Assurance de qualité pour le cancer rectal – phase 2: développement et test d'un ensemble d'indicateurs de qualité

KCE reports 81B

Federaal Kenniscentrum voor de Gezondheidszorg
Centre fédéral d'expertise des soins de santé
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PREFACE

L'amélioration de la qualité des soins constitue l'une des priorités du Plan National Cancer. Dans ce cadre, la ministre a formulé un certain nombre de propositions concrètes, notamment la mise en place d'une structure au sein du Collège d'Oncologie qui serait chargée de définir des mécanismes de contrôle, le financement de datamanagers pour l'enregistrement des données sur les cancers dans les hôpitaux, etc. En outre, la Fondation Registre du Cancer sera renforcée afin d'optimiser l'enregistrement et l'analyse des données sur les cancers.

L'initiative PROCARE (PROject on CAncer of the REctum) s'inscrit parfaitement dans un tel contexte. Il y a peu, dans le cadre d'une première phase de ce projet, des recommandations de bonne pratique evidence-based ont été définies en collaboration avec le KCE par un groupe multidisciplinaire de spécialistes belges en cancer du rectum. Dans un second temps, ces recommandations ont été traduites par ce même groupe, en critères de qualité concrets. Avec l'aide de la Fondation Registre du Cancer, le présent rapport étudie dans quelle mesure ces critères de qualité sont mesurables avec les données belges sur les cancers dont nous disposons et quelles conditions doivent être remplies pour pouvoir transposer cette mesure de la qualité dans la pratique. Il apparaît qu'il ne s'agit pas d'un exercice évident.

Quelques primeurs caractérisent ce projet et méritent d'être épinglées. Ainsi, c'est la première fois que les données de la Fondation Registre du Cancer sont utilisées à des fins qualitatives. En outre, dans PROCARE, un couplage inédit entre les données de la Fondation Registre du Cancer, de l'Agence Intermutualiste et de la Cellule technique de l'INAMI, a été réalisé. Nul doute que de futurs projets de la même veine pourront s'inspirer de l'expérience engrangée dans le cadre de PROCARE.

Il est bien entendu que la mesure de la qualité ne représente qu'un premier pas dans un processus d'amélioration continue. L'interprétation des résultats et des actions d'amélioration ciblées sont les étapes logiques suivantes. Il incombe maintenant aux acteurs intéressés de prouver dans les années qui viennent que cette initiative aura vraiment eu pour résultat une amélioration de la qualité des soins.

Jean Pierre Closon
Directeur général adjoint

Dirk Ramaekers
Directeur général

Résumé

I INTRODUCTION

Le projet PROCARE (PROject on CAncer of the REctum) a démarré en 2004 en Belgique. Cette initiative a pour but d'améliorer et de standardiser la qualité des soins dans le cancer rectal grâce à la définition et à la mise en œuvre de recommandations spécifiques et à une surveillance de la qualité via un enregistrement et un feedback. Toutes les spécialités médicales impliquées dans le traitement du cancer du rectum ont été rassemblées au sein d'un groupe de travail multidisciplinaire avec des représentants de leurs associations scientifiques respectives. Une première version provisoire des recommandations PROCARE a été rédigée en 2005. Elles ont été diffusées via des ateliers (chirurgie, pathologie, radiothérapie, chimiothérapie et radiologie). Une base de données prospective contenant les données individuelles des patients a été développée et un enregistrement volontaire par l'intermédiaire de la Fondation Registre du Cancer a débuté en 2006. Toutes les données pertinentes (du staging au follow-up) des centres participants relatives aux nouveaux patients atteints de cancer du rectum ont été introduites dans cette base de données prospective. Enfin, fin 2007, les recommandations provisoires PROCARE ont été actualisées par un groupe de travail multidisciplinaire en collaboration avec le KCE (phase 1 du projet).

Afin de permettre un feed-back individuel et une comparaison (inter)nationale, il a été décidé de construire d'abord un système d'indicateurs de qualité. Le but étant de se concentrer sur le traitement primaire des patients atteints de cancer du rectum, et ce, pour l'ensemble de leur parcours de soins (à partir du diagnostic et du staging jusqu'au suivi).

Le présent rapport décrit le processus de recherche d'une sélection d'indicateurs de qualité pertinents. La faisabilité d'une mesure des indicateurs sélectionnés a été testée dans la base de données prospective PROCARE, d'une part, et une base de données administratives d'autre part. Le rapport apporte une réponse aux questions suivantes:

1. Parmi les indicateurs de qualité sélectionnés, lesquels sont mesurables ?
2. A quel niveau ces indicateurs sont-ils mesurables (national, hôpital, prestataire de soins) ?
3. Quelles données minimales sont-elles nécessaires pour mesurer et interpréter les indicateurs ? La base de données PROCARE et la base de données administratives sont-elles complémentaires ?
4. Comment seront présentés les résultats de la mesure ?

En outre, sur la base de cet exercice, on s'efforcera de définir une méthodologie générique de mesure des indicateurs de qualité oncologiques en Belgique. Enfin, le rapport fournit encore un tour d'horizon des expériences internationales en matière de mesure de la qualité des soins dans le cancer du rectum.

2 ÉLABORATION D'UNE SÉRIE D'INDICATEURS DE QUALITÉ

2.1 MÉTHODOLOGIE

Les auteurs ont consulté aussi bien la littérature indexée (Medline et Cochrane Library) que la littérature grise (recommandations de bonne pratique, sites Internet d'organisations, National Quality Measures Clearinghouse).

Les critères suivants ont été utilisés pour sélectionner les indicateurs de qualité:

- pertinence;
- niveau de preuve;
- lien avec les recommandations PROCARE;
- niveau de qualité (niveau 1 : indicateurs de qualité influencés par toutes les phases de soins ; niveau 2 : indicateurs de qualité essentiels, influencés par un phase de soins spécifique (par exemple chirurgie) ; niveau 3 : indicateurs de qualité nécessaires pour l'interprétation des indicateurs de niveau 1 et 2).

Seuls les indicateurs de qualité de niveau 1 et 2 ont été pris en considération pour leur inclusion. Un groupe de travail multidisciplinaire a proposé des indicateurs de qualité additionnels avec comme point de départ les recommandations PROCARE.

2.2 RÉSULTATS

Au total, quelque 205 indicateurs de qualité ont été trouvés dans la littérature, dont 23 ont été retenus. Le groupe de travail multidisciplinaire a de son côté proposé 17 indicateurs de qualité supplémentaires. Le tableau 1 présente un aperçu des 40 indicateurs sélectionnés.

Tableau 1. Aperçu des indicateurs de qualité sélectionnés

Indicateurs de qualité généraux
Survie absolue à 5 ans par stade
Survie spécifique à 5 ans par stade
Proportion de patients avec récidive locale
Proportion de patients dont le cas a été débattu au cours d'une concertation multidisciplinaire
Diagnostic et staging
Proportion de patients avec une distance documentée de la marge anale
Proportion de patients chez qui un CT du foie et une RX ou un CT du thorax ont été effectués avant le traitement
Proportion de patients chez qui un CEA a été déterminé avant le traitement
Proportion de patients soumis à une imagerie préopératoire de la totalité du côlon avant une chirurgie élective
Proportion de patients ayant subi une échographie transrectale du rectum et une CT ou une IRM du petit bassin avant le traitement
Proportion de patients de stade clinique II-III avec cCRM rapporté
Délai entre le premier diagnostic histopathologique et le premier traitement
Traitement néo-adjuvant
Proportion de patients de stade clinique II-III ayant bénéficié d'un schéma court de radiothérapie néo-adjuvante du petit bassin
Proportion de patients de stade clinique II-III ayant bénéficié d'un schéma long de radiothérapie néo-adjuvante du petit bassin

Proportion de patients de stade clinique II-III ayant reçu une irradiation néo-adjuvante en combinaison avec une chimiothérapie néo-adjuvante à base de 5-FU
Proportion de patients de stade clinique II-III ayant reçu une chimioradiothérapie néo-adjuvante de type 5-FU et chez qui le 5-FU a été administré en perfusion continue
Proportion de patients de stade clinique II-III ayant bénéficié d'un schéma long de radiothérapie néo-adjuvante du petit bassin et ayant finalisé le traitement dans le délai prévu
Proportion de patients de stade clinique II-III ayant bénéficié d'un schéma long de radiothérapie néo-adjuvante du petit bassin et ayant été opérés dans les 6 à 8 semaines après la fin de la radiothérapie.
Proportion de complications aiguës de degré 4 associées à la radio(chimio)thérapie
Chirurgie
Proportion de résections R0
Proportion de résections abdominopérinéales et de procédures de Hartmann
Proportion de patients avec une stomie 1 an après une chirurgie conservatrice sphinctérienne
Proportion de patients présentant une fuite majeure résultant d'une anastomose après une chirurgie conservatrice sphinctérienne
Mortalité à l'hôpital ou à 30 jours
Proportion de perforations rectales intraopératoires
Traitement adjuvant
Proportion de patients stade (y)p III ayant subi une résection R0 qui ont reçu une chimiothérapie adjuvante
Proportion de patients stade (y)p II-III ayant subi une résection R0 qui ont reçu une (chimio)radiothérapie adjuvante
Proportion de patients stade (y)p II-III ayant subi une résection R0 qui ont reçu une chimiothérapie adjuvante dans les 3 mois qui suivent la résection chirurgicale
Proportion de patients stade (y)p II-III ayant subi une résection R0 qui ont reçu une chimio(radio)thérapie adjuvante à base de 5-FU
Proportion de complications aiguës de degré 4 associées à la radiothérapie ou à la chimiothérapie
Traitement palliatif
Proportion de patients stade clinique IV ayant reçu une chimiothérapie
Proportion de complications aiguës de degré 4 associées à la chimiothérapie chez des patients de stade IV
Follow-up
Proportion de patients ayant suivi un traitement curatif chez qui une coloscopie totale a été réalisée dans l'année suivant le traitement
Proportion de patients ayant bénéficié d'un follow-up selon les recommandations PROCARE
Proportion de complications tardives de degré 4 associées à la radio- ou chimiothérapie
Examen histopathologique
Utilisation du rapport de pathologie
Qualité de l'excision mésorectale totale définie selon les critères de Quirke et mentionnée dans le rapport de pathologie
Marge de sécurité distale mentionnée dans le rapport de pathologie
Nombre de ganglions lymphatiques examinés
(y)pCRM mentionné dans le rapport de pathologie en millimètres
Degré de régression tumorale mentionné dans le rapport de pathologie (après traitement néo-adjuvant)

3 ETUDE DE FAISABILITÉ POUR LA MESURE DES INDICATEURS DE QUALITE

3.1 METHODOLOGIE

La faisabilité de la mesure des indicateurs de qualité sélectionnés a été testée sur deux bases de données différentes:

1. Base de données prospective PROCARE: aux fins de cette étude, on a utilisé les données de 1071 premiers patients atteints d'un cancer du rectum enregistrés en 2006-2007.
2. Base de données administratives: aux fins de cette étude, on a réalisé un couplage entre les données de la Fondation Registre du Cancer (FRC) (2000-2004), de l'Agence Intermutualiste (AIM) (2001-2004) et de la Cellule technique (CT) (juillet 2001-2004). Pour la sélection primaire des patients, on a utilisé les codes topographiques ICD-O-3 de la FRC (C20.9, tumeur maligne du rectum). Une sélection complémentaire via la base de données de la CT (ICD-9-CM 154.1, cancer du rectum) est apparue impossible. La sélection finale comprenait 7074 patients souffrant de cancer du rectum.

Pour chaque indicateur de qualité sélectionné, le dénominateur et le numérateur ont été traduits en codes mesurables des bases de données respectives. Dans la base de données PROCARE, chaque variable s'est vu attribuer un code spécifique. Pour les données administratives, on a utilisé les codes de la nomenclature, les codes ICD-9-CM, les codes FRC et les codes ATC.

Pour chaque indicateur de qualité mesurable, les résultats ont été exprimés en tant que moyenne pondérée et non pondérée (avec un intervalle de confiance de 95%). Les résultats ont par ailleurs été déclinés par centre.

Enfin, les résultats ont été agrégés selon deux méthodes. D'une part, on a calculé une moyenne globale de tous les résultats par centre. D'autre part, un "classement moyen corrigé" a été calculé en attribuant à chaque centre par indicateur un classement, celui-ci étant corrigé pour le nombre de centres pour lesquels l'indicateur était mesurable. Ensuite, une moyenne de tous les classements corrigés a été calculée par centre. Pour les centres participants au projet PROCARE, on a en outre calculé la corrélation entre le classement moyen corrigé calculé avec, d'une part, la base de données PROCARE et, d'autre part, la base de données administrative.

3.2 RÉSULTATS

Au total, il est apparu que 30 indicateurs étaient mesurables avec la base de données PROCARE et 9 avec la base de données administratives. Six indicateurs sont mesurables avec les deux bases de données, tandis que 7 autres indicateurs ne sont mesurables avec aucune des deux. L'absence de codes (spécifiques) est la principale raison pour laquelle les indicateurs ne sont pas mesurables. Pour la base de données administrative, il s'agit surtout de l'absence de codes pour les issues cliniques (par exemple, résection R0) ou les résultats cliniques (par exemple, cCRM).

Il est apparu que différents indicateurs avaient des dénominateurs et numérateurs relativement petits. Ceci s'explique en raison de deux problèmes. D'une part, dans la base de données PROCARE, on a constaté qu'un nombre important de données faisaient défaut. Par ailleurs, pour des raisons techniques, dans le cas de 6 indicateurs, il n'a pas été possible de calculer les données manquantes. Enfin, le nombre de patients inclus par centre est apparu relativement faible.

La plupart des indicateurs individuels affichent une variation suffisante pour rendre possible une distinction entre les centres qui dispensent des soins de haute qualité par rapport à ceux dont les soins sont de qualité médiocre. Toutefois, la variation entre les moyennes globales par centre et les classements moyens corrigés est moins accentuée. De plus, on n'a trouvé aucune corrélation entre le classement moyen corrigé calculé avec la base de données PROCARE, d'une part, et la base de données administratives, d'autre part.

4 EXPERIENCES INTERNATIONALES

En janvier 2008, des experts de quelques pays d'Europe occidentale (Danemark, France, Allemagne, Norvège, Suède, Espagne, Pays-Bas et Grande-Bretagne) ont été contactés. On les a, d'une part, interrogés à propos des caractéristiques principales de leur base de données/registre. D'autre part, les auteurs de l'étude ont vérifié dans quelle mesure les informations nécessaires pour mesurer les indicateurs de qualité sélectionnés étaient disponibles.

La Suède, la Norvège, le Danemark et la Grande-Bretagne disposent d'une base de données nationale fonctionnelle de type "population-based" des patients atteints de cancer du rectum. Aux Pays-Bas, une base de ce type a été introduite récemment. La France, l'Allemagne et les Pays-Bas possèdent des bases de données régionales.

Il ressort qu'en Suède et en Norvège, les informations nécessaires sont disponibles pour la plupart des indicateurs de qualité. Certains indicateurs de niveau 1, notamment la survie à 5 ans, sont manifestement mesurables dans la plupart des pays contactés.

5 CONCLUSIONS ET RECOMMANDATIONS

- Pour la plupart des indicateurs sélectionnés, les informations sont disponibles dans les bases de données PROCARE et/ou administrative. Sur la base de l'exercice actuel, une adaptation de certains indicateurs et données/variables PROCARE est toutefois nécessaire.
- Afin de réduire le nombre de données manquantes dans PROCARE et d'améliorer les performances au niveau de l'enregistrement des données, une application Internet s'impose. Pour diminuer la charge administrative, le formulaire d'enregistrement des données PROCARE – qui est pour l'instant très exhaustif – doit être adapté. Le nombre de données à enregistrer doit être fortement diminuées, d'une part en intégrant les données prospectives et administratives et d'autre part en ne sélectionnant que quelques indicateurs clés. De plus, l'accès aux données administratives nécessaires devrait être octroyé automatiquement à la FRC.
- Le couplage entre la base de données de la FRC et d'autres bases de données administratives est faisable et fiable. Les données de la FRC sont exploitables et pertinentes pour certains indicateurs. En outre, la FRC possède la capacité nécessaire pour un enregistrement prospectif et une analyse des données. En conséquence, la FRC représente un partenaire crucial pour des projets similaires futurs.
- Pour ce projet, c'est le couplage entre les bases de données de la FRC et de l'AIM qui est apparu le plus pertinent. En revanche, l'apport de la base de la CT a été limité.
- Compte tenu du fait que pour l'heure, l'interprétation de la plupart des indicateurs est encore difficile en raison de leur nombre réduit, provisoirement, il est préférable que le feedback individuel soit donné sans interprétation. Fin 2009, la pertinence et la possibilité d'interprétation des indicateurs devront être réévaluées. Cette évaluation doit permettre la sélection d'indicateurs clés. L'étape suivante devrait être l'implémentation du système.
- Aux fins d'une comparaison internationale "population-based" qui soit significative, l'enregistrement PROCARE doit être garanti dans sa totalité (par exemple, via un couplage avec les bases de données administratives) et il convient d'inclure un nombre plus élevé de patients.

Scientific summary

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ABBREVIATIONS

5-FU	5-fluorouracil
95% CI	95 percent confidence interval
ACPGBI	Association of Coloproctology of Great Brittain and Ireland
AHRQ	Agency for Healthcare Research and Quality
AJCC	American Joint Committee on Cancer
APR	Abdomino-perineal resection of the rectum
ASA	American Association of Anaesthetists score
ATC	Anatomical Therapeutic Chemical
BCR	Foundation Belgian Cancer Registry
CEA	Carcinoembryonic antigen
CIST	Clinical Indicator Support Team
CNK	Code National(e) Kode
CPG	Clinical practice guideline
CRM	Circumferential resection margin
CRT	Chemoradiation therapy
CTV	Clinical Target Volume
CT	Computed tomography
DFS	Disease-free survival
ECCO	European CanCer Organisation
EPJ	Electronic Patient Journal
EUS	Endoscopic ultrasonography
Gy	Gray
HIC	Health Insurance Companies
ICD	International classification of diseases
IMA	Common Sickness Funds Agency (Intermutualistisch Agentschap/ L'Agence Intermutualiste)
IV	Intravenous
LBI	Large bowel-imaging
LE	Local excision
MDT	Multidisciplinary team
MeSH	Medical Subject Headings
MCD	Minimal Clinical Data (Minimale klinische gegevens/Résumé clinique minimum)
MFD	Minimal Financial Data (Minimale financiële gegevens/Résumé financier minimum)
MRI	Magnetic resonance imaging
NBOCAP	National Bowel Cancer Audit Programme
NCASP	National Clinical Audit Support Programme
NICCQ	National Initiative on Cancer Care Quality
NYCRIS	Northern and Yorkshire Cancer Registry Information Services

PET	Positron Emission Tomography
PROCARE	PROject on CAncer of the REctum
QI	Quality indicator
RCT	Randomised controlled trial
RT	Radiotherapy
RX	X-ray
SD	Standard deviation
SSO	Sphincter-sparing surgery
TC	Technical Cell
TEMS	Transanal endoscopic microsurgical resection
TME	Total mesorectal excision
TRUS	Transrectal ultrasonography
UICC	International Union Against Cancer

1 INTRODUCTION

In 2004, the Belgian Section for Colorectal Surgery, a section of the Royal Belgian Society for Surgery, decided to start PROCARE (PROject on CAncer of the REctum) as a multidisciplinary, profession-driven and decentralized project (www.belgiancancerregistry.be). All medical specialties involved in the care of rectal cancer established a multidisciplinary steering group in 2005. Delegates from the respective scientific societies as well as from the Belgian Professional Association were included from the start, as it was evident that the project should not only have a scientific backbone, but should be driven by the professionals. In a questionnaire more than 80 % of the Belgian hospitals expressed their willingness to participate in the project.

The main objective of this multidisciplinary project is to reduce diagnostic and therapeutic variability and to improve outcome in patients with rectal cancer by means of:

- standardization through guidelines;
- implementation of these guidelines (workshops, meetings, training for TME, pathology, radiotherapy and radiology);
- quality assurance through registration and feedback.

Multidisciplinary guidelines on the management of rectal cancer were discussed and a first draft was written in 2005. This first version of the PROCARE guidelines was made available by the respective scientific societies. In the context of a study assigned by the KCE to PROCARE (summer 2006), the guidelines were updated with recently published evidence (part I of the study) [1].

During the years 2005 – 2008, several workshops, postgraduate courses and seminars on rectal cancer were organised in the context of the PROCARE project. Specific documents (e.g. an atlas on Clinical Target Volume [CTV] during radiotherapy for rectal cancer, a handbook on histopathologic examination of a TME specimen) were composed and discussed during discipline-specific workshops.

Central registration of credible and high-quality data is a key issue in a national project like this. Fortunately, PROCARE found a partner at the Belgian Cancer Registry (BCR). In 2005, a multidisciplinary dataset was elaborated for registration in a rectal cancer specific database at the BCR. Registration started in October 2005.

In 2007, the RIZIV/INAMI decided to financially support the project for 5 years. About half of the budget is dedicated to registration with feedback, while the other half is reserved for (re)training in order to foster implementation of the guidelines. The latter will be done by means of peer-review of radiological pre-treatment staging results, planned CTV and TME specimens, and by 'TME training' by peers or candidate TME trainers who fulfilled predefined criteria.

In order to allow individual feedback and national/international benchmarking, it was decided to set up a quality indicator (QI) system. For this cause, the conceptual flowchart provided in a previous KCE report on clinical QI [2] was consulted and adapted to the specific oncologic context. In general, some important steps need to be taken when developing and instauring a QI system in oncology (Figure 1). First, a multidisciplinary group should be composed, including all relevant specialties involved in the work-up of the tumour of interest. Specific to the Belgian situation, the College of Oncology (https://portal.health.fgov.be/portal/page?_pageid=56,512693&_dad=portal&_schema=PORTAL) – which is in charge of organizing the external evaluation in all domains of oncology – should be represented. For the present study, all relevant specialties are represented in the multidisciplinary working group and the PROCARE steering group. Above this, the College of Oncology is represented in the PROCARE steering group.

Next, the multidisciplinary group should decide on the scope of the QI system (Figure 1).

This not only involves the decision on which phases of the clinical work-up to include in the quality assessment, but also the decision on the quality of care dimensions of interest [2].

The present project aims at measuring the quality of care during the entire clinical course of patients with primary rectal cancer, including diagnosis and staging, treatment (neoadjuvant treatment, surgery, adjuvant treatment, palliative treatment), pathology and follow-up. This project focuses on the primary treatment of rectal cancer, but not on the treatment of recurrent or progressive disease. The quality of care dimensions 'effectiveness', 'efficiency', 'safety', 'timeliness' and 'continuity' are the focus of the PROCARE QI system.

Once the scope is defined, a literature search (including grey literature and clinical practice guidelines) should identify existing QI (Figure 1). Based on predefined criteria, a selection of QI should be made ensuring the coverage of all predefined treatment phases and quality of care dimensions. In case the identified QI do not cover all important aspects, the selection should be complemented by additional QI, preferentially based on recent clinical practice guidelines. The methodology used for the present project is described in chapter 2.1.

For the selected QI the specifications should be written (Figure 1), including a definition, in- and exclusion criteria, data sources and data collection specifications. Based on this information, the selected QI should be piloted in order to detect potential problems and to modify the QI set accordingly. Finally, the QI system should be disseminated, implemented and evaluated.

An important aim of the present project is to identify QI for the management of rectal cancer and to construct a QI set for the quality assessment of rectal cancer care in Belgium (chapter 2). Furthermore, the feasibility of measuring the selected QI will be tested on 2 different databases: the prospective PROCARE database and an administrative database (chapter 3). This feasibility test will allow a fine-tuning and/or adaptation of the selected QI. Consequently, it cannot be the intention of the authors to measure the quality already. Therefore, no judgement about quality or target values will be provided in this report or can be deduced from this report.

To construct and pilot test the QI set, the following questions will be addressed:

1. Which of the selected quality indicators can be measured using a) the prospective PROCARE database and b) administrative databases?

2. If the quality indicators are measurable, at what level are they (national, hospital, individual care provider)?

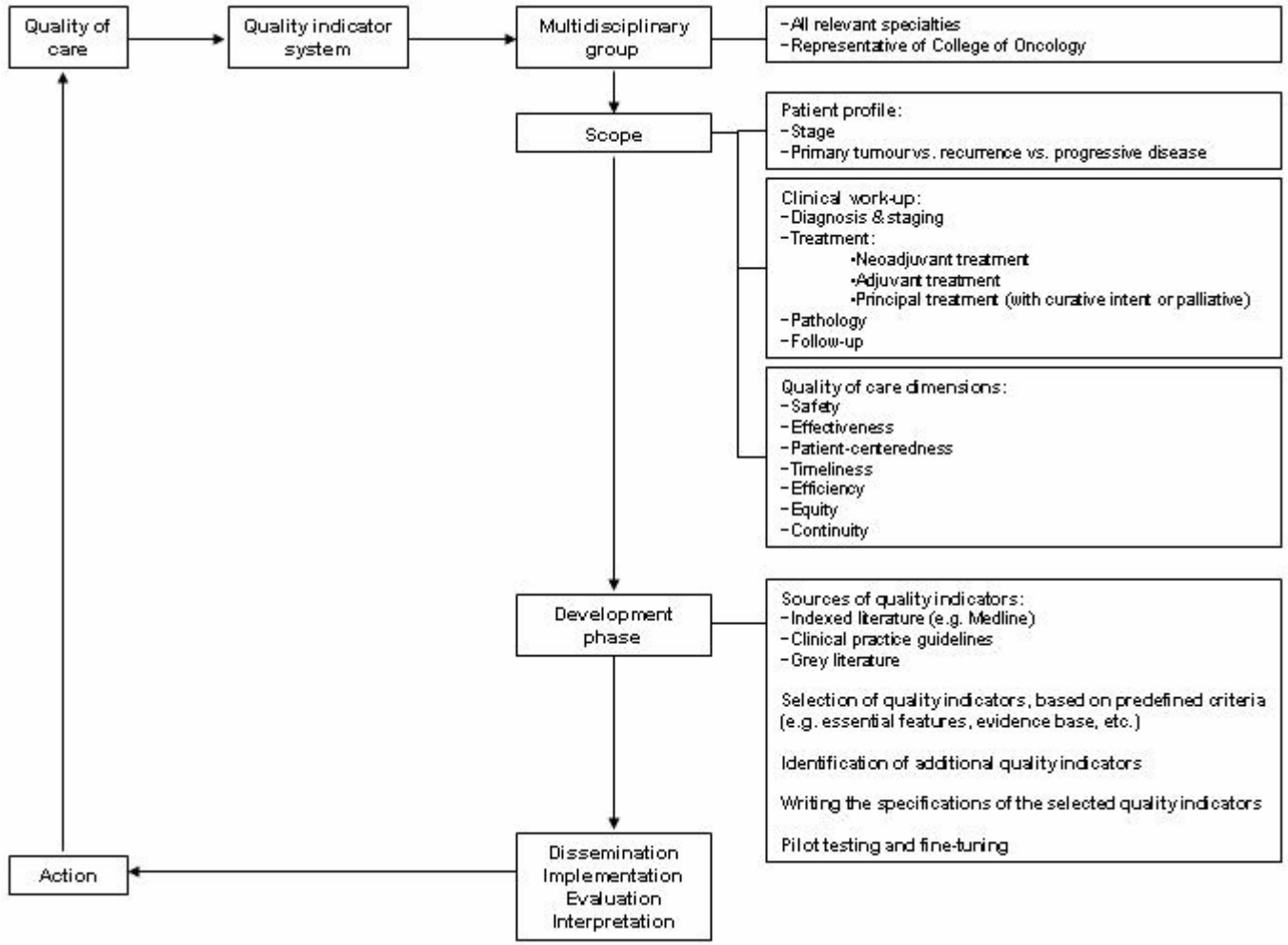
3. Which data are needed at the minimum to measure and interpret these quality indicators? Can the PROCARE database and the administrative databases complement each other?

4. How will results of the quality measurement be presented?

In addition, an attempt will be made to project the results of this exercise to other cancers, in order to have a generic methodology to measure oncologic quality indicators in Belgium.

Finally, an overview will be given of international experiences with measuring the quality of rectal cancer care (chapter 4). This will allow a judgment on how the present project can connect to similar international projects.

Figure 1. Conceptual flowchart for the set-up of a quality indicator system in oncology.



2 DEVELOPMENT OF A QUALITY INDICATOR SET

2.1 METHODOLOGY

2.1.1 Literature search

During the pre-assessment of the literature, an interesting good-quality systematic review of colorectal cancer quality indicators was identified [3] . Although only studies with US data were included in this review, it was decided to take this study as a starting point, and to perform an update of the review, expanding the inclusion criteria to studies with non-US data.

The Medline database was searched using the following combination of MeSH terms: ("Colorectal Neoplasms" [MeSH] or "Rectal Neoplasms" [MeSH] or "Colonic Neoplasms" [MeSH]) AND ("Quality of Health Care" [MeSH] OR "Patient Care Management" [MeSH] OR "Organization and Administration" [MeSH] OR "Health Care Quality, Access, and Evaluation" [MeSH] OR "Quality Indicators, Health Care" [MeSH]). The Cochrane Library was also searched using the free text words rectal and indicator. The search was done in January 2007 by 2 independent researchers (LVE and JV), and limited to papers published from 2005 on. Studies were only considered if they concerned the description of a quality indicator set for (colo)rectal cancer. Papers were excluded if they were already included in the study of Patwardhan et al. The search was limited to humans and to papers published in English, French, German or Dutch.

The websites of the following organizations were also searched: the Agency for Healthcare Research and Quality (http://www.ahrq.gov/), the Joint Commission (http://www.jointcommission.org/), the Clinical Indicators Support Team (http://www.indicators.scot.nhs.uk/), and the National Health Service (http://www.nhs.uk/). The CPGs that were selected for the development of the PROCARE guideline were also evaluated for included QI [1]. Finally, the National Quality Measures Clearinghouse was also searched (http://www.qualitymeasures.ahrq.gov/).

2.1.2 Definition of quality levels

Three quality levels were defined. The first level covers the QI that are affected by all treatment phases and that were considered essential for general quality measurement. Second level QI were also considered essential for general quality measurement, but are affected by one specific treatment phase (e.g. surgery). Finally, third level QI were defined as those QI that deserved attention from individual centres if possible quality problems were identified through a level 1 or 2 QI. In other words, level 3 QI are required to interpret the results of level 1 and 2 QI.

2.1.3 Selection process of quality indicators

The quality indicators identified through the literature search were summarized in an Excel-table per subdiscipline. For each quality indicator, an assessment was made by a small working group, taking into account the following items:

- relevance
- level of evidence
- related PROCARE recommendation(s)
- quality level

Only level 1 and 2 QI were considered for inclusion in the final quality indicator set. QI were excluded if they did not specifically address rectal cancer care. Importantly, availability of data to allow measurement of the selected QI was not taken into account during the selection process.

The final selection was discussed by a multidisciplinary team. In case important areas were not covered by a QI from the literature, this multidisciplinary team proposed additional QI based on key elements from the PROCARE guideline [1].

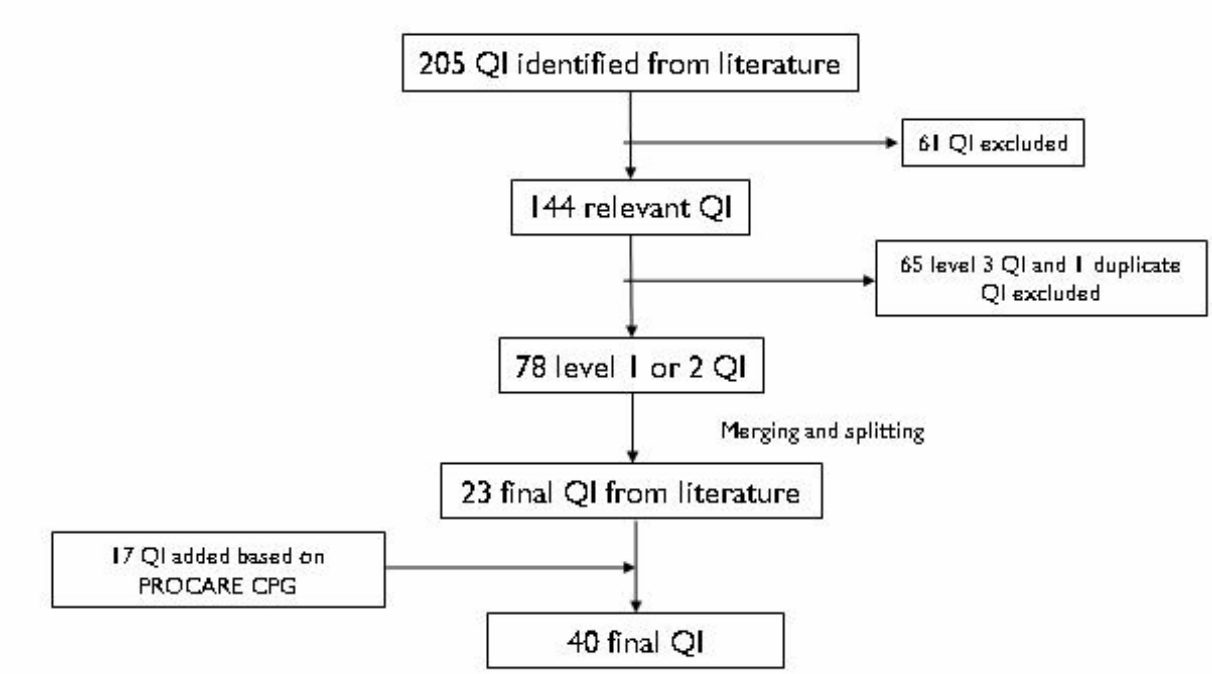
2.2 RESULTS

2.2.1 Search for and selection of quality indicators

The Medline search yielded 4421 articles of which 4 were selected based on title and abstract [4-7]. However, the study of Prosnitz et al. [7] was excluded because it was part of the study of Patwardhan et al. [3]. No relevant studies were found in the Cochrane Library. Of the consulted websites, only the Clinical Indicators Support Team included QI on rectal cancer care (http://www.indicators.scot.nhs.uk/). No QI were identified in the CPGs that were selected for the development of the PROCARE guideline [1].

In total, 205 QI were identified (Figure 2). An overview of all identified QI is provided in appendix. Fifteen QI were excluded since they did not address rectal cancer care. Twenty-one other QI were excluded because they were not specific to rectal cancer care, and 11 QI were found irrelevant to this project. Finally, 14 QI were considered to address technical aspects only and were also excluded.

Figure 2. Selection process of the rectal cancer QI.



Of the 144 remaining QI, 65 were considered to be of level 3 and were therefore excluded (see appendix). Also, one duplicate QI was excluded. After merging related QI and splitting complex QI (i.e. QI with a too large scope), a list of 23 QI was retained. This list was complemented by 17 additional QI that were not found in the literature, but that were considered very relevant by the multidisciplinary project team based on the literature retrieved for the PROCARE guideline [1].

The final QI set consists of 40 QI: 4 general (level 1) QI, 7 QI related to diagnosis and staging, 7 QI related to neoadjuvant treatment, 6 QI related to surgery, 5 QI related to adjuvant treatment, 2 QI related to palliative treatment, 3 QI related to follow-up, and 6 QI related to histopathologic examination. The rationale behind the selected QI will be discussed below per sub-discipline.

2.2.2 Overview of selected quality indicators

2.2.2.1 General quality indicators

Four general QI were selected:

- Overall 5-year survival by stage (QI 1111) (high level of evidence)
- Disease-specific 5-year survival by stage (QI 1112) (high level of evidence)
- Proportion of patients with local recurrence (QI 1113) (high level of evidence)
- Proportion of patients discussed at a multidisciplinary team meeting (QI 1114) (low level of evidence)

Both overall and disease-specific 5-year survival by stage and the local recurrence rate were identified in the literature [3, 4]. Another QI on survival (relative 3-year survival) was identified on the website of the Clinical Indicator Support Team (CIST) (http://www.indicators.scot.nhs.uk/). Both survival and local recurrence rate are affected by most processes of rectal cancer care [1]. In fact, several studies have concluded that using combined modalities and total mesorectal excision (TME), local recurrence remains acceptable (< 10%), with overall survival of 64% compared with conventional surgical techniques, where local failure rate was 27% [8].

Disease-free survival (DFS) is frequently used as an outcome in clinical studies. In our opinion, DFS is sufficiently covered by using disease-specific 5-year survival and local recurrence rate as QI.

Several QI were identified referring to the importance of a multidisciplinary approach in the work-up of rectal cancer [3-6]. Several recommendations in the PROCARE CPG stress the need of such a multidisciplinary approach, although the supporting evidence is low [1]. In Belgium, a specific nomenclature code is available for a multidisciplinary oncologic consultation (see below). It was therefore decided to merge all identified QI into 1 QI referring to this multidisciplinary consultation.

2.2.2.2 Quality indicators related to diagnosis and staging

Seven QI related to diagnosis and staging were selected:

- Proportion of patients with a documented distance from the anal verge (QI 1211) (low level of evidence)
- Proportion of patients in whom a CT of the liver and RX or CT of the thorax was performed before any treatment (QI 1212) (moderate level of evidence)
- Proportion of patients in whom a CEA was performed before any treatment (QI 1213) (moderate level of evidence)
- Proportion of patients undergoing elective surgery that had preoperative complete large bowel-imaging (QI 1214) (low level of evidence)
- Proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment (QI 1215) (moderate level of evidence)
- Proportion of patients with cStage II-III that have a reported cCRM (QI 1216) (moderate level of evidence)
- Time between first histopathologic diagnosis and first treatment (QI 1217) (low level of evidence)

The distance from the lower edge of the tumour to the anal verge is an important clinical parameter, since it co-determines the indication for neoadjuvant treatment, the type of surgery and outcome [1]. This QI was identified through the literature search [5, 6], and – although supported by low-quality evidence – was deemed very relevant by the project team.

The aim of imaging techniques such as CT, MRI and PET is to detect hepatic and extra-hepatic metastatic disease [1].

A combined thorax and abdomen/pelvis spiral contrast-enhanced CT is recommended for routine use. A QI measuring this standard was identified through the literature search [4].

Pre-treatment CEA levels have been related to cancer stage and survival independent of pTN stage in nonmetastatic colorectal cancer [1]. Therefore, the serum CEA level should be determined in all patients before the start of any treatment. This QI was also identified through the literature search [6].

It is recommended that patients with rectal cancer undergo a total colonoscopy with resection of concomitant polyps if possible [1]. However, if total colonoscopy is judged to be too risky or if colonoscopy is refused after informed consent, a high-quality double contrast barium enema should be performed. Numerous QI related to this recommendation were identified in the literature [3-6].

Patients with rectal cancer should have locoregional cTN staging. TRUS and high-resolution MRI (or CT) play an important role in the staging of rectal cancer [1]. Numerous related QI were identified in the literature [4-6]. An important outcome of the preoperative staging is the circumferential resection margin (CRM), which is a predictor of local and distant recurrence as well as survival. The CRM status can be reliably predicted by preoperative high-resolution MRI [1]. No related QI was identified in the literature. Therefore, the PROCARE recommendations served as a basis for the formulation of an additional QI.

According to the guidelines of the Association of Coloproctology of Great Britain and Ireland (ACPGBI), the interval between making a diagnosis of cancer and the start of treatment should be less than 4 weeks [1, 9]. One related QI was identified in the literature [6].

2.2.2.3 Quality indicators related to neoadjuvant treatment

Seven QI on neoadjuvant treatment were included:

- Proportion of cStage II-III patients that received a short course of neoadjuvant pelvic RT (QI 1221) (high level of evidence)
- Proportion of cStage II-III patients that received a long course of neoadjuvant pelvic RT (QI 1222) (high level of evidence)
- Proportion of cStage II-III patients that received neoadjuvant chemoradiation with a regimen containing 5-FU (QI 1223) (high level of evidence)
- Proportion of cStage II-III patients treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU (QI 1224) (low level of evidence)
- 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 (QI 1225) (high level of evidence)
- Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 6 to 8 weeks after completion of the (chemo)radiation (QI 1226) (high level of evidence).
- Rate of acute grade 4 radio(chemo)therapy-related complications (QI 1227) (moderate level of evidence)

Although many QI on chemotherapy and radiotherapy were identified in the literature [3, 5, 6], none of these specifically addressed neoadjuvant treatment. Therefore, the PROCARE recommendations on neoadjuvant treatment were used as a basis to formulate additional QI [1]. We refer to these recommendations for the background of the selected QI (recommendation 21 – 31).

2.2.2.4 *Quality indicators related to surgery*

Six QI related to surgery were selected:

- Proportion of R0 resections (QI 1231) (moderate level of evidence)
- Proportion of APR and Hartmann's procedures (QI1232a) (moderate level of evidence)
- Proportion of patients with stoma 1 year after sphincter-sparing surgery (QI 1232b) (high level of evidence)
- Rate of patients with major leakage of the anastomosis after sphincter-sparing surgery (QI 1233) (high level of evidence)
- Inpatient or 30-day mortality (QI 1234) (high level of evidence)
- Rate of intra-operative rectal perforation (QI 1235) (moderate level of evidence)

Curative resection rate is used very often as a QI [3, 4, 6]. Indeed, the main emphasis of surgery is to obtain clear surgical margins yielding a curative R0 resection (no residual tumour) [1].

The proportion of APR and Hartmann operations is considered a very important QI (being an outcome of importance to patients) and was identified in the AHRQ report [3]. Surgeons should aim, wherever possible and desirable, to preserve the anal sphincter [1].

QI 1232b and QI 1233 [4] are related in that a temporary defunctioning stoma should be considered each time the anastomosis is at risk for leakage after sphincter-sparing surgery [1]. Results of a recent RCT even suggest that a derivative stoma should be constructed routinely. In general, a temporary stoma is closed within 1 year after surgery, i.e. after the end of adjuvant chemotherapy.

Inpatient or 30-day mortality is an outcome that is affected by many processes in the perioperative period [1]. This QI was identified in 2 studies [3, 4]. Importantly, for the interpretation of this QI several factors (stage, age, comorbidity, mode of surgery i.e. elective/scheduled vs. urgent/emergency) need to be taken into account for risk adjustment [3].

One QI on intra-operative rectal perforation was added based on recommendation 42 of the PROCARE CPG [1]. Intra-operative perforation increases local recurrence and decreases survival. It occurs more frequently during abdominoperineal rectum excision as compared with anterior resection [1].

2.2.2.5 *Quality indicators related to adjuvant treatment*

Five QI on adjuvant treatment were selected:

- Proportion of p-ypStage III patients with R0 resection that received adjuvant chemotherapy (QI 1241) (moderate level of evidence)
- Proportion of pStage II-III patients with R0 resection that received adjuvant radiotherapy or chemoradiotherapy (QI 1242) (moderate level of evidence)
- Proportion of p-ypStage II-III patients with R0 resection that started adjuvant chemotherapy within 3 months after surgical resection (QI 1243) (expert opinion)
- Proportion of p-ypStage II-III patients with R0 resection treated with adjuvant chemo(radio)therapy, that received 5-FU based chemotherapy (QI 1244) (high level of evidence)
- Rate of acute grade 4 radio- or chemotherapy-related complications (QI 1245) (expert opinion)

Several QI were identified in the literature [3, 5]. The first two selected QI (QI 1241 & 1242) provide an overview of the relative proportion of the 3 possible adjuvant treatment modalities (chemotherapy, radiotherapy and chemoradiotherapy). The supporting evidence and treatment algorithm can be found in the PROCARE CPG [1].

One QI was found addressing the need to start adjuvant chemotherapy within 8 weeks of surgical resection [5]. The rationale is that adjuvant therapy is able to treat micrometastatic disease at a time when tumour burden is at a minimum. This QI was selected, but adapted to the PROCARE recommendation of administering adjuvant chemotherapy within 3 months of surgery [1].

QI 1244 and 1245 were not found in the literature, but were added to the final QI selection based on the PROCARE recommendations [1]. The rationale behind QI 1244 is that 5-FU given by IV injection for 5 days every 4 weeks for 6 cycles is the regimen for which the most evidence is available and that is clearly effective in prolonging survival in patients with stage III [1]. Treatment with chemotherapy is associated with an acceptable complication rate. However, complication rate is dose-dependent and can be artificially kept low by lowering the dose.

2.2.2.6 Quality indicators related to palliative care

Two QI on palliative care were selected:

- Rate of cStage IV patients receiving chemotherapy (QI 1251) (high level of evidence
- Rate of acute grade 4 chemotherapy-related complications in stage IV patients (QI 1252) (expert opinion)

Two QI were identified in the literature addressing palliative chemotherapy [3]. The aim of palliative systemic therapy is to improve survival and quality of live in patients with advanced rectal cancer [1].

No QI was identified in the literature addressing chemotherapy-related complications. However, this was considered a very important topic related to many recommendations of the PROCARE guideline [1]. It was therefore added to the final QI selection.

2.2.2.7 Quality indicators related to follow-up

Three QI on follow-up were selected:

- Rate of curatively treated patients that received a total colonoscopy within 1 year after resection (QI 1261) (moderate level of evidence)
- Rate of patients undergoing regular follow-up (according to the PROCARE recommendations) (QI 1262) (moderate level of evidence)
- Late grade 4 complications of radiotherapy or chemoradiation (QI 1263) (expert opinion)

For curatively treated patients it is recommended to perform a colonoscopy 1 year after the resection [1]. Several related QI were identified in the literature [3], and merged into 1 final QI.

The aim of regular follow-up is to detect local recurrence and/or metastasis at an early potentially (surgically) curable stage, and to detect new primary tumours [1]. Patients that are fit for further treatment in case of recurrent disease should be offered intensive follow-up. However, individual randomised trials show no advantage of follow-up in terms of survival. Meta-analyses indicate that follow-up can offer survival benefit by means of earlier detection of metastatic or recurrent disease. There is some evidence that intensive follow-up does improve long-term survival for stage II and III colorectal cancer [1]. No related QI were identified in the literature, but based on the PROCARE recommendations this QI was added to the final selection.

QI addressing late (chemo)radiotherapy-related complications were also not found in the literature, but was added to the final selection in view of the relation with several PROCARE recommendations [1].

2.2.2.8 Quality indicators related to histopathologic examination

Six QI related to histopathologic were selected:

- Use of the pathology report sheet (QI 1271) (expert opinion)
- Quality of TME assessed according to Quirke and mentioned in the pathology report (QI 1272) (low level of evidence)
- Distal tumour-free margin mentioned in the pathology report (QI 1273) (low level of evidence)
- Number of lymph nodes examined (QI 1274) (low level of evidence)
- (y)pCRM mentioned in mm in the pathology report (QI 1275) (low level of evidence)
- Tumour regression grade mentioned in the pathology report (after neoadjuvant treatment) (QI 1276) (low level of evidence)

For most of the selected QI on pathology, no QI were identified in the literature. The final selection is therefore primarily based on the PROCARE recommendations [1].

Only for QI 1274, several QI were found in the literature [5, 6]. The pathologist should find as many lymph nodes as possible. The median number found is an indication of the quality of the pathological examination. Ideally, it should exceed 12 lymph nodes [1].

During the first external expert meeting of this project, it was suggested to use the mentioning of the (y)pTN in the pathology report as a QI. However, to our opinion this is not a QI, since it has no direct relation with the quality of care. Nevertheless, it is essential information for stage grouping and adjustment, and resultantly for the calculation of many selected QI. Therefore, this information will always be reported along the results of the QI where relevant.

2.3 DISCUSSION

In total, 40 QI were selected covering all aspects of the management of rectal cancer and representing a balanced mix of process and outcome indicators. The selection of these QI was based on a literature search and completed with QI based on the PROCARE recommendations [1]. No formalised procedure was used to select the QI, but on different occasions the selection was discussed with a multidisciplinary expert panel. Above this, the selection was approved by the PROCARE board and an external expert panel. The final selection is therefore considered very relevant.

Several selected (mainly outcome) QI are also relevant for other cancers, such as 5-year survival, local recurrence rate, multidisciplinary discussion, time to treatment, rate of (late) grade 4 chemotherapy and/or radiotherapy-related complications, proportion of R0 resections, and the inpatient or 30-day mortality. The routine registration of these parameters for all cancers would therefore be of high relevance for the measurement of the quality of care in oncology.

The final QI selection represents the current state of the art according to the PROCARE recommendations [1]. In view of the changing evidence, this QI set will probably need an update in about 5 years.

3 FEASIBILITY STUDY OF QUALITY INDICATOR MEASUREMENT

3.1 METHODOLOGY

3.1.1 Definition of selected quality indicators

For each selected quality indicator, numerator and denominator (and their respective in- and exclusion criteria) were defined by a small working group (LVE, JV, DDC, FP) and afterwards discussed by the multidisciplinary team.

3.1.2 Source databases

3.1.2.1 Prospective PROCARE data

The PROCARE registration form was constructed in consensus by a multidisciplinary group based on the data entry for the Dutch TME trial (van de Velde C, personal communication) and on data from the literature considered to be relevant for quality assessment and assurance. The form has undergone two revisions and currently the third version is being prepared for data collection based on the evidence as presented in the PROCARE guidelines [1]. Participating centres prospectively submit their data on a voluntary basis to the Belgian Cancer Registry, where they are put into an Access Database. A data manager checks the data on quality and completeness, and purchases correct data if necessary.

Active input into the database was started in January 2006. Currently (April 2008), data are available from more than 1400 rectal cancer patients. Sixty-one centres (with 105 surgeons) are participating at present. However, for the present study, inclusion was stopped on December 4th 2007. At that time, 1071 patients with rectal cancer were included, involving 56 centres and 98 surgeons.

3.1.2.2 Coupled administrative data

General description of the used databases

For the present study, data from the following 3 administrative databases were coupled:

1. The **Technical Cell** (TC) of the RIZIV/INAMI and Ministry of Health, Food Chain Safety and Environment (MOH) yearly composes a database of coupled hospital registration data. These data are based on a) the *Minimal Clinical Data* (MCD) collected in the hospitals by the MOH for each hospital stay (including day care), and b) the *Minimal Financial Data* (MFD) collected by the RIZIV/INAMI in the Sickness Funds. This coupled database contains clinical data and facturation data per hospital stay. For the present study these data are available from July 2001 – December 2004.
2. The **Belgian Cancer Registry** (BCR) has a database containing records on incident rectal cancer. Tumour data consist of the ICD-O-3 and ICD-10 code, TNM classification (cStage and pStage), incidence date (i.e. date of first diagnosis), received and planned treatment. For each cancer patient, these data are registered in a continuous longitudinal way. Moreover, this database is coupled with administrative data, making it possible to retrieve the date of decease (before December 31st 2006).

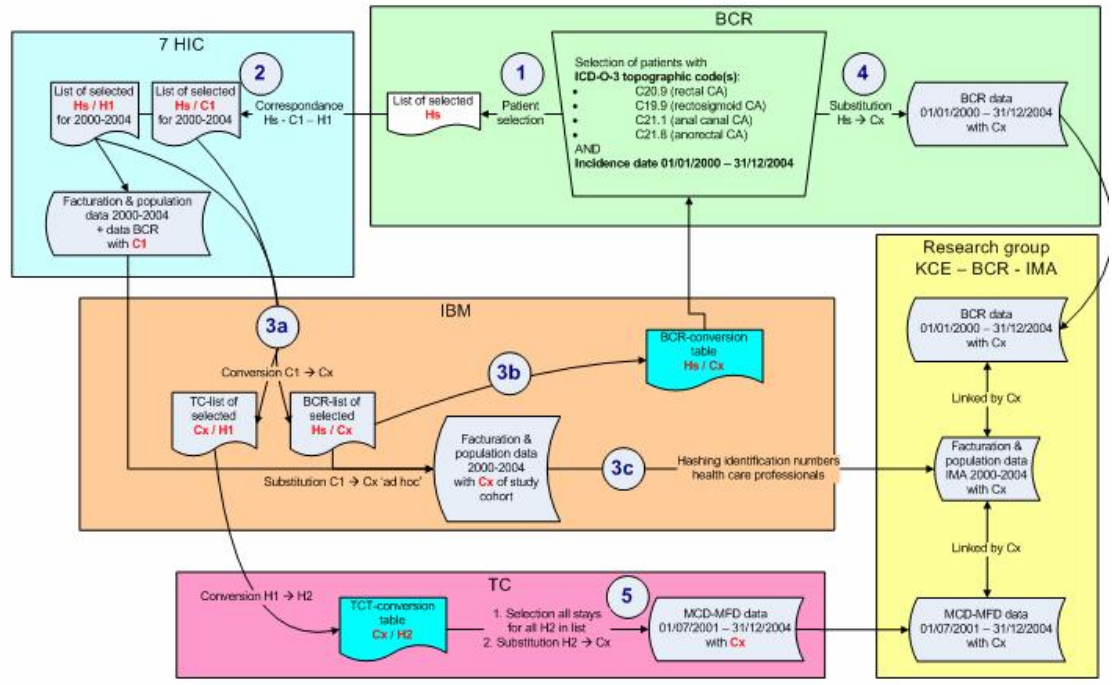
   Patients are identified based on their unique identification number of social security (identificatienummer sociale zekerheid, INSZ) and a specific patient pseudonym (Hs), which is obtained by irreversible hashing of the full name, birth date and sex by all data providers of the BCR. For the present study these data are available from 2000 – 2004 (the year 2004 was only partially covered at the moment of data closure).
3. The **Health Insurance Companies** (HIC) possess nomenclature data and individual facturation data of all their members. They also have data on social security and date of death (if applicable). All these data can be obtained through the Common Sickness Funds Agency (IMA). For the present study, these data are available from 2000 – 2004.

Selection criteria for data extraction

The patient cohort consists of those patients with a diagnosis of primary rectal cancer from January 1st 2000 until December 31st 2004. *Primary selection* is done using the ICD-O-3 topographic codes of the BCR (Figure 3):

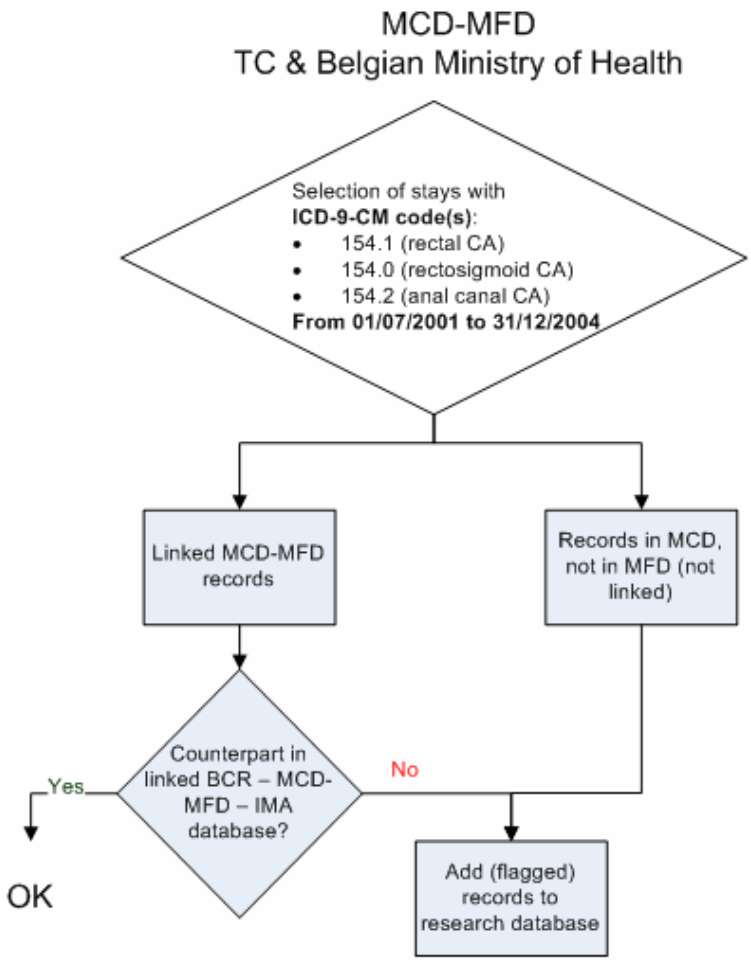
- C20.9: malignant neoplasm of rectum ,
- C19.9: malignant neoplasm of rectosigmoid
- C21.1: malignant neoplasm of the anal canal
- C21.8: malignant neoplasm of the anorectal junction

Figure 3. Primary selection of the administrative cohort.



An attempt was made for a *complementary selection* to investigate the exhaustivity of the BCR and thus the completeness of the patient cohort (Figure 4). This complementary selection was done in the MCD-MFD database of the TC using the ICD-9-CM codes 154.1 (rectal cancer), 154.0 (rectosigmoidal cancer) and 154.2 (cancer of the anal canal). Patients with primary rectal cancer identified through this complementary step but not through the primary selection were added to the final patient cohort if possible.

Figure 4. Complementary selection of the administrative cohort.



3.1.3 Translation of selected quality indicators into measurable codes

3.1.3.1 Prospective PROCARE data

All variables of the PROCARE data entry set received a specific code (see appendix). Translation of the selected QI into these codes was done by a small working group (MV, JV, LVE, FP) and afterwards discussed by the multidisciplinary team.

3.1.3.2 Coupled administrative data

For the measurement of the QI using the coupled administrative data, the QI were translated into codes using the sources discussed below. The selected codes were discussed by a small working group (CM, JV, LVE, FP) and approved by a multidisciplinary clinical expert group.

Healthcare nomenclature

Using the nomenclature codes (available in the HIC database) it is possible to verify whether a patient underwent a certain type of surgery, received radiotherapy or chemotherapy, or whether a specific diagnostic procedure was carried out. Moreover, the HIC database contains precise information on the professional who prescribed the medical act and the professional who realised it. This makes it possible to identify nomenclature codes associated with e.g. surgeons. The HIC database also contains information on the hospital of the hospitalisation stay and the hospital where the medical act was realised, allowing an analysis of the quality indicators by hospital. Date of hospital admission and discharge can be used to analyse inpatient mortality.

A major drawback of the HIC database is that medical acts are not linked to diagnoses. This makes it very difficult to find out whether the surgery, radiotherapy, chemotherapy or diagnostic procedures were done in relation with the diagnosis of rectal cancer.

On the other hand, as the date of the medical act is recorded, it is possible to determine whether the intervention took place in a certain time interval close to the diagnosis of rectal cancer.

Another drawback of the database is that it only concerns medical acts that are reimbursed. No information is available on treatments received as part of a clinical trial.

ICD-9-CM

For the present study the version of ICD-9-CM was used according to the recommendations of the 'FOD Volksgezondheid, Veiligheid van de Voedselketen, Leefmilieu' ('SPF Santé Publique, Sécurité de la Chaîne alimentaire et Environnement'). For each intervention or diagnosis, all relevant ICD-9-CM codes were identified.

