



# CRITÈRES DE LA QUALITÉ THÉRAPEUTIQUE DANS LE CANCER DU RECTUM



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**PRO CARE**

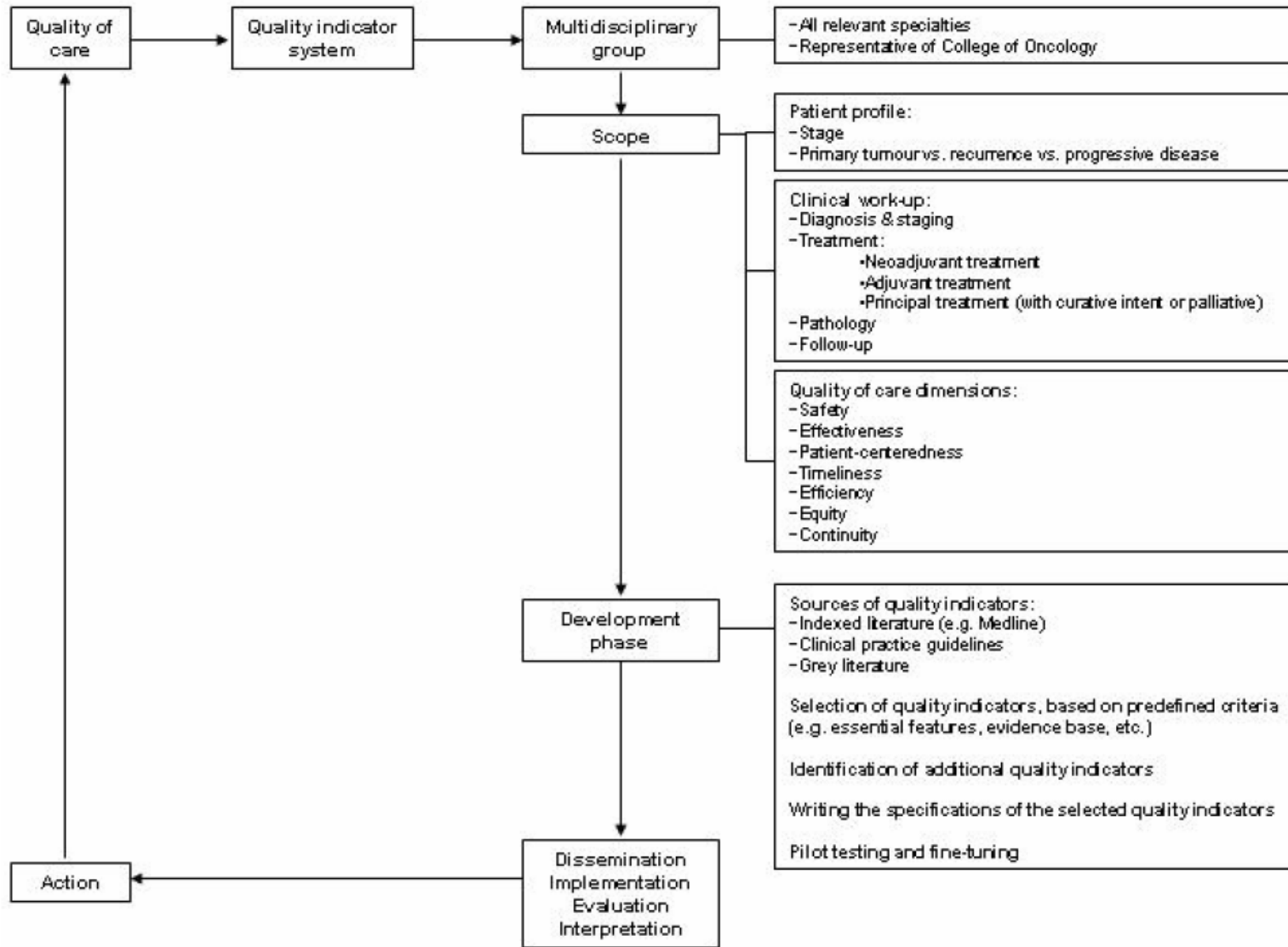
PROJECT ON CANCER OF THE RECTUM

# AIMS OF THE PROCARE PROJECT

- Standardization through guidelines
- Quality assurance through registration and feedback
  
