A02/S/b

2013/14 NHS STANDARD CONTRACT FOR CANCER: PANCREATIC (ADULT)

SECTION B PART 1 - SERVICE SPECIFICATIONS

Service Specification No.	A02/S/b
Service	Cancer: Pancreatic (Adult)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

National context

Diseases of the liver and pancreas are frequently interlinked through common aetiological causes such as alcohol, gallstones and diabetes, and 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.

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. Not infrequently, some aspects of such tertiary care can be administered closer to the patient’s home by the tertiary centre on an outreach hub and spoke basis.

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 tumours

There are around 2000 new cases a year of primary liver cancers, but it is more difficult to determine the numbers for metastases. There are around 2000 resections being undertaken per annum for metastatic colorectal cancers.

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 magnetic resonance imaging (MRI) with special contrast agents, and careful case selection for these modalities is required to achieve optimal results and 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.

Secondary liver tumours - colorectal, neuroendocrine

Colorectal cancer (CRC) secondary tumours in the liver are one of the most common of liver tumours. Imaging, using computed tomography (CT) and 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.

Pancreatic tumours

Pancreatic cancer refers to a malignant epithelial neoplasm of the pancreas. There are around 7,000 newly diagnosed cases of pancreatic cancer in England each year with a crude incidence rate of 13.6 per 100,000 population and similar rates seen in both sexes. Survival is poor with one-year relative survival estimates of around 19 per cent for both sexes. The most common type of pancreatic tumour, accounting for 90 per cent of these malignancies is pancreatic ductal adenocarcinoma, which arises within the exocrine component of the pancreas and is commonly referred to as “pancreatic cancer”. The remaining 10 per cent 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. Less than half of these will be malignant and management of cystic tumours is complex requiring careful assessment. Treatment is not appropriate in all cases.

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. A careful multidisciplinary approach is therefore essential.

There are three defined levels of care to manage upper gastro-intestinal cancers:
- The diagnostic process.
- Local care.
- Specialist care.

The diagnostic process

Local services should be available to meet the two week standard for patients with suspected cancer. Patients should be referred in line with NICE referral guidelines for suspected cancer. Services will include direct access for GPs to Upper gastro-intestinal endoscopy and/or ultrasound as well as outpatient appointments.

All patients who are diagnosed with pancreatic cancer (or suspected or having the disease) should be individually discussed with a member of the specialist team prior to any proposed treatment. Subject to this and subject to agreement in the network's own guidelines, local care may be delivered under the care of a member(s) of the local upper gastro-intestinal team.

Local care

The treatment and procedures classed as local care are:
- Palliative stenting.
- Other endoscopic debulking methods to clear blockage by tumour, except intraluminal radiotherapy.
- Palliative chemotherapy.
- Palliative and supportive care, not involving active, tumour shrinking or debulking therapy.
- 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 and this is not subject to change by the network's own guidelines.

The treatments and procedures classed as specialist care are:

- All tumour resective 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. Palliative surgical bypass is a procedure that also carries high mortality and morbidity and this should also only be carried out at a specialist centre.
- 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 or perioperative chemotherapy (recommended currently only for gastric cancer).
    - Intraluminal radiotherapy
    - The 2001 guidance states each specialist team should aim to draw patients from a catchment area with a population of two to four million. A team with a population base of two million could expect to manage at on average 250 patients with pancreatic cancer who might require specialist treatment each year. In addition such a team would manage a further 200 patients per year with confirmed or suspected related pancreato-biliary tumours, periampullary tumours, duodenal tumours and cystic pancreatic tumours. Resections would be appropriate for about 15 per cent of pancreatic tumours and 40-50 per cent of malignant periampullary tumours. At least 60 per cent 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 specialist in the various forms of management. Centres covering populations lower than 2 million will not gain sufficient experience for individual members of the team.
    - 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 pancreatic 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.