The registration of procedures and diagnoses necessary to assign a patient to a homogenous patient group is obligatory in the Technical Cell database. For other procedures and diagnoses registration is free. Importantly, in this database each procedure is linked to a diagnosis and a code reflecting the emergency. This is a major advantage in comparison to the HIC database.

Belgian Cancer registry

See above.

ATC classification

In the HIC database, information is available on prescribed medication (Farmanet). Each drug is linked to a specific CNK code (code national – nationale kode), which can be translated in an ATC code (http://www.whocc.no/atcddd/).

3.1.4 Per-centre-analysis

For each measurable QI the result was computed per centre. However, this per-centre-analysis was done without risk-adjustment, since it was not the intention of the authors to judge the quality already. The centre where the surgery was performed was considered the unit of analysis. If no surgery was performed, the centre where the radiotherapy or chemotherapy was performed was selected.

In the PROCARE database, this information was readily available for each individual patient. For the administrative database, an anonymous code was available in the HIC database for each individual centre. However, different codes could correspond to the same centre. Therefore, a correspondence table was prepared by the KCE, enabling the identification of unique centres. Moreover, it was possible to identify whether the anonymous code corresponded to a centre participating at the PROCARE project.

Importantly, since no risk-adjustment was performed, the results of the per-centre-analyses in this report cannot be used to position centres to one another. Therefore, in order to avoid an inappropriate quality judgement, it was also decided to present graphs for only some examples.

3.1.5 Statistics

Statistical analysis was done using SAS/Base Version 9.1 and SAS EG 4 (SAS Institute, Cary, NC, USA). A chi-square test was used to compare the age and cStage distribution between the PROCARE database and the administrative database.

For each measurable QI a weighted and unweighted mean were calculated. The weighted mean corresponds to the QI result for the cohort as a whole, while the unweighted mean corresponds to the average of the QI results of each centre. The 95% confidence interval (CI) was computed for the unweighted mean using a normal

distribution ($CI_{95\%} = \left[a - 2 \cdot \frac{s}{\sqrt{N}};\quad a + 2 \cdot \frac{s}{\sqrt{N}} \right]$ with a the unweighted mean, $s = \sqrt{\frac{\sum_{i=1}^{N} (x_i - a)^2}{N-1}}$, and N the number of centres). The 95%CI was computed for the weighted mean using a binomial distribution ($CI_{95\%} = \left[p - 2 \cdot \sqrt{\frac{p \cdot (1-p)}{N}};\quad p + 2 \cdot \sqrt{\frac{p \cdot (1-p)}{N}} \right]$ with p the weighted mean).

3.1.6 Aggregation of the results

In order to examine the ability of the set of QI to provide a global impression on the quality of care for rectal cancer patients, the QI results were aggregated for the 2 databases separately using two different methods.

First, a global mean of the values of all measurable QI was computed per centre. For each centre, only the values of the QI with a denominator of 10 or more were taken into account. A complementary analysis was performed with the values of those QI with a denominator of 20 or more. For the presentation of the results, centres with less than 15 measurable QI for the prospective database or less than 6 measurable QI for the administrative database were not selected. These cut-off values relate to the overall number of measurable QI for each database (30 QI for the prospective database, 10 QI for the administrative database; see below).

To allow a calculation of the global mean, all QI needed to be reported in the same way (i.e. a proportion) and needed to point in the same direction. For most QI a high proportion reflects good quality of care. However, for some QI a low proportion is desired. These QI were 'redirected' by calculating the complement, i.e. 1 – the QI value. One QI (time between first histopathologic diagnosis and first treatment) is reported in days, and was transformed in the proportion of patients for whom the first treatment started within 28 days after the first histopathologic diagnosis.

A second method consisted of the calculation of a 'mean corrected rank' per centre. For this calculation, the same selection criteria were applied as above. Only centres with at least 15 measurable QI for the prospective database or 6 measurable QI for the administrative database using a minimum of 10 (20) patients in the denominator were taken into account. For each QI, a rank was assigned to each centre using the proc rank procedure in SAS (rank 1 for the best centre). The lowest rank was assigned in case of ties. A corrected rank per centre was obtained by dividing the rank by the number of centres for which the QI was measurable. Finally, for each centre the mean of all corrected ranks was calculated.

A correlation analysis was done to verify whether the PROCARE centres were ranked in the same way using the prospective and the administrative database. A Spearman's rank correlation coefficient was calculated on the mean corrected ranks for the centres with at least 10 patients in the denominator for at least 15 QI in the prospective database and at least 6 QI in the administrative database. The link between the anonymous codes in the prospective and administrative databases for the centres participating at the PROCARE project was provided by the KCE. The null hypothesis of the Spearman's rank correlation test corresponded to no association between the mean corrected ranks. As we were only interested to know whether the correlation between the mean corrected ranks was positive, the test was one-tailed with alpha = 0.05. The Spearman's rank correlation coefficient and p-value were calculated using the correlation procedure (proc corr) in SAS.

3.2 RESULTS

3.2.1 Description of study cohorts

3.2.1.1 Prospective PROCARE cohort

For the present study, patient inclusion was stopped on December 4th 2007. At that time, 1071 patients with rectal cancer were included, involving 56 centres and 98 surgeons. More then 60% of these patients are males, and about 75% is 60 years or older (Table 1). Mean age is 67 years (SD 12).

The number of included patients per hospital ranges from 1 to 87, with a mean of 19 patients per hospital (SD 16). Twenty-one centres included 20 patients or more.

For about one third of patients the clinical stage is unknown (Table 2). The main reason is insufficient information on the cT and/or cN to calculate the clinical stage. Of the patients with a known clinical stage, 49% has cStage III.

About 64% of all patients received neoadjuvant treatment (Table 3). More specifically, 66% of the cStage II patients and 85% of the cStage III patients received neoadjuvant treatment. Only 1% of the patients was not treated with surgery, while 28% was exclusively treated with surgery (Table 4). Table 5 clearly shows a shift towards lower stages from cStage to (y)pStage. Importantly, two different elements are covered by the (y)pStage. First, in patients not treated with neoadjuvant treatment (and more specifically those patients not treated with a long course of neoadjuvant radiotherapy), the shift from cStage to pStage could represent a wrong clinical staging. On the other hand, in patients treated with neoadjuvant treatment (mainly those patients treated with a long course of neoadjuvant radiotherapy), a shift from a given cStage to a lower ypStage also represents a downstaging.

Table 1. Age and gender distribution according to used databases*.

	PROCARE database			Administrative database		
Age	Males	Females	Total (%)	Males	Females	Total (%)
?	1	1	2 (0.2%)	0	0	0 (0.0%)
20-24	0	0	0 (0.0%)	2	3	5 (0.1%)
25-29	1	1	2 (0.2%)	2	2	4 (0.1%)
30-34	1	2	3 (0.3%)	15	14	29 (0.4%)
35-39	5	6	11 (1.0%)	29	26	55 (0.8%)
40-44	16	11	27 (2.5%)	70	52	122 (1.7%)
45-49	26	16	42 (3.9%)	124	105	229 (3.2%)
50-54	39	24	63 (5.9%)	279	176	455 (6.4%)
55-59	82	46	128 (12.0%)	402	237	639 (9.0%)
60-64	99	54	153 (14.3%)	512	297	809 (11.4%)
65-69	109	66	175 (16.3%)	711	383	1094 (15.5%)
70-74	113	55	168 (15.7%)	765	439	1204 (17.0%)
75-79	76	52	128 (12.0%)	643	485	1128 (15.9%)
80-84	66	55	121 (11.3%)	363	373	736 (10.4%)
85+	22	26	48 (4.5%)	215	350	565 (8.0%)
Total	656 (61.3%)	415 (38.7%)	1071 (100%)	4132 (58.4%)	2942 (41.6%)	7074 (100%)

* Chi-Square (for age distribution) 53.3208, p < 0.0001

Table 2. Distribution of cStage according to used databases*.

	PROCARE database	Administrative database
0	1 (0.1%)	10 (0.4%)
I	107 (14.5%)	446 (16.9%)
II	160 (21.7%)	801 (30.4%)
III	357 (48.5%)	813 (30.8%)
IV	111 (15.1%)	567 (21.5%)
0-IV	736 (100%)	2637 (100%)
X	335	4437
Total	1071	7074

* Chi-Square 75.9994, p < 0.0001

Table 3. Neoadjuvant treatment* per cStage according to used databases (missing data not shown).

	PROCARE database				Administrative database		
	Yes	No	Total known	Total unknown	Yes	No	Total known
0	0	1	1	0	0	10	10
I	16	73	89	18	75	363	438
II	89	46	135	25	434	356	790
III	288	49	337	20	561	246	807
IV	35	46	81	30	89	470	559
0-IV	428	215	643	93	1159	1445	2604
X	168	118	286	49	922	3470	4392
Total	596 (64%)	333 (36%)	929 (100%)	142	2081 (30%)	4915 (70%)	6996 (100%)

* Radiotherapy, chemotherapy or chemoradiotherapy.

Table 4. Number of patients per cStage exclusively treated with surgery, according to used databases (missing data not shown)*.

	PROCARE database				Administrative database			
	Sx	No Sx	Sx+	Total known	Sx	No Sx	Sx+	Total known
0	1	0	0	1	8	2	0	10
I	67	0	40	107	231	37	170	438
II	39	0	121	160	141	51	598	790
III	44	1	312	357	65	46	696	807
IV	35	7	69	111	81	195	283	559
0-IV	186	8	542	736	526	331	1747	2604
X	110	5	220	335	1486	767	2139	4392
Total	296 (28%)	13 (1%)	762 (71%)	1071 (100%)	2016 (29%)	1092 (16%)	3888 (55%)	6996 (100%)

* Sx = surgery only, No Sx = no surgery, Sx+ = surgery combined with neoadjuvant and/or adjuvant treatment

Table 5. Relation cStage - (y)pStage in the prospective cohort.

	(y)pStage						
cStage	0	I	II	III	IV	X	Total
0	0	1	0	0	0	0	1
I	10	46	15	18	1	17	107
II	0	43	63	34	1	19	160
III	3	78	93	119	6	58	357
IV	0	3	9	41	30	28	111
X	13	75	93	84	11	59	335
Total	26	246	273	296	49	181	1071

3.2.1.2 BCR-IMA-TCT cohort

Only patients with a diagnosis of malignant neoplasm of the rectum (rectum ampulla) (ICD10 code = C20.9) were selected for inclusion in the cohort (n = 7074). For 16 of these patients no coupled data are available. For 6996 of these patients (98.9%) data are available in the HIC database, while for 4569 and 4535 patients data are available in the MCD database and the MFD database respectively. For 4556 patients (64.4%) data are available in both the HIC database and MCD databases.

HIC facturation data are available for 6996 patients of the cohort (98.9%). These facturation data are retrieved from two sources: expenses related to health care in general and expenses related to drugs sold in drugstores (Farmanet). The first expenses cover a period from January 1st 2000 till December 31st 2004, the latter cover expenses from the January 1st 2001 till December 31st 2004. Apart from the facturation data, HIC demographic data are available for 6735 patients of the cohort (95.2%).

Both the MCD and MFD database contain data on hospitalizations for which the admission date falls between July 2001 and December 2004.

In the MFD database information is available on 14216 hospitalisations of 4535 patients in the cohort (64.1%).

13977 of these hospitalisations have been coupled between the MFD and MCD databases. In the MCD database information is available on 14467 hospitalisations of 4569 patients in the cohort (64.6%). This percentage can be explained by the fact that the cohort includes patients with an incidence date between January 2000 and December 2004, whereas the MCD and MFD databases only cover the period between July 2001 and December 2004. Moreover, it is not excluded that, due to the complexity of identification in the MCD and MFD databases, some records could not be linked between the BCR and MCD – MFD databases.

It is impossible to select complementary cases from the MCD-MFD database, as the patient ID used in these databases can change from one year to another and from one centre to another for the same patient.

Above this, exclusively using the information from the MCD-MFD database (which would be the case for these complementary patients) is insufficient to calculate any of the selected QI.

In the final cohort of 7074 patients, a similar gender distribution can be found as in the PROCARE cohort (Table 1). More than 78% of patients is older than 60 years. As compared to the prospective cohort, there is a clear shift towards older age categories in the administrative cohort (Chi-Square 53.3208, $p < 0.0001$). Mean age is 69 years (SD 12).

For 5986 patients (85%) it was possible to identify the hospital where the treatment (related to rectal cancer) was given. In total, 126 hospitals are involved. The median number of rectal cancer patients per hospital was 38 (range 1 – 374). Thirty-eight hospitals had less than 20 rectal cancer patients, while 12 hospitals had more than 100 rectal cancer patients. For a minority of patients it was impossible to identify the hospital of treatment because no treatment was given (9%), the hospital was unknown (5%), or no information was available on treatment (1%).

For an important proportion of patients the clinical stage is unknown (Table 2). This is due to an important underregistration of this variable before 2003. Since the introduction of the multidisciplinary consultation, the registration of this variable is obligatory for the cancer registration. Of the patients with a known clinical stage, 31% has cStage III, which is significantly lower than in the prospective cohort (Chi-Square 75.9994, $p < 0.0001$) (Table 2). A higher proportion of patients of the administrative cohort have cStage IV. The relative underrepresentation of cStage IV patients in the prospective cohort is due to the fact that the PROCARE registration originally was a surgeon-driven initiative. Initially, and until recently, mainly cStage IV patients undergoing radical resection (with or without metastasectomy) were registered by surgeons. Since it is a voluntary registration, the clinician decides which patients are included.

In comparison to the prospective cohort, a small number of patients received neoadjuvant treatment (Table 3). More specifically, 55% and 70% of the cStage II and III patients were treated with neoadjuvant treatment. Sixteen percent of patients was not treated with surgery, while 29% was exclusively treated with surgery (Table 4). As for the prospective cohort, there is a clear shift towards lower stages from cStage to (y)pStage, although this shift is less pronounced. The same remarks as for Table 5 should be taken into account for the interpretation of Table 6.

Table 6. Relation cStage - (y)pStage in the administrative cohort.

	(y)pStage						
cStage	0	I	II	III	IV	X	Total
0	0	7	3	0	0	0	10
I	0	214	51	46	4	131	446
II	0	87	276	122	14	302	801
III	0	64	133	221	14	381	813
IV	0	6	26	93	151	291	567
X	0	514	703	612	169	2439	4437
Total	0	892	1192	1094	352	3544	7074

3.2.2 Results of pilot testing per sub-discipline

3.2.2.1 General quality indicators

Overall 5-year survival by stage

DEFINITION

Numerator: all RC patients that survived after 5 years, by stage.

Denominator: all RC patients.

Exclusion criteria:

- patients treated abroad
- patients without a social security number
- patients without a Belgian postal code
- patients without a known incidence date or with an incidence date after December 31st 2006.

RESULTS

The PROCARE database is relatively young with incidence dates starting from 2005. Therefore, a 5-year survival analysis is not yet possible. At present, an accurate survival analysis is only possible at 1 year (Table 7 and Table 8). Using the coupled administrative database, a full 5-year survival analysis is possible (Table 9 and Table 10).

For 1062 of the 1071 PROCARE patients (99%) all necessary data were known. Of these 1062 patients, 866 had an incidence date before January 1st 2007. Importantly, since mortality data are collected from the mortality database of the sickness funds, no mortality data are available for patients with a private insurance. Therefore, the survival is probably slightly overestimated.

The 1-year observed survival is measurable for 55 centres using the PROCARE database. Thirty-seven centres have a 1-year observed survival (for (y)pStage I-III patients) above the weighted (94%; 95%CI 92 – 96%) and unweighted mean (94%; 95%CI 92 – 97%).

Table 7. 1-year observed survival rate by cStage using the PROCARE database*, calculated with actuarial (life table) method.

		N	N deaths on 31/12/2006	1-year
All	I	73	0	100%
	II	124	6	92%
	III	279	10	95%
	IV	80	13	75%
	X	310	21	91%
	I-III	476	16	95%
	Total (I-IV)	866	50	92%
Males	I	42	0	100%
	II	81	4	92%
	III	175	8	93%
	IV	43	4	85%
	X	181	17	89%
	I-III	298	12	94%
	Total (I-IV)	522	33	91%
Females	I	31	0	100%
	II	43	2	92%
	III	104	2	97%
	IV	37	9	63%
	X	129	4	95%
	I-III	178	4	97%
	Total (I-IV)	344	17	92%

* Mean follow-up: 8 months (range 0-24 months).

Table 8. 1-year observed survival rate by (y)pStage using the PROCARE database*, calculated with actuarial (life table) method.

		N	N deaths on 31/12/2006	1-year
All	0	20	2	92%
	I	197	3	98%
	II	225	12	93%
	III	246	14	92%
	IV	36	4	83%
	X	142	15	83%
	I-III	668	29	94%
	Total (0-IV)	866	50	92%
Males	0	14	2	89%
	I	122	3	96%
	II	130	10	90%
	III	137	5	96%
	IV	27	3	83%
	X	92	10	83%
	I-III	389	18	94%
	Total (0-IV)	522	33	91%
Females	0	6	0	100%
	I	75	0	100%
	II	95	2	97%
	III	109	9	87%
	IV	9	1	82%
	X	50	5	83%
	I-III	279	11	94%
	Total (0-IV)	344	17	92%

* Mean follow-up: 8 months (range 0-24 months).

Table 9. 5-year observed survival rate by cStage using the administrative databases*, calculated with actuarial (life table) method.

c-stage		N	N deaths on 31/12/2006	1-year	2-year	3-year	4-year	5-year
All	0	10	5	80%	80%	80%	68%	51%
	I	446	130	91%	84%	78%	74%	70%
	II	801	308	89%	81%	70%	64%	59%
	III	813	326	90%	80%	71%	63%	56%
	IV	567	491	56%	34%	22%	13%	11%
	X	4437	2239	80%	69%	60%	54%	49%
	I-III	2060	764	90%	81%	72%	66%	60%
	Total (0-IV)	7074	3499	81%	70%	61%	54%	49%
Males	0	6	3	83%	83%	83%	63%	63%
	I	255	82	91%	84%	76%	72%	67%
	II	480	182	89%	82%	72%	65%	60%
	III	507	208	90%	79%	71%	62%	56%
	IV	368	322	58%	35%	22%	12%	10%
	X	2516	1270	81%	70%	60%	53%	49%
	I-III	1242	472	89%	81%	72%	65%	60%
	Total (0-IV)	4132	2067	81%	70%	61%	53%	49%
Females	0	4	2	75%	75%	75%	75%	38%
	I	191	48	91%	85%	81%	77%	73%
	II	321	126	88%	80%	68%	62%	58%
	III	306	118	91%	81%	72%	64%	56%
	IV	199	169	52%	32%	23%	16%	14%
	X	1921	969	79%	68%	60%	54%	48%
	I-III	818	292	90%	82%	72%	66%	61%
	Total (0-IV)	2942	1432	80%	69%	61%	55%	49%

* Mean follow-up: 38 months (range 0-83 months).

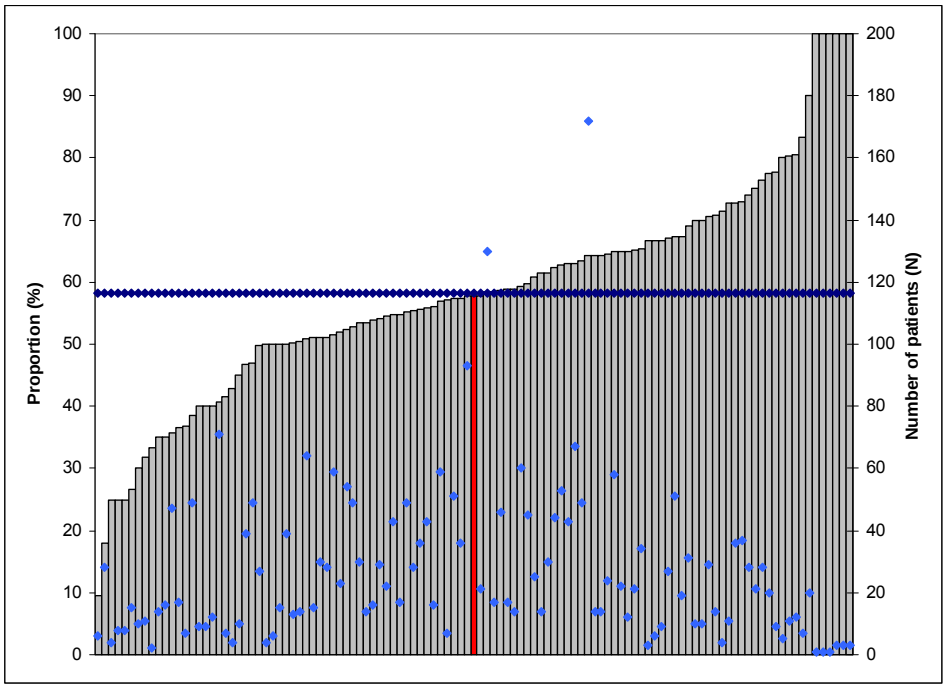
Table 10. 5-year observed survival rate by (y)pStage using the administrative databases*, calculated with actuarial (life table) method.

	(y)p-stage	N	N deaths on 31/12/2006	1-year	2-year	3-year	4-year	5-year
All	I	892	226	93%	89%	84%	79%	74%
	II	1192	460	90%	83%	74%	66%	60%
	III	1094	610	85%	70%	57%	48%	42%
	IV	352	292	70%	46%	27%	17%	14%
	X	3544	1911	75%	63%	55%	49%	45%
	I-III	3178	1296	89%	80%	71%	63%	58%
	Total (I-IV)	7074	3499	81%	70%	61%	54%	49%
Males	I	547	147	92%	88%	82%	78%	72%
	II	704	259	90%	84%	77%	68%	62%
	III	629	369	83%	68%	54%	45%	40%
	IV	227	193	69%	46%	26%	14%	11%
	X	2025	1099	76%	64%	55%	49%	45%
	I-III	1880	775	89%	80%	71%	63%	57%
	Total (I-IV)	4132	2067	81%	70%	61%	53%	49%
Females	I	345	79	95%	91%	86%	81%	77%
	II	488	201	89%	81%	72%	64%	56%
	III	465	241	86%	72%	61%	52%	46%
	IV	125	99	73%	45%	29%	22%	20%
	X	1519	812	72%	62%	55%	49%	45%
	I-III	1298	521	89%	80%	72%	64%	58%
	Total (I-IV)	2942	1432	80%	69%	61%	55%	49%

* Mean follow-up: 38 months (range 0-83 months).

Figure 5 provides an overview of the 5-year observed survival of the (y)pStage I-III patients per centre using the administrative database. Fifty-six and 55 centres have a 5-year observed survival above the weighted (58%; 95%CI 56 – 59%) and unweighted mean (58%; 95%CI 55 – 62%) respectively.

Figure 5. Per-centre-analysis (n = 112) of the 5-year observed survival of (y)pStage I-III patients (administrative cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Disease-specific 5-year survival by stage

DEFINITION

Numerator: all RC patients that survived after 5 years or that died due to a disease-unrelated cause, by stage.

Denominator: all RC patients.

Exclusion criteria:

- patients treated abroad
- patients without a social security number
- patients without a Belgian postal code
- patients without a known incidence date or with an incidence date after December 31st 2006.

RESULTS

Since no accurate data are available on the cause of death in both databases, disease-specific survival as such is not measurable at present. Above this, follow-up in the PROCARE database ends in case of local or distant recurrence.

However, relative survival is a frequently used parameter in cancer epidemiology and can be used as a proxy of the disease-specific survival [10]. For the calculation of the relative survival, the numerator is defined as the observed rate of rectal cancer patients surviving five years after diagnosis, while the denominator is defined as the expected survival rate of a comparable group (age, gender and region) from the general population.

Again, since the PROCARE database is relatively young, a 5-year survival analysis is not yet possible. At present, an accurate survival analysis is only possible at 1 year (Table 11 and Table 12) Using the coupled administrative database, a full 5-year survival analysis is possible (Table 13 and Table 14).

For 1062 of the 1071 PROCARE patients (99%) all necessary data were known. Of these 1062 patients, 866 had an incidence date before January 1st 2007.

The relative 1-year survival is measurable for 55 centres using the PROCARE database and ranges from 66 – 105% for the (y)pStage I-III patients. Thirty-seven centres have a 1-year relative survival (for the (y)pStage I-III patients) above the weighted (96%; 95%CI 95 – 98%) and unweighted mean (97%; 95%CI 94 – 99%).

Table 11. 1-year relative survival rate by cStage using the PROCARE database*, calculated with actuarial (life table) method.

		N	N deaths on 31/12/2006	1-year
All	I	73	0	103%
	II	124	6	95%
	III	279	10	97%
	IV	80	13	76%
	X	310	21	94%
	I-III	476	16	97%
	Total (I-IV)	866	50	94%
Males	I	42	0	103%
	II	81	4	95%
	III	175	8	96%
	IV	43	4	87%
	X	181	17	92%
	I-III	298	12	97%
	Total (I-IV)	522	33	94%
Females	I	31	0	102%
	II	43	2	94%
	III	104	2	99%
	IV	37	9	65%
	X	129	4	97%
	I-III	178	4	98%
	Total (I-IV)	344	17	94%

* Mean follow-up: 8 months (range 0-24 months).

Table 12. 1-year relative survival rate by (y)pStage using the PROCARE database*, calculated with actuarial (life table) method.

		N	N deaths on 31/12/2006	1-year
All	0	20	2	95%
	I	197	3	100%
	II	225	12	96%
	III	246	14	94%
	IV	36	4	84%
	X	142	15	86%
	I-III	668	29	96%
	Total (0-IV)	866	50	94%
Males	0	14	2	93%
	I	122	3	99%
	II	130	10	93%
	III	137	5	98%
	IV	27	3	85%
	X	92	10	86%
	I-III	389	18	97%
	Total (0-IV)	522	33	94%
Females	0	6	0	102%
	I	75	0	102%
	II	95	2	99%
	III	109	9	89%
	IV	9	1	83%
	X	50	5	86%
	I-III	279	11	96%
	Total (0-IV)	344	17	94%

* Mean follow-up: 8 months (range 0-24 months).

Table 13. 5-year relative survival rate by cStage using the administrative databases*, calculated with actuarial (life table) method.

	c-stage	N	N deaths on 31/12/2006	1-year	2-year	3-year	4-year	5-year
All	0	10	5	85%	91%	97%	89%	72%
	I	446	130	94%	91%	87%	86%	84%
	II	801	308	92%	87%	78%	73%	70%
	III	813	326	92%	83%	77%	69%	64%
	IV	567	491	58%	36%	24%	15%	13%
	X	4437	2239	83%	75%	68%	62%	59%
	I-III	2060	764	92%	86%	79%	74%	70%
	Total (0-IV)	7074	3499	84%	75%	68%	62%	58%
Males	0	6	3	88%	93%	100%	81%	82%
	I	255	82	94%	91%	85%	85%	82%
	II	480	182	92%	88%	80%	75%	73%
	III	507	208	92%	83%	77%	69%	65%
	IV	368	322	60%	37%	24%	14%	11%
	X	2516	1270	84%	76%	68%	63%	59%
	I-III	1242	472	93%	86%	80%	75%	71%
	Total (0-IV)	4132	2067	85%	76%	68%	62%	59%
Females	0	4	2	80%	86%	93%	102%	59%
	I	191	48	94%	91%	88%	87%	86%
	II	321	126	91%	85%	74%	69%	66%
	III	306	118	93%	84%	76%	68%	61%
	IV	199	169	53%	34%	25%	17%	15%
	X	1921	969	82%	73%	67%	62%	58%
	I-III	818	292	92%	86%	78%	73%	69%
	Total (0-IV)	2942	1432	83%	74%	67%	62%	58%

* Mean follow-up: 38 months (range 0-83 months).

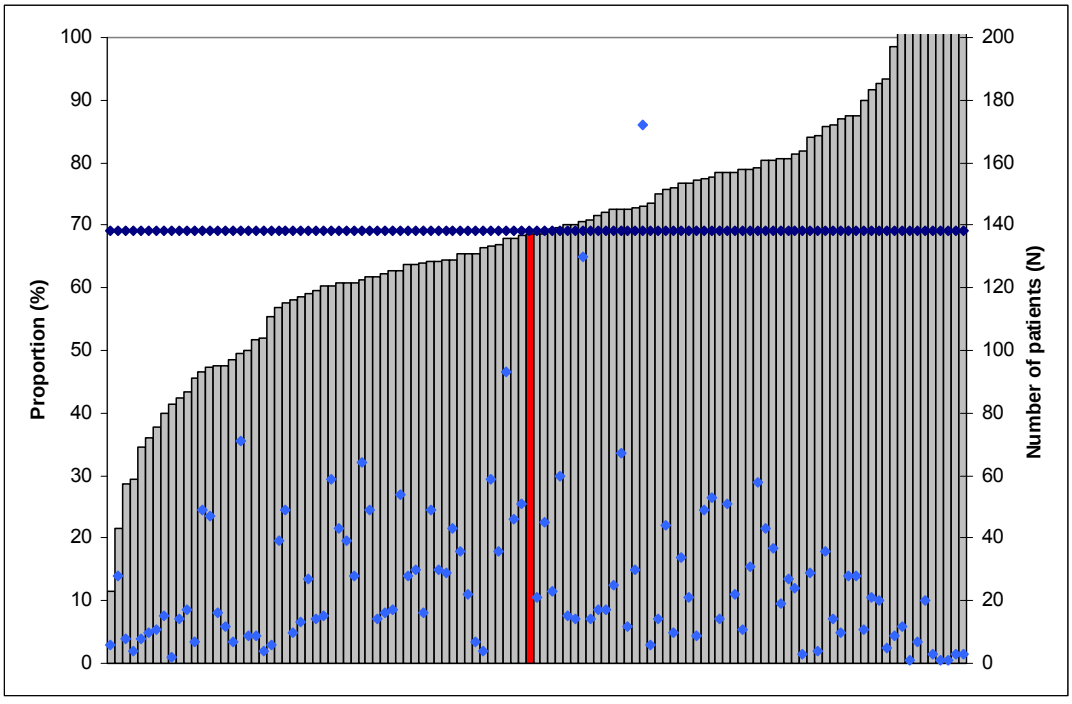
Table 14. 5-year relative survival rate by (y)pStage using the administrative databases*, calculated with actuarial (life table) method.

	(y)p-stage	N	N deaths on 31/12/2006	1-year	2-year	3-year	4-year	5-year
All	I	892	226	96%	96%	93%	91%	89%
	II	1192	460	93%	89%	82%	76%	71%
	III	1094	610	88%	75%	63%	55%	50%
	IV	352	292	72%	48%	30%	19%	17%
	X	3544	1911	78%	68%	61%	57%	53%
	I-III	3178	1296	92%	86%	79%	73%	69%
	Total (I-IV)	7074	3499	84%	75%	68%	62%	58%
Males	I	547	147	95%	95%	92%	91%	88%
	II	704	259	94%	90%	85%	79%	75%
	III	629	369	87%	73%	60%	52%	47%
	IV	227	193	71%	49%	29%	16%	13%
	X	2025	1099	79%	69%	62%	57%	54%
	I-III	1880	775	92%	86%	79%	73%	69%
	Total (I-IV)	4132	2067	85%	76%	68%	62%	59%
Females	I	345	79	98%	97%	94%	91%	90%
	II	488	201	91%	86%	78%	72%	66%
	III	465	241	89%	76%	67%	58%	53%
	IV	125	99	74%	47%	30%	24%	22%
	X	1519	812	75%	67%	61%	57%	53%
	I-III	1298	521	92%	85%	78%	72%	68%
	Total (I-IV)	2942	1432	83%	74%	67%	62%	58%

* Mean follow-up: 38 months (range 0-83 months).

Figure 6 provides an overview of the 5-year relative survival of the (y)pStage I-III patients per centre using the administrative database. The 5-year relative survival ranges from 12 – 130%. Fifty-seven and 55 centres have a 5-year relative survival above the weighted (69%; 95%CI 67 – 70%) and unweighted mean (69%; 95%CI 65 – 73%) respectively.

Figure 6. Per-centre-analysis (n = 112) of the 5-year relative survival of (y)pStage I-III patients (administrative cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Proportion of patients with local recurrence

DEFINITION

Numerator: all (y)pStage 0-III patients with an R0 resection that developed a local recurrence.

Denominator: all curatively treated (y)pStage 0-III patients (defined as all R0 resections).

Exclusion criteria:

- patients not treated with surgery
- patients with R1 or R2 resection, or with type of resection uncertain or unknown
- patients without follow-up data
- patients with c or pStage IV
- patients with unknown (y)pStage

RESULTS

Local recurrence rate at 1 year (calculated with Kaplan-Meier analysis) is 3% for the PROCARE cohort (Table 15). This figure should be interpreted with caution because of the low follow-up rate at present (registration started in 2006): of the 707 patients with (y)pStage 0-III and an R0 resection, only 233 patients (33%) had follow-up data available. However, in a few years it should be possible to accurately calculate the local recurrence rate at 3 years.

For 76 of the 1071 patients, no information was available on the type of resection. Above this, for 122 of the 914 patients with an R0 resection, no information was available on the (y)pStage. Missing data for local recurrence cannot be measured, since the default value of the variable is '0' (i.e. missing values also receive value '0'). Therefore, the total number of missing data is at least 672/1071 (63%), including the 474 patients with (y)pStage 0-III and an R0 resection without follow-up data at 1 year.

Importantly, the number of patients with an R0 resection is probably overestimated, since the results of the pathology report are not taken into account in the variable used to register R0 resections (see appendix). Ideally, the real R0 should be used in the future, taking into account the pathology results (CRM > 1 mm for R0) and absence of intraoperative rectal perforation.

Local recurrence (free) rate is measurable for 38 centres using the PROCARE database. The 1-year local recurrence free rate ranges from 50 – 100%. Thirty-three centres have a 1-year local recurrence free rate above the weighted (97%; 95%CI 95 – 99%) and unweighted mean (97%; 95%CI 94 – 100%). Risk-adjustment (tumour localisation [low – mid – upper], stage) is necessary for more appropriate interpretation of the results.

This QI is not measurable using the administrative databases due to an absence of specific codes for R0 resection and local recurrence.

Table 15. Number of (y)pStage 0-III patients with local recurrence at 1 year, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with rectal cancer that underwent R0 resection	914
Patients with (y)pStage 0-III rectal cancer that underwent R0 resection	707
Proportion with follow-up data at 1 year	233
Proportion with local recurrence at 1 year	5 (2%)*

* This result represents a ratio, in contrast to the calculation with the Kaplan-Meier analysis.

Proportion of patients discussed at a multidisciplinary team meeting

DEFINITION

Numerator: all patients with RC, cT3-4, cN+ and/or cStage IV, discussed at a multidisciplinary team (MDT) meeting within 6 months after the incidence date.

Denominator: all patients with RC, cT3-4, cN+ and/or cStage IV.

Exclusion criteria:

- patients with an incidence date before February 1st 2003 (date at which the administrative code became available)
- patients with cT, cN and/or cStage unknown

RESULTS

Overall, 65% of patients with rectal cancer cT3-4, cN+ and/or cStage IV were discussed at the MDT in 2003 (Table 16). The results of 2004 are not presented since the BCR data were not complete for 2004 at the time of the study. Of the 1473 patients with a correct incidence date, it was not possible to retrieve the cStage and/or cN and/or cT for 617 patients (total missings: 617/7074, 9%).

Discussion at the MDT is measurable for 100 centres using the administrative database. Thirty-two of the 101 centres have a score of 100%, while 13 centres have a score of 0%. All these 13 centres treated less than 5 eligible patients. Sixty-four centres have a score above the weighted (65%; 95%CI 61 – 69%) and unweighted mean (66%; 95%CI 59 – 73%).

The QI is not measurable for the prospective cohort, since this information is not registered.

Table 16. Number of patients with rectal cancer (cT3-4, cN+ and/or cStage IV) discussed at a multidisciplinary meeting in 2003, measured with administrative data.

	N
Patients with rectal cancer: cT3-4, cN+ and/or cStage IV (denominator)	673
Proportion discussed at the MDT (numerator)	435 (65%)

Discussion

At present, only one general QI (local recurrence rate) is measurable using the PROCARE database, while one other QI will only be measurable in the future (overall 5-year survival by stage) (Table 17). Using administrative databases, overall 5-year survival by stage and discussion at a multidisciplinary team meeting are both measurable.

Disease-specific 5-year survival by stage is not measurable for both databases. However, this QI will be replaced by the relative 5-year survival by stage, which is (potentially) measurable for both databases. Another option would be to add a specific code to the PROCARE data entry form that registers the cause of death both in the postoperative period and during follow-up (providing a choice between cancer-related and cancer-unrelated cause of death). However, in this case an important precondition is to continue the registration of events after local or distant recurrence. Obviously, this is not a solution for the administrative database.

For the interpretation of the overall survival, it is important to take into account the postoperative mortality, which has an important impact on the 1-year survival. Postoperative mortality is measured in QI 1234 (see below).

Finally, QI 1114 can be rendered measurable using the PROCARE database by adding a specific code to the PROCARE data entry form, or by linking the PROCARE database to the administrative databases using the unique patient identification number. The latter option is preferred, since it would reduce the registration burden of the participating centres. However, in view of a changing law (making a discussion at the MDT obligatory for all oncologic patients) and in view of the inability to check the quality of the multidisciplinary discussion itself, one can discuss on the value of this indicator as a quality indicator.

Table 17. Measurability of selected general QI.

QI	Prospective Db		Administrative Db	
	Measurable?	**If not: reason?**	**Measurable?**	**If not: reason?**
1111	Not yet	Follow-up too short	Yes	-
1112	No	No code	No	No code
1113	Yes	-	No	No code
1114	No	No code	Yes	-

3.2.2.2 Quality indicators related to diagnosis and staging

Proportion of patients with a documented distance from the anal verge

DEFINITION

Numerator: all RC patients that underwent resection for rectal cancer (endoscopic, LE/TEMS, radical resection) and who have a documented distance from the anal verge.

Denominator: all patients with RC that underwent resection (endoscopic, LE/TEMS, radical resection) for rectal cancer.

Exclusion:

- patients that didn't undergo resection

RESULTS

More than 97% of patients with rectal cancer undergoing resectional surgery have a documented distance from the anal verge (Table 18). No missing data were identified. A potential problem with the measurement of this QI is that the distance from the anal verge is registered in the PROCARE database on 3 occasions (pre-treatment data, intra-operative data and pathology report; see appendix). This may lead to inconsistencies which may need interpretation by a clinician.

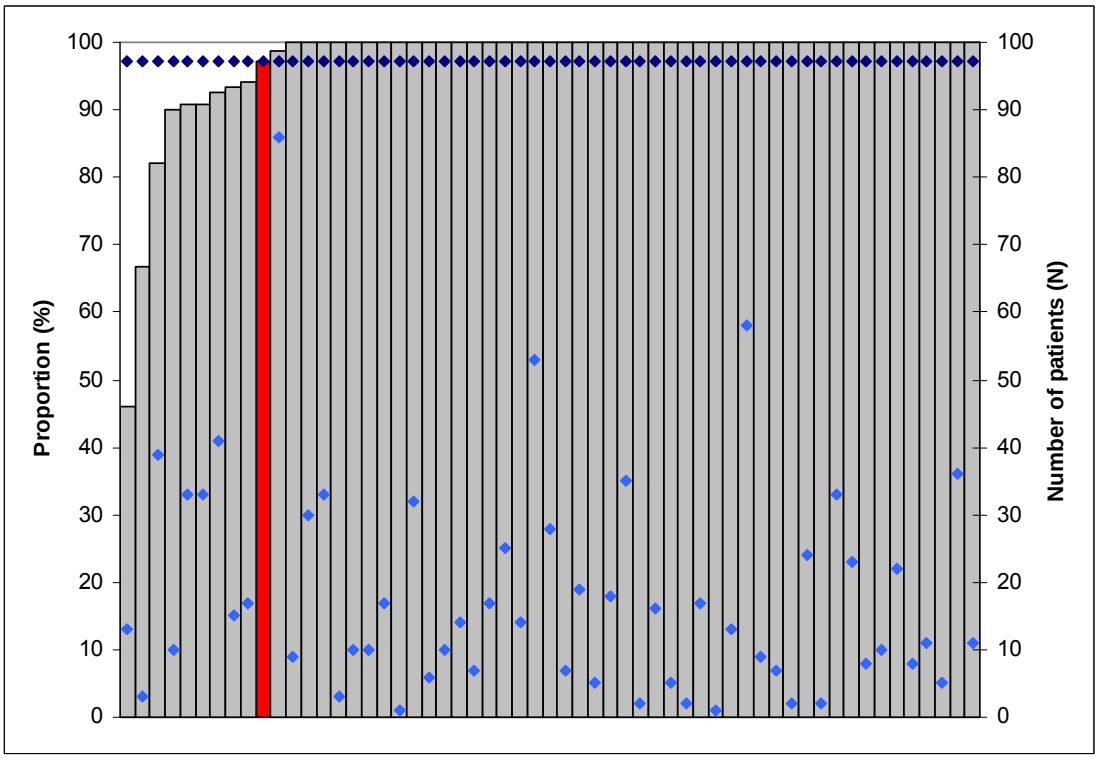
Figure 7 provides an overview of the documented distance from the anal verge per participating centre using the prospective database. Forty-six of the 56 centres have a score of 100%. Forty-seven centres have a score above the weighted (97%; 95%CI 96 – 98%) and unweighted mean (97%; 95%CI 95 – 100%).

The QI is not measurable for the administrative cohort, since no administrative code exists for the (documentation of the) distance from the anal verge.

Table 18. Number of patients with a documented distance from the anal verge, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with rectal cancer that underwent surgery	1058
Patients with rectal cancer that underwent resectional surgery (local or radical) (denominator)	1018
Patients with documented distance to anal verge (numerator)	990 (97%)

Figure 7. Per-centre-analysis (n = 56) of documented distance from the anal verge (prospective cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Proportion of patients in whom a CT of the liver and RX or CT thorax was performed before any treatment

DEFINITION

Numerator: all patients with RC that underwent CT liver and RX or CT thorax before the first treatment.

Denominator: all patients with RC that underwent treatment.

Exclusion:

- patients that didn't receive treatment

RESULTS

Because no specific variable for CT liver, CT thorax or thorax X-ray is available in the PROCARE database, this QI is not measurable for the PROCARE cohort.

In the administrative database, more specific codes are available (nomenclature codes for thorax X-ray, ICD-9-CM codes for CT thorax and abdomen; see appendix). However, important limitations also render this QI incalculable and not interpretable for the administrative cohort:

- ICD-9-CM coding of CT thorax and abdomen is not obligatory for the MCD database. Above this, ambulatory tests are only available through the IMA database (nomenclature codes). Therefore, using ICD-9-CM codes to track CT thorax and liver causes an important underestimation (Table 19).

Table 19. Proportion of patients with a CT thorax or abdomen in the Technicall Cell database (ICD-9-CM codes).

	N (%)
CT thorax	191 (4%)
CT abdomen	608 (13%)
Total	4556 (100%)

- When using the ICD-9-CM codes to select these imaging techniques, it is difficult to determine the exact date of the intervention. In the Technical Cell database, information is only available on the hospitalisation period during which the intervention was carried out. Above this, only year, month and day of the week of the admission and discharge are available. Theoretically, this could be solved by linking the interventions encoded in the Technical Cell database to those in the IMA database. However, the correspondence between these two databases is low (data not shown).
- In the administrative database, it is impossible to determine if an imaging study was carried out in relation with the rectal cancer.

Proportion of patients in whom a CEA was performed before any treatment

DEFINITION

Numerator: all patients with RC that underwent CEA measurement before the first treatment.

Denominator: all patients with RC that underwent treatment.

Exclusion:

- patients that didn't receive treatment

RESULTS

CEA measurement before any treatment occurs in 84% of patients in the PROCARE cohort vs. 66% in the administrative cohort (Table 20). No missings were identified in the PROCARE database. For 78 of the 7074 patients from the administrative cohort, it was impossible to identify the treatment (1%).

An important difference between the two measurements is the time frame. In the PROCARE database, the serum CEA before treatment is registered, without justification of the actual date of the test. In the administrative database, the date of the test and first treatment are available. A timeframe of 3 months before the incidence date was chosen, since in some cases the CEA measurement can be done before the actual diagnosis of rectal cancer, and duplication of the test is unnecessary in these cases.

Importantly, unavailability of the CEA result in the PROCARE registry does not mean that the measurement was not carried out.

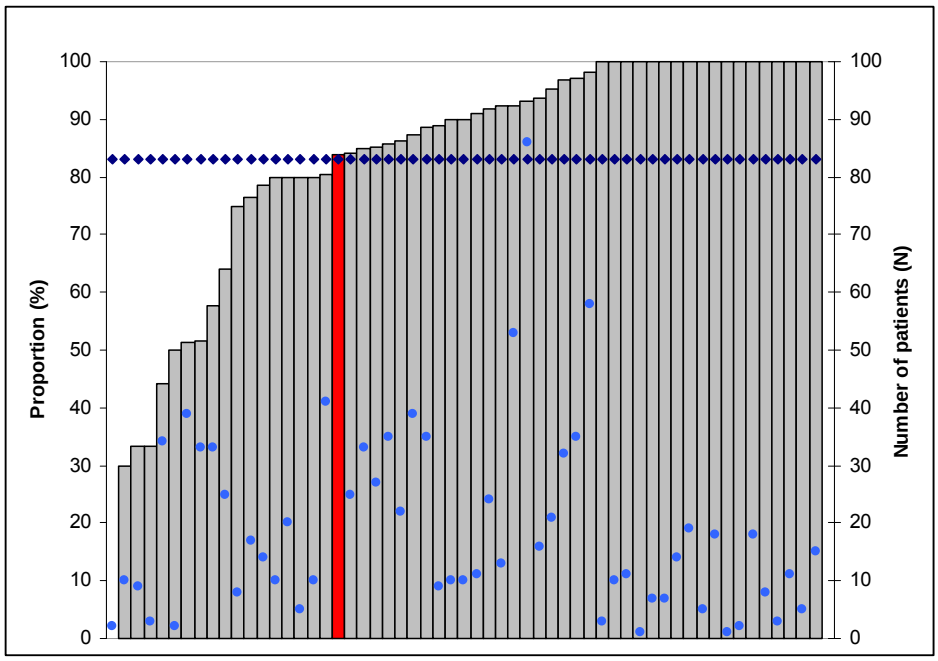
Table 20. Number of patients in whom a CEA was performed before any treatment.

	PROCARE cohort	Administrative cohort
Patients with rectal cancer	1071	6996
Patients with rectal cancer that received treatment (denominator)	1067	6337
Patients with rectal cancer in whom a CEA was performed before any treatment (numerator)	894 (84%)	4198 (66%)

Figure 8 provides an overview of the CEA registration per participating centre using the prospective database. Eighteen centres have a score of 100%, while in 5 centres less than 50% of patients have a pre-treatment CEA registration. Thirty-eight centres have a score above the weighted (84%; 95%CI 82 – 86%) and unweighted mean (83%; 95%CI 77 – 89%).

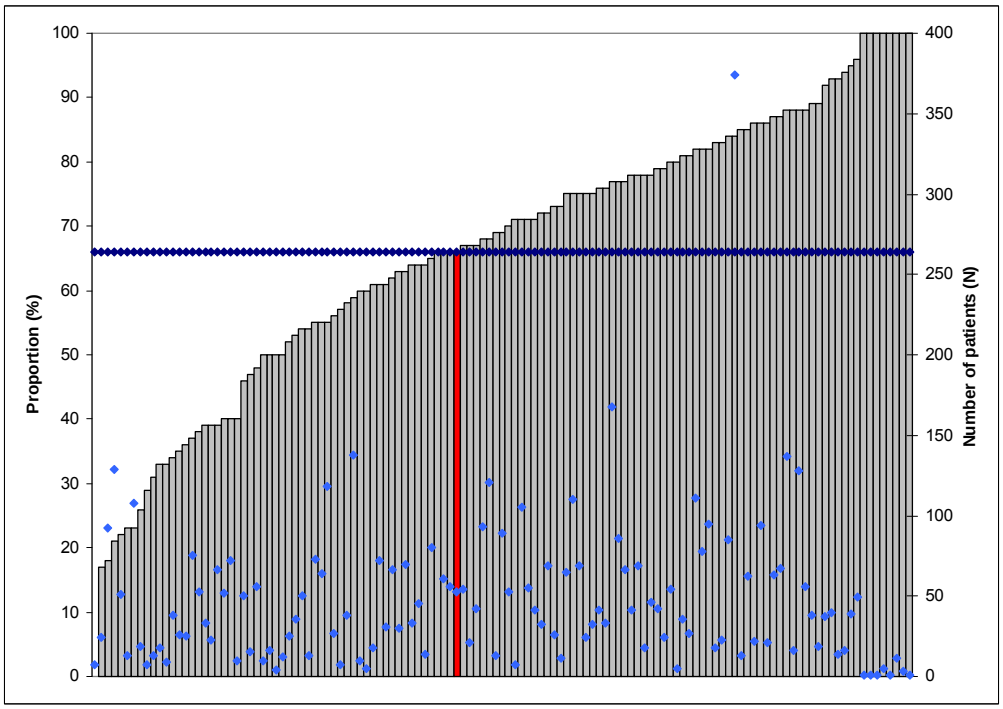
Figure 9 provides an overview of the CEA registration per centre using the administrative database. Eight centres have a score of 100%, while in 26 centres less than 50% of patients have a pre-treatment CEA registration. Forty-seven centres have a score above the weighted (66%; 95%CI 65 – 67%) and unweighted mean (66%; 95%CI 62 – 70%).

Figure 8. Per-centre-analysis (n = 56) of CEA registration (prospective cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Figure 9. Per-centre-analysis (n = 126) of CEA registration (administrative cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Proportion of patients undergoing elective surgery that had preoperative complete large bowel-imaging

DEFINITION

Numerator: all patients with RC that underwent elective surgery and had total colonoscopy and/or barium x-ray before surgery.

Denominator: all patients with RC that underwent elective surgery.

Exclusion:

- patients not treated with surgery
- patients with urgent or emergency surgery

RESULTS

In the PROCARE cohort, 81% of the RC patients undergoing elective surgery had preoperative complete large bowel-imaging (LBI) (Table 21). Of the patients that didn't undergo LBI, 85% provided at least one reason, of which stenosis was the most important reason (60% of patients) (Table 22).

For 33 of the 1058 patients that underwent surgery, no information was available on the elective character of the surgery. Above this, for 3 of the 1003 patients undergoing elective surgery, no information was available on preoperative imaging (total missings: 36/1071, 3%).

The preoperative complete LBI is measurable for 55 centres using the prospective database. Twelve centres have a score of 100%. Thirty-three centres have a score above the weighted (81%; 95%CI 79 – 84%) and unweighted mean (80%; 95%CI 75 – 85%).

For the administrative cohort, the QI is not measurable, since patients undergoing elective surgery cannot be selected accurately (see appendix).

Ignoring this selection bias and thus allowing an underestimation (by not excluding urgent surgery between 8 am and 21 pm on working days), 59% of patients had preoperative complete LBI.

Table 21. Number of patients undergoing elective surgery that had preoperative complete large bowel-imaging, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with rectal cancer that underwent surgery	1058
Patients with rectal cancer that underwent elective surgery (denominator)	1003
Patients undergoing preoperative complete large bowel-imaging (numerator)	811 (81%)

Table 22. Reasons for not undergoing preoperative large bowel-imaging, measured with prospective PROCARE data*.

	%
Tumour stenosis	60
Insufficient bowel preparation	8
Intolerance of the patient	8
Technical reasons	6
Other	11
No reason	15

* More than one reason is possible per patient.

Proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment

DEFINITION

Numerator: all patients with RC that underwent treatment and had a TRUS and pelvic CT and/or MRI before treatment.

Denominator: all patients with RC that underwent treatment.

Exclusion:

- patients that didn't receive treatment

RESULTS

Thirty-four percent of RC patients undergoing treatment received a TRUS and pelvic CT/MRI in the PROCARE cohort (Table 23). Of the 1067 patients receiving treatment, 8 patients had no data on pre-treatment imaging (1%).

The pre-treatment TRUS and pelvic CT/MRI is measurable for 56 centres using the prospective database. Eleven centres have a score above 50%, while 10 centres score 0%. Of these 10 centres, 7 centres included less than 5 eligible patients. Seventeen and 24 centres have a score above the weighted (34%; 95%CI 31 – 37%) and unweighted mean (28%; 95%CI 22 – 35%) respectively. Risk-adjustment (tumour localisation [low – mid – upper], tumour stenosis) is necessary for the correct interpretation of these results.

In the administrative cohort, this QI is not measurable due to an absence of a specific code for pelvic CT and MRI.

Table 23. Number of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with rectal cancer that received treatment (denominator)	1067
Patients in whom a TRUS and pelvic CT/MRI was performed before any treatment (numerator)	366 (34%)

Proportion of patients with cStage II-III RC that have a reported cCRM

DEFINITION

Numerator: all patients with cStage II-III RC that underwent surgery and that have a reported cCRM.

Denominator: all patients with cStage II-III RC that underwent surgery.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery

RESULTS

Of the patients with cStage II-III that underwent surgery, 26% have a reported cCRM in the PROCARE cohort (Table 24). For 330 patients the cStage was unknown (total missings: 330/1071, 31%). Again, unavailability of the cCRM in the PROCARE registry does not always mean that the measurement was not carried out.

The reported cCRM is measurable for 51 centres using the prospective database. Two centres have a score of 100%, while 27 centres have a score of 0%. Twelve and 14 centres have a score above the weighted (26%; 95%CI 22 – 30%) and unweighted mean (19%; 95%CI 11 – 28%) respectively.

The QI is not measurable for the administrative cohort, since no administrative code exists for the (documentation of the) cCRM.

Table 24. Number of patients that underwent surgery and have a reported cCRM, measured with prospective PROCARE data.

	cStage							
	0	**I**	**II**	**III**	**IV**	**X**	**All**	**II-III**
Patients with rectal cancer	1	107	160	357	111	335	1071	517
Patients with rectal cancer that underwent surgery (denominator)	1	107	160	356	104	330	1058	516
Patients with a reported cCRM (numerator)	0	14	26	107	16	53	216	133 (26%)

Time between first histopathologic diagnosis and first treatment

DEFINITION

Numerator: median time between first histopathologic diagnosis and first treatment of all patients with RC that underwent treatment.

Denominator: all patients with RC that underwent treatment.

Exclusion:

- patients that didn't receive treatment

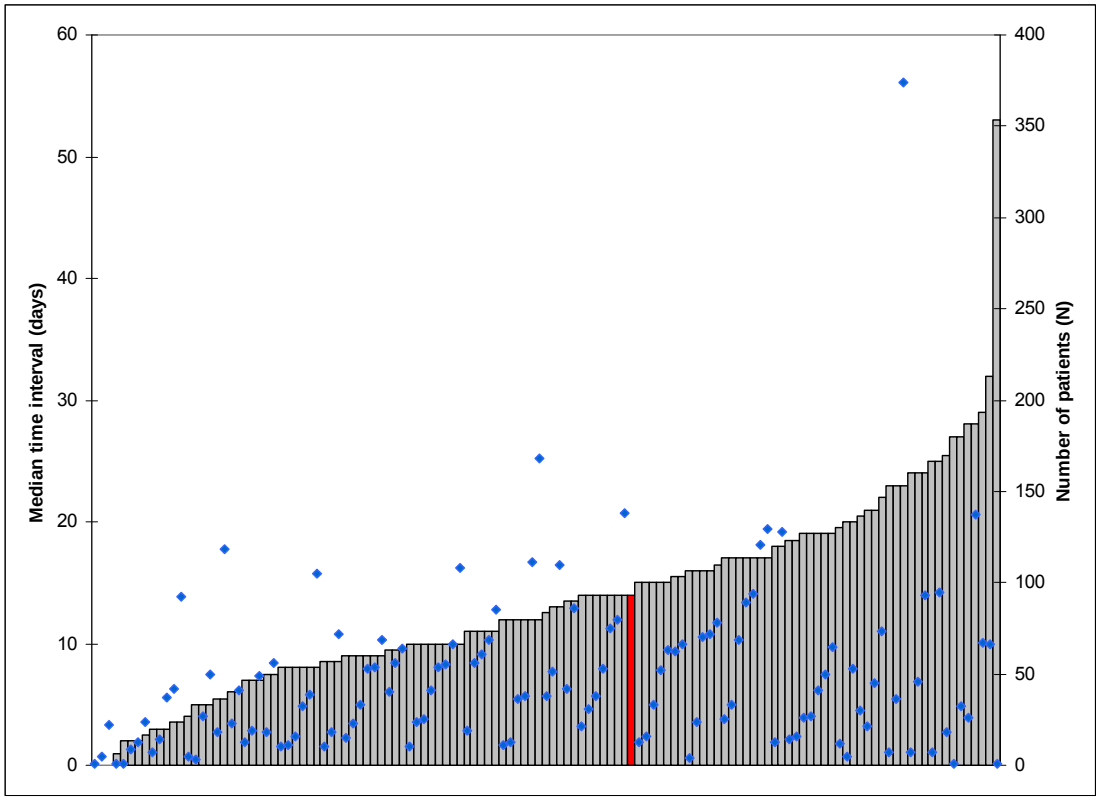
RESULTS

The median time between first histopathologic diagnosis and first treatment is 28 days for the prospective cohort. Unfortunately, a high number of missing data was identified. Of the 1067 patients receiving treatment for their rectal cancer, the first treatment was not known in 146 cases. Above this, of the 921 patients with a known first treatment, the date of biopsy was not known for 812 cases (total missings: 958/1071, 89%). Within the PROCARE database, the date of first consultation (in the hospital) is also registered, which is in fact a more accurate reflection of the date of diagnosis. The median time between the first consultation and the first treatment was 24 days (total missings: 242/1071, 23%).

For the 6337 patients that received treatment in the administrative cohort, the median time between first histopathologic diagnosis and first treatment is 14 days, with a mean of 28 days (SD 79). For 78 patients no information was available on the received treatment (total missings: 78/7074, 1%).

Prospective data on time-to-treatment were available from only 15 centres. For these centres, the median time-to-treatment varies from 13 – 37 days. Figure 10 provides an overview of the time-to-treatment per centre using the administrative database. The median time-to-treatment varies from 0 – 53 days.

Figure 10. Per-centre-analysis (n = 126) of time-to-treatment (days) (administrative cohort)[$].



[$] The weighted mean is presented with a red bar. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Discussion

Using the PROCARE database, only one QI (CT liver and CT/RX thorax before treatment) is not measurable (Table 25). This can be easily solved by adding a specific code registering the receiving of preoperative imaging studies (CT liver yes/no, CT thorax yes/no, etc.). Using administrative databases, only 2 QI are measurable, mainly because of the absence of codes for clinical data (e.g. distance to the anal verge), the absence of specific codes (e.g. pelvic CT or MRI), or the fact that some codes are not obligatory (e.g. CT thorax and abdomen in the MCD database).

