The roles of all members of the local MDTs and the tertiary HPB cancer MDTs need to incorporate the education and development of generalists to support those affected by HPB cancer.

### *Diagnosis*

The service shall work to Wales Cancer Network agreed assessment and referral guidelines that have been developed with the lead clinicians of the HPB diagnostic teams. These guidelines are to ensure that:

- Patients with jaundice will have fast-track access to the HPB centre for definitive treatment.
- Patients who have pain or other symptoms which could be due to pancreatic cancer will undergo urgent pancreas protocol CT and be referred to the specialist pancreatic cancer multidisciplinary team.

Patients who present as an emergency on their route to being diagnosed with cancer have poorer survival. HPB surgery services should:

- Develop an algorithm to support decision-making in A&E or primary care

[10] National Standards for Rehabilitation of Adult Cancer Patients, 2010, Welsh Assembly Government

- Set up an emergency communication alert system service for Primary Care/A&E/ Assessment units/Acute Oncology Services/ clinicians to enable rapid specialty assessment and outpatient investigations.

### *Imaging, Endoscopy and Pathology*

The service should agree imaging modalities and their specific indications. HPB protocol CT should be performed locally if possible.

Further assessment of the tumour should be carried out at the centre, but may involve local MRI, EUS, ERCP, PTC, Peroral cholangioscopy and/or laparoscopy. If biliary drainage is to be carried out this should be discussed with the HPB centre.

When symptoms or imaging clearly show that the disease is metastatic or inoperable or the patient is not sufficiently fit to undergo radical treatment, the team shall consider the appropriate palliative treatment.
The endoscopic services at the regional specialist centre should be JAG accredited and should include enhanced diagnostic and therapeutic facilities for EUS and ERCP, and Peroral Cholangioscopy (POC) for patients with bile duct strictures.

The endoscopic service at the HPB centre will provide interventional (linear) endoscopic ultrasound (EUS), including Fine Needle Aspiration (FNA) or Fine Needle (core) Biopsy. The results of EUS obtained pathology should be continuously audited. The centre must have pathologists with HPB interest on site who are able to provide a fresh frozen histology service as and when required.

Pancreato-biliary endoscopic ultrasound is used for differential diagnosis and/or tissue diagnosis in many cases. This is a complex technique which should only be carried out by fully trained practitioners who have had specific training according to BSG guidelines.

Peroral Cholangioscopy is useful in the assessment and diagnosis of hilar biliary strictures and should be available to the HPB centre (ideally within the HPB centre)

Histological confirmation of tumour is required before treatment with chemotherapy or radiotherapy.

The pathology services should comply with Clinical Pathology Accreditation (UK) Ltd (CPA)[11] and the Human Tissue Authority (HTA)[12].

[11] CPA, the principle accrediting body of clinical pathology services and External Quality Assessment (EQA) Schemes in the UK. Modernising Pathology Services. Department of Health (2004)
[12] HTA Regulatory body for all matters concerning the removal, storage, use and disposal of human tissue. www.hta.gov.uk

### *Staging*

Clinicopathological stage should be documented for all patients with detailed histopathology for resected cancers. Providers must include staging information in their cancer registration dataset.

### *Treatment and surgery*

Surgeons based at the HPB centre should provide a 24 hour advice service and an emergency outreach system to district general hospitals for complex HPB problems. The HPB centre should be informed when surgical patients have been readmitted locally. Patients diagnosed with HPB cancers should be offered Prehabilitation and optimisation for both surgical and non-surgical treatments and an enhanced recovery[13] strategy post operatively for optimal patient outcomes.

The HPB centre must have access to adequate intensive care, high dependency facilities and specialist post-operative care (including out of hours consultant cover, for advice or surgical emergencies, access to 24/7 interventional radiology and specialist allied health professional services) to ensure that it is able to minimise the risk of peri-operative morbidity and mortality.

### *Chemotherapy and Radiotherapy*

The management of HPB cancers with intent to cure involves chemotherapy in the majority of cases. Treatment may also involve radiotherapy. Palliative treatment frequently involves chemotherapy and/or radiotherapy. Chemotherapy and radiotherapy should be carried out at designated centres or at sites agreed within the network guidelines by appropriate specialists as recommended by a specialist pancreatic multidisciplinary team. Audits of compliance with these protocols will need to be demonstrated.