- First draft of the guidelines written in 2005
- Implemented by workshops, meetings, training for TME, pathology, radiotherapy and oncology
- Final guidelines published in 2007, in collaboration with the KCE



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

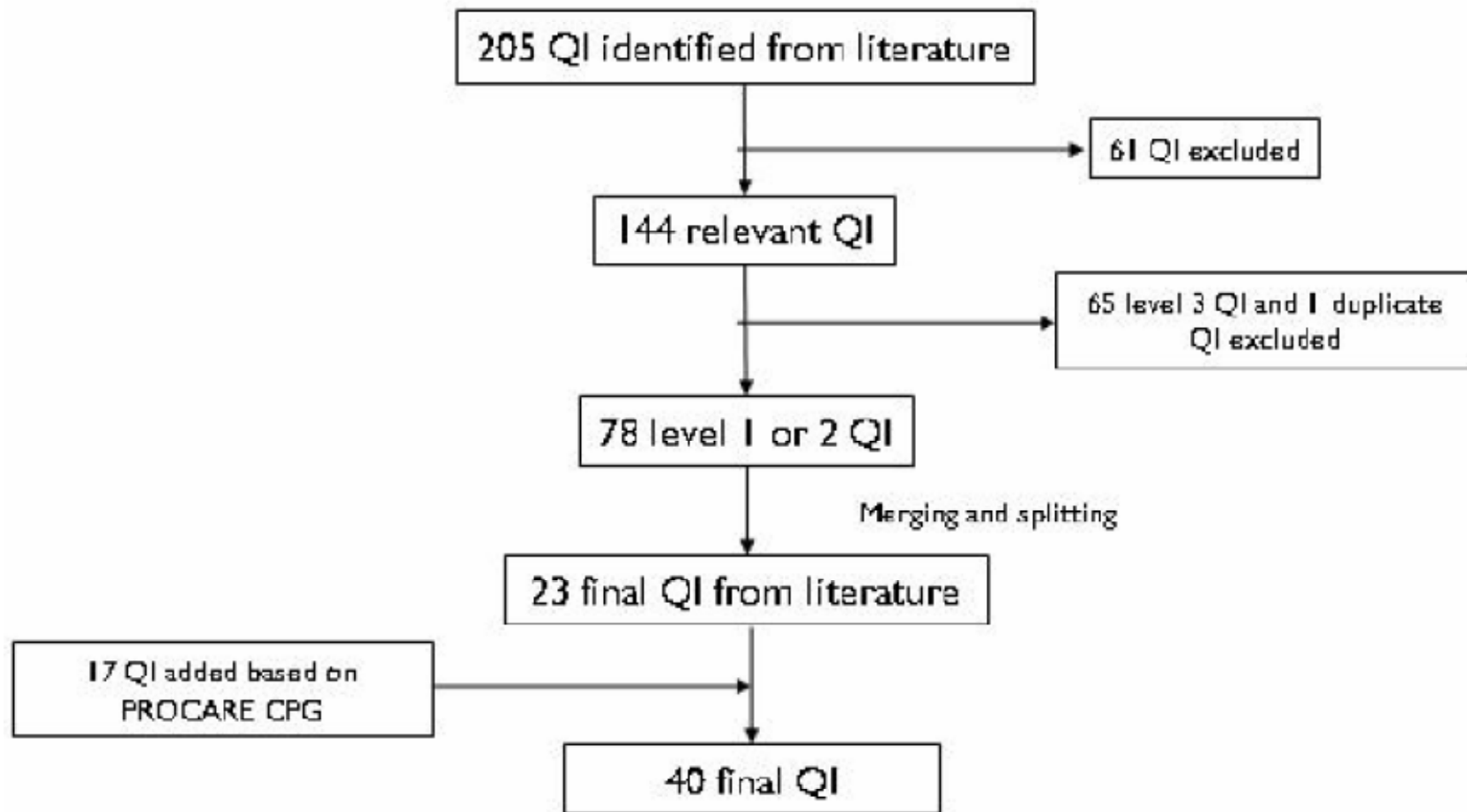


# DEVELOPMENT OF A QUALITY INDICATOR SET: METHODOLOGY

- Literature search
- Selection process of quality indicators
  - Relevance
  - Level of evidence
  - Related PROCARE recommendation(s)
  - Quality level
    - Level 1: affected by all treatment phases
    - Level 2: affected by one specific treatment phase
    - Level 3: deserve attention from individual centres if possible quality problems were identified through a level 1 or 2 QI



Figure 2. Selection process of the rectal cancer QI.



Process	Proportion of R0 resections
Outcome	Proportion of APR, Hartmann's procedures or TME with definitive ileostomy
Outcome	Proportion of patients with stoma 1 year after sphincter-sparing surgery
Outcome	Rate of patients with major anastomotic leakage after sphincter-sparing surgery
Outcome	Inpatient and 30-day mortality
Process	Rate of intra-operative rectal perforation



# Measurability of the selected quality indicators

- Test on
  - PROCARE database
  - Administrative databases
    - Belgian Cancer Registry
    - Common Sickness Funds Agency
    - Technical Cell



# Revision of QI (July 2010)

- KCE report
- Suggestions and decisions taken by the PROCARE team



# GENERAL QUALITY INDICATORS

- Overall 5-year survival by stage
- Disease-specific 5-year survival by stage
- Relative survival
- % with local recurrence
- Disease-free survival



# QUALITY INDICATORS RELATED TO DIAGNOSIS AND STAGING

- % with a documented distance from the anal verge
- % in whom a CT of the abdomen and RX or CT of the thorax was performed before any treatment
