PROCARE

PROJECT ON CANCER OF THE RECTUM

FEEDBACK 2011

Belgian Cancer Registry

FEEDBACK 2011

Definitions

Version 1.0
(21/02/2012)

Realised by: David Jegou (Statistician) & **Tamara Vandendael** (Datamanager)
david.jegou@registreducancer.org / tamara.vandendael@kankerregister.org

With the collaboration of:

- **Prof Dr Freddy Penninckx,** chairman of the PROCARE Steering Group
- **Dr Liesbet Van Eycken**, Director of the Belgian Cancer Registry

TABLE OF CONTENTS page

Introduction

This document accompanies **the feedback** on the results of central registration about the management of patients with rectal cancer within PROCARE **as per December 1st 2011**. It contains a list of the general and more specific definitions used to calculate the different items of the report.

The feedback document provides data concerning patients of the team to which the report is addressed on the one hand, and data of the whole PROCARE database on the other hand. They are presented in **tables and graphics**.

List of documents:

- Annex 1: Overall feedback. The 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 data on oncologic outcome.
- Annex 1a: Individual feedback for a centre. This report is done only for centre with at least 10 patients registered as per December 1st 2011.
- Annex 2: Overall observed survival analysis
- Annex 2a: Observed survival analysis for a centre. This report is made only for a centre with data available of at least 50 patients for each observed survival analysis.
- Annex 3: Overall plots
- Annex 3a: Centre plots. This report is done only for centre with at least 10 patients registered.
- Annex 4: TNM tables
- Annex 5: Missing data evaluation

1.1 Methods

Number & Frequency: 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).

Missing data: 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 4009 patients or 87.5% of the global database. Tumour levels were subdivided in high (17.4% or 696/4009), mid (39.9% or 1598/4009) and low rectum (42.8% or 1715/4009). The sum of the percentages of these subsections is 100% because the 573 patients (12.5% of all registered patients) for whom the lowest tumour level was missing were not taken into account.

Percentiles: percentile 25th (p25), percentile 75th (p75) and median are computed for global data in the PROCARE database.

- p25 percentile is the value that has 25% of the measurements below it and 75% above it.
- Median (p50) is the value that has 50% of the measurements below it and 50% above it.
- p75 percentile is the value that has 75% of the measurements below it and 25% above it.

Example, number of patients registered: 25% of the centres have registered less than 10 patients (p25) and 75% of the centers have registered more than 68 patients (p75).

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

1.2 Data cleaning

The PROCARE database has been ócleanedô in several aspects before performing analyses for this feedback.

Inclusion/exclusion criteria:

1. Only invasive adenocarcinomas of the rectum have been included for analysis. This means that other pathologies, such as polyps with noninvasive intramucosal tumour (Tis) or carcinoid tumours, are excluded for analysis. 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.

2. Cases where the lower limit of the tumour is superior to 15 cm have been excluded for analysis.

3. All patients with synchronous tumours outside of the rectum are excluded for analyses for feedback. A synchronous tumour might influence treatment of the rectal cancer as well as the outcome of the patient.

4. Patients who do not reside in Belgium are excluded from the database used for analysis.

Pretreatment diagnosis, staging and function:

5. cStage (cTNM). Because knowledge of the cStage is crucial in order to determine the treatment, missing cStage and cStage X is not desirable. Records with cStage X and missing cStage were checked:
   - if no information was given for any of the staging imaging techniques (CT, MRI, TRUS or others) and no cTNM summary was given, cStage is **missing**
   - if no CT, MRI, TRUS or other techniques for staging were performed (e.g. in emergency circumstances) then cStage is **X** (TxNxMx)
   - if CT, MRI, TRUS or other techniques were done, but no tumour was seen, then cStage is **0**

6. cTNM and pTNM were converted to c or pStage missing when not enough information was given to determine the corresponding stage (e.g. cN missing).

7. The lower limit of the tumour cannot be higher than the upper limit of that same tumour. Patients in which this was the case were checked. Tumour levels were adapted based on information on distal and proximal resection margins.

