# Definitions used for feedback PROCARE - 2009

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## Introduction

This document accompanies **the second feedback** on the results of central registration about the management of patients with rectal cancer within PROCARE. It contains a list of the general and more specific definitions used to calculate the different items of the report.

Besides analysis of the global database, analyses for feedback per team were performed for those teams submitting at least 10 cases in the database before the 13th of October 2009.

The feedback document provides data concerning only the team to which the report is addressed on the one hand and the data of the whole PROCARE database on the other hand. They are presented in **tables**. In contrast with the previous one, this feedback is presented in sections related to demographic data, pretreatment diagnosis, staging and function, time to first treatment, neoadjuvant treatment, surgery, pathology, adjuvant treatment, follow-up, and the first data on oncologic outcome.
Quality of care indicators are indicated by QCI in each section. Further information on QCI can be found at:
http://coldfusionwebhostings.be/PSK/Upload/GENERAL//procare/Fr-qual-ind-030708.pdf or
http://coldfusionwebhostings.be/PSK/Upload/GENERAL//procare/PROC-final_document_QI.pdf
Some data are subdivided in subsections. The sum of the percentages corresponding with subsections is 100%. Indeed, missing data were not taken into account. Example: level of tumour was documented in 2260 patients or 92.7% of the global database. Tumour levels were subdivided in high (17.7% or 400/2260), mid (38.4% or 868/2260) and low rectum (43.9% or 991/2260). The sum of the percentages of these subsections is 100% because the 179 patients

(7.3% of all registered patients) for whom the tumour level was missing were not taken into account.
Results of individual teams that registered more than 10 patients per quality indicator are also provided in some additional **graphics**.

**Percentiles** p25, p75 and median are computed for global data in the PROCARE database and are presented in the tables. If only absolute numbers are reported, the p25, median and p75 are computed for the absolute numbers:

- p25: the value of the variable below which 1 in 4 values lie
- median: the value of the variable below which 1 in 2 values lie
- p75: the value of the variable above which 1 in 4 values lie

The absolute numbers (N) in the report correspond to the numerator (N), whereas the relative numbers (%) correspond to the ratio between the numerator and denominator (D).

We would like to remark that the PROCARE database has been **'cleaned' in some aspects**. pTis cases have been eliminated from the database for this feedback. In fact, they were not planned to be inserted in the databank because they are not invasive rectal cancers. In contrast, ypTis cases have been retained if the cT stage was cT1 or more and/or a biopsy or endoscopic resection proved the presence of an invasive cancer. Cases where the lower limit of the tumour is superior to 15 cm have been eliminated from the database. If information about the total dose and the number of fractions of the radiotherapy treatment was missing, it is impossible to determine whether a short or long course was given to the patient. cTNM and pTNM had to be converted to cStage missing when not enough information was given (e.g. cN missing) to determine the corresponding stage..In some forms errors in date of first contact or in the treatment dates were detected and corrected.

A note was added to some of the items following below. These notes aim to improve the quality (completeness and correctness) of the data entered in the database in the future.

**Several data should be still be interpreted with caution in view of e.g. limited number of data, a relevant amount of missing data for some aspects, limited follow-up, absence of risk adjustment, etc.**

# Demographic data

No specific remarks on definitions.

# Pretreatment diagnosis, staging and function

**Date of incidence**

**Missing date of first consultation/hospitalisation**
N: Number of patients for whom the date of first consultation or hospitalisation is missing
D: Number of registered patients

**Missing date pathologic diagnosis**
N: Number of patients for whom date of pretreatment biopsy is missing
D: Number of patients with biopsy (87 pat zonder biopsie)

**Note: it is important to mention the date of the first contact when the diagnosis of rectal cancer was made (by any physician) or the date of pretreatment biopsy. They determine the 'incidence date' and are used to calculate the interval to first treatment (therapeutic delay).**

**Level of tumour**

**Note: for risk adjustment it is essential to categorize the tumours into one of the rectal thirds. Therefore, the lower limit of the tumour from the anal verge, preferentially as measured at rigid rectoscopy (proctoscopy), should be known.**

If available, the lower limit measured with rectoscopy is taken as lower limit of the tumour in patients without neoadjuvant treatment or with no long course neoadjuvant radiotherapy. If this is not available, the lower limit measured with coloscopy is taken as lower limit of the tumour.

For patients with long course neoadjuvant radiotherapy the pretreatment lower limit is taken as lower limit of the tumour. If no lower limit is available before neoadjuvant treatment, the lower limit measured at surgery is taken as lower limit of the tumour.

For patients who received neoadjuvant treatment but for whom it is not known whether they received short or long course radiotherapy, the lowest limit of either the pretreatment or the lower limit at surgery is taken.

