

CANCERS OF THE PANCREAS

PREFERRED MODEL OF CARE AND CRITERIA FOR REFERENCE CENTRES

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PREFERRED MODEL OF CARE AND CRITERIA FOR REFERENCE CENTRES

A. Type of cancer

Peri-ampullary and pancreatic cancers

B. Short description of the cancer

Peri-ampullary and pancreatic cancers are linked with a very poor prognosis, due to an aggressive biology, poor response to therapy, late diagnosis and no efficient screening program established. Their incidence is 13/100 000 in Belgium. Surgery combined with chemotherapy is the only curative therapy, but is only possible in 10-15% of the patients. For the locally advanced (35%) and metastatic (50%) patients, chemotherapy is the only efficient therapy, but remains palliative. Surgery is highly complex, linked with significant morbidity/mortality in non-expert hands. Furthermore, the accurate staging of the non-metastatic patients also needs expertise, so as not to consider for useless surgery those patients with locally advanced disease, but also not to overstage the patients that could be cured by surgery/chemotherapy. Multidisciplinarity is thus crucial in the diagnostic but also therapeutic stage, as peri-operative chemotherapy/chemo-radiotherapy combinations need to be accurately designed at the time of diagnosis.



C. Model of care pathway suggested for adult patients with pancreatic cancer

Model of care pathway	Preferred model
<p>1. <u>Model 1: Reference Centres exclusively (from diagnosis to follow-up)</u>. Once there is a suspicion of the pancreatic cancer or this cancer has been diagnosed, the patient should be referred to a Reference Centre. A network with other Reference centres or with specific experts working in other centres is encouraged.</p>	
<p>2. <u>Model 2: Shared care between Reference Centres and peripheral hospitals</u>. Part of the care pathway is performed in the Reference Centre and for another part of the care pathway, the patient is referred (back) to the peripheral hospital.</p>	
<p>3. <u>Model 3:</u></p> <p>Level 3: high reference centre</p> <ul style="list-style-type: none">• <u>Pathology to be treated at this level:</u> all pancreatic tumours with vascular reconstruction (portal vein, superior mesenteric vein, inferior vena cava, all surgery in patients ASA ≥ 3)• <u>Minimal requirements:</u> single balloon ERCP and interventional ERCP (Endoscopic retrograde cholangio-pancreatography), expertise in vascular reconstruction techniques + <i>minimal requirements of Level 2</i> <p>Level 2: reference centre</p> <ul style="list-style-type: none">• <u>Pathology to be treated at this level:</u> surgery in ASA 2 patients, with no vascular involvement and no risk for organ failure.• <u>Minimal requirements:</u> availability and knowledge of per-operative ultrasound, of ERCP and endoscopic ultrasound, interventional imaging (CT-guided punctures and angiography on 24/7 base), and being part of a team comprising 2 surgeons performing a minimum of 10 pancreas resections for cancer per year at one hospital site, as well as experienced GI-oncologists, radiation oncologists, pathologists and radiologists, defined as below. <p>Level 1: peripheral centre</p> <ul style="list-style-type: none">• No pancreatic surgery, only diagnosis (imaging) and follow-up	X



D. Phase(s) of the clinical pathway for which Reference Centres are required

Phase of the Clinical Pathway	Reference Centre (Level 2+3)	Peripheral centre (Level 1)
1. MOC	For non metastatic cancer	For metastatic cancer, based on current systemic treatments; subject to change with advances in treatment
2. Diagnostic confirmation	Molecular diagnosis	X
3. Comprehensive AP diagnosis	X	X
4. Therapeutic modalities:		
• Interventional therapies (radiology, gastroenterology; ERCP; EUS;..)	X	
• Surgery	Level 3	Level 2
5. Follow-up		X

Multidisciplinary Oncological Consult (COM/MOC)

Based on the stage, patients would be discussed in Peripheral Centre or Reference Centre, according to above defined model:

- Metastatic: Level 1
- Non-metastatic: Level 2 and 3

Diagnostic and staging confirmation

Pathology

- Diagnosis

Preoperative diagnosis is usually made on endoscopic ultrasound-guided fine needle aspiration cytology (EUS-FNA). Preoperative diagnosis can be made in all centres (Level 1, Level 2, Level 3) if pathologists have developed in their laboratory a method for collection of suitable material for ancillary immunocytochemical stains (e.g. preparation of cell blocks). Moreover, if pathologists feel uncertain about their diagnosis, the material can be sent to a pathologist with special experience in this topic for second opinion.