Evidence base

This specification draws its evidence and rationale from a range of documents and reviews as listed below:

- Available from the Department of Health – www.dh.gov.uk
    - Improving Outcomes (IOG) in upper gastro-intestinal cancers Department

of Health (2001)
    - Improving Outcomes; a Strategy for Cancer – Department of Health (2011)
    - Cancer commissioning guidance - Department of Health (2011)
- Available from the national Institute of Health and Clinical Excellence – www.nice.org.uk
    - 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
    - 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
- National Cancer Peer Review
    - National Cancer Peer Review (NCPR) Handbook - National Cancer Action Team (2011)
    - Manual for Cancer Services: Upper gastro-intestinal measures, version 2.0 – NCPR, National Cancer Action Team (2011)
    - Manual for Cancer Services: Acute oncology measures – NCPR, National Cancer Action Team (April 2011)
    - Manual for Cancer Services: Chemotherapy measures NCPR, NCAT (June 2011)
- Other
    - Chemotherapy services in England. National Chemotherapy Advisory Group (2009)
    - The provision of services for upper gastrointestinal surgery, The Association of Upper Gastrointestinal Surgeons (AUGIS), November 2011
    - UK Guidelines for the management of patients with pancreatic cancer, periampullary and ampullary cancers (2005) - currently being updated in 2011-2012
    - AUGIS Guidance on minimum surgeon volumes (2010)

2. Scope

2.1 Aims and objectives of service

The aim of the service is to provide specialist treatment and care for adults with agreed hepatobiliary and pancreatic diseases (as set out in section 2.2 below), in accordance with the best available evidence or in the absence of evidence in line with best practice / consensus clinical opinion 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 pancreatic and hepatobiliary multi-disciplinary team.

The specialist hepato-billiary (HPB) service will serve a population base for between 2-4million, agreed and signed off by commissioners. Work is currently underway with the national cancer peer review programme to develop some further specific requirements as their IOG did not cover the HPB service in detail.

The specialist pancreatic cancer service will serve a population of 2 million people or more, agreed and signed off by commissioners. The service is required to agree the following areas with their local cancer networks:

- Service configuration and population coverage
- Referral criteria, clinical protocols and network policies and treatment pathways
- Engagement with the local networks groups and national cancer peer review for pancreatic tumours

The overall objectives of the services are:

- To provide an exemplary and comprehensive service for all referred patients with suspected pancreatic or periampullary cancer.
- To identify those individuals at high risk of developing pancreatic and duodenal cancer and to develop a clear plan for monitoring them.
- To ensure radiological, pathological and diagnostic facilities are available in order to effectively diagnose, classify and stage the condition prior to planning treatment.
- To advise and undertake investigations to plan whether the patient is appropriate for radical or palliative treatment and to provide high quality surgical treatment for patients with pancreatic cancer and high quality services for relief of obstructive jaundice by endoscopic retrograde cholangiopancreatography (ERCP) and interventional radiology.
- To ensure high quality supportive care and treatment for those patients not suitable for curative therapies.
- To carry out effective monitoring of patients to ensure that clinical treatment is safe and effective.
- To provide care to promote the optimal functioning and quality of life for each individual patient.
- To provide appropriate follow-up & surveillance after definitive treatment.
- To 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.
- To provide care with a patient and family-centred focus to minimise the unpleasant experience of the illness.
- To ensure that every patient with suspected or confirmed cancer is seen or discussed with the specialist team.
- To support local healthcare providers to manage patients with pancreatic cancer whenever it is safe to do so and clinically appropriate.
- To provide high quality information for patients, families and carers in appropriate and accessible formats and media.
- To ensure there is accurate and timely information given to the patient's General Practitioner.

- To ensure that there is involvement of service users and carers in all aspects of the service.
- To ensure there is a commitment to continual service improvement.
- To ensure compliance with peer review cancer measures
- To ensure compliance with Care Quality Commission regulations[1].
- To identify individuals at risk of pancreatic and related tumours and provide appropriate genetic counselling and screening.

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 IOG.

2.2 Service description/care pathway

Multidisciplinary team membership

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

- Hepatologist.
- Surgeon.
- Gastroenterologist.
- Dietician.
- Radiologist.
- Radiotherapist.
- Oncologist.
- Pathologist.
- Histopathologists.
- Specialist nurses.

The multidisciplinary team members must hold specific and relevant training, expertise and experience to the relevant HPB condition.

The multidisciplinary team must have agreed formal links; clinical policies and care pathways with the relevant cancer networks. It is essential that the full membership of the multidisciplinary team has minuted discussion of all new cases.

