A02/S/a

2013/14 NHS STANDARD CONTRACT
FOR HEPATOBILIARY AND PANCREAS (ADULT)

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

Service Specification No.	A02/S/a
Service	Hepatobiliary and Pancreas (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

National Context:

Liver disease is the 5th largest cause of death in the UK[1]

The number of deaths due to liver disease, and the burden of liver disease on the healthcare system, has been increasing significantly for the past thirty years in England. Many people are drinking too much alcohol too regularly for their health and many are also eating more and exercising less, putting an additional strain on their livers. Injecting drug use exposes individuals to the risk of viral hepatitis. So most of the growth in liver disease is due to the adverse effects of lifestyle choices, particularly alcohol and obesity, but also from hepatitis B and C viruses, which can be transmitted through sex or injecting drug use, or may be acquired in other ways in parts of the world where the viruses are common. Chronic liver disease may remain asymptomatic until the development of complications, including acute bleeding from varices in the gut and liver cancer, all of which have an increased risk of death and often require high dependency or intensive care. Acute liver failure is a rare condition that also requires the same facilities. Many patients with complications of cirrhosis or acute liver failure need rapid referral to liver transplant centres.

Direct healthcare costs of liver disease are currently in excess of £0.5bn per annum and

[1] National Plan for Liver Services UK, 2009, British Associate for the Study of the Liver (BASL) & British Society of Gastroenterology (BSG) British Liver Trust (Analysis of Office of National Statistics Mortality Data)

rising by 10% per year[2]

It is estimated that there are about 640,000 known liver patients in England as at 2009/10 with HES data showing that there were approximately 150,000 inpatients treated for liver disease at NHS Acute Trusts in 2009/10.

Frontline clinicians have seen an increase in people presenting with liver disease, often detected by abnormal liver function tests in blood, routine abdominal ultrasound imaging or jaundice, and in the numbers of referrals for investigation of liver disease – liver disease now accounts for almost 25% of outpatient referrals and 50% of inpatient admissions to Gastroenterology services.

The liver is frequently affected by cancer (both primary and secondary, spreading to the liver because of its rich blood supply). Pancreatic cancer remains largely incurable. 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. Liver cancer responds better to treatment with improved outcomes when the cancer is detected by ultrasound at earlier stages. Currently surveillance is only instituted with local protocols. Cholangiocarcinoma, cancer of the bile ducts is increasing in incidence in the UK and elsewhere.

There are 100 new cases per million population per year of pancreatic cancer; 35 per million of population of new malignant cases of periampullary/cystic tumours and 25 per million of population of premalignant pancreatic and duodenal lesions. Resection rates and 5 year survival rates vary two-fold across the UK. In some cancer networks, up to 40% of patients are still not referred or discussed with the specialist pancreatic team. There is no national guidance on the screening of high risk groups.

There are 600 new cases per million population of acute pancreatitis and 50 new cases per million population per year of chronic pancreatitis.

Complex non-transplant HPB surgery (cancer and non-cancer) has already been centralised under the 2001 Improving Outcomes Guidance (IOG) for upper gastrointestinal (GI) cancer management. Each centre ideal serves 3 million population and, in exceptional geographic circumstances, a minimum of 2 million.

Evidence Base:

Available from the National Institute of Health and Clinical Excellence (NICE) - www.nice.org.uk

- NICE (2001) 'Improving outcomes on upper GI cancers, NICE Cancer Service Guidance'
- NICE (2000) 'Guidance on the use of ribavirin and interferon alpha for hepatitis C, NICE Technology Appraisal (TA)14'

[2] Consultation on a Strategy for Improving Liver Disease Outcomes in England 2011, Department of Health