- % in whom a CEA was performed before any treatment
- % undergoing elective surgery that had preoperative complete large bowel-imaging
- % in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment
- % with cStage II-III that have a reported cCRM
- Time between first histopathologic diagnosis and first treatment
- Accuracy of cM0 staging
- Accuracy of cT/cN staging if no or short radiotherapy
- Use of TRUS in cT1/cT2
- Use of MRI in cStage II or III



# QUALITY INDICATORS RELATED TO NEOADJUVANT TREATMENT

- % cStage II-III that received a neoadjuvant pelvic RT
- % with cCRM  $\leq$  2mm on MRI/CT that received long course neoadjuvant radio(chemo)therapy
- % with cStage I that received neoadjuvant radio(chemo)therapy
- % cStage II-III treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU
- % cStage II-III treated with a long course of preoperative pelvic RT or chemoradiation, that completed this neoadjuvant treatment within the planned timing
- % of cStage II-III treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 4 to 12 weeks after completion of the (chemo)radiation
- % of acute grade 4 radio(chemo)therapy-related complications



# Quality indicators related to surgery

- % R0 resections
- Distal margin involvement mentioned after SSO or Hartmann
- (y)p Distal margin involved (positive) after SSO or Hartmann for low rectal cancer (< or =5cm)
- Mesorectal (y)pCRM positivity after radical surgical resection
- % APR, Hartmann's procedure or total excision of colon and rectum with definitive ileostomy
- % with stoma 1 year after sphincter-sparing surgery
- % with major leakage after PME+SSO+reconstruction
- % with major leakage after TME+SSO+reconstruction
- Inpatient or 30-day mortality
- % intra-operative rectal perforation
- Postoperative major surgical morbidity with reintervention under narcosis after radical surgical resection



