Complex Surgery Oesophagus and Gastro-Oesophageal Junction

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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.

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

    Please note that the obligatory MOC/COM cancer registration (bijlage/ annexe 55) for this tumour should be performed within 60 days of the Multidisciplinary Consult (MC/CM).
  - ❍ Benign tumour, specify: .....
  - ❍ Achalasia
  - ❍ Toxic/caustic substances
  - ❍ Boerhaave syndrome
  - ❍ Other, specify: .....

- 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 *

  Please note that the obligatory MOC/COM cancer registration (bijlage/annexe 55) for this tumour should be performed within 100 days of the date of surgery.
- ❍ Benign tumour **, specify: .....
- ❍ Achalasia
- ❍ Toxic/caustic substances
- ❍ Boerhaave syndrome
- ❍ Other, specify: .....

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

- Date of diagnosis: ……/……/…… (dd/mm/yyyy)
  (Priority: 1. Pathology prior to complex surgery 2. Endoscopy 3. Imaging)

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

PET/CT performed prior to surgery?

- ❍ No
- ❍ Yes

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)
  - ❑ Targeted therapy/biologicals
    - Start date: ……/……/…… (dd/mm/yyyy)
    - Date latest treatment: ……/……/…… (dd/mm/yyyy)
  - ❑ Radiotherapy
    - Start date: ……/……/…… (dd/mm/yyyy)
    - Date latest treatment: ……/……/…… (dd/mm/yyyy)
  - ❑ Prior major thoracic or abdominal surgery
    - Type of surgery: .....
    - Date latest surgery: ……/……/…… (dd/mm/yyyy)
  - ❑ Endoscopic treatment
    - ❑ EMR/ESD
      - Date latest treatment: ……/……/…… (dd/mm/yyyy)
    - ❑ RFA
      - Date latest treatment: ……/……/…… (dd/mm/yyyy)
    - ❑ Ablation techniques other than RFA
      - Specify: .....
      - Date latest treatment: ……/……/…… (dd/mm/yyyy)
  - ❑ Other treatment modality (that could affect the oesophagus), specify: .....

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

, Only to be filled out for a malignant or benign tumour:*

- Tumour location:
  - ❍ Proximal third
  - ❍ Middle third
  - ❍ Lower third
  - ❍ Gastro-Oesophageal Junction / cardia
- Surgery intention:
  - ❍ Surgery as primary treatment
  - ❍ Post-induction (neoadjuvant chemo- and/or radiotherapy) °
  - ❍ Salvage post-radical chemo- and/or radiotherapy
  - ❍ Palliative
  - ❍ Recurrence

Mode of surgery:

- ❍ Elective
- ❍ Emergency

Type of surgery:

- ❍ Minimally invasive surgery (MIS)
  - ❍ Total laparoscopic/Video-Assisted Thoracoscopic Surgery (VATS)
  - ❍ Partial/hybrid
- ❍ Open
  - ❍ Transthoracic
  - ❍ Transhiatal
- ❍ Conversion from MIS to open surgery
  - Reason for conversion: .....

Nomenclature code:

- ❍ 228270-228281: Thoracic or thoracic-abdominal oesophagectomy or gastro-oesophagectomy in one surgery with continuity recovery
- ❍ 228292-228303: Subtotal oesophagectomy up to the level of the arcus aortae, with continuity recovery
- ❍ 228314-228325: Thoracic or thoracic-abdominal oesophagectomy or gastro-oesophagectomy in one surgery with continuity recovery and extensive lymph node removal
- ❍ 228336-228340: Subtotal oesophagectomy up to the level of the arcus aortae, with continuity recovery and extensive lymph node removal

Oesophagectomy:

- ❍ Partial
- ❍ Subtotal
- ❍ Total + laryngectomy

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

- Was a macroscopic R0-resection performed (surgical)?
  - ❍ No
  - ❍ Yes
- Was a microscopic R0-resection performed (pathological)?
  - ❍ No
    - Was the proximal margin involved?
      - ❍ No
      - ❍ Yes
  - ❍ Yes
- Was there lymphovascular invasion?
  - ❍ No
  - ❍ Yes
- Was there perineural invasion?
  - ❍ No
  - ❍ Yes