### *Surveillance of untreated lesions*

Protocols should be developed for the management of cystic lesions in the pancreas or liver. A proportion of these patients, particularly those with small non-mucinous lesions, will be managed by surveillance. Patients with pancreatic masses and biliary strictures which are of low suspicion of malignancy may also be managed by surveillance. Surveillance of these patients should always be co- ordinated by the specialist pancreatic multidisciplinary team and the patients discussed at the specialist pancreatic multidisciplinary team meeting.

### *Follow-up*

The IOG series of documents made recommendations on follow-up care. Providers will need to adhere to cancer specific guidelines for follow up agreed through the NSSG and ensure patients have a follow up plan. The

[13] ERAS: Improving outcome in the cachetic HPB patient, 2017, van Dijk et al, Journal of Surgical Oncology.

cancer specific guidelines will identify that some patients will need to continue receiving follow up from the specialised service, but it is deemed to be clinically appropriate by the HPB MDTs, follow up may be provided locally. The provider will need to ensure effective hand over of care and/ or work collaboratively with other agencies to ensure patients have follow up plans appropriate to their needs.

***Dietitian and nutritional support***

All patients with HPB disease are at risk of nutritional problems. Patients should be regularly screened for risk of malnutrition and referred to dietetic services at the earliest opportunity in the pathway. This service is available and co-ordinated between the local level and tertiary centre.

It is essential that dietitians be involved both in the care of patients where the aim is surgical intervention, and in the management of patients requiring palliative care and/or receiving non-surgical therapies. Optimisation of nutrition, reversal of sarcopenia and adequate pancreatic enzyme replacement therapy have been shown to have positive benefits for patients both in terms of quality of life and length of survival.

Dietitians managing the care of these patients should have specialist skills, knowledge and an appropriate level of experience to manage the complex needs of these patients.

Relevant knowledge and skills include gastrointestinal disease, oncology, type 3c diabetes and management of nutrition in surgical patients.

Dietitians should be involved throughout the entire patient journey – from diagnosis and throughout treatment and/or palliation. Dietitians should be available to see patients in acute and community settings including MDT outpatient clinics, peri-operative care, consultation on ward rounds and multidisciplinary team meetings providing advice on required nutritional interventions to manage undernutrition, glycaemic control, pancreatic enzyme replacement therapy, enteral tube feeding and parenteral nutrition.

***Rehabilitation***

There should be appropriate assessment of patients' rehabilitative needs before, during and after treatment and the provider must ensure that high quality rehabilitation is provided in line with the network agreed rehabilitation pathway and standards[14].

The Macmillan cancer rehabilitation pathway is available at: https://www.macmillan.org.uk/assets/macmillan-cancer-rehabilitation-pathways.pdf

Prehabilitation is a multidisciplinary pre-treatment rehabilitation programme, which aims to improve physical condition, nutritional status and emotional status. Exercise should include endurance exercises such as

[14] National Standards for Rehabilitation of Adult Cancer Patients, 2010, Welsh Assembly Government

walking, cycling, inspiratory muscle training and resistance training. Managing anxiety should be addressed by psychological intervention which can improve mood, improve adherence to treatments and the ability to cope with the rigours of treatment.

***Supportive and Palliative Care***
The provider will give high quality supportive and palliative care in line with NICE guidance. The extended team for the multidisciplinary team should include additional palliative care specialists to achieve this requirement. All patients who are managed by a specialist pancreatic cancer multidisciplinary team will be allocated a key worker.

Each patient should be offered a holistic needs assessment, including screening for psychological reactions, at key points in their cancer pathway including at the beginning, and end of primary treatment and the beginning of the end of life A formal care plan should be developed, which includes appropriate psychological care based upon the tiered care model. The health care professional should ensure the results of patients' holistic needs assessment are taken into account in the multidisciplinary team decision making.

Patients who require palliative care will be referred directly to a palliative care team in the hospital and the team will be involved early to liaise directly with the community services. Specialist palliative care advice will be available on a 24 hour, seven days a week basis.

***End of life care***
The provider shall provide end of life care in line with NICE guidance and in particular the markers of high quality care set out in the NICE Quality Standard for end of life care for adults.

***Acute oncology service***
All hospitals with an ED should have an "acute oncology service" (AOS), bringing together relevant staff from ED, general medicine, haematology and clinical/medical oncology, oncology nursing, oncology pharmacy and allied health professionals. This will provide emergency care not only for cancer patients who develop complications following chemotherapy, but also for patients admitted suffering from the consequences of their cancer.