8. Lower limit of the tumour and categorization in rectal thirds: **(low 0 - Ò5 cm ; mid Ò10 ; high > 10 cm -- <15.1 cm)**

a) For patients who did not have long course radiotherapy, the level obtained by rigid proctoscopy at surgery (if available) overrules pre-treatment data obtained by coloscopy.
b) For tumours at 6 or more cm above the anal verge as indicated on pre-treatment and/or intra-operative data entry, the lowest level has been accepted for definitive classification.
c) For tumours reported to be located in the lower third (Ò5 cm) either before treatment or at surgery, that were treated by a sphincter saving radical resection (LE/TEMS, APER and Hartmann excluded) with stapled distal anastomosis, the following was checked: lowest level at pre-treatment examination or at surgery (in cm) ï (1.5x) the tumour free distal margin in cm as mentioned in the pathology report) must be Ó2 cm in female after stapled SSO and Ó3 cm in male after stapled SSO. If the result of this calculation fits with a remaining length of Ó2 cm in female or Ó3 cm in male, the reported (lowest) level is accepted and the tumour classified as being located in the distal/lower third. If the result of this calculation would indicate a remaining length of <2 cm in female or <3 cm in male, the tumour was classified as being located in the middle third. NB. A factor 1.5 is used because there is shrinkage/shortening of the tumour-free distal margin after fixation and ex vivo measurement.

Operative data:

9. The field ñtype of reconstructionò contains a number of reconstruction types defined as ñotherò which are in fact reconstruction types, present in the option list. Therefore, those ñotherò reconstructions were reassigned according to the description provided.

10. TME and PME (type of resection) and type of reconstruction:
    When ñTMEò is marked for the type of resection, the following resection/reconstruction types are possible:
    - APER (AbdominoPerineal Excision of the Rectum) or Hartmann
    - Restorative Rectum Resection (including all suboptions)
    - IPAA (Ileal Pouch Anal Anastomosis)

    When ñPMEò is indicated for the type of resection, the following reconstruction types are possible
    - High anterior resection + CRA (ColoRectal Anastomosis)
    - Low anterior resection + CRA

    Inconsistencies were cleaned.

11. APER or Hartmann always include a definitive stoma. Therefore, if a derivative stoma was marked, this was deleted.

12. The approach of surgical exploration, resection and reconstruction can be laparotomy, laparoscopy or converted laparoscopy. The 3 approaches need to follow a certain order e.g. once a laparotomy is performed, all further approaches will be laparotomy. Inconsistencies were cleaned.

13. Discharge date if postoperative death. When a patient dies in hospital, a discharge date is not needed. Therefore discharge dates of patients who died in hospital were deleted.

Radiotherapy and/or chemotherapy:

14. 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, except if the first and last radiotherapy dates are not missing.

15. Neoadjuvant chemotherapy without radiotherapy is very rare in cStage II-III. The medical files were checked and if it was not clear that radiotherapy had been given (e.g. from pathology report) the data manager asked complementary information, as appropriate.

Pathology:

16. In general, the proximal margin should be greater than the distal margin. All forms in which the distal margin was greater than the proximal margin were checked and it was decided whether both margins needed to be reversed or adapted; when available, the pathology report was checked.
    Also, the total length of the tumour must be larger than the sum of the proximal and distal margin of the tumour.

17. In a previous version of the data entry set, two rectal cancer regression indices were used: the Dworak regression grade and the Rectal Cancer Regression Grade (RCRG). Both were cleaned as follows:
    - A regression grade can only be marked in case of an ypStage and vice versa. Therefore pStages with regression grade and ypStages without regression grade were cleaned.
    - ypStage 0 needs to have a Dworak 4 (or a RCRG 1)
    Furthermore, all ñRCRGsò were transformed into ñDworaksò.

General data:

18. Checking dates. Dates of first contact, neoadjuvant treatment, surgery and discharge need to be in a logical sequence. The following date-inconsistencies were checked:
    - Date of first contact (or biopsy) needs to be before neoadjuvant treatment and surgery date
    - Date of neoadjuvant treatment needs to be before surgery date
    - Date of discharge needs to be after surgery date
    If these dates were missing, the medical files were checked to complete these dates. In most cases the exact dates are mentioned in accompanying documents e.g. pathology protocol. For others, the data manager contacted the submitting physician.

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 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.

II - Demographic data

No specific remarks on definitions.

III - Pretreatment diagnosis, staging and function

Date of incidence

Defined by the date of pathological diagnosis (biopsy), if missing by the date of first consultation or hospitalization, if still missing by the date of first treatment (any type).

Note: it is important to mention the date of the first contact when the <u>diagnosis</u> 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.

