

Complex Surgery Pancreas and Peri-Ampullary Region - Registration form

Dataset established by the Expert Working Group and approved by the “Stuurgroep Complexe Chirurgie - Groupe de Pilotage Chirurgie Complexe” on 30/04/2019. – Revision September 2020



All variables are required to be filled out unless stated otherwise (e.g. 'if possible', 'if applicable').

- Single-select variables: only one answer can be selected
- Multi-select variables: one or more answers can be selected

Administrative patient data

Hospital:

Health insurance institution:

National number for social security (INSZ/NISS)*:

** if filled out in the WBCR application, the following variables will be completed automatically:*

Last name:

First name:

Postal code:

City:

Country:

Health insurance number: (if possible)

Date of birth:/...../..... (dd/mm/yyyy)

Date of death:/...../..... (dd/mm/yyyy) (if applicable)

Sex: Male
 Female

General information

Did the patient undergo surgery?

No

- Indication:

- Malignant tumour °
- Adenoma
- Cystadenoma
- Intraductal Papillary Mucinous Neoplasm (IPMN) with low grade or moderate dysplasia (8453/0)
- Other benign tumour, specify:
- Chronic pancreatitis
- Other, specify:

° Only to be filled out for a malignant tumour:

- Lesion to treat (in (peri-)pancreas)

Primary tumour §

Relapse of primary tumour

Metastasis (primary tumour not located in/near (peri-)pancreas) §

- Incidence date primary tumour/relapse: /..... /..... (dd/mm/yyyy)

- Primary tumour/relapse localisation:

- Histological diagnosis primary tumour/relapse:

§ Only to be filled out for a primary tumour or metastasis, not a relapse:

- Clinical TNM primary tumour (cTNM): cT: cN: cM:

- Pathological TNM primary tumour (pTNM): pT: pN: pM:

- MC/CM date:/...../..... (dd/mm/yyyy)

- MC/CM report, without patient identification variables (e.g. name, INSZ/NISS):
..... (include as text)



- Was the patient referred?
 - No
 - Yes
- Referring hospital: Belgian: or foreign:

If the patient did not undergo surgery, the registration can be terminated here.

- Yes

If the patient underwent surgery, please fill out the following variables

Indication:

- Malignant tumour *
- Adenoma
- Cystadenoma
- Intraductal Papillary Mucinous Neoplasm (IPMN) with low grade or moderate dysplasia (8453/0)
- Other benign tumour, specify:
- Chronic pancreatitis
- Other, specify:

** Only to be filled out for a malignant tumour:*

- Lesion to treat (in (peri-)pancreas)
 - Primary tumour §
 - Relapse of primary tumour
 - Metastasis (primary tumour not located in/near (peri-)pancreas) §
- Incidence date primary tumour/relapse: /..... /..... (dd/mm/yyyy)
- Primary tumour/relapse localisation:
- Histological diagnosis primary tumour/relapse:

§ Only to be filled out for a primary tumour or metastasis, not a relapse:

- Clinical TNM primary tumour (cTNM): cT: cN: cM:
- Pathological TNM primary tumour (pTNM): pT: pN: pM:

Type of FIRST diagnostic method:

- CT
- MRI
- PET
- PET/CT
- ERCP (endoscopic retrograde cholangio-pancreatography)
- EUS (endoscopic ultrasound)/endoscopy
- Surgery (laparoscopy/laparotomy)
- Date:/...../..... (dd/mm/yyyy)

Method to obtain first tissue sample for histopathological evaluation:

- ERCP (endoscopic retrograde cholangio-pancreatography)
- EUS (endoscopic ultrasound)/endoscopy
- Surgery (laparoscopy/laparotomy/'complex' surgery)
- CT
- MRI
- Date:/...../..... (dd/mm/yyyy)



MC/CM date:/...../..... (dd/mm/yyyy)

Surgeon 1: number RIZIV/INAMI:

Surgeon 2: number RIZIV/INAMI: (if applicable)

Please upload the following reports without patient identification variables (e.g. name, INSZ/NISS):

- MC/CM report: (include as text)
- Pathology report: (include as text)
- Surgery report: (include as text)

Was the patient referred?