- NICE (2004) 'Interferon alpha and ribavirin for the treatment of chronic hepatitis C– part review of existing guidance no.14, NICE Technology Appraisal TA75'
- NICE (2006) 'Adefovir dipivoxil and pegylated interferon alfa-2a for the treatment of chronic hepatitis B, NICE Technology Appraisal TA96'
- NICE (2006) 'Peginterferon alfa and ribavirin for the treatment of mild hepatitis C, NICE Technology Appraisal TA106'
- NICE (2010) 'Hepatocellular carcinoma (advanced and metastatic) - sorafenib (first line), NICE Appraisal' TA189
- NICE TA176 (2009) 'Use of cetuximab in first line treatment of unresectable kras wild type liver limited metastatic colorectal cancer'
- NICE Clinical Guideline (CG)131 (2011) 'Guidance on the management of colorectal cancer'
- NICE TA252 (2012) 'Telaprevir for the treatment of genotype 1 chronic hepatitis C'
- NICE TA253 (2012) 'Boceprevir for the treatment of genotype 1 chronic hepatitis C

NB: Liver related quality improvement measures (QIs) and quality standards (QSs) are now being finalised by NICE and will be available at the end of the 2012-13.

Available from the Department of Health

- Guidance on commissioning cancer services: Improving outcomes in upper gastro-intestinal cancer, the manual. (Note: this includes pancreatic cancer), Department of Health (2001)
- National survey of hepatitis C services in prisons in England. Department of Health (2012), Cathie Railton (nee Gillies), Dr Autilia Newton, Dr Eamonn O'Moore, Professor Martin Lombard

Available from NHS Liver Care – www.liver.nhs.uk

- Liver Disease Patient Landscape and Care Provision, 2011, http://www.liver.nhs.uk/publications/
- Deaths from liver disease: Implications for end of life care in England (2012), www.endoflifecare-intelligence.org.uk

Available from the British Association for the Study of the Liver – www.basl.org.uk

- British Association for the Study of the Liver, the British Society of Gastroenterology (Liver Section) (2009), A Time to Act: Improving liver health and outcomes in liver disease. (The National plan for liver services 2009)

Available from the British Society of Gastroenterology – www.bsg.org.uk

- The British Society of Gastroenterology has developed guidelines for the management of acute liver failure, the various advanced complications of cirrhosis hepatocellular cancer and cholangiocarcinoma, colorectal liver metastases, pancreatic and periampullary cancers, acute pancreatitis.

Available from the Association of Upper Gastrointestinal Surgeons of Great Britain & Ireland – www.augis.org

- Association of Upper Gastrointestinal Surgeons, 2010. Guidance on minimum surgeon volumes
- Association of Upper Gastrointestinal Surgeons of Great Britain & Ireland, (AUGIS), Provision of Services Document, 2011

Other

- Gruen R. L., Pitt V., Green S., Parkhill A., Campbell D., Jolley D. The effect of provider case volume on cancer mortality: systematic review and meta-analysis. CA Cancer J Clin 2009; 59: 192-211.
- EASL–EORTC Clinical Practice Guidelines: Management of hepatocellular carcinoma, Journal of Hepatology 2012 vol. 56 j 908–943

2. Scope

2.1 Aims and objectives of service

The aim of the service is to provide specialist treatment and care for adolescent and adults with agreed hepatobiliary and pancreatic diseases (as set out in section 2.2 below). This will be in accordance with the best available evidence or, in the absence of evidence, in line with best practice /consensus of clinical opinion in order to maximise the health outcomes and quality of life for the patient.

For most conditions in these categories patients have a common presentation (jaundice, abnormal LFTs, abnormal radiology) and the professional expertise and training required usually encompasses all three areas of liver, hepatobiliary and pancreas. Services will, therefore, be configured as described below, providing a multi-disciplinary approach to diagnosis and treatment and care, delivered through a network model.

The main diagnostic and monitoring methods include blood laboratory diagnostics (e.g. biochemistry, immunology, virology); endoscopy, (e.g. upper and lower, both routine and emergency); histopathology, (e.g. biopsies including of the liver and pancreas); and radiological investigations, (e.g. ultrasounds, computerised tomography (CT) and magnetic resonance imaging (MRI)).