The specialist multidisciplinary team shall deliver the service in line with the following:

- The gastroenterology and surgical team shall work very closely together.
- They shall work with other team members to plan treatment according to designated treatment protocols. Individuals shall work together with the same aims and clinical understanding of the condition and its management
- To create a multidisciplinary team approach. The team will ensure that:
  - All patients are discussed at a specialist multidisciplinary team.
  - All jaundiced patients presenting with mild to moderate jaundice should have the opportunity to be fast-tracked to early surgery without drainage. Logistical reasons should not prevent fast-tracking of patients.
  - All curative pancreatic surgery shall be carried out by the designated surgical teams.
  - In the majority of patients an absence of a tissue diagnosis should not delay referral for surgery.
  - A tissue diagnosis by histology or cytology is required before chemotherapy or radiotherapy. This will be achieved by biliary brushings, EUS guided fine needle aspiration, direct endoscopic biopsy, laparoscopic biopsy, ultrasound or CT guided biopsy, or at open surgery.
- There will be agreed protocols for urgent transfer of patients from outlying hospitals within a specified time. For instance a patient in whom biliary drainage has failed should be transferred with 24 hours.
- Inpatients shall be reviewed daily on a ward round supported by core members of the specialist team with input from other members as clinically required. Care plans shall be clearly documented in the notes. Relevant investigations will be carried out. Urgent referrals will be discussed on a daily basis and the need for urgent transfer arranged as necessary.
- The timing of surgery will be discussed between the pancreatic surgical team and other members of the specialist team according to evidence based treatment protocols agreed with the local cancer network.
- There will be a weekly multidisciplinary team meeting led by the pancreatic cancer team at the pancreatic centre. All patients will be discussed at this meeting and a formal treatment plan agreed. At the multidisciplinary team the stage of disease at presentation will be documented. At a minimum this should be recorded as locally respectable, locally advanced and/or distant metastatic
- Direct input to the specialist multidisciplinary team by referring clinicians from outlying hospitals is expected. This might be by a weekly visit from a pancreatic surgeon or gastroenterologist from the centre to the referring hospital's multidisciplinary team or by videoconferencing between the centre and the cancer units.
- The specialist multidisciplinary team decision will be relayed to the cancer unit within 24 hours by fax or electronic transfer.
- There will be a reliable process for electronic image transfer between the cancer units and the cancer centre which is also available for emergency patients.
- Aside from or as part of the weekly multidisciplinary team meeting, a weekly team meeting at the centre will be held to discuss urgent admissions, to audit the complications of surgery and to address service delivery and governance issues.

- There will be agreed clinical protocols for the oncological treatment of patients with pancreatic cancer and related cancers.

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 Neuro-Endocrine Tumours (NETs) to be in line with the 2000 National Cancer Plan, 2007 Cancer Reform Strategy, and 2012 NICE Quality Standards for colorectal cancer management.
- NETs management should reference the Specialised Hepato-Biliary and Pancreas service specification, and Specialised Endocrinology service specification.
- Treatment with curative intent for all tumours (malignant and benign)
- Involving the liver, bile ducts and pancreas.

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 results and 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
- Photodynamic therapy
- Palliative endoscopic stenting is provided by many local hospitals based on agreed protocols (national or local cancer networks).

Secondary liver tumours - colorectal, neuroendocrine

Colorectal cancer (CRC) secondary tumours in the liver are one of the most common of liver tumours. Imaging, using CT and 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.

Members of the specialist pancreatic cancer multidisciplinary team

All members of the multidisciplinary team should be specialists in the management of pancreatic cancer. The number of people required to fulfil each role will depend on the team's workload.

- A designated lead clinician (physician or surgeon) who will take overall responsibility for assessment and treatment of patients with pancreatic cancer.
- Specialist HPB surgeons - these surgeons will also operate on patients with non-malignant disease, since malignancy may not be confirmed until after resection. There should be at least four pancreatic or HPB surgeons within the team.
- Gastroenterologists.
- Anaesthetists/intensivists.
- Radiotherapy specialists (clinical oncologists).
- Chemotherapy specialists with expertise in the treatment of upper gastrointestinal cancers (medical oncologist or clinical oncologist).
- Radiologists with a specific pancreatic interest.
- Interventional radiologists.
- Histopathologists.
- Cytopathologists.
- Dieticians
- Clinical nurse specialists.
- Palliative care and pain management specialists.