***Documented distance from anal verge (QCI)***
N: Number of patients in denominator for whom lower limit of the tumour is known (see definition lower limit of tumour)
D: Number of registered patients

**Level of tumour (lower limit determined by distance from anal verge)**

| Lower limit tumour (LL) | Level tumour |
|---|---|
| ≤ 5 cm | Low |
| >5 - ≤ 10 cm | Mid |
| >10 cm | High |

***High***
N: Number of patients in denominator for whom the level of the tumour is superior to 10 cm
D: Number of patients for whom the level of the tumour is known
***Mid***
N: Number of patients in denominator for whom the level of the tumour is superior to 5 cm and inferior or equal to 10 cm
D: Number of patients for whom the level of the tumour is known
***Low***
N: Number of patients in denominator for whom the level of the tumour is inferior or equal to 5 cm.
D: Number of patients for whom the level of the tumour is known

***Complete large bowel-imaging (QCI)***
N: Number of patients in denominator who underwent a total coloscopy or a complete double contrast enema or virtual colonography
D: Number of patients treated with elective or scheduled surgery.

**Use of imaging**

***Use of TRUS (any stage)***
N: Number of patients in denominator in whom cT and/or cN was based on TRUS
D: Number of registered patients with rectal cancer of any stage

***Use of CT pelvis (any stage)***
N: Number of patients in denominator in whom cT and/or cN was based on CT
D: Number of registered patients with rectal cancer of any stage

***Use of MRI pelvis (any stage)***
N: Number of patients in denominator in whom cT and/or cN was based on MRI
D: Number of registered patients with rectal cancer of any stage

***Use of TRUS in cT1/cT2***
N: Number of patients in denominator in whom cT was based on TRUS
D: Number of patients with cT1 or cT2 rectal cancer

***Use of MRI in cT3/cT4***
N: Number of patients in denominator in whom cT was based on MRI
D: Number of patients with cT3 or cT4 rectal cancer based on any imaging technique

***Staging by TRUS + CT and/or MRI (QCI)***
N: Number of patients in whom cT or cN were based on TRUS and at least one of the two following:
- pelvic CT
- pelvic MRI

D: Number of registered patients

***cCRM reported in cStage II-III (QCI)***
N: Number of patients in denominator for whom cCRM is reported
D: Number of patients with cStage II-III treated with radical surgical resection

**Note: for risk adjustment it is important to know the pretreatment cCRM in patients with T3/T4 and/or N+**

**Tumour clinical Stage**

**Note: for risk adjustment it is important to know the pretreatment cTNM stage**

***cStage 0***
N: Number of patients in denominator with cStage 0
D: Number of patients for whom cStage (incl. cStageX, but not cStage missing) is reported

Note: patients with cStage 0 are included if pStage different from pStage 0

***cStage I***
N: Number of patients in denominator with cStage I
D: Number of patients for whom cStage (incl. cStageX) is reported

***cStage II***
N: Number of patients in denominator with cStage II
D: Number of patients for whom cStage (incl. cStageX) is reported

***cStage III***
N: Number of patients in denominator with cStage III
D: Number of patients for whom cStage (incl. cStageX) is reported

***cStage IV***
N: Number of patients in denominator with cStage IV
D: Number of patients for whom cStage (incl. cStageX) is reported

***cStage X***
N: Number of patients in denominator with cStage X (cTX and/or cNX and/or cMX reported as such and – supposedly - meaning that tumour and/or regional nodes and/or metastases were not assessed by any means)
D: Number of patients for whom cStage (incl. cStageX) is reported

***Accuracy of cT/cN staging if no or short radiotherapy (separately presented in 2 tables)***

For patients who did not receive neoadjuvant long course radio(chemo)therapy, the (y)pT/(y)pN is shown related to the cT/cN for these patients.

***CEA before any treatment (QCI)***
N: Number of patients in denominator for whom CEA serum level before treatment is reported
D: Number of registered patients

# Time to first treatment

***Median time in days from pathologic diagnosis or first contact to treatment***

For the patients treated by surgery and/or radiotherapy and/or chemotherapy, the time interval in days is computed between the date of pathologic diagnosis, if available, otherwise the date of first contact/hospitalization, and the date of first treatment.

- Global: median time from pathologic diagnosis or first contact to treatment independently of the kind of first treatment

- First treatment surgery: median time from pathologic diagnosis or first contact to treatment in patients treated with surgery without neoadjuvant therapy

- First treatment (C)RT: median time from pathologic diagnosis or first contact to treatment in patients who received neoadjuvant treatment

- First treatment palliative (C)RT: median time from pathologic diagnosis or first contact to treatment in patients who received palliative chemo and/or radiotherapy.

# Neoadjuvant treatment

## Neoadjuvant radiotherapy

If the radiotherapy form is completed or the pathology or chemotherapy forms indicate radiotherapy was given, the patient is considered to be treated with radiotherapy.

Short course regimen are 5 x 5, 10 or 13 x 3 Gy (always without chemotherapy).

Long course regimen are 25 or more x 1.8 Gy (with or without chemotherapy).