# Quality indicators related to adjuvant treatment

- % (y)pStage III with R0 resection that received adjuvant chemotherapy within 3 months after surgery
- % (y)pStage II-III with R0 resection that received adjuvant radiotherapy or chemoradiotherapy within 3 months after surgery
- % (y)pStage II-III with R0 resection that started adjuvant chemotherapy within 12 weeks after surgical resection
- % (y)pStage II-III with R0 resection treated with adjuvant chemo(radio)therapy, that received 5-FU based chemotherapy
- % acute grade 4 chemotherapy-related complications

# Quality indicators related to palliative treatment

- % cStage IV receiving chemotherapy



# Quality indicators related to follow-up

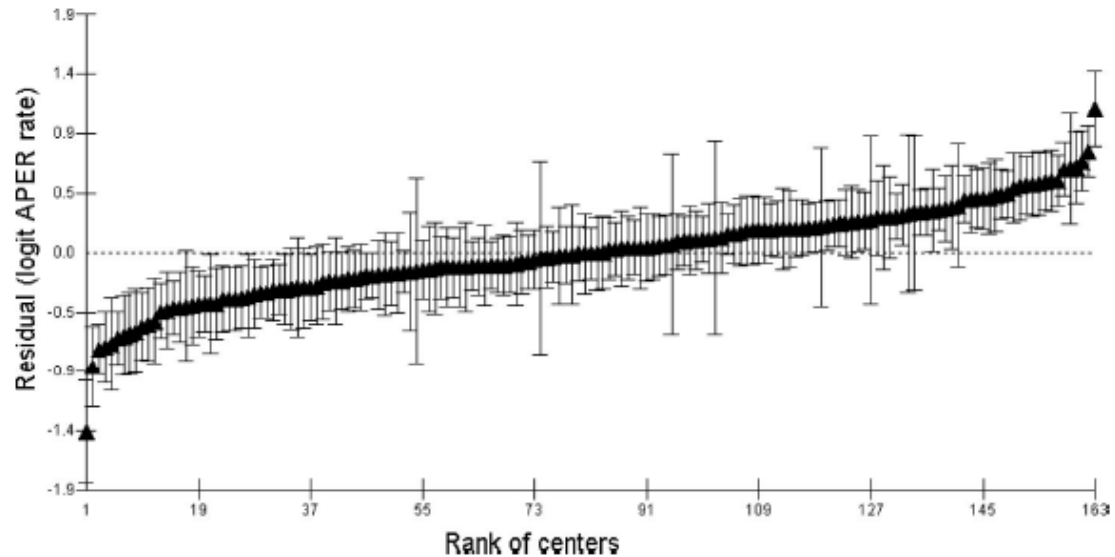
- % curatively treated patients that received a colonoscopy within 1 year after resection
- % late grade 4 complications of radiotherapy or chemoradiation



# Quality indicators related to histopathologic examination

- Use of the pathology report sheet
- Quality of TME assessed according to Quirke and mentioned in the pathology report
- Distal tumour-free margin mentioned in the pathology report
- Number of lymph nodes examined
- (y)pCRM mentioned in mm in the pathology report
- Tumour regression grade mentioned in the pathology report (after neoadjuvant treatment)