At least two members of the team (surgeon, gastroenterologist or radiologist) should be trained in pancreato-biliary endoscopic ultrasonography

- There should be a single named lead clinician for the specialist pancreatic cancer service who should also be a core team member.

Members of the specialist multidisciplinary team for HPB services

Work is underway by the national cancer peer review team working closely with members of the hepatobiliary clinical reference group to develop this section specifically for the HPB service. Other sections of this service specification will be revised once the measures have been agreed.

Patient Experience

The service should be patient centred and should respond to patient and carer feedback. Excellent communication between professionals and patients is vital and can prevent complaints and improve patient satisfaction. The service should be in line with the markers of high quality care set out in the NICE quality standard for patient experience in adult NHS services.

Patient experience is reported in the National Cancer Patient Survey. In this survey patients with a Clinical Nurse Specialist (CNS) reported much more favourably than those without on a range of items related to information, choice and care. The national programme for advanced communications skills training provides the opportunity for senior clinicians to improve communications skills and all core multidisciplinary team members who have direct clinical contact with patients should have attended this.

Patient Information

Every patient and family / carer must receive information about their condition in an appropriate format. Verbal and written information should be provided in a way that is clearly understood by patients and free from jargon The information must cover:

- Description of the disease.
- Management of the disease within the scope of the
- commissioned service as described in the specification, clinical pathways and service standards
- Drugs and other treatments commissioned in the clinical pathway.
- Self-management and care.
- Dietary and nutrition information.
- Contact details of the patient's allocated key worker.
- Support organisations or internet resources recommended by the clinical team.

The service must also provide education to patients and carers on:

- Symptoms of infection.
- Wound healing problems.
- Contact in case of concern.
- A useful reference is the Information Prescription Service (IPS) which allows users, both professional and public, to create information prescriptions (IPs) for long-term health needs. http://www.nhs.uk/IPG/Pages/AboutThisService.aspx

Referral Processes and Sources

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:

- Pancreatic cancer.
- Duodenal cancer
- Bile duct cancer in the lower or mid-bile duct.
- Pancreatic cystic tumour.
- Pancreatic neuro-endocrine tumour.

Symptomatic patients

Referrals to the service will come from a local referring hospital. Steps prior to referral to the specialist team include:

- The local Upper GI cancer multidisciplinary team will already have organised a pancreas protocol CT scan
- The patient will have been informed of the suspected diagnosis
- The patient will have been referred to the specialist pancreatic cancer multidisciplinary team

A dedicated pancreas protocol CT is essential and should be performed by the upper gastro-intestinal diagnostic team at the local district general hospital. Because a patient with a biliary stricture and no past history of complicated gall bladder surgery has at least a 92 per cent chance of having cancer, (a proportion that is even higher if there is a mass present in the pancreas), all patients with suspected cancer must be referred to the specialist pancreatic team straight away. It is not appropriate to wait for this to be confirmed by the local upper gastro-intestinal multidisciplinary team. In the case of suspected cancer, differentiating cancer from non- calcific chronic pancreatitis and auto-immune pancreatitis is difficult and should be done by the specialist multidisciplinary team.

Patients can be referred direct from primary care, A&E or secondary care. To avoid delay in making the diagnosis, appropriate radiological investigations, including EUS, CT, MRI and PET are usually performed by the specialist multidisciplinary team. Following imaging and biopsy where appropriate, the case is discussed at the specialist multidisciplinary team.

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).

Diagnosis

The service shall work to network agreed assessment and referral guidelines that have been developed with the lead clinicians of the upper gastro-intestinal unit diagnostic teams. These guidelines are to ensure that:

- Patients with jaundice will have fast-track access to the upper gastro-intestinal unit diagnostic team for initial assessment by abdominal ultrasound. If distal biliary obstruction is confirmed with no gallstones, pancreas protocol CT should be carried out on the same day and the patient referred immediately to the specialist pancreatic cancer multidisciplinary team.
- Patients who have pain or other symptoms which could be due to pancreatic cancer will also 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. 50 per cent of pancreatic cancer patients present through an emergency route so it is important to have good emergency systems in place. Providers should:

- Develop an algorithm to support decision-making in A&E or primary care
- Set up an emergency communication alert system service for GPs/A&E/ Assessment units/ clinicians to enable rapid specialty assessment and outpatient investigations.