For both CEA and cCRM, unavailability of the parameter in the PROCARE registry does not always mean that the measurement was not carried out. Therefore, real missing data cannot be distinguished from unavailable data. This can be solved by asking for the availability of the result (yes/no), and for the result itself if available.

At present, QI 1214 only measures the proportion of preoperative total colonoscopy and/or barium x-ray. However, although not recommended for routine use, virtual colonoscopy can also be considered a valuable option for complete large-bowel imaging (e.g. in case of stenosing rectal cancer) [1]. Therefore, a variable should be added to the PROCARE data entry form registering virtual colonoscopies.

QI 1215 measures the proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment. For feedback to individual healthcare providers, it is necessary to have this information per stage and level of the tumour (risk-adjustment). Above this, since this QI involves three different imaging techniques, separate information on the proportion of TRUS only, pelvic CT only, pelvic MRI only, TRUS and CT, etc. would be useful to allow specific quality improvement actions (level 3 information). This information is readily available in the PROCARE database.

Importantly, most selected QI on diagnosis and staging measure procedures for patients undergoing treatment/surgery.

Of course, many of these procedures – such as CT liver, CT/RX thorax, TRUS, etc. – are necessary to decide on further treatment/surgery, and should therefore be preformed in all patients [1].

Table 25. Measurability of selected QI on diagnosis and staging.

QI	Prospective Db		Administrative Db	
	Measurable?	If not: reason?	Measurable?	If not: reason?
1211	Yes	-	No	Clinical data: no code
1212	No	No specific code	No	Code not obligatory
1213	Yes	-	Yes	-
1214	Yes	-	No	No specific code
1215	Yes	-	No	No specific code
1216	Yes	-	No	Clinical data: no code
1217	Yes	-	Yes	-

3.2.2.3 Quality indicators related to neoadjuvant treatment

Proportion of cStage II-III patients that received a short course of neoadjuvant pelvic RT

DEFINITION

Numerator: all patients with cStage II or III RC that underwent surgery and received a short course of neoadjuvant pelvic RT (with or without chemotherapy).

Denominator: all patients with cStage II or III RC that underwent surgery.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery

RESULTS

Six percent (95%CI 4 – 9%) of the PROCARE patients with cStage II-III that underwent surgery received a short course of neoadjuvant pelvic radiotherapy, compared to 52% (95%CI 47 – 57%) of the patients that received a long course (Table 26). Thirteen percent received another course of neoadjuvant pelvic radiotherapy, while 28% received no neoadjuvant radiotherapy. The total number of missing data was 430/1071 or 40% (including 335 patients with unknown cStage).

Short and long course neoadjuvant radiotherapy are measurable for 48 centres using the prospective database. In 6 centres all cStage II-III patients are treated with a long course of neoadjuvant radiotherapy. However, all 6 centres have 3 eligible patients or less. On the contrary, in 10 centres no cStage II-III patients are treated with a long course. Nine of these centres have 10 eligible patients or less. In 38 centres, no patient is treated with a short course of neoadjuvant radiotherapy, while in 5 centres more than 10% of cStage II-III patients is treated with a short course.

Importantly, for the interpretation of these results risk-adjustment (tumour localisation, cCRM, age, comorbidities) is necessary.

The QI is not measurable for the administrative cohort due to an inability to distinguish a short or long course from another course of radiotherapy (see appendix).

Table 26. Number of patients that received a short or long course of neoadjuvant pelvic radio(chemo)therapy, measured with prospective PROCARE data.

	cStage				
	I	II	III	X	II-III
Patients with rectal cancer	107	160	357	335	517
Patients with rectal cancer that underwent surgery	107	160	356	330	516
Patients with a short course (numerator QI 1221)	2	7	19	17	26 (6%)
Patients with a long course (numerator QI 1222)	7	42	178	104	220 (52%)
Patients with other course	5	13	43	23	56
No neoadjuvant radiotherapy	88	57	62	153	119
Patients with neoadjuvant radiotherapy unknown or regimen unknown (missing data)*	5	41	54	33	95

*The denominator is calculated by subtracting the missing data from the proportion of patients that underwent surgery (see appendix for algorithm).

Proportion of cStage II-III patients that received a long course of neoadjuvant pelvic RT

DEFINITION

Numerator: all patients with cStage II or III RC that underwent surgery and that received a long course of neoadjuvant pelvic RT (with or without chemotherapy).

Denominator: all patients with cStage II or III RC that underwent surgery.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery

RESULTS

See previous QI.

Proportion of cStage II-III patients that received neo-adjuvant chemoradiation with a regimen containing 5-FU

DEFINITION

Numerator: all patients with cStage II or III RC that underwent surgery and that received neoadjuvant CRT with a regimen containing 5-FU.

Denominator: all patients with cStage II or III RC that underwent surgery and that received neoadjuvant CRT.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery
- cStage II and III patients receiving neoadjuvant radiotherapy or chemotherapy as a monotherapy

RESULTS

In the prospective cohort 95% (95%CI 90 – 100%) of the cStage II-III patients that underwent surgery and received neoadjuvant chemoradiotherapy, received a chemotherapy regimen with 5-FU (Table 27). However, a high number of missing data was identified, which is due to the complete absence of a specific chemotherapy form in the first data entry version and the complex data entry form for chemotherapy at present. For 335 patients the cStage was unknown. For 18 of the 516 patients undergoing surgery, no information was available on neoadjuvant treatment. Above this, for 227 of the 290 patients receiving neoadjuvant chemoradiation, no information was available on the administered regimen (total missings: 580/1017, 54%).

In the administrative cohort 99% (95%CI 98 – 100%) of the cStage II-III patients that underwent surgery and received neoadjuvant chemoradiotherapy, received a chemotherapy regimen with 5-FU (Table 28). For 78 patients, no information was available on the received treatment. Above this, for 3520 of the 5677 patients undergoing radical surgery, no information was available on the cStage (total missings: 3598/7074, 51%).

Prospective data were available from 16 centres, with a range of 1 – 13 eligible patients per centre. Fourteen centres had a score of 100%.

This QI was measurable for 91 centres using the administrative database. Again, little variation can be found, with 89 of the 91 centres scoring 100%. Importantly, 80 centres treated less than 10 eligible patients.

Table 27. Number of patients that received neoadjuvant chemoradiotherapy with 5-FU, measured with prospective PROCARE data.

	cStage				
	I	II	III	X	II-III
Patients with rectal cancer	107	160	357	335	517
Patients with rectal cancer that underwent surgery	107	160	356	330	516
Patients that received neoadjuvant chemoradiotherapy	11	53	237	127	290
Patients with known regimen (denominator)	2	12	51	4	63
Patients with 5-FU (numerator)	2	12	48	4	60 (95%)

Table 28. Proportion of patients that received neoadjuvant chemoradiotherapy with 5-FU, measured with administrative data.

	cStage				
	I	II	III	X	II-III
Patients with rectal cancer	438	790	807	4392	1597
Patients with rectal cancer that underwent surgery	392	709	733	3521	1442
Proportion with known regimen (denominator)	31	206	383	497	589
Proportion with 5-FU (numerator)	31	206	382	496	588 (99%)

Proportion of cStage II-III patients treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU

DEFINITION

Numerator: all patients with cStage II or III RC that underwent surgery and that received neoadjuvant CRT with a regimen containing 5-FU via continuous infusion.

Denominator: all patients with cStage II or III RC that underwent surgery and that received neoadjuvant CRT with a regimen containing 5-FU.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery
- cStage II and III patients receiving neoadjuvant radiotherapy or chemotherapy as a monotherapy
- cStage II-III patients not receiving 5-FU based neoadjuvant chemoradiotherapy

RESULTS

Due to the absence of a specific code for the administration of a continuous infusion of 5-FU, this QI is not measurable in both the prospective and administrative cohort.

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

DEFINITION

Numerator: all patients with cStage II or III RC that underwent surgery and that received a long course of neoadjuvant pelvic (C)RT and completed this treatment within the planned time.

Denominator: all patients with cStage II or III RC that underwent surgery and that received a long course of neoadjuvant pelvic (C)RT.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery
- cStage II and III patients not treated with a long course of neoadjuvant (chemo)radiotherapy

RESULTS

In the prospective cohort 95% (95%CI 93 – 98%) of the cStage II-III patients that received a long course of neoadjuvant (chemo)radiotherapy completed this treatment within the planned timing (Table 29). For 335 patients the cStage was unknown. For 20 of the 516 patients undergoing surgery, no information was available on neoadjuvant radiotherapy. Above this, for 75 of the 377 patients receiving neoadjuvant (chemo)radiotherapy, no information was available on the course of the radiotherapy. The number of missing data for treatment interruption cannot be calculated, since the default value of the variable is '0' (i.e. missing data also receive a value '0'). Therefore, the total number of missing data is at least 430/1071 (40%).

Prospective data were available from 38 centres. Thirty-five centres had a score of 100%, while one centre scored 38%. Importantly, 31 centres included less than 10 eligible patients.

The identification of a long course of RT, i.e. at least 25 fractions of 1.8 Gy, is impossible in the administrative databases. The QI is therefore not measurable for the administrative cohort.

Table 29. Number of patients that received a long course of neoadjuvant (chemo)radiotherapy and completed this treatment within the planned timing, measured with prospective PROCARE data.

	cStage				
	I	II	III	X	II-III
Patients with rectal cancer	107	160	357	335	517
Patients with rectal cancer that underwent surgery	107	160	356	330	516
Patients that received a long course of neoadjuvant chemoradiotherapy (denominator)	7	42	178	104	220
Patients that completed treatment within planned timing (numerator)	7	40	170	99	210 (95%)

Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 6 to 8 weeks after completion of the (chemo)radiation

DEFINITION

Numerator: all patients with cStage II or III RC who underwent surgery and received a long course of neoadjuvant pelvic (C)RT and were operated 6-8 weeks after completion of the (C)RT.

Denominator: all patients with cStage II or III RC who underwent surgery and received a long course of neoadjuvant pelvic (C)RT.

Exclusion:

- patients with cStage other than II and III
- cStage II and III patients not treated with surgery
- cStage II and III patients not treated with a long course of neoadjuvant (chemo)radiotherapy

RESULTS

In the prospective cohort 64% of the cStage II-III patients that received a long course of neoadjuvant (chemo)radiotherapy was operated 6-8 weeks after completion of the (chemo)radiotherapy (Table 30). About one-fourth was operated within 6 weeks after completion, while 11% was operated more than 8 weeks after completion. For 335 patients the cStage was unknown. For 20 of the 516 patients undergoing surgery, no information was available on neoadjuvant radiotherapy. Above this, for 75 of the 377 patients receiving neoadjuvant (chemo)radiotherapy, no information was available on the course of the radiotherapy. Finally, for 4 of the 220 patients receiving a long course of neoadjuvant (chemo)radiotherapy, no information was available on the treatment dates (total missings: 434/1071, 41%).

This QI was measurable for 38 centres using the prospective database. Eight centres have a score of 100%, while 15 centres have a score of 50% or less. Twenty centres have a score above the weighted (64%; 95%CI 58 – 71%) and unweighted mean (62%; 95%CI 52 – 72%). Again, 31 centres included less than 10 eligible patients.

The identification of a long course of RT, i.e. at least 25 fractions of 1.8 Gy, is impossible in the administrative databases. The QI is therefore not measurable for the administrative cohort.

Table 30. Number of patients that received a long course of neoadjuvant (chemo)radiotherapy and was operated 6-8 weeks after completion of the (chemo)radiotherapy, measured with prospective PROCARE data.

	cStage				
	I	**II**	**III**	**X**	**II-III**
Patients with rectal cancer	107	160	357	335	517
Patients with rectal cancer that underwent surgery	107	160	356	330	516
Patients that received a long course of neoadjuvant chemoradiotherapy	7	42	178	104	220
Patients with a known surgery date and end date of (chemo)radiotherapy (denominator)	6	42	174	97	216
Patients that were operated 6-8 weeks after completion (numerator)	4	28	111	62	139 (64%)
Patients that were operated <6 weeks after completion	2	11	42	26	53
Patients that were operated >8 weeks after completion	0	3	21	9	24

Rate of acute grade 4 radio(chemo)therapy-related complications

DEFINITION

Numerator: all patients with RC that received neoadjuvant (C)RT and had acute grade 4 complications.

Denominator: all patients with RC that received neoadjuvant (C)RT.

Exclusion:

- patients with cStage other than II and III
- cStage II-III patients not treated with (chemo)radiotherapy

RESULTS

Due to the absence of a specific code for grade 4 radio(chemo)therapy-related complications, this QI is not measurable in both the prospective and administrative cohort.

Discussion

Two QI (continuous 5-FU infusion and grade 4 radio[chemo]therapy-related complications) are not measurable with the prospective database due to the absence of codes registering the necessary information (Table 31). Both QI are also not measurable with the administrative databases. To capture the necessary information for both QI, specific codes need to be added to the PROCARE data entry form. Above this, the chemotherapy section of the form needs to be introduced to the participants of PROCARE and to be modified to allow an unambiguous and more complete registration of all necessary chemotherapy-related information.

Five QI are not measurable with the administrative databases, because the dose and number of fractions of the radiotherapy regimen cannot be retrieved with administrative codes. One other QI (grade 4 radio[chemo]therapy-related complications) is not measurable, because no specific administrative codes exists for grade 4 complications.

In the prospective database, a high number of missing values was identified for the radiotherapy regimen. Above this, no information on the prescribed radiotherapy regimen is available (only the administered regimen is registered), which is more indicative of the appropriateness of the treatment. Therefore, a specific variable registering the prescribed radiotherapy regimen should be added to the radiotherapy section of the PROCARE data entry form.

Most of the selected QI are defined for cStage II-III patients that underwent surgery. However, it is clear that these QI apply to all cStage II-III patients, irrespective of the receival of surgery (taking into account age, fitness, stage, tumour localisation).

Table 31. Measurability of selected QI on neoadjuvant treatment.

QI	Prospective Db		Administrative Db	
	Measurable?	If not: reason?	Measurable?	If not: reason?
1221	Yes	-	No	No specific code
1222	Yes	-	No	No specific code
1223	Yes	-	Yes	-
1224	No	No specific code	No	No specific code
1225	Yes	-	No	No specific code
1226	Yes	-	No	No specific code
1227	No	No code	No	No code

3.2.2.4 Quality indicators related to surgery

Proportion of R0 resections

DEFINITION

Numerator: all cStage I-III patients with RC that underwent radical resection and had a R0 resection.

Denominator: all cStage I-III patients with RC that underwent radical resection.

Exclusion:

- patients with cStage IV
- patients undergoing local surgery or no surgery

RESULTS

Of the cStage I-III patients that underwent radical resection, 93% had an R0 resection in the prospective cohort (Table 32). For 335 patients the cStage was unknown. For 10 of the 612 patients that underwent radical resection, no information was available on the type of resection (total missings: 345/1071, 32%).

The proportion of R0 resections is measurable for 52 centres using the prospective database. Thirty-one centres have 100% R0 resections, while 7 centres have a score of 80% or less. Thirty-three and 34 centres have a score above the weighted (93%; 95%CI 91 – 95%) and unweighted mean (93%; 95%CI 90 – 96%) respectively. For the correct interpretation of these results, risk-adjustment (stage, cCRM) is necessary.

As mentioned above (see page 28), the number of patients with an R0 resection is probably overestimated, since the results of the pathology report are not taken into account in the variable used to register R0 resections (see appendix). Ideally, the real R0 should be used in the future, taking into account the pathology results (e.g. on pCRM) and intra-operative perforation.

This QI is not measurable for the administrative cohort, since no administrative code exists for R0 resections.

Table 32. Number of patients that underwent radical resection and had an R0 resection, measured with prospective PROCARE data.

	cStage			
	I	II	III	I-III
Patients with rectal cancer	107	160	357	624
Patients with rectal cancer that underwent radical resection and information on type of resection (denominator)	96	157	349	602
Patients with R0 resection (numerator)	94	143	325	562 (93%)
Patients with R1 or R2 resection	2	5	12	19
Patients with uncertain resection	0	9	12	21

Proportion of APR and Hartmann's procedures

DEFINITION

Numerator: all patients with RC that underwent radical resection and had an APR or Hartmann's procedure.

Denominator: all patients with RC that underwent radical resection.

Exclusion:

- patients not undergoing radical resection

RESULTS

In the prospective cohort, 18% of the patients that had radical resection underwent an APR, while 2% had a Hartmann's procedure (Table 33). For 19 of the 1018 patients that had radical resection (2%), no information was available on the type of reconstruction.

In the administrative cohort, 38% of the patients that had radical resection underwent an APR or Hartmann's procedure (Table 34). Importantly, some patients had administrative codes for more than one surgical procedure: for the analysis only the first procedure was taken into account. For 78 patients, no information was available on the received treatment (1%).

Figure 11 provides an overview of APR and Hartmann's procedures per participating centre using the prospective database (weighted mean: 20%, 95%CI 18 – 23%; unweighted mean: 26%, 95%CI 20 – 31%). Seven centres (of which 6 included 5 or less eligible patients) did not perform APR or Hartmann's procedures. In 8 centres, at least 50% of the radical resections are APR or Hartmann's procedures.

Figure 12 provides an overview of APR and Hartmann's procedures per centre using the administrative database. Two centres (both with 1 eligible patient) have a score of 0%, while in 2 centres (both with ≤3 eligible patients) all radical resections are APR or Hartmann's procedures. Fifty-five and 68 centres have a score above the weighted (38%; 95%CI 37 – 39%) and unweighted mean (40%; 95%CI 37 – 43%) respectively.

Risk-adjustment (e.g. tumour localisation) is necessary for the correct interpretation of these results.

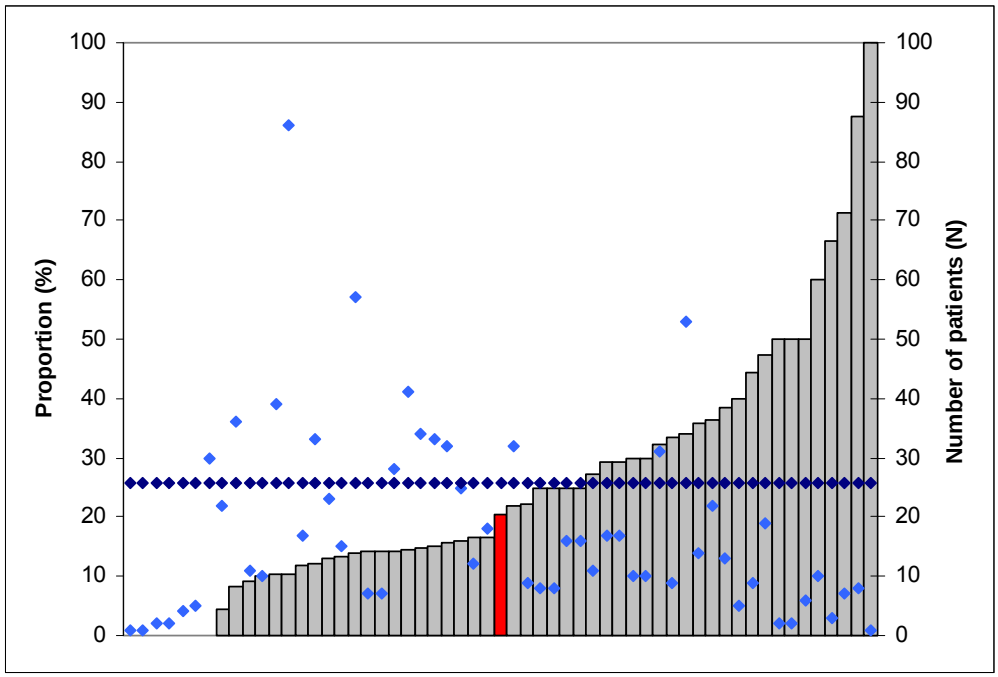
Table 33. Number of patients that underwent radical resection and had an APR or Hartmann's procedure, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with rectal cancer that underwent surgery	1058
Patients with rectal cancer that underwent radical resection and information on type of reconstruction (denominator)	999
Patients with APR (numerator– part 1)	180 (18%)
Patients with Hartmann's procedure (numerator – part 2)	24 (2%)

Table 34. Number of patients that underwent radical resection and had an APR or Hartmann's procedure, measured with administrative data.

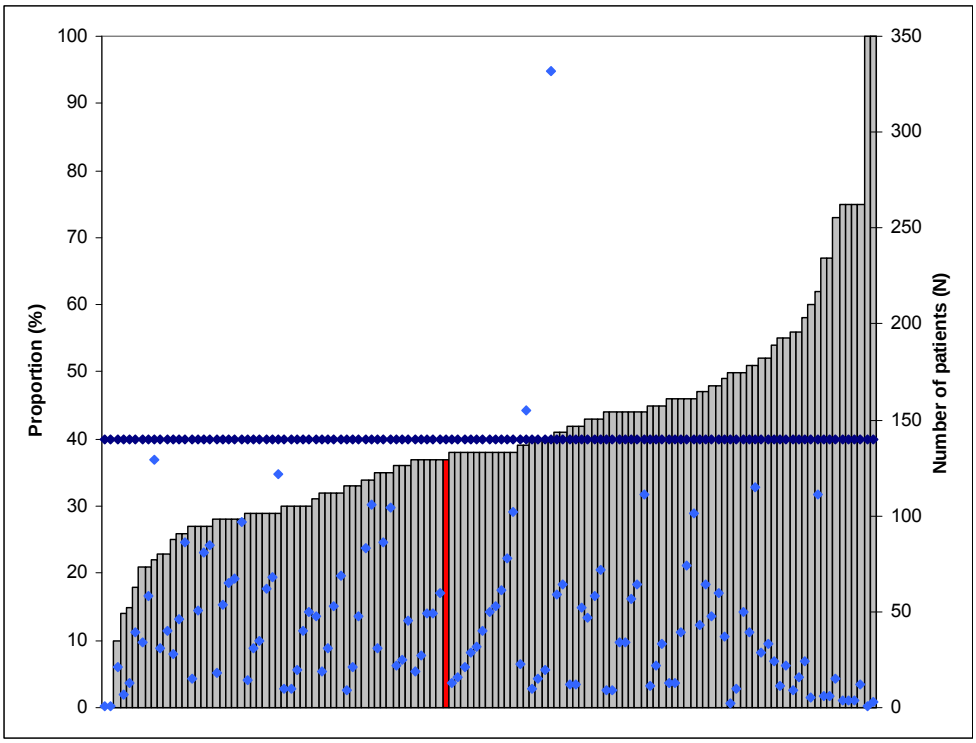
	N
Patients with rectal cancer	7074
Patients with rectal cancer that underwent radical resection (denominator)	5472
Patients with APR or Hartmann's procedure (numerator)	2053 (38%)

Figure 11. Per-centre-analysis (n = 56) of APR and Hartmann's procedure (prospective cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Figure 12. Per-centre-analysis (n = 124) of APR and Hartmann's procedure (administrative cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Proportion of patients with stoma 1 year after sphincter-sparing surgery

DEFINITION

Numerator: all patients with RC undergoing sphincter-sparing radical surgery with or without a temporary stoma at primary resective surgery, and still having this stoma 1 year after surgery.

Denominator: all patients with RC undergoing sphincter-sparing radical surgery with or without a temporary stoma.

Exclusion:

- patients not undergoing sphincter-sparing radical surgery
- patients dying within one year after sphincter-sparing surgery

RESULTS

Due to variable follow-up dates in the PROCARE database and a too unspecific variable in the data entry, a calculation at 1 year of this QI is impossible. Therefore, the QI is not measurable for the prospective cohort at present.

In the administrative cohort, 3692 patients were identified undergoing sphincter-sparing surgery (SSO) (no information was available for 78 patients) (Table 35). Of these, 1504 patients had stoma surgery or the use of stoma material within one year after SSO. Within one year after SSO, 194 of these 1468 patients died. Of the remaining 1310 patients, no information was available on stoma closure or the use of stoma material for 217 patients (total missings: 295/7074, 4%). Of the 1093 patients with available information (denominator), 292 still had a stoma after 1 year (27%).

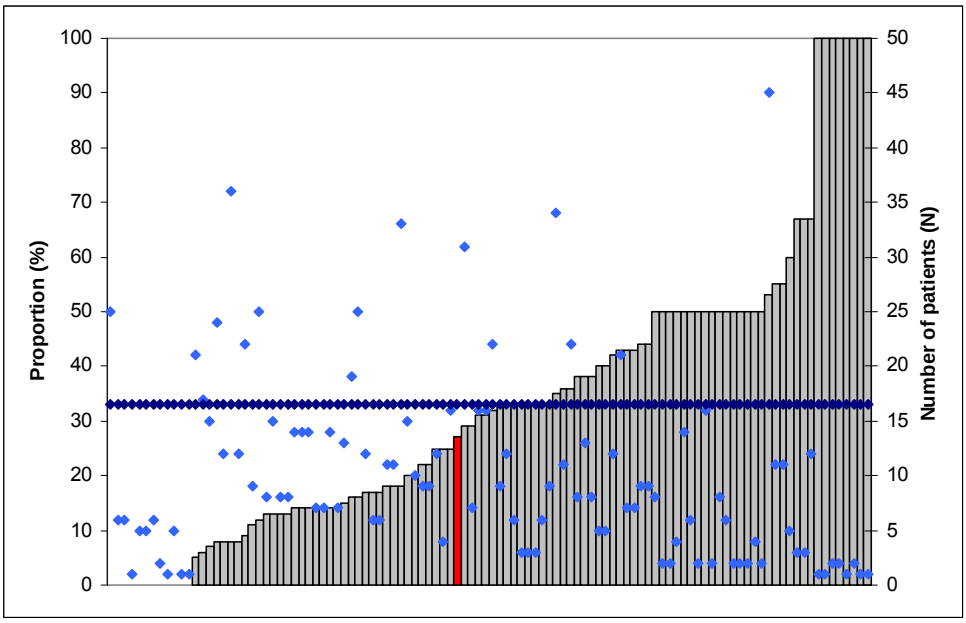
Importantly, based on the administrative codes for stoma material, it is impossible to distinguish patients with an ileo/colostomy from patients with a urostomy. Therefore, the result may be slightly overestimated.

Figure 13 provides an overview of the per-centre-analysis using the administrative database. Twelve centres (of which 11 centres treated 6 or less eligible patients) have a score of 0%, while in 8 centres all patients still have a stoma 1 year after SSO with temporary stoma. All these 8 centres treated 2 or less eligible patients. Forty-nine and 54 centres have a score above the weighted (27%; 95%CI 24 – 30%) and unweighted mean (33%; 95%CI 28 – 38%) respectively. Risk-adjustment (e.g. tumour localisation, stage, comorbidities) is necessary for the correct interpretation of these results.

Table 35. Number of patients with stoma 1 year after sphincter-sparing surgery, measured with administrative data.

	N
Patients with rectal cancer that underwent sphincter-sparing surgery	3692
Patients with stoma surgery and/or use of stoma material within 1 year	1504
Patients with stoma and available information on stoma after 1 year (denominator)	1093
Patients with stoma after 1 year (numerator)	292 (27%)

Figure 13. Per-centre-analysis (n = 107) of stoma 1 year after sphincter-sparing surgery (administrative cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

Rate of patients with major leakage of the anastomosis

DEFINITION

Numerator: all patients with RC undergoing sphincter-sparing radical resection and having major leakage of the anastomosis requiring re-intervention(s) during or after hospitalisation for radical resection.

Denominator: all patients with RC undergoing sphincter-sparing radical resection.

Exclusion:

- patients not undergoing sphincter-sparing surgery
- patients undergoing LE/TEMS

RESULTS

Of the patients that underwent sphincter-sparing surgery, 5% had a major leakage of the anastomosis requiring re-intervention (Table 36). Importantly, the code used to calculate this QI does not take into account late leakages of the anastomosis.

For 108 of the 1058 patients that underwent surgery, no information was available on the type of surgery.

Above this, for 10 of the 734 patients undergoing sphincter-sparing surgery, no information was available on the occurrence of leakage of the anastomosis (total missings: 118/1071, 11%).

Major leakage of the anastomosis is measurable for 53 centres using the prospective database. Thirty-two centres have no major leakages, while 9 centres have a score of 10% or more. Thirty-seven and 35 centres have a score above the weighted (5%; 95%CI 3 – 6%) and unweighted mean (4%; 95%CI 2 – 5%) respectively. Risk-adjustment (tumour localisation, presence of stoma at primary surgery) is necessary for the correct interpretation of these results.

For the administrative cohort no specific code is available for leakage of the anastomosis. The QI is therefore not measurable for these patients.

Table 36. Number of patients that underwent sphincter-sparing surgery and had a major leakage of the anastomosis, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with rectal cancer that underwent surgery	1058
Patients with rectal cancer that underwent sphincter-sparing surgery and have information on leakage (denominator)	724
Patients with major leakage (numerator)	33 (5%)
Patients with minor leakage	22

Inpatient or 30-day mortality

DEFINITION

Numerator: all patients with RC that underwent surgery and died in hospital and/or within 30 days after primary surgery.

Denominator: all patients with RC that underwent surgery.

Exclusion:

- patients treated abroad
- patients without a social security number
- patients without a Belgian postal code
- patients without a known incidence date or with an incidence date after December 31st 2006
- patients with a surgery date after December 1st 2006

RESULTS

Inpatient or 30-day mortality in the prospective cohort is 3% (Table 37). For 7 patients no social security number and Belgian postal code was available.

Above this, for 26 of the 1064 patients with a social security number and Belgian postal code that underwent surgery, no surgery date was available (total missings: 33/1071, 3%).

In theory, the QI can be underestimated, since some patients having had surgery before December 2nd 2006 could have died in hospital after December 31st 2006. However, this was manually checked and didn't occur.

In the administrative cohort, inpatient or 30-day mortality is 5% (281/5863). For 78 of the 7074 rectal cancer patients, no information was available on treatment. Above this, for 41 of the 5904 patients that underwent (resective) surgery, no information was available on hospitalisation date (total missings: 119/7074, 2%).

The inpatient or 30-day mortality is measurable for 54 centres using the prospective database. Thirty-seven centres have a score of 0%, while 7 centres have a score of 10% or more. Thirty-eight centres have a score above the weighted (3%; 95%CI 2 – 4%) and unweighted mean (3%; 95%CI 1 – 4%).

Using the administrative database, this QI is measurable for 124 centres. Thirty-two centres have a score of 0%, while in 14 centres the inpatient or 30-day mortality exceeds 10%. Sixty-three centres have a score above the weighted (5%; 95%CI 4 – 6%) and unweighted mean (5%; 95%CI 4 – 6%).

Importantly, extensive risk-adjustment (e.g. age, stage, comorbidities) is necessary for the correct interpretation of these results.

Table 37. Inpatient or 30-day mortality, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with social security number and Belgian postal code, and underwent surgery	1064
Patients with surgery before December 2nd 2006 (denominator)	693
Patients that died in hospital or within 30 days after surgery (numerator)	20 (3%)

Rate of intra-operative rectal perforation

DEFINITION

Numerator: all patients with RC that underwent radical resection and had intra-operative rectal perforation.

Denominator: all patients with RC that underwent radical resection.

Exclusion:

- patients not undergoing radical resection

RESULTS

Seven percent of the PROCARE patients undergoing radical resection had a rectal perforation during surgery (Table 38). It was not possible to identify missing data, since the default value of the variable was '0' (see appendix).

Intra-operative rectal perforation is measurable for 56 centres using the prospective database. Twenty-five centres have a score of 0%, while 17 centres have a score of 10% or more. Thirty-five centres have a score above the weighted (7%; 95%CI 5 – 8%) and unweighted mean (6%; 95%CI 4 – 8%). Risk-adjustment (tumour localisation [including dorsal – ventral], stage) is necessary for the correct interpretation of these results.

The QI is not measurable for the administrative cohort, since no specific code exists for intra-operative rectal perforation.

Table 38. Number of intra-operative rectal perforations, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients having radical resection (denominator)	1018
Patients with intra-operative rectal perforation (numerator)	69 (7%)

Discussion

Using the prospective database, 5 of the 6 surgical QI are measurable (Table 39). The rate of stoma at 1 year after SSO is not measurable at present, but can be rendered measurable by asking specifically for the presence of a stoma at 1 year. Another solution is to link the prospective database to the administrative databases, where this QI is already measurable. However, in that case, ileo/colostomies should be distinguished from urostomies, e.g. by excluding patients undergoing a Bricker's procedure.

Three QI are not measurable using the administrative databases due to the absence of administrative codes (for R0 resection, major leakage of the anastomosis and intra-operative perforation). All three QI are measurable using the prospective database.

As already stated, in the number of R0 resections the results of the pathology report are not taken into account at present. Ideally, the real R0 should be used in the future, i.e. taking into account the pathology results and intra-operative perforation.

At present, late leakages of the anastomosis are not included in QI 1233, since these are not specifically registered in the PROCARE database. To capture this information, a specific code should be added to the follow-up section of the data entry form.

Interesting additional information related to QI 1232b would be to distinguish patients receiving a temporary stoma during primary surgery from those receiving a stoma afterwards (e.g. because of a leakage of the anastomosis). However, this is considered to be 3rd level information, which is available in the prospective database.

Importantly, for the correct interpretation of most QI, risk-adjustment is necessary. For the inpatient or 30-day mortality, this risk-adjustment should be extensive, at least taking into account age, stage and comorbidities. An expected/observed ratio is desirable and feasible using the PROCARE data.

Table 39. Measurability of selected QI on surgery.

QI	Prospective Db		Administrative Db	
	Measurable?	**If not: reason?**	**Measurable?**	**If not: reason?**
1231	Yes	-	No	No code
1232a	Yes	-	Yes	-
1232b	No	Unspecific code & variable follow-up	Yes	-
1233	Yes	-	No	No code
1234	Yes	-	Yes	-
1235	Yes	-	No	No code

3.2.2.5 Quality indicators related to adjuvant treatment

Proportion of (y)pStage III patients with R0 resection that received adjuvant chemotherapy

DEFINITION

Numerator: all patients with (y)pStage III RC with R0 resection that received adjuvant chemotherapy (without radiotherapy).

Denominator: all patients with (y)pStage III RC with R0 resection.

Exclusion:

- patients with (y)pStage other than (y)pStage III
- (y)pStage III patients without R0 resection

RESULTS

Twenty-one percent of the (y)pStage III patients with an R0 resection received adjuvant chemotherapy as monotherapy in the prospective cohort (Table 40). However, a high number of missing values was identified. For 181 patients the (y)pStage was unknown. For 7 of the 296 patients with (y)pStage III, no information was available on the type of resection. Above this, for 152 of the 246 (y)pStage III patients that had an R0 resection, no information was available on adjuvant treatment (total missings: 340/1071, 32%).

Since no administrative code is available for R0 resection, this QI is not measurable for the administrative cohort.

This QI is measurable for 31 centres using the prospective database. Two centres (both including 1 eligible patient) have a score of 100%, while 22 centres have a score of 0%. Eight centres have a score above the weighted (21%; 95%CI 13 – 30%) and unweighted mean (16%; 95%CI 5 – 27%). Importantly, the range of included eligible patients is 1 – 9 per centre. For the correct interpretation of these results, risk-adjustment (age, comorbidities, postoperative morbidity) is necessary.

Table 40. Proportion of patients with R0 resection that received adjuvant treatment, measured with prospective PROCARE data.

	(y)pStage		
	I	II	III
Patients with rectal cancer	246	273	296
Proportion with R0 resection and information on adjuvant treatment (denominator)	111	123	94
Proportion with adjuvant chemotherapy (numerator)	8	11	20 (21%)
Proportion with adjuvant chemoradiotherapy	0	5	3 (3%)
Proportion with adjuvant radiotherapy	0	0	0 (0%)

Proportion of pStage II-III patients with R0 resection that received adjuvant radiotherapy or chemoradiotherapy

DEFINITION

Numerator: all patients with pStage II-III RC with R0 resection that received adjuvant radiotherapy or chemoradiotherapy.

Denominator: all patients with pStage II-III RC with R0 resection.

Exclusion:

- patients with pStage other than pStage II-III
- pStage II-III patients without R0 resection

RESULTS

In total, 7% of the pStage II-III patients with an R0 resection received adjuvant (chemo)radiotherapy (Table 41). For 5 patients, the pStage was unknown. For 5 of the 226 pStage II-III patients no information was available on the type of resection. Above this, for 72 of the 193 pStage II-III patients that had an R0 resection, no information was available on adjuvant treatment (total missings: 82/1071, 8%).

This QI is measurable for 38 centres using the prospective database. One centre (including 1 eligible patient) has a score of 100%, while 34 centres have a score of 0%. Four centres have a score above the weighted (7%; 95%CI 2 – 11%) and unweighted mean (7%; 95%CI 0 – 14%). Again, the range of included eligible patients is 1 – 9 per centre.

For the correct interpretation of these results, risk-adjustment (age, comorbidities, postoperative morbidity) is necessary.

Since no administrative code is available for R0 resection, this QI is not measurable for the administrative cohort.

Table 41. Proportion of patients with R0 resection that received adjuvant treatment, measured with prospective PROCARE data.

	pStage			
	I	II	III	II-III
Patients with rectal cancer	90	104	122	226
Proportion with R0 resection and information on adjuvant treatment (denominator)	69	69	52	121
Proportion with adjuvant chemotherapy	1	0	2	2
Proportion with adjuvant (chemo)radiotherapy (numerator)	0	5	3	8 (7%)

Proportion of (y)pStage II-III patients with R0 resection that started adjuvant chemotherapy within 12 weeks after surgical resection

DEFINITION

Numerator: all patients with (y)pStage II-III RC with R0 resection that started adjuvant chemotherapy within 12 weeks after surgical resection.

Denominator: all patients with (y)pStage II-III RC with R0 resection that received adjuvant chemotherapy.

Exclusion:

- patients with (y)pStage other than (y)pStage II-III
- (y)pStage II-III patients without R0 resection
- (y)pStage II-III patients that didn't receive adjuvant chemotherapy

RESULTS

In the prospective cohort, 92% of the (y)pStage II-III patients with an R0 resection and treated with adjuvant chemo(radio)therapy, received this treatment within 12 weeks after surgery (Table 42). However, a high rate of missings was identified. For 181 patients the (y)pStage was unknown. Of the 569 (y)pStage II-III patients undergoing surgery, 13 had no information on the type of resection. Above this, for 260 of the 492 having undergone an R0 resection, no information was available on adjuvant treatment. Finally, for 18 of the 54 patients treated with adjuvant chemo(radio)therapy, information was lacking on the treatment dates (total missings: 472/1071, 44%).

This QI is measurable for 13 centres using the prospective database. Eleven centres have a score of 100%. Also eleven centres have a score above the weighted (92%; 95%CI 82 – 100%) and unweighted mean (94%; 95%CI 86 – 100%). The range of included eligible patients is 1 – 7 per centre. For the correct interpretation of these results, risk-adjustment (age, comorbidities, postoperative morbidity) is necessary.

Again, since no administrative code is available for R0 resection, this QI is not measurable for the administrative cohort. However, when considering all patients that underwent surgery (i.e. not exclusively those with an R0 resection), 95% of the (y)pStage II-III patients received adjuvant treatment within 3 months after surgery.

Table 42. Number of patients with R0 resection that started adjuvant chemo(radio)therapy within 12 weeks after surgery, measured with prospective PROCARE data.

	(y)pStage			
	I	**II**	**III**	**II-III**
Patients with rectal cancer	246	273	296	569
Patients with R0 resection and information on adjuvant treatment	112	127	105	232
Patients with adjuvant chemo(radio)therapy and information on treatment dates (denominator)	7	15	21	36
Patients with chemo(radio)therapy within 12 weeks after surgery (numerator)	7	12	21	33 (92%)

Proportion of (y)pStage II-III patients with R0 resection treated with adjuvant chemo(radio)therapy, that received 5-FU based chemotherapy

DEFINITION

Numerator: all patients with (y)pStage II-III RC with R0 resection treated with adjuvant chemo(radio)therapy, that received 5-FU based chemotherapy.

Denominator: all patients with (y)pStage II-III RC with R0 resection treated with adjuvant chemo(radio)therapy.

Exclusion:

- patients with (y)pStage other than (y)pStage II-III
- (y)pStage II-III patients without R0 resection
- (y)pStage II-III patients that didn't receive adjuvant chemo(radio)therapy

RESULTS

In the prospective cohort, 94% of the (y)pStage II-III patients with an R0 resection and treated with adjuvant chemo(radio)therapy, received 5-FU based chemotherapy (Table 43). However, again a high rate of missings was identified. For 181 patients the (y)pStage was unknown. Of the 569 (y)pStage II-III patients undergoing surgery, 13 had no information on the type of resection. Above this, for 260 of the 492 having undergone an R0 resection, no information was available on adjuvant treatment.

Finally, for 19 of the 54 patients treated with adjuvant chemo(radio)therapy, information was lacking on the chemotherapy regimen (total missings: 473/1071, 44%).

This QI is measurable for 12 centres using the prospective database. Ten centres have a score of 100%. Ten centres have a score above the weighted (94%; 95%CI 86 – 100%) and unweighted mean (94%; 95%CI 86 – 100%). The range of included eligible patients is 1 – 7 per centre.

Again, since no administrative code is available for R0 resection, this QI is not measurable for the administrative cohort. However, when considering all patients that underwent surgery (i.e. not exclusively those with an R0 resection), 99% of the (y)pStage II-III patients that were treated with adjuvant chemotherapy received 5-FU based adjuvant treatment.

Table 43. Number of patients with R0 resection treated with adjuvant chemo(radio)therapy containing 5-FU, measured with prospective PROCARE data.

	(y)pStage			
	I	II	III	II-III
Patients with rectal cancer	246	273	296	569
Patients with R0 resection and information on adjuvant treatment	112	127	105	232
Patients with chemo(radio)therapy and regimen known (denominator)	9	15	20	35
Patients with 5-FU regimen (numerator)	8	14	19	33 (94%)

Rate of acute grade 4 chemotherapy-related complications

DEFINITION

Numerator: all patients with (y)pStage 0-III RC that underwent surgery and received adjuvant chemotherapy (with or without radiotherapy), and with acute grade 4 chemotherapy-related complications.

Denominator: all patients with (y)pStage 0-III RC that underwent surgery and received adjuvant chemotherapy (with or without radiotherapy).

Exclusion:

- patients with (y)pStage IV
- (y)pStage 0-III patients without surgery
- (y)pStage 0-III patients that didn't receive adjuvant chemo(radio)therapy

RESULTS

No acute grade 4 chemotherapy-related complications were identified for the (y)pStage 0-III patients treated with adjuvant chemo(radio)therapy (Table 44). As for the previous QI on adjuvant treatment, a high number of missings was identified. For 181 patients the (y)pStage was unknown. For 426 of the 841 (y)pStage 0-III patients undergoing surgery, no information was available on adjuvant treatment. Above this, 9 of the 68 patients receiving adjuvant chemo(radio)therapy had a complication, but no information was available on the grade of the complication. For 12 other of these 68 patients, no chemotherapy-related information was available at all. Finally, the number of missing data for complications cannot be calculated, since the default value of the variable is '0' (i.e. missing data also receive a value '0'). Therefore, the total number of missing data is at least 628/1071 or 59%.

Since no patient with a grade 4 complication was identified, a per-centre-analysis is irrelevant.

Due to the absence of a specific code for grade 4 chemotherapy-related complications, this QI is not measurable in the administrative cohort.

Table 44. Number of acute grade 4 chemotherapy-related complications, measured with prospective PROCARE data.

	N
Patients with (y)pStage 0-III rectal cancer	841
Patients having adjuvant chemo(radio)therapy and with adequate information on adverse events (denominator)	47
Patients with acute grade 4 complications (numerator)	0 (0%)

Discussion

All five QI are measurable using the prospective database, but not measurable using the administrative databases (Table 45). The most important reason for not being measurable is the absence of an administrative code for R0 resections.

An important problem with the interpretation of these QI is the high number of missing values, ranging from 34% for QI 1242 to 54% for QI 1241. Several explanations can be given. First, mainly surgeons and pathologists transmitted their data to the PROCARE register during the study period. Also, there was no specific chemotherapy form in the first version of the data entry. At present, data from oncologists and gastroenterologists (including data on chemotherapy) are often lacking. Therefore, more effort should be made by the data managers to pursue the necessary data. Second, the chemotherapy section of the data entry form does not allow an unambiguous analysis of chemotherapy regimens or other chemotherapy-related information at present. This section therefore needs a careful revision.

Table 45. Measurability of selected QI on adjuvant treatment.

QI	Prospective Db		Administrative Db	
	Measurable?	**If not: reason?**	**Measurable?**	**If not: reason?**
1241	Yes	-	No	No code
1242	Yes	-	No	No code
1243	Yes	-	No	No code
1244	Yes	-	No	No code
1245	Yes	-	No	No code

3.2.2.6 Quality indicators related to palliative treatment

Rate of cStage IV patients receiving chemotherapy

DEFINITION

Numerator: all patients with cStage IV RC receiving chemotherapy.

Denominator: all patients with cStage IV RC.

Exclusion:

- patients with cStage other than cStage IV

RESULTS

Of the cStage IV patients in the prospective cohort, 61% received chemotherapy (Table 46). For 335 patients the cStage was unknown (total missings: 335/1071, 31%). Above this, the number of cStage IV patients can be underestimated, since in some cM0 patients metastases are identified peroperatively. Ideally, a 'corrected' cStage should be used that takes into account the peroperative findings.

In the administrative cohort, 63% of the cStage IV patients (n = 559) received chemotherapy. For 4437 patients the cStage was unknown (total missings: 4437/7074, 63%).

Chemotherapy for cStage IV patients is measurable for 39 centres using the prospective database. Fifteen centres have a score of 100%, while in 16 centres 50% or less of the cStage IV patients receive chemotherapy. Twenty-three centres have a score above the weighted (61%; 95%CI 52 – 71%) and unweighted mean (59%; 95%CI 45 – 72%). Importantly, the range of included eligible patients is 1 – 13 per centre. Thirty-seven centres included 7 or less eligible patients.

Using the administrative database, this QI is measurable for 97 centres. Forty centres have a score of 100%, while in 31 centres 50% or less of the cStage IV patients receive chemotherapy. Sixty-two and 53 centres have a score above the weighted (63%; 95%CI 59 – 67%) and unweighted mean (69%; 95%CI 62 – 76%) respectively.

For the correct interpretation of these results, risk-adjustment (age, comorbidities) is necessary.

Table 46. Proportion of patients that received chemotherapy, measured with prospective PROCARE data.

	cStage						
	0	**I**	**II**	**III**	**IV**	**X**	**All**
Patients with rectal cancer (denominator)	1	107	160	357	111	335	1071
Proportion that received chemotherapy (numerator)	0	35	90	291	68 (61%)	190	674

Rate of acute grade 4 chemotherapy-related complications in stage IV patients

DEFINITION

Numerator: all patients with cStage IV RC that received chemotherapy and with acute grade 4 chemotherapy-related complications.

Denominator: all patients with cStage IV RC that received chemotherapy.

Exclusion:

- patients with cStage other than cStage IV
- cStage IV patients not treated with chemotherapy

RESULTS

Two percent of the cStage IV patients that received chemotherapy had acute grade 4 complications (Table 47). The exact number of missing data cannot be calculated for this QI. For 335 patients the cStage was unknown. Of the 68 cStage IV patients that received chemotherapy, 1 had grade 4 complications, 1 had grade 3 complications, and 5 had complications with an unknown grade (i.e. missings). For the other 61 cStage IV patients, it is impossible to differentiate between no complications or a missing value, since the default value of the variable was '0' (i.e. missing values also received a value '0') (see appendix). Therefore, the total number of missing data is at least 340/1071 or 32%.

Since only one patient with a grade 4 complication was identified, a per-centre-analysis is irrelevant.

Due to the absence of a specific code for grade 4 chemotherapy-related complications, this QI is not measurable in the administrative cohort.

Table 47. Proportion of patients that received chemotherapy with acute grade 4 chemotherapy-related complications, measured with prospective PROCARE data.

	cStage						
	0	**I**	**II**	**III**	**IV**	**X**	**All**
Patients with rectal cancer	1	107	160	357	111	335	1071
Proportion that received chemotherapy with adequate information on complications (denominator)	0	35	87	278	63	187	650
Proportion with acute grade 4 complications (numerator)	0	1	0	0	1 (2%)	0	2

Discussion

Both QI are measurable using the prospective database, while only one QI is measurable using the administrative databases (Table 48).

Only minor adaptations are needed to optimise these QI. For QI 1251 a 'corrected' cStage should be used, taking into account peroperative findings for metastasis.

This information is already available from the PROCARE database. For QI 1252 the use of a variable with default value '0' should be avoided (which is in fact a general remark). For both QI, it is important to increase the effort to identify the exact cStage.

Table 48. Measurability of selected QI on palliative treatment.

QI	Prospective Db		Administrative Db	
	Measurable?	**If not: reason?**	**Measurable?**	**If not: reason?**
1251	Yes	-	Yes	-
1252	Yes	-	No	No code

3.2.2.7 Quality indicators related to follow-up

Rate of curatively treated patients that received a colonoscopy within 1 year after resection

DEFINITION

Numerator: all RC patients with R0 resection receiving a colonoscopy within 1 year after resection.

Denominator: all RC patients with R0 resection.

Exclusion:

- patients not treated with R0 resection

RESULTS

This QI is not measurable for the prospective cohort, since no code is available for a colonoscopy in the follow-up section of the PROCARE registration. Above this, follow-up dates are variable, making a calculation at 1 year impossible.

Again, since no administrative code is available for R0 resection, this QI is not measurable for the administrative cohort.

Rate of patients undergoing regular follow-up (according to the PROCARE recommendations)

Numerator: all RC patients with R0 resection undergoing regular follow-up according to the PROCARE recommendations.

Denominator: all RC patients with R0 resection.

Exclusion:

- patients not treated with R0 resection

RESULTS

This QI is not measurable for the prospective cohort, since no code is available for diagnostic techniques in the follow-up section of the PROCARE registration.

Again, since no administrative code is available for R0 resection, this QI is not measurable for the administrative cohort.

Late grade 4 complications of radiotherapy or chemoradiation

Numerator: all RC patients that received radiotherapy with or without chemotherapy and having late grade 4 complications.

Denominator: all RC patients that received radiotherapy with or without chemotherapy.

Exclusion:

- patients not treated with (chemo)radiotherapy
- patients dying within 1 year after incidence date

RESULTS

One percent of the PROCARE patients treated with (chemo)radiotherapy experienced late grade 4 complications (Table 49). This result needs to be interpreted with caution, since in 633 patients no follow-up data were available. Above this, for 9 of the 112 patients with follow-up data, no information was available on late complications.

Since the variable on late complications has a default value '0', the exact number of missing values cannot be determined.

Since only one patient with a grade 4 complication was identified, a per-centre-analysis is irrelevant.

This QI cannot be calculated for the administrative cohort, since no code is available for late grade 4 complications.

Table 49. Rate of late grade 4 complications of (chemo)radiotherapy, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Patients with (chemo)radiotherapy	771
Proportion with follow-up data and information on late complications (denominator)	103
Proportion with grade 4 complications (numerator)	1 (1%)

Discussion

Only 1 QI is measurable using the prospective database, while no QI are measurable using the administrative database (Table 50). To render QI 1261 and 1262 measurable, the follow-up section of the PROCARE data entry form needs revision, specifically asking which follow-up study was done at what moment.

At this moment, all data related to medium- and long-term follow-up need to be interpreted with caution, since only a minority of PROCARE patients already entered the follow-up stage of their disease.

Table 50. Measurability of selected QI on follow-up.

QI	Prospective Db		Administrative Db	
	Measurable?	**If not: reason?**	**Measurable?**	**If not: reason?**
1261	No	No code	No	No code
1262	No	No code	No	No code
1263	Yes	-	No	No code

3.2.2.8 Quality indicators related to histopathologic examination

Use of the pathology report sheet

DEFINITION

Numerator: all patients with RC that underwent local or radical resective surgery and have a pathology report sheet.

Denominator: all patients with RC that underwent local or radical resective surgery.

Exclusion:

- patients not treated with local or radical surgery

RESULTS

In the PROCARE database, no code is available that registers the use of a pathology report sheet by the pathologist. Also, the suggested pathology report sheet was only distributed by surface mail to all Belgian pathologists in November 2006 and has been only gradually in use since then. Therefore, this QI is not measurable for the prospective cohort at present.

Also, no administrative code exists for the use of a pathology report sheet.

Quality of TME assessed according to Quirke and mentioned in the pathology report

DEFINITION

Numerator: all patients with RC that underwent TME and had the quality of TME assessed according to Quirke and mentioned in the pathology report.

Denominator: all patients with RC that underwent TME.

Exclusion:

- patients not treated with TME

RESULTS

In 30% of the PROCARE patients undergoing TME, the quality of TME was mentioned in the pathology report (Table 51). For 76 of the 1058 patients that underwent surgery, no information was available on used surgical technique (total missings: 76/1071, 7%). Importantly, registration of the quality of TME only gradually started in November 2006. Therefore, the reported result is probably an underestimation.

This QI is measurable for 56 centres using the prospective database. Five centres have a score of 100%, while 26 centres score 0%. Twenty-four centres have a score above the weighted (30%; 95%CI 27 – 33%) and unweighted mean (29%; 95%CI 19 – 38%). For the correct interpretation of these results, risk-adjustment (tumour localisation, stage) is necessary.

No administrative code exists for the result of a TME quality assessment, which in fact is information that can only be retrieved from the medical file and the anatomopathological report. The QI is therefore not measurable for the administrative cohort.

Table 51. Quality of TME mentioned in the pathology report, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Proportion treated with surgery	1058
Proportion treated with TME (denominator)	833
Porportion with quality of TME mentioned in the pathology report (numerator)	252 (30%)

Distal tumour-free margin mentioned in the pathology report

DEFINITION

Numerator: all patients with RC that underwent sphincter saving surgery or Hartmann's procedure having their distal tumour-free margin mentioned in the pathology report.

Denominator: all patients with RC that underwent sphincter saving surgery or Hartmann's procedure.

Exclusion:

- patients not treated with sphincter-sparing surgery or Hartmann's procedure

RESULTS

In 89% of the PROCARE patients undergoing sphincter saving surgery or Hartmann's procedure the distal tumour-free margin is mentioned in the pathology report (Table 52). For 51 of the 1058 patients undergoing surgery, no information was available on the type of reconstruction. Above this, for 38 patients undergoing sphincter saving surgery or Hartmann's procedure, no pathology data were available (total missings: 89/1071, 8%).

This QI is measurable for 53 centres using the prospective database. Twenty-three centres have a score of 100%. Thirty-four centres have a score above the weighted (89%; 95%CI 87 – 92%) and unweighted mean (89%; 95%CI 84 – 94%). For the correct interpretation of these results, risk-adjustment (tumour localisation) is necessary.

No administrative code exists for the distal tumour-free margin, which are also data that can only be retrieved from the medical file. The QI is therefore not measurable for the administrative cohort.

Table 52. Distal tumour-free margin mentioned in the pathology report, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Proportion treated with surgery	1058
Proportion treated with sphincter saving surgery or Hartmann's procedure	815
Proportion with pathology data (denominator)	777
Proportion with distal tumour-free margin mentioned (numerator)	695 (89%)

Number of lymph nodes examined

DEFINITION

Numerator: total number of lymph nodes examined in patients with rectal cancer undergoing radical resection.

Denominator: all patients with RC that underwent radical resection.

Exclusion:

- patients not treated with radical resection
- patients treated with local surgery

RESULTS

In the prospective cohort, 1018 patients underwent radical surgery. For 956 patients (94%) the number of lymph nodes examined was available in the database. The mean number of lymph nodes examined for these patients was 12 (range 0 – 50). In 449 patients (47%), the number of lymph nodes examined was 12 or higher. Table 53 provides an overview of the number of lymph nodes examined according to the neoadjuvant treatment (n = 584).

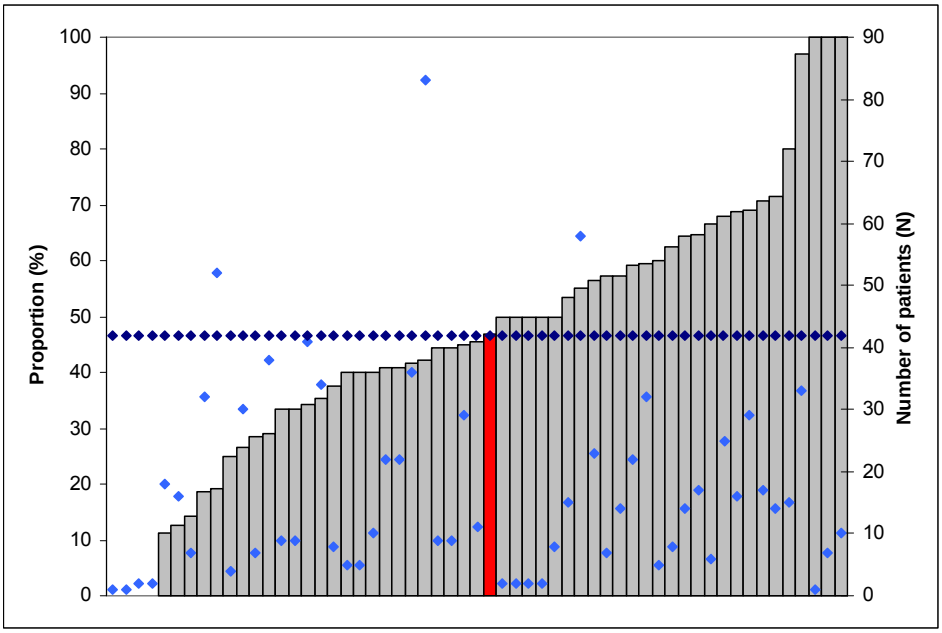
Figure 14 provides an overview of the per-centre-analysis using the prospective database (% of patients with at least 12 lymph nodes examined). In three centres all patients have at least 12 lymph nodes examined, while in four centres the score is 0%. Twenty-seven centres have a score above the weighted (47%; 95%CI 44 – 50%) and unweighted mean (47%; 95%CI 40 – 53%). For the correct interpretation of these results, risk-adjustment (neoadjuvant treatment, (y)pN) is necessary.

No administrative code exists for the number of lymph nodes examined, which are also data that can only be retrieved from the medical file and the anatomopathological report. The QI is therefore not measurable for the administrative cohort.

Table 53. Number of lymph nodes examined according to neoadjuvant treatment, measured with prospective PROCARE data.

Type of neoadjuvant treatment	N	Mean	Median
Radiotherapy, 1 – 25 Gy	66	14	12
Radiotherapy, 26 – 44 Gy	26	9	10
Radiotherapy, 45 Gy or more	415	10	9
Radiotherapy, dose unknown	76	13	13
No neoadjuvant radiotherapy	1	5	5

Figure 14. Per-centre-analysis (n = 56) of proportion of patients with at least 12 lymph nodes examined (prospective cohort)[$].



[$] The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

(y)pCRM mentioned in mm in the pathology report

DEFINITION

Numerator: all patients with RC that underwent radical resection having their (y)pCRM mentioned in mm in the pathology report.