## Neoadjuvant chemotherapy

If the chemotherapy form is completed or if the pathology form indicate chemotherapy was given, the patient is considered to be treated with neoadjuvant chemotherapy.

***Short course RT in cStage II-III (QCI)***
N: Number of patients in denominator that received a short course of neoadjuvant pelvic radiotherapy
D: Number of patients with cStage II-III treated with radical surgical resection and for whom the course of radiotherapy treatment is not missing

***Long course (C)RT in cStage II-III (QCI)***
N: Number of patients in denominator that received a long course of neoadjuvant pelvic (chemo)radiotherapy
D: Number of patients with cStage II-III treated with radical surgical resection and for whom the course of radiotherapy treatment is not missing

***Long course (C)RT in cStage II-III without interruption (QCI)***
N: Number of patients in denominator for whom the radiotherapy treatment was not interrupted for more than five working days
D: Number of patients with cStage II-III who started with long course neoadjuvant radiotherapy which was followed by radical surgical resection

## Neoadjuvant treatment for cStage II-III

***For high rectal cancer (> 10 cm)***
N: Number of patients in denominator who received neoadjuvant treatment
D: Number of patients in cStage II or III, treated with radical resection with tumour in upper third

***For mid rectal cancer (>5 - 10 cm)***
N: Number of patients in denominator who received neoadjuvant treatment
D: Number of patients in cStage II or III, treated with radical resection with tumour in middle third

***For low rectal cancer (≤ 5 cm)***
N: Number of patients in denominator who received neoadjuvant treatment
D: Number of patients in cStage II or III, treated with radical resection with tumour in lower third

**Long course neoadjuvant radio(chemo)therapy if cCRM ≤ 2 mm on MRI/CT**
N: Number of patients in denominator who received long course neoadjuvant radio(chemo)therapy
D: Number of patients treated with radical resection and for whom cCRM is ≤ 2 mm

**Neoadjuvant treatment in cStage I**
N: Number of patients in denominator who received neoadjuvant treatment
D: Number of patients treated with radical resection for cStage I rectal cancer

***Missing date of first irradiation***
N: Number of patients in denominator for whom the date of first irradiation is missing
D: Number of patients treated with neoadjuvant radiotherapy

***Missing date of last irradiation***
N: Number of patients in denominator for whom the date of last irradiation is missing
D: Number of patients treated with neoadjuvant radiotherapy

***Missing number of fractions***
N: Number of patients in denominator for whom the number of fractions is missing
D: Number of patients treated with neoadjuvant radiotherapy

***Missing total dose***
N: Number of patients in denominator for whom the total dose at ICRU reference point is missing
D: Number of patients treated with neoadjuvant radiotherapy

***Missing radiation compliance***
N: Number of patients in denominator for whom it is not stated whether the radiotherapy treatment was interrupted for more than five working days
D: Number of patients treated with neoadjuvant radiotherapy

***Missing concomitant chemotherapy***
N: Number of patients in denominator for whom it is not stated whether they received concomitant chemotherapy or not
D: Number of patients treated with neoadjuvant radiotherapy

***Surgery 6 to 8 weeks after long course (C)RT in cStage II-III (QCI)***
N: Number of patients in denominator that was operated 6 to 8 weeks after completion of the (chemo)radiotherapy
D: Number of patients with cStage II-III treated with long course neoadjuvant radiotherapy and for whom date of surgery and date of last irradiation are not missing

***Surgery 4 to 12 weeks after long course (C)RT in cStage II-III (QCI)***
N: Number of patients in denominator that was operated 4 to 12 weeks after completion of the (chemo)radiotherapy
D: Number of patients with cStage II-III treated with long course neoadjuvant radiotherapy and for whom date of surgery and date of last irradiation are not missing

# Surgery

**Surgical resection and reconstruction**

1. **Treated with radical surgical resection**
A patient treated with abdominoperineal resection (APER), Hartmann's procedure, or sphincter sparing/saving radical rectum resection (PME or TME) with reconstruction (SSO) is considered to be treated with radical resection.

**2. Treated with sphincter sparing/saving radical rectum resection (PME or TME) with reconstruction (SSO)**
A patient is treated with SSO and reconstruction if one of the following is indicated:
- High anterior resection + CRA (anastomosis above peritoneal reflection)
- Low anterior resection + CRA (anastomosis below peritoneal reflection)
- Complete rectum resection (TME) + straight CAA
- Complete rectum resection (TME) + colon J pouch
- Complete rectum resection (TME) + coloplasty
- Complete rectum resection (TME) + side-to-end anastomosis
- Complete rectum resection (TME) + other (specified)

**Planned type of surgery**

**No resection (palliative)**
N: Number of patients in denominator for whom there was no resection planned
D: Number of patients treated with surgery (any type) for whom the planned type of surgery is known

**Hartmann**
N: Number of patients in denominator for whom a Hartmann's procedure was planned
D: Number of patients treated with surgery (any type) for whom the planned type of surgery is known