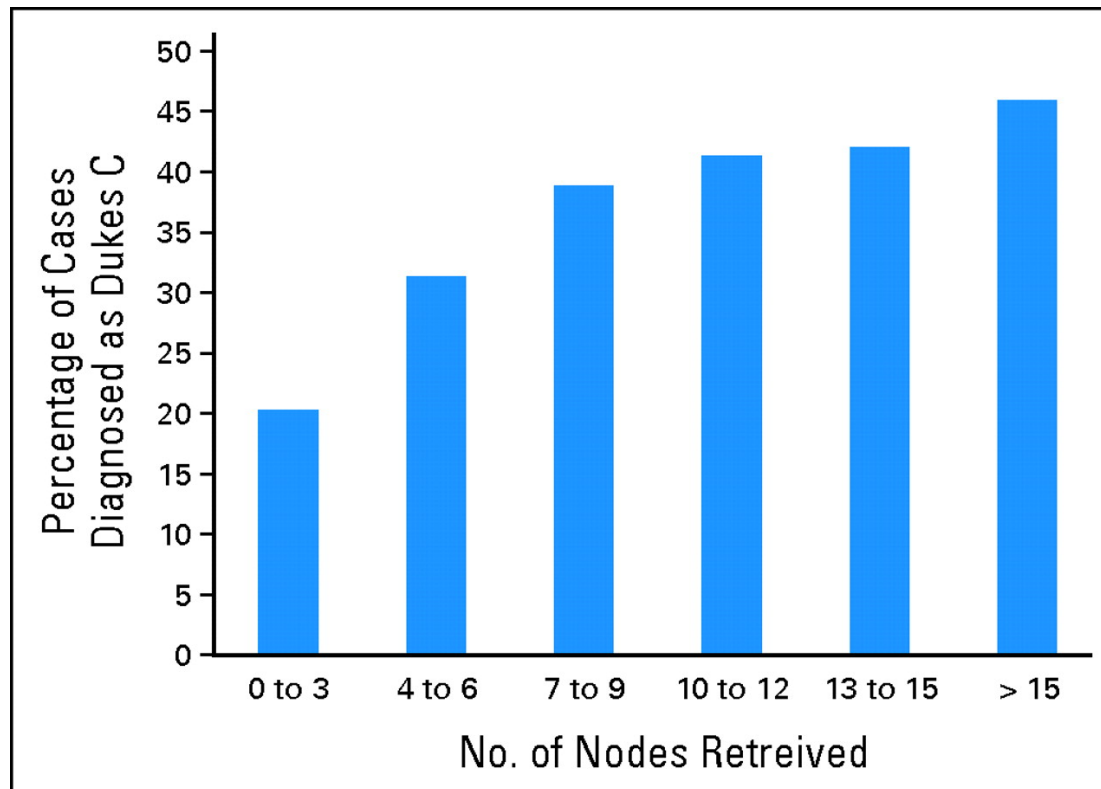
**FIGURE 1.** Between-center variability in APER rate. The “excess” APER rate for each center is depicted with 95% confidence intervals adjusted for the volume of cases submitted by each center. On the “residuals” plot the population mean APER rate is indicated by the dotted line at zero. Units with 95% confidence intervals lying completely below or above this dotted line have APER rates that are significantly different from the population mean.