Denominator: all patients with RC that underwent radical resection.

Exclusion:

- patients not treated with radical resection
- patients having local excision or TEMS

RESULTS

In 73% of the PROCARE patients undergoing radical resection the (y)pCRM is mentioned in the pathology report (Table 54). For 50 of the 1018 patients undergoing radical resection, no pathology data were available (total missings: 50/1071, 5%). Importantly, unavailability of the (y)pCRM in the PROCARE registry does not mean that the measurement was not carried out.

This QI is measurable for 53 centres using the prospective database. Nine centres have a score of 100%, while 8 centres have a score of 0%. Thirty-two centres have a score above the weighted (73%; 95%CI 70 – 76%) and unweighted mean (73%; 95%CI 67 – 79%). For correct interpretation, patients with complete pathological response after chemoradiation (ypT0N0) should be excluded.

No administrative code exists for the (y)pCRM, which are also data that can only be retrieved from the medical file and the anatomopathological report. The QI is therefore not measurable for the administrative cohort.

Table 54. (y)pCRM mentioned in mm in the pathology report, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Proportion treated with surgery	1058
Proportion treated with radical resection	1018
Proportion with pathology data (denominator)	968
Proportion with (y)pCRM mentioned in mm (numerator)	706 (73%)

Tumour regression grade mentioned in the pathology report (after neoadjuvant treatment)

DEFINITION

Numerator: all patients with RC that underwent surgery and neoadjuvant treatment, and having their tumour regression grade mentioned in the pathology report.

Denominator: all patients with RC that underwent surgery and neoadjuvant treatment.

Exclusion:

- patients not treated with surgery
- patients not treated with neoadjuvant treatment

RESULTS

In only 9% of the PROCARE patients treated with neoadjuvant therapy and surgery, the tumour regression grade is mentioned in the report (Table 55). For 129 of the 1058 patients treated with surgery, no information was available on neoadjuvant treatment. Above this, for 21 of the 596 patients receiving neoadjuvant treatment, no pathology data were available (total missings: 150/1071, 14%).

As for the quality of TME, registration of the tumour regression grade only started in November 2006. Above this, different classification systems are used across the participating centres. Therefore, the result is probably underestimated and not reliable. Also, ideally only long course radiotherapy is taken into account.

This QI is measurable for 52 centres using the prospective database. Four centres have a score of at least 50%, while 39 centres have a score of 0%. Eight and 9 centres have a score above the weighted (9%; 95%CI 7 – 12%) and unweighted mean (8%; 95%CI 2 – 13%) respectively. For the correct interpretation of these results, risk-adjustment (e.g. neoadjuvant treatment regimen, interval to surgery) is necessary.

No administrative code exists for the tumour regression grade, which are also data that can only be retrieved from the medical file. The QI is therefore not measurable for the administrative cohort.

Table 55. Tumour regression grade mentioned in the pathology report, measured with prospective PROCARE data.

	N
Patients with rectal cancer	1071
Proportion treated with surgery	1058
Proportion treated neoadjuvant therapy	596
Proportion with pathology data (denominator)	575
Proportion with tumour regression grade mentioned (numerator)	53

Discussion

Overall, 5 QI related to histopathologic examination were measurable using the prospective database, while none were measurable using the administrative databases (Table 56). The most important reason for not being measurable is the absence of administrative codes for clinical results, e.g. (y)pCRM. Such clinical information can only be retrieved from medical files and the anatomopathological report itself.

In November 2006, the pathology section of the PROCARE data entry form underwent revision, with some variables only being registered from then on.

Therefore, for some QI (1272 and 1276) the necessary information was unavailable if the patient was included before November 2006. This probably led to an underestimation and an unreliable result.

For QI 1271, no code was available registering the use of a pathology report sheet by the pathologist. This can be easily solved by adding this variable to the data entry form.

Table 56. Measurability of selected QI on histopathologic examination.

QI	Prospective Db		Administrative Db	
	Measurable?	**If not: reason?**	**Measurable?**	**If not: reason?**
1271	No	No code	No	No code
1272	Yes		No	Clinical data: no code
1273	Yes	-	No	Clinical data: no code
1274	Yes	-	No	Clinical data: no code
1275	Yes	-	No	Clinical data: no code
1276	Yes	-	No	Clinical data: no code

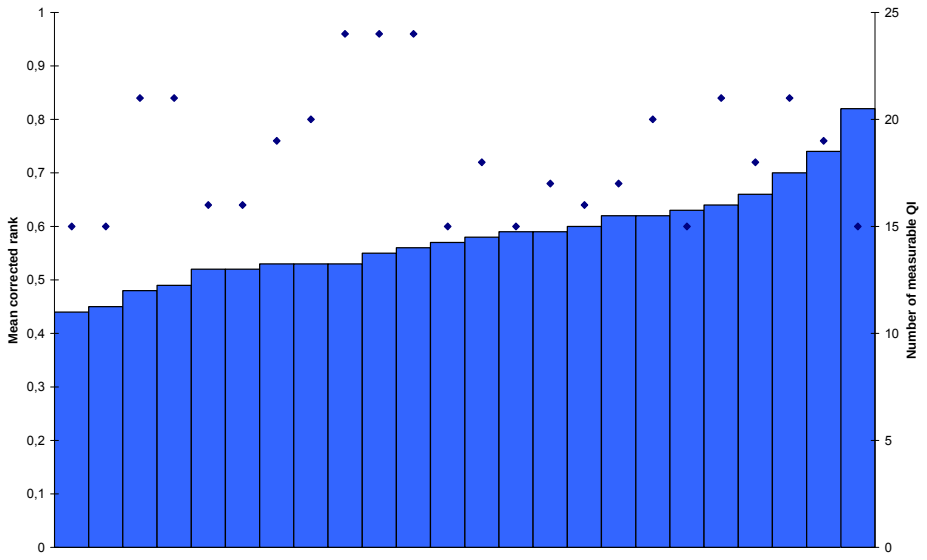
3.2.3 Aggregation of the results at hospital level

3.2.3.1 Prospective database

Twenty-four centres had at least 10 patients in the denominator for at least 15 of the 30 measurable QI (Figure 15). The mean corrected rank ranged from 0.44 – 0.82. Increasing the minimum number of patients in the denominator to 20 (for at least 15 QI), the analysis included only 8 centres. For these 8 centres the variability was clearly less, with a mean corrected rank ranging from 0.48 – 0.71 (data not shown).

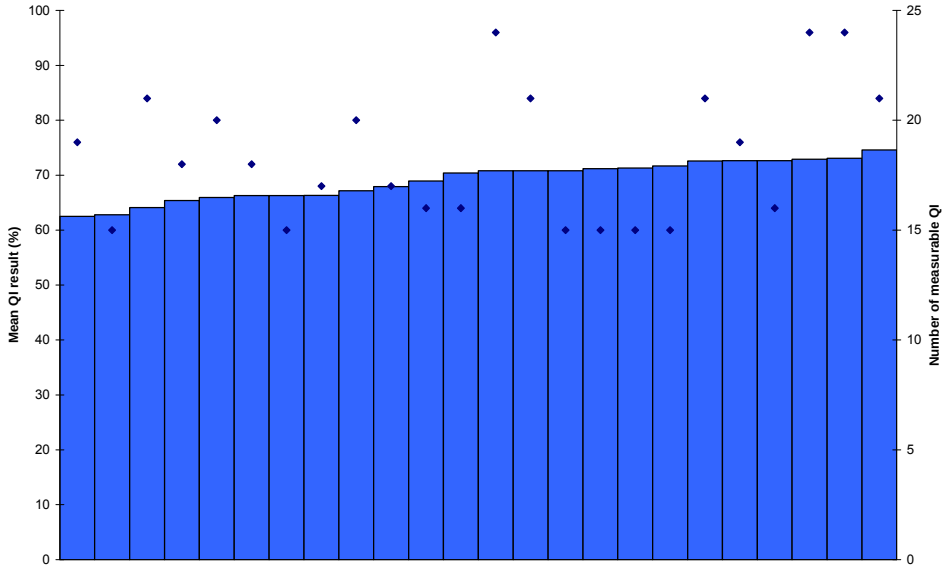
For the 24 centres with at least 10 patients in the denominator for at least 15 of the 30 measurable QI, the mean QI result ranged from 63 – 75% (Figure 16). Increasing the minimum number of patients in the denominator to 20 (for at least 15 QI) changed the range to 67 – 78% (data not shown).

Figure 15. Mean corrected rank per centre with at least 10 patients in the denominator for at least 15 of the 30 measurable QI (prospective cohort).



The bars represent the mean corrected ranks, while the dots represent the number of measurable QI per centre. A lower mean corrected rank is associated with better performance. These results are preliminary, and cannot be used to judge the quality of care.

Figure 16. Mean QI result per centre with at least 10 patients in the denominator for at least 15 of the 30 measurable QI (prospective cohort).



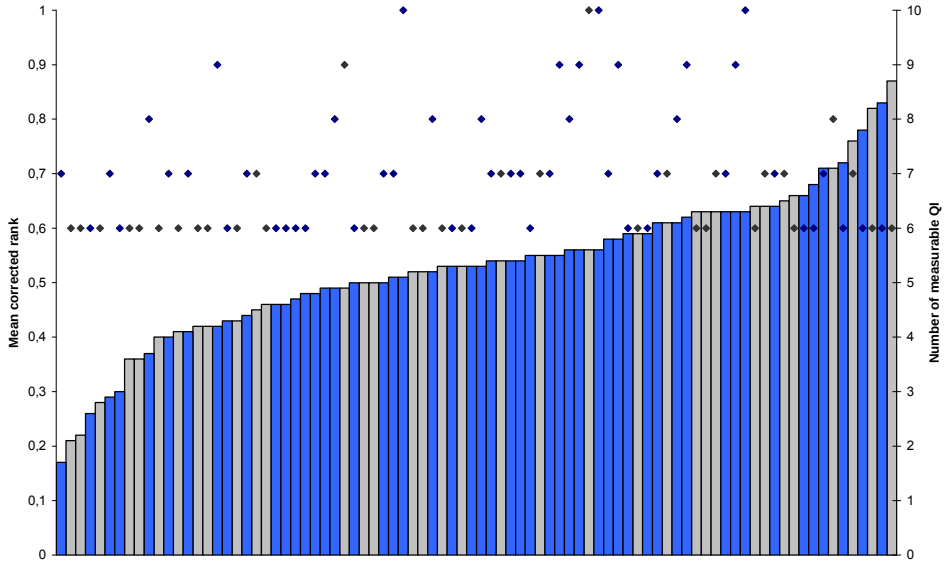
The bars represent the mean QI results, while the dots represent the number of measurable QI per centre. A higher mean QI result is associated with better performance. These results are preliminary, and cannot be used to judge the quality of care.

3.2.3.2 Administrative database

Eighty-six centres had at least 10 patients in the denominator for at least 6 of the 10 measurable QI, of which 51 centres are involved in the PROCARE project (Figure 17). The mean corrected rank ranged from 0.17 – 0.87. Increasing the minimum number of patients in the denominator to 20 (for at least 6 QI), the analysis included 56 centres (39 centres involved in the PROCARE project) (Figure 18). For these 56 centres the mean corrected rank ranged from 0.09 – 0.81. Visually, the PROCARE centres are represented across the entire spectrum of mean corrected ranks (Figure 17 and Figure 18).

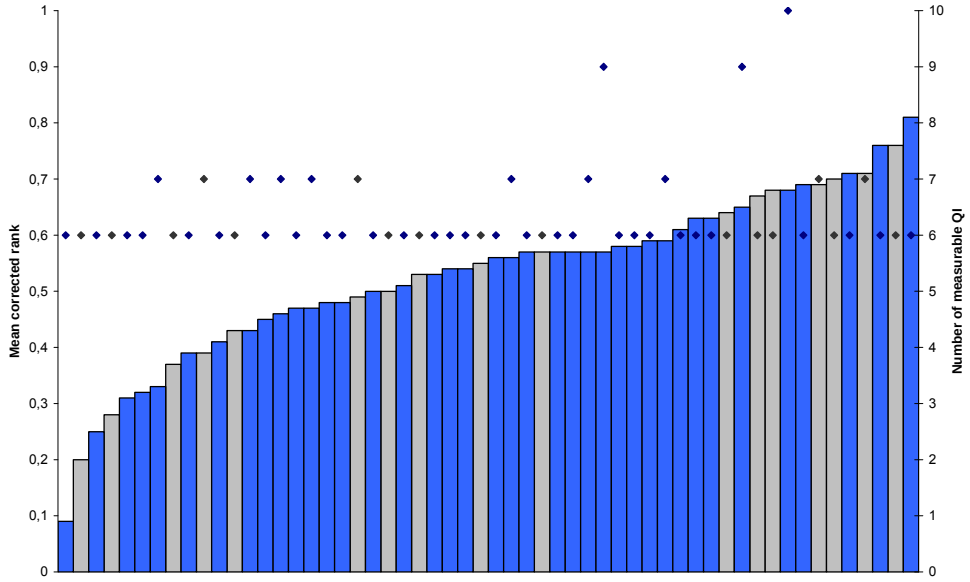
For the 86 centres with at least 10 patients in the denominator for at least 6 of the 10 measurable QI, the mean QI result ranged from 46 – 78% (Figure 19). Increasing the minimum number of patients in the denominator to 20 (for at least 6 QI) did not change this range (data not shown). Visually, the PROCARE centres tend to be on the right (i.e. 'good') side of the graph.

Figure 17. Mean corrected rank per centre with at least 10 patients in the denominator for at least 6 of the 10 measurable QI (administrative cohort).



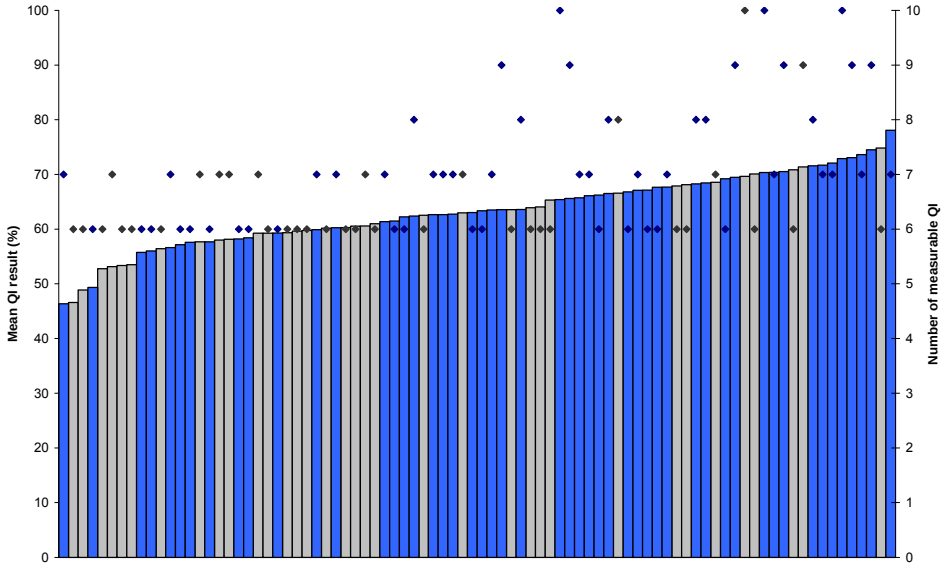
The grey bars represent the mean corrected ranks for non-PROCARE centres, while the blue bars represent the results of the PROCARE centres. The dots represent the number of measurable QI per centre. A lower mean corrected rank is associated with better performance. These results are preliminary, and cannot be used to judge the quality of care.

Figure 18. Mean corrected rank per centre with at least 20 patients in the denominator for at least 6 of the 10 measurable QI (administrative cohort).



The grey bars represent the mean corrected ranks for non-PROCARE centres, while the blue bars represent the results of the PROCARE centres. The dots represent the number of measurable QI per centre. A lower mean corrected rank is associated with better performance. These results are preliminary, and cannot be used to judge the quality of care.

Figure 19. Mean QI result per centre with at least 10 patients in the denominator for at least 6 of the 10 measurable QI (administrative cohort).



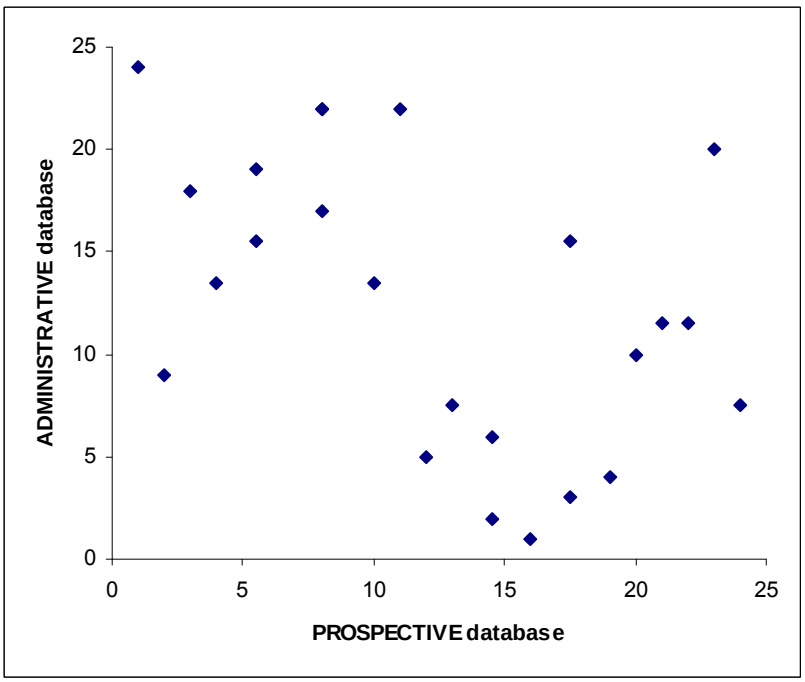
The grey bars represent the mean QI results for non-PROCARE centres, while the blue bars represent the results of the PROCARE centres. The dots represent the number of measurable QI per centre. A higher mean QI result is associated with better performance. These results are preliminary, and cannot be used to judge the quality of care.

3.2.3.3 Correlation analysis

The correlation analysis concerned 24 PROCARE centres. The results of the Spearman's rank correlation test did not allow to reject the null hypothesis (rs=-0.45, p-value = 0.98). This indicates that there is no association between the mean corrected ranks in the prospective and the administrative database for these 24 centres.

Figure 20 shows the plots of the ranks based on the mean corrected ranks using the PROCARE and administrative database respectively. The points are scattered around, rather than lying on a line with a positive slope, reflecting the absence of positive correlation between the two measures.

Figure 20. Correlation between the ranks based on the mean corrected ranks using the PROCARE and administrative database respectively.



3.3 DISCUSSION

3.3.1 Measurability of the selected quality indicators

A major objective of the present study was to analyse the feasibility of measuring QI for rectal cancer care using a prospective database and an administrative database. Of the 40 final QI, 30 were measurable for the prospective cohort and 9 were measurable for the administrative cohort. For the overall 5-year survival (and relative 5-year survival) the follow-up in the prospective cohort was too short to be measurable yet. This QI (and the relative 5-year survival) was measurable for the administrative cohort. Of the 8 QI that were not measurable for the prospective cohort, 2 were measurable for the administrative cohort (discussion in MDT and proportion of patients with stoma 1 year after sphincter-sparing surgery). Six QI were measurable for both cohorts, while 7 other QI were not measurable for both cohorts (including the disease-specific 5-year survival).

In the prospective database, the main reason for not being measurable was the absence of a code (n = 5) or a specific code (n = 2). One QI was not measurable because of inconsistencies in the database. In theory, these problems can be solved by adding variables to or adjusting existing variables in the PROCARE registration form. However, adding variables would increase the burden of registration for the involved healthcare providers. Ideally and where possible, the PROCARE database should be linked to the administrative databases for those QI that are not measurable using the PROCARE database alone. In theory, this is possible through the unique patient identifier.

In the administrative database, the absence of codes for clinical outcomes (mainly R0 resection) and results (e.g. cCRM) was the main reason for not being measurable (n = 21). For 7 other QI, the available administrative codes were too unspecific. In comparison to the prospective database, it is much more difficult (and probably impossible) to add codes. The used administrative databases, in particular the HIC and TC databases, were build for financing reasons rather than for measuring the quality of care.

3.3.2 Definition of quality indicators

Some of the selected QI are defined for specific subpopulations, such as patients undergoing surgery or treatment in general. Of course, many of these QI are also applicable to a broader group of patients with rectal cancer. For example, staging procedures (such as pelvic CT, large bowel-imaging, etc.) are necessary to decide on further treatment for all patients, and not only for patients eventually undergoing treatment [1]. Nevertheless, the message of this study should be that most QI are measurable or can be rendered measurable. In a later phase, it can be decided to enlarge the scope of each individual QI. Additional risk-adjustment will then be necessary for some QI.

3.3.3 Possible problems with the interpretation of the quality indicators

A high number of missing data was identified. For 18 of the 30 QI measurable with the prospective database, the % missing data exceeded 10% (Table 57). Most frequently, missing data were caused by an unknown cStage or (y)pStage or an unknown chemotherapy or radiotherapy regimen. The % missing data was lower for the administrative database, with more than 10% missing data for 2 of the 10 measurable QI. The single most important cause was an unknown cStage.

For 6 QI it was impossible to calculate the exact % of missing data in the prospective database because of the presence of variables with a default value '0'. To increase the reliability of the PROCARE database, all variables with default value '0' should be identified and adapted to allow an identification of missing data.

Partially related to the problem of missing data, a high number of QI – measurable with the PROCARE database – had small denominators, with 13 QI having less than 250 patients included in the denominator (Table 57). For some QI, the follow-up was too short to include an adequate number of patients in the denominator. The problem of sample size is also reflected in the number of patients included in the denominator per centre (Table 57). For 15 QI measurable with the PROCARE database this number is less than 10. This problem emphasizes the need to improve the exhaustiveness of the PROCARE database, not only in terms of participating centres, but also in terms of patients. Indeed, it is not inconceivable that some centres did not register all of their patients or even selectively transmitted their 'good' patients. Also, in some centres only one surgeon is involved in the project, while others aren't. To avoid this threat of selection bias, the PROCARE database can be coupled with the administrative database to check the completeness of the patient inclusion.

In order to provide meaningful feedback to the participating centres, their individual score should be positioned against the other (anonymized) centres and against a desired score. For most QI these desired scores are available from the literature [9, 11] and/or the PROCARE guideline [1]. However, since it is not the intention of the authors to judge the quality already, these desired scores are not provided in the document. For the interpretation of most QI, it is also necessary to risk-adjust and to provide additional 'third level' information to the participating centres. For example stage and level of the tumour (upper vs. middle vs. lower third of the rectum) have an important influence on the choice of treatment and on patient outcomes.

It is important to emphasize that the results of the 6 QI that are measurable in both databases cannot be compared between the 2 databases. First, a time lag exists between the 2 databases, with different treatment standards available. Second, both cohorts differ in terms of age and stage distribution (see chapter 3.2.1), mainly because of the selection bias mentioned above.

Based on the results of this feasibility study, suggestions were made for each individual QI to improve the measurability or interpretability. These suggestions are summarised in Table 58. Although it is tempting for the reader to already interpret the QI results presented in this report, the suggested adaptations are first needed. Therefore, these results cannot be used to judge the quality of rectal cancer care at present.

Table 57. Missing data and sample size per QI.

QI	Prospective database			Administrative database		
	% missing data	N denominator	Mean N denominator per centre (number of centres)	% missing data	N denominator	Mean N denominator per centre (number of centres)
1111	1%	866	12 (55)	0%	7074	27 (112)
1112*	1%	866	12 (55)	0%	7074	27 (112)
1113	≥ 63%	233	6 (38)	-	-	-
1114	-	-	-	9%	673	6 (100)
1211	0%	1018	18 (56)	-	-	-
1212	-	-	-	-	-	-
1213	0%	1067	19 (56)	1%	6337	48 (126)
1214	3%	1003	18 (55)	-	-	-
1215	1%	1067	19 (56)	-	-	-
1216	31%	516	10 (51)	-	-	-
1217	89%	109	7 (15)	1%	6337	48 (126)
1221	40%	421	9 (48)	-	-	-
1222	40%	421	9 (48)	-	-	-
1223	54%	63	4 (16)	51%	589	6 (91)
1224	-	-	-	-	-	-
1225	≥ 40%	220	6 (38)	-	-	-
1226	41%	216	6 (38)	-	-	-
1227	-	-	-	-	-	-
1231	32%	602	12 (52)	-	-	-
1232a	2%	999	18 (56)	1%	5472	43 (124)
1232b	-	-	-	4%	1093	10 (107)
1233	11%	724	14 (53)	-	-	-
1234	3%	693	13 (54)	2%	5863	46 (124)
1235	?	1018	18 (56)	-	-	-
1241	32%	94	3 (31)	-	-	-
1242	8%	121	3 (38)	-	-	-
1243	44%	36	3 (13)	-	-	-
1244	44%	35	3 (12)	-	-	-
1245	≥ 59%	47	3 (18)	-	-	-
1251	31%	111	3 (39)	63%	559	4 (97)
1252	≥ 32%	63	2 (29)	-	-	-

QI	Prospective database			Administrative database		
	% missing data	N denominator	Mean N denominator per centre (number of centres)	% missing data	N denominator	Mean N denominator per centre (number of centres)
1261	-	-	-	-	-	-
1262	-	-	-	-	-	-
1263	≥ 60%	103	4 (29)	-	-	-
1271	-	-	-	-	-	-
1272	7%	833	15 (56)	-	-	-
1273	8%	777	15 (53)	-	-	-
1274	6%	956	17 (56)	-	-	-
1275	5%	968	17 (56)	-	-	-
1276	14%	575	11 (52)	-	-	-

* Figures are presented for the relative 5-year survival.

Table 58. Overview of suggested actions per QI.

QI	Suggested actions
1111	• Continue follow-up (at least 5 years) • Take into account postoperative mortality (through link with administrative database)
1112	• Use relative 5-year survival as proxy • Continue follow-up (at least 5 years)
1113	• Continue follow-up (at least 5 years) • Remove default '0' value in PROCARE database • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Reduce number of missing data (type of resection, (y)pStage) • Risk-adjustment: e.g. tumour level, stage
1114	• Link PROCARE database to administrative databases • Reconsider relevance of this indicator
1211	• Data cleaning necessary
1212	• Adapt PROCARE variable in data entry set to render QI measurable
1213	• Consider measuring the QI for all patients
1214	• Adapt PROCARE data entry set • Consider measuring the QI for all patients
1215	• Risk-adjustment: tumour level, tumour stenosis • Consider measuring the QI for all patients
1216	• Reduce number of missing data (cStage)
1217	• Reduce number of missing data (date of biopsy) • Consider redefining the QI (time between first consultation and first treatment)
1221	• Reduce number of missing data (cStage, radiotherapy regimen) • Add PROCARE variable asking for prescribed radiotherapy regimen • Risk-adjustment: e.g. tumour level, age, comorbidities • Consider measuring the QI for all cStage II-III patients
1222	• Reduce number of missing data (cStage, radiotherapy regimen) • Add PROCARE variable asking for prescribed radiotherapy regimen • Risk-adjustment: e.g. tumour level, age, comorbidities • Consider measuring the QI for all cStage II-III patients
1223	• Reduce number of missing data (cStage, chemotherapy regimen) • Consider measuring the QI for all cStage II-III patients
1224	• Add PROCARE variable to render QI measurable • Consider measuring the QI for all cStage II-III patients
1225	• Remove default '0' value in PROCARE database • Reduce number of missing data (cStage, radiotherapy regimen) • Consider measuring the QI for all cStage II-III patients
1226	• Reduce number of missing data (cStage, radiotherapy regimen)
1227	• Add PROCARE variable to render QI measurable
1231	• Reduce number of missing data (cStage) • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: stage, cCRM
1232a	• Risk-adjustment: e.g. tumour level
1232b	• Adapt PROCARE variable to render QI measurable for the PROCARE database • Risk-adjustment: tumour level, comorbidities, stage
1233	• Reduce number of missing data (type of surgery) • Risk-adjustment: tumour level, type of resection, presence of stoma
1234	• Risk-adjustment: age, stage, comorbidities (expected/observed ratio)
1235	• Remove default '0' value in PROCARE database • Risk-adjustment: tumour level (including dorsal – ventral), stage
1241	• Reduce number of missing data (adjuvant treatment, (y)pStage)

QI	Suggested actions
	• Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: age, comorbidities, postoperative morbidity
1242	• Reduce number of missing data (adjuvant treatment) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: age, comorbidities, postoperative morbidity
1243	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: age, comorbidities, postoperative morbidity
1244	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation)
1245	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Remove default '0' value in PROCARE database • Adapt PROCARE data entry form on adjuvant treatment
1251	• Reduce number of missing data (cStage) • Risk-adjustment: age, comorbidities • Use 'corrected cStage' taking into account peroperative findings of metastasis
1252	• Reduce number of missing data (cStage) • Remove default '0' value in PROCARE database
1261	• Add PROCARE variable to render QI measurable
1262	• Add PROCARE variable to render QI measurable
1263	• Longer follow-up necessary • Remove default '0' value in PROCARE database
1271	• Add PROCARE variable to render QI measurable
1272	• Risk-adjustment: tumour level, stage
1273	• Risk-adjustment: tumour level
1274	• Risk-adjustment: neoadjuvant treatment, (y)pN
1275	• Reduce missing data (pathology data)
1276	• Reduce missing data (neoadjuvant treatment) • Risk-adjustment: neoadjuvant treatment

3.3.4 Complementarity of both databases

Working with *prospectively collected data* clearly has some important advantages. The availability of clinical data is of major importance for the evaluation of the quality of care. This is probably the most important reason for the difference in measurability of the QI between both databases. Although the collection of the PROCARE data started about 1,5 years before the start of the present study (i.e. without having a clear idea about which QI to measure), already 75% of the selected QI is measurable using these data. Based on the present exercise, the prospective data collection can be rendered even more specific.

Another advantage is the quality control of the data collection. Data managers can contact the responsible clinicians in case of missing data or inconsistencies. At the same time, this is a major disadvantage of prospective databases. Data collection, data cleaning and chasing missing data is expensive and time-consuming. At present, the PROCARE data collection is done manually. Ideally, a system is used where data can be collected electronically (this is planned in the near future). However, for the involved clinicians prospective data collection still remains a burden.

As already mentioned above, a possible threat for the PROCARE database is the selective inclusion of 'good' patients. Coupling with the administrative database to check the completeness of inclusion can be a solution.

The advantage of *administrative data* is their efficiency. Since these data are already collected for other reasons (e.g. epidemiology, financing, accreditation, etc.), the extra workload for clinicians is negligible. Above this, in contrast to the PROCARE database, the administrative database (which is population-based) includes all Belgian patients with rectal cancer.

However, administrative data lack specificity and detail. Indeed, the selected QI in this report were often not measurable using administrative data, because of the absence of specific administrative codes or clinical data. Although the MCD database offers the advantage to link procedures to diagnoses (in contrast to the HIC database), the linkage of the 3 different administrative databases did not have much impact on the measurability of the QI.

Administrative data are only available 2 to 3 years after registration. The quality of care is therefore measured with an important delay. Above this, the request for the administrative data and the coupling of the 3 databases turned out to be a long procedure taking several months. Furthermore, many weeks were needed to gain insight in the information available from this large database. Of course, the experience from the present study can be used for future exercises.

Importantly, since these administrative data are collected for (often financing) reasons other than quality and are therefore associated with risks of up- or under-coding, their use for the measurement of the quality of care is at least questionable.

3.3.5 High versus low performance on quality indicators

Most individual QI show enough variation to allow a distinction between centres offering high vs. less quality care. This is essential and very relevant, since it offers centres the opportunity to act on specific procedures and outcomes.

However, the QI set as a whole has less potential to distinguish overall high from low performance. While the variation in mean corrected rank is acceptable using the PROCARE database (with a high number of measurable QI, but a low number of centres) (Figure 15), the variation in mean QI result is less pronounced (Figure 16). On the contrary, the variation in both mean corrected rank and mean QI result increases using the administrative database (with a low number of measurable QI, but a high number of centres).

It is difficult to give straightforward explanations for these results. One possible reason is that most PROCARE centres are performing on a similar overall quality level. This is supported by the analysis of the mean QI result using the administrative databases, where the PROCARE centres tend to be on the right side of the graph (Figure 19), but refuted by the analysis of the mean corrected rank using the administrative databases, where the PROCARE centres are represented on both sides of the graph (Figure 17 and Figure 18).

Another possible explanation is that this QI set is simply not balanced enough to allow a distinction between overall high and less quality care. Nevertheless, it is obvious that more centres and more patients per centre need to get involved in order to increase the relevance of these results. This would also allow risk-adjustment (e.g. ASA score for postoperative mortality, tumour level for type of resection, tumour stage for (y)pCRM, etc.), which is essential for the distinction between high and low performance.

No correlation was shown between the mean corrected ranks of 24 PROCARE centres using the prospective and administrative databases respectively. This can have several reasons. First, for some hospitals the data in the PROCARE database are not representative for their entire rectal cancer population because of the selection bias (see above). Above this, a time lag exists between the 2 databases, reflecting different standards of care. Finally, the mean corrected ranks are not calculated using the same QI for both databases, and therefore may reflect other aspects of quality of care.

Most importantly, several QI need to be risk-adjusted (e.g. postoperative mortality, type of resection, (y)pCRM, etc.). Risk-adjustment is essential for the identification of potentially low performance.

3.3.6 Generalisability of this project

Although it is irrelevant to project the algorithms and results of the QI using the prospective database – which was set up specifically for rectal cancer – to other cancer types, at least part of the reasoning behind some QI measurable with the administrative database can be generalised.

First, it is essential to identify an 'anchor time point' for each patient, at which the clinical trajectory starts. Ideally, this is the date of first (histopathological) diagnosis, which is available from the BCR. Second, several other milestones of the trajectory need to be identified. For patients undergoing surgery, the date of surgery is essential to allow a distinction between neoadjuvant and adjuvant treatment (if applicable). Above this, it allows a distinction between preoperative and follow-up diagnostic studies. The date of surgery (and the dates of other diagnostic and therapeutic procedures) is available from the HIC database using surgical procedural codes specific to the cancer type. Another important milestone is death, which is available from the health insurers.

Once all possible milestones are identified (which should be possible for most cancer types), it depends on the available administrative codes specific to the cancer type how detailed the selected QI can be measured. Some QI, such as 5-year survival, time to treatment and inpatient or 30-day mortality, should be measurable for most cancer types using the same algorithm as in the present study. Therefore, for these QI and for the identification of common milestones, a manual will be prepared internally, including the program algorithms using SAS and the necessary administrative codes and their sources.

Finally, the coupling procedure that was used for the present study can also be used for future exercises.

4 INTERNATIONAL EXPERIENCES WITH QUALITY MEASUREMENT OF RECTAL CANCER CARE

4.1 INTRODUCTION

In addition to national benchmarking, i.e. comparing results from individual hospitals or teams with national performances with feedback to participating teams, PROCARE also aims for international benchmarking. This would allow an audit of the national quality of care and can be performed by comparing the results in Belgium with those in other comparable countries or foreign populations. This comparison could indicate whether further improvement is possible and/or warranted. Comparison of Belgian performances can be done with nationwide or population-based databases or with results from multicentre prospective trials. For international benchmarking, comparison with population-based data is preferred above a comparison with results from large trials. While the latter give an indication of potentially reachable targets, population-based results more accurately represent the quality of care in a given nation/region.

Nationwide initiatives in other European countries, e.g. Norway, Denmark and Sweden, have illustrated the positive impact on multiple aspects of rectal cancer care by means of registration with feedback to participating hospitals [12-15]. In Sweden, a national cancer registry already started in 1995. The well-known Swedish rectal cancer trial was performed afterwards [16]. Thus, it can be expected that an exchange of data with Sweden would allow adequate national quality comparison with Belgium. In Denmark and Norway, national initiatives have been undertaken in order to introduce TME as the standard for rectal cancer surgery. Its impact on improved quality of care was demonstrated [15]. Moreover, Norway has installed a national rectal cancer database.

Although a Dutch nationwide colorectal cancer database will only start in 2008 or afterwards, some regional databases have been installed and exemplary results and consequences are available from the Dutch TME trial [17]. The same applies for Germany where a large trial on rectal cancer comparing pre- and postoperative chemoradiotherapy was performed [18]. Nationwide data are absent in Germany, but regional databases are functioning. In France, several smaller regional databases seem to be functioning [19, 20]. In Spain, colorectal surgeons recently started a national database for quality control [21]. Finally, the national bowel cancer audit programme in the United Kingdom – instaured since several years – is well-known (http://www.nbocap.org.uk/). It is expected that data specific for rectal cancer will become available. Also, regional data from the Northern and Yorkshire County seem to be available [22, 23].

4.2 METHODOLOGY

Contacts were made with other Western European countries in May 2006. These contacts were updated in January 2008 with Denmark, France, Germany, Norway, Sweden, Spain, The Netherlands and the United Kingdom.

In January 2008, a questionnaire was sent to contact persons mentioned in Table 59. The questionnaire consisted of a first part related to characteristics of the database/registry, while the second part asked for information on the availability for cross-border comparison of quality of care indicators, as determined in the present study. A reminder was sent to these contact persons who did not answer by February 1st, asking for a reply before the end of February 2008. All contacted persons responded within 3 weeks, except for the registry of the NBOCAP. However, the NYCRIS and NBOCAP registries were found to be linked (cfr. infra).

Table 59. Overview of contacted persons for international benchmarking.

Country	Organisation/project	Contacted person(s)
Denmark	Danish Colorectal Cancer Registry	Dr. H. Harling
France	Registre Bourguignon des Cancers Digestifs	Prof. Dr. J. Faivre
Germany	Baverian Cancer Register	Dr. M. Meyer
The Netherlands	LUMC Leiden	Prof. Dr. C. van de Velde
	Association of Comprehensive Cancer Centres (ACCC)	Dr. R. Otter
Norway	Norwegian Colorectal Cancer Registry	Prof. B. Vonen L. Dørum
Spain	Asociación Española de Cirujanos	Prof. Dr. H. Ortiz
Sweden	Swedish Rectal Cancer Registry	Prof. Dr. L. Pahlman
UK	National bowel cancer audit project (NBOCAP)	Prof. M. Thompson
	Northern and Yorkshire Cancer Registry (NYCRIS)	Prof. D. Froman

4.3 RESULTS

4.3.1 Rectal cancer databases in Western Europe

A database with specific (hence more detailed) data on patients with rectal cancer exists for more than a decade in most of the evaluated countries (Table 60). In the Netherlands and UK, rectal and colon cancer data are registered together, but it seems that specific data related to rectal cancer can be retrieved (at least in the regional database of the Netherlands). Registration started very recently in Spain (2006) and the Netherlands (2008).

Data registration is compulsory in the national databases of Denmark, Norway, Sweden and the UK, where the completeness of patient inclusion is checked. Data are managed and analysed by scientific/professional bodies or associations, and several registries are funded by the government. The frequency of feedback to participating centres is variable, but at least on an annual basis. The Danish registry uses a system with 'on-line' feedback.

Based on the characteristics of the respective databases, those of Denmark, Norway, Sweden and the UK seem to be of greatest interest for benchmarking with the PROCARE data/results. These registries are compulsory and national, and have experience with analysis and regular feedback since several years. The Spanish registry started recently (2006) and participation is partial (based on voluntary collaboration, mainly from sub-specialised colorectal surgeons).

Table 60. Characteristics of international rectal cancer databases/registries.

Characteristics	Germany	France	The Netherlands *	Sweden	Spain	UK	Denmark	Norway
Specific for rectal cancer	Yes	Yes	No, but retrievable	Yes	Yes	No	Yes	Yes
Start of registration	1998	1976	1989	1995	2006	1970	?	1993
Registration ongoing	Ongoing	Ongoing	Ongoing	Ongoing	In development	Ongoing	Ongoing	Ongoing
Location of registry	Scientific	Scientific	Professional	Professional and scientific	Scientific	Governmental	Scientific	Scientific
National or regional registry	Regional	Regional (2 areas)	Regional	National	National	National	National	National
Percentage of population covered	76%	?	?	100%	20%	100%	> 95%	100%
Registration on voluntary or compulsory basis	Voluntary	Voluntary	Voluntary	Compulsory	Voluntary	Compulsory	Compulsory	Compulsory
Completeness of patients in registry checked	Yes (76%)	Yes	Yes (98%)	Yes	No	Yes	Yes	Yes
Exclusion of some patients	No	No	No (yes in studies)	No	No	No	No	No
Risk adjustment possible (e.g. for postoperative mortality)	No	Yes	No	Yes	Yes	Yes	Yes	Partly
Frequency of follow-up update	1/year	1/ 2 years	Variable	1/year	1/year	In development	Variable	Variable
Frequency of feedback	1/year	Variable	Variable	1/year	1/year	In development	Continuous	1/ 2 years
Possibilities of benchmarking	No	No	Yes	Yes	Yes	Yes	Yes	Yes

* This is a classical cancer registry, but two large scale documentation studies have been performed (1994-1997 and 2001-2004).

4.3.2 Availability of PROCARE quality indicators in Western European databases

In chapter 2, quality of care indicators for the management of patients with rectal cancer have been identified. It was explored whether these QI could be compared with data from other Western European rectal cancer databases. In view of their characteristics (cfr. supra), the results from Denmark, Norway, Sweden and the UK are of most interest (see appendix).

It appears that benchmarking with the national and compulsory registries from Norway and Sweden have the best potential to be explored. The Norwegian registry remarked that neoadjuvant short course radiotherapy as well as adjuvant chemotherapy is not (routinely) used in Norway, in contrast to Sweden. Also, the quality of TME is not registered in Norway. Data from the Danish registry do not allow benchmarking for disease-free survival and use of neoadjuvant or adjuvant therapy. Data from the UK would not allow stratification of patients according to the level/location of rectal cancer. Most of the other QI are able to be compared, although some only on subsets of patients.

The following additional information was provided at the occasion of the above mentioned questionnaire:

4.3.2.1 Denmark

Until now, the Danish Colorectal Cancer Database has been a surgical-based database with only basic radiological, pathological and oncological data. However, they are in the process of extending the database with data relevant to the PROCARE project.

4.3.2.2 The Netherlands

A nationwide specific database on rectal cancer is not installed. At this moment, only data on rectal cancer patients in randomized trials and limited data from retrospective analyses in rectal cancer are available. As of January 1st 2008, prospective data registration on colorectal cancer has started in 2 regions, eventually to cover the entire country (cfr. infra). It was proposed to the new ECCO organisational board to set up a European structure preferably also including the PROCARE study (Van de Velde C., February 2008, personal communication).

The contacted persons also confirmed and specified that their regional cancer registry of the Northern Netherlands does only allow for a limited analysis of treatment quality, i.e. only for some main indicators of completeness of treatment. In the last decade two large documentation studies were performed which allow for more in depth analysis. The first and most extensive study was started in 1994, and is likely of limited interest for current quality of rectal cancer care. The second study concerns patients diagnosed and treated between 2001 and 2004 and might be more relevant for this project.

4.3.2.3 United Kingdom

There are 8 regional cancer registries in England. Each registry collects data on all cancers diagnosed in the country and NYCRIS covers the Northern and Yorkshire regions. Each registry records the diagnosis of all cancers, but they also collect varying amounts of additional information on treatment and stage. The national data registered at NYCRIS are specific to colorectal cancer. Colorectal cancer specialists have looked at patterns of care across the country in the respective databases for colorectal cancer. To do so, extracts of colorectal cancer data were taken from each cancer registry and pooled to form a national dataset. Currently, the data set covers the period of 1996 – 2005 and incorporates information on about 300.000 patients. However, because of the varying amounts of treatment information available in the different registries, patterns of practice in some areas of the country could not really be distinguished using the registry data alone. Therefore, these data have been linked to a dataset known as hospital episode statistics which holds information about every inpatient stay in an NHS hospital. This gives information about all treatments that require a stay in an NHS hospital.

Also, an attempt is made to extend the dataset to incorporate extra information on other aspects of care by linking it to other routine data sources, such as radiotherapy, chemotherapy and pathology databases. However, variable amounts of information on these aspects of care are available across the country.

The National Bowel Cancer Audit Project (NBOCAP) is a collaboration between the Association of Coloproctologists of Great Britain and Ireland (ACPGBI) and the National Clinical Audit Support Programme (NCASP). It is a voluntary audit and members of the ACPGBI can submit information about their patients to it. It is not population-based and only covers about one third of the colorectal cancer patients at most. The NBOCAP dataset has more detailed clinical information than the PROCARE database (e.g. ASA grade), but unfortunately – as it is a voluntary audit – it is often very incomplete and many key fields are missing. When comparing their data to the population-based data at NYCRIS, it was found that members of the ACPGBI have significantly better outcomes than non-members. Therefore, using NBOCAP data as a proxy for national work may be biased as it overestimates outcomes. NYCRIS is very keen, however, to link its data to the NBOCAP data as this would supplement the dataset with more clinical information and it would give them national coverage. They are actively trying to collaborate with NBOCAP to achieve this.

NYCRIS is also interested to collaborate with colleagues in Dutch cancer registries, and they suggested that a Belgian dimension could be of interest (personal communication with David Forman).

4.3.2.4 Spain

The Spanish registry has recently been set up by professionals and the Spanish surgical society. Participation is on a voluntary basis. Unfortunately, resources are lacking to pay for a data manager travelling around Spain.

The database was based on an agreement between surgeons, pathologists, radiologists and oncologists. Unfortunately, data concerning adverse effects or the use of new drug combinations are incomplete.

No unequivocal mechanism is available to check whether all participating teams/hospitals submit their consecutive patients for registration. Hospitals willing to be included have to complete a questionnaire, which includes two questions about the annual case load (number of cases treated in the last 5 years, number of cases treated in the last year). If the number of observed cases from a hospital is less than 5% of the expected cases, all data of this hospital are excluded from the registry for that particular year.

4.3.2.5 Germany

The population-based cancer registry Bavaria is one of the 10 regional cancer registries in Germany (http://www.ekr.med.uni-erlangen.de/GEKID/Doc/kid2006_english.pdf). It is a classical epidemiologic cancer registry that does not provide data for benchmarking (except for non-adjusted overall survival).

4.3.2.6 Norway

The Norwegian rectal cancer registry has more or less "automatic" merges with the national cause of death registry and all EPJ systems in Norway.

4.4 DISCUSSION

A nationwide population-based database on rectal cancer has been installed and is functioning in Sweden, Norway, Denmark, and the UK. Participation in these registries is compulsory. In the Netherlands, a similar database was installed only very recently (January 2008). On the other hand, regional population-based databases on patients with rectal cancer, with participation on a voluntary basis, are available in France, Germany, and the Netherlands.

Most of these databases are located in a scientific organisation, supported by the clinicians and financially supported by the government (at least in Sweden and the UK).

Data in these registries are regularly checked for completeness of coverage (i.e. missing patients). No type of patients or tumour is excluded from registration. Frequency of follow-up varies from 4 times during the first 2 postoperative years (Norway) to every two year. Usually, an annual feedback to participating centres and teams is provided. In Denmark, 'on-line' feedback has been installed.

It appears that most QI that have been identified in the context of the present PROCARE project can best be compared with data from Sweden and Norway. However, several level 1 QI such as overall five-year survival and disease-specific survival at 2 and 5 years, can be compared with almost all databases.

In conclusion, it seems to be of most interest to intensify and regularise contacts with Sweden and Norway because of the comparability of QI in the respective databases. Of course, benchmarking is subject to regulatory approval and permission of (national) data-governing bodies will have to be obtained. In addition, the information obtained through the present survey will need further exploration and updating once the plans for international benchmarking are much more concrete.

5 CONCLUSIONS

The ultimate aim of PROCARE is to decrease diagnostic and therapeutic variability between centres and to improve the quality of care for all patients presenting with rectal cancer. The identification of teams with suboptimal performance is a delicate matter and requires well-developed quality indicators, high-quality data (with adequate application of definitions), and adjustment for risk factors. The combination of a literature search and expert opinion made it possible to construct a set of 40 relevant QI for rectal cancer. For most selected QI, all necessary elements to be measurable are available in the PROCARE database and/or administrative databases. However, based on the results of the present study, a refinement of some QI and of the PROCARE data entry form is necessary. Also, in order to minimise the number of missing data and to increase the performance of the PROCARE data registration and analysis, a web application for data submission should be developed. Training of datamanagers is essential for an efficient and correct collection of patient data.

The present study shows that a linkage between the BCR database and other administrative databases is feasible and highly accurate (at least for the linkage between the BCR and HIC databases). The BCR data were shown to be exploitable and relevant for at least part of the selected quality indicators. Apart from the administrative BCR data, the BCR has also proved to have the necessary capacity for prospective data registration and analysis. Therefore, the BCR is an essential partner for future similar projects.

Using the administrative databases, some relevant QI were measurable. However, the total number of measurable QI was rather low. Of these, the outcome indicators on survival and mortality, measurable with data coming from the Sickness Funds, can probably be considered the most meaningful. For this project, the contribution of the MCD-MFD database was limited.

The PROCARE project is a pilot project for Belgium. So far, many centres involved in the PROCARE project only included a low number of patients, making an interpretation of most QI difficult at present. Nevertheless, the involved centres expect a first individual feedback very soon. Therefore, it should be considered to give this feedback without further interpretation until the end of 2009. By then, the total amount of included patients can be expected to exceed 2500. At that time, the relevance and interpretability of the QI should be reassessed, e.g. by comparing the PROCARE data to the administrative data for the same time period and by performing risk-adjustment where necessary. At a later stage, it can also be considered to pool the results of the smaller centres (i.e. with 5 or less patients per year), and to provide these pooled results in addition to the individual feedback.

In view of the needed refinements and difficult interpretation of the QI at present, it should be stressed again that the preliminary QI results presented in this report cannot be used to judge the quality of rectal cancer care. Indeed, given the relatively low number of included patients per PROCARE centre, this study seems to be done too soon to draw firm conclusions. Ideally, this exercise was piloted with a much more frequent cancer, such as breast cancer.

The prospective PROCARE registration is on a voluntary basis, and to increase the ownership of the project, this voluntarism should be encouraged. Registration burden is an important threat for this project, and it is therefore recommended to revise the current data entry form, which is very exhaustive at present. By providing the individual feedback in an attractive, professional and comprehensible lay-out, additional centres can be convinced to join the project.

In the long run, the coverage of the PROCARE registration needs to be improved and assured, e.g. by providing incentives or by checking the coverage through linkage with administrative databases. Indeed, as complete as possible coverage is essential to allow a meaningful population-based international benchmarking. The present study has shown the potential for such an international exercise. However, it is recommended to await a higher amount of included patients.