- No
- Yes

- Referring hospital: Belgian: or foreign:
- Was there a M(O)C/C(O)M at the referring hospital?
 - No
 - Yes
 - Date:/...../..... (dd/mm/yyyy)
- Was the patient hospitalized at the referring hospital (before referral)?
 - No
 - Date of last consultation before referral:/...../..... (dd/mm/yyyy)
 - Yes
 - Date of discharge at the referring hospital:/...../..... (dd/mm/yyyy)

Patient characteristics

Height: cm

Weight at time of surgery: kg

WHO performance status at time of surgery:

- 0 - Asymptomatic, normal activity
- 1 - Symptomatic, but ambulant
- 2 - Symptomatic, bedbound <50% of the day
- 3 - Symptomatic, bedbound >50% of the day
- 4 - Completely dependent, 100% bedbound

ASA score (pre-operative risk):

- 1 - Healthy person
- 2 - Mild systemic disease, normal activity
- 3 - Serious systemic disease, limited activity
- 4 - Life-threatening illness, handicapped
- 5 - Dying

Comorbidity (prior to surgery) - Charlson Modified Index (not the current surgery indication!):

- No
- Yes
 - Myocardial infarction
 - Peripheral vascular disease
 - Cerebrovascular disease
 - Congestive heart failure
 - Connective tissue disease



- Mild liver disease
- Moderate-severe liver disease
- Moderate-severe renal disease
- Chronic pulmonary disease
- Peptic ulcer
- Hemiplegia
- Dementia
- Diabetes without any damage to end-organs
- Diabetes with damage to end-organs
- Any tumour (without metastasis)
- Leukaemia (acute or chronic)
- Lymphoma
- Metastatic solid tumour
- AIDS (not just HIV positive)

Is the patient currently (= at time of surgery) treated with antithrombotic medication?

- No
- Yes
 - B01AA: Vitamin K antagonists (e.g. warfarin)
 - B01AB: Heparin group (e.g. heparin)
 - B01AC: Platelet aggregation inhibitors excluding heparin (e.g. acetylsalicylic acid)
 - B01AD: Enzymes (e.g. streptokinase)
 - B01AE: Direct thrombin inhibitors (e.g. desirudin)
 - B01AF: Direct Xa inhibitors (e.g. rivaroxaban)
 - B01AX: Other antithrombotic agents (e.g. dermatan sulfate)

Surgery

Did the patient receive any other treatment modality before this surgical procedure?

- No
- Yes
 - Chemotherapy
 - Start date:/...../..... (dd/mm/yyyy)
 - Date latest treatment:/...../..... (dd/mm/yyyy)
 - Type of chemotherapy:
 - Gemcitabine-based regimen
 - FOLFIRINOX (5-Fluorouracil, Leucovorin, Irinotecan and Oxaliplatin)-based regimen
 - Other, specify:
 - Radiotherapy
 - Start date:/...../..... (dd/mm/yyyy)
 - Date latest treatment:/...../..... (dd/mm/yyyy)
 - Prior abdominal surgery
 - Type of surgery:
 - Date latest surgery:/...../..... (dd/mm/yyyy)
 - Other treatment modality (that could affect the pancreas), specify:



Date of surgery:/...../..... (dd/mm/yyyy)

Type of surgery:

- Minimally invasive surgery (MIS)
 - Total laparoscopic
 - Total robotic
 - Hybrid (laparoscopic + robotic)
- Open
- Conversion from MIS to open surgery
 - Reason for conversion:

Nomenclature code:

- 242830-242841: Pancreaticoduodenectomy
 - Pancreaticoduodenectomy
 - Total pancreatectomy
 - Localisation lesion:
 - Pancreatic head / peri-ampullary region
 - Pancreatic body or tail
- 242852-242863: Hemipancreatectomy left with jejunal anastomosis of the resection plane of the pancreas, or almost total pancreatectomy (95 pct)
- 242874-242885: Hemipancreatectomy left
- 242896-242900: Enucleation of a pancreatic tumour
 - Localisation tumour:
 - Pancreatic head / peri-ampullary region
 - Pancreatic body or tail

Simultaneous vascular resection?