Imaging, Endoscopy and Pathology

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

Further assessment of the tumour should be carried out at the centre and may involve EUS, MRI and/or laparoscopy. If biliary drainage is to be carried out this should be discussed with the pancreatic 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 accredited2 and should include enhanced diagnostic and therapeutic facilities for EUS and ERCP

The endoscopic service at the pancreatic centre will provide interventional (linear) endoscopic ultrasound (EUS), including Fine Needle Aspiration (FNA). The results of EUS-FNA should be continuously audited. The services of an in-room cytopathologist to assess the quality of the fresh specimens should be available during EUS-FNA procedures.

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 the specialist multidisciplinary team by fully trained practitioners who have had specific training according to BSG guidelines.

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

The pathology services should comply with Clinical Pathology Accreditation (UK) Ltd (CPA)3 and the Human Tissue Authority (HTA).4

Staging

Clinico-pathological stage should be documented for all patients with detailed histopathology for resected cancers

Providers must include staging information in their cancer registration dataset (this will become mandated in the Cancer Outcomes Service Dataset from early 2013). Staging data are essential for directing the optimum treatment, for providing prognostic information for the patient and are also essential to the better understanding of the reasons behind the UK's poor cancer survival rates. Cancer stage is best captured electronically at multidisciplinary team meetings and transferred directly to cancer registries. Staging and other pathological data can also be extracted direct from pathology reports and sent to cancer registries.

Treatment and surgery

Surgeons based at the centre should provide a 24 hour advice service and an emergency outreach system to local hospitals for complex HPB problems. Increasingly enhanced recovery is starting to be adopted in upper gastro-intestinal surgery and providers are encouraged to adopt this approach where possible.

Adequate intensive care, high dependency facilities and specialist post-operative care (including out of hours consultant cover) must be provided to minimise peri-operative mortality.

Chemotherapy and Radiotherapy

The management of pancreatic cancer 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.

Refer to the following documents for more detailed description of these services:

- Adult Systemic Anti-Cancer Therapy (SACT/chemotherapy) service specification
- Radiotherapy model service specification 2012/13

Surveillance of untreated lesions

Protocols should be developed for the management of cystic lesions of the pancreas. 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 cancer specific guidelines will identify that som patients will need to continue receiving follow up from the specialised service but it is expected the majority will be able to receive follow up 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.

Dietician and nutritional support

All patients with upper gastrointestinal disease are at risk of dietary problems and should have access to full dietetic inpatient and outpatient services. Dieticians should be available to see patients during regular outpatient clinics and available for consultation on ward rounds and multidisciplinary team meetings.

Rehabilitation

There should be appropriate assessment of patients' rehabilitative needs across the pathway and the provider must ensure that high quality rehabilitation is provided in line with the network agreed upper gastor-intestinal rehab pathway at: www.ncat.nhs.uk/our-work/living-with-beyond-cancer/cancer-rehabilitation

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 an holistic needs assessment 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. The nurse specialist(s) 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.

Survivorship

The National Cancer Survivorship Initiative (NCSI) is testing new models of care aimed at improving the health and well being of cancer survivors. The new model stratifies patients on the basis of need including a shift towards supported self management where appropriate. In some circumstances traditional outpatient follow-up may be replaced by remote monitoring. The model also incorporates care coordination through a treatment summary and written plan of care.

Providers will need to ensure that future policy is incorporated into network guidelines to ensure that care can be provided as locally as possible.

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 Accident and Emergency (A&E) department should have an "acute oncology service" (AOS), bringing together relevant staff from A&E, general medicine, haematology and clinical/medical oncology, oncology nursing and oncology pharmacy. 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. For full details on AOS please refer to the service specification for chemotherapy which is currently being developed.

Care pathways

The local care pathway for pancreatic cancer should be consistent with the national pathway on the Map of Medicine. The process of producing the pathways and subsequent updates has been accredited by the National Cancer Action Team. http://eng.mapofmedicine.com/evidence/map/pancreatic_cancer1.html

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). Specifically, this service is for adults with pancreatic cancers requiring specialised intervention and management, as outlined within this specification.

The service is accessible to all patients with a suspected pancreatic cancer 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 Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation

2.4 Any acceptance and exclusion criteria

Referrals will usually be accepted from general hepatologists, gastroenterologists, 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.