Recommendations

- **For most selected quality indicators the necessary elements to be measurable are available in the PROCARE database and/or administrative databases. Based on the present exercise, an adaptation of some indicators and of the PROCARE data/variables is necessary.**
- **In order to reduce the number of missing PROCARE data and to improve the performance of the PROCARE data registration, a web application for data submission is necessary. To reduce the administrative burden, the PROCARE data entry form – which is very exhaustive at the moment – needs to be adapted. The number of data to register should be reduced significantly, on the one hand by maximally integrating the prospective and administrative data, and on the other hand by selecting a limited number of key indicators. Above this, the BCR should have an automatic access to the necessary administrative data.**
- **The link between the BCR database and other administrative database is feasible and accurate. The BCR data are exploitable and relevant for at least some quality indicators. Furthermore, the BCR has the necessary capacity for prospective data registration and analysis. Therefore, the BCR is an essential partner for future similar projects.**
- **For this project the link between the BCR and HIC database was the most relevant. The contribution of the MCD-MFD database was limited.**
- **In view of the small sample size at present, it is recommended to provide the individual feedback without further interpretation. By the end of 2009, the relevance and interpretability of the quality indicators needs to be reassessed. This evaluation should allow the selection of the key indicators. In a next phase, the system should be implemented.**
- **In order to allow a meaningful population-based international benchmarking, a complete coverage needs to be garantueed (e.g. through linkage with administrative databases) and a higher number of included patients is necessary.**

6 APPENDICES

APPENDIX 1: OVERVIEW OF ALL IDENTIFIED QUALITY INDICATORS*

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
Use of chemotherapy in Stage II and III rectal patients	Neoadjuvant, adjuvant	AHRQ	Inclusion	2	1223, 1224, 1241
Percentage of patients with stage II and III rectal cancer receiving radiation therapy	Neoadjuvant, adjuvant	AHRQ	Inclusion	2	1221, 1222, 1242
Non-receipt of standard radiation therapy	Neoadjuvant, adjuvant	AHRQ	Inclusion	2	1221, 1222, 1242
Adjuvant therapy rates	Adjuvant	AHRQ	Inclusion	2	1241, 1242
Percentage of late stage rectal cancer (stage III-IV) that received one or more courses of adjuvant chemotherapy within 1 year of initial cancer surgery	Adjuvant, palliative	AHRQ	Inclusion	2	1241, 1251
Pathology report in concordance with CAP guidelines	Pathology	AHRQ	Inclusion	2	1271
Adequacy of pathology reports on CRC	Pathology	AHRQ	Inclusion	2	1271
Adequate lymph node retrieval and evaluation	Pathology	AHRQ	Inclusion	2	1274
Local control rate	Surgery	AHRQ	Inclusion	2	1231
Percentage of patients referred to medical oncologist for consideration of adjuvant chemotherapy	General, adjuvant	AHRQ	Inclusion	1,2	1114, 1241
Percentage of patients with local or regional CRC who had colonoscopy or flexible sigmoidoscopy with barium enema	Staging	AHRQ	Inclusion	2	1214
Percentage of patients with colon or rectal cancer undergoing colonoscopy as part of their evaluation	Staging	AHRQ	Inclusion	2	1214
Percentage of patients who underwent colonoscopy pre- or postoperatively	Staging, follow-up	AHRQ	Inclusion	2	1214, 1261
Surgical resection rates	Surgery	AHRQ	Inclusion	2	1231
Curative resection rate	Surgery	AHRQ	Inclusion	2	1231
Ostomy rates	Surgery	AHRQ	Inclusion	2	1232a, 1232b
Abdominoperineal resection (APR) rate	Surgery	AHRQ	Inclusion	2	1232a
Percentage of rectal cancer cases receiving a sphincter preservation procedure at time of surgery	Surgery	AHRQ	Inclusion	2	1232a, 1232b
Complication rate	Surgery	AHRQ	Inclusion	2	1233
30-day mortality rate	Surgery	AHRQ	Inclusion	2	1234
In-hospital mortality rate	Surgery	AHRQ	Inclusion	2	1234
Percentage of patients with stage III colon and stage II and III rectal cancer receiving adjuvant chemotherapy	Adjuvant	AHRQ	Inclusion	2	1241
Rate of adjuvant chemotherapy for CRC	Adjuvant	AHRQ	Inclusion	2	1241

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy	Adjuvant	AHRQ	Inclusion	2	1242
Percentage of patients receiving adjuvant radiotherapy who also received adjuvant chemotherapy for cancer of the sigmoid, colon or rectum	Adjuvant	AHRQ	Inclusion	2	1242
Rate of adjuvant radiation therapy for patients with stage II or III rectal cancer	Adjuvant	AHRQ	Inclusion	2	1242
Percentage of patients with stage IV colon cancer or stage IV rectal cancer receiving palliative chemotherapy	Palliative	AHRQ	Inclusion	2	1251
Percentage of patients with stage IV colon or rectal cancer receiving palliative chemotherapy, radiation therapy, or both	Palliative	AHRQ	Inclusion	2	1251
Percentage of patients with CRC receiving postoperative (surveillance) colonoscopy	Follow-up	AHRQ	Inclusion	2	1261
Number of stage I to stage III CRC cases with a colonoscopy within 1 year of surgery	Follow-up	AHRQ	Inclusion	2	1261
Percentage of rectal cancer cases that received a post surgical endoscopic examination within 12 months postsurgery	Follow-up	AHRQ	Inclusion	2	1261
Time from patient presentation with symptoms to cancer diagnosis		AHRQ	Exclusion	3	
Proportion of colonoscopies that were completed in a timely fashion		AHRQ	Exclusion	3	
Complication rate of colonoscopy		AHRQ	Exclusion	3	
Serious postendoscopic procedure complication rate		AHRQ	Exclusion	3	
Non-receipt of surgery		AHRQ	Exclusion	3	
Percentage of CRC patients who underwent cancer-directed surgery		AHRQ	Exclusion	3	
Intraprocedure colonoscopy complication rate		AHRQ	Exclusion	3	
Colonoscopy completion rate		AHRQ	Exclusion	3	
Cecal intubation rate		AHRQ	Exclusion	3	
Percentage of patients with adequate bowel preparation prior to colonoscopy		AHRQ	Exclusion	3	
Proportion of colonoscopies performed by physicians with specialized training		AHRQ	Exclusion	3	
Adherence of radiotherapy management treatment guidelines for patients with adenocarcinoma of the rectum or sigmoid colon		AHRQ	Exclusion	3	
Rate of use of modern radiation therapy techniques and adherence to recommendations of NCIsponsored randomized controlled trials in rectal cancer patients		AHRQ	Exclusion	3	
Percentage of newly diagnosed CRC cases who were staged using the AJCC system		AHRQ	Exclusion	3	
Proportion of CRC cases in which pathologic staging preceded		AHRQ	Exclusion	3	

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
chemotherapy and radiation treatment					
Percentage of reports mentioning how specimen was received		AHRQ	Exclusion	3	
Percentage of reports mentioning how specimen was identified		AHRQ	Exclusion	3	
Percentage of reports mentioning part of intestine included		AHRQ	Exclusion	3	
Percentage of reports mentioning the tumour site		AHRQ	Exclusion	3	
Percentage of reports mentioning proximity of tumour to the nearest margin		AHRQ	Exclusion	3	
Percentage of reports mentioning macroscopic subtype		AHRQ	Exclusion	3	
Percentage of reports mentioning tumour dimensions		AHRQ	Exclusion	3	
Percentage of reports mentioning macroscopic depth of penetration		AHRQ	Exclusion	3	
Percentage of reports mentioning appearance of serosa adjacent to the tumour		AHRQ	Exclusion	3	
Percentage of reports mentioning appearance of residual bowel		AHRQ	Exclusion	3	
Percentage of reports mentioning histological features including histologic type and grade		AHRQ	Exclusion	3	
Percentage of reports mentioning depth of infiltration		AHRQ	Exclusion	3	
Percentage of reports mentioning lymph node metastases		AHRQ	Exclusion	3	
Percentage of reports mentioning involvement of margins		AHRQ	Exclusion	3	
Colonoscopy miss rate for significant colonic neoplasia		AHRQ	Not rectal		
Percentage of stage III colon cancer patients receiving surgery and chemotherapy		AHRQ	Not rectal		
Percentage of colon cancer patients (stages specified as 0-III or I-II or II & III) who underwent surgery		AHRQ	Not rectal		
Percentage of patients with stage III colon cancer receiving adjuvant chemotherapy		AHRQ	Not rectal		
Percentage of colon cancer cases who receive followup colonoscopy within 36 months of surgical treatment		AHRQ	Not rectal		
Rate of appropriate primary therapy for CRC as defined by the NCI guidelines		AHRQ	Irrelevant		
Metastastectomy rate for rectal cancer		AHRQ	Irrelevant		
Rate of unplanned reversal of sedation medication		AHRQ	Irrelevant		
Percentage of patients with positive FOBT who underwent an appropriate evaluation.		AHRQ	Irrelevant		
Adenoma removal rate for patients over 50 years old		AHRQ	Irrelevant		
Percentage of patients with an adequate understanding of the colonoscopy procedure		AHRQ	Irrelevant		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
Percentage of patients with stage II or III rectal cancer receiving chemoradiotherapy		AHRQ	Duplicate		
Relative three-year survival for patients diagnosed with colorectal cancer	General	CIST	Inclusion	1	1112
Proportion of patients who have undergone colon or rectal cancer surgery whose pathology report includes margin status (distal, radial)	Pathology	Gagliardi	Inclusion	2	1273, 1275
Proportion of patients who have undergone colon or rectal cancer surgery whose pathology report indicates number of lymph nodes examined and the number of positive lymph nodes	Pathology	Gagliardi	Inclusion	2	1274
5-yr and adjusted 5-yr overall survival rate for rectal cancer by stage and for colon cancer by stage	General	Gagliardi	Inclusion	1	1111
Rate of local recurrence for patients who have had rectal cancer surgery, by stage, and for patients who have had colon cancer surgery, by stage	General	Gagliardi	Inclusion	1	1113
Proportion of patients with known or suspected rectal cancer who see a radiation oncologist preoperatively or whose cancer is stage II or III and see a radiation oncologist within 8 wk of surgery	General, neoadjuvant, adjuvant	Gagliardi	Inclusion	1,2	1114, 1221, 1222, 1242
Proportion of patients with rectal cancer who see a medical oncologist preoperatively or whose cancer is stage II or III and see a medical oncologist within 8 wk of surgery	General, neoadjuvant, adjuvant	Gagliardi	Inclusion	1,2	1114, 1223, 1241
Proportion of patients undergoing surgery for colon or rectal cancer who have preoperative imaging of the liver with ultrasonography, CT or MRI	Staging	Gagliardi	Inclusion	2	1212
Proportion of patients undergoing surgery for colon or rectal cancer who have preoperative complete large-bowel imaging (colonoscopy or barium enema plus sigmoidoscopy) 3 mo before surgery or within 6 mo after surgery	Staging	Gagliardi	Inclusion	2	1214
Proportion of patients undergoing surgery for rectal cancer who have preoperative imaging of the pelvis with CT, MRI and/or TRUS	Staging	Gagliardi	Inclusion	2	1215
Proportion of patients with rectal cancer undergoing surgery with a positive distal margin	Surgery	Gagliardi	Inclusion	2	1231
Proportion of patients undergoing surgery for rectal cancer who experience an anastomotic leak	Surgery	Gagliardi	Inclusion	2	1233
Proportion of in-hospital mortality or mortality within 30 d of nonemergent colon or rectal cancer surgery	Surgery	Gagliardi	Inclusion	2	1234
Proportion of patients who have undergone rectal cancer surgery whose operative report includes mention of total mesorectal type dissection, location of tumour, extent of resection (en bloc removal and margins), degree of nerve preservation, extent of lymphadenectomy		Gagliardi	Exclusion	3	
Proportion of patients with colon cancer who undergo surveillance colonoscopy within 1 yr after surgery		Gagliardi	Not rectal		
Proportion of colon and rectal carcinomas detected by screening		Gagliardi	Irrelevant		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient is undergoing rectal cancer surgery and preoperative workup suggests stage IV disease, THEN in addition to the surgeon the patient should be evaluated preoperatively by: (a) medical oncologist (b) radiation oncologist (c) multidisciplinary tumour board (d) a and b, or c	General	McGory	Inclusion	1	1114
IF a patient is undergoing rectal cancer surgery and preoperative workup suggests stage II–III disease, THEN in addition to the surgeon the patient should be evaluated preoperatively by: (a) medical oncologist (b) radiation oncologist (c) multidisciplinary tumour board (d) a and b, or c	General, neoadjuvant, adjuvant	McGory	Inclusion	1,2	1114, 1221, 1222, 1223, 1241, 1242
IF a patient undergoes colorectal cancer surgery and <12 lymph nodes are obtained, THEN the patient should be referred to a medical oncologist	General, adjuvant	McGory	Inclusion	1,2	1114, 1241, 1242
IF a patient undergoes colorectal cancer surgery and has a tumour requiring chemotherapy, THEN the patient should be offered referral to a medical oncologist	General, adjuvant	McGory	Inclusion	1,2	1114, 1241
IF a patient undergoes colorectal cancer surgery and has a tumour requiring radiation therapy, THEN the patient should be offered referral to a radiation oncologist	General, adjuvant	McGory	Inclusion	1,2	1114, 1242
IF a patient undergoes colorectal cancer surgery and the surgical treatment is completed, THEN there should be documentation of who will perform colorectal cancer surveillance	General	McGory	Inclusion	1	1114
IF a patient is undergoing rectal cancer surgery, THEN the tumour location relative to the anal sphincters must be determined and documented before surgery (or before neoadjuvant therapy, if given) by the: (a) operating surgeon	Staging	McGory	Inclusion	2	1211
IF a patient is undergoing rectal cancer surgery and receives neoadjuvant therapy, THEN the tumour location relative to the anal sphincters must be determined and documented in the period after neoadjuvant therapy and before surgery by the: (a) operating surgeon	Staging	McGory	Inclusion	2	1211
IF a patient is undergoing colorectal cancer surgery without neoadjuvant therapy, THEN a carcinoembryonic antigen (CEA) level should be obtained preoperatively (between diagnosis and surgery)	Staging	McGory	Inclusion	2	1213

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient is undergoing colorectal cancer surgery with neoadjuvant therapy, THEN a CEA level should be obtained preoperatively: (a) before neoadjuvant therapy	Staging	McGory	Inclusion	2	1213
IF a patient is undergoing colorectal cancer surgery, THEN a total colonic examination should be performed preoperatively between 12 mo before initiation of treatment OR 12 mo after surgery OR document reason why not performed	Staging	McGory	Inclusion	2	1214
IF a patient is undergoing rectal cancer surgery, THEN imaging of the abdomen/pelvis with CT or MRI should be performed	Staging	McGory	Inclusion	2	1215
IF a patient is undergoing rectal cancer surgery and receives neoadjuvant therapy, THEN imaging of the abdomen/pelvis with CT or MRI should be performed: (a) before neoadjuvant therapy	Staging	McGory	Inclusion	2	1215
IF a patient is undergoing rectal cancer surgery, THEN the depth of tumour invasion should be evaluated preoperatively or preneoadjuvant therapy (if neoadjuvant given)	Staging	McGory	Inclusion	2	1215
IF a patient is undergoing rectal cancer surgery and CT does not show obvious wall invasion, THEN the depth of tumour invasion should be performed preoperatively or preneoadjuvant therapy (if neoadjuvant given) by the following: (a) TRUS or EUS (b) MRI (d) a or b (but not c)	Staging	McGory	Inclusion	2	1215
IF a patient is undergoing rectal cancer surgery, THEN the characterization of perirectal lymph nodes should be performed preoperatively or preneoadjuvant therapy (if neoadjuvant given)	Staging	McGory	Inclusion	2	1215
IF a patient is undergoing rectal cancer surgery, THEN the characterization of perirectal lymph nodes should be performed preoperatively or preneoadjuvant therapy (if neoadjuvant given) by the following: (a) TRUS or EUS (b) MRI (e) a or b	Staging	McGory	Inclusion	2	1215
IF a patient is diagnosed with colorectal cancer, THEN treatment should be initiated within 10 weeks after biopsy or 6 weeks after seeing the surgeon for consultation or documented why performed later	Staging	McGory	Inclusion	2	1217
IF a patient undergoes rectal cancer surgery, THEN the distal margin should be documented in the operative report and be: (a) at least 1 cm	Surgery	McGory	Inclusion	2	1231

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient undergoes colorectal cancer surgery, THEN the completeness of resection should be documented in the operative report	Surgery	McGory	Inclusion	2	1231
IF a patient undergoes rectal cancer surgery for a mid or high rectal tumour, THEN the following procedure should be performed: (b) tumour-specific mesorectal excision (with at least a 2-cm margin mesentery)	Surgery, pathology	McGory	Inclusion	2	1231, 1272
IF a patient undergoes rectal cancer surgery for a low rectal tumour, THEN a total mesorectal excision should be performed	Surgery, pathology	McGory	Inclusion	2	1231, 1272
IF a patient undergoes rectal cancer surgery and the radial/circumferential margin is grossly positive, THEN the reason should be documented	Surgery	McGory	Inclusion	2	1231
IF a patient undergoes colorectal cancer surgery and <12 lymph nodes are obtained, THEN the pathologist should be asked to look again	Pathology	McGory	Inclusion	2	1274
IF a patient undergoes colorectal cancer surgery, THEN the surgeon should document details of the pathology report including TNM stage, number of lymph nodes obtained, and margin status	Pathology	McGory	Inclusion	2	1274
IF a patient is undergoing colorectal cancer surgery, THEN a history of present illness should be documented before operation including: (a) presenting symptoms (b) diagnostic tests and results (c) receipt of neoadjuvant therapy (for rectal cancer), with date of completion		McGory	Exclusion	3	
IF a patient is undergoing rectal cancer surgery, THEN a history of current functional status should be documented before operation including: (a) bowel function (c) sexual function in males (d) urinary function		McGory	Exclusion	3	

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient is undergoing colorectal cancer surgery, THEN the following additional history should be documented before operation including the following: (a) past medical history (including presence or absence of cardiac disease, pulmonary disease, and diabetes) (b) past surgical history (c) medications/allergies (including most recent list of outpatient medications and dosages) (d) tobacco use (current or previous smoker) (e) alcohol use (g) any family history of cancer (h) if family history of cancer positive, then include details of cancer history, age of patients, and type of cancer (i) evaluation for bleeding disorders		McGory	Exclusion	3	
IF a patient undergoes laparoscopic rectal cancer surgery, THEN to be credentialed for these procedures the operating surgeon must have completed five open rectal cancer cases and: (a) credentialing criteria for laparoscopic colon cancer surgery		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery and a liver lesion suspicious for metastatic disease is present, THEN the lesion should be biopsied or a reason provided for not performing the biopsy		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery and has tumour adherent to local structures, THEN en bloc resection should be performed		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery and en bloc resection is performed, THEN the surgeon should document (in the operative report) the specimen margins by the following method: (a) gross evaluation		McGory	Exclusion	3	
IF a patient is undergoing laparoscopic colorectal cancer surgery, THEN the tumour site should be tattooed preoperatively if radiologic localization not performed for the following: (a) all tumours		McGory	Exclusion	3	
IF a patient is undergoing colorectal cancer surgery, THEN a digital rectal examination by the operating surgeon must be performed and documented before surgery		McGory	Exclusion	3	
IF a patient is undergoing colorectal cancer surgery and had a diagnostic endoscopy performed by another provider, THEN there should be a note describing the details of the endoscopy including the following: (a) location (b) size of tumour — includes descriptive terms (e.g., small, medium, large, circumferential) or measured size		McGory	Exclusion	3	

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient is undergoing colorectal cancer surgery and had a biopsy specimen that was obtained preoperatively, THEN the surgeon should review and document the results		McGory	Exclusion	3	
IF a patient is undergoing colorectal cancer surgery and has a total colonic examination before surgery, THEN adequacy of the examination should be documented		McGory	Exclusion	3	
IF a patient is undergoing rectal cancer surgery and creation of an ostomy is planned, THEN location of the ostomy should be marked preoperatively		McGory	Exclusion	3	
IF a patient is undergoing colorectal cancer surgery, THEN the following issues should be discussed and documented by the surgeon in the medical record: (a) treatment options with patient's priorities and preferences (including operative and nonoperative alternatives) (b) operative risks, including complications and mortality (c) functional outcome, including period of disability, time to resume normal function, likelihood of better or worse function, and ostomy issues (if appropriate) (d) advance directive or living will (e) advance directive or durable power of attorney for health care indicating the patient's surrogate decision maker (f) need for possible chemotherapy or radiation (if appropriate)		McGory	Exclusion	3	
IF a patient is undergoing rectal cancer surgery for a tumour that is a distal, T1, and well differentiated without lymphovascular invasion, THEN a transanal local excision should be discussed including possible role of adjuvant therapy		McGory	Exclusion	3	
IF a patient is undergoing colorectal cancer surgery and requires a mechanical bowel preparation, THEN the patient should be admitted for the mechanical bowel preparation if they have no social support at home and have any of the following: (c) inability to ambulate		McGory	Exclusion	3	
IF a patient is undergoing colorectal cancer surgery, THEN intravenous antibiotic prophylaxis should be given within 1 h of surgical incision		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery, THEN intravenous antibiotic prophylaxis should be discontinued within 24 h postoperatively		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery, THEN postoperative deep venous thrombosis prophylaxis should be provided with low-dose unfractionated heparin or low–molecular weight heparin, in addition to mechanical prophylaxis (intermittent pneumatic compression and/or graduated compression stockings) according to the Seventh ACCP Conference on Antithrombotic Therapy		McGory	Exclusion	3	

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient undergoes colorectal cancer surgery, THEN the abdomen should be explored (or reason exploration could not be done documented) including the following: (a) liver (b) peritoneal lining (h) ovaries and uterus (if present)		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery and there is known tumour left behind (i.e., the primary), THEN the location should be marked with a radio-opaque guide (e.g., surgical clips)		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery, THEN the surgeon should discuss the final pathology with the patient and document discussion in chart		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery and follows up with the surgeon, THEN the functional status should be assessed at least once in the first year after surgery including the following: (a) bowel function (b) sexual function in males (d) urinary function in males		McGory	Exclusion	3	
IF a patient undergoes colorectal cancer surgery, THEN the following should be performed before skin incision: (a) time-out		McGory	Technical		
IF a patient undergoes colorectal cancer surgery and requires the lithotomy position, THEN proper positioning of the lower extremities should be performed and documented		McGory	Technical		
IF a patient undergoes rectal cancer surgery, THEN the ureter(s) should be identified intraoperatively including the following: (b) both ureters		McGory	Technical		
IF a patient undergoes colorectal cancer surgery, THEN ureteral stents should be placed preoperatively for the following: (b) recurrent rectal tumours (f) presence of ureteral obstruction and/or hydronephrosis		McGory	Technical		
IF a patient undergoes laparoscopic colorectal cancer surgery and the ipsilateral ureter is not identified, THEN the case should be converted to open (b) left-sided procedure		McGory	Technical		
IF a patient undergoes colorectal cancer surgery, THEN ligation of major vessels (at their origin) to the specimen should be performed and documented, including naming the major vessels ligated (i.e., ileocolic, right colic branch of midcolic, left colic, sigmoid vessels)		McGory	Technical		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient undergoes colorectal cancer surgery and an iatrogenic perforation occurs, THEN this should be documented in the operative report		McGory	Technical		
IF a patient undergoes colorectal cancer surgery that involves the transverse colon, THEN the omentum of the resected colon should be removed		McGory	Technical		
IF a patient undergoes laparoscopic colorectal cancer surgery, THEN intracorporeal ligation of the vessels should be performed (b) left-sided procedure		McGory	Technical		
IF a patient undergoes laparoscopic colorectal cancer surgery, THEN the following should be used to remove the specimen: (a) wound protector (b) specimen bag (c) either of the above		McGory	Technical		
IF a patient undergoes laparoscopic colorectal cancer surgery, THEN the fascial layer should be closed for all bladed trocar sites 10 mm or larger		McGory	Technical		
IF a patient undergoes colorectal cancer surgery, THEN a correct lap/instrument count should be documented or an intraoperative plain film should show no retained lap/instruments		McGory	Technical		
IF a patient is undergoing colorectal cancer surgery and the patient is not anemic, THEN the following should be performed preoperatively: (b) type and screen in rectal cancer		McGory	Technical		
IF a patient undergoes rectal cancer surgery with a low rectal–coloanal anastomosis and no defunctioning stoma, THEN the anastomosis should be tested intraoperatively		McGory	Technical		
IF a patient undergoes laparoscopic colon cancer surgery, THEN to be credentialed for these procedures the operating surgeon must have completed: (a) experience in 20 laparoscopic colon resections during training (b) 20 proctored laparoscopic colon resection cases (c) 20 laparoscopic colon cases for benign disease (f) a, b, or c		McGory	Not rectal		
IF a patient undergoes laparoscopic colon cancer surgery, THEN the surgeon should complete a minimum annual volume of these cases: (b) at least 12		McGory	Not rectal		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient is undergoing colon cancer surgery, THEN a history of current functional status should be documented before operation including: (a) bowel function		McGory	Not rectal		
IF a patient is undergoing colon cancer surgery and preoperative workup suggests metastatic disease, THEN in addition to the surgeon the patient should be offered evaluation preoperatively by: (a) medical oncologist		McGory	Not rectal		
IF a patient undergoes colon cancer surgery, THEN the ureter(s) should be identified intraoperatively including the following: (b) on side where the lesion is located during left-sided procedure		McGory	Not rectal		
IF a patient undergoes colon cancer surgery (specifically hemicolectomy) and the procedure is started laparoscopically, THEN the procedure should be completed in <6 h even if converted to an open approach		McGory	Not rectal		
IF a patient is undergoing colorectal cancer surgery and meets Amsterdam I or II criteria, THEN genetic counseling should be recommended		McGory	Irrelevant		
IF a patient is undergoing colorectal cancer surgery and genetic testing is positive, THEN the following should be performed: (a) discussion of subtotal colectomy with males and females (b) discussion of hysterectomy and oophorectomy with females (c) discussion regarding follow-up surveillance for other cancers		McGory	Irrelevant		
IF a patient undergoes colorectal cancer surgery that is in the rectosigmoid area, THEN the surgeon should specify whether the tumour should be treated as a colon versus a rectal cancer		McGory	Irrelevant		
IF a patient is undergoing colorectal cancer surgery, THEN a panel of preoperative studies should be performed within 8 weeks before surgery and the results documented in the chart. The panel should include: (a) hemoglobin or hematocrit (c) platelet count (e) electrolytes (Na, K, Cl, CO 2 , glucose) (g) renal function (blood urea nitrogen, Cr) (k) chest radiograph (l) height and weight		McGory	Aspecific		
IF a patient is undergoing colorectal cancer surgery, THEN there should be documentation of cardiac evaluation performed, if necessary		McGory	Aspecific		
IF a patient is undergoing colorectal cancer surgery, THEN in addition to the surgeon, a baseline preoperative risk assessment should be obtained by:		McGory	Aspecific		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
(b) anesthesiologist or equivalent					
IF a patient who smokes is undergoing colorectal cancer surgery, THEN the patient should be encouraged to stop smoking and the discussion documented in the chart		McGory	Aspecific		
IF a patient is undergoing colorectal cancer surgery and has valvular or congenital heart disease, an intracardiac valvular prosthesis, hypertrophic cardiomyopathy, mitral valve prolapse with regurgitation, or a previous episode of endocarditis, THEN endocarditis prophylaxis should be given		McGory	Aspecific		
IF a patient is undergoing colorectal cancer surgery and meets criteria for perioperative beta blockade, THEN unless contraindicated, beta blocker therapy should be initiated before surgery		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and meets criteria for perioperative beta blockade, THEN unless contraindicated, beta blocker therapy should be continued postoperatively at least until discharge from the hospital		McGory	Aspecific		
IF a patient is undergoing colorectal cancer surgery and is taking one of the following classes of medications, THEN specific instructions regarding preoperative management of the following classes of medications should be given to the patient: (a) antiplatelet medications (b) diabetes medications (c) cardiovascular medications		McGory	Aspecific		
IF a patient taking warfarin is undergoing colorectal cancer surgery, THEN withdrawal of warfarin before surgery should be managed according to recommendations from the Seventh ACCP Conference on Antithrombotic Therapy		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery, THEN a nasogastric tube should not be used postoperatively, unless the patient has signs/symptoms of obstruction		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery, THEN the patient's fluid status needs to be monitored while the patient is receiving intravenous fluids: (a) daily input and output (b) daily weights		McGory	Aspecific		
IF a patient with diabetes undergoes colorectal cancer surgery, THEN postoperative blood glucose control should be monitored at least daily and if >150 then treatment should be initiated		McGory	Aspecific		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient undergoes colorectal cancer surgery, THEN pain assessments should be performed and documented with each set of vital signs		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and was able to ambulate preoperatively, THEN ambulation should be performed within 2 days after surgery, or documented why the patient cannot ambulate		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and cannot ambulate by postoperative day 2, THEN mobilization should be performed by postoperative day 2, or documented why the patient cannot be mobilized		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and is discharged home and was able to ambulate preoperatively, THEN the patient should be able to ambulate before discharge OR the reason why the patient is unable to ambulate is addressed and a treatment plan outlined		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and has a new fever (greater than 38.5 °C) after postoperative day 2, THEN evaluation of the wound(s) should be documented including erythema, warmth, and presence of drainage		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and has a new fever (greater than 38.5 °C) after postoperative day 2 and there is no obvious source of infection, THEN the following should be performed within 8 h (unless fever workup completed within the past 24 h): (f) history and physical examination linked to the fever		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery and has a foley catheter placed during the operation, THEN the catheter should be removed (or documented why not removed) by postoperative day 5		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery, THEN the patient should be able to tolerate an adequate diet before discharge		McGory	Aspecific		
IF a patient undergoes colorectal cancer surgery, THEN pain should be controlled with oral or other nonparenteral medications before discharge		McGory	Aspecific		
IF a patient has a stage II or III rectal cancer, THEN the patient should have received neoadjuvant chemotherapy or adjuvant chemotherapy with a regimen listed in the associated table or was in a clinical trial	Neoadjuvant, adjuvant	NICCQ	Inclusion	2	1223, 1241
IF a patient has stage II or III rectal cancer, THEN the patient should receive radiation therapy either before definitive surgical excision OR after definitive surgical excision	Neoadjuvant, adjuvant	NICCQ	Inclusion	2	1221, 1222, 1242
IF a patient has stage II or III rectal cancer and received radiation therapy, THEN the patient should receive radiation (25 Gy total dose or greater) therapy either before definitive surgical excision OR after definitive surgical excision	Neoadjuvant, adjuvant	NICCQ	Inclusion	2	1221, 1222, 1242
IF a patient has stage II or III rectal cancer, THEN the patient should have a consultation with a radiation oncologist	General, neoadjuvant, adjuvant	NICCQ	Inclusion	1,2	1114, 1221, 1222, 1242

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient has a malignant rectal tumour excised, THEN a medical record should state the distance from the anal verge	Staging	NICCQ	Inclusion	2	1211
IF a patient has surgical excision of a malignant colorectal tumour, THEN the patient should have colonoscopy or barium enema to assess for the presence of synchronous tumours or polyps between 6 months before and 16 weeks after the surgical excision	Staging	NICCQ	Inclusion	2	1214
IF a patient has a malignant rectal tumour and undergoes transrectal ultrasound, THEN the transrectal ultrasound should occur before radiotherapy	Staging	NICCQ	Inclusion	2	1215
IF a patient has a stage II or III rectal cancer and received chemotherapy, THEN the patient should start chemotherapy within 8 weeks of first positive biopsy OR within 8 weeks of surgical resection	Adjuvant	NICCQ	Inclusion	2	1243
IF a patient has a malignant tumour of the colon or rectum excised, THEN the pathology report should state whether or not the tumour involves lymph nodes	Pathology	NICCQ	Inclusion	2	1274
IF a patient has a malignant tumour of the colon or rectum excised, THEN there should be evidence that a lymphadenectomy was performed		NICCQ	Exclusion	3	
IF a patient has primary rectal cancer and does not have a T4 tumour OR a documented intraoperative complication that led to premature termination of the operation, THEN the surgical pathology report should document that the radial margin of the surgical specimen is free of tumour		NICCQ	Exclusion	3	
IF the patient receives a diverting ileostomy or colostomy, THEN the patient should receive enterostomy care and management instructions before discharge or receive a home healthcare follow-up		NICCQ	Exclusion	3	
IF a patient has a malignant rectal tumour and undergoes transrectal ultrasound, THEN the ultrasound report should state the depth of invasion of the tumour		NICCQ	Exclusion	3	
IF a patient has malignant tumour of the colon or rectal cancer and has the malignant tumour excised and is seen in consultation by a medical oncologist, THEN the medical oncologist's medical records should document at least one of the following: 1. AJCC stage or TNM stage OR 2. Nodal status and, if lymph nodes negative, the depth of invasion		NICCQ	Exclusion	3	

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient has a malignant tumour of the colon or rectum surgically excised and is seen in consultation by a radiation oncologist, THEN the radiation oncologist's medical record should document at least one of the following: 1. AJCC stage or TNM stage OR 2. Nodal status and, if lymph nodes negative, the depth of invasion size and lymph node status		NICCQ	Exclusion	3	
IF a patient is treated with chemotherapy, THEN the planned dose (dose per cycle x number of cycles) should be documented in the medical oncology or integrated record		NICCQ	Exclusion	3	
IF a patient is treated with chemotherapy, THEN the planned dose (dose per cycle x number of cycles) should fall within a range that is consistent with published regimens		NICCQ	Exclusion	3	
IF a patient is treated with chemotherapy, THEN body-surface area should be documented		NICCQ	Exclusion	3	
IF a patient has a malignant tumour of the colon or rectum excised, THEN the pathology report should state the depth of invasion of the tumour		NICCQ	Exclusion	3	
IF a patient has a malignant rectal tumour excised, THEN the pathology report should state the presence or absence of lymphovascular invasion		NICCQ	Exclusion	3	
IF a patient has a malignant rectal tumour excised, THEN the pathology report should comment on the presence or absence of microscopic tumour cells at the resection margin		NICCQ	Exclusion	3	
IF a patient has resection of a malignant tumour of the colon (but not rectum) and not a T4 lesion OR a documented intraoperative complication that led to premature termination of the operation, THEN the last pathology report associated with the resection should note that the margins of the operative specimen should be free of tumour		NICCQ	Not rectal		
IF a patient has stage II colon cancer features that increase the risk of recurrence (obstruction, perforation, or T4 lesions) or stage III colon cancer, THEN the patient should receive adjuvant chemotherapy with a regimen listed in Table A or was in a clinical trial		NICCQ	Not rectal		

Quality indicator	Subdiscipline(s)	Source	Ex/inclusion	Level	Final QI(s)
IF a patient has resection of a malignant tumour for stage II colon cancer with high risk for recurrence (obstruction, perforation, or T4 lesions) or stage III colon cancer and received chemotherapy, THEN the patient should start adjuvant chemotherapy within 8 weeks of surgical resection		NICCQ	Not rectal		
IF the patient has resection of stage II or III colon or rectal cancer, THEN the patient should be counseled about the need to have first-degree relatives undergo colorectal cancer screening		NICCQ	Irrelevant		

* The subdiscipline and related final QI is only provided for the included QI.

APPENDIX 2: ALGORITHMS OF SELECTED QUALITY INDICATORS

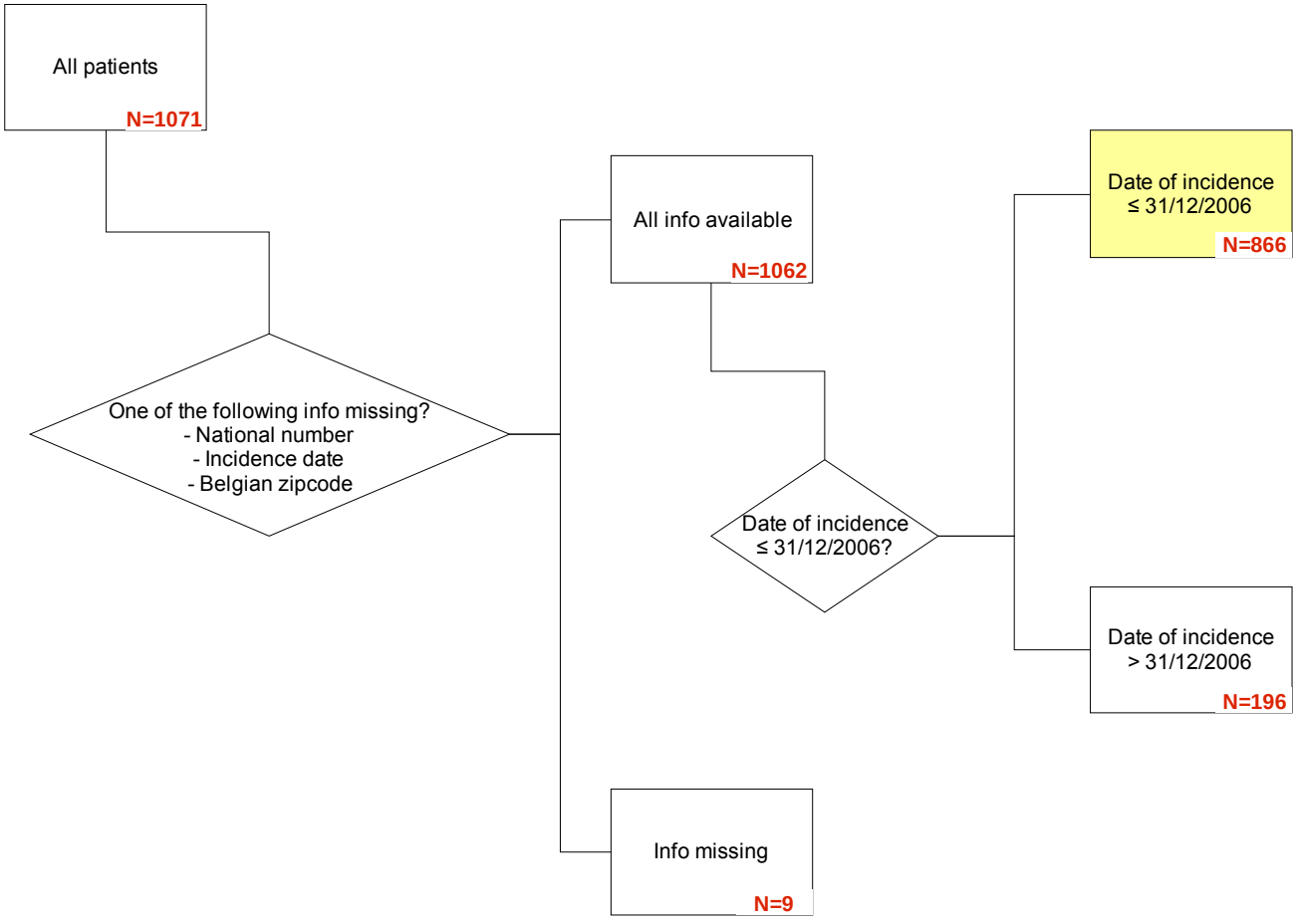
OVERALL 5-YEAR SURVIVAL AND DISEASE-SPECIFIC 5-YEAR SURVIVAL (FIGURE 21)

For the calculation of survival statistics, it is essential to include only those patients with a follow-up of the date of death. Mortality data are collected from the mortality database of the sickness funds, and are available until December 31st 2006 for the present study. Coupling with the PROCARE database is done using the social security number. Therefore, an accurate follow-up is only available for patients with a known social security number and Belgian postal code. Since no mortality data are available for patients with a private insurance, the survival is probably overestimated.

Above this, to calculate the survival period between the incidence date (see below for the definition of incidence date) and mortality date, it is of course essential to have the incidence date. Since mortality data are only available until December 31st 2006, patients with an incidence date after December 31st 2006 are excluded.

As explained in the scientific summary, the calculation of the disease-specific survival is impossible at present, and the relative survival (i.e. observed survival / expected survival) is calculated as a proxy. Expected survival rates were retrieved from the mortality tables of 2004 (http://statbel.fgov.be/pub/home_nl.asp#3) and were linked to the individual patient, taking into account age, gender and region.

Figure 21. Algorithm for QI 1111 - 1112 (PROCARE database).



PROPORTION OF PATIENTS WITH LOCAL RECURRENCE

Measurement in prospective PROCARE database (Figure 22)

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Variable 'SG_V216' permits the distinction between R0, R1 and R2 resections. However, the results of the pathology report and intra-operative tumour perforation are not taken into account in this variable.

Local recurrence is measured through variable 'FU_V139' in the follow-up section of the data entry form. However, since the PROCARE registration started in January 2006, follow-up data are only available for a minority of patients at present.

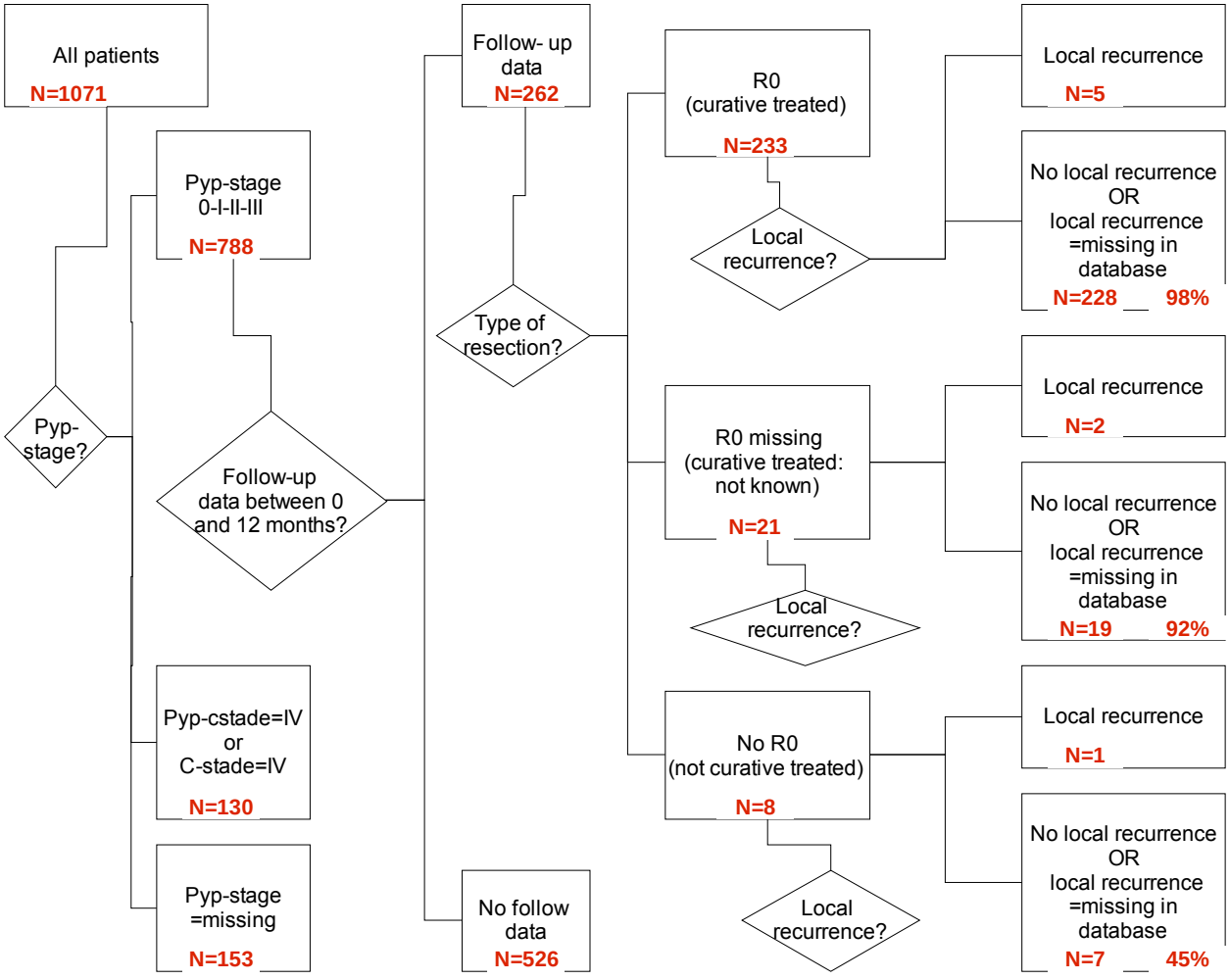
Up till now, the default value of variable 'FU_V139' was '0' (i.e. no local recurrence; however, missing values also received a value '0'), making it impossible to distinguish absence of local recurrence from missing values. However, in a random sample of 20 forms with a value '0' for variable 'FU_V139' only 1 missing value (5%) was found.

Variable 'FU_V102' encodes the date of each follow-up visit, permitting to add a time dimension to this QI. Since this follow-up visit is not at the same time for each patient, it is impossible to calculate an absolute local recurrence rate at 1 year after incidence date. Therefore, a Kaplan-Meier analysis was used.

Measurement in coupled administrative database

No administrative code exists for R0 resection or local recurrence.

Figure 22. Algorithm for QI 1113 (PROCARE database).



PROPORTION OF PATIENTS DISCUSSED AT A MULTIDISCIPLINARY TEAM (MDT) MEETING

Measurement in prospective PROCARE database

Discussion at the MDT is not registered in the PROCARE database.

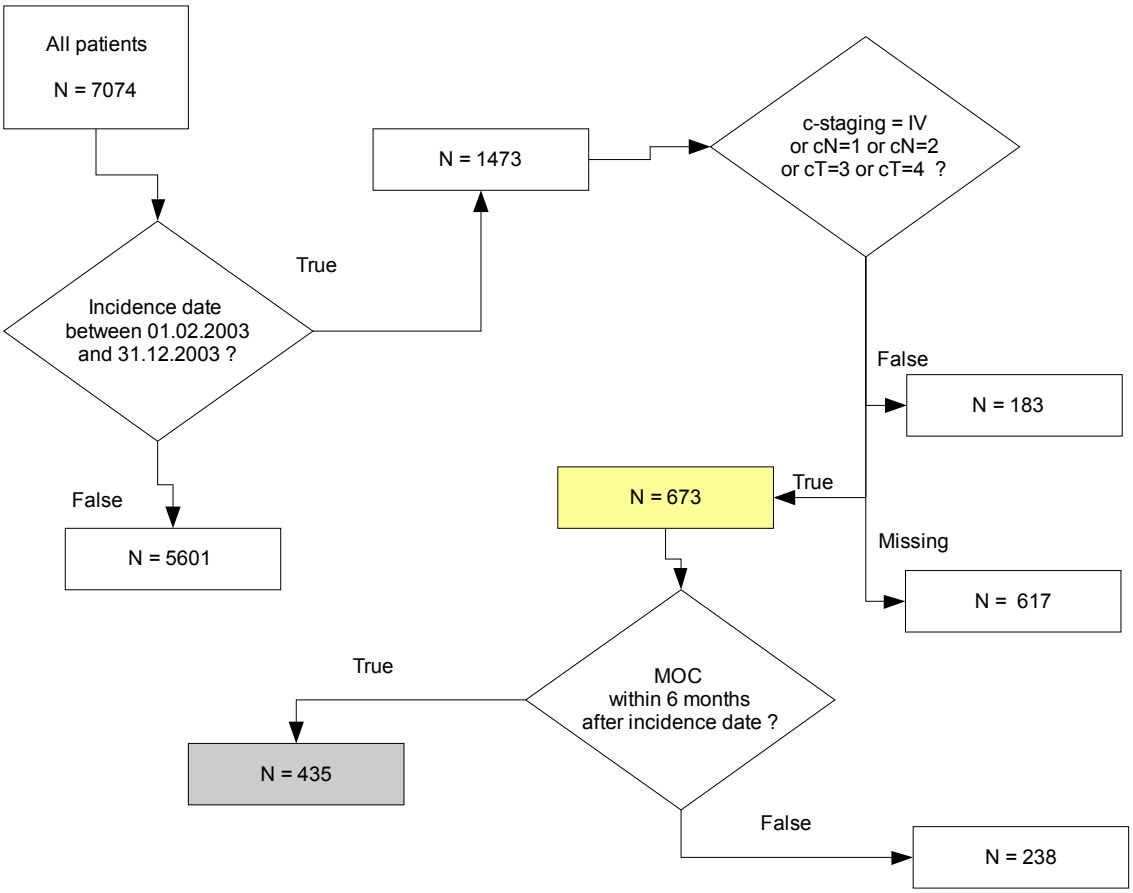
Measurement in coupled administrative database (Figure 23)

Specific nomenclature codes for a multidisciplinary oncologic consultation are available since February 1st 2003 (Table 61). Therefore, only RC patients diagnosed after February 1st 2003 were taken into account for the pilot testing of this QI. Above this, since the BCR data are incomplete for the year 2004, patients with an incidence date after June 30th 2004 are not considered. Since there is a possibility of more than one primary tumour (other than the rectal tumour) and in order to increase the likelihood that the MDT was linked to the rectal tumour, a timeframe of 6 months after the incidence date was chosen.

Table 61. Nomenclature codes for multidisciplinary oncologic consultation.

Nomenclature code	Description (Dutch)	Description (French)
350372 – 350383	Schriftelijk verslag van een multidisciplinair oncologisch consult met deelname van minstens drie geneesheren van verschillende specialismen onder leiding van een geneesheer-coördinator, met beschrijving van de diagnose en van het behandelingsplan	Rapport écrit d'une concertation oncologique multidisciplinaire avec la participation d'au moins trois médecins de spécialités différentes sous la direction d'un médecin-coordinateur et reprenant la description du diagnostic et du plan de traitement
350394 – 350405	Deelname aan multidisciplinair oncologisch consult	Participation à la concertation oncologique multidisciplinaire
350416 – 350420	Deelname aan multidisciplinair oncologisch consult door de behandelende arts die geen deel uitmaakt van de ziekenhuisstaf	Participation à la concertation oncologique multidisciplinaire par le médecin traitant qui n'est pas membre de l'équipe hospitalière

Figure 23. Algorithm for QI 1114 (administrative database).



PROPORTION OF PATIENTS WITH DOCUMENTED DISTANCE FROM THE ANAL VERGE

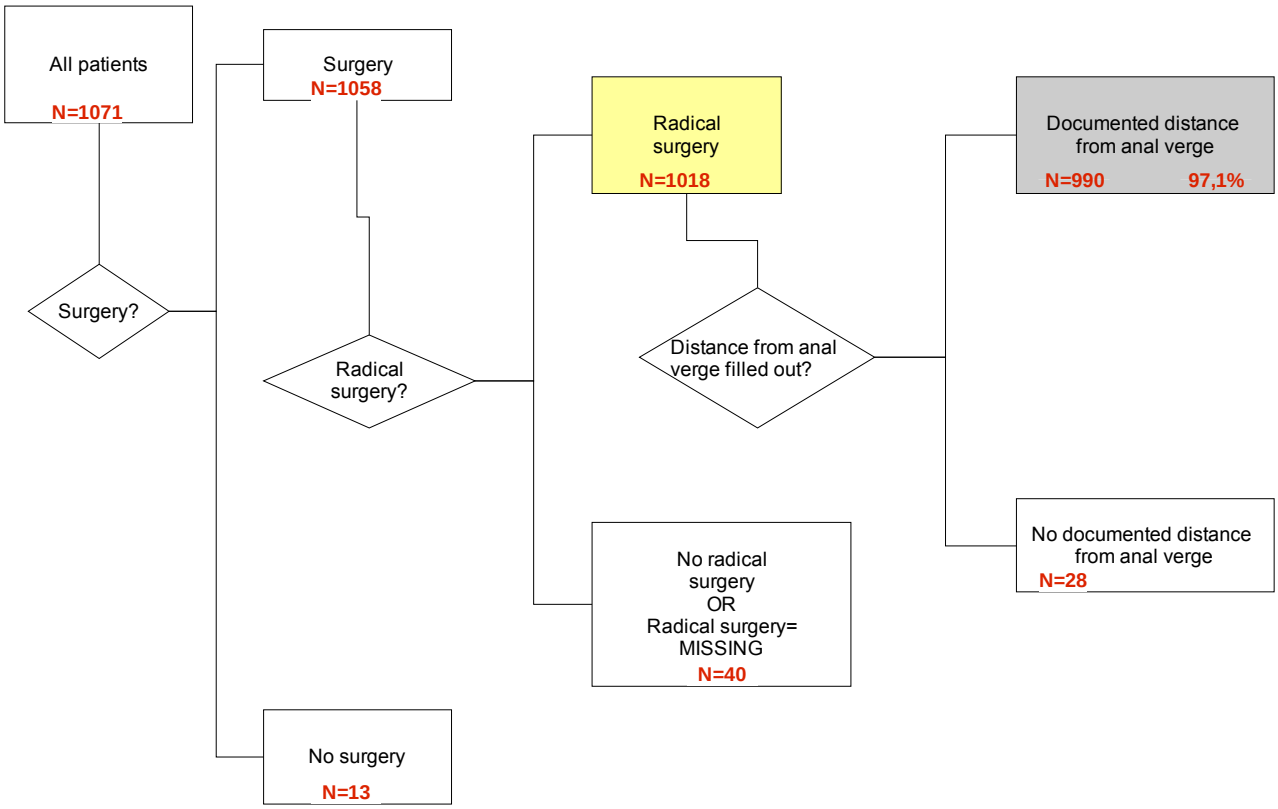
Measurement in prospective PROCARE database (Figure 24)

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Within this group of patients, those undergoing resection (i.e. endoscopic, LE/TEMS, radical resection) are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'. The distance from the anal verge is available from 3 variables: two before any treatment ('SPR_V110' and 'SPR_V112') and one at surgery ('SG_V110', which can have another value than the previous two variables because of neoadjuvant treatment). A fourth variable is available in the pathology section ('PT_V105'), but this was not used because it is often based on inaccurate information. Importantly, unavailability of the distance from the anal verge in the PROCARE dataset does not necessarily mean that the distance was not documented, but that the distance was not registered.

Measurement in coupled administrative database

No administrative code exists for the (documentation of the) distance from the anal verge.

Figure 24. Algorithm for QI 1211 (PROCARE database).



PROPORTION OF PATIENTS IN WHOM A CT OF THE LIVER AND CT OR RX OF THE THORAX WAS PERFORMED BEFORE ANY TREATMENT

Measurement in prospective PROCARE database

Variables 'SPR_V141' and 'SPR_V143' register the use of a CT scan or RX respectively for the determination of the cM stage. However, no specification is given for the anatomic region of the CT or RX. Therefore, this QI is not measurable.

Measurement in coupled administrative database (Figure 25)

A nomenclature code exists for the performance of a CT, however without specification of the anatomic region (Table 62). On the other hand, specific ICD-9-CM codes exist for CT of the abdomen (not liver!) and thorax (Table 63). However, these codes are only available from the Technical Cell database (see 3.1.2.2), which is a database of coupled hospital registration data (i.e. no information on ambulatory performance of these tests). Importantly, coding of these procedures is not obligatory. Therefore, using these codes causes an important underestimation of the frequency of these tests.

In order to identify if the imaging test was done before any treatment, the date of the first treatment (surgery, radiotherapy, chemotherapy) after diagnosis should be known (see algorithm). To identify if and when a patient underwent surgery, nomenclature codes (Table 64 and 65) or surgical ICD-9-CM codes (Table 66, 67 and 68) in combination with diagnostic ICD-9-CM codes (Table 69) were used. For radiotherapy, nomenclature codes were used (Table 70), since for only 12 patients ICD-9-CM codes related to radiotherapy (Table 71) were found. For chemotherapy, the CNK codes of the HIC database were used (Table 72). An important problem with the Technical Cell database is the absence of the exact date of the procedure.

Figure 25. Algorithm for QI 1212 (administrative database).

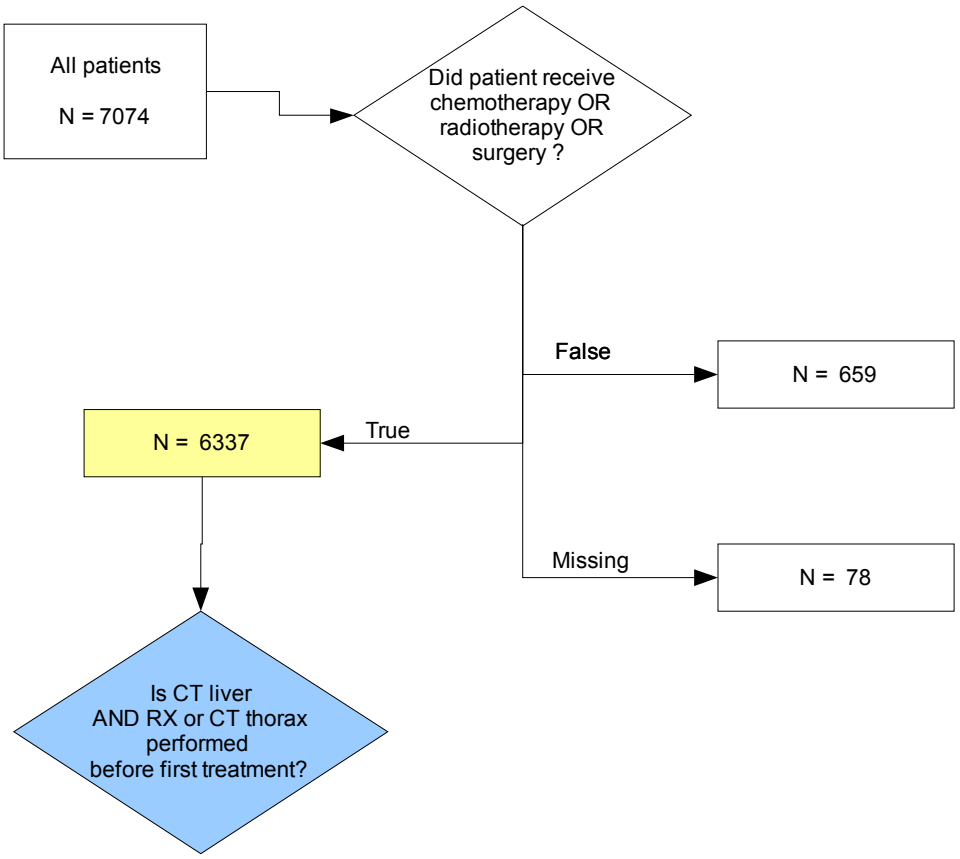


Table 62. Nomenclature codes for CT and for thorax X-ray.

Nomenclature code	Description (Dutch)	Description (French)
458813 – 458824	Computergestuurde tomografie van de hals (weke delen) of van de thorax of van het abdomen, met en/of zonder contrastmiddel, met registreren en clichés, minimum 15 coupes, voor het hele onderzoek	Tomographie commandée par ordinateur, du cou (parties molles) ou du thorax, ou de l'abdomen,avec et/ou sans moyen de contraste, avec enregistrement et clichés, 15 coupes au minimum, pour l'ensemble de l'examen
452690 – 452701	Radiografie van de thorax en de inhoud ervan, één cliché	Radiographie du thorax et de son contenu, un cliché
452712 – 452723	Radiografie van de thorax en de inhoud ervan, minimum twee clichés	Radiographie du thorax et de son contenu, minimum 2 clichés
463691 – 463702	Radiografie van de thorax en de inhoud ervan, één cliché	Radiographie du thorax et de son contenu, un cliché
463713 – 463724	Radiografie van de thorax en de inhoud ervan, minimum twee clichés	Radiographie du thorax et de son contenu, minimum 2 clichés

Table 63. ICD-9-CM codes for CT liver and thorax and for thorax X-ray.

Code	Description	Comments
87.41	C.A.T scan of thorax Crystal linea scan of x-ray beam of thorax Electronic substraction of thorax Photoelectric response of thorax Tomography with use of computer, x-rays, and camera of thorax	
88.01	C.A.T scan of abdomen *Excludes :* *C.A.T. scan of kidney (87.71)*	Not specific for CT liver
87.39	Other soft tissue x-ray of chest wall	
87.44	X-ray of chest NOS	
87.49	Other chest x-ray X-ray of: bronchus NOS diaphragm NOS heart NOS lung NOS mediastinum NOS trachea NOS	

Table 64. Nomenclature codes for resectional surgery.

Nomenclature code	Description (Dutch)	Description (French)
Abdominoperineal resection		
244016 – 244020	Abdomino-perineale amputatie van het rectum, inclusief de anastomose van de darm met de huid (type Miles)	Intervention type Miles
Hartmann's procedure		
244053 – 244064	Operatie van Hartmann	Opération de Hartmann
Sphincter-sparing surgery		
243036 – 243040	Totale colectomie met ileostomie of ileorectale anastomose	Colectomie totale avec iléostomie ou anastomose iléorectale
244031 – 244042	Anterior rectumresectie met behoud van de sfincter en colo-anale anastomose (type TME)	Résection antérieure du rectum avec conservation du sphincter et anastomose colo-anale (type TME)
244753 – 244764	Restauratieve proctocolectomie of colectomie met constructie van een ileumreservoir, aanleggen van een ileo-anale anastomose met of zonder een tijdelijke proximale ileostomie	Proctocolectomie ou colectomie de restauration avec construction d'un réservoir iléal, mise en place d'une anastomose iléo-anale et éventuelle iléostomie proximale temporaire
Local excision - TEMS		
244311 – 244322	Resectie, langs natuurlijke weg, van een tumour villosus uit rectum	Résection d'une tumeur villeuse du rectum par les voies naturelles

Table 65. Nomenclature codes for stoma surgery (placement).

Nomenclature code	Description (Dutch)	Description (French)
243176 – 243180	Terminale ileo- of colostomie	Iléo- ou colostomie terminale
243191 – 243202	Laterale ileo- of colostomie	Iléo- ou colostomie latérale

Table 66. Possible ICD-9-CM codes for resectional surgery.

Code	Description	Comment
Abdominoperineal resection		
48.5	Abdominoperineal resection of the rectum Includes : with synchronous colostomy Combined abdominoendorectal resection Complete proctectomy Code also any synchronous anastomosis other than end-to-end (45.90, 45.92-45.95) *Excludes :* *Duhamel abdominoperineal pull-through (48.65)* *that as part of pelvic exenteration (68.8)*	
Hartmann's procedure		
45.75	Left hemicolectomy *Excludes:* *proctosigmoidectomy (48.41-48.69)* *second stage Mikulicz operation (46.04)*	Not specific for Hartmann's procedure
Sphincter-sparing surgery		
45.95	Anastomosis to anus Formation of endorectal ileal pouch (H-pouch) (J-pouch) (S-pouch) with anastomosis of small intestine to anus	
48.62	Anterior resection of rectum with synchronous colostomy	
48.63	Other anterior resection of rectum *Excludes :* *that with synchronous colostomy (48.62)*	
48.64	Posterior resection of rectum	
Abdominoperineal resection or sphincter-sparing surgery		
48.6	Other resection of rectum Code also any synchronous anastomosis other than end-to-end (45.90, 45.92-45.95)	
48.61	Transsacral rectosigmoidectomy	
48.69	Other : Partial proctectomy Rectal resection NOS	
Local excision - TEMS		
48.35	Local excision of rectal lesion or tissue *Excludes :* *Biopsy of rectum (48.24 – 48.25)* *Excision of perirectal tissue (48.82)* *Hemorrhoidectomy (49.46)* *[endoscopic] polypectomy of rectum (48.36)* *rectal fistulectomy (48.73)*	
48.36	[Endoscopic] polypectomy of rectum	

Table 67. Possible ICD-9-CM codes for palliative surgery.

Code	Description	Comment
48.31	Radical electrocoagulation of rectal lesion or tissue	
48.32	Other electrocoagulation of rectal lesion or tissue	
48.33	Destruction of rectal lesion or tissue by laser	
48.34	Destruction of rectal lesion or tissue by cryosurgery	

Table 68. Possible ICD-9-CM codes for stoma surgery (placement).

Code	Description	Comment
46.0	Exteriorization of intestine Includes: loop enterostomy Multiple stage resection of intestine	
46.01	Exteriorization of small intestine Loop ileostomy	
46.02	Resection of exteriorized segment of small intestine	
46.03	Exteriorization of large intestine Exteriorization of intestine NOS First stage Mikulicz exteriorization of intestine Loop colostomy	
46.04	Resection of exteriorized segment of large intestine Resection of exteriorized segment of intestine NOS Second stage Mikulicz operation	
46.1	Colostomy : Code also any synchronous resection (45.49, 45.71-45.79, 45.8) *Excludes :* *Loop colostomy (46.03)* *that with abdominoperineal resection of rectum (48.5)* *that with synchronous anterior rectal resection (48.62)*	
46.10	Colostomy, not otherwise specified	
46.11	Temporary colostomy	
46.14	Delayed opening of colostomy	

Table 69. Possible diagnostic ICD-9-CM codes related to rectal cancer.

Code	Description	Comment
154.0	Rectosigmoid junction Colon with rectum Rectosigmoid (colon)	
154.1	Rectum Rectal ampulla	
154.2	Anal canal Anal sphincter *Excludes:* *skin of anus (172.5, 173.5)*	
154.8	Other Anorectum Cloacogenic zone Malignant neoplasm of contiguous or overlapping sites of rectum, rectosigmoid junction, and anus whose point of origin cannot be determined	

Table 70. Nomenclature codes for radiotherapy.