Treatments offered include medical, surgical or interventional radiology management of acute and chronic liver failure and diseases requiring complex multidisciplinary interventions; antiviral treatment of complex hepatitis C infection; chemotherapy and surgical treatment of primary and secondary cancers of the liver and the pancreas and other specialised elective and emergency hepatobiliary surgery and interventional radiology.

Overall the broad objectives of the service are to:

- provide accurate and timely diagnosis utilising best practice in the assessment of these specialised conditions, with protocols to enable rapid access for new and existing patients,
- deliver evidence based treatment plans depending on personal circumstances of the individual and in line with agreed and published standards and guidelines, (or best practice/clinical consensus where limited evidence exists),
- ensure treatment is provided consistently and equitably provided to all individuals independent of social circumstances, behaviour and lifestyle choices,
- ensure early identification of patients with complex multisystem disease, ensuring that they have timely access to specialist care,
- ensure the establishment of appropriate shared care arrangements between specialties for the management of co-morbidities directly associated with the patients' disease / condition,
- ensure integration of patient care between regional/national specialised centres and local services through the use of standardised shared-care protocols, ensuring that support is delivered as close to patients' homes as possible, but access to specialised services is maintained - a network model of care,
- audit patient outcomes and experience, to be shared with colleagues in other centres, enabling the dissemination of best practice and appropriate benchmarking of quality; to implement the results of national and local audits,
- enable patients to have access to clinical trials as appropriate.

Specifically the service will:

Hepatitis C (HCV):

- ensure HCV infected individuals with complex infections are supported to access and use treatment and care in order to reduce health inequalities in accessing antiviral therapy for hepatitis C and in order to improve morbidity and mortality,
- provide a consistent, comprehensive, effective and appropriate outpatient service for patients with complex HCV. This includes:
  - providing assessment in a specialist HCV clinic staffed by trained specialists and viral hepatitis nurses within 12 weeks of diagnosis (as per British Viral Hepatitis Group - BVHG - standards)
  - providing access to appropriate support including mental health services, dermatology and other specialists as required
  - conducting appropriate assessment and diagnostics on patients to determine appropriate, safe antiviral therapy for patients with complex HCV in line with National Institute for Health and Clinical Excellence (NICE) guidelines
  - providing consistent and equitable decision making and access to NICE approved drug therapies provided by appropriately trained and supported health care professionals in an environment that meets the needs of the patient
  - providing tailored and personalised support to individuals and empowering them

to manage their HCV through appropriate information and support. Patients should have information about their condition, their medication, how to contact services out of hours, and about local third sector organisations that can provide support. The aim is to help patients enact and maintain behaviour change to stay healthy and avoid onward transmission, to maintain optimal adherence to therapy, and to access primary/community and third sector services to support in the management of their HCV or related conditions. A multi-disciplinary approach is key
  - ensuring clear pathways/network arrangements are in place, publicised and implemented in respect of referral for liver transplantation.
- increase the proportion of patients with complex Hepatitis C achieving a sustained virological response and to minimise the side effects of therapy.

Hepatobiliary Surgery (HPB Surgery):

- provide complex tertiary elective and emergency HPB surgery in line with the NICE 2001 IOG for Upper Gastrointestinal Cancers and the nationally designated trauma centre network (2012). This includes meeting the standards for:-
  - early detection of liver disease in patients
  - 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 Improving Outcomes Guidance (IOG)
- provide 24/7 emergency HPB surgery cover for the designated Major Trauma Networks and Major Trauma Centres

Pancreatic Surgery

- operate a service consisting of a network of outlying hospitals (units) feeding into a pancreatic centre providing specialist care for a population of 2-4 million
- for suspected and confirmed pancreato-biliary cancers (pancreatic cancer and cystic tumours; lower bile duct cancer; duodenal cancer; ampullary cancer:
  - the centre will work with the units to enable first line diagnostic and palliative services for unresectable patients to be provided locally
  - more complex imaging such as endoscopic ultrasound will be provided in the centre
  - all patients with suspected pancreato-biliary cancers will be discussed at the centre specialist MDT meeting to formulate a decision regarding resectional, oncological or palliative treatment;
  - the pancreatic team will be constituted according to IOG.
- For acute pancreatitis:
  - each pancreatic centre will provide a specialist service.
  - patients with confirmed severe acute pancreatitis, according to modified Atlanta criteria, (approx 100 per million population per year) will have their details and 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 pancreatic centre (where facilities and expertise for minimally invasive and endoscopic therap will be available)
- For chronic pancreatitis:
    - patients will be transferred to the pancreatic 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 Service description/care pathway