Proportion of patients with a documented distance from the anal verge (KCE 2008 QCI 1211; process indicator)

Priority sequence to determine lower limit: (1) pretreatment rectoscopy, (2) pretreatment colonoscopy, (3) rectoscopy or colonoscopy at surgery

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

Lower limit tumour (LL)	**Level tumour**
Ò5 cm	Low
>5 - Ò10 cm	Mid
>10 cm ï 15.0 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

Missing lower limit:
N: Number of patients for whom the level of the tumour is missing
D: Number of registered patients

Proportion of patients undergoing elective surgery that had preoperative complete large bowel-imaging (KCE 2008 QCI 1214; process indicator)

N: Number of patients in denominator who underwent a total coloscopy or a complete double contrast enema or virtual colonoscopy
D: Number of patients treated with elective or scheduled surgery

Proportion of patients in whom a CT of the abdomen and RX or CT thorax was performed before any treatment (KCE 2008 QCI 1212; process indicator)

N: Number of patients in denominator in whom an abdominal CT and (RX thorax or CT thorax) was performed before any treatment. (Abdominal)CT for cT and/or cN staging and RX thorax or CT for cM staging.
D: Number of patients who are registered since the 1st of august 2008 and who underwent elective/scheduled surgery

Use of imaging

Note: Definitions of ñUse of imagingò have been changed since the previous version.

Use of any imaging (CT/MRI/TRUS)
N: Number of patients in denominator in whom cT and/or cN was based on imaging (TRUS or CT or MRI)
D: Number of patients with rectal cancer of any stage and registered since the 1st of august 2008 without missing data for imaging information.

Use of TRUS (any stage)
N: Number of patients in denominator in whom cT and/or cN was based on TRUS
D: Number of patients with rectal cancer of any stage and registered since the 1st of august 2008 without missing data for imaging information.

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 patients with rectal cancer of any stage and registered since the 1st of august 2008 without missing data for imaging information..

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 patients with rectal cancer of any stage and registered since the 1st of august 2008 without missing data for imaging information.

Use of TRUS in cT1/cT2 (new QCI; process indicator)

N: Number of patients in denominator in whom cT was based on TRUS
D: Number of patients with cT1 or cT2 rectal cancer, who underwent elective/scheduled surgery and are registered since the 1st of august 2008 without missing data for imaging information.

Use of MRI in cStage II or III (new QCI; process indicator)

N: Number of patients in denominator in whom cStaging was based on MRI
D: Number of patients with cStage II or III rectal cancer based on any imaging technique, who underwent elective/scheduled surgery and are registered since the 1st of august 2008 without missing data for imaging information.

Proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment (KCE QCI 1215; process indicator)
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 patients with rectal cancer of any stage and registered since the 1st of august 2008

Proportion of patients with cStage II-III RC that have a reported cCRM (KCE QCI 1216; process indicator)

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, especially 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 ï 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

cStage missing
N: Number of patients for whom cStage is missing
D: Number of registered patients

Proportion of patients in whom a CEA was performed before any treatment (KCE 2008 QCI 1213; process indicator)

N: Number of patients in denominator for whom CEA serum level before treatment is reported
D: Number of registered patients

Accuracy of cT/cN staging if no or short radiotherapy (separately presented in 2 tables) (new QCI; process indicator)

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.

D: All patients with TRUS/CT/MRI with no or short neoadjuvant radiotherapy (without long R(C)T) and for whom the pT and pN is known and for whom the cT and cN is known (excluding patients with c and/or pTx and/or c and/or pNx

IV - Time to first treatment

Missing date of biopsy or first consultation

N: Number of patients for whom the date of biopsy and/or the date of first consultation is missing
D: Number of registered patients

Time between first histopathologic diagnosis and first treatment (KCE QCI 1217; process indicator)

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.

V - 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 or radiotherapy form indicates that chemotherapy was given, the patient is considered to be treated with neoadjuvant chemotherapy.

Proportion of cStage II-III patients with radical surgical resection that received a neoadjuvant pelvic RT (new QCI : process indicator replacing KCE 2008 QCI 1221 and 1222).