Nomenclature code	Description (Dutch)	Description (French)
440016 – 440020	Behandeling (één of meer lokalisaties) met hoge energie of gammatherapie (betatron, lineaire accelerator, telekobalt) : In een dienst die beschikt over telekobalt én een een simulator én een dosimetriesysteem met computer	Traitement (une ou plusieurs localisations) au moyen des hautes énergies ou de gammathérapie (bêtatron, accélérateur linéaire, télécobalt) : Dans un service disposant de télécobalt et d'un accélérateur et

Nomenclature code	Description (Dutch)	Description (French)
	(min 20 zittingen)	d'un simulateur et d'un système de dosimétrie avec ordinateur (min. 20 séances)
440053 – 440064	Behandeling (één of meer lokalisaties) met hoge energie of gammatherapie (betatron, lineaire accelerator, telekobalt) met maskers of individuele beschermingsmiddelen bij specifieke indicaties : In een dienst die beschikt over telekobalt én een een simulator én een dosimetriesysteem met computer (min 20 zittingen)	Traitement (une ou plusieurs localisations) au moyen des hautes énergies ou de gammathérapie (bêtatron, accélérateur linéaire, télécobalt) avec masques ou protections individuelles dans des indications spécifiques : Dans un service disposant de télécobalt et d'un accélérateur et d'un simulateur et d'un système de dosimétrie avec ordinateur (min. 20 séances)
444113 – 444124	Forfaitair honorarium voor een eenvoudige uitwendige bestralingsreeks van 1 tot 10 fracties voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 1 (zie KB 19APR2001)	Honoraires forfaitaires pour une série d'irradiations externes simples de 1 à 10 fractions chez un patient qui répond aux critères ou pathologie repris en catégorie 1
444135 – 444146	Forfaitair honorarium voor een eenvoudige uitwendige bestralingsreeks van 11 tot 35 fracties voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 2 (zie KB 19APR2001)	Honoraires forfaitaires pour une série d'irradiations externes simples de 11 à 35 fractions chez un patient qui répond aux critères ou pathologie repris en catégorie 2
444150 – 444161	Forfaitair honorarium voor een complexe uitwendige bestralingsreeks voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 3 (zie KB 19APR2001)	Honoraires forfaitaires pour une série d'irradiations externes complexes chez un patient qui répond aux critères ou pathologie repris en catégorie 3
444172 – 444183	Forfaitair honorarium voor een complexe uitwendige bestralingsreeks voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 4	Honoraires forfaitaires pour une série d'irradiations externes complexes chez un patient qui répond aux critères ou pathologie repris en catégorie 4
444216 – 444220	Forfaitair honorarium voor exclusieve curietherapie voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 7	Honoraires forfaitaires pour curiethérapie exclusive chez un patient qui répond aux critères ou pathologie repris en catégorie 7
444253 – 444264	Forfaitair honorarium voor exclusieve curietherapie voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 8	Honoraires forfaitaires pour curiethérapie exclusive chez un patient qui répond aux critères ou pathologie repris en catégorie 8
444290 – 444301	Forfaitair honorarium voor curietherapie gecombineerd met uitwendige bestralingsreeks voor een patiënt die beantwoordt aan de criteria of lijdt aan een aandoening opgenomen in categorie 5	Honoraires forfaitaires pour curiethérapie combinée à une série d'irradiations externes chez un patient qui répond aux critères ou pathologie repris en catégorie 5

Nomenclature code	Description (Dutch)	Description (French)
444592 – 444603	Individuele blokken bij een behandeling met uitwendige bestraling en/of curietherapie van patiënten van categorie 1, 2, 3, 4, 5, 6, 7 of 8, per bestralingsreeks	Blocs individualisés pour traitement par irradiation externe et/ou par curiethérapie des patients de catégorie 1, 2, 3, 4, 5, 6, 7 ou 8, par série d'irradiation

Table 71. Possible ICD-9-CM codes for radiotherapy.

Code	Description	Comment
92.21	Superficial radiation Contact radiation [up to 150 KVP]	
92.22	Orthovoltage radiation Deep radiation [200-300 KVP]	

Table 72. ATC, CNK and RIZIV/INAMI codes for chemotherapeutic substances, relevant to rectal cancer.

Substance name	ATC code	CNK public	CNK amb and hosp	RIZIV/INAMI code
5-fluorouracil				
Efudix	L01BC02	38521	706044	00126100
Fluorouracil amp 5x250mg/10ml	L01BC02	42184	707521	
Fluorouracil amp 10x250mg/10ml	L01BC02	42200	707521	
Fluorouracil oncovial 1x2500mg/50ml	L01BC02	1745223	772814	00426291
Fluorouracil Vial 1x100ml 25mg/ml	L01BC02	1149996	742080	00135901
Fluorouracil Vial 5x10ml 25mg/ml	L01BC02	1149970	742098	00135796
Fluorouracil Vial 5x20ml 25mg/ml	L01BC02	1149988	742106	00135800
Fluorouracil Vial Inj 1x500mg/20ml	L01BC02	497511	736843	
Fluorouracil Vial Inj 5x250mg/10ml	L01BC02	497529	736835	
Fluracedyl Fl Inj 1x5ml 50mg/ml	L01BC02	1173764	742783	
Fluracedyl Fl Inj 1x10ml 50mg/ml	L01BC02	1173772	742791	
Fluracedyl Fl Inj 1x100ml 50mg/ml	L01BC02	1458710	762476	00053651
Fluracedyl Fl Inj 1x20ml 50mg/ml	L01BC02	1173780	742775	00053449
Fluroblastine Fl IV Perf 1g/20ml	L01BC02	1360429	746891	00076586
Fluroblastine Fl IV Perf 250mg/5ml	L01BC02	1360411	746883	
Fluroblastine Fl IV Perf 500mg/10ml	L01BC02	615229	731273	00076687
Campto				
Campto Fl Sol Inj Perf 1x40mg/2ml	L01XX19	1310382	760496	00229160
Campto Fl Sol Inj Perf 1x100mg/5ml	L01XX19	1310374	760504	00229059
Eloxatin				
Eloxatin Pulv Sol IV 5mg/ml	L01XA03	1537828	767244	0026223

Substance name	ATC code	CNK public	CNK amb and hosp	RIZIV/INAMI code
100mg				
Eloxatin Pulv Sol IV 5mg/ml 50mg	L01XA03	1537802	767236	00264324
Eloxatin Inj IV 5mg/ml 10ml	L01XA03		784264	00607561
Eloxatin Inj IV 5mg/ml 20ml	L01XA03		784272	00607662
UFT				
UFT Caps 28x100/224mg	L01BC53	1626738	770586	00395575
UFT Caps 42x100/224mg	L01BC53	1620491	770586	00395474
Xeloda				
Xeloda Comp 60x150mg	L01BC06	1415314	768093	1415314
Xeloda Comp 120x500mg	L01BC06	1415322	768101	1415322

PROPORTION OF PATIENTS IN WHOM A CEA WAS PERFORMED BEFORE ANY TREATMENT

Measurement in prospective PROCARE database (Figure 26)

CEA measurement before treatment is registered through variable 'SPR_V148'. Patients undergoing treatment are selected using the variables 'AD_V111', 'AD_V113', 'AD_V114', 'AD_V117', 'AD_V118', 'AD_V121' and 'AD_V122' (hospital data section of data entry form).

Similar to the distance from the anal verge, unavailability of CEA in the PROCARE dataset does not necessarily mean that the CEA was not measured, but that the CEA was not registered.

Measurement in coupled administrative database (Figure 27)

Nomenclature codes are available for CEA measurement (Table 73). The date of first treatment is more difficult to identify and involves the identification of all possible treatments through their specific nomenclature (surgery and radiotherapy) or ATC codes (chemotherapy) (see previous QI).

A timeframe of 3 months before the incidence date (which in most cases is the date of biopsy) was chosen, since in some cases the CEA measurement can be done before the actual diagnosis of rectal cancer (e.g. when ordered by the general practitioner during the diagnostic workup). Also, the incidence date (see appendix 3 for the definition) can be the same as the date of first treatment, e.g. in case of emergency surgery.

Figure 26. Algorithm for QI 1213 (PROCARE database).

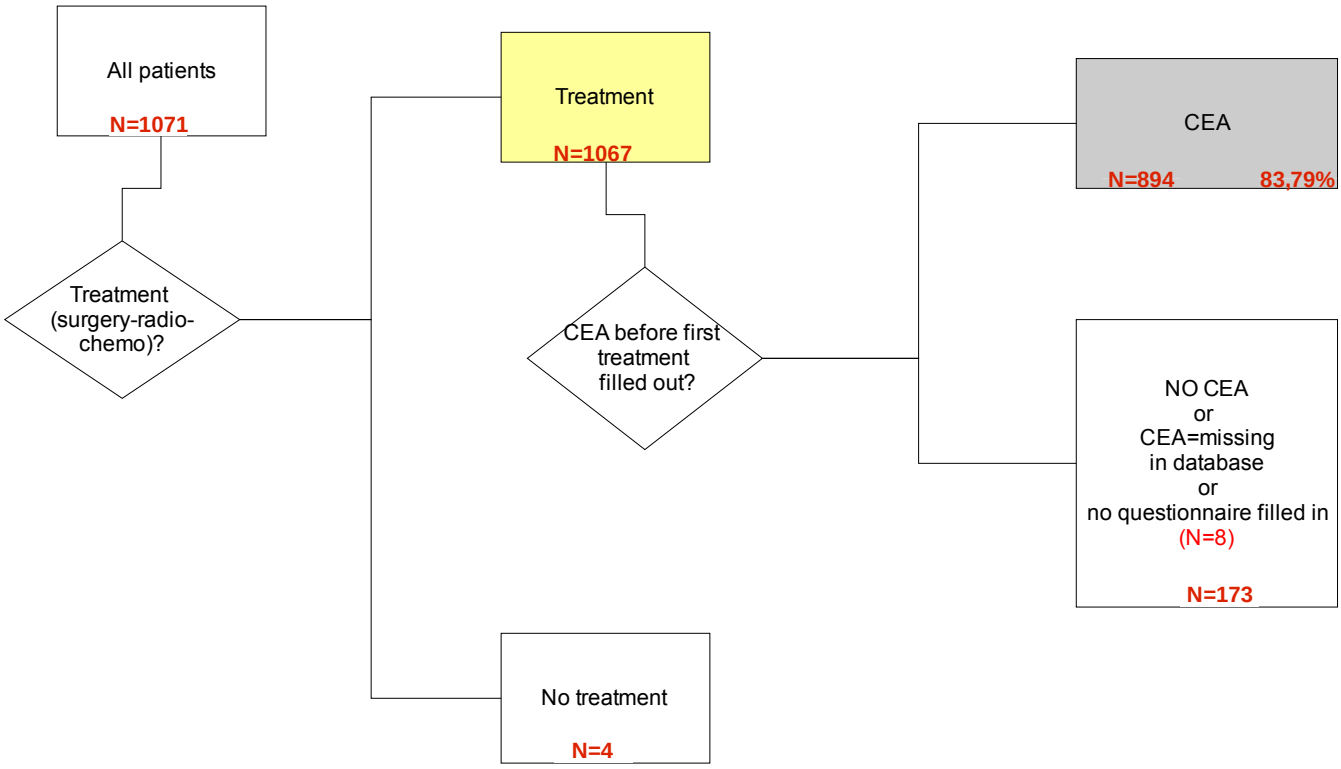


Figure 27. Algorithm for QI 1213 (administrative database).

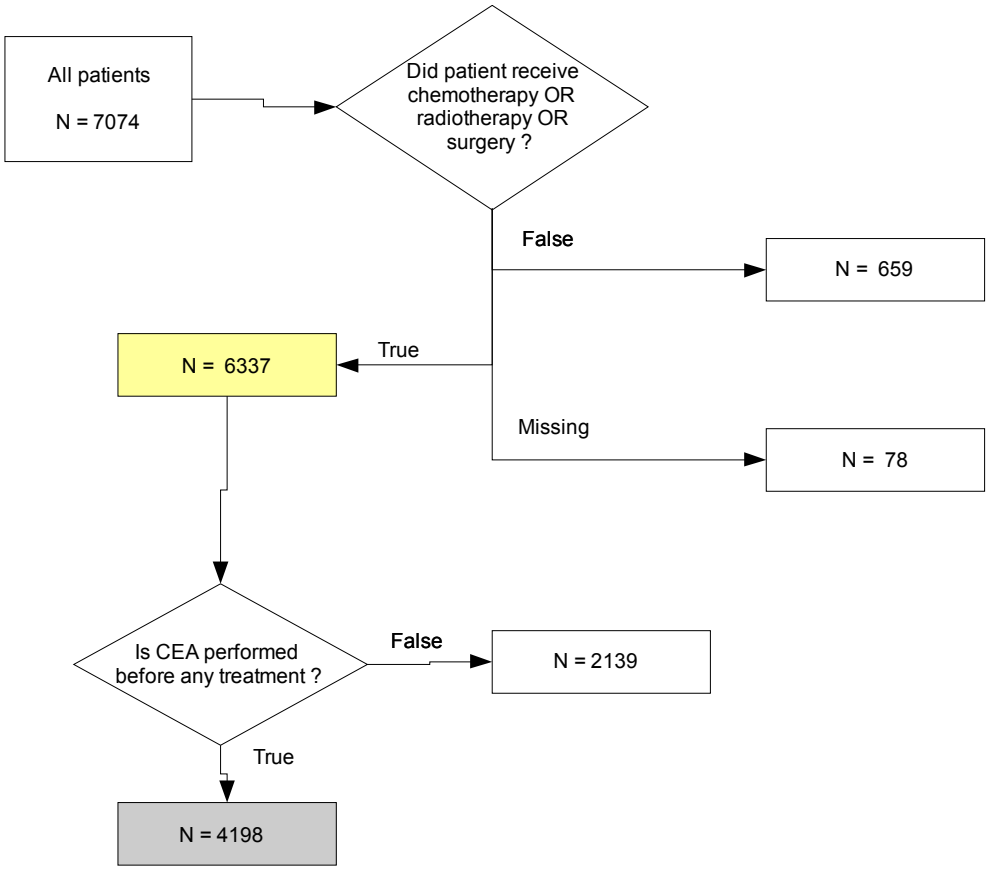


Table 73. Nomenclature codes for CEA measurement.

Nomenclature code	Description (Dutch)	Description (French)
548332 – 548343	Doseren van C.E.A. met niet isotopen-methode (Maximum 1) (Cumulregel 201, 317) (Diagnoseregel 46) Klasse 15	Dosage de C.E.A. par méthode non-isotopique (Maximum 1) (Règle de cumul 201, 317) (Règle diagnostique 46) Classe 15
436192 – 436203	Doseren van C E A (Maximum 1) (Cumulregel 201, 317) (Diagnoseregel 46) Klasse 15	Dosage de C E A (Maximum 1) (Règle de cumul 201, 317) (Règle diagnostique 46) Classe 15

PROPORTION OF PATIENTS UNDERGOING PREOPERATIVE COMPLETE LARGE BOWEL-IMAGING

Measurement in prospective PROCARE database (Figure 28)

Again, variable 'AD_V111' is used to select patients undergoing surgery. Variable 'SG_V109' enables the selection of elective/scheduled vs. urgent/emergency surgery. In the pre-treatment section of the data entry, total colonoscopy is registered through the variable 'SPR_V149'. The default value of this variable is '0' (i.e. no colonoscopy; however, missing values also received a value '0'), making it impossible to distinguish non-performance of colonoscopy from missing values. Also in the pre-treatment section, complete double contrast barium enema (DCBE) is registered through variable 'SPR_V171'.

If a patient did not undergo colonoscopy, the reason is registered through variables SPR_V154 – V159.

Measurement in coupled administrative database

Nomenclature codes are available for both total colonoscopy (codes for left colonoscopy were not included) and DCBE (Table 74). Above this, ICD-9-CM codes are available for both procedures (ICD-9-CM code 45.24 is for a left colonoscopy, and was not used), although the code of Barium Swallow is unspecific (Table 75). Furthermore, coding of DCBE in ICD-9-CM is not obligatory. The correspondence of the nomenclature and ICD-9-CM codes for colonoscopy for the 4556 patients that have both data is shown in Table 76.

Since complete large bowel-imaging can be done during the diagnostic work-up before the incidence date, a timeframe of 1 month before the incidence date was chosen. The surgery date was identified through specific nomenclature codes and ICD-9-CM codes for rectal surgery (Table 64, 65, 66, 67 and 68). The elective character of surgery was identified through nomenclature codes of urgency (exclusion of patients with these codes) (Table 77). However, these codes can only be used for interventions between 21 pm and 8 am or during the weekend. Urgent interventions between 8 am and 21 pm on working days are not captured with these codes. Apart from these codes, the MCD database also allows differentiation between urgent (code 1, within 6 hours after diagnosis) or elective (code 2, after 6 hours after diagnosis).

Figure 28. Algorithm for QI 1214 (PROCARE database).

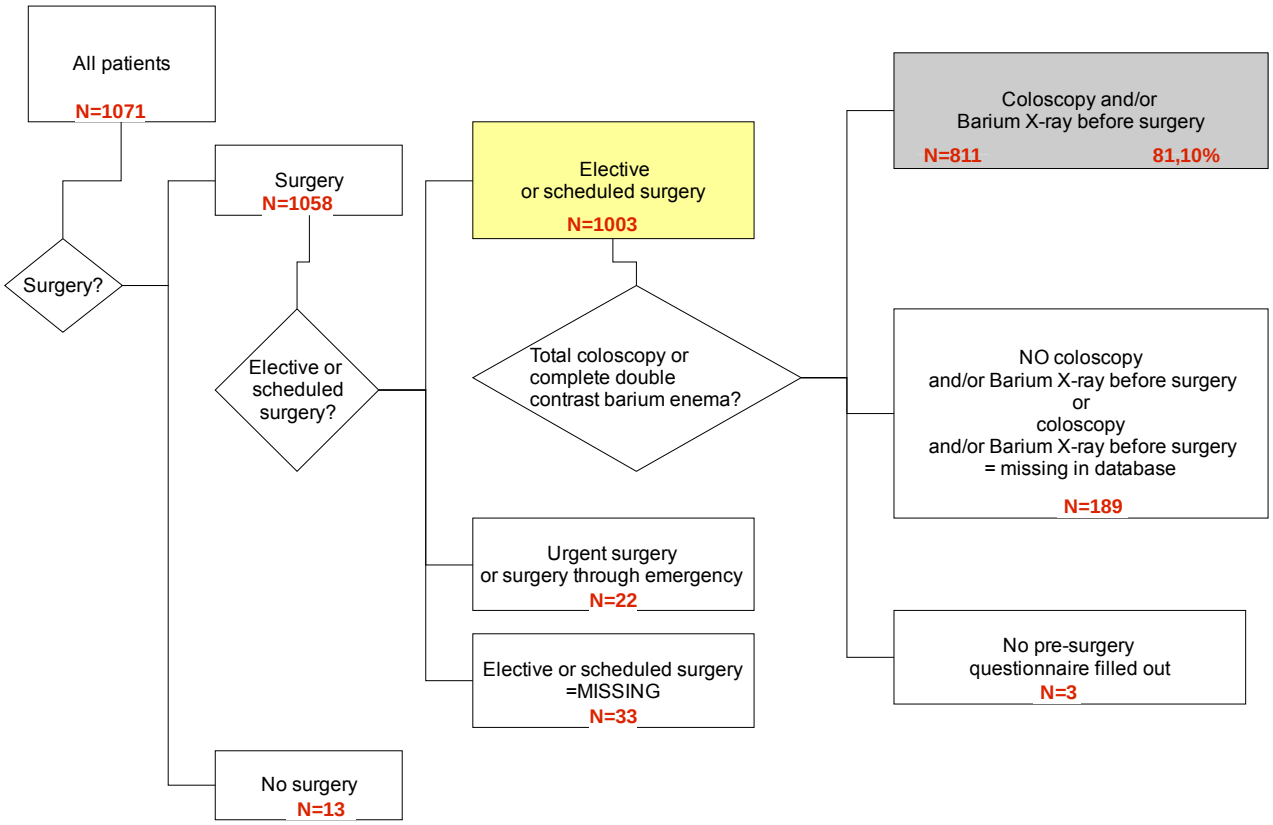


Table 74. Nomenclature codes for total colonoscopy and DCBE.

Nomenclature code	Description (Dutch)	Description (French)
473174 – 473185	Volledige colonoscopie, d.w.z. tot de rechterhoek van het colon of de ileocoecale klep	Colonoscopie totale, c.à.d. atteignant l'angle droit du côlon ou la valvule iléocoecale
473432 – 473443	Ileoscopie	Iléoscopie
451710 – 451721	Radiografie van het colon inclusief eventueel de ileocoecale streek met bariumlavement, na vulling, evacuatie en eventueel insufflatie, minimum vier clichés, met radioscopisch onderzoek met beeldversterker en televisie in gesloten keten	Radiographie du côlon, y compris éventuellement la région iléocoecale, par lavement baryté après remplissage, évacuation et éventuellement insufflation, minimum 4 clichés avec examen radioscopique avec amplificateur de brillance et chaîne de télévision
451754 – 451765	Radiografie van het colon, inclusief eventueel de ileocoecale streek, met bariumlavement, na vulling, evacuatie en insufflatie, volgens de dubbelcontrasttechniek, minimum acht clichés, met radioscopisch onderzoek met beeldversterker en televisie in gesloten keten	Radiographie du côlon, y compris éventuellement la région iléocoecale, par lavement baryté après remplissage, évacuation et insufflation par la technique du double contraste, minimum 8 clichés avec examen radioscopique avec amplificateur de brillance et chaîne de télévision
462711 – 462722	Radiografie van het colon inclusief eventueel de ileocoecale streek met bariumlavement, na vulling, evacuatie en eventueel insufflatie, minimum 4 clichés, met radioscopisch onderzoek met beeldversterker en televisie in gesloten	Radiographie du côlon, y compris éventuellement la région iléocoecale, par lavement baryté après remplissage, évacuation et éventuellement insufflation, minimum 4 clichés avec examen radioscopique avec

Nomenclature code	Description (Dutch)	Description (French)
	keten	amplificateur de brillance et chaîne de télévision
462755 – 462766	Radiografie van het colon, inclusief eventueel de ileocoecale streek, met bariumlavement, na vulling, evacuatie en insufflatie, volgens de dubbelcontrasttechniek, minimum 8 clichés, met radioscopisch onderzoek met beeldversterker en televisie in gesloten keten	Radiographie du côlon, y compris éventuellement la région iléocoecale, par lavement baryté après remplissage, évacuation et insufflation, par la technique du double contraste, minimum 8 clichés avec examen radioscopique avec amplificateur de brillance et chaîne de télévision

Table 75. ICD-9-CM codes for colonoscopy and DCBE.

Code	Description	Comments
45.23	Flexible fiberoptic colonoscopy Excludes : Endoscopy of large intestine through artificial stoma (45.22) Flexible sigmoidoscopy (45.24) Rigid proctosigmoidoscopy (48.23) Transabdominal endoscopy of large intestine (45.21)	Not specific for *complete* colonoscopy
87.61	Diagnostic radiology : Other X-ray of digestive system : Barium swallow	Not specific for DCBE

Table 76. Correspondance of nomenclature* and ICD-9-CM[$] codes for colonoscopy.

	ICD-9-CM		
	Yes	No	Total
Nomenclature			
Yes	235	1355	1590
No	176	2790	2966
Total	411	4145	4556

[2] 473174 – 473185 and 473432 – 473443; [$] 45.23

Table 77. Nomenclature codes for urgent interventions between 21 pm and 8 am or during the weekend.

Nomenclature code	Description (Dutch)	Description (French)
599513 – 599524	Bijkomend honorarium voor de 's nachts, tijdens het weekend of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 300 of N 500 of I 500	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 300 ou N 500 ou I 500
599535 – 599546	Bijkomend honorarium voor de 's nachts, tijdens het week of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 180 of N 300 of I 300 en gelijk aan of lager dan K 300 of N 500 of I 500	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 180 ou N 300 ou I 300 et égale ou inférieure à K 300 ou N 500 ou I 500
599550 – 599561	Bijkomend honorarium voor de 's nachts, tijdens het weekend of op een	Supplément d'honoraires pour les prestations urgentes effectuées pendant

Nomenclature code	Description (Dutch)	Description (French)
	feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 120 of N 200 of I 200 en gelijk aan of lager dan K 180 of N 300 of I 300	la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 120 ou N 200 ou I 200 et égale ou inférieure à K 180 ou N 300 ou I 300
599572 – 599583	Bijkomend honorarium voor de 's nachts, tijdens het weekend of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 75 of N 125 of I 125 en gelijk aan of lager dan K 120 of N 200 of I 200	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 75 ou N 125 ou I 125 et égale ou inférieure à K 120 ou N 200 ou I 200
599594 – 599605	Bijkomend honorarium voor de 's nachts, tijdens het weekend of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 50 of N 85 of I 85 en gelijk aan of lager dan K 75 of N 125 of I 125	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 50 ou N 85 ou I 85 et égale ou inférieure à K 75 ou N 125 ou I 125
599616 – 599620	Bijkomend honorarium voor de s'nachts, tijdens het weekend of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 25 of N 42 of I 42 en gelijk aan of lager dan K 50 of N 85 of I 85	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 25 ou N 42 ou I 42 et égale ou inférieure à K 50 ou N 85 ou I 85
599631 – 599642	Bijkomend honorarium voor de 's nachts, tijdens het weekend of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde hoger is dan K 10 of N 17 of I 17 en gelijk aan of lager dan K 25 of N 42 of I 42	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est supérieure à K 10 ou N 17 ou I 17 et égale ou inférieure à K 25 ou N 42 ou I 42
599653 – 599664	Bijkomend honorarium voor de 's nachts, tijdens het weekend of op een feestdag verrichte dringende verstrekkingen, met uitzondering van de in § 8 vermelde verstrekkingen : Voor de verstrekkingen waarvan de betrekkelijke waarde gelijk is aan of lager is dan K 10 of N 17 of I 17	Supplément d'honoraires pour les prestations urgentes effectuées pendant la nuit ou le week-end ou durant un jour férié, à l'exception des prestations citées au § 8 : Pour les prestations dont la valeur relative est égale ou inférieure à K 10 ou N 17 ou I 17

PROPORTION OF PATIENTS IN WHOM A TRUS AND PELVIC CT AND/OR MRI WAS PERFORMED BEFORE ANY TREATMENT

Measurement in prospective PROCARE database (Figure 29)

Patients undergoing treatment are again selected using the variables 'AD_V111', 'AD_V113', 'AD_V114', 'AD_V117', 'AD_V118', 'AD_V121' and 'AD_V122' (hospital data section of data entry form). In the pre-treatment section, 2 variables are available for TRUS ('SPR_V124' and 'SPR_V128') and pelvic CT ('SPR_V122' and 'SPR_V126'). Four variables are available for pelvic MRI ('SPR_V123', 'SPR_V125', 'SPR_V127' and 'SPR_V129'). For al these variables, it is asked to fill in all available data. However, a blank field does not necessarily mean that the investigation was not carried out, but that it was not registered in the database.

Measurement in coupled administrative database

Specific nomenclature codes exist for TRUS (Table 78). Also, a nomenclature code exists for the performance of a CT (Table 62) or MRI (Table 79), although without specification of the anatomic region. Table 80 provides an overview of the possible ICD-9-CM codes for TRUS, pelvic CT and MRI. However, these codes are too unspecific to select these procedures.

In conclusion, this QI is not measurable for the administrative cohort due to an absence of specific administrative codes.

Figure 29. Algorithm for QI 1215 (PROCARE database).

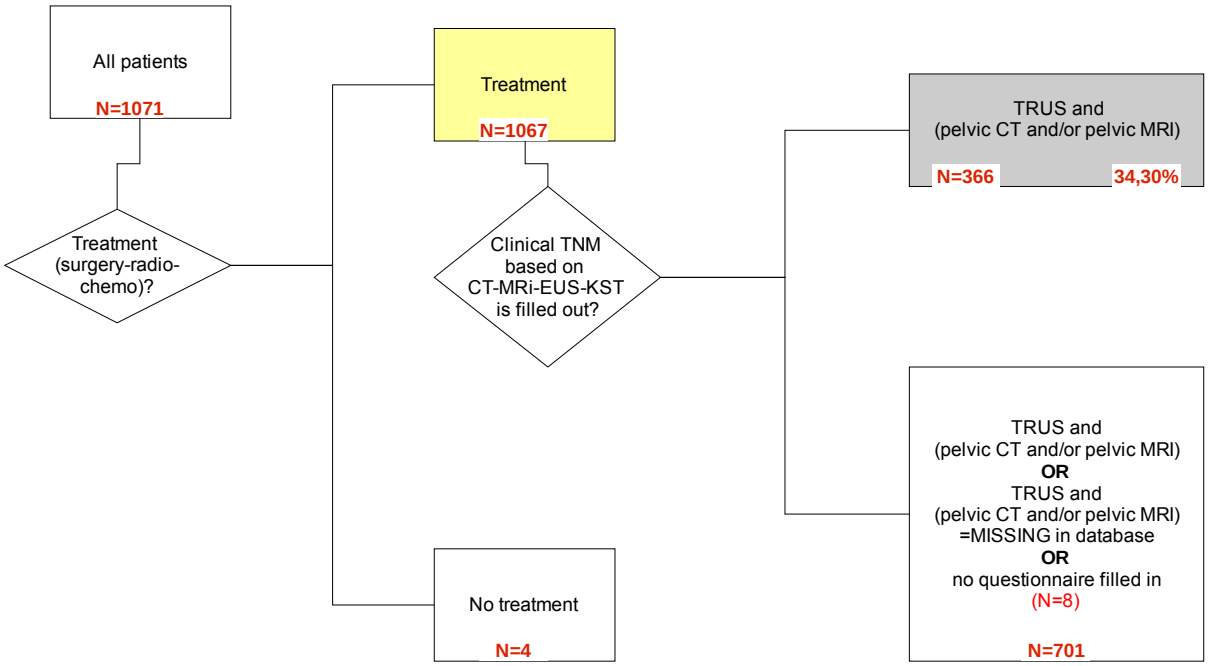


Table 78. Nomenclature codes for TRUS.

Nomenclature code	Description (Dutch)	Description (French)
460493 – 460504	Bidimensionele echografie met geschreven protocol en iconografische drager die ontstaat na digitale beeldverwerking van de gegevens ongeacht het aantal echogrammen : Transrectale echografie	Echographie bidimensionnelle avec protocole écrit et support iconographique issu d'un traitement digital des données quel que soit le nombre d'échogrammes : Echographie transrectale
469571 – 469582	Bidimensionele echografie met geschreven protocol en iconografische drager die ontstaat na digitale beeldverwerking van de gegevens ongeacht het aantal echogrammen - Van het abdomen : Transrectale echografie	Echographie bidimensionnelle avec protocole écrit et support iconographique issu d'un traitement digital des données quel que soit le nombre d'échogrammes - De l'abdomen : Echographie transrectale
473896 – 473900	Anorectale echo-endoscopie	Echoendoscopie ano-rectale

Table 79. Nomenclature code for MRI.

Nomenclature code	Description (Dutch)	Description (French)
459410 – 459421	NMR-onderzoek van de hals of van de thorax of van het abdomen of van het bekken, minstens drie sequenties, met of zonder contrast, met registratie op optische of elektromagnetische drager	Examen d'IRM du cou ou du thorax ou de l'abdomen ou du bassin, minimum 3 séquences, avec ou sans contraste, avec enregistrement sur support soit optique, soit électromagnétique

Table 80. Possible ICD-9-CM codes for TRUS, CT pelvis and MRI pelvis.

Code	Description	Comment
TRUS		
88.74	Diagnostic ultrasound of digestive system	Not specific for TRUS
88.76	Diagnostic ultrasound of abdomen and retroperitoneum	Not specific for TRUS
Pelvic CT		
88.38	C.A.T scan NOS *Excludes :* *C.A.T. scan of :* *abdomen (88.01)* *head (87.03)* *kidney (87.71)* *thorax (87.41)*	Not specific for pelvic CT
Pelvic MRI		
88.95	Magnetic resonance imaging of pelvis, prostate and bladder	

PROPORTION OF PATIENTS WITH CSTAGE II-III RC THAT HAVE A REPORTED CCRM

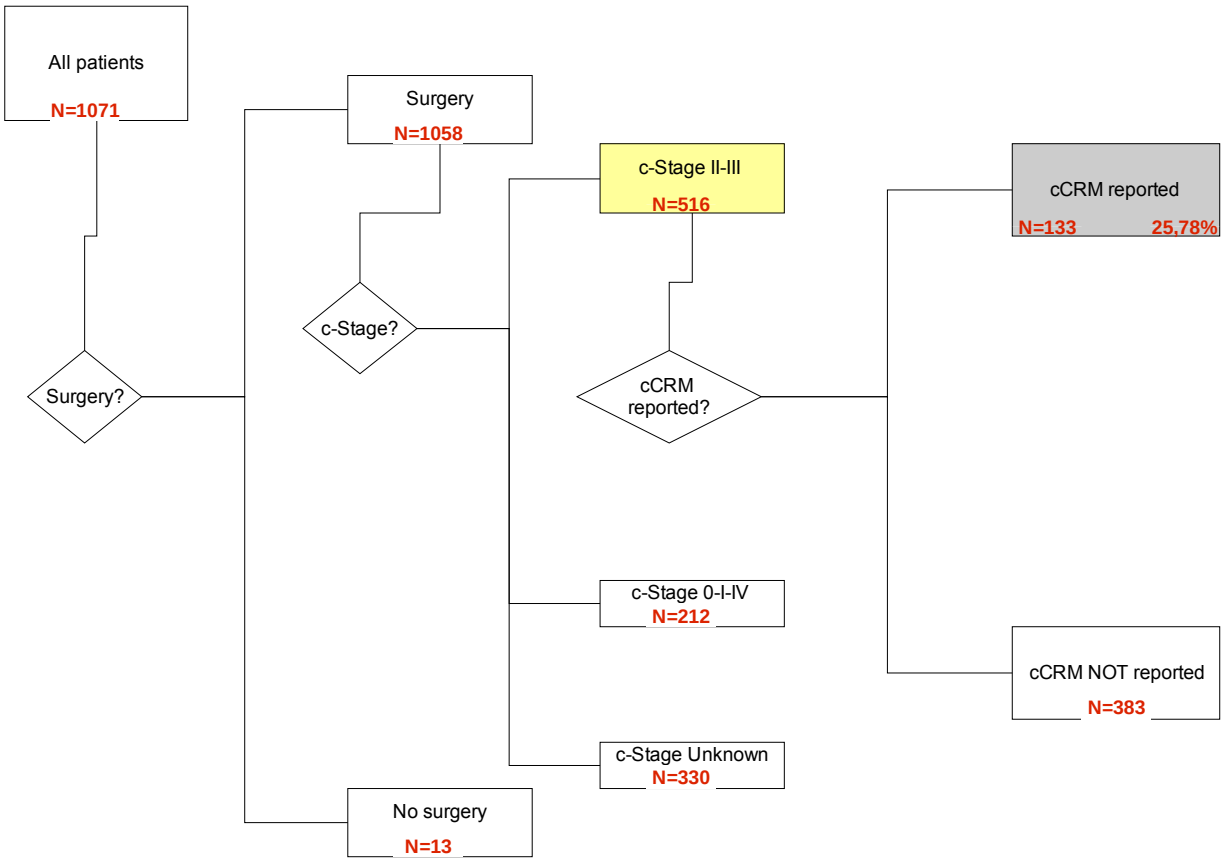
Measurement in prospective PROCARE database (Figure 30)

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. cStage II-III patients are selected through variables 'SPR_V147' and 'PT_V106'. The cCRM is registered through the variables: 'SPR_V130' and 'SPR_V131'. Importantly, unavailability of the cCRM in the PROCARE dataset does not mean that the cCRM was not documented, but that the cCRM was not registered.

Measurement in coupled administrative database

No administrative code exists for the (documentation of the) cCRM. The QI is therefore not measurable for the administrative cohort.

Figure 30. Algorithm for QI 1216 (PROCARE database).



TIME BETWEEN FIRST HISTOPATHOLOGIC DIAGNOSIS AND FIRST TREATMENT

Measurement in prospective PROCARE database (Figure 31)

Patients undergoing treatment are again selected using the variables 'AD_V111', 'AD_V113', 'AD_V114', 'AD_V117', 'AD_V118', 'AD_V121' and 'AD_V122' (hospital data section of data entry form). For these patients, the date of first treatment is retrieved from the variables 'SG_V106', 'CH_V115' and 'RD_V104'. The date of the biopsy of the tumour is retrieved from variable 'SPR_V161'.

Measurement in coupled administrative database (Figure 32)

Date of first treatment can only be calculated for those patients having undergone treatment. Selection of these patients is identical to QI 1212 and 1214. The incidence date is retrieved from the BCR database.

Figure 31. Algorithm for QI 1217 (prospective database).

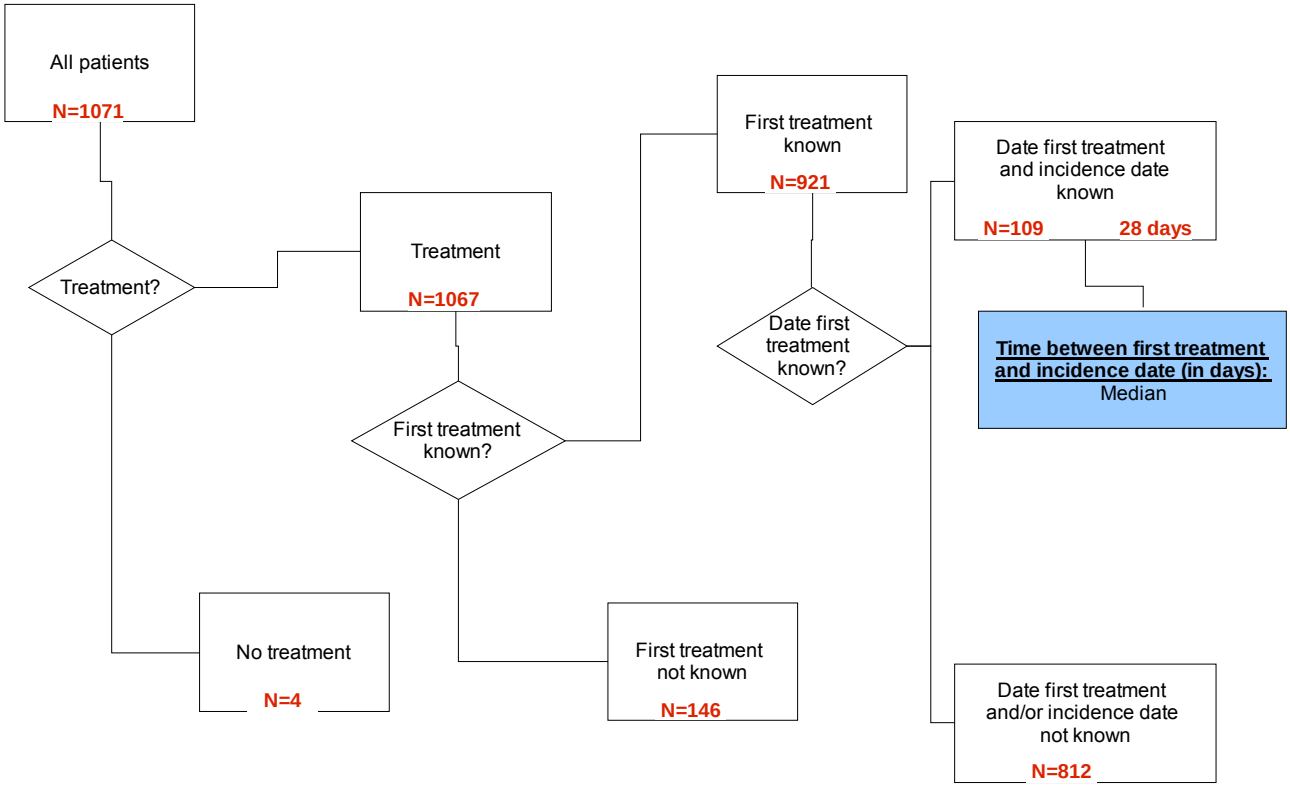
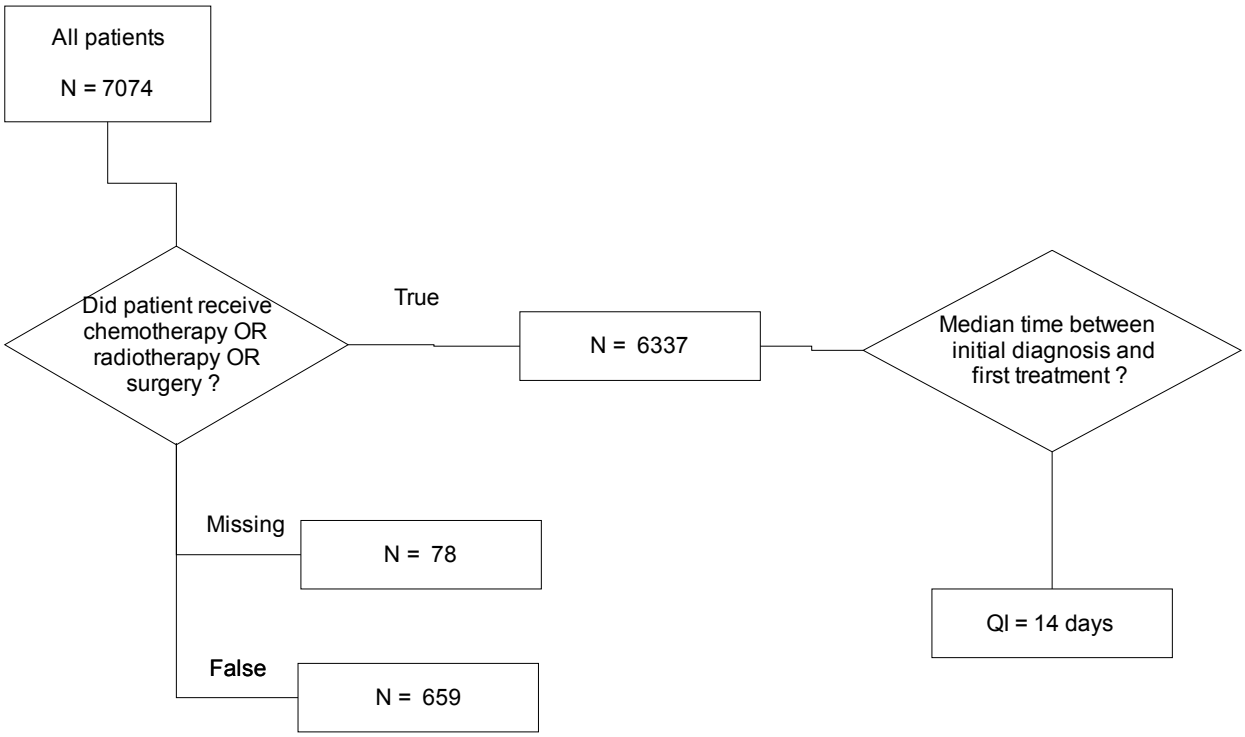


Figure 32. Algorithm for QI 1217 (administrative database).



PROPORTION OF CSTAGE II-III PATIENTS THAT RECEIVED A SHORT COURSE OF NEOADJUVANT PELVIC RT

Measurement in prospective PROCARE database (Figure 33)

Stage II and III RC patients are selected using the variables 'SPR_V147' and 'PT_V106' for the cStage. In this group of patients, those receiving surgery are selected using variable 'AD_V111'. Within this group of patients, patients receiving preoperative radiotherapy are selected using variable 'RD_V101'. Patients receiving a short course of radiotherapy (i.e. 5 fractions of 5 Gy) are selected using variables 'RD_V106' (number of fractions) and 'RD_V109' (total dose).

Measurement in coupled administrative database

In the nomenclature, several codes are available for radiotherapy (Table 70). However, it is impossible to identify the exact number of fractions and radiation dose with these codes (e.g. both 25 x 1.8 Gy and 13 x 3 Gy can be billed with nomenclature code 444150 – 444161). Some hospitals bill the entire radiotherapy regimen once (i.e. on the patient level, the nomenclature code was found only once in the HIC database), other hospitals bill every fraction separately (i.e. on the patient level, the nomenclature code was found several times in the HIC database) (Table 81). Above this, the exact radiation dose cannot be retrieved from nomenclature codes. Therefore, the identification of a short course of RT through nomenclature codes is impossible.

In ICD-9-CM, two codes were identified for radiotherapy, again without specification of dose and fractions (Table 71).

Figure 33. Algorithm for QI 1221 & 1222 (prospective database).

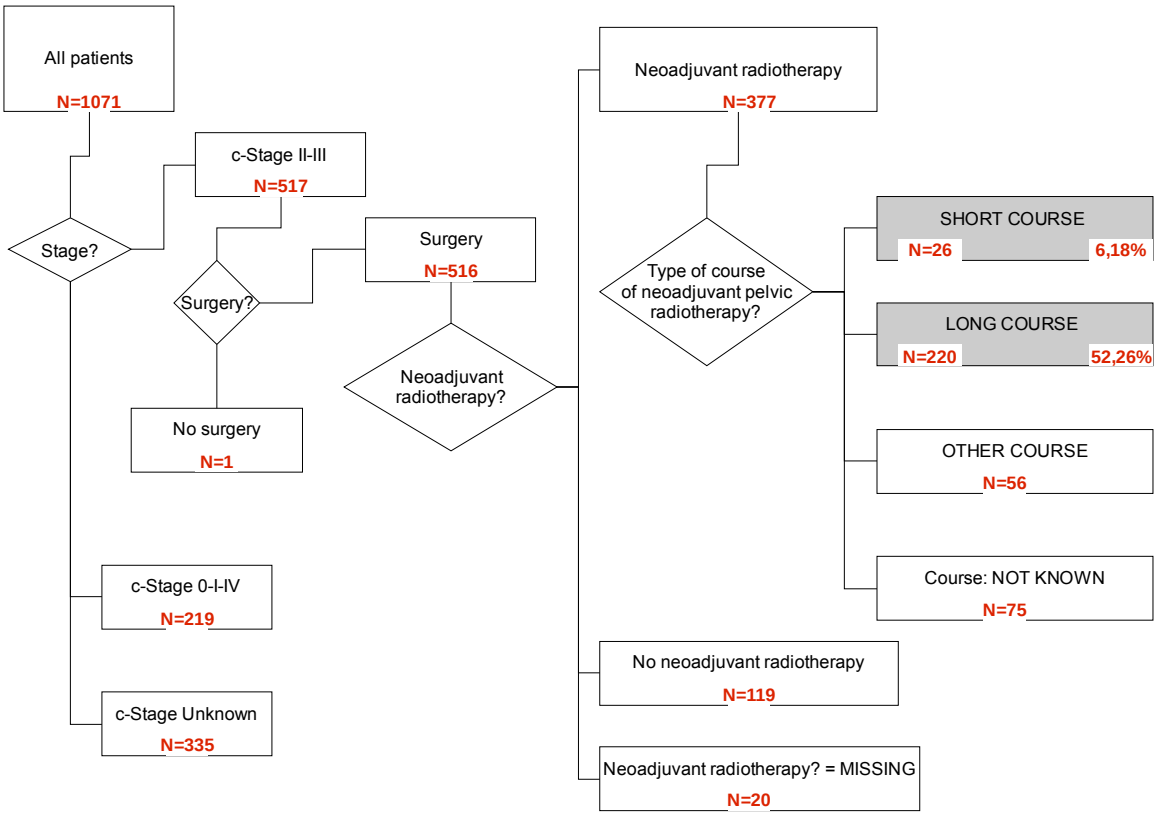


Table 81. Number of bills with nomenclature code 444150 – 444161 for cStage II-III patients (neoadjuvant radiotherapy).

Number of bills for neoadjuvant radiotherapy	N cStage II-III patients
1	95
2	1
8	1
9	1
10	3
11	10
12	3
13	23
14	1
17	2
19	2
20	2
21	1
22	1
23	2
24	20
25	85
26	1
27	1
28	6
30	1

PROPORTION OF CSTAGE II-III PATIENTS THAT RECEIVED A LONG COURSE OF NEOADJUVANT PELVIC RT

(the same algorithm is used as the previous QI)

Measurement in prospective PROCARE database (Figure 33)

As for the previous QI, stage II and III RC patients are selected using the variables 'SPR_V147' and 'PT_V106' for the cStage. In this group of patients, those receiving surgery are selected using variable 'AD_V111'. Within this group of patients, patients receiving preoperative radiotherapy are again selected using variable 'RD_V101'. Patients receiving a long course of radiotherapy (i.e. at least 25 fractions of 1.8 Gy) are selected using variables 'RD_V106' (number of fractions) and 'RD_V109' (total dose).

Measurement in coupled administrative database

Again, in the nomenclature, codes are available for radiotherapy (Table 70). However, it is not possible to identify the exact number of fractions and radiation dose with these codes. Therefore, the identification of a long course of RT is impossible. The same applies to the ICD-9-CM codes (Table 71).

PROPORTION OF STAGE II-III PATIENTS THAT RECEIVED NEOADJUVANT CHEMORADIATION WITH A REGIMEN CONTAINING 5-FU

Measurement in prospective PROCARE database (Figure 34)

cStage II and III RC patients receiving surgery are selected in the same way as the two previous QI. When neoadjuvant CRT is provided (patients receiving neoadjuvant radiotherapy or chemotherapy as monotherapy are excluded), the variable 'CH_V101' is checked in the chemotherapy section of the data entry form. When the neoadjuvant chemotherapy regimen contained 5-FU, this is registered in variables 'CH_V109' and 'CH_V110' or in variables 'CH_V119' and 'CH_V120'.

Measurement in coupled administrative database (Figure 35)

Patients with rectal cancer cStage II-III are selected from the BCR database. Those patients receiving surgery are selected using the nomenclature codes for abdominoperineal resection, Hartmann's procedure and sphincter-sparing surgery (Table 64). The identified ICD-9-CM codes were not used for this selection (Table 66).

Within the group of cStage II-III patients undergoing surgery, those receiving neoadjuvant chemoradiotherapy are selected using the nomenclature codes for radiotherapy (Table 70) and the ATC codes for chemotherapy (Table 72), but only if the date of chemoradiotherapy falls within the interval between the incidence date and surgery date. The ATC codes for 5-fluorouracil are used to calculate the denominator (Table 72).

Figure 34. Algorithm for QI 1223 (prospective database).

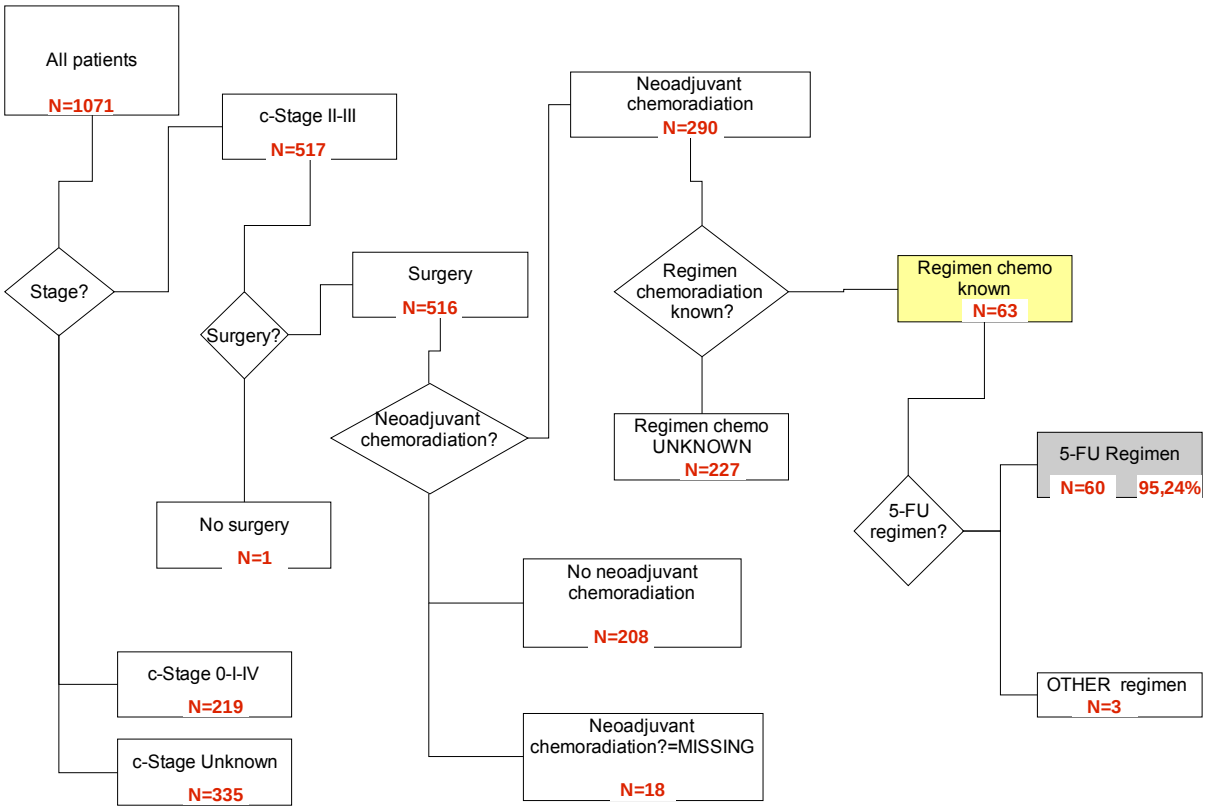
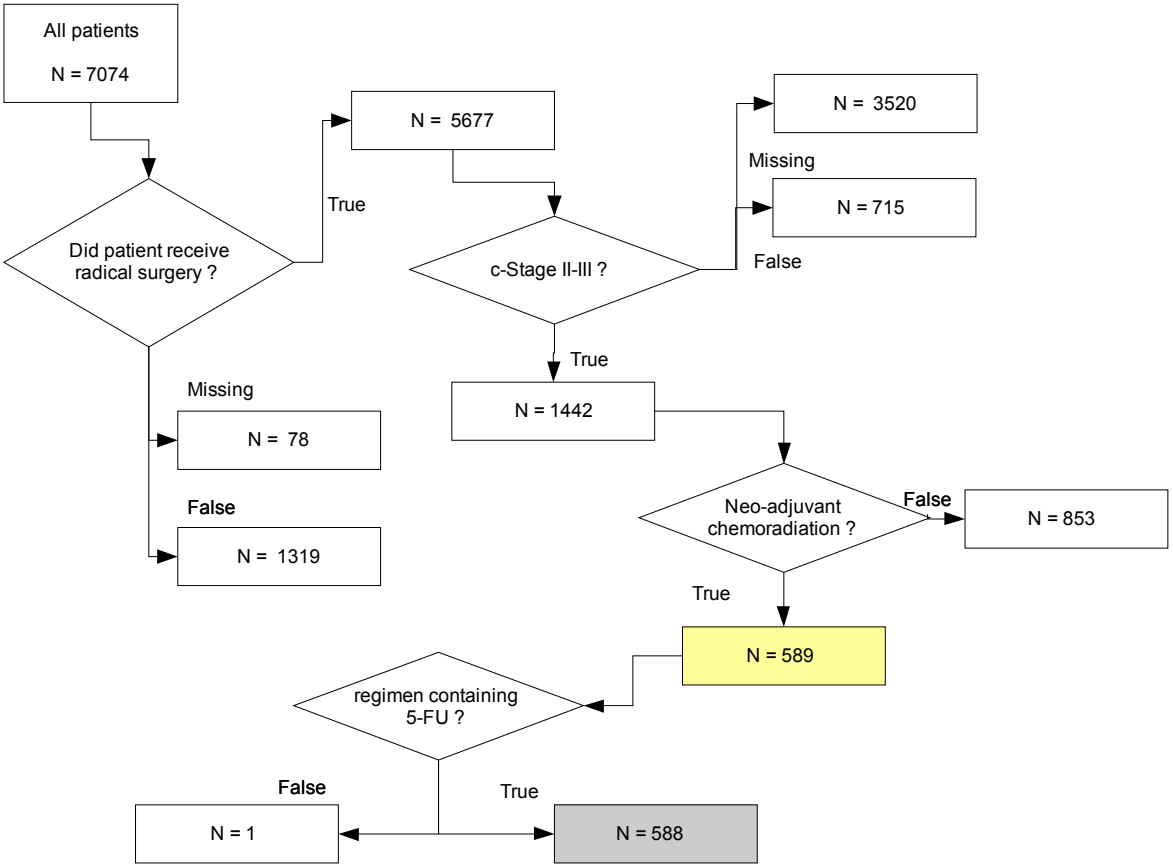


Figure 35. Algorithm for QI 1223 (administrative database).



PROPORTION OF CSTAGE II-III PATIENTS TREATED WITH NEOADJUVANT 5-FU BASED CHEMORADIATION, THAT RECEIVED A CONTINUOUS INFUSION OF 5-FU

Measurement in prospective PROCARE database

The calculation of the denominator of this QI is identical to that of the numerator of the previous QI. In the data entry form, no specific variable is available for the registration of continuous infusion. This information can be extracted from the variables 'CH_V112' and 'CH_V122', where the chemotherapy regimen is registered. However, this needs too much interpretation to allow a calculation in SAS, rendering the QI not measurable at this moment.

Measurement in coupled administrative database

Although it is possible to identify patients receiving 5-FU through a specific CNK-code in the IMA database (cfr. supra), it is impossible to know if this 5-FU is given via continuous infusion. Therefore, this QI is not measurable with the administrative databases.

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

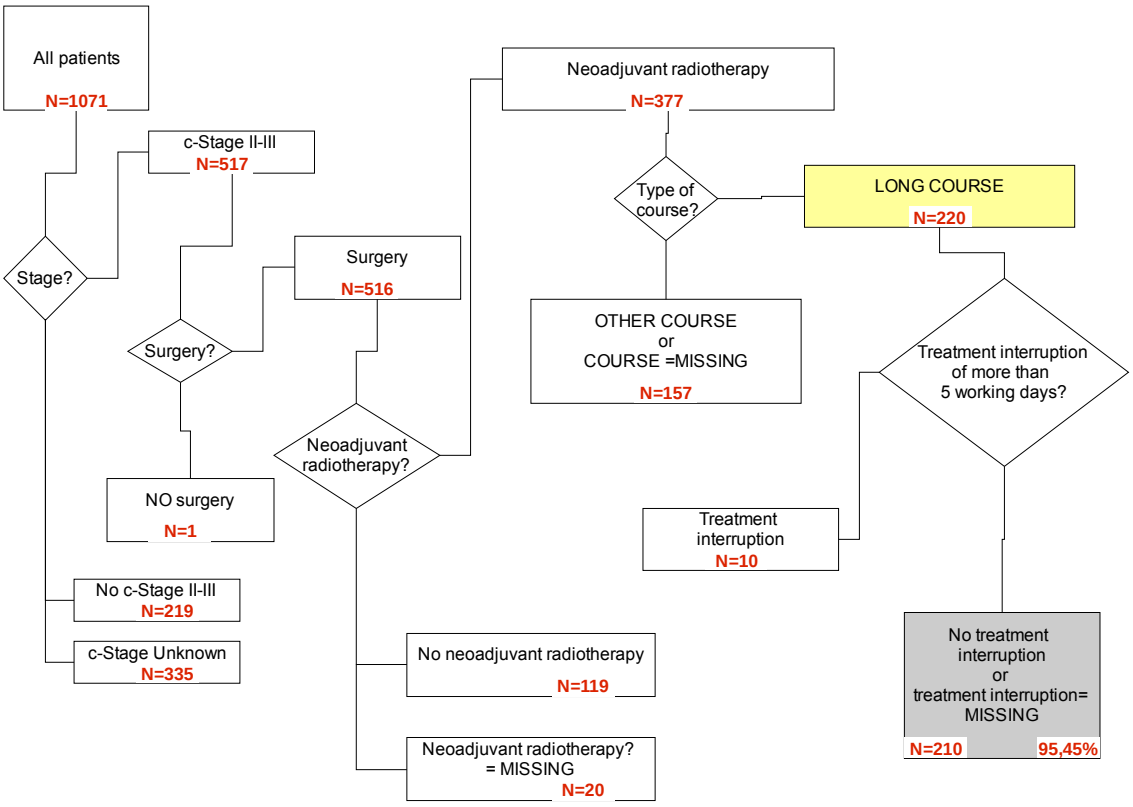
Measurement in prospective PROCARE database (Figure 36)

The calculation of the denominator of this QI is identical to that of the numerator of QI 1222. Within this group of patients, those without a treatment interruption of more than 5 working days are selected using variable 'RD_V107'. As for variable 'FU_V139' (see above), the default value of variable 'RD_V107' was '0' (i.e. missing values also received a value '0'), making it impossible to distinguish absence of treatment interruption from missing values. However, in a random sample of 20 forms with a value '0' for variable 'RD_V107' only 1 missing value (5%) was found.