**APR**
N: Number of patients in denominator for whom an APER resection was planned
D: Number of patients treated with surgery (any type) for whom the planned type of surgery is known

**SSO**
N: Number of patients in denominator for whom a SSO resection was planned
D: Number of patients treated with surgery (any type) for whom the planned type of surgery is known

**Local excision/TEM**
N: Number of patients in denominator for whom local excision/TEM was planned
D: Number of patients treated with surgery (any type) for whom the planned type of surgery is known

**Missing data on planned type of surgery**
N: Number of patients treated with surgery for whom the planned type of resection is missing
D: Number of patients treated with surgery (any type)

**Mode of surgery**

**Elective/Scheduled**
N: Number of patients in denominator for whom the mode of surgery is 'elective' or 'scheduled'
D: Number of patients treated with surgery (any type) and for whom the mode of surgery is not missing

**Urgent/Emergency**
N: Number of patients in denominator for whom the mode of surgery is 'urgent' or 'emergency'
D: Number of patients treated with surgery (any type) and for whom the mode of surgery is not missing

**Missing mode of surgery**
N: Number of patients in denominator for whom mode of surgery is missing
D: Number of patients treated with surgery (any type)

**Note: for risk adjustment it is important to know the mode of surgery**

**Approach surgical exploration/resection/reconstruction if radical resection**

**Exploration/Resection/Reconstruction by laparotomy**
N: Number of patients in denominator for whom the exploration/resection/reconstruction approach is laparotomy
D: Number of patients treated with radical surgical resection for whom the surgical approach at exploration/resection/reconstruction is known

**Exploration/Resection/Reconstruction by laparoscopy**
N: Number of patients in denominator for whom the exploration/resection/reconstruction approach is laparoscopy
D: Number of patients treated with radical surgical resection for whom the surgical approach at exploration/resection/reconstruction is known

**Exploration/Resection/Reconstruction by converted laparoscopy**
N: Number of patients in denominator for whom the exploration/resection/reconstruction approach is converted laparoscopy
D: Number of patients treated with radical surgical resection for whom the surgical approach at exploration/resection/reconstruction is known

**Missing data on approach for surgical exploration/resection/reconstruction if radical resection**
N: Number of patients in denominator for whom the surgical approach at exploration/resection/reconstruction is missing
D: Number of patients treated with radical surgical resection

**R status after radical resection (QCI)**

R2 status. Resections are classified as R2 if cM equals M1 and/or metastasis are discovered at surgery (and not completely resected). Thus, if the type of resection at surgery is reported to be 'R2' then R status equals 'R2'.

R1 status. Resections are classified as R1 if cM does not equal 'M1' and if type of resection at surgery is not 'R2' and if at least one of the following four conditions are present:

- (y)pCRM < 1 mm
- distal resection margin < 1 mm
- rectum perforation as indicated by the surgeon
- rectum perforation as indicated by the pathologist

R0 status. Resections are classified as R0 if cM does not equal 'M1' and if type of resection at surgery is not 'R2' and if no one of the four criteria of R1 status are present.

R status is reported as missing if cM status is missing and/or if data on two or more of the following criteria are missing: tumor free status of the (y)pCRM, the tumor free status of the distal resection margin, rectum perforation as indicated by the surgeon or pathologist.

***R0 resection***
N: Number of patients in denominator with R0 resection
D: Number of patients treated with radical resection and for whom R status is not missing

***R1 resection***
N: Number of patients in denominator with R1 resection
D: Number of patients treated with radical resection and for whom R status is not missing

***R2 resection***
N: Number of patients in denominator with R status equal 'R2'
D: Number of patients treated with radical resection and for whom R status is not missing

***Missing data on R status***
N: Number of patients in denominator for whom R status is missing
D: Number of patients treated with radical resection

***Intra-operative rectal perforation (QCI)***
N: Number of patients in denominator for whom the surgeon and/or pathologist reported rectal perforation
D: Number of patients treated with radical resection and for whom perforation of the rectum (yes or no) is reported by either the surgeon or the pathologist

***Missing data on perforation of rectum***
N: Number of patients in denominator for whom perforation of the rectum is not reported by the surgeon
D: Number of patients treated with radical resection

**Technique of resection**

PME
N: Number of patients in denominator for whom PME is the technique of resection
D: Number of patients with radical resection for whom the technique of resection is known

TME
N: Number of patients in denominator for whom TME is the technique of resection
D: Number of patients with radical resection for whom the technique of resection is known

Conventional
N: Number of patients in denominator for whom the technique of resection is 'conventional'
D: Number of patients with radical resection for whom the technique of resection is known

Missing technique of resection
N: Number of patients in denominator for whom the technique of resection is missing
D: Number of patient with radical resection