The service is commissioned to provide treatment and care for the following specialised services for liver, biliary and pancreatic medicine and surgery:

- acute liver failure
- complicated chronic liver disease
- complicated viral hepatitis
- primary cancers of the liver and biliary tree
- secondary liver tumours
- non-cancer related complex hepatobiliary surgery
- pancreatic cancer including neuroendocrine tumours and cystic neoplasms
- benign pancreatic disease including acute and chronic pancreatitis.
- liver and pancreatic transplant services (where designated or referral to a such a centre where not)

Multidisciplinary Team (MDT) membership:

The hepatobiliary and pancreas MDT should have multidisciplinary teams who have the appropriate training, experience and resources to treat the relevant area(s) of HPB services.

- Dietician
- Gastroenterologist
- Hepatologist
- Histopathologists
- Nuclear medicine
- Oncologist
- Pathologist
- Radiologist (Diagnostic and Interventional)
- Radiotherapist
- Specialist nurses
- Surgeon

The MDT members must hold specific and relevant training, expertise and experience to

the relevant HPB condition.

The MDT must have agreed formal links; clinical policies and care pathways with the relevant cancer networks, harm reduction services and community based drug action teams and Hepatitis C and alcohol services.

It is essential that the full membership of the MDT has minuted discussion of all new cases.

Interventional Radiology

Interventioal radiology procedures need to be discussed and appropriately provided through the specialist HPB MDTs. Specialist HPB procedures would include:

- Transjugular Intrahepatic Portosystemic Shunt (TIPSS) and related shunt manipulation, trans-TIPSS embolisations etc.
- Tumour ablation: including alcohol ablation, radiofrequency ablation(RFA), microwave ablation (MWA), irreversible electroporation (IRE), high intensity focused ultrasound (HIFU) of hepatocellular carcinoma, metastatic colorectal cancer (mCRC), neuroendocrine tumour (NET) etc.
- Radio-embolisation and work-up(liver isolation embolisation), including nuclear medicine support
- Elective bland and chemo-embolisation of liver tumours
- Portal vein embolisation
- Elective management of complications of HPB surgery, both vascular and non-vascular
- Management of Budd Chiari syndrome needing dilatation, stenting or TIPSS
- Elective management of post- liver transplant complications, eg.vein and artery stenoses and biliary strictures.

Network Model

Due to the interrelated and complex nature of hepatobiliary and pancreas services the expectation is that these services will be delivered by a multidisciplinary team through a network model. Where appropriate the services and care will be delivered near to the patient, but with clear and robust referral protocols and pathways to the specialist HPB centre where required, (either at the HPB centre itself or to an outreach team at the local provider). The key principle is that the patient will have timely and appropriate access to the required level of diagnostics, treatment and care wherever and whenever in the network they present.

It is not the intention in supporting a network model of delivery that all complex or specialist procedures or care are only undertaken at the specialist centre. Rather it is in the intention that by delivering care through a network model that there will be increased local access to complex or specialist procedures and care, but within an appropriate framework which ensures that the required expertise, resources, support and clinical governance are available, standards followed and outcomes reported. Configuration of the network and the patient pathway will be for local determination by commissioners and clinicians

informed by this specification, best practice, the location of providers and the needs of patients.