- No
- Yes
 - Superior mesenteric vein/portal vein (SMV/PV) resection
 - Type of SMV/PV reconstruction:
 - with primary wedge-reconstruction
 - with primary end-to-end reconstruction
 - with vascular autograft interposition
 - with vascular allograft interposition
 - with synthetic/prosthetic interposition
 - with peritoneal patch wedge-reconstruction
 - without reconstruction
 - Arterial resection
 - Type of arterial resection:
 - Hepatic artery
 - Coeliac trunk
 - Superior mesenteric artery (SMA)
 - Type of arterial reconstruction:
 - with primary wedge-reconstruction
 - with primary end-to-end reconstruction
 - with vascular autograft interposition
 - with vascular allograft interposition
 - with synthetic/prosthetic interposition
 - without reconstruction



Simultaneous other organ resection?

- No
- Yes
 - Colon
 - Stomach
 - Sur-renal gland
 - Spleen
 - Other, specify:

** Only to be filled out for a malignant tumour:*

- Residual disease - resection margins:
 - R0: tumour-free resection margin > 1 mm
 - R1 indirect: tumour-free resection margin < 1 mm
 - R1 direct: tumour involvement of the resection margin
 - R2: macroscopic tumour transection

Lymphadenectomy:

- No
- Yes
 - Region:
 - Peri-tumoural
 - Coeliac trunk
 - SMA origin (superior mesenteric artery)
 - Para-aortic
 - Number of lymph nodes retrieved:
 - Number of lymph nodes with tumoural involvement:

Post-surgery

Postoperative complications (90 days post-op, in-hospital complications):

- No
- Yes
 - Type of postoperative complication(s):
 - Clinically relevant pancreatic fistula [cf. Bassi *et al.* (ISGPS), Surgery, 2017]
 - ISGPS grade B
 - ISGPS grade C
 - Haemorrhage [cf. Wente *et al.* (ISGPS), Surgery, 2007]
 - ISGPS grade A
 - ISGPS grade B
 - ISGPS grade C
 - Delayed gastric emptying [cf. Wente *et al.* (ISGPS), Surgery, 2007]
 - ISGPS grade A
 - ISGPS grade B
 - ISGPS grade C
 - Bile leakage [cf. Koch *et al.* (ISGLS), Surgery, 2011]
 - ISGLS grade A
 - ISGLS grade B
 - ISGLS grade C
 - Intra-abdominal abscess
 - Other, specify:



- General Clavien-Dindo classification (90 days post-op, in-hospital complications): (https://www.baus.org.uk/patients/surgical_outcomes/grading_of_surgical_complications.aspx)
 - TOSGS grade 1
 - TOSGS grade 2
 - TOSGS grade 3a
 - TOSGS grade 3b
 - TOSGS grade 4a
 - TOSGS grade 4b
 - TOSGS grade 5

Re-operation necessary?

- No
- Yes

- Type of surgery:

Please upload the following reports without patient identification variables:

- MC/CM report (if applicable): (include as text)
- Pathology report (if applicable): (include as text)
- Surgery report: (include as text)

Was the patient discharged after surgery during the 90-day post-op period?

- No
- Yes

- Discharge date after surgery:/...../..... (dd/mm/yyyy)

- Destination?

- Home
- Rehabilitation centre
- Nursing home
- Transfer to another hospital

- Name:

- Because of complications?