**Type of resection and reconstruction**

**1) Local excision / TEM(S)**

***Global***
N: Number of patients in denominator in whom local excision or TEM(S) was performed as the only surgical treatment
D: Number of patients treated with any type of resectional surgery

**For cT1N0M0**
N: Number of patients in denominator treated with local excision or TEM(S)
D: Number of patients in cStage I having cT1 and for whom surgical 'type of reconstruction' is not missing

**For cT2 N0M0**
N: Number of patients in denominator treated with local excision or TEM(S)
D: Number of patients in cStage I having cT2 and for whom surgical 'type of reconstruction' is not missing

**2) APER/Hartmann (QCI)**

***Global (QCI)***
N: Number of patients in denominator in whom APER or Hartmann's procedure was performed
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***For high rectal cancer (> 10 cm)***
N: Number of patients in denominator in whom APER or Hartmann's procedure was performed
D: Number of patients treated with any type of resectional surgery for tumour in upper third

***For mid rectal cancer (>5 - 10 cm)***
N: Number of patients in denominator in whom APER or Hartmann's procedure was performed
D: Number of patients treated with any type of resectional surgery for tumour in middle third

***For low rectal cancer (≤ 5 cm)***
N: Number of patients in denominator in whom APR or Hartmann's procedure was performed
D: Number of patients treated with any type of resectional surgery for tumour in lower third

**3) SSO**

***Global***
N: Number of patients in denominator in whom a high or low anterior resection with CRA, or complete rectum resection (TME) with straight CAA, coloplasty, pouch, side-to-end CAA, or another specified type of reconstruction was performed
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***High anterior resection + CRA (colorectal anastomosis above the peritoneal reflexion)***
N: Number of patients in denominator with high anterior resection + CRA
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Low anterior resection + CRA (colorectal anastomosis below the peritoneal reflexion)***
N: Number of patients in denominator with low anterior resection + CRA
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Complete rectum resection (TME) + CAA of any type (global)***
N: Number of patients in denominator with complete rectum resection (TME) + straight CAA, coloplasty, pouch, side-to-end CAA, or another specified type of reconstruction
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Straight CAA***
N: Number of patients in denominator with complete rectum resection + straight coloanal anastomosis
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Coloplasty***
N: Number of patients in denominator with complete rectum resection + coloplasty and CAA
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Colon J-Pouch***
N: Number of patients in denominator with complete rectum resection + colon J-pouch-anal anastomosis
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Side-to-end***
N: Number of patients in denominator with complete rectum resection + side-to-end coloanal anastomosis
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

***Complete rectum resection (TME) + other (specified) type of reconstruction***
N: Number of patients in denominator with complete rectum resection + 'other (specified) type of reconstruction'
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

**3) Other specified types of reconstruction not mentioned above**

N: Number of patients in denominator with 'other specified type of reconstruction'
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

**4) Missing type of reconstruction**

N: Number of patients in denominator for whom the type of reconstruction is missing
D: Number of patients treated with any type of resectional surgery for rectal cancer at any known level

**Distal anastomosis technique after SSO for low rectal cancer (≤ 5 cm)**

**Stapled anastomosis after SSO for RC in lower third**
N: Number of patients in denominator in whom a stapled anastomosis was performed
D: Number of patients with tumour in lower third treated with SSO and reconstruction and for whom anastomosis technique is reported

**Manual anastomosis after SSO for RC in lower third**
N: Number of patients in denominator in whom a manual anastomosis was performed
D: Number of patients with tumour in lower third treated with SSO and reconstruction and for whom anastomosis technique is reported

**Missing data on distal anastomosis technique after SSO for RC in lower third**
N: Number of patients in denominator for whom the distal anastomosis technique (stapled/manual) is missing

**Derivative stoma after SSO with reconstruction**

***After PME***
N: Number of patient in denominator with a primary derivative stoma (constructed at the time of SSO)
D: Number of patients in whom PME and SSO with reconstruction were performed

***After TME (restorative rectum resection)***
N: Number of patient in denominator with a primary derivative stoma (constructed at the time of SSO)
D: Number of patients in whom TME and SSO with reconstruction ('restorative rectum resection') were performed

***Missing data on derivative stoma after TME(restorative rectum resection)***
N: Number of patients in denominator for whom it is not stated whether they had a primary derivative stoma (constructed at the time of SSO) or not
D: Number of patients in whom TME and SSO with reconstruction ('restorative rectum resection') were performed

**Note: for risk adjustment it is important to know whether a derivative stoma was constructed or not**

**Major leakage after PME + SSO + reconstruction**

N: Number of patients with major leakage of the anastomosis (requiring reoperation for leakage)
D: Number of patients treated with PME (high or low anterior resection with colorectal anastomsosis) and for whom it is reported whether there were postoperative complications or not

**Major leakage after TME + SSO + reconstruction (global, i.e. with or without primary derivative stoma)**

N: Number of patients with major leakage of the anastomosis (requiring reoperation for leakage)
D: Number of patients treated with TME (complete rectum resection (TME) + straight CAA, coloplasty, pouch, side-to-end CAA, or another specified type of reconstruction) and for whom it is reported whether there were postoperative complications or not