Global (all rectal cancer at any level)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients in cStage II or III, treated with radical surgical resection with rectal cancer at any level and for whom the course of radiotherapy treatment is not missing

For high rectal cancer (> 10 cm)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients in cStage II or III, treated with radical surgical resection with tumour in upper third and for whom the course of radiotherapy treatment is not missing

For mid rectal cancer (>5 - Ò10 cm)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients in cStage II or III, treated with radical surgical resection with tumour in middle third .and for whom the course of radiotherapy treatment is not missing

For low rectal cancer (Ò5 cm)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients in cStage II or III, treated with radical surgical resection with tumour in lower third and for whom the course of radiotherapy treatment is not missing

Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that completed this neoadjuvant treatment within the planned timing (KCE 2008 QCI 1225; process indicator)

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

Proportion of patients with cCRM Ò 2 mm on MRI/CT that received long course neoadjuvant radio(chemo)therapy (new QCI; process indicator)

N: Number of patients in denominator who received long course neoadjuvant radio(chemo)therapy
D: Number of patients treated with radical surgical resection and for whom cCRM is **Ò**2 mm and for whom it is known whether they received neoadjuvant treatment or not

Proportion of patients with cStage I that received neoadjuvant radio(chemo)therapy (new QCI; process indicator)

Global (all rectal cancer at any level)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients treated with radical surgical resection for cStage I rectal cancer

For high rectal cancer (> 10 cm)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients in cStage I, treated with radical surgical resection with tumour in upper third

For mid rectal cancer (>5 - Ò10 cm)
N: Number of patients in denominator who received neoadjuvant **R(C)T**
D: Number of patients in cStage I, treated with radical surgical resection with tumour in middle third

For low rectal cancer (Ò5 cm)
N: Number of patients in denominator who received neoadjuvant treatment **R(C)T**
D: Number of patients in cStage I, treated with radical surgical resection with tumour in lower third

Proportion of cStage II-III patients treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU (KCE 2008 QCI 1224; process indicator)

N: Number of patients in denominator that received a continuous infusion of 5-FU.
D: Number of patients with cStage II-III treated with radical surgical resection and long course pelvic chemoradiotherapy

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 long course radiotherapy

Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 4 to 12 weeks after completion of the (chemo)radiation (KCE 2008 QCI 1226 adapted; process indicator)

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

VI - Surgery

Surgical resection and reconstruction

1. **Treated with radical surgical resection**
A patient treated with abdominoperineal resection (APER), Hartmannôs procedure, or sphincter sparing/saving radical rectum resection (PME or TME) with reconstruction (SSO) is considered to be treated with radical surgical 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 (ColoRectal Anastomosis above peritoneal reflection)
- Low anterior resection + CRA (ColoRectal Anastomosis below peritoneal reflection)
- Complete rectum resection (TME) + straight CAA (Colo-Anal Anastomosis)
- Complete rectum resection (TME) + colon J pouch
- Complete rectum resection (TME) + coloplasty
- Complete rectum resection (TME) + side-to-end coloanal anastomosis
- Complete rectum resection (TME) + other (specified)
- Total excision of Colon and Rectum with IPAA (Ileal Pouch Anal Anastomosis)

Mode of surgery

Elective/Scheduled
N: Number of patients in denominator for whom the mode of surgery is ôelectiveô or ôscheduledô
D: Number of patients treated with surgical resection (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 ôurgentô or ôemergencyô
D: Number of patients treated with surgical resection (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 surgical resection (any type)

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

Approach surgical resection/reconstruction if radical surgical resection

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

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

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

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

Proportion of R0 resections (KCE 2008 QCI 1231; outcome indicator)

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 óR2ô or the simultaneous complete resection of metastases in cStage IV patients is not mentioned, then R status equals óR2ô.

R1 status. Resections are classified as R1 if cM does not equal óM1ô (i.e. in the absence of clinical metastases) and if type of resection at surgery is not óR2ô and if at least one of the following four conditions is 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 óM1ô and if type of resection at surgery is not óR2ô and if none 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: tumour free status of the (y)pCRM, the tumour 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 surgical 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 surgical resection and for whom R status is not missing

R2 resection
N: Number of patients in denominator with R status equal ôR2ô
D: Number of patients treated with radical surgical 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 surgical resection

Rate of intra-operative rectal perforation (KCE 2008 QCI 1235; outcome indicator)

N: Number of patients in denominator for whom the surgeon and/or pathologist reported rectal perforation
D: Number of patients treated with radical surgical 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 and/or the pathologist
D: Number of patients treated with radical surgical resection

(y)p distal margin involved (positive) after SSO or Hartmann for low rectal cancer (Ò5 cm) (new QCI; outcome indicator)

N: Number of patients in denominator for whom the (y)p distal margin is invaded
D: Number of patients treated with Hartmannôs 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.
Note: For this indicator, patients with ypStage 0 or (y)pStage X are excluded from the analysis

Mesorectal (y)pCRM positivity after radical surgical resection (new QCI; outcome indicator)

Note: The definition of positivity is a mesorectal circumferential resection margin Ò1 mm.
Note: For this indicator, patients with ypStage 0 or (y)pStage X are excluded from the analysis.