## 2.5 Interdependencies with other services or providers

**Hepatobiliary Cancers**
It is common for members of the pancreatic cancer team to provide services for hepatobiliary cancers often as part of a HPB Surgery Centre. The organisation of services for pancreatic cancer and hepatobiliary cancers (including services for liver metastases and neuro- endocrine tumours)

overlap considerably in that many of the specialists will manage patients with both groups of cancer.

**Liver Cancers**
For the provision of liver surgery there are interdependencies with:

- Radiology services, especially interventional Radiology, for procedures such as Portal Vein Embolisation (PVE), Trans Arterial Chemo Embolisation (TACE) etc.
- Oncology
- Hepatology – to manage patients with portal hypertension, liver failure etc.
- Pathology

**Benign HPB disease**
The management of complex benign pancreato-biliary disorders has much in common with the management of pancreatic cancer. Differential diagnosis of benign from HPB disease is not straightforward. The same specialists who treat HPB cancer are therefore also involved in the management of complex benign pancreato-biliary disorders and it is clear that services (gastroenterology, radiology, surgery, nutrition, etc.) for these diseases need to be available and develop alongside the development of cancer services in all HPB centres.

The specialist HPB multidisciplinary team may link into multiple clinical and administrative teams including:

- Upper gastro-intestinal unit diagnostic team
- Local upper gastro-intestinal cancer multidisciplinary team
- Local and specialist palliative care teams
- Local and specialist therapy teams
- Local radiology and pathology teams

The HPB multidisciplinary team should be regarded as the leaders in the NHS for patient care in this area. They provide a direct source of advice and support when other clinicians refer patients into the regional specialist services. This support will continue until the patient is transferred into the regional specialist pancreas centre or it becomes apparent that the patient does not have a pancreatic cancer.

HPB services depend upon adequate provision of a number of services including the following:-

Services generally required access to:

- ***Cancer Services*** - involvement of oncology services is required in the management of patients with liver, hepatobiliary and pancreatic cancer. With the overlap with neuroendocrine cancer, the tertiary neuroendocrine tumour service is required to manage these complex patients.

Services generally required to be onsite:

- ***Endoscopic services including endoscopic ultrasound and therapeutic endoscopy*** - should be available at the HPB centre for both the diagnosis and interventional management of HPB disease.
- ***Interventional Radiology*** – the service should be collocated with interventional radiology
- ***Hepatology, Pancreatic Medicine and Endoscopic Services*** – Non-complex hepatology (viral hepatitis, metabolic parenchymal liver disease, and alcoholic liver disease) is managed in most district general hospitals, whereas complex problems (acute and chronic) and complications of these conditions are usually managed at the recognised liver centres.
- ***Viral Hepatitis services*** - links to referring hospitals, local substance misuse services, liver transplant centres, HPB centres, human immunodeficiency virus (HIV), haemophilia, thalassemia and renal services.
- ***Biliary endoscopic services*** (interventional and non-interventional) are provided by most district general hospitals, but as with the interface with General Surgery, distinctions between non-complex (district-provided) and complex (specialised centre provided) services may be difficult to define.
- ***Nutrition and Dietetic Services***
  - ***Dietetics*** Specialist advice and support regarding nutrition including oral nutritional support and supplementation, maximise pre-operatively, pancreatic enzyme replacement therapy, management of enteral tube feeding in hospital and community, glycaemic control in liaison with diabetes specialist nurses and endocrine, symptom control and improved quality of life.
  - ***Nutrition Nurse Specialist role***
    Specialist advice and support in the management of patients requiring enteral feeding devices.
  - ***Nutrition Support Team***
    To assist in the management of patients requiring parenteral nutrition both in hospital and the community.
  - ***Home parenteral nutrition network*** – supports discharge and management of patients requiring parenteral nutrition in the community

- ***Other therapy services*** including physiotherapy and occupational therapy
- ***Pharmacy Services*** – from a medicines management perspective and provision of parenteral nutrition
- ***Renal Services*** - Renal dialysis is frequently required in patients with acute liver failure and occasionally in patients with decompensated chronic liver disease.
- ***Endocrinology Services*** – there is an increased risk of diabetes following pancreatic surgery
- ***Trauma Services*** – liver and pancreatic injuries are common in both blunt and penetrating trauma. Following the designation of regional trauma centres, if not coterminous, the designated HPB surgery centres need to have robust management protocols and pathways to provide 24/7 emergency cover for patients with HPB trauma.