**Major leakage after TME + SSO + reconstruction with primary derivative stoma (constructed at the time of SSO)**
N: Number of patients with major leakage of the anastomosis (requiring reoperation for leakage)
D: Number of patients treated with TME (complete rectum resection (TME) + straight CAA, coloplasty, pouch, side-to-end CAA, or another specified type of reconstruction) with primary derivative stoma constructed at the time of SSO and for whom it is reported whether there were postoperative complications or not

**Major leakage after TME + SSO + reconstruction without primary derivative stoma (constructed at the time of SSO)**
N: Number of patients with major leakage of the anastomosis (requiring reoperation)
D: Number of patients treated with TME (complete rectum resection (TME) + straight CAA, coloplasty, pouch, side-to-end CAA, or another specified type of reconstruction)

without primary derivative stoma constructed at the time of SSO and for whom it is reported whether there were postoperative complications or not

**Proportion of patients with derivative stoma 1 year after SSO**

N: Number of patients in denominator still having a stoma 1 year after surgery
D: Number of patients treated with TME (complete rectum resection (TME) + straight CAA, coloplasty, pouch, side-to-end CAA, or another specified type of reconstruction) with a primary (constructed at the time of SSO) or secondary (constructed after SSO) derivative stoma still alive 1 year after surgery and for whom follow-up at 1 year or more is known

***In hospital mortality after radical resection (QCI)***

N: Number of patients in denominator who died in hospital
D: Number of patients treated with radical surgical resection and for whom it is known whether they died in hospital or not

**ASA (only for patients with radical resection)**

**Note: for risk adjustment it is important to know the pretreatment ASA classification as well as the Hct.**

***ASA 1***
N: Number of patients in denominator having ASA 1
D: Number of patients treated with radical surgical resection and for whom ASA is known

***ASA 2***
N: Number of patients in denominator having ASA 2
D: Number of patients treated with radical surgical resection and for whom ASA is stated

***ASA 3***
N: Number of patients in denominator having ASA 3
D: Number of patients treated with radical surgical resection and for whom ASA is stated

***ASA > 3***
N: Number of patients in denominator having ASA greater than 3
D: Number of patients treated with radical surgical resection and for whom ASA is stated

***Missing data on ASA***
N: Number of patients in denominator for whom ASA is missing
D: Number of patients treated with radical surgical resection

**Median length of hospital stay (in days) after radical resection**

Hospital stay is computed as the number of days between date of radical surgical resection and discharge date for the patients treated with radical resection who did not die in-hospital.

**Missing discharge date**
N: Number of patients in denominator for whom discharge date is missing
D: Number of patients treated with radical resection who did not die in-hospital.

# Pathology

**Use of pathology report sheet (since 1/ 2007) (QCI)**
N: Number of patients in denominator for whom a pathology report sheet was completed
D: Number of patients treated with (local or radical) surgery and for whom date of surgery is later than or equal to the 1st of January 2007

**Report on quality of TME (since 1/2007) (QCI)**
N: Number of patients for whom the external surface of TME was reported in the pathology report sheet
D: Number of patients treated with TME as indicated by the surgeon after the 1st of January 2007

**TME severely irregular (since 1/2007)**
N: Number of patients in denominator for whom the mesorectal surface is severely irregular
D: Number of patients treated with radical resection and TME as indicated by the surgeon and for whom the TME quality is reported (after 1st January 2007)

**Missing data on TME quality (since 1/2007)**
N: Number of patients in denominator for whom the external surface of TME (regular/ mildly irregular/ severely irregular) is missing
D: Number of patients treated with TME as indicated by the surgeon (after 1st January 2007)

**(y)pCRM mentioned in the pathology report if radical resection (QCI)**

N: Number of patients in denominator for whom (y)pCRM was mentioned in the pathology report
D: Number of patients treated with radical resection and for whom a pathology report was completed

**(y)pCRM positivity after radical resection (QCI)**

***Global***
N: Number of patients in denominator for whom (y)pCRM ≤ 1 mm
D: Number of patients treated with radical resection and for whom (y)pCRM is known

***For high rectal cancer (> 10 cm)***
N: Number of patients in denominator for whom (y)pCRM ≤ 1 mm
D: Number of patients treated with radical resection with tumour in highest third and for whom (y)pCRM is known

***For mid rectal cancer (>5 - 10 cm)***
N: Number of patients in denominator for whom (y)pCRM ≤ 1 mm
D: Number of patients treated with radical resection with tumour in middle third and for whom (y)pCRM is known

***For low rectal cancer (≤ 5 cm)***
N: Number of patients in denominator for whom (y)pCRM ≤ 1 mm

D: Number of patients treated with radical resection with tumour in lowest third and for whom (y)pCRM is known