- Evaluation after resection

Appropriate handling of the resection specimen is possible in each laboratory. However, for rare tumour types, Level 2 centres will not have all immunohistochemical stains needed for differential diagnosis. It is advised that centres that do not have all antibodies required (as stated in the literature) send their cases for second opinion to a Level 3 centre with special experience in this type of pathology.



Pathology criteria to ask a second opinion

Adenocarcinoma with variants of pancreas	Does not need review in Level 2+3
Squamous cell carcinoma with variants of pancreas	Does not need review in Level 2+3
Carcinoma with osteoclast-like giant cells of pancreas	Does not need review in Level 2+3
Acinar cell carcinoma of pancreas and Solid pseudopapillary carc of pancreas	The distinction between acinar cell carcinomas, solid pseudopapillary tumours and neuroendocrine tumours cannot be made without ancillary immunohistochemical stains. There are however some pitfalls in interpretation of these immunohistochemical stains. It thus seems appropriate that they are analysed in a Level 3 centre OR by an expert panel.
Mucinous cystadenocarcinoma of the pancreas	Does not need review in Level 2+3 (tumours with similar characteristics occur in the ovary and are well known by pathologists, as they are less rare)
Intraductal papillary muc carc invas of pancreas	Does not need review in Level 2+3 In case the pathologist is not familiar with this type of tumour s/he can send it to a pathologist with more experience in this type of pathology for second opinion, especially in case there is doubt about the fact that there is invasion
Serous cystadecarcinoma of pancreas	Does not need review in Level 2+3 In case the pathologist is not familiar with this type of tumour s/he can send it to a pathologist with more experience in this type of pathology for second opinion

- Staging
The therapeutic strategy has to be planned in a reference centre (Level 2+3) for resectable and borderline resectable tumours (according to the [KCE report 105A](#) and NCCN guidelines, www.nccn.org). Concerning imaging, assess the quality of imaging, and if quality criteria are not met, repeat.
- Facilities and equipment required
Level 1 of the model
Professional expertise required both to perform the diagnostic procedure and to interpret the results
Level 1+2+3 of the model



Radiology

Multi-detector Computed Tomography (MD-CT) and/or Magnetic Resonance (MR) with Magnetic Resonance CholangioPancreatography (MRCP) are required for pancreatic and periampullary cancer detection and staging.

These cross-section imaging modalities should be performed before any endoscopic procedures to avoid the lack of useful diagnostic imaging features and also eventual post-procedural pancreatitis that may limit the ability to visualise the tumour and the interface between the tumour and the vessels.

Comprehensive AP diagnosis

- Complexity and new approaches: Level 1 of the model
- Facilities and equipment required, use of new technology to predict a tumour's aggressiveness or its response to certain forms of therapy, as well as to identify genetic abnormalities in some tumours: Currently, this does not apply to pancreas cancer. In the future, this will be performed in BELAC certified laboratories.
- Expertise required both to perform the cell or tissue sampling and to interpret the results: According to the model proposed, this will be performed in Level 2+3 centres. Pancreatic Cancer Pathology Reports should include all information necessary to provide quality patient care. Cancer Protocols and checklists are for example provided by the College of American Pathologists (CAP) at no charge, and are available on the CAP website. The protocols consist of cancer case summaries accompanied by background documentation.

Therapeutic modalities

- Complexity, new therapeutic strategies: Level 2+3; this is performed in centres doing research in the field. Clinical trials are performed in Level 2+3
- Facilities and equipment required: according to our model, Level 2+3 for surgery, Level 1 for chemotherapy.
- Expertise required to perform the treatment: according to our model, Level 2+3 for surgery
- Para-medical expertise required: Clinical nurse specialist (Onco-coach specifically dedicated to pancreas cancer patients), nutritionists, dieticians, psychologists specifically dedicated to pancreas cancer patients and introduced early in the care pathway, nursing staff with specific expertise in the management of operated pancreas cancer patients: Level 2+3

Follow-up

- Level 1 centre, based on current treatment options for recurrence.