Services which do not generally need to be on-site but to which rapid access is required:

- ***Haemophilia and Other Related Bleeding Disorders*** - a large proportion of haemophilia patients have HCV infection and require anti-viral therapy and some need treatment for hepatocellular cancer.
- ***Infectious Diseases / HIV*** - for HIV and Hepatitis C co-infected patients where local treatment pathways involve infectious disease physicians the patients are normally be managed by infectious disease physicians working in conjunction with liver services locally so as to ensure optimal management of the complications of cirrhosis.
- ***Medical Genetic Services*** - some chronic liver disorders and some pancreatic disorders may have a genetic basis requiring liaison with genetic services.
- ***Mental Health Services*** - . Liaison with drug and alcohol services is needed due to the high frequency of viral and alcohol-related liver disease in patients presenting to these services and vice versa.
- ***Specialised Services for Children*** – the treatment of liver disease in children is organised in three nationally designated centres in the UK; medical input is provided by specialist paediatricians and surgery by specially trained hepatobiliary surgeons. Pancreatic disease in children requiring specialist treatment is unusual and should be carried out in conjunction with an experienced HPB surgeon.
- ***Palliative Care Team*** – concentrates on quality of life issues for patients, and their families, with advanced, progressive illness (both cancer and non-cancer) and provide expert guidance on end of life care. The team has specialist skills in pain and symptom management and provides supportive care on complex social, emotional and spiritual matters at the end of life. The team also sees patients at an earlier stage where there are persistent, complex symptom control issues.

- ***Teenage Young Adult MDT*** – supports the treatment recommendations made by the HPB MDTs, and considers against the perspective of the psychosocial needs at the time of diagnosis, changes in condition, and at the end of treatment and transition into adult services.
- ***Prehabilitation Services –*** for surgical and non-surgical patients. Where possible these should be provided locally.

Services with which there is a relationship but may not require to be onsite or have rapid access:

- ***Weight Management Services*** -obesity commonly results in fatty liver disease and this may progress to cirrhosis. Interventions for management of obesity may have an effect on the outcomes of the liver disease.
- ***General Surgery Services*** – non-complex gallstone disease and acute pancreatitis is managed by general surgeons working in all district general hospitals. However, distinctions between non-complex and complex presentations for both conditions may be difficult to define
- ***Social Worker*** – assess and plan and support clients to cope with social, emotional, economic and environmental problems. They help clients maintain their independence and to live as normal a life as possible in the community and to work jointly with health staff on social matters that may affect present and future health.
- ***Drug and Alcohol Support Services*** - confidential advice, assessment, treatment, and referral for people who have a problem with alcohol or other drugs.
- ***Prisons (or other institutions)*** – appropriate outreach diagnostic and treatment services run from the relevant liver centre and delivered in the prison/institution.

**Core Services:**
Liver, biliary and pancreatic services will require appropriate access to core clinical support services, such as haematology, pathology; pharmacy, diagnostics; blood and blood products; X-Ray, CT, MRI, EUS, ERCP, PTC, etc. Access to and the level of service available should be appropriate for the service being delivered as well as the treatment and care required by the patient group.

## 2.6 Exclusion criteria

Patients under 16 years of age.

## 2.7 Acceptance criteria

Referrals will usually be accepted from general hepatologists, gastroenterologists, infective diseases, oncologists, general and colorectal

surgeons, though exceptionally directly from GPs where appropriate pathways have been established. Once referred the patient will be assessed by a specialist multidisciplinary team.

The service outlined in this specification is for patients, aged 16 or over, ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patient's resident in England who are registered with a GP Practice in Wales.

Local UGI cancer services are commissioned by Health Boards for their resident population. These services must be fully aware of the need for urgent referral and for awareness and early diagnosis initiatives as this will be the only way of increasing earlier stage disease at diagnosis to improve prognosis.

## 2.8 Care pathway

***Tertiary Hepatobiliary MDT***

There should be a single named lead clinician for the tertiary hepatobiliary cancer MDT who should also be a core team member. The team should include the following core members:

| Essential | Desirable |
|---|---|
| • Clinical Oncologist<br>• Gastroenterologist<br>• Hepatologist<br>• Histopathologist<br>• Medical Oncologist<br>• Nuclear medicine<br>• Palliative care<br>• Pathologist<br>• Pharmacist<br>• Radiologist (Interventional and Diagnostic)<br>• Specialist Dietitian<br>• Specialist nurses<br>• Surgeon<br>• Therapists – including specialist physiotherapists and specialist occupational therapists | • Clinical Nutrition Support Team including Nutrition Nurse Specialist<br>• Clinical Psychologist |