**Distal margin involvement mentioned after SSO or Hartmann (QCI)**

N: Number of patients in denominator for whom it was reported whether the distal resection margin was free or invaded
D: Number of patients treated with Hartmann's procedure or SSO with reconstruction and for whom a pathology report sheet was completed

**(y)p Distal margin involved (positive) after SSO or Hartmann for low rectal cancer (≤ 5 cm)**

N: Number of patients in denominator for whom the (y)p distal margin is invaded
D: Number of patients treated with Hartmann's procedure or SSO for rectal cancer in the lower third and for whom it is reported whether the (y)p distal margin is free or invaded

**Mean tumour-free distal margin (cm)**

For patients treated with Hartmann or SSO with reconstruction the mean of the tumour free distal margin is computed by level of the tumour.

***Missing data on length of tumour-free distal margin (cm) after SSO or Hartmann***
N: Number of patients in denominator for whom the distance of the distal free tumour free margin is not stated
D: Number of patients treated with SSO or Hartmann's procedure

**(y)pT categories after radical resection**

**Note**: if no tumour was found in a radical resection specimen after previous endoscopic or local excision, the pT category of the endoscopic or local excision (was asked and) was used for stadification whether the patient received (chemo)radiation between local and radical treatment or not.

***ypT0***
N: Number of patients with ypT0
**Note**: this category includes resection specimen of patients in whom no tumour was found after neoadjuvant treatment followed by radical resection
D: Number of patients treated with radical resection after neoadjuvant chemoradiation and for whom ypT is not missing

***ypTis***
N: Number of patients with ypTis
**Note**: pTis rectal cancer is not included in the PROCARE database.
D: Number of patients treated with radical resection after neoadjuvant chemoradiation and for whom ypT is not missing

***(y)pT1***
N: Number of patients with (y)pT1
D: Number of patients treated with radical resection and for whom (y)pT is not missing

***(y)pT2***

N: Number of patients with (y)pT2
D: Number of patients treated with radical resection and for whom (y)pT is not missing

***(y)pT3***
N: Number of patients with (y)pT3
D: Number of patients treated with radical resection and for whom (y)pT is not missing

***(y)pT4***
N: Number of patients with (y)pT4
D: Number of patients treated with radical resection and for whom (y)pT is not missing

***Missing data on (y)pT status***
N: Number of patients in denominator for whom (y)pT is missing
D: Number of patients treated with radical resection

**(y)pN categories after radical resection**

***(y)pN 0***
N: Number of patients in denominator with (y)pN0
**Note**: this category includes resection specimen of patients in whom no nodes were found after neoadjuvant treatment followed by radical resection
D: Number of patients treated with radical resection and for whom (y)pN is not missing

***(y)pN +***
N: Number of patients in denominator with (y)pN1 or (y)pN2
D: Number of patients treated with radical resection and for whom (y)pN is not missing

***Missing data on (y)pN status***
N: Number of patients in denominator for whom (y)pN is missing
D: Number of patients treated with radical resection

**Median number of lymph nodes examined (QCI)**

The median number of lymph nodes examined is computed for the following conditions:
- no or short course neoadjuvant RT
- long course neoadjuvant RT
- course type missing

**Tumour regression grade (Dworak) mentioned in the pathology report (after long course neoadjuvant (C)RT) (QCI)**

N: Number of patients in denominator having their tumour regression grade mentioned in the pathology report
D: Number of patients treated with surgery and neoadjuvant long course radio(chemo)therapy

**(y)pStage after radical resection**

***ypStage 0***

N: Number of patients in denominator with ypStage 0 or ypTisN0
D: Number of patients treated with radical resection after neoadjuvant chemoradiation and for whom ypStage is not missing

***(y)pStage I***
N: Number of patients in denominator with (y)pStage I
D: Number of patients treated with radical resection and for whom (y)pStage is not missing

***(y)pStage II***
N: Number of patients in denominator with (y)pStage II
D: Number of patients treated with radical resection and for whom (y)pStage is not missing

***(y)pStage III***
N: Number of patients in denominator with (y)pStage III
D: Number of patients treated with radical resection and for whom (y)pStage is not missing

***(y)pStage IV***
N: Number of patients in denominator with (y)pStage IV
**Note**: including patients with cM+ based on imaging and/or preoperative findings
D: Number of patients treated with radical resection and for whom (y)pStage is not missing

***(y)pStage X***
N: Number of patients in denominator with (y)pStage X due to (y)pTX (4 cases) and/or (y)pNX (16 cases) and/or cMX (169 cases).
D: Number of patients treated with radical resection and for whom (y)pStage is not missing

***Missing data on (y)pStage***
N: Number of patients in denominator for whom (y)pStage is missing
D: Number of patients treated with radical resection

# Adjuvant treatment

Data on adjuvant treatment have **to be interpreted with great caution** in view of the limited number of patients with adequate information on this aspects of rectal cancer management.