Global
N: Number of patients in denominator for whom the mesorectal (y)pCRM is positive
D: Number of patients treated with radical surgical resection for rectal cancer located at least partially below the peritoneal reflection and for whom the mesorectal (y)pCRM is known

For high rectal cancer (> 10 cm)
N: Number of patients in denominator for whom the mesorectal (y)pCRM is positive
D: Number of patients treated with radical surgical resection (PME and TME) with tumour in highest third but located at least partially below the peritoneal reflection and for whom (y)pCRM is known

For mid rectal cancer (>5 - Ò10 cm)
N: Number of patients in denominator for whom the mesorectal (y)pCRM is positive
D: Number of patients treated with radical surgical resection with tumour in middle third, located at least partially below the peritoneal reflection, and for whom (y)pCRM is known

For low rectal cancer (Ò5 cm)
N: Number of patients in denominator for whom the mesorectal (y)pCRM is positive
D: Number of patients treated with radical surgical resection with tumour in lowest third and for whom the mesorectal (y)pCRM is known

Missing (y)pCRM
N: Number of patients in denominator for whom the mesorectal (y)pCRM is missing
D: Number of patients treated with radical surgical resection

Technique of resection

PME
N: Number of patients in denominator for whom PME (as indicated by the surgeon) is the technique of resection
D: Number of patients with radical surgical resection for whom the technique of resection is known

TME
N: Number of patients in denominator for whom TME (as indicated by the surgeon) is the technique of resection
D: Number of patients with radical surgical resection for whom the technique of resection is known

Conventional
N: Number of patients in denominator for whom the technique of resection is ócconventionalô, as indicated by the surgeon.
D: Number of patients with radical surgical 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 surgical 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 resection

2) Proportion of APER, Hartmannôs procedure or total excision of colon and rectum with definitive ileostomy (KCE 2008 QCI 1232a adapted; outcome indicator)

Global (QCI)
N: Number of patients in denominator in whom APER or Hartmannôs procedure or total excision of colon and rectum with definitive ileostomy was performed
D: Number of patients treated with any type of resection for rectal cancer at any known level

For high rectal cancer (> 10 cm)
N: Number of patients in denominator in whom APER or Hartmannôs procedure or total excision of colon and rectum with definitive ileostomy was performed
D: Number of patients treated with any type of resection for tumour in upper third

For mid rectal cancer (>5 - Ò10 cm)
N: Number of patients in denominator in whom APER or Hartmannôs procedure or total excision of colon and rectum with definitive ileostomy was performed
D: Number of patients treated with any type of resection for tumour in middle third

For low rectal cancer (Ò5 cm)
N: Number of patients in denominator in whom APER or Hartmannôs procedure or total excision of colon and rectum with definitive ileostomy was performed
D: Number of patients treated with any type of resection 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, total excision of colon and rectum with IPAA, or another specified type of reconstruction was performed
D: Number of patients treated with any type of resection for rectal cancer at any known level

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

Low anterior resection + CRA (colorectal anastomosis below the peritoneal reflection)
N: Number of patients in denominator with low anterior resection + CRA
D: Number of patients treated with any type of resection 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, total excision of colon and rectum with IPAA, or another specified type of reconstruction
D: Number of patients treated with any type of resection 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 resection 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 resection 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 resection 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 resection for rectal cancer at any known level

Complete resection of colon and rectum with IPAA (ileal pouch-anal anastomosis)
N: Number of patients in denominator with complete resection of colon and rectum with IPAA
D: Number of patients treated with any type of resection 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 resection for rectal cancer at any known level

Distal anastomosis technique after SSO for low rectal cancer (Ò5 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
D: Number of patients with tumour in lower third treated with SSO and reconstruction