General Overview of the Service

The following HPB disorders should be provided either by the specialist HPB centre itself within a multidisciplinary setting or where appropriate, through outreach clinics run by a specialist team at the local centre via a network model:

- initiation of active treatment (chemotherapy, radiotherapy, surgery, tumour ablation and embolisation) of all HPB cancers (both primary HPB and those metastasising to the liver including NETs [cross reference Specialised Cancers, Specialised Endocrinology]) in line with the 2000 National Cancer Plan, 2007 Cancer Reform Strategy, and 2012 NICE Quality Standards for colorectal cancer management
- treatment with curative intent for all tumours (malignant and benign) involving the liver, bile ducts and pancreas
- acute or chronic liver failure requiring escalation to Level 2 or Level 3 dependency care
- management of complex portal hypertension requiring TIPSS insertion
- all strictures (narrowing) of the bile ducts and pancreatic ducts of any aetiology requiring surgery
- biliary manometry
- patients with chronic Hepatitis C viral infection requiring treatment that necessitates specialised input. This includes patients with genotype 1 infection requiring protease inhibitors, patients co-infected with HIV, presence of haemophilia, presence of blood dyscrasias, chronic kidney disease 3-6 and/or cirrhosis.
- complications of acute pancreatitis requiring surgical intervention
- chronic pancreatitis requiring surgery
- liver, biliary and pancreas trauma, including iatrogenic bile duct injuries following laparoscopic cholecystectomy
- clinical genetics services for patients with benign and malignant hereditary HPB disorders.

Acute liver failure (all causes e.g. drug or viral in origin)

- The commonest causes of acute liver failure are drug-induced (mainly paracetamol)
- The second most common cause is viral hepatitis. The severity of the liver disease and the rapidity of the onset (very rapid in the case of fulminant hepatic failure) determine the clinical necessity for treatment at the specialist liver centre or a liver transplant centre.

Complicated chronic liver disease (usually cirrhosis) – e.g. with coma, bleeding, renal failure

The most common cause of chronic liver disease is non-alcoholic fatty liver disease but the most common cause of complicated chronic liver disease is alcohol. More advanced or complex cases of chronic liver disease require specialist multidisciplinary expertise

involving hepatologists, HPB surgeons, pathologists and radiologists and care for these patients is provided either by the local hospital with support from the liver centre via a network model, or at the liver centre itself depending on the expertise available in the local hospital.

Advanced complications of cirrhosis include:

- uncontrollable variceal haemorrhage – this may require advanced interventional radiological management, e.g. transjugular intrahepatic portasystemic stent shunt (TIPSS,which is generally only available in liver centres; more rarely this may require surgical management
- intractable ascites (despite therapy with high dose diuretics and paracentesis) – this may also require TIPSS
- hepatorenal syndrome – this frequently requires joint input from specialist liver and renal services in a centre experienced in both liver and renal support
- multi-organ failure - patients have poor survival rates although with high quality category 3 support, over 30% of patients survive. Some are transferred after discussion with a liver centre depending on whether transfer and specialist therapy is possible.

In many cases, specialist input is needed to diagnose and treat uncommon liver diseases e.g. cases of primary sclerosing cholangitis, Budd Chiari syndrome, Wilson's disease and metabolic liver disease. While mild cases of many of these conditions are treated by hepatologists in local hospitals, it is the severity and need for specialist therapy that determines discussion with the centre and need for transfer.

Complicated viral hepatitis – e.g. HIV co-infection or hepatitis related to haemophilia

Some patients with particular complications will need to be treated at the specialist liver centre, e.g. co-infection with HIV, haemophilia, cirrhosis, drug-resistant hepatitis, patients with genotype 1 infection requiring protease inhibitors, patients with severe complications of therapy and multi-organ failure. In a few cases referral for transplant may be necessary.

Care of patients with viral hepatitis should be considered in conjunction with the service specification for infectious diseases which deals with patients with non-complicated viral hepatitis.