2.5 Interdependencies with other services

Hepatobiliary Cancers

It is common for members of the pancreatic cancer team to provide services for hepatobiliary cancers often as part of a regional Hepato-Pancreatico-Biliary (HPB) 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. Because of the strong link it is not appropriate for pancreatic cancers and hepatobiliary cancers from a cancer unit to be referred to more than one cancer centre.

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 malignant pancreatic disease is not straightforward. The same specialists who treat pancreatic 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 pancreatic centres.

The specialist pancreatic cancer multidisciplinary team will link into multiple clinical and administrative including:

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

The specialist pancreatic cancer 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.

The specialist pancreatic cancer service providers should also provide education within the NHS to raise and maintain awareness of upper gastro-intestinal cancer specifically pancreatic cancer and their management.

The specialist pancreatic cancer service providers will form a relationship with local health and social care providers to help optimise any care for upper gasto-intestinal cancer provided locally for the patient. This may include liaison with consultants, GPs, community nurses or social workers etc.

Co-located services – Intensive/critical care services may be required for some patients undergoing complex surgery and providers will be required to refer to the service specification for critical care.

Strategic Clinical Networks

Strategic clinical networks will be in place from April 2013 located in 12 areas across England. They will be established in areas of major healthcare challenge where a whole system, integrated approach is needed to achieve a real change in quality and outcomes of care for patients. Cancer has been identified as one of the conditions that will be within this new framework. Strategic clinical networks will help commissioners reduce unwarranted variation in services and will encourage innovation. They will use the NHS single change model as the framework for their improvement activities.

- Each network area will have NSSG covering HPB cancers. This group is made up of clinicians across the network who specialise in HPB cancer. It is the primary source of clinical opinion on issues relating to HPB cancer within the cancer network and is an advisor to commissioners locally. The specialist pancreatic cancer multidisciplinary team should ensure they fully participate in the cancer network systems for planning and review of services.
- The NSSG is responsible for developing referral guidelines, care pathways, standards of care and to share good practice and innovation.
- They should also collectively implement NICE Improving Outcomes Guidance including the use of new technologies and procedures as appropriate and carry out network and national audits
- Each Cancer network should agree an up-to-date list of appropriate clinical trials and other well designed studies for pancreatic cancer patients and record numbers of patients entered into these trials/studies by each multidisciplinary team.

3. Applicable Service Standards

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

Care delivered by the specialist pancreatic cancer multidisciplinary team must be of a nature and quality to meet the CQC care standards and the IOG for pancreatic cancers. It is the Trust's responsibility to notify the commissioner should there be any breaches of the care standards. Where there are breaches any consequences will be the Trust's responsibility to address.

Pancreatic cancer services are required to achieve the two week wait for all patients where pancreatic cancer is suspected. In addition the services are required to meet the following standards for all pancreatic cancer patients,

- 31 day wait from diagnosis to first treatment.
- 31 day wait to subsequent treatment.
- 62 day wait from urgent GP referral or screening referral or consultant upgrade to first treatment

Teams should as a minimum aim to achieve the median value for compliance with the Cancer Peer Review measures, and if a team had immediate risks or serious concerns identified then remedial action plans should be in place.

Further details are available at www.cquins.nhs.uk

The provider must be able to offer patient choice. This will be both in the context of appointment time and of treatment options and facilities including treatments not available locally.
The service will comply with the relevant NICE quality standards which defines clinical best practice.

4. Key Service Outcomes

The service is expected to monitor the following clinical outcomes:

- Times from onset of symptoms (e.g. jaundice) to definitive treatment.
- Numbers of patients seen by specialist team
- Resection rates for ductal carcinoma and periampullary carcinoma.
- Resection rates for jaundiced patients without stenting (definition required).
- Proportion of surgical procedures during which anticipated resection is abandoned due to metastatic spread.
- Stage of disease at diagnosis – usually clinical stage.
- One, two and five year survival rates for each histological group.
- Peri-operative mortality rates and complication rates.
- Outcome (survival, response and complications) of all treatments.
- Adverse effects of ECRP and EUS.
- Number of patients who were never placed on a 62 day pathway.

5. Location of Provider Premises

Some regions do not have compliant services agreed or will be undergoing major reconfiguration so a list is not included in this section.

A list of current providers of these services is held by specialised commissioners