- No
- Yes

- Re-admission within 30 days after discharge (from the centre that performed the surgery):

- No
- Unknown
- Yes, in the hospital where the surgery was performed

- Reason for re-admission:

Yes, in another hospital

- Reason for re-admission:

Did the patient die during the 90-day post-op period?

- No
- Yes

- In-hospital?

- No
- Yes

- Date of death:/...../..... (dd/mm/yyyy)

- Cause of death:



** Only to be filled out for a malignant tumour:*

- Was there adjuvant therapy after surgery?

No

Yes

Systemic therapy

Radiotherapy

Combined therapy (systemic + radiotherapy)

Was the patient included in a clinical trial for (neo)adjuvant therapy or surgery?

No

Unknown

Yes

- EudraCT number: or NCT number:



Registration form - version overview

Version	Changes
v1.0	Original document (28/06/2019)
v1.1	<ul style="list-style-type: none"> - The variable 'Nomenclature code' changed from multi- to single-select variable - The variable 'Re-admission within 30 days after discharge' was moved under the variable 'Was the patient discharged after surgery during the 90-day post-op period' – option 'Yes', so that it should only be answered when the patient was discharged
v1.2	<ul style="list-style-type: none"> - The symbols related to the variable 'Indication' in case surgery is performed, were altered to * for malignant tumoural indications - The answer option 'EUS (endoscopic ultrasound)' was expanded to 'EUS (endoscopic ultrasound)/endoscopy' for the variables 'Type of FIRST diagnostic method' and 'Method to obtain first tissue sample for histopathological evaluation' - The variable 'Was the patient hospitalized at the referring hospital' was further clarified by adding: (before referral) to the question - The variable 'Comorbidity (prior to surgery) - Charlson Modified Index' was further clarified by adding: 'not the current surgery indication!' - The MC/CM report (if applicable), pathology report (if applicable) and surgery report are requested when re-operation was necessary - The variable 'Re-admission within 30 days after discharge' was further clarified by adding: 'from the centre that performed the surgery' - The variable 'Was there adjuvant therapy after surgery?' and the variable to specify the adjuvant therapy were moved further down the document
v1.3	<ul style="list-style-type: none"> - For the nomenclature code '242830-242841: Pancreaticoduodenectomy', the answering option 'Whipple' has been changed to 'Pancreaticoduodenectomy' - For the nomenclature code '242830-242841: Pancreaticoduodenectomy' and '242896-242900: Enucleation of a pancreatic tumour', the answering option 'Pancreatic tail' has been changed to 'Pancreatic body or tail' - The option 'without reconstruction' has been added in case of a SMV/PV resection - A question has been added regarding the type of reconstruction in case of an arterial resection - The definitions corresponding to R0 and R1 resection margins have been changed: <ul style="list-style-type: none"> o From 'R0: no residual disease' to 'R0: tumour-free resection margin > 1 mm' o From 'R1 indirect: R0 with magnitude of resection margin < 1 mm' to 'R1 indirect: tumour-free resection margin < 1 mm' o From 'R1 direct: microscopic tumour positive margin' to 'R1 direct: tumour involvement of the resection margin' - The question on lymph node retrieval has been changed from 'number of loco-regional lymph nodes retrieved' to 'number of lymph nodes retrieved' - The question on the number of involved lymph nodes has been changed from 'number of metastatic loco-regional lymph nodes' to 'number of lymph nodes with tumoural involvement'
v2.0	<ul style="list-style-type: none"> - Added additional question in case of malignant indication (lesion to treat): primary tumour, relapse of primary tumour or metastasis - Added specific variables from the MOC/COM cancer registration (bijlage/annexe 55) in case of a malignant indication: incidence date primary tumour/relapse, primary tumour/relapse localization, histological diagnosis primary tumour/relapse, cTNM and pTNM in case of primary tumour or



	<p>metastasis</p> <ul style="list-style-type: none">- MC/CM date- RIZIV numbers surgeon(s)
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