The participation of oncologists will be stimulated with high priority in the first quarter of 2010 by means of regular reminders asking to submit the appropriate data entry form.

**Note. Data on adjuvant treatment are essential for risk adjustment of DFS, observed survival, as well as for assessment of its adverse events/toxicity.**

**Proportion of patients receiving adjuvant chemotherapy for (y)pStage III after R0 radical resection (QCI)**

N: Number of patients in denominator receiving adjuvant chemotherapy within 6 mo after surgery
D: Number of patients treated with R0 radical resection for (y)pStage III and for whom it is known whether they received adjuvant chemotherapy within 6 mo after surgery or not

***Data on adjuvant chemotherapy for (y)pStage III after R0 resection***

N: Number of patients in denominator for whom it is not known whether adjuvant chemotherapy was administered within 6 mo after surgery or not
D: Number of patients treated with R0 radical resection for (y)pStage III

**Proportion of patients receiving adjuvant radio(chemo)therapy for pStage II or III after R0 radical resection (QCI)**

N: Number of patients in denominator receiving adjuvant radio(chemo)therapy within 6 mo after surgery
D: Number of patients treated with R0 radical resection for pStage II or III without neoadjuvant treatment and for whom it is known whether they received adjuvant radio(chemo)therapy or not

***Data on adjuvant radio(chemo)therapy for pStage II or III after R0 resection***

N: Number of patients in denominator for whom it is not known whether adjuvant radio(chemo)therapy was administered within 6 mo after surgery or not
D: Number of patients treated with R0 radical resection for pStage II or III without neoadjuvant treatment

**Proportion of patients receiving adjuvant chemotherapy for (y)pStage II or III within 3 months after R0 radical resection (QCI)**

N: Number of patients in denominator receiving adjuvant chemotherapy within 3 mo after surgery
D: Number of patients treated with R0 radical resection for (y)pStage II or III who received adjuvant chemotherapy within 6 mo after surgery

***Data on start of adjuvant chemotherapy after R0 resection for (y)pStage II or III***

N: Number of patients in denominator for whom the starting date of adjuvant chemotherapy is known
D: Number of patients treated with R0 radical resection for (y)pStage II or III who received adjuvant chemotherapy

**Proportion of patients receiving 5-fluorouracil based adjuvant (radio)chemotherapy for (y)pStage II or III after R0 resection (QCI)**

N: Number of patients in denominator receiving 5-fluorouracil based adjuvant chemotherapy
D: Number of patients who received adjuvant (radio)chemotherapy within 6 months after R0 radical resection for (y)pStage II or III and for whom the type of adjuvant chemotherapy is known

***Data on type of adjuvant chemotherapy after R0 resection for (y)pStage II or III***

N: Number of patients in denominator for whom the type of adjuvant chemotherapy is known
D: Number of patients who received adjuvant (radio)chemotherapy within 6 months after R0 radical resection for (y)pStage II or III

# Follow-up

Data on the proportion of patients with incidence date before July 2007 undergoing regular follow-up, i.e. having at least 1 follow-up form per year till death, local recurrence or occurrence of metachronous metastasis (a QCI), can not yet be provided.

This is related, in part, to logistic problems with data management in the past and to the fact that follow-up forms have not been submitted at regular intervals to the registry for many patients.

Solving the logistic problem with datamanagement will be high priority in December 2009 – January 2010. This will immediately be followed by regular reminder to submit follow-up forms.

**Note. Regular submission of follow-up data is essential for calculation and assessment of important quality of care indicators such as disease-free survival, late grade 4 toxicity after radio(chemo)therapy. Detailed follow-up data should be provided at least annually.**

# Oncologic outcome

***Proportion of patients with local recurrence (QCI)***
N: Number of patients in denominator who developed a local recurrence at 1 or 2 year
D: Number of (y)pStage 0-III patients with R0/R1 resection who have a follow-up of 1 or 2 years, respectively. Local recurrence rate curves were calculated using the Kaplan Meier method.

***Disease-free survival (QCI)***
N: Number of patients in denominator who did not develop a local recurrence and/or distant metastasis at 1 or 2 year of follow-up.
D: Number of (y)pStage 0-III patients with R0/R1 resection who have a follow-up of 1 or 2 years, respectively. Disease-free survival rate curves were calculated using the Kaplan Meier method.

***Relative survival***
The relative survival is the ratio of observed survival in a population to the expected survival rate. It estimates the chance that a patient will survive a set number of years after a cancer diagnosis. It is calculated to exclude the chance of death from diseases other than the cancer and shows whether or not that specific disease shortens a person's life.

***Observed survival (QCI)***
N: Number of patients in denominator that survived 1 or 2 years
D: Number of patients for whom the national registry number is known and have a follow-up of 1 or 2 years, respectively. Survival status was obtained through cross-link with the Crossroads Bank for Social Security (CBSS). Survival curves were calculated using the Kaplan Meier method.