Primary cancers of the liver and biliary tree (hepatocellular carcinoma and cholangiocarcinoma)

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 MRI with special contrast agents, and careful case selection for these modalities is required to achieve optimal result. This is best done by a liver 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 liver centres. Treatment options include:

- surgical management (curative resections, palliative bypass surgery or liver transplantation in selected cases)
- interventional radiological management (percutaneous ethanol injection, radiofrequency ablation, microwave ablation, focused ultrasound, chemoembolisation)
- endoscopic stenting and other endoscopic therapies of biliary tumours
- chemotherapy
- palliative endoscopic stenting is provided by many local hospitals based on agreed protocols
- national or local cancer networks

This service specification should be considered in conjunction with the chemotherapy service specification

Secondary liver tumours - colorectal, neuroendocrine

Colorectal cancer (CRC) secondary tumours in the liver are one of the most common of liver tumours. Imaging, using computerized tomography (CT) and magnetic resonance imaging (MRI), is performed in most local hospitals, but decisions on surgery and interventional radiology will be taken by the specialist liver 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 local hospitals as an emergency and initial stabilization may take place there, before discussion of the case with a liver centre. Transfer to a liver centre is usually required for further imaging and a decision on surgery or interventional radiology. Where the acute liver damage 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, then liaising with the liver centre depending on severity of the case.

Pancreatic cancer including duodenal cancers, neuroendocrine tumours and cystic neoplasms

Pancreatic centres provide a multi-disciplinary approach which involves surgical, medical,

endocrine, interventional endoscopy and radiology and pathology 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. (Note: 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 pancreatic 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. Increasingly patients with acute pancreatitis and chronic pancreatitis are discussed with the pancreatic centre and severe acute pancreatitis cases are often transferred urgently from the local hospital to the pancreatic centre. More severe cases are transferred to the pancreatic centre.

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 a pancreatic centre.'

Infrastructure Required

- Theatres
- Outpatient Clinics
- Access to critical care intensive treatment unit (ITU) facilities
- Remote / networked access to diagnostics and results; referrals; advice and guidance
- Patients with HPB conditions and clinicians treating them require extensive access to CT, MRI, Nuclear Medicine and PET scanning services. This service specification

should therefore be read in conjunction with the CT, MRI and PET scanning service specification.

Excluded from the scope of this service specification:

- management, monitoring and surveillance of cirrhosis, alcoholic liver disease, non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD) not requiring intervention
- prevention, identification and treatment of viral Hepatitis B
- prevention, identification and treatment of viral Hepatitis C, other than complex cases outlined above
- simple gallstone disease without suspicion of gallbladder cancer
- acute and chronic pancreatitis not requiring surgery
- initial diagnostic investigations of suspected HPB cancers under the direction of the designated HPB specialist MDT
- diagnosis and initial assessment of jaundice
- delivery of outpatient chemotherapy for HPB cancers by outreach teams from the centre
- outreach oncology clinics led by the specialist team from the centre
- palliative/best supportive care for patients with incurable HPB cancers
- identification and surveillance of populations at risk of HPB cancers

2.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner, and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).
*Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

Specifically, this service is for adults requiring medical and surgical treatment for one or more of the following conditions:

- liver transplant, (see separate specification)
- pancreas transplant, (see separate specification)
- acute liver failure
- complicated chronic liver disease
- complicated viral hepatitis
- primary cancers of the liver and biliary tree
- secondary liver tumours
- non-cancer related complex hepatobiliary surgery
- benign and malignant tumours of the pancreas, biliary tract, duodenum and ampulla including pancreatic cancer, neuroendocrine tumours and cystic neoplasms
- benign pancreatic disease including acute and chronic pancreatitis.

Patients are referred from general practitioners, hospital consultant for medical or surgical assessment and management of specialised hepatobiliary diseases or conditions. Once referred the patient will be assessed by a specialist multidisciplinary team.

The service is accessible to all patients with a suspected specialised hepatobiliary disease or condition regardless of sex, race, or gender**.** Providers 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 providers will use translators and printed information available in multiple languages.

The provider has a duty to co-operate with the commissioner in undertaking Equaliy Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equalit legislation.

2.4 Any acceptance and exclusion 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 has a duty to query the content of a referral prior to accepting it if the information provided does not indicate that the patient has a condition that fits into the specialised hepatobiliary and pancreas service. If a service chooses to query a referral it must do so within 48 hours.