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

Missing data on derivative stoma after PME
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 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 (órestorative rectum resectionô) 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 (órestorative rectum resectionô) were performed

Note: for potential improvement it is important to know whether a primary derivative stoma was constructed (i.e. at primary radical surgery with SSO procedure or not

Rate of patients with major leakage of the anastomosis (KCE 2008 QCI 1233; outcome indicator)

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, total excision of colon and rectum with IPAA, 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, total excision of colon and rectum with IPAA, 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 for leakage)
D: Number of patients treated with TME (complete rectum resection (TME) + straight CAA, coloplasty, pouch, side-to-end CAA, total excision of colon and rectum with IPAA, 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 stoma 1 year after sphincter-sparing surgery (KCE 2008 QCI 1232b; outcome indicator)

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, total excision of colon and rectum with IPAA, or another specified type of reconstruction) with a primary (constructed at the time of SSO) or secondary (constructed after SSO) derivative stoma or dismantling of anastomosis still alive 1 year after surgery and for whom follow-up at 1 year or more is known

30-day mortality (KCE 2008 QCI 1234; outcome indicator)

N: Number of patients in denominator who died within 30 days after surgery
D: Number of patients treated with radical surgical resection and for whom it is known whether they died within 30 days after surgery and for whom the dates of surgery and survival or death are known

Postoperative major surgical morbidity with reintervention under narcosis after radical surgical resection (new QCI; outcome indicator)

N: Number of patients in denominator who presented major surgical morbidity requiring reintervention under narcosis
D: Number of patients treated with radical surgical resection and for whom postoperative data on morbidity/mortality are available

ASA (only for patients with radical surgical 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 surgical 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 surgical 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 surgical resection who did not die in-hospital.

VII - Pathology

Use of the pathology report sheet (KCE 2008 QCI 1271; process indicator)

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

Quality of TME assessed according to Quirke and mentioned in the pathology report (KCE 2008 QCI 1272; process indicator)

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 surgical resection and TME as reported by the surgeon and for whom the TME quality is reported (after 1st January 2007)

Mesorectal (y)pCRM mentioned in mm in the pathology report if radical surgical resection (KCE 2008 QCI 1275; process indicator)

N: Number of patients in denominator for whom the mesorectal (y)pCRM was mentioned in mm in the pathology report
D: Number of patients treated with radical surgical resection and for whom a pathology report was completed.
Note: For this indicator, patients with ypStage 0 or (y)pStage X are excluded for analysis

Distal margin involvement mentioned after SSO or Hartmann (new QCI; outcome QCI)

N: Number of patients in denominator for whom it was reported whether the distal resection margin was invaded or not
D: Number of patients treated with Hartmannôs procedure or SSO with reconstruction and for whom a pathology report sheet was completed.
Note: For this indicator, patients with ypT0 and ypTis are excluded for analysis

Distal tumour-free margin mentioned in the pathology report (KCE 2008 QCI 1273; process indicator)

N: Number of patients in denominator for whom the length of the distal free tumour free margin was reported in the pathology report
D: Number of patients treated with SSO or Hartmannôs procedure.
Note: patients with ypT0 and ypTis are excluded for the analysis

Mean distal tumour-free margin after SSO or Hartmannôs procedure

Note: For this indicator, patients with ypT0 and ypTis are excluded for analysis

For high rectal cancer (> 10 cm)
Mean distal tumour-free margin (in cm) of patients in the upper third treated with SSO or Hartmann for whom the distal tumour-free margin is known

For mid rectal cancer (>5 - Ò10 cm)
Mean distal tumour-free margin (in cm) of patients in the middle third treated with SSO or Hartmann for whom the distal tumour-free margin is known

For low rectal cancer (Ò5 cm)
Mean distal tumour-free margin (in cm) of patients in the lower third treated with SSO or Hartmann for whom the distal tumour-free margin is known

Missing data on length of distal margin
N: Number of patients in denominator for whom the distal tumour-free margin is not mentioned
D: Number of patients treated with SSO or Hartmannôs procedure

(y)pT categories after radical surgical resection

Note: if no tumour was found in a radical surgical resection specimen after previous endoscopic or local excision, the pT category of the endoscopic or local excision (was asked and) was used for T-staging 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 surgical resection
D: Number of patients treated with radical surgical resection and for whom (y)pT is not missing
Note: Patients with pT0 or pTis at endoscopic polypectomy, LE, TEMS or radical resection are excluded from the database for analysis.