° Only to be filled out for post-induction surgery (after neoadjuvant chemo- and/or radiotherapy):

- Mandard grade: ❍ TRG1 ❍ TRG2 ❍ TRG3 ❍ TRG4 ❍ TRG5

Gastrectomy:

- ❍ No
- ❍ Partial
- ❍ Total

Lymphadenectomy:

- ❍ No
- ❍ Yes
  - Region lymphadenectomy:
    - ❑ Abdomen
    - ❑ Chest
    - ❑ Neck unilateral
    - ❑ Neck bilateral
  - Number of lymph nodes retrieved: .....
  - Number of lymph nodes with tumoural involvement: .....

Other resections:

- ❍ No
- ❍ Yes
  - ❑ Pulmonary metastasis
  - ❑ Adrenal metastasis
  - ❑ Liver metastasis
  - ❑ Other, specify: .....

Oesophageal conduit:

- ❍ Stomach
- ❍ Small bowel
- ❍ Colon

Anastomosis:

- ❍ Cervical
- ❍ Intrathoracic
- ❍ Other, specify: .....

Post-surgery

Which of the following postoperative complications occurred (all Clavien-Dindo grades, 90 days post-op, in-hospital)?
(Link Clavien-Dindo grade: https://www.baus.org.uk/patients/surgical_outcomes/grading_of_surgical_complications.aspx)

- ❑ Pneumonia
  - Clavien-Dindo grade: ❍ I ❍ II ❍ IIIa ❍ IIIb ❍ IVa ❍ IVb ❍ V
- ❑ Oesophago-enteric leak from anastomosis, staple line, or localized conduit necrosis
  - Clavien-Dindo grade: ❍ I ❍ II ❍ IIIa ❍ IIIb ❍ IVa ❍ IVb ❍ V
- ❑ Chyle leak
  - Clavien-Dindo grade: ❍ I ❍ II ❍ IIIa ❍ IIIb ❍ IVa ❍ IVb ❍ V
- ❑ None of the above

Did other major postoperative complications occur (Clavien-Dindo grade IIIb, IVa, IVb or V, 90 days post-op, in-hospital)?

- ❍ No
- ❍ Yes ‡

- ‡ Type of postoperative complication(s):
  - ❑ **Pulmonary**
    - ❑ Pleural effusion requiring additional drainage procedure
    - ❑ Pneumothorax requiring treatment
    - ❑ Atelectasis mucous plugging requiring bronchoscopy
    - ❑ Respiratory failure requiring reintubation
    - ❑ Acute respiratory distress syndrome (ARDS)
    - ❑ Acute aspiration
    - ❑ Tracheobronchial injury
    - ❑ Chest tube maintenance for air leak >10 days
  - ❑ **Cardiac**
    - ❑ Cardiac arrest requiring CPR
    - ❑ Myocardial infarction
    - ❑ Dysrhythmia atrial requiring treatment
    - ❑ Dysrhythmia ventricular requiring treatment

- ❑ Congestive heart failure requiring treatment
- ❑ Pericarditis requiring treatment

❑ **Gastrointestinal**
- ❑ Conduit necrosis / failure
- ❑ Ileus, defined as small bowel dysfunction preventing or delaying enteral feeding
- ❑ Small bowel obstruction
- ❑ Feeding J-tube complication
- ❑ Pyloromyotomy/pyloroplasty complication
- ❑ Clostridium difficile infection
- ❑ Gastrointestinal bleeding requiring intervention or transfusion
- ❑ Delayed conduit emptying requiring intervention or delaying discharge or requiring maintenance of nasogastric tube drainage >7 days
- ❑ Pancreatitis
- ❑ Liver dysfunction