2.5 Interdependencies with other services

Liver, biliary and pancreatic services depend upon adequate provision of a number of services including the following:-

Services generally required to be onsite:

Cancer Services - involvement of oncology services is required in the management of patients with liver, hepatobiliary and pancreatic cancer.

HCV services - links to referring hospitals, local substance misuse services, liver transplant centres, HPB centres, human immunodeficiency virus (HIV), haemophilia, thalassemia and renal services

Gastrointestinal 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. Likewise, non-complex hepatology (viral hepatitis, metabolic parenchymal liver disease, 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.

Dietetics – specialist advice and support around diet as well around temporary and permanent parenteral feeding.

Renal Services - Renal dialysis is frequently required in patients with acute liver failure and occasionally in patients with decompensated chronic liver disease (hepatorenal syndrome).

Services which don't generally need to be on-site but to which rapid access is required:

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.

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 - urgent liaison is needed for cases of acute liver failure following self-poisoning where liver transplantation is being considered. 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 pancreatic 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.

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

Morbid Obesity Services - morbid obesity commonly results in fatty liver disease and this may progress to cirrhosis. Therapy for morbid 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; diagnostics; blood and blood products; X-Ray, CT, MRI 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.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Core Standards:

- NICE (2001) 'Improving outcomes on upper GI cancers, NICE Cancer Service Guidance'
- NICE (2000) 'Guidance on the use of ribavirin and interferon alpha for hepatitis C, NICE Technology Appraisal TA14'
- NICE (2004) 'Interferon alpha and ribavirin for the treatment of chronic hepatitis C – part review of existing guidance no.14, NICE Technology Appraisal TA75'
- NICE (2006) 'Adefovir dipivoxil and pegylated interferon alfa-2a for the treatment of chronic hepatitis B, NICE Technology Appraisal TA96'

- NICE (2006) ‘Peginterferon alfa and ribavirin for the treatment of mild hepatitis C, NICE Technology Appraisal TA106’
- NICE (2009 - tbc) ‘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 typ liver limited metastatic colorectal cancer’
- NICE CG131 (2011) ‘Guidance on the management of colorectal cancer’
- NICE TA252 (2012) ‘TelaprevirTelaprevir for the treatment of genotype 1 chronic hepatitis C’
- NICE TA253 (2012) ‘Boceprevir for the treatment of genotype 1 chronic hepatitis C’
- Department of Health. Guidance on Commissioning Cancer Services: Improving Outcomes in Upper Gastrointestinal Cancers, London 2001

Recommended Standards:

- Association of Upper Gastrointestinal Surgeons, 2010. Guidance on minimum surgeon volumes http://www.augis.org/pdf/reports/AUGIS_recommendations_on_minimum_volumes.pdf
- British Viral Hepatitis Group, Provision of antiviral services for patients with chronic viral hepatitis, 2010

4. Key Service Outcomes

General Outcomes:

- increased earlier diagnosis of liver disease so that treatment can start earlier when they are more effective
- mortality: In and out of hospital mortality (including cause of death). Comparison with published survival data
- post-operative morbidity and mortality
- awaiting times and numbers: time to operation, time from referral to operation from hospital data systems
- 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
- maintenance of Disease Registry(ies)
- participation in clinical trials
- evidence of programme of joint working with non-specialist centres: Shared Care Protocols, Outreach Clinics

HCV Specific Outcomes:

- improved and equitable access to specialist HCV treatment and care and prescription of antiviral medication
- increase in the number of patients achieving a sustained virological response
- reduction in the number of HCV related inpatient admissions
- reduction in HCV related transplantation, liver cell cancer and decompensated cirrhosis

HPB Specific Outcomes

- improved and equitable access to specialist HPB treatment and care services for both elective and acute conditions
- reduction in transplantation due to late diagnosis / delayed access to treatment

Pancreatic Specific Outcomes

- improved and equitable access to specialist pancreatic treatment and care services for both elective and acute conditions