### *Tertiary HCC MDT*

There should be a single named lead clinician for the tertiary hepato cellular carcinoma cancer MDT who should also be a core team member. The team should include the following core members:

| Essential | Desirable |
|---|---|
| • Clinical oncologist (SABR)<br>• Diagnostic radiologist,<br>• Hepatologist<br>• Histopathologist<br>• Interventional radiologist,<br>• Medical oncologist<br>• Pathologist,<br>• Specialist Dietitian<br>• Specialist nurse,<br>• Surgeon | |

### *Tertiary Pancreatic MDT*

There should be a single named lead clinician for the tertiary pancreatic cancer MDT who should also be a core team member. The team should include the following members:

| Essential | Desirable |
|---|---|
| • Clinical oncologist<br>• Endocrinologist and Diabetes Specialist Nurses<br>• Gastroenterologist<br>• Histopathologist<br>• Medical oncologist<br>• Palliative care<br>• Pathologist<br>• Pharmacist<br>• Radiologist<br>• Specialist dietitian<br>• Specialist nurses<br>• Surgeon<br>• Therapists – including specialist physiotherapists and specialist occupational therapists | • Clinical Nutrition Support Team including Nutrition Nurse Specialist<br>• Clinical Psychologist<br>• Pain management team |

Benign pancreatic disease patients needing specialist intervention are not uncommonly in critical care, and hence would need a consultant Intensivist being represented in these MDTs (potentially).

Services are mandated to collect the all Wales Cancer Minimum Reporting Requirements, covering both core and tumour site specific data items to enable the appropriate national cancer reporting. This supports cancer

registration, cancer clinical audits, and cancer waiting times/single cancer pathway and quality outcome indicators for Wales.

The local and tertiary services are expected to monitor the following clinical outcomes:

- All Single Cancer Pathway Dataset items.
- Peer Review dataset.

# 3. Quality and patient safety

Services must work to written quality standards and provide monitoring information to commissioners. The quality management systems must be externally audited and accredited.

Services must enable the patients, carers and advocates informed participation and be able to demonstrate this. Provision should be made for patients with communication difficulties.

## 3.1 Quality indicators (standards)

***Minimum volumes***

- HPB surgeons should each perform at least 15 liver surgical procedures per year for neoplastic disease, at least 10 of which should be major (3 or more segments).
- Liver resections include intrahepatic bile duct resections.
- If two surgeons share the surgery of a given case, this would count as a case for each in relation to this standard.
- More complex and infrequent procedures (e.g. resection for hilar cholangiocarcinoma) should be performed by only one or two surgeons with expertise in operating these cases in order to maintain their expertise.

The HPB services are required to:

- hold quarterly mortality and morbidity meetings;
- participate in annual quality assurance; and
- participate in collection and submission of data into appropriate databases
- provide data to commissioners to support the assessment of compliance with the service specification.
- Undertake regular patient experience surveys, patient reported outcome measures and develop and implement an action plan based on findings
- report the following outcomes:
    - Mortality
        - Intraoperative deaths
        - early post-operative deaths including deaths in ITU
        - deaths in hospital prior to discharge
        - deaths up to 90 days (at home or in another hospital)
    - Open and close rate
    - Complication rates, including:
    - Blood loss
    - Requirement for blood transfusion
    - Length of stay

Providers are expected to plan and provide services in line with the quality standards for hepatobiliary cancer surgical services which are outlined below:

- NICE (2001) 'Improving outcomes on upper GI cancers, NICE Cancer Service Guidance'
- NICE (2009) 'Hepatocellular carcinoma (advanced and metastatic) - sorafenib (first line), NICE Technology Appraisal'
- NICE TA176 (2009) 'Use of cetuximab in first line treatment of unresectable kras wild type liver limited metastatic colorectal cancer'
- NICE CG131 (2011) 'Guidance on the management of colorectal cancer'
- Department of Health. Guidance on Commissioning Cancer Services: Improving Outcomes in Upper Gastrointestinal Cancers, London 2001
- Association of Upper Gastrointestinal Surgeons, 2010. Guidance on minimum surgeon volumes
- Association of Upper Gastrointestinal Surgeons, 2011. The Provision of Services for Upper GI Surgery. Welsh Assembly Government. National Standards for Colorectal Cancer Services, 2005, Welsh Assembly Government. National Standards for Upper Gastrointestinal Cancer Services, 2005
- Welsh Cancer Networks 'MDT Working Charter', 2013.