E. General and specific criteria for Reference Centres (Level 2+3)

Human Resources and dedicated team

Specialized staff (number, qualification, experience...):

- Surgeon: Part of a team of 2 surgeons performing a minimum of 10 pancreas resections for cancer per year on one hospital site.
- Radiologist: At least two radiologists with main activity (> 50% of work time) in abdominal imaging (CT/MR) and in particular with dedicated interest in pancreatic diseases, including cancer.
- Gastroenterologist with endoscopic expertise:
 - Part of a team of 2 gastroenterologists performing ≥ 100 Endoscopic Retrograde Cholangio-Pancreatography (ERCP)/year and ≥ 50 Endoscopic ultrasound (EUS)/year, on one hospital site.
 - One Interventional radiologist, for the treatment of surgical complications (bleeding, collections)
- Pathologist
- GI oncologist: Part of a team of 2 GI oncologists seeing a minimum of 40 patients with pancreatic cancer/year on one hospital site.
- Radiotherapist
- Level 2+3 centres should have easy access to or collaborate with a team of at least 3 radiation oncologists, of which 1 radiation oncologist with experience in the treatment of digestive cancer, including concomitant chemotherapy, on one hospital site.
- One nutritionist - dietician on-site.
- At least one psychologist on-site specifically dedicated to the support of pancreas cancer patients and their families.
- Clinical nurse specialist (Onco-coach/ CSO) specifically dedicated to pancreas cancer patients.
- Nursing staff with specific expertise in the management of pancreas cancer patients (management of postoperative course after major pancreatic surgical procedures, management of complications...).

Multidisciplinary management:

Specialists required for a reference (Level 2+3) MOC: pathologist, gastroenterologist, GI-oncologist, radiologist with specific expertise in pancreas liver MRI/CT, nuclear medicine specialist, general surgeon with interest in HPB surgery, radiotherapist. Among the members, 3 specialists with proven experience based upon publications or study involvement or lectures during symposia and knowledge of guidelines.



Required facilities and equipment

- Surgery: See proposed model; i.e. Level 2+3:
 - Expertise how to perform vascular reconstructions in HPB surgery: Level 3 only
 - Minimal invasive surgery: Level 2+3
- Radiotherapy: Intensity modulated radiotherapy and/or intensity modulated arc therapy should be available; also the possibility to fuse planning images with FDG-PET images is recommended: Level 2+3
- Interventional imaging: CT-guided punctures and angiography on 24/7 base, Level 2+3
- Collaboration with a reference laboratory for molecular diagnosis

Patient centred care

- Waiting and throughput times: Maximum 1 week to first visit
- Continuity of care (care covered 7 days a week by specialised staff, agreements concerning the continuity of care...)
- Support services for the patient (care coordinator: nurse coordinator in oncology – CSO/ Oncocoach dedicated to pancreas cancer patients, Psychologist...)
- National and international networking with other Reference Centres (appropriate arrangements for referrals within Belgium and from/to other EU countries if applicable)
- Shared care: formal links with other hospitals, specialists and general practitioners (Consideration of E-Health solutions -e.g. shared case management systems, expert systems for tele-expertise and shared repository of cases-).

Minimal volume of patients

- 40 patients/centre/year for oncosurgical approach (including metastatic) → Level 2+3
- At least 10 pancreatic resections for cancer per year for a team of 2 surgeons at 1 hospital site, Level 2+3

Quality Assurance

- Capacity to propose quality indicators (structure, process, outcomes)
- Exhaustive and reliable information sent to Cancer Registry
- Compliance with existing guidelines and documentation of deviations from guidelines (e.g. NCCN guidelines, KCE guidelines)
- Involvement in quality initiatives (e.g. benchmarking)
- MOC Annual activity report ensuring transparency: advised but not required.



Research and other scientific activities

- Involvement in clinical studies (RCTs, cohort studies, translational studies), participation rate in clinical trials
- Publications in peer-reviewed journals
- Link with a tumour bank
- Development of clinical practice guidelines for diagnosis and care (e.g. Manual in oncology)

Educational activities: Teaching and dissemination

- Involvement in training and continuous education programs (annual or multi-annual training / educational programme for physicians, nurses, supportive disciplines)
- Organisation / communication in scientific congresses

Additional comments: Funding for second opinion in expert pathology and radiology is MANDATORY.