Measurement in coupled administrative database

As mentioned before, the identification of a long course of RT, i.e. at least 25 fractions of 1.8 Gy, is impossible in the administrative databases.

Figure 36. Algorithm for QI 1225 (prospective database).



PROPORTION OF CSTAGE II-III PATIENTS TREATED WITH A LONG COURSE OF PREOPERATIVE PELVIC RT OR CHEMORADIATION, THAT WAS OPERATED 6 TO 8 WEEKS AFTER COMPLETION OF THE (CHEMO)RADIATION

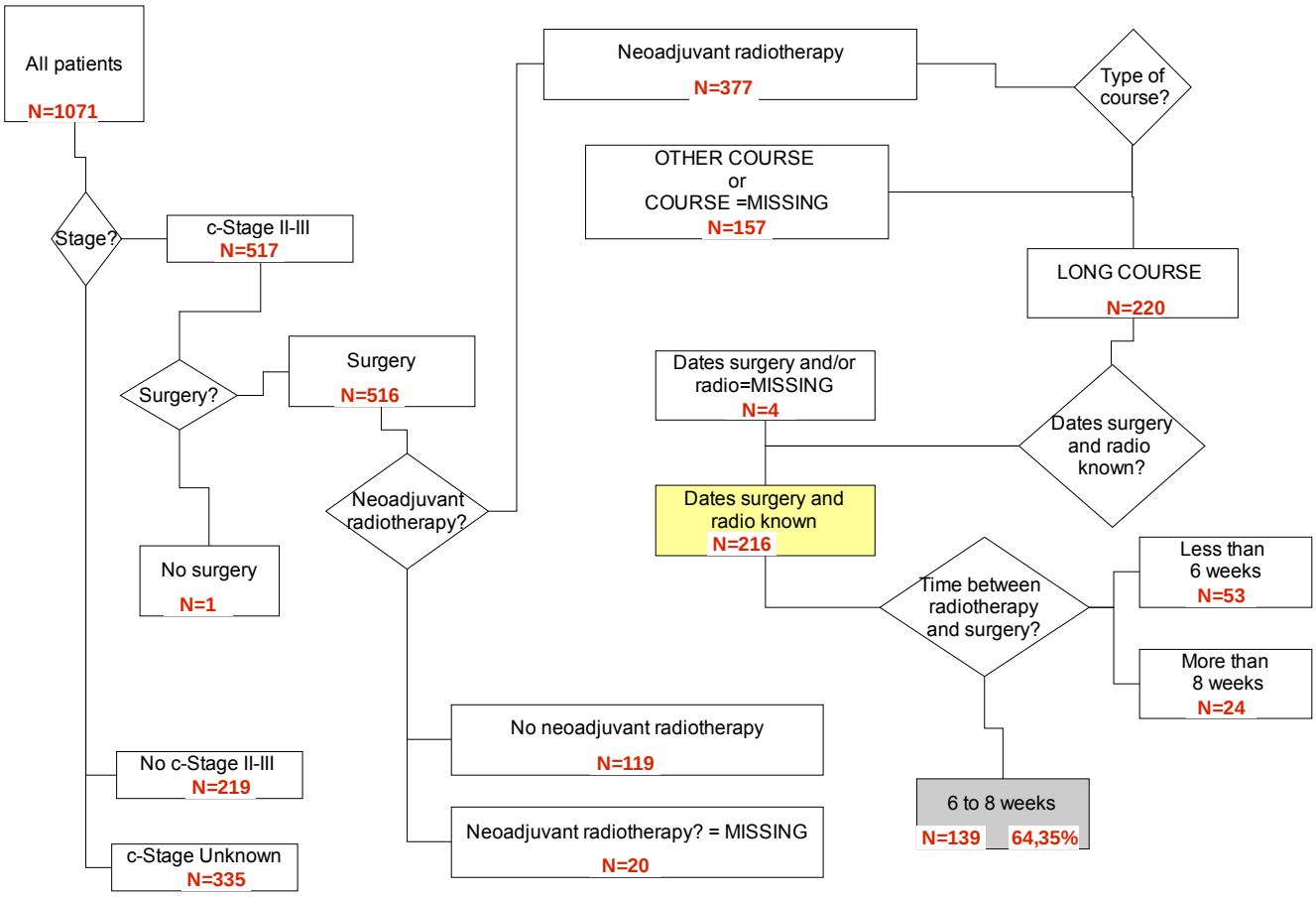
Measurement in prospective PROCARE database (Figure 37)

The calculation of the denominator of this QI is identical to that of the numerator of QI 1222. The date of surgery and the last date of radiotherapy are registered through variables 'SG_V106' and 'RD_V105' respectively, which allows calculation of the time interval between preoperative radiotherapy and surgery. Six weeks is defined as 42 days and 8 weeks as 56 days.

Measurement in coupled administrative database

As mentioned before, the identification of a long course of RT, i.e. at least 25 fractions of 1.8 Gy, is impossible in the administrative databases.

Figure 37. Algorithm for QI 1226 (prospective database).



RATE OF ACUTE GRADE 4 RADIO(CHEMO)THERAPY-RELATED COMPLICATIONS

Measurement in prospective PROCARE database

Patients with RC receiving neoadjuvant (C)RT are easily identifiable with the variable 'RD_V124'. However, no specific code is available for the registration of radiotherapy-related complications (variable 'CH_V146' only registers chemotherapy- and radiochemotherapy-related complications). Therefore, this QI is not measurable.

Measurement in coupled administrative database

No specific administrative codes are available for (C)RT-related complications. In the ICD-9-CM coding system some aspecific codes are available (990 effects of radiation, unspecified; 963.1 poisoning by primarily systemic agents: antineoplastic and immunosuppressive drugs; 558.1 gastroenteritis and colitis due to radiation; etc.), but there is no mentioning of grade. Therefore, these codes cannot be used. The QI is not measurable.

PROPORTION OF R0 RESECTIONS

Measurement in prospective PROCARE database (Figure 38)

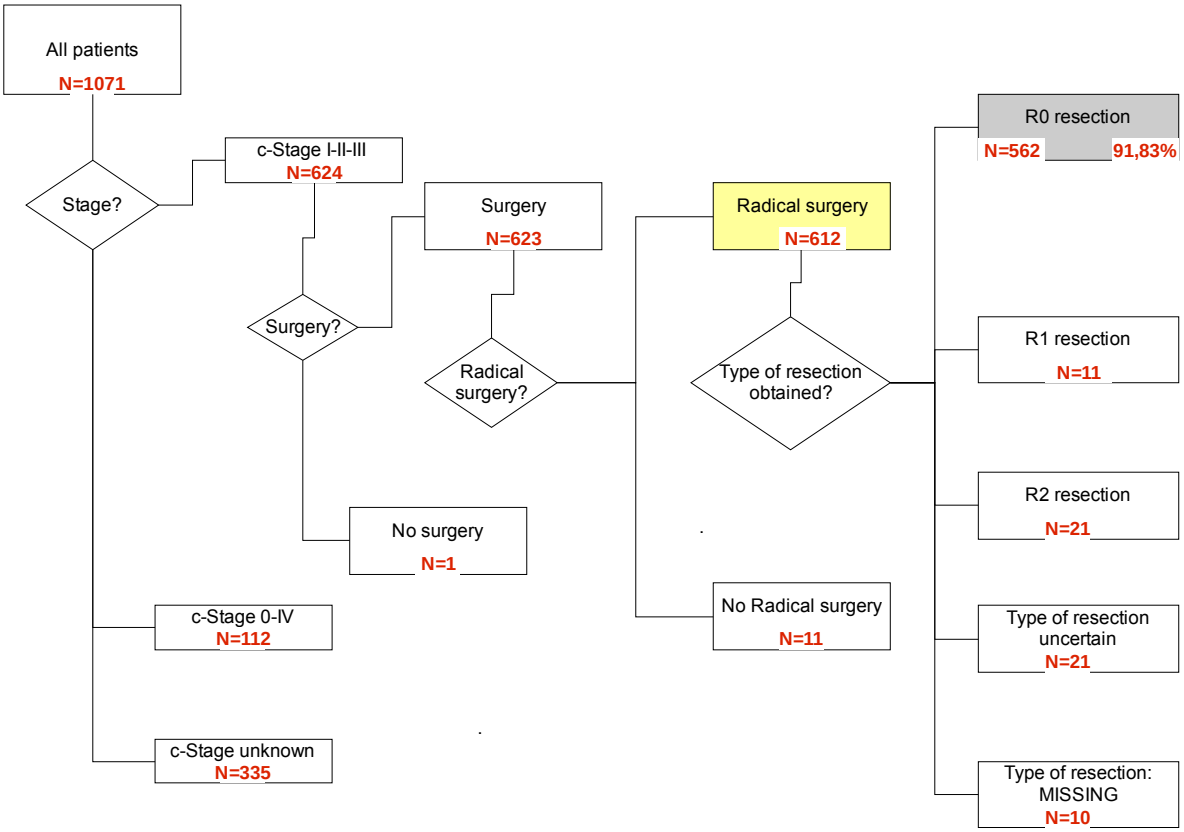
In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients undergoing radical resection are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'. Within this selection, patients undergoing an R0 resection are selected using variable 'SG_V216'.

Results are separated for cStage I-III and cStage IV patients through variables 'SPR_V147' and 'PT_V106'.

Measurement in coupled administrative database

No specific code is available for R0 resection.

Figure 38. Algorithm for QI 1231 (prospective database).



PROPORTION OF APR AND HARTMANN'S PROCEDURES

Measurement in prospective PROCARE database (Figure 39)

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients undergoing radical resection (local resection not included) are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'. Within this group, patients undergoing APR and Hartmann's procedure are selected using variable 'SG_V234' (subcode 4 and 5).

Measurement in coupled administrative database (Figure 40)

Patients undergoing radical resection (local resection not included) are selected using the administrative codes in Table 64 and Table 66. These patients constitute the denominator. Within this selection, the administrative codes for APR and Hartmann's procedure are used to calculate the numerator (Table 64 and Table 66).

Figure 39. Algorithm for QI 1232a (prospective database).

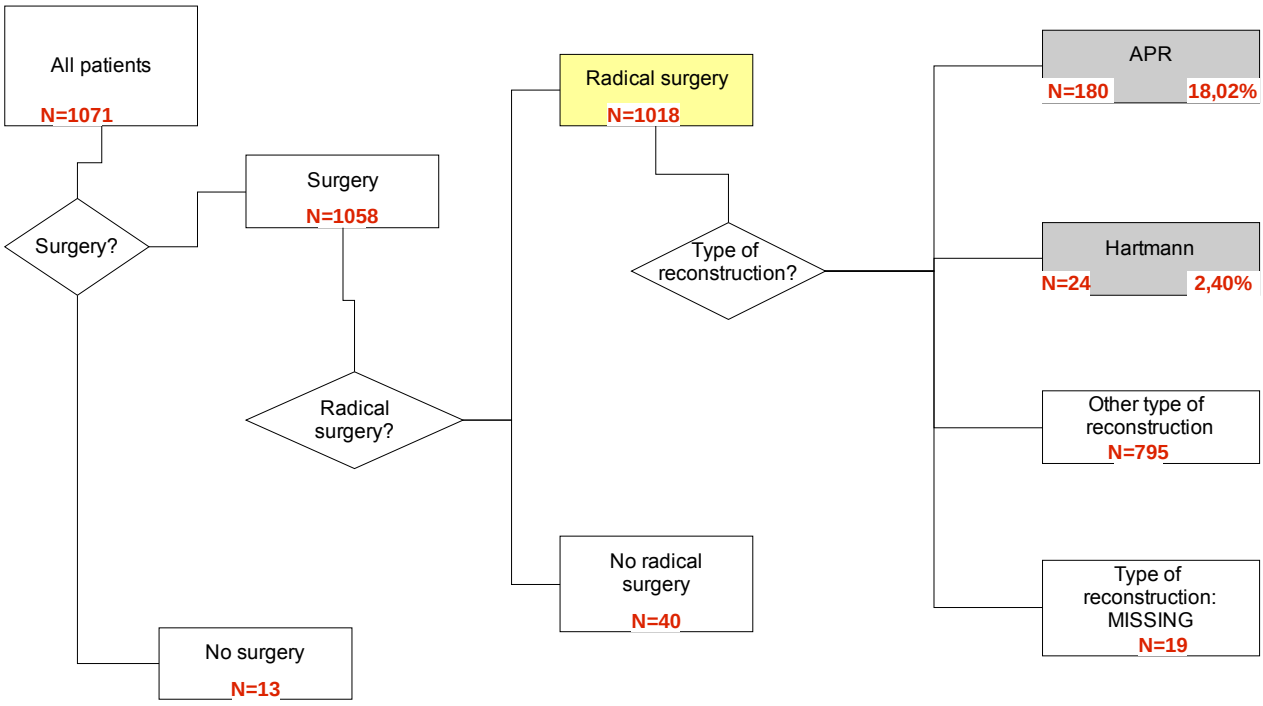
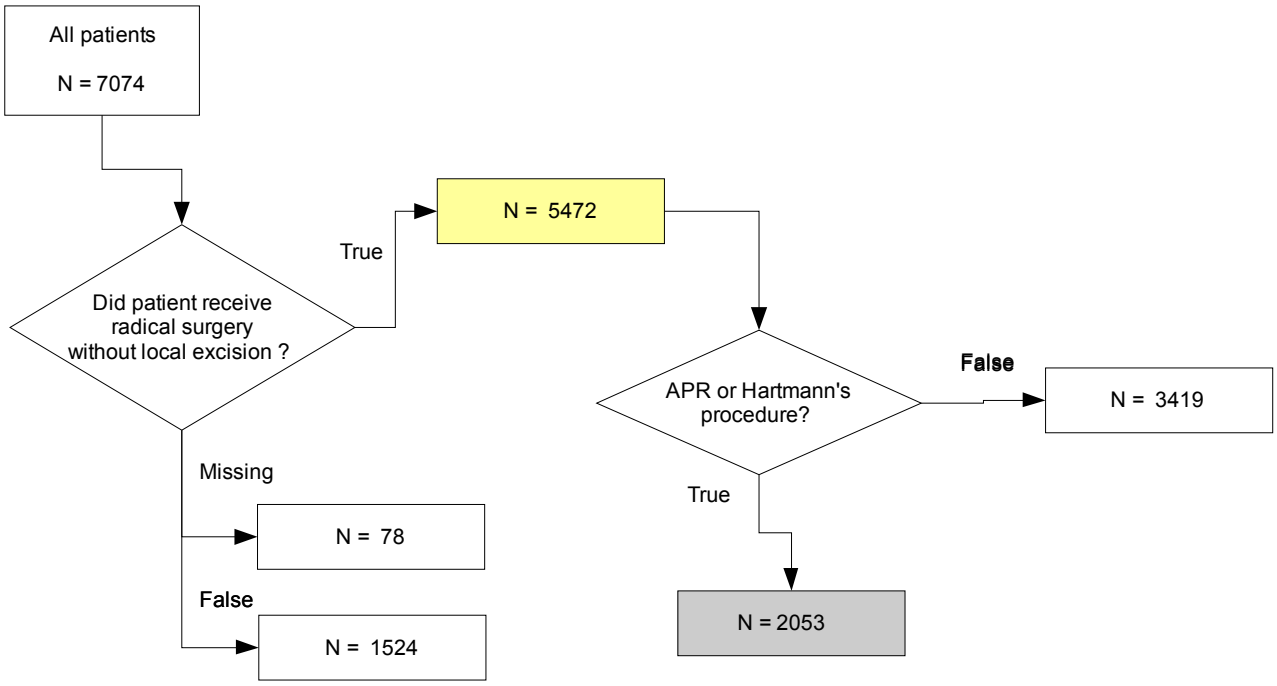


Figure 40. Algorithm for QI 1232a (administrative database).



PROPORTION OF PATIENTS WITH STOMA 1 YEAR AFTER SPHINCTER-SPARING SURGERY

Measurement in prospective PROCARE database

Patients undergoing sphincter-sparing surgery (SSO) are registered through variable 'SG_V234' (subcodes 6-9). Patients receiving a stoma during SSO are registered through variable 'SG_V245'. The follow-up of stoma closure/presence is registered through variables 'FU_V113' and 'FU_V114'. However, the follow-up dates are variable from one patient to another, making a calculation at 1 year impossible.

Measurement in coupled administrative database (Figure 41)

Patients undergoing sphincter-sparing surgery are selected using specific administrative codes (Table 64 and Table 66). Within this selection, patients with a stoma within 1 year after sphincter-sparing surgery are selected using the administrative codes for stoma surgery (Table 65, 68 and 82) or stoma material (Table 83). To calculate the numerator, those patients having received a permanent stoma (Table 82) not having undergone stoma closure within 1 year (Table 84; note that 243224 – 243213 also concerns closure of a colonic fistula) or still using stoma material after 1 year (Table 83) were selected.

Figure 41. Algorithm for QI 1232b (administrative database).

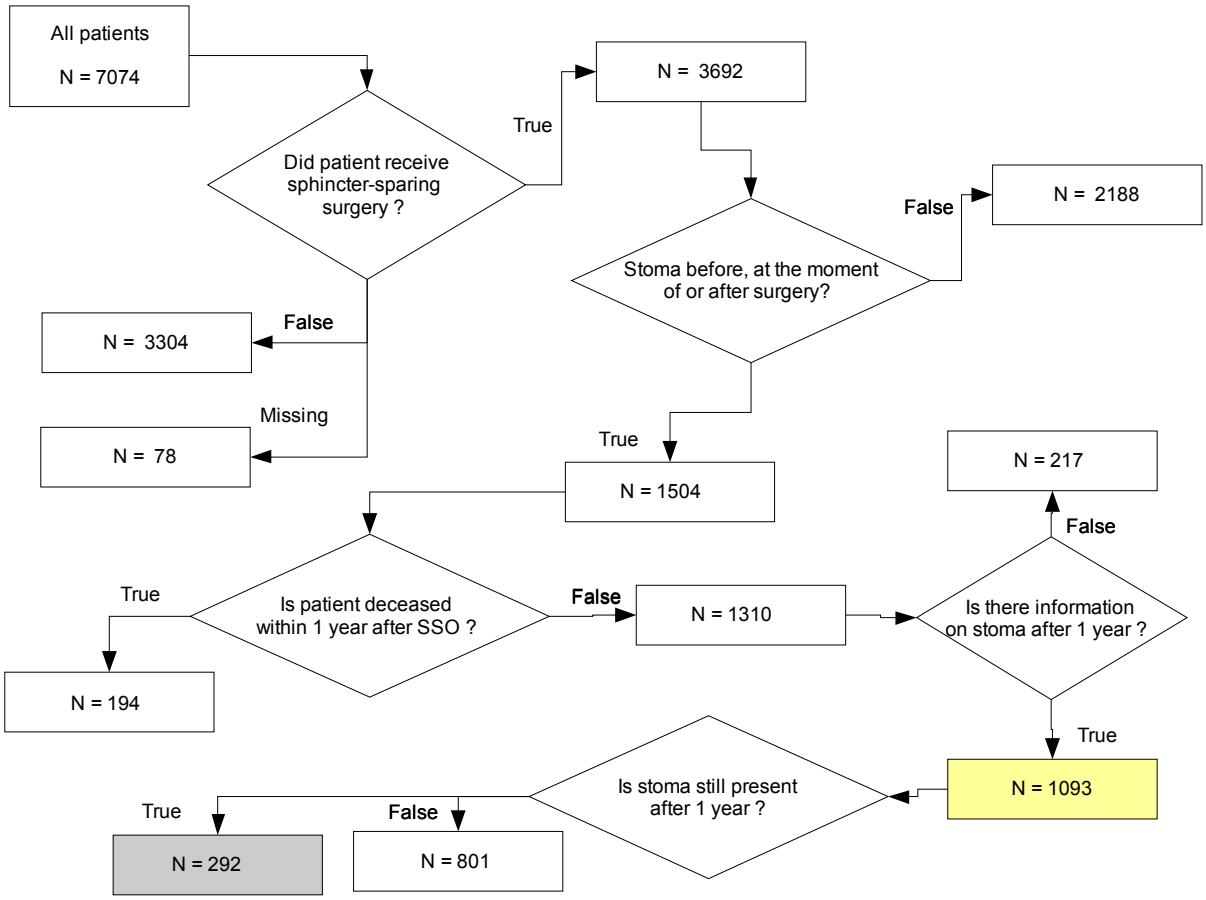


Table 82. ICD-9-CM codes for permanent stoma.

Code	Description	Comment
46.13	Permanent colostomy	
49.6	Excision of anus	

Table 83. Nomenclature codes for stoma material.

Nomenclature code	Description (Dutch)	Description (French)
640275 – 640286	Gesloten, zelfklevend opvangzakje, voorzien van een peristomale beschermlaag, ongeacht de bijbehorende produktattributen - Dotatie : 1° 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere systemen ; 2° 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentiesystemen - LIJST 0275	Collecteur, adhésif fermé muni d'une couche protectrice péristomale, quels que soient les accessoires . Dotation : 1° 180 pièces/3 mois, si pas utilisé en combinaison avec d'autres systèmes ; 2° 90 pièces/3 mois, si utilisé en combinaison avec d'autres systèmes collecteurs ou de continence - LISTE 0275
640290 – 640301	Ledigbaar zelfklevend opvangzakje voorzien van een peristomale beschermlaag, ongeacht de overige bijbehorende produktattributen - Dotatie : 90 stuks/3 maanden - LIJST 0290	Collecteur adhésif à vider mini d'une couche protectrice péristomale, quels que soient les autres accessoires - Dotation : 90 pièces/3 mois - LISTE 0290
640371 – 640382	Peristomale beschermschijf met bevestigingssysteem (bv. opklikring),	Disque protecteur péristomal avec système de fixation (par exemple

Nomenclature code	Description (Dutch)	Description (French)
	ongeacht de overige bijbehorende produktattributen - Dotatie : 45 stuks/3 maanden(ileostomie), 35 stuks/3 maanden (colostomie) - LIJST 0371	anneau-clip), quels que soient les autres accessoires - Dotation : 45 pièces/3 mois(iléostomie), 35 pièces/3 mois (colostomie) - LISTE 0371
640430	Peristomale beschermschijf met kleefsysteem, ongeacht de overige bijbehorende produktattributen - Dotatie : 45 stuks/3 maanden (ileostomie) 35 stuks/3 maanden (colostomie) - LIJST 0430	Disques protecteur péristomal avec système adhésif, quels que soient les autres accessoires - Dotation : 45 pièces/3 mois (iléostomie) 35 pièces/3 mois (colostomie) - LISTE 0430
640533 – 640544	Minizakje met peristomale beschermlaag en geïntegreerde filter, ongeacht de overige bijbehorende produktattributen - Dotatie : 1° 180 stuks/3 maanden indien niet gebruikt in combinatie met andere opvang- of continentiesystemen ; 2° 90 stuks/3 maanden indien gecombineerd gebruikt met opvang- of continentiesystemen - LIJST 0533	Mini-poche avec couche protectrice péristomale et filtre intégré, quels que soient les autres accessoires - Dotation : 1° 180 pièces/3 mois, si pas utilisé en combinaison avec d'autres systèmes collecteurs ou de continence ; 2° 90 pièces/3 mois, si utilisé en combinaison avec des systèmes collecteurs ou de continence - LISTE 0533
640555 – 640566	Inwendige afsluitplug, voorzien van een peristomale beschermlaag, ongeacht de overige bijbehorende produktattributen - Dotatie : 1° 120 stuks/3 maanden indien niet gebruikt in combinatie met opvang- of andere continentiesystemen ; 2° 90 stuks/3 maanden indien gecombineerd gebruikt met opvang- of andere continentiesystemen - LIJST 0555	Bouchon de fermeture interne muni d'une couche protectrice péristomale, quels que soient les autres accessoires - Dotation : 1° 120 pièces/3 mois, si pas utilisé en combinaison avec des systèmes collecteurs ou d'autres systèmes de continence ; 2° 90 pièces/3 mois, si utilisé en combinaison avec des systèmes collecteurs ou d'autres systèmes de continence - LISTE 0555
640872 – 640883	Peristomale beschermschijf, voorzien van een bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen - Dotatie : 45 stuks/3 maanden - LIJST 0872	Disque protecteur péristomal muni d'un système de fixation (par ex. anneau-clip), quels que soient les autres accessoires - Dotation : 45 pièces/3 mois - LISTE 0872
641196	Ledigbaar opvangzakje voorzien van een individueel aanpasbare peristomale beschermschijf, waarvan de kleinste diameter minimum 70 mm bedraagt, ongeacht de overige bijkomende produktattributen - Dotatie : 90 suks/3 maanden - LIJST 1196	Collecteur à vider avec plaque protectrice péristomale individuellement adaptable, dont le plus petit diamètre est de 70 mm, quels que soient les autres accessoires - Dotation : 90 pièces/3 mois - LISTE 1196
641270	Individueel aanpasbare peristomale beschermschijf waarvan de kleinste diameter minimum 70 mm bedraagt, ongeacht de overige bijbehorende produktattributen - Dotatie : 45 stuks/3 maanden(ileostomie), 35 stuks/3 maanden (colostomie) - LIJST 1270	Plaque protectrice péristomale individuellement adaptable dont le plus petit diamètre s'élève au moins à 70 mm, quels que soient les autres accessoires - Dotation : 45 pièces/3 mois(iléostomie), 35 pièces/3 mois (colostomie) - LISTE 1270

Nomenclature code	Description (Dutch)	Description (French)
641351 – 641362	Convexe peristomale beschermschijf met een minimum plaatdikte van 3 mm in het centrum, met bevestigingsssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen - Dotatie : 45 stuks/3 maanden - LIJST 1351	Plaque protectrice péristomale convexe, avec une épaisseur minimale de la plaque de 3 mm au centre avec système de fixation (p ex. anneau-clip) quels que soient les autres accessoires - Dotation : 45 pièces/3 mois - LISTE 1351
641465	Forfaitair dagbedrag voor een colostomie patiënt	Forfait journalier pour un patient ayant subi une colostomie

Table 84. Nomenclature codes for stoma closure.

Nomenclature code	Description (Dutch)	Description (French)
243224 – 243213	Sluiten van een ileo- of colostomie of colonfistel	Fermeture d'une iléo- ou colostomie ou d'une fistule colique
243235 – 243246	Segmentaire resectie van de dunne darm	Résection segmentaire du grêle
243051 – 243062	Hemicolectomie rechts of links of segmentaire colonresectie of sigmoïdresectie of partïele rectumresectie met herstel van de continuïteit	Hémi-colectomie droite ou gauche ou résection segmentaire du colon ou résection du sigmoïde ou résection partielle du rectum avec rétablissement de la continuité

RATE OF PATIENTS WITH MAJOR LEAKAGE OF THE ANASTOMOSIS

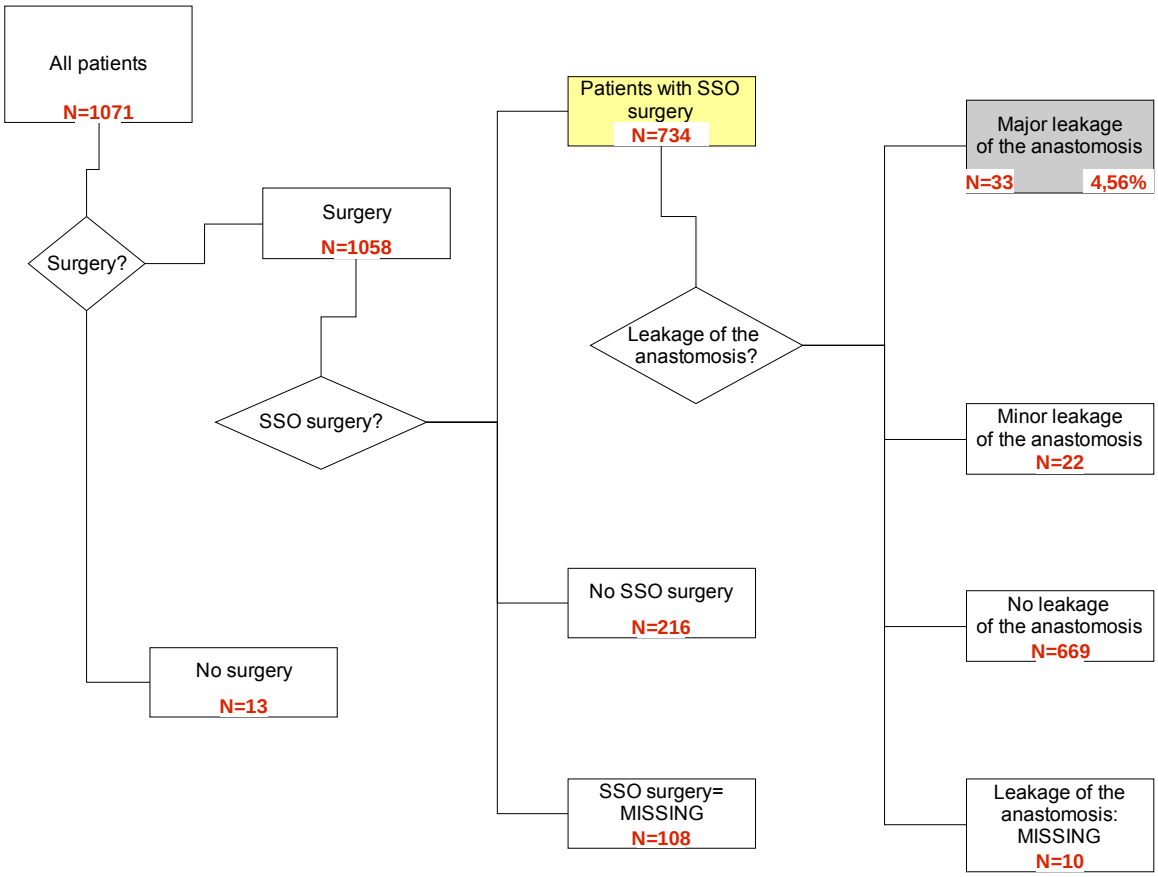
Measurement in prospective PROCARE database (Figure 42)

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients undergoing SSO are selected using variable 'SG_V234' (subcodes 6-9). Major leakage is registered through variable 'SPO_V117'.

Measurement in coupled administrative database

Leakage of the anastomosis can be coded as a complication using ICD-9-CM code 997.4 (digestive system complications). However, this is a very unspecific code covering several complications. The QI is therefore not measurable for the administrative cohort.

Figure 42. Algorithm for QI 1233 (prospective database).



INPATIENT OR 30-DAY MORTALITY (FIGURE 43 AND FIGURE 44)

Mortality data are collected from the mortality database of the sickness funds, and are available until December 31st 2006. Coupling with the PROCARE database is done using the social security number. Therefore, an accurate follow-up is only available for patients with a known social security number and Belgian postal code. Since data are available until December 31st 2006, the analysis of the 30-day mortality can only be done for patients with a surgery date before December 2nd 2006.

Inpatient mortality is calculated using the same time frame. When the date of death occurs at the date of discharge (variable 'SPO_V216' in PROCARE database), death is considered inpatient. In theory, the QI can be underestimated, since some patients having had surgery before December 2nd 2006 could have died in hospital after December 31st 2006. However, this was manually checked and didn't occur.

Figure 43. Algorithm for QI 1234 (prospective database).

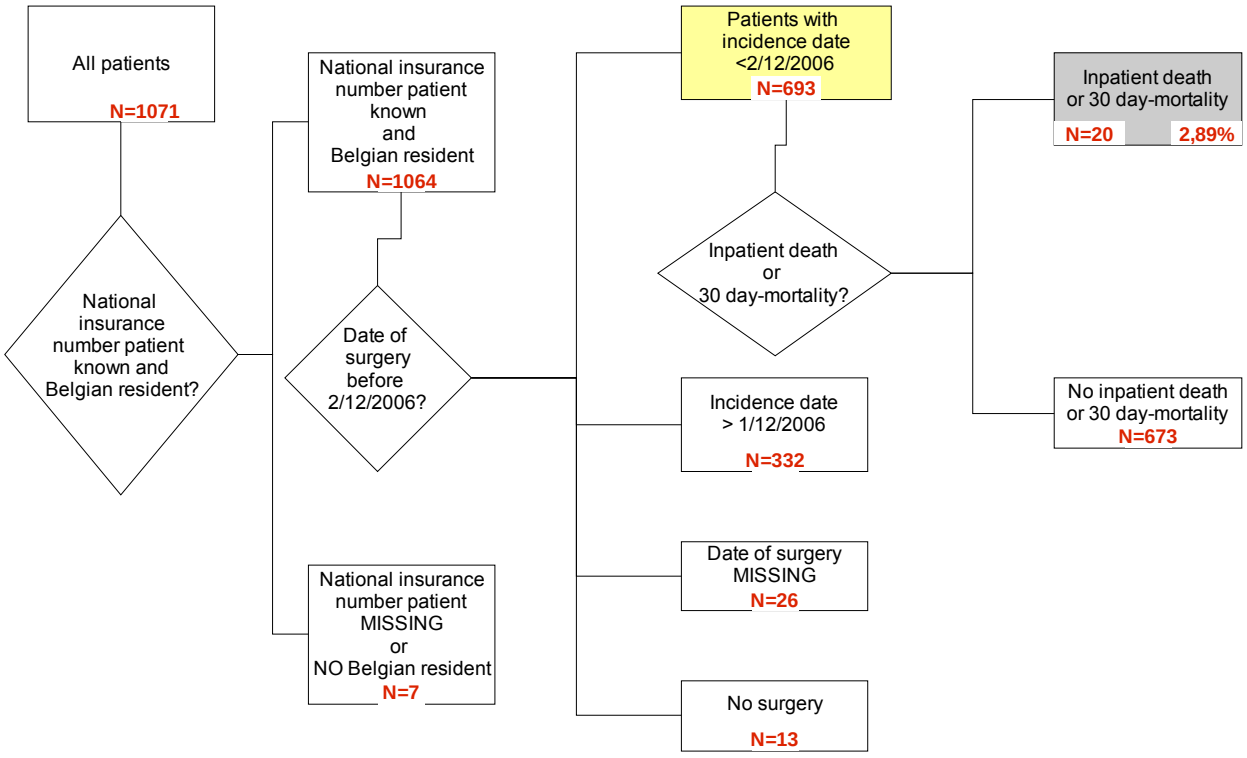
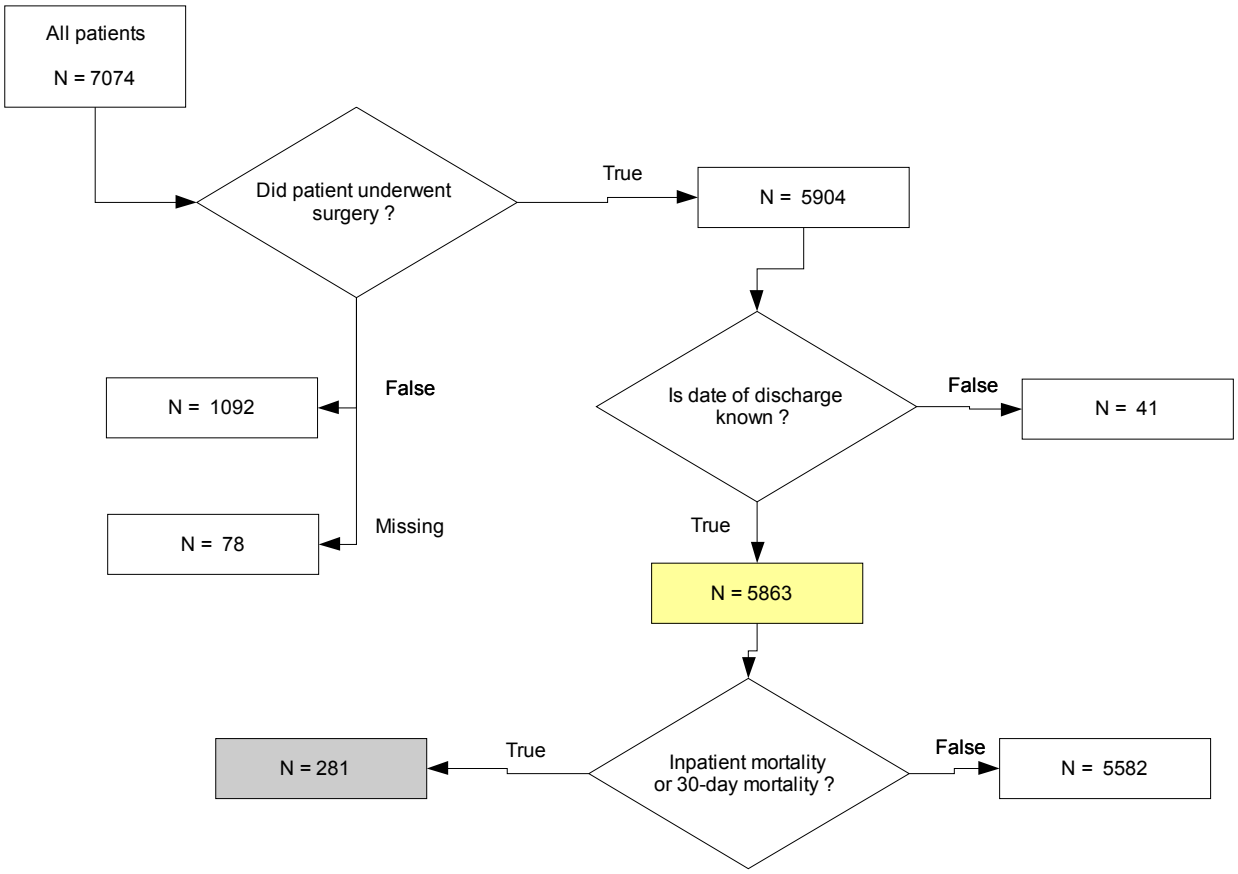


Figure 44. Algorithm for QI 1234 (administrative database).



RATE OF INTRA-OPERATIVE RECTAL PERFORATION

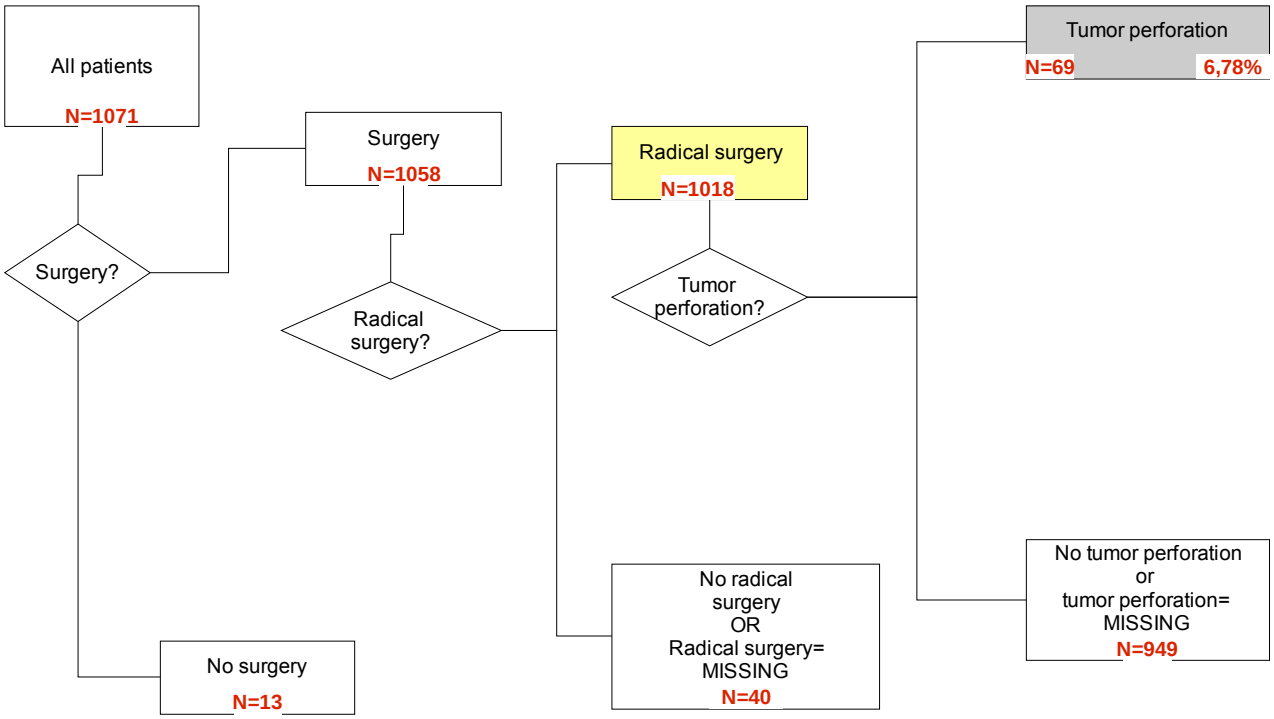
Measurement in prospective PROCARE database (Figure 45)

Of the patients with RC undergoing surgery (variable 'AD_V111'). Patients undergoing radical resection are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'. Within this group, patients having a perforation of the rectum are selected using variables 'SG_V207' and 'PT_V127'. As for variables 'FU_V139' and 'RD_V107' (see above), the default value of variables 'SG_V207' and 'PT_V127' was '0' (i.e. missing values also received a value '0').

Measurement in coupled administrative database

Intestinal perforation can be coded in ICD-9-CM with code 569.83 (perforation of intestine). However, this is an unspecific code, also covering non-tumoral perforation. Therefore, this QI is not measurable for the administrative cohort.

Figure 45. Algorithm for QI 1235 (prospective database).



PROPORTION OF (Y)PSTAGE III PATIENTS WITH R0 RESECTION THAT RECEIVED ADJUVANT CHEMOTHERAPY

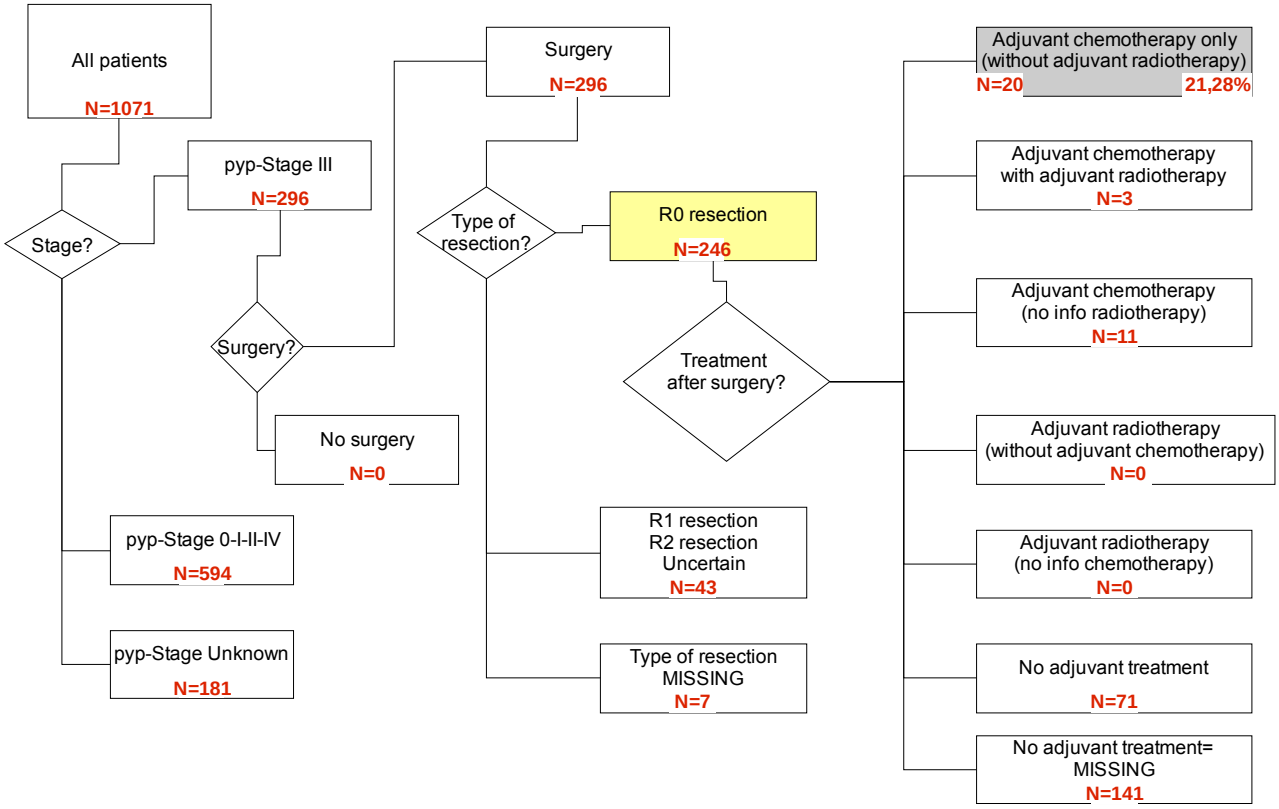
Measurement in prospective PROCARE database (Figure 46)

Patients with (y)pStage III RC are selected through variable 'PT_V151'. Those patients undergoing R0 resection are selected using variable 'SG_V216' (subcode 1). Patients receiving adjuvant chemotherapy without radiotherapy are selected with variables 'CH_V105' (subcode 3) and 'CH_V106' (subcode not 2).

Measurement in coupled administrative database

Selection of (y)pStage III patients can be done easily using the BCR database. Above this, accurate information is available on the use of adjuvant chemotherapy (Table 72). However, no administrative code exists for R0 resection. Therefore, this QI is not measurable for the administrative cohort.

Figure 46. Algorithm for QI 1241 (prospective database).



PROPORTION OF PSTAGE II-III PATIENTS WITH R0 RESECTION THAT RECEIVED ADJUVANT RADIOTHERAPY OR CHEMORADIOTHERAPY

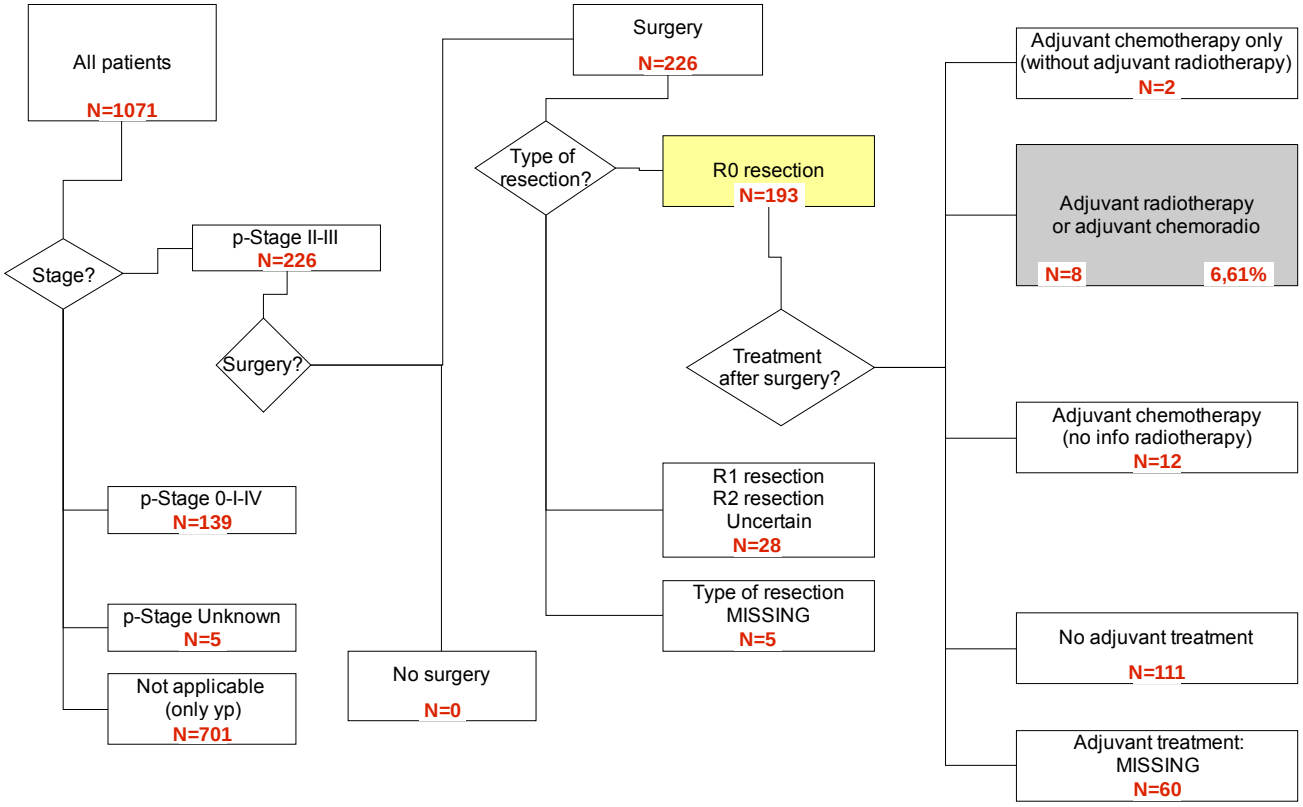
Measurement in prospective PROCARE database (Figure 47)

Patients with pStage II-III RC are selected through variable 'PT_V151'. Those patients undergoing R0 resection are selected using variable 'SG_V216' (subcode 1). Patients receiving adjuvant radio(chemo)therapy are selected with variables 'RD_V101' (subcode 2) and 'RD_V124' (subcode 1 if without chemotherapy, subcode 2 if with chemotherapy).

Measurement in coupled administrative database

Selection of pStage II-III patients can be done easily using the BCR database. Above this, accurate information is available on the use of adjuvant radio(chemo)therapy (Table 70, 71 and 72). However, no administrative code exists for R0 resection. Therefore, this QI is not measurable for the administrative cohort.

Figure 47. Algorithm for QI 1242 (prospective database).



PROPORTION OF (Y)PSTAGE II-III PATIENTS WITH R0 RESECTION THAT STARTED ADJUVANT CHEMOTHERAPY WITHIN 12 WEEKS AFTER SURGICAL RESECTION

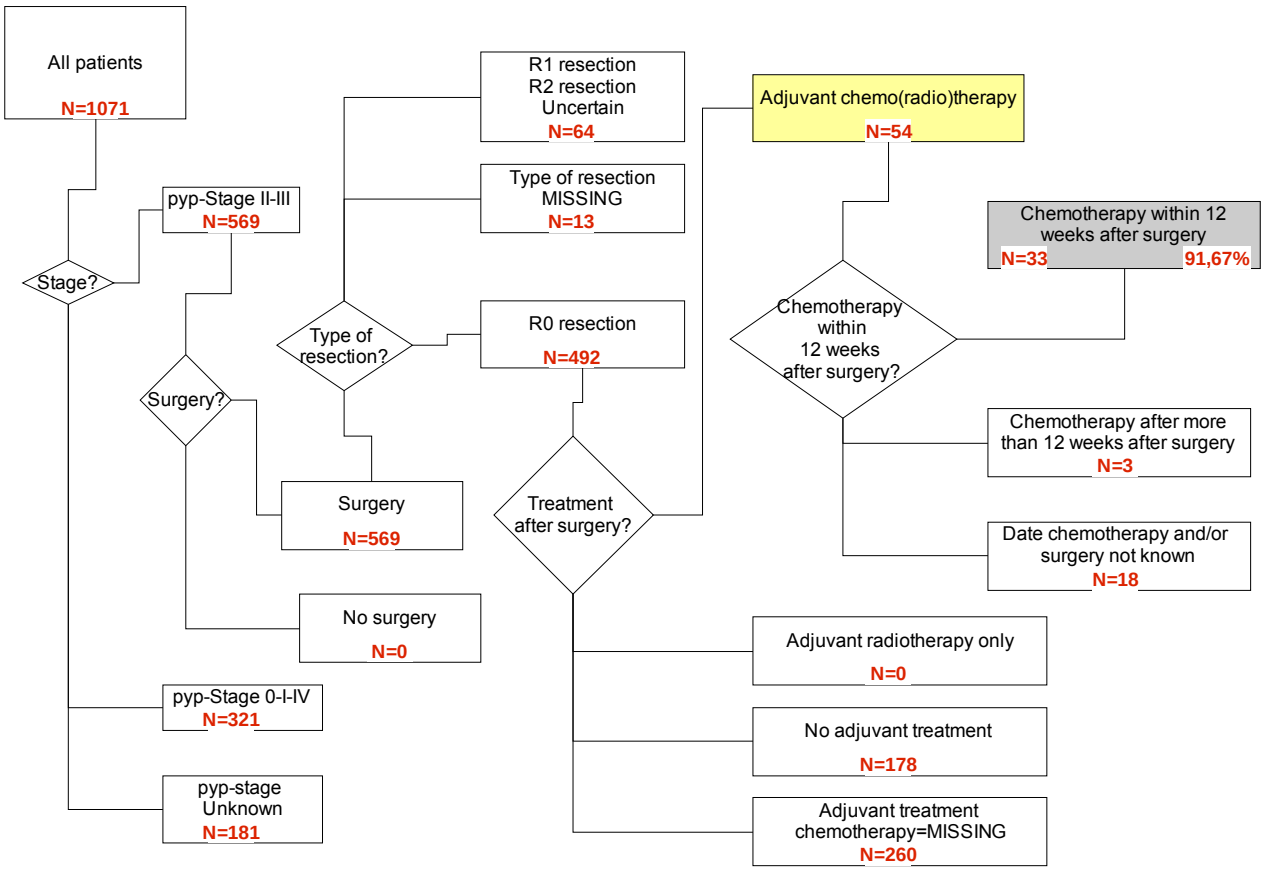
Measurement in prospective PROCARE database (Figure 48)

Patients with (y)pStage II-III RC are selected through variable 'PT_V151'. Those patients undergoing R0 resection are selected using variable 'SG_V216' (subcode 1). Patients receiving adjuvant chemotherapy are selected with variables 'CH_V104' (subcode 1) and 'CH_V106' (subcode not 2). The dates of surgery and chemotherapy are registered through variables 'SG_V106' and 'CH_V115' respectively, allowing the calculation of the time interval between the two treatments.

Measurement in coupled administrative database

Selection of (y)pStage II-III patients can be done easily using the BCR database. Above this, accurate information is available on the use of adjuvant chemotherapy (Table 72) and the surgery date (Table 64 and 66). However, no administrative code exists for R0 resection. Therefore, this QI is not measurable for the administrative cohort.

Figure 48. Algorithm for QI 1243 (prospective database).



PROPORTION OF (Y)PSTAGE II-III PATIENTS WITH R0 RESECTION TREATED WITH ADJUVANT CHEMO(RADIO)THERAPY, THAT RECEIVED 5-FU BASED CHEMOTHERAPY

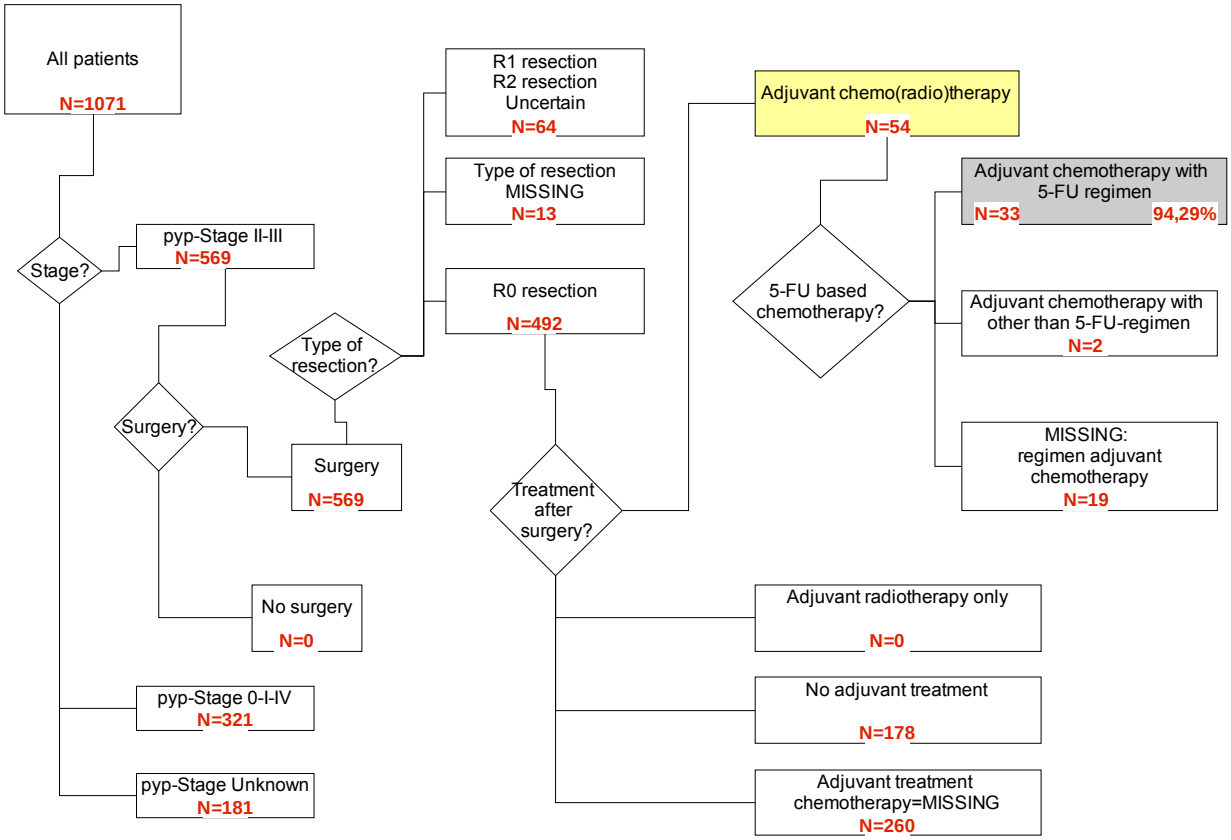
Measurement in prospective PROCARE database (Figure 49)

Patients with (y)pStage II-III RC are selected through variable 'PT_V151'. Those patients undergoing R0 resection are selected using variable 'SG_V216' (subcode 1). Patients receiving adjuvant chemotherapy are selected with variables 'CH_V104' (subcode 1) and 'CH_V106' (subcode not 2). The use of a 5-FU based regimen is registered through variable 'CH_V110'.

Measurement in coupled administrative database

Selection of (y)pStage II-III patients can be done easily using the BCR database. Above this, accurate information is available on the use of adjuvant chemo(radio)therapy (Table 70, 71 and 72). However, no administrative code exists for R0 resection. Therefore, this QI is not measurable for the administrative cohort.

Figure 49. Algorithm for QI 1244 (prospective database).