The following document has also been used a reference:

- NHS England Improving Quality, 2013. National Peer Review Programme HPB Cancer Measures.

## 3.2 Other quality requirements

The HPB surgery service will:

- Perform quarterly reviews of its functionality and performance.
- Participate in national UK audits, where available, in order to ensure the best possible clinical outcomes. All audits should take into account the results of all surgeons in the centre
- Use a recognised system to demonstrate service quality and standards.
- Use detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site.
- Participate in National Cancer Peer Review.
- Ensure that the quality system and its treatment protocols will be subject to regular clinical and management audit.
- Hold other meetings regularly on a quarterly basis to address clinical, service delivery and governance issues.

- Have appropriate resources in place to ensure pathways are seamless and timely and to aid the tracking of patients from referral to treatment in order that clinicians can focus on supporting patients.
- Ensure patients have equitable access to high quality clinical research trials.

The above should form the basis of an annual report shared with Health Boards who refer to the service or participate in it.

Care delivered by the service must be of a nature and quality to meet the Improving Outcomes in Upper Gastro-intestinal Cancers. It is the Provider's responsibility to notify the commissioner on an exceptional basis should there be any breaches of the care standards. Where there are breaches any consequences will be deemed as being the Provider's responsibility.

Services must comply with the relevant NICE quality standards which defines clinical best practice.

### 3.3 Patient experience

The HPB surgery service will ensure that patients have access to the relevant support groups and education, and will conduct regular surveys of patient / carer satisfaction in line with national guidance.

# 4. Performance monitoring and information requirement

## 4.1 Performance monitoring

Health Boards will be responsible for commissioning services in line with this policy. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this policy the following approach will be adopted:

- Services to evidence quality and performance controls.
- Services to evidence compliance with standards of care.

The Wales Cancer Network will conduct performance and quality reviews on an annual basis.

## 4.2 Key performance indicators

The providers will be expected to monitor against the full list of Quality Indicators derived from the service description components described in Sections 3.1 and 3.2.

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

In particular, the provider will be expected to monitor against the following target outcomes:

- Single Cancer Pathway waiting time target
- Surgery component waiting time for patients
- Resection rates
- Hospital stay (median length of stay in days)
- Equitable access (by LHB population) to HPB surgery
- Equitable access to Prehabilitation for both surgical and non-surgical patients
- The length of stay of acute severe pancreatitis patients in critical care (data available from ICNARC).

The provider will be expected to monitor against the following outcomes, and present to WHSSC at an annual Audit Day meeting:

- Number of cases with confirmed histology
- Staging - to monitor the stage of diagnosis of liver disease and to monitor the effect on the effectiveness of treatment

- Mortality – to monitor in and out of hospital mortality (including cause of death) and to make a comparison with published survival data
- Post-operative morbidity and mortality
- Waiting times and numbers – weekly time from referral to treatment and weekly numbers waiting
- Remission and relapse rates - using recognised disease-specific measures of disease activity
- Disease related damage - using recognised disease-specific damage indices
- Quality of life
- Patient / carer satisfaction - questionnaire survey Access to support groups and education - questionnaire survey plus patient / carer participation
- Compliance with maintenance of disease registry/ies
- Participation in clinical trials
- Evidence of programme of joint working with non-specialist centres (e.g. shared care protocols, outreach clinics)
- Equitable access (by percentage of health board population) to specialist hepatobiliary treatment and care services for both elective and acute conditions
- Transplantation rates by LHB (linked to indicator above)
- One, two and five year survival rates.
- Percentage of patients with a key worker (as per national performance measure)
- Percentage of patients with a written care plan (as per national performance measure)

## 4.3 Date of review

This document is scheduled for review before 2023, when we will check if any new evidence is available.

If an update is carried out the policy will remain extant until the revised policy is published.

# 5. Equality impact and assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Health Boards to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re- assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy will be subjected to an Equality Impact Assessment.

# 6. Putting things right: raising a concern

## 6.1 Raising a concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to provider Health Board.

## 6.2 Individual patient funding request (IPFR)

If the patient does not meet the criteria for treatment as outlined in the service specification, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the IPFR Panel of the Local Health Board in which the patient is resident.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with the policy, arrangements can be made for an independent review of the process to be undertaken. The grounds for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated.

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted to the Local Health Board in which the patient is resident.