❑ **Urologic**
- ❑ Acute renal insufficiency (doubling of baseline creatinine)
- ❑ Acute renal failure requiring dialysis
- ❑ Urinary tract infection
- ❑ Urinary retention requiring reinsertion of urinary catheter, delaying discharge or discharge with urinary catheter

❑ **Thromboembolic**
- ❑ Deep venous thrombosis
- ❑ Pulmonary embolus
- ❑ Stroke (CVA)
- ❑ Peripheral thrombophlebitis

❑ **Neurologic / psychiatric**
- ❑ Recurrent nerve injury
- ❑ Other neurologic injury
- ❑ Acute delirium
- ❑ Delirium tremens

❑ **Infection**
- ❑ Wound infection requiring opening wound or antibiotics
- ❑ Central IV line infection requiring removal or antibiotics
- ❑ Intrathoracic / intraabdominal abscess
- ❑ Generalized sepsis
- ❑ Other infections requiring antibiotics

❑ **Wound / diaphragm**
- ❑ Thoracic wound dehiscence
- ❑ Acute abdominal wound dehiscence
- ❑ Acute diaphragmatic hernia

❑ **Other**
- ❑ Prolonged fluid drainage >500 cc / day
- ❑ Reoperation for reasons other than bleeding, anastomotic leak or conduit necrosis
- ❑ Multiple organ dysfunction
- ❑ Non-listed, specify: .....

- ‡ General Clavien-Dindo grade (90 days post-op, in-hospital complications):
  - ❍ IIIb
  - ❍ IVa
  - ❍ IVb
  - ❍ V

Redo surgery?

- ❍ No
- ❍ Yes
  - ❍ Take down conduit
  - ❍ Delayed reconstruction
  - ❍ Other, specify: .....

  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	- 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	- The symbols related to the variable 'Indication' in case surgery is performed, were altered to * for malignant and ** for benign tumoural indications - The priorities to determine the date of diagnosis for a benign tumour were further clarified by specifying that the pathologic diagnosis should be based on a tumour sample that has been retrieved prior to complex surgery - 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 variable 'Type of endoscopic treatment' changed from single- to multi-select variable - The variable 'Mandard grade' was moved further down the document to a set of variables related to the pathology report - The term 'chemoradiotherapy' within the answer options 'Post-induction (neoadjuvant chemoradiotherapy)' and 'Salvage post-radical chemoradiotherapy' regarding the variable 'Surgery intention' were altered to 'chemo- and/or radiotherapy' - For the variable 'Type of surgery' the answering options were changed from 'Minimally invasive' to 'Minimally invasive surgery (MIS)' and from 'Conversion' to 'Conversion from MIS to open surgery'. Also, the answer options for specifying the MIS changed places. - The variable conversion 'To?' with three answering options (Laparoscopy, VATS, Open) was deleted - Addition of the variable 'Which of the following postoperative complications occurred (all Clavien-Dindo grades, 90 days post-op, in-hospital)?' with four answer options. For each mentioned complication, the variable 'Clavien-Dindo grade' is asked, with 7 answer options (grades I to V) - The variable 'Postoperative complication(s) (90 days post-op, in hospital, Clavien-Dindo grade IIIb, IVa, IVb or V)' was adapted to 'Did other major postoperative complications occur (Clavien-Dindo grade IIIb, IVa, IVb or V, 90 days post-op, in-hospital?)'. The following options and accompanying 'Clavien-Dindo grade' variables were excluded (because they are now included in the previous question where all grades are asked): o 'Pneumonia' under 'Pulmonary' o 'Oesophago-enteric leak from anastomosis, staple line, or localized conduit necrosis' under 'Gastrointestinal' o 'Chyle leak' under 'Other' - The MC/CM report (if applicable), pathology report (if applicable) and surgery report are requested when surgery is redone - 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

Version	Changes
v1.3	- For the variable 'Lymphadenectomy', the question related to the number of fields (1-field, 2-field, 3-field) has been deleted, as this can be calculated based on the indicated region(s) of lymphadenectomy' - 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'