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 surgical resection and for whom (y)pT is not missing
Note: Patients with pT0 or pTis at endoscopic polypectomy, LE, TEMS or radical resection are excluded from the database

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

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

(y)pN categories after radical surgical resection

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

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

Number of lymph nodes examined (KCE 2008 QCI 1274; process indicator)

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 treatment) (KCE 2008 QCI 1276; process indicator)

N: Number of patients in denominator having their tumour regression grade mentioned in the pathology report

D: Number of patients treated with neoadjuvant long course radio(chemo)therapy and surgery (incl. any type of "local excision")

(y)pStage after radical surgical resection

ypStage 0

N: Number of patients in denominator with ypStage 0 or ypTisN0

D: Number of patients treated with radical surgical 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 surgical 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 surgical 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 surgical 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 intra-operative findings

D: Number of patients treated with radical surgical 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 and/or (y)pNx and/or cMx.

D: Number of patients treated with radical surgical 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 surgical resection

VIII - Adjuvant treatment

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 (y)pStage III patients with R0 resection that received adjuvant chemotherapy starting within 3 months after surgery (KCE 2008 QCI 1241; process indicator)

N: Number of patients in denominator receiving adjuvant chemotherapy within 3 months after surgery
D: Number of patients treated with R0 radical surgical resection for (y)pStage III and for whom the start date of adjuvant chemotherapy is known

Missing data on adjuvant chemotherapy for (y)pStage III after R0 resection

N: Number of patients in denominator for whom the date of the start of adjuvant chemotherapy is not known
D: Number of patients treated with R0 radical surgical resection for (y)pStage III

Proportion of (y)pStage II-III patients with R0 resection that started adjuvant chemotherapy for (y)pStage II or III within 3 months after surgery (KCE 2008 QCI 1243; process indicator)

N: Number of patients in denominator receiving adjuvant chemotherapy within 3 months after surgery
D: Number of patients treated with R0 radical surgical resection for (y)pStage II or III and for whom the start date of adjuvant chemotherapy is known

Missing data on adjuvant chemotherapy for (y)pStage II or III after R0 resection

N: Number of patients in denominator for whom the date of the start of adjuvant chemotherapy is not known
D: Number of patients treated with R0 radical surgical resection for (y)pStage II or III

IV - Follow-up

Number of follow-up forms registered per follow-up time period..

For each follow-up period: 6,12,18,24,30,36,42,48,54,60 months.

N: Number of patients in denominator for whom the follow-up form is completed
D: Number of patients alive at the time of follow-up and without local recurrence or metastasis.

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.

In view of the limited number of adequate and updated follow-up data, no valuable feedback can be provided.

V - Oncologic outcome

Overall 5-year survival (KCE 2008 QCI 1111; outcome indicator)

N: Number of patients in denominator that survived 5 years
D: Number of patients for whom the national number is known.

This QCI is called observed survival in PROCARE feedback. Survival curves were calculated using the Kaplan Meier method. The incidence date is the date of start for the calculation of survival time. Survival status was obtained through cross-link with the Crossroads Bank for Social Security (CBSS).

VI - Missing data evaluation

Missing data are a potential source of bias. The interpretation of the results of a study is always problematic when the proportion of missing values is important. Moreover, there is no methodological approach for handling missing values that is universally accepted in all situations. The best way to avoid bias is to reduce the number of missing data. Missing data in Procare database was evaluated since 2008. Table in Annex 5 highlights the evolution of missing data by variable in Procare database.

VII ï Plots

These kinds of plots (Annex 3 / Annex 3a) order centres by percentage (with their 95% confidence interval) of the observed parameter (Reported cCRM, Rectal perforationé) as shown on the figure below.

95% confidence interval was obtained using the Wilson ôscoreô method without continuity correction.

Median, percentile 25th, percentile 75th were computed for centres with at least 10 patients registered in Procare database. Note that these indicators were not exactly the same for the overall Procare database (with all centres).

The grey zone indicated observed extreme values compared to the others centres with at least 10 patients. All centres with the upper (or lower) boundary of the 95% confidence interval below the percentile 25th (or above the percentile 75th) are inside the grey zone. Note that this analysis was not adjusted for confounding factors (age, cStageé); thus, results are exploratory and interpretation must be done with caution.