RATE OF ACUTE GRADE 4 CHEMOTHERAPY-RELATED COMPLICATIONS

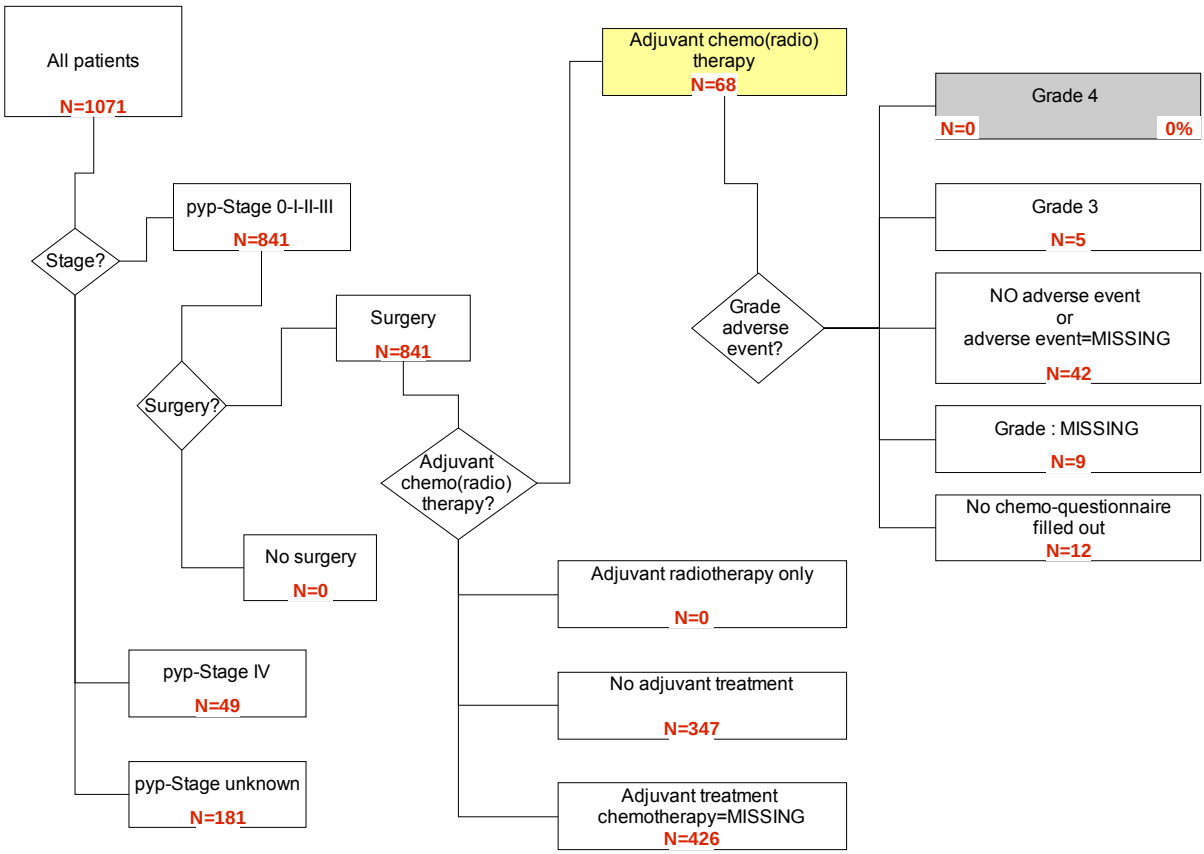
Measurement in prospective PROCARE database (Figure 50)

Patients with (y)p Stage 0-III are selected through variable 'PT_V151'. The subgroup treated with surgery is selected using variable 'AD_V111'. Within this selection, patients receiving adjuvant chemo(radio)therapy are selected with variable 'CH_V104'. Chemo(radio)therapy-related complications are registered through variables 'CH_V136' – 'CH_V144', the grade is registered with variable 'CH_V146'.

Measurement in coupled administrative database

No specific administrative codes are available for chemotherapy-related complications. In the ICD-9-CM coding system some aspecific codes are available (e.g. 963.1 poisoning by primarily systemic agents: antineoplastic and immunosuppressive drugs), but there is no mentioning of grade. Therefore, these codes cannot be used. The QI is not measurable.

Figure 50. Algorithm for QI 1245 (prospective database).



RATE OF CSTAGE IV PATIENTS RECEIVING CHEMOTHERAPY

Measurement in prospective PROCARE database (Figure 51)

Patients with cStage IV RC are selected through variable 'PT_V151'. Those patients receiving chemotherapy are selected with variables 'AD_V114', 'AD_V118' and 'AD_V122'.

Measurement in coupled administrative database (Figure 52)

Patients with cStage IV are selected using the BCR database. Data on chemotherapy are available in the HIC database (Table 72), which are used to select those cStage IV patients receiving chemotherapy.

Figure 51. Algorithm for QI 1251 (prospective database).

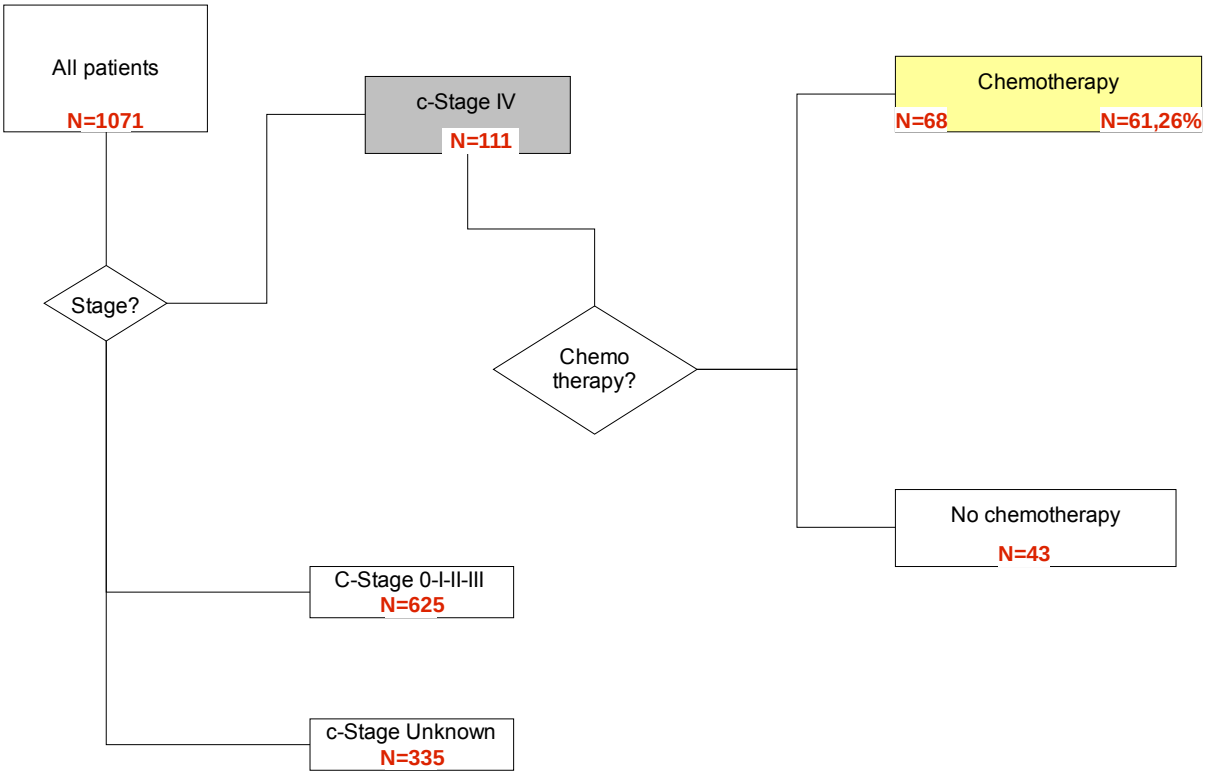
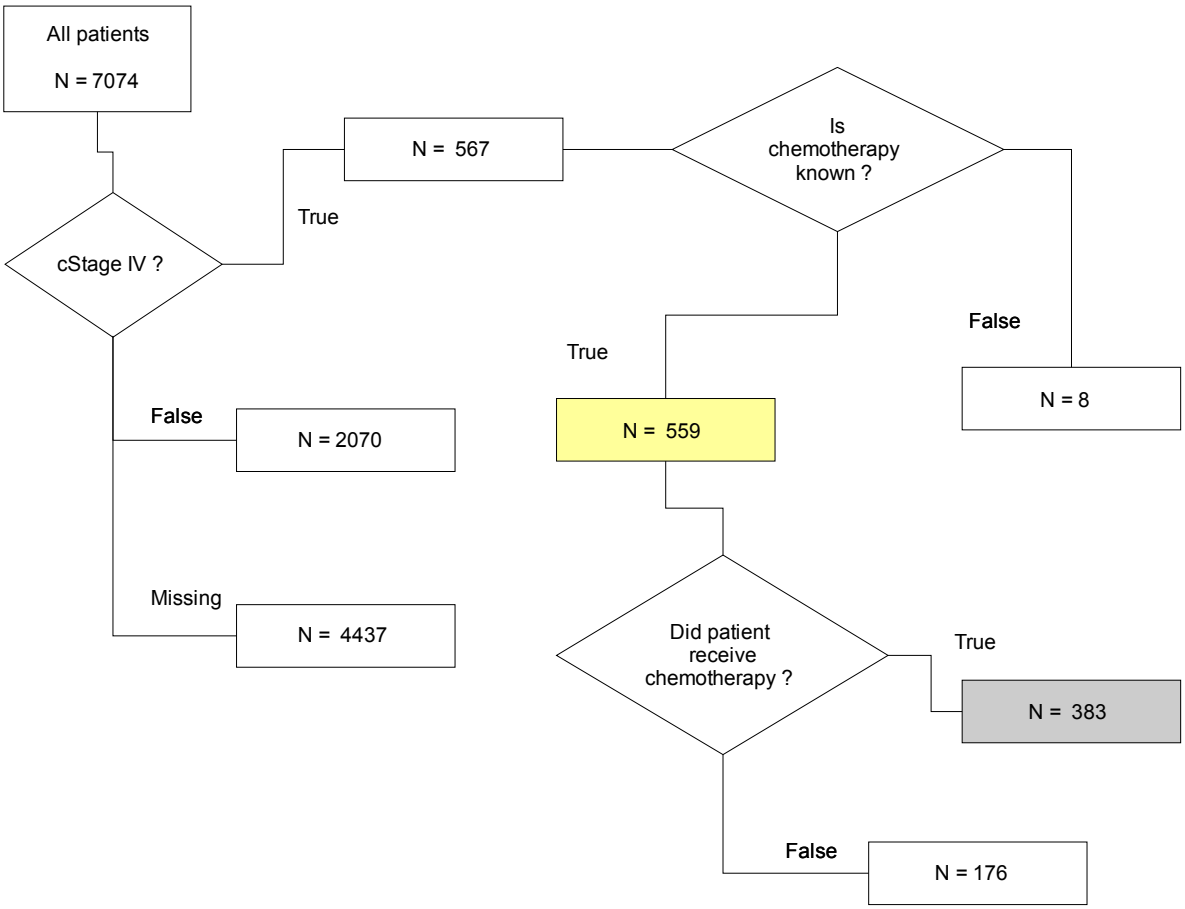


Figure 52. Algorithm for QI 1251 (administrative database).



RATE OF ACUTE GRADE 4 CHEMOTHERAPY-RELATED COMPLICATIONS IN STAGE IV PATIENTS

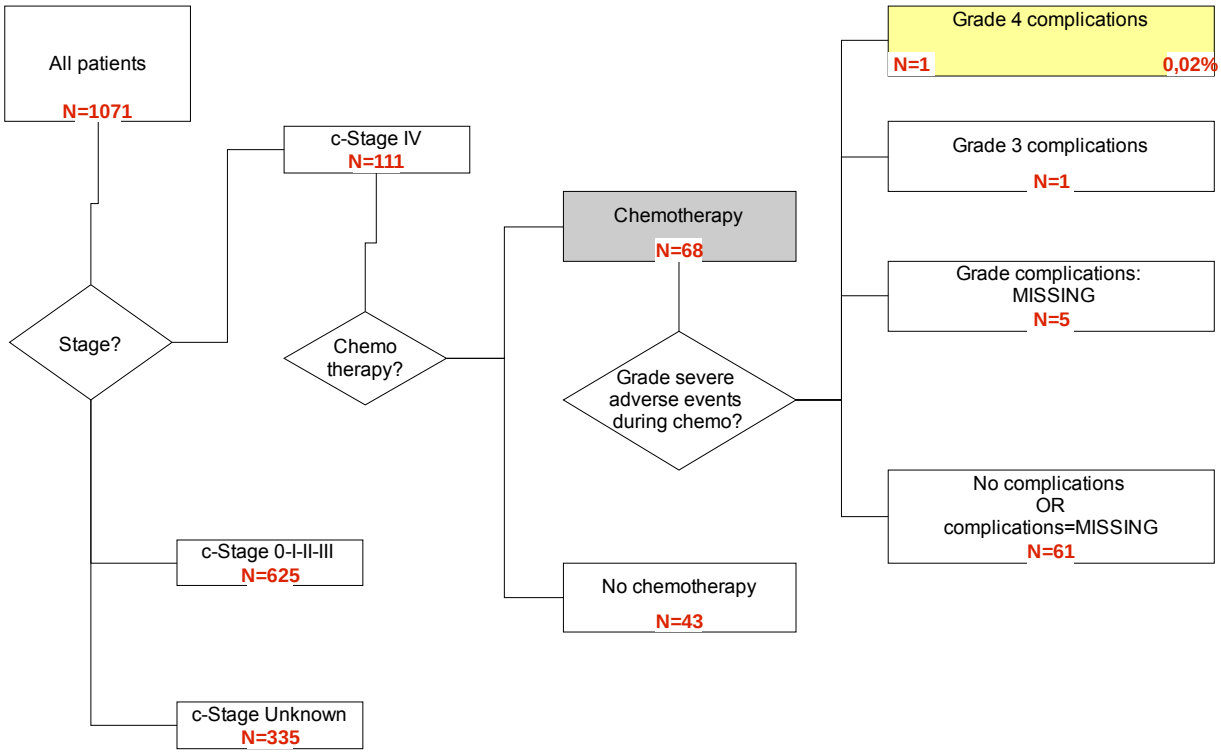
Measurement in prospective PROCARE database (Figure 53)

Patients with cStage IV RC are selected through variable 'PT_V151'. Those patients receiving chemotherapy are selected with variables 'AD_V114', 'AD_V118' and 'AD_V122'. Chemo(radio)therapy-related complications are registered through variables 'CH_V136' – 'CH_V144', the grade is registered with variable 'CH_V146'.

Measurement in coupled administrative database

No specific administrative codes are available for chemotherapy-related complications. In the ICD-9-CM coding system some aspecific codes are available (e.g. 963.1 poisoning by primarily systemic agents: antineoplastic and immunosuppressive drugs), but there is no mentioning of grade. Therefore, these codes cannot be used. The QI is not measurable.

Figure 53. Algorithm for QI 1252 (prospective database).



RATE OF CURATIVELY TREATED PATIENTS THAT RECEIVED A COLONOSCOPY WITHIN 1 YEAR AFTER TREATMENT

Measurement in prospective PROCARE database

Patients undergoing R0 resection are selected using variable 'SG_V216' (subcode 1). However, no code is available for colonoscopy in the follow-up section.

Measurement in coupled administrative database

Although administrative codes exist for colonoscopy (Table 74 and 75) and radical resection (Table 64 and 66), no code exists for R0 resection. This QI is therefore not measurable for the administrative cohort.

RATE OF PATIENTS UNDERGOING REGULAR FOLLOW-UP (ACCORDING TO THE PROCARE RECOMMENDATIONS)

Measurement in prospective PROCARE database

Patients undergoing R0 resection are selected using variable 'SG_V216' (subcode 1). However, no code is available for colonoscopy in the follow-up section.

Measurement in coupled administrative database

Although administrative codes exist for diagnostic procedures (Table 62, 63, 73, 74, 75, 78, 79 and 80) and radical resection (Table 64 and Table 66), no code exists for R0 resection. This QI is therefore not measurable for the administrative cohort.

LATE GRADE 4 COMPLICATIONS OF RADIOTHERAPY OR CHEMORADIATION

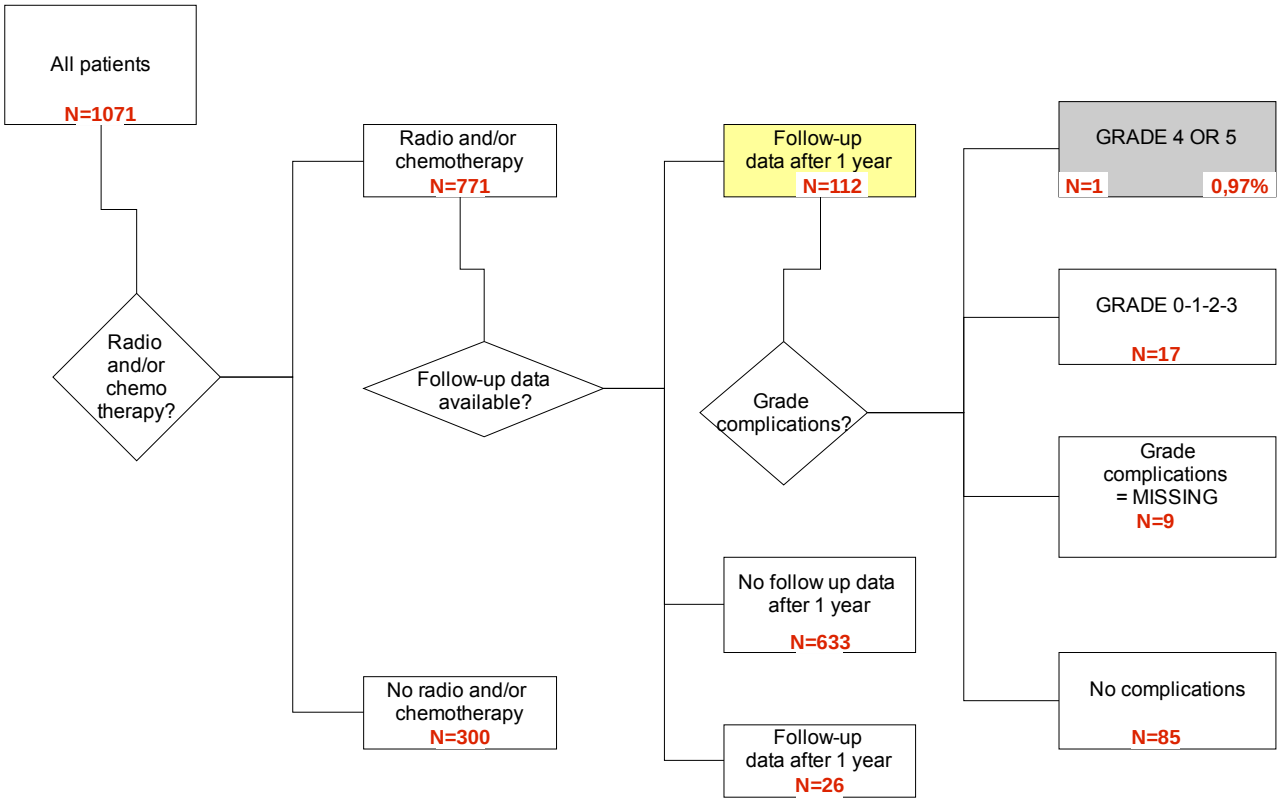
Measurement in prospective PROCARE database (Figure 54)

Patients receiving radio(chemo)therapy are selected with variables 'AD_V113', 'AD_V114', 'AD_V117', 'AD_V118', 'AD_V121' and 'AD_V122'. Late complications of radio(chemo)therapy are registered with variables 'FU_V106' – 'FU_V110'.

Measurement in coupled administrative database

No specific administrative codes are available for late (C)RT-related complications. In the ICD-9-CM coding system some aspecific codes are available (990 effects of radiation, unspecified; 963.1 poisoning by primarily systemic agents: antineoplastic and immunosuppressive drugs; 558.1 gastroenteritis and colitis due to radiation; etc.), but there is no mentioning of grade. Therefore, these codes cannot be used. The QI is not measurable.

Figure 54. Algorithm for QI 1263 (prospective database).



USE OF THE PATHOLOGY REPORT SHEET

Measurement in prospective PROCARE database

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Those patients undergoing resectional surgery (including local excision or TEMS) are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'. However, no code is available that registers the use of a pathology report sheet by the pathologist. Also, the suggested pathology report sheet is only in use since November 2006.

Measurement in coupled administrative database

No administrative code exists for the use of a pathology report sheet.

QUALITY OF TME ASSESSED ACCORDING TO QUIRKE AND MENTIONED IN THE PATHOLOGY REPORT

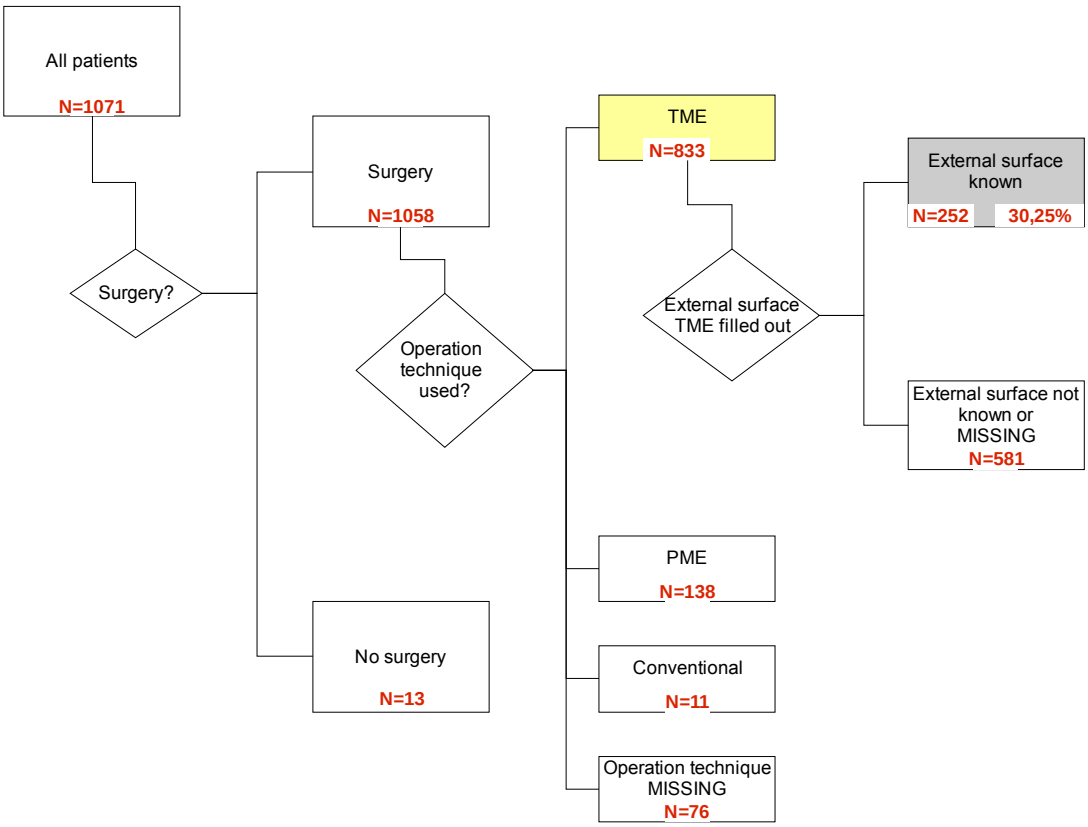
Measurement in prospective PROCARE database (Figure 55)

Patients undergoing TME are registered using the variable 'SG_V210' in the operative data section. Within this group of patients, those having a quality assessment of TME according to Quirke are selected with variable 'PT_V111' in the pathology section.

Measurement in coupled administrative database

No administrative code exists for the result of a TME quality assessment, which in fact are data that can only be retrieved from the medical file.

Figure 55. Algorithm for QI 1272 (prospective database).



DISTAL TUMOUR-FREE MARGIN MENTIONED IN THE PATHOLOGY REPORT

Measurement in prospective PROCARE database (Figure 56)

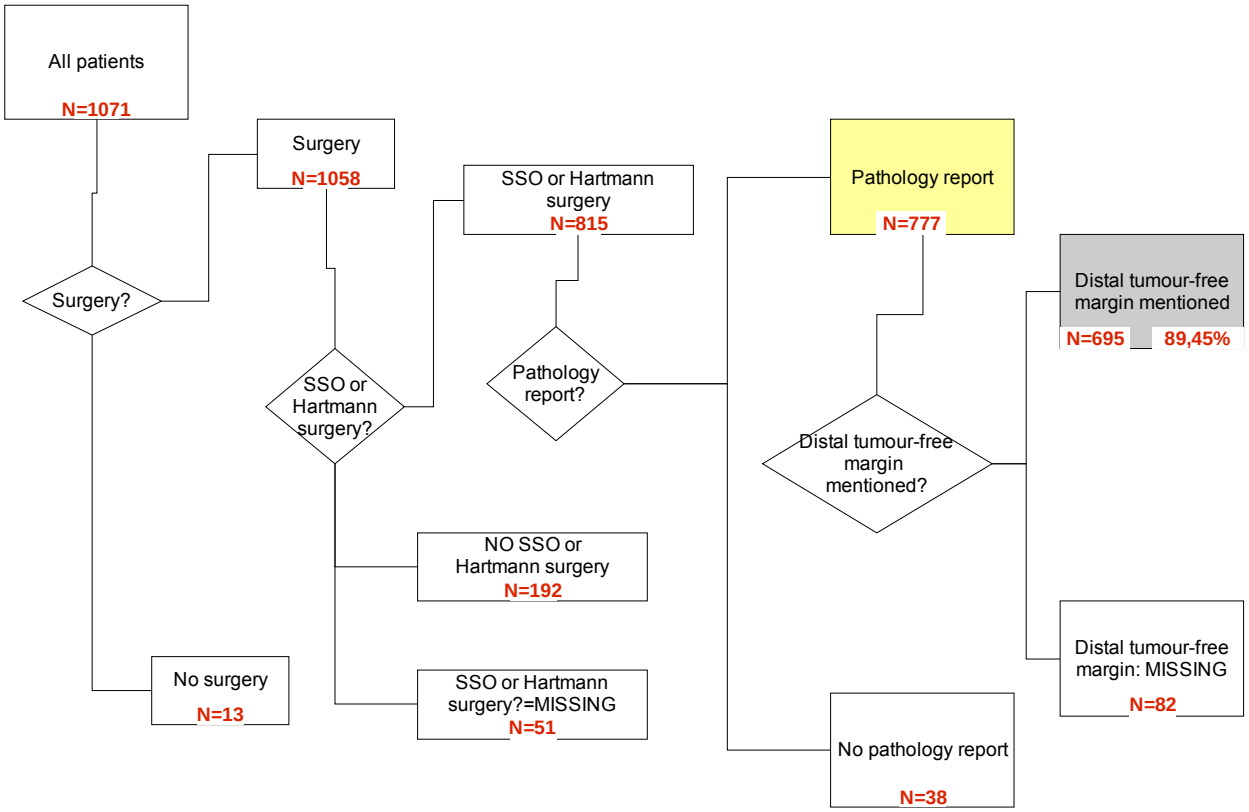
In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients undergoing radical resective sphincter saving surgery with curative intent are selected using variable 'SG_V234' (subcodes 5-9).

The distal tumour-free margin is registered through variable 'PT_V140' in the pathology section.

Measurement in coupled administrative database

No administrative code exists for the distal tumour-free margin, which are also data that can only be retrieved from the medical file.

Figure 56. Algorithm for QI 1273 (prospective database).



NUMBER OF LYMPH NODES EXAMINED

Measurement in prospective PROCARE database (Figure 57 and Figure 58)

In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients undergoing radical resection are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'.

Number of lymph nodes examined is registered through variable 'PT_V142' in the pathology section.

Since neoadjuvant radiotherapy has an important influence on the number of retrieved lymph nodes, results are presented taking into account the receival of a long course of neoadjuvant radiotherapy vs. no neoadjuvant radiotherapy or a short course of neoadjuvant radiotherapy vs. another course of neoadjuvant radiotherapy (using the same calculations as for QI 1221 and 1222).

Measurement in coupled administrative database

No administrative code exists for the number of lymph nodes examined, which are also data that can only be retrieved from the medical file.

Figure 57. Algorithm for QI 1274, part 1 (prospective database).

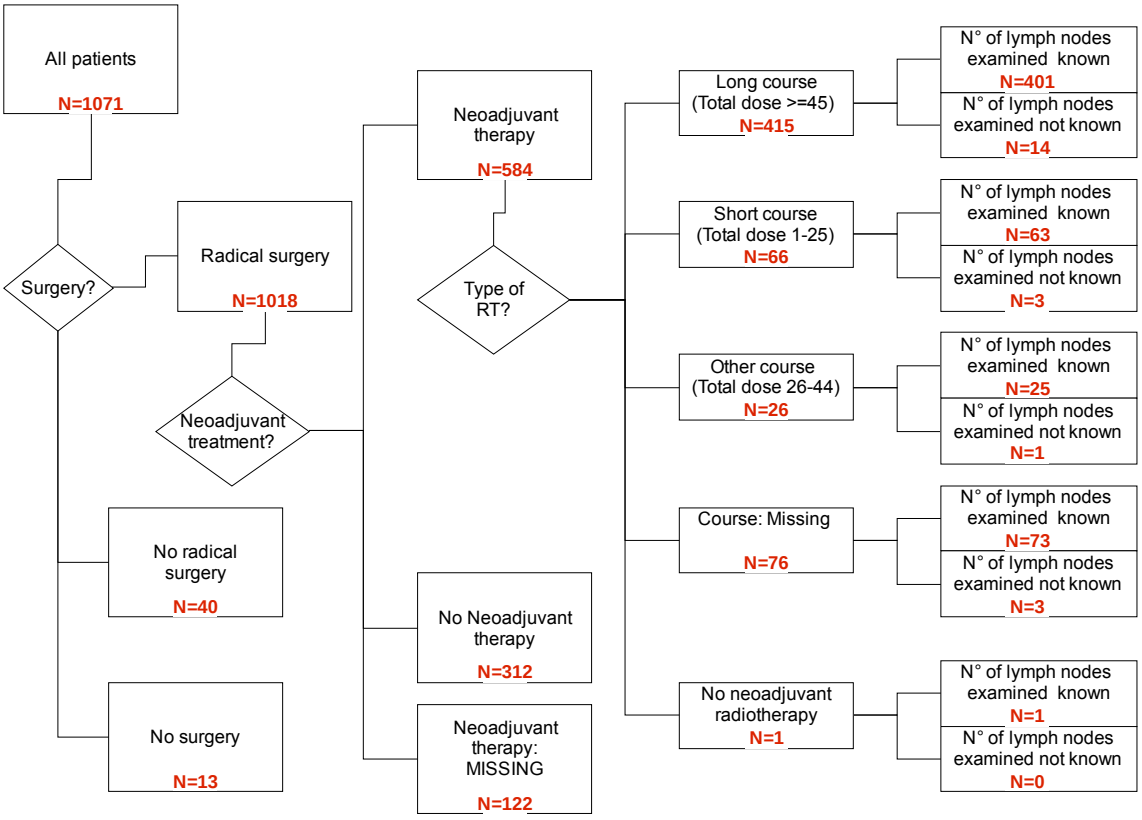
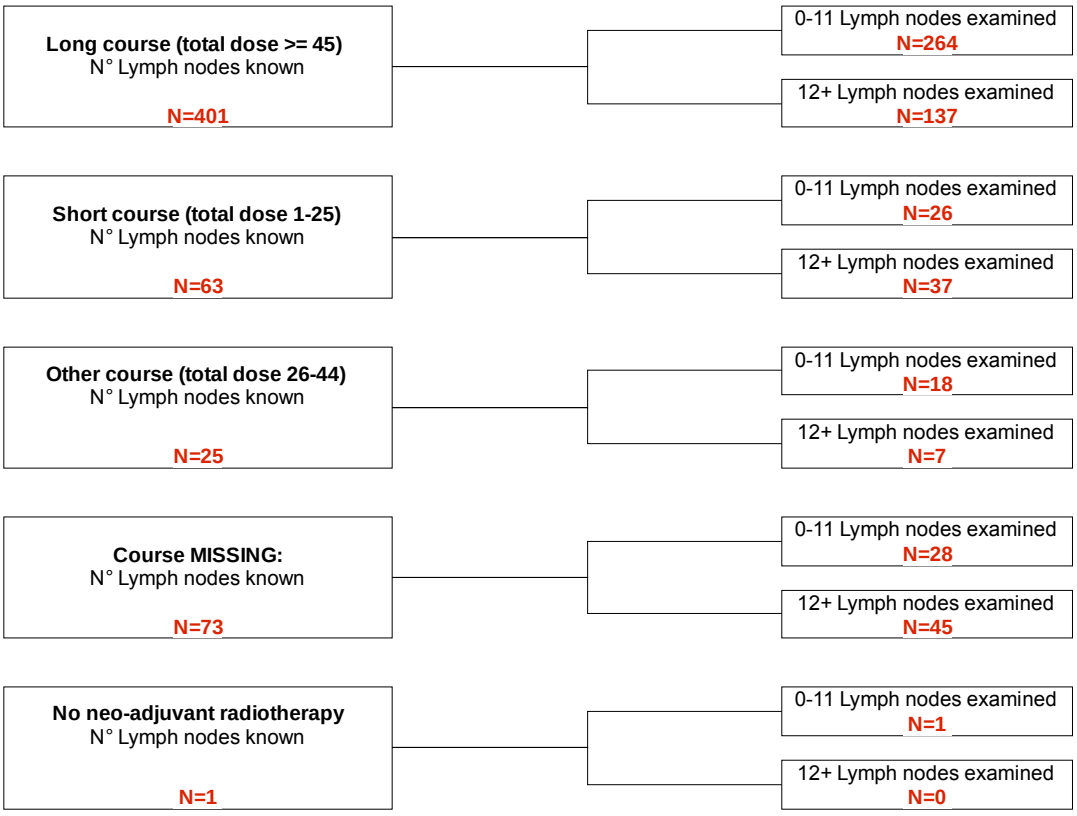


Figure 58. Algorithm for QI 1274, part 2 (prospective database).



(Y)PCRM MENTIONED IN MM IN THE PATHOLOGY REPORT

Measurement in prospective PROCARE database (Figure 59)

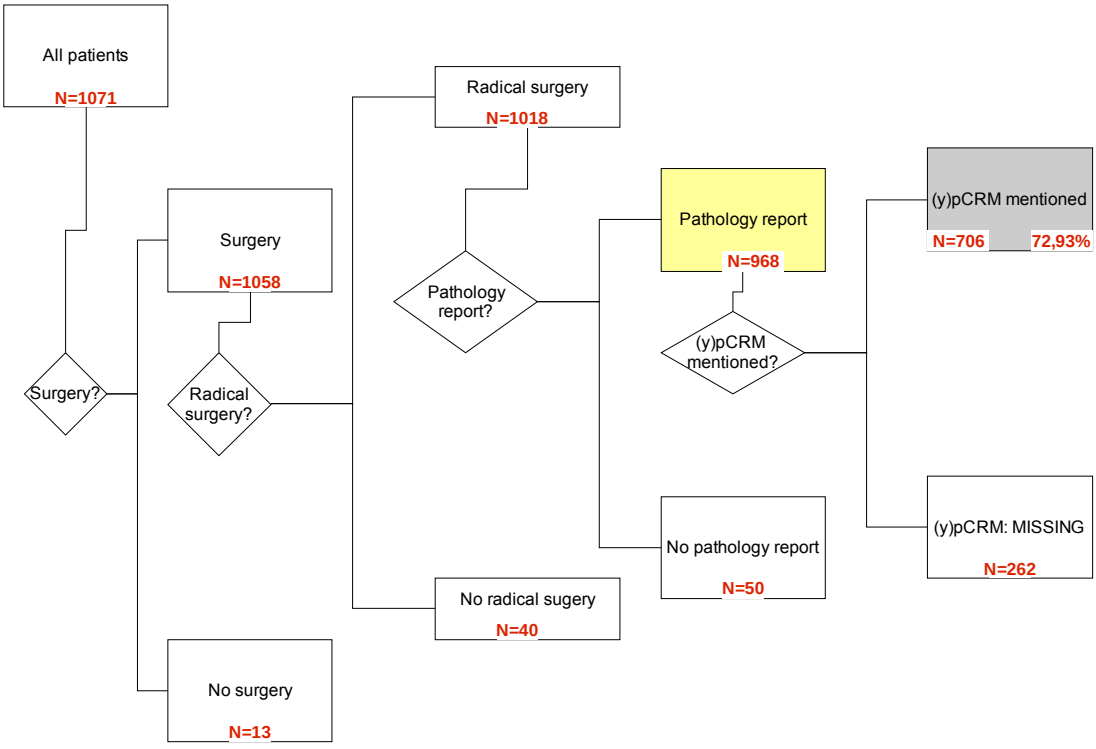
In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients undergoing radical resection (not local) are selected using variables 'SG_V168', 'SG_V210', 'SG_V216' and 'SG_V234'.

The (y)pCRM is registered through variable 'PT_V141' in the pathology section.

Measurement in coupled administrative database

No administrative code exists for the (y)pCRM, which are also data that can only be retrieved from the medical file.

Figure 59. Algorithm for QI 1275 (prospective database).



TUMOUR REGRESSION GRADE MENTIONED IN PATHOLOGY REPORT (AFTER NEOADJUVANT TREATMENT)

Measurement in prospective PROCARE database (Figure 60)

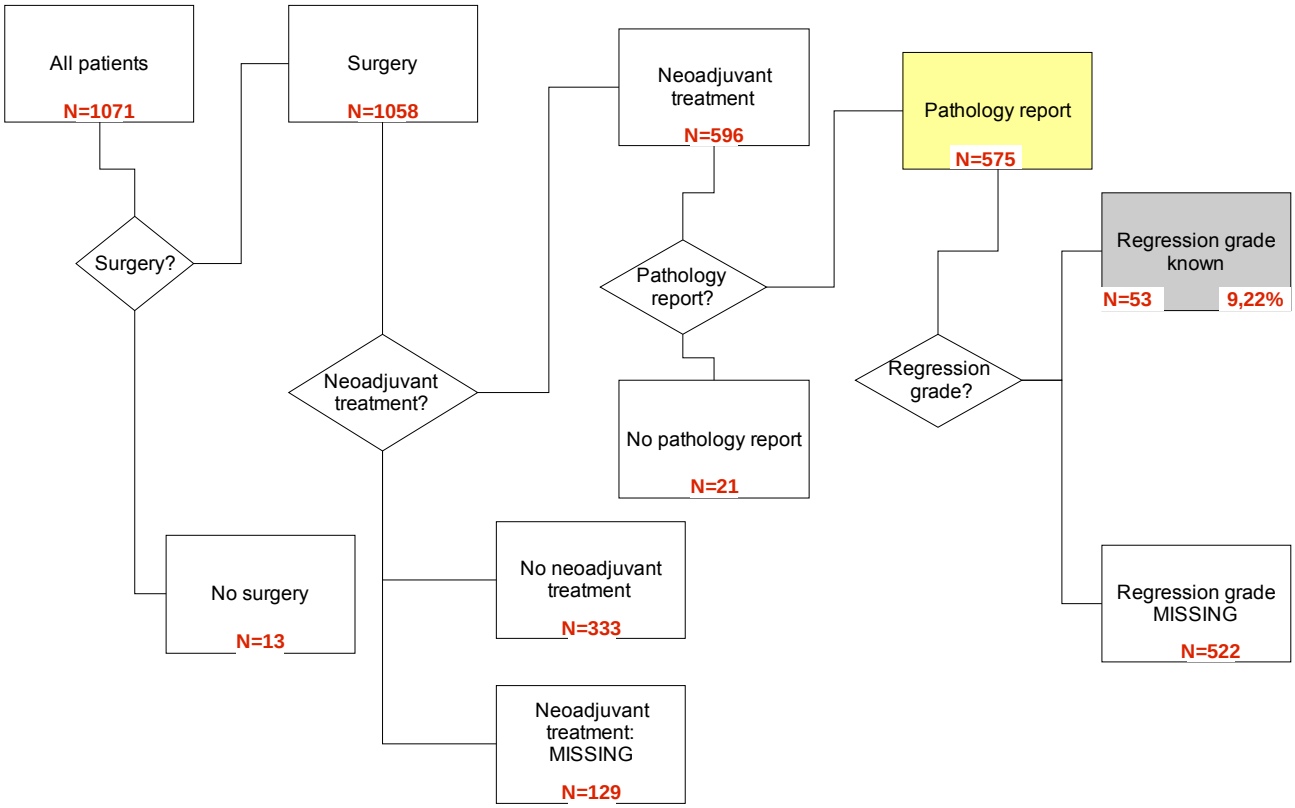
In the hospital data section of the PROCARE data entry form, the variable 'AD_V111' is checked if the patient underwent rectal surgery. Patients receiving neoadjuvant treatment are registered using variables 'RD_V101' (radiotherapy), 'CH_V101' (chemoradiotherapy) or 'CH_V103' (chemotherapy).

Tumour regression grade is registered through variables 'PT_V149' and 'PT_V150' in the pathology section.

Measurement in coupled administrative database

No administrative code exists for the tumour regression grade, which are also data that can only be retrieved from the medical file.

Figure 60. Algorithm for QI 1276 (prospective database).



APPENDIX 3: CODES USED FROM THE PROSPECTIVE DATASET

Code	Description	Value(s)
AD_V111	Surgery	0 = no/missing, 1 = yes
AD_V113	Radiotherapy (1)	0 = no/missing, 1 = yes
AD_V114	Chemotherapy (1)	0 = no/missing, 1 = yes
AD_V117	Radiotherapy (2)	0 = no/missing, 1 = yes
AD_V118	Chemotherapy (2)	0 = no/missing, 1 = yes
AD_V121	Radiotherapy (3)	0 = no/missing, 1 = yes
AD_V122	Chemotherapy (3)	0 = no/missing, 1 = yes
SPR_V110	Lower limit primary tumour based on rigid rectoscopy	Numeric
SPR_V112	Lower limit primary tumour based on coloscopy	Numeric
SPR_V122	cT based on CT	1 = Tx, 2 = T0, 3 = Tis, 4 = T1, 5 = T2, 6 = T3, 7 = T4, 8 = TisM, 9 = T1M, 10 = T2M, 11 = T3M, 12 = T4M
SPR_V123	cT based on KST	Same as SPR_V122
SPR_V124	cT based on EUS	Same as SPR_V122
SPR_V125	cT based on MRI	Same as SPR_V122
SPR_V126	cN based on CT	1 = N0, 2 = N1, 3 = N2, 4 = Nx
SPR_V127	cN based on KST	Same as SPR_V126
SPR_V128	cN based on EUS	Same as SPR_V126
SPR_V129	cN based on MRI	Same as SPR_V126
SPR_V130	cCRM lateral or circumferential margin estimated at MRI - CT	Numeric
SPR_V131	cCRM lateral or circumferential margin estimated at NMR - CT	Numeric
SPR_V141	cM based on CT	0 = no/missing, 1 = yes
SPR_V143	cM based on RX	0 = no/missing, 1 = yes
SPR_V147	Summary clinical TNM	
SPR_V148	CEA serum before treatment	Numeric
SPR_V149	Total coloscopy	0 = no/missing, 1 = yes
SPR_V154	No total coloscopy – reason = tumour stenosis	0 = no/missing, 1 = yes
SPR_V155	No total coloscopy – reason = insufficient preparation	0 = no/missing, 1 = yes
SPR_V156	No total coloscopy – reason = intolerance of patient	0 = no/missing, 1 = yes
SPR_V157	No total coloscopy – reason = technical reasons	0 = no/missing, 1 = yes
SPR_V158	No total coloscopy – reason = other	0 = no/missing, 1 = yes
SPR_V161	Coloscopy – biopsy of the tumour: date	Date
SPR_V171	Double contrast barium enema complete/incomplete	1 = complete, 2 = incomplete
SG_V105	Planned type resection	1 = local excision, 2 = sphincter saving radical resection, 3 = APR, 4 = Hartmann, 5 = no resection (e.g. palliative stoma)
SG_V106	Date of surgery	Date
SG_V109	Mode of surgery	1 = elective, 2 = scheduled, 3 = urgent, 4 = emergency
SG_V110	Lower limit primary tumour above margo ani	Numeric

Code	Description	Value(s)
SG_V128	Surgical exploration metastasis	1 = no, 2 = exploration limited because of adherences, 3 = yes
SG_V168	Surgical resection	0 = no/missing, 1 = yes
SG_V207	Perforation rectum?	0 = no/missing, 1 = yes
SG_V209	Distal level resection (at SSO)	1 = rectum, 2 = anorectal (on top of the anal canal), 3 = anal (intra-anal)
SG_V210	Resection technique	1 = PME, 2 = TME, 3 = conventional
SG_V216	Type resection	1 = R0, 2 = R1, 3 = R2, 4 = uncertain
SG_V234	Type reconstruction	1 = endoscopic polypectomy, 2 = local excision (disc excision), 3 = TEMS, 4 = APR, 5 = Hartmann, 6 = high anterior resection + CRA, 7 = low anterior resection + CRA, 8 = restorative rectum resection (TME) + straight CAA, 9 = restorative rectum resection (TME) + colon J pouch, 10 = restorative rectum resection (TME) + coloplasty, 11 = restorative rectum resection (TME) + other, 12 = other
SG_V245	Derivative stoma	0 = no/missing, 1 = yes
SPO_V102	Date postoperative death	Date
SPO_V104	Discharge date	Date
SPO_V117	Leakage of anastomosis	1 = minor, 2 = major
RD_V101	Radiotherapy treatment	1 = preoperative, 2 = postoperative
RD_V104	Date first irradiation	Date
RD_V105	Date last irradiation	Date
RD_V106	Number of fractions	Numeric
RD_V107	Radiation compliance: treatment interruption of more than five working days	0 = no/missing, 1 = yes
RD_V109	Total dose given at ICRU reference point	Numeric
RD_V124	Concomittant chemotherapy	0 = no/missing, 1 = yes
PT_V105	Distance anal verge	Numeric
PT_V106	cTNM staging	
PT_V111	Surface TME	1 = smooth & regular, 2 = mildly irregular, 3 = severely irregular
PT_V122	Distance distal (cm)	Numeric
PT_V127	Tumour perforation	Numeric
PT_V140	Longitudinal margin distal	1 = free, 2 = invaded
PT_V141	Circumferential margin (mm)	Numeric
PT_V143	Number of invaded lymph nodes	Numeric
PT_V149	RCRG	1 = grade 1, 2 = grade 2, 3 = grade 3
PT_V150	RCR (Dworak)	1 = grade 0, 2 = grade 1, 3 = grade 2, 4 = grade 3, 5 = grade 4
PT_V151	Conclusion (y)pTNM	1 = pTNM, 2 = ypTNM
PT_V152	Conclusion T	1 = Tx, 2 = T0, 3 = Tis, 4 = T1, 5 = T2, 6 = T3, 7 = T4
PT_V153	Conclusion N	1 = N0, 2 = N1, 3 = N2, 4 = Nx
PT_V154	Conclusion M	1 = Mx, 2 = M1
CH_V101	Preoperative chemotherapy with radiotherapy	0 = no/missing, 1 = yes
CH_V103	Preoperative chemotherapy without radiotherapy	0 = no/missing, 1 = yes
CH_V104	Postoperative chemotherapy	0 = no/missing, 1 = yes
CH_V105	Postoperative chemotherapy – specification	1 = with radiotherapy, 2 = with radiotherapy and continuation of chemotherapy after radiotherapy, 3 = chemotherapy alone

Code	Description	Value(s)
CH_V106	Postoperative chemotherapy alone – specification	1 = adjuvant, 2 = palliative
CH_V107	Palliative chemotherapy	0 = no/missing, 1 = yes
CH_V109	Medication period	1 = during preoperative RT, 2 = preoperative chemotherapy without RT, 3 = postoperative chemotherapy during RT, 4 = postoperative adjuvant chemotherapy without RT, 5 = palliative chemotherapy
CH_V110	Specification of chemotherapy	1 = 5-FU, 2 = oral fluoropyrimidines, 3 = other
CH_V112	Chemotherapy schedule	Free text
CH_V115	Medication period	
CH_V119	Medication period	
CH_V120	Specification of chemotherapy	1 = 5-FU, 2 = oral fluoropyrimidines, 3 = oxalliplatin, 4 = irinotecan, 5 = other
CH_V122	Chemotherapy schedule	Free text
CH_V136	Chemotherapy-related adverse events – diarrhea	0 = no/missing, 1 = yes
CH_V137	Chemotherapy-related adverse events – nausea	0 = no/missing, 1 = yes
CH_V138	Chemotherapy-related adverse events – vomiting	0 = no/missing, 1 = yes
CH_V139	Chemotherapy-related adverse events – anorexia	0 = no/missing, 1 = yes
CH_V140	Chemotherapy-related adverse events – neutropenia	0 = no/missing, 1 = yes
CH_V141	Chemotherapy-related adverse events – neutropenic fever or infection	0 = no/missing, 1 = yes
CH_V142	Chemotherapy-related adverse events – stomatitis	0 = no/missing, 1 = yes
CH_V143	Chemotherapy-related adverse events – neurotoxicity	0 = no/missing, 1 = yes
CH_V144	Chemotherapy-related adverse events – other	0 = no/missing, 1 = yes
CH_V146	Type of adverse events - grade	1 = grade 3, 2 = grade 4
FU_V102	Date of follow-up consultation	Date
FU_V105	Late complications radio- and/or chemotherapy	0 = no/missing, 1 = yes
FU_V106	Late complications – skin	0 = no/missing, 1 = yes
FU_V107	Late complications – gastrointestinal	0 = no/missing, 1 = yes
FU_V108	Late complications – bladder	0 = no/missing, 1 = yes
FU_V109	Late complications – ureter	0 = no/missing, 1 = yes
FU_V110	Late complications – nerves	0 = no/missing, 1 = yes
FU_V111	Late complications – other	0 = no/missing, 1 = yes
FU_V113	Stoma	1 = not applicable (never had), 2 = present, 3 = closed
FU_V114	Date of stoma closure	Date
FU_V139	Local recurrence	0 = no/missing, 1 = yes

APPENDIX 4: GENERAL DEFINITIONS

Incidence date

The first known date of the following list is considered the incidence date:

- date of biopsy of the tumour (variable 'SPR_V161' in the PROCARE database)
- date of first consultation or hospitalisation for rectal cancer ('SPR_V102')
- date of first treatment: surgery, chemotherapy, radiotherapy ('SG_V106', 'CH_V115' or 'CH_V125', 'RD_V104'

cStage

Clinical stage (cStage) is based on all of the available information obtained before treatment. Thus, it may include information about the tumour obtained by physical examination, radiologic examination, endoscopy, etc.(including laparoscopy and surgical exploration) The cStage is obtained from the clinical TNM (cTNM) using the international Classification of Malignant Tumours (UICC, 6th edition, 2002).

Neoadjuvant treatment

Neoadjuvant treatment refers to treatment (chemotherapy, radiotherapy or a combination of both) given prior to surgery.

pStage

Pathologic stage (pStage) adds additional information gained by examination of the resected specimen and/or biopsies (metastasis) microscopically by a pathologist.

ypStage

If neoadjuvant preoperative chemoradiotherapy or radiotherapy (or both) has been given, the prefix 'yp' should be used to indicate that the original pStage may have been modified by therapy.

Adjuvant treatment

Adjuvant treatment refers to treatment (chemotherapy, radiotherapy or a combination of both) given after surgery.

APPENDIX 5: AVAILABILITY OF QUALITY INDICATORS IN OTHER COUNTRIES

	Bavaria	Burgundy	North NL	SW	SPAIN	UK	DK	N
Overall 5-year survival by stage	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Disease-specific survival by stage at 2 yr, 5 yr	Yes	Yes	No *	Yes	Yes	Yes (death certif)	Yes	No
Proportion of patients with local recurrence by stage at 2 yr, 5 yr	No	Yes	No *	Yes	Yes	No	No	Yes
Proportion of patients discussed at a multidisciplinary team (MDT) meeting	No	Yes	No *	Yes	Yes	No	No	No
Proportion of patients with a documented distance from the anal verge	No	Yes	No *	Yes	Yes	No	Yes	Yes
Proportion of patients in whom a CT of the liver and thorax was performed before any treatment	No		No *	Yes	Yes	No	Yes	Yes
Proportion of patients in whom a CEA was detrmined before any treatment	No		No *	No	No	No	No	Yes
Proportion of patients undergoing preoperative complete large bowel-imaging	No		No *	Yes	No	No	No	No
Proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment	No	Yes	No *	Yes	Yes	No	Yes	Yes after 2001
Proportion of patients with a reported cCRM	No		No *	Yes	Yes	Yes (subsets)	Yes	Yes
Pretreatment cStage (TNM)	Yes		Yes	Yes	Yes	No	Yes	Yes
Time between initial diagnosis and first treatment	No	No	Yes	No	Yes	Yes	Yes	Yes
Proportion of stage II-III patients that received a short course of neoadjuvant pelvic RT	No	Not used	No *	Yes	Yes	Yes	No	Not used
Proportion of stage II-III patients that received a long course of neoadjuvant pelvic RT	No	Yes	No *	Yes	Yes	Yes	No	Yes
Proportion of stage II-III patients that received neo-adjuvant chemoradiation with a regimen containing 5-FU	No	Yes	Yes	Yes	Yes	No	No	Yes

	Bavaria	Burgundy	North NL	SW	SPAIN	UK	DK	N
Proportion of stage II-III patients treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU	No	Not used	No	No	No	No	No	No
Proportion of stage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that completed this neoadjuvant treatment within the planned timing	No	No	No	Yes	No	No	No	No
Proportion of stage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 6 to 8 weeks after completion of the (chemo)radiation	No	Yes	No *	Yes	Yes	No	No	Yes
Rate of acute grade 4 radio(chemo)therapy-related complications	No	No	No	No	No	No	No	No
Patients treated with local excision or TEMS by stage/level	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proportion of R0 resections per stage/level	No	Yes	Yes	Yes	Yes	No	Yes	Yes
Proportion of APR and Hartmann's procedures per stage/level	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proportion of patients undergoing sphincter-sparing surgery with/without temporary stoma at primary surgery, still having their stoma 1y after surgery	No	Yes	No	Yes	Yes	Yes	No	No
Rate of patients with major leakage of the anastomosis after SSO	No	No	limited	Yes	Yes		Yes	Yes
Inpatient or 30-day mortality	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rate of intra-operative tumour soiling	No	Yes	No *	No	No	?	Yes	Yes
Proportion of stage II-III patients that received adjuvant chemotherapy	No	Yes	Yes	Yes	Yes	Yes	No	Not used
Proportion of stage II-III patients that received adjuvant radiotherapy or chemoradiotherapy if no neoadjuvant therapy	No	Yes	Yes	Yes	Yes	Yes	No	Yes (for RT)
Proportion of stage II-III patients that started adjuvant chemotherapy within 1 month after surgical resection	No	Yes	No	Yes	No	Yes	No	Not used

	Bavaria	Burgundy	North NL	SW	SPAIN	UK	DK	N
Proportion of stage II-III pts treated with adjuvant chemo(radio)therapy, that received 5-FU based chemo	No	?	No	Yes	No	No	No	Not used
Rate of acute grade 4 chemotherapy complications	No	No	No	No	No	No	No	Not used
Rate of stage IV patients receiving chemotherapy	Yes	Yes	Yes	No	Yes	Yes	No	No
Rate of acute grade 4 chemotherapy complications in stage IV patients	No	No	No	No	No	No	No	No
Rate of curatively treated patients that received a colonoscopy within 1 year after treatment	No	No	No	No	Yes	No	Yes	No
Rate of patients undergoing regular follow-up	No	No	No	Yes	Yes	No	Yes	No
Late grade 4 complications of radio(chemo)therapy	No	No	No	Yes	Yes	No	No	No
Use of the pathology report sheet	No	Yes	No	Yes	Yes	Yes (subsets)	Yes	Yes
Quality of TME (according to Quirke)		No	No	Yes	Yes	No	No	No
Rate of good or moderate quality TME	?	No	No *	No	Yes	No	No	No
Distal tumour-free margin after SSO	?		No *	Yes	Yes	Yes (subsets)	Yes	Yes
Number of lymph nodes examined	No	Yes	Yes	Yes	Yes	Yes (subsets)	Yes	Yes
(y)pCRM mentioned in the pathology report	Yes		No	Yes	Yes	Yes (subsets)	Yes	Yes

* only for studies 1994-1997 and 2001-2004

APPENDIX 6: TNM CLASSIFICATION ADAPTED FROM UICC AND AJCC [24, 25]

T - Primary tumour

Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis*	Carcinoma in situ: intraepithelial or invasion of lamina propria
T1°	Tumour invades submucosa
T2	Tumour invades muscularis propria
T3	Tumour invades through muscularis propria into subserosa or into non-peritonealized perirectal tissues
T4	Tumour perforates visceral peritoneum or directly invades other organs or structures

* The extent of mucosal cancer can be expressed in depth of invasion relative to the thickness of the mucosa: i.e. superficial third m1, middle third m2 and deepest third m3.

° The extent of submucosal cancer can be assessed absolutely (sm1 = less than 0.5 mm; sm2 = 0.5–1 mm; sm3 = more than 1 mm) or relatively (sm1 = superficial third; sm2 = middle third; sm3 = invasion reaching the deepest third) [26].

Tis – Primary tumour: invasion of lamina propria

m1	Superficial third of the mucosa
m2	Middle third of the mucosa
m3	Deepest third of the mucosa

T1 – Primary tumour: invasion of submucosa

sm1	Superficial third of the submucosa or invasion depth of less than 0.5 mm
sm2	Middle third of the submucosa or invasion depth of between 0.5 and 1 mm
sm3	Deepest third of the submucosa or invasion depth of more than 1 mm

N – Regional lymph nodes

Nx	Regional lymph nodes cannot be assessed. It should be mentioned if no nodes are found.
N0	No regional lymph node metastasis. The number of nodes examined should be mentioned
N1	Metastasis in 1 to 3 regional lymph nodes
N2	Metastasis in 4 or more regional lymph nodes

For this project, extramural deposits of tumour that are not obviously within lymph nodes are regarded as discontinuous extensions of the main tumour if they measure <3 mm in diameter, but as lymph node involvement if they measure >3 mm in diameter [25].

M – Distant metastasis

Mx	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

Pathological M staging can only be based on distant metastases that are submitted for histology. Pathologists will therefore only be able to use M1 (distant metastasis present) or Mx (distant metastases unknown).

TNM Stage grouping

Stage 0	Tis	N0	M0
Stage I	T1 or T2	N0	M0
Stage II A	T3	N0	M0
Stage II B	T4	N0	M0
Stage III A	T1 or T2	N1	M0
Stage III B	T3 or T4	N1	M0
Stage III C	Any T	N2	M0
Stage IV	Any T	Any N	M1

APPENDIX 7 : REFERENCES

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