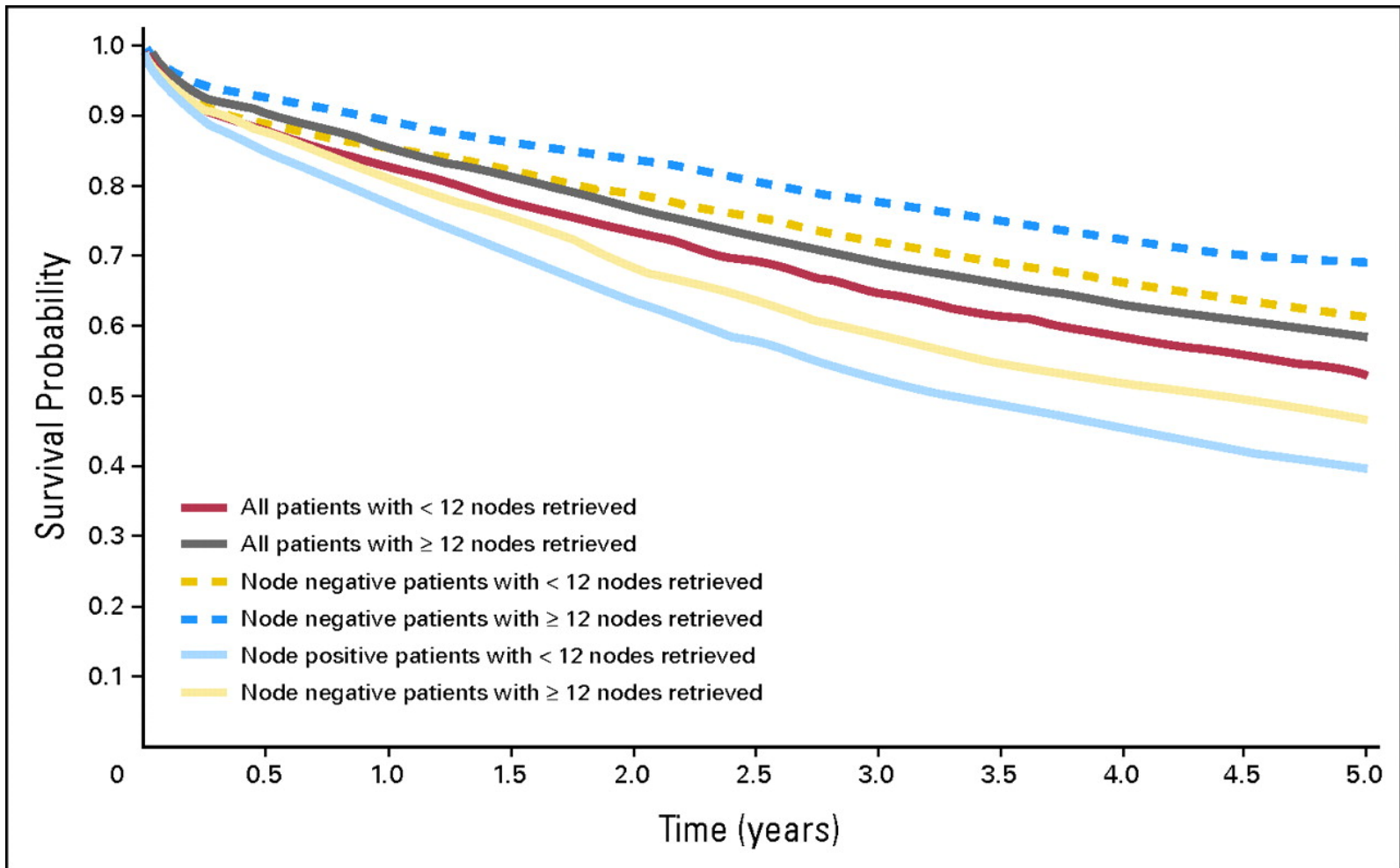


# Quality insurance of rectal cancer – phase 3: statistical methods to benchmark centres on a set of quality indicators

- KCE
- UG
- PROCARE





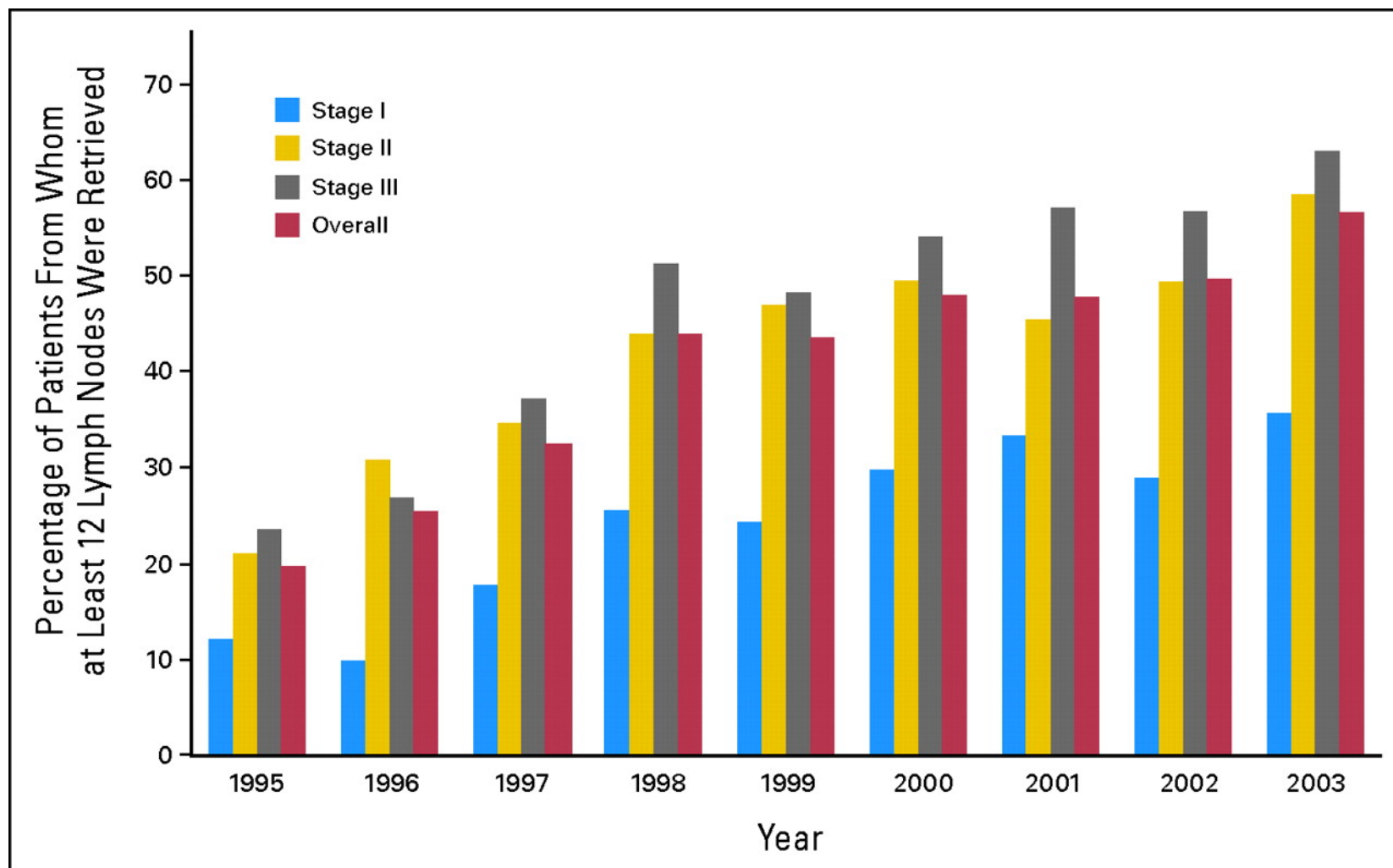


**Table 1.** Median No. of Nodes Retrieved in Relation to Patient, Tumor, and Management Characteristics

Characteristic	No.	%	Median No. of Nodes Retrieved	IQR	P
Overall	7,062		10	6-15	
<b>Sex</b>					
Male	3,851	54.5	10	6-15	.02
Female	3,211	45.5	10	6-15	
<b>Age, years</b>					
< 51	379	5.4	12	8-18	< .001
51-60	952	13.5	11	7-16	
61-70	1,942	27.5	10	6-16	
71-80	2,501	35.4	10	6-15	
≥ 80	1,288	18.2	9	5-15	
<b>Cancer site</b>					
Colon	5,326	75.4	10	6-15	.54
Rectal	1,736	24.6	10	6-15	
<b>Maximum tumor diameter, cm</b>					
0-5	4,751	67.3	10	6-15	< .001
5.1-10	1,720	24.4	11	7-17	
> 10	176	2.5	11	6-16	
Unknown	415	5.9	8	5-13	
<b>Local invasion</b>					
T1	358	5.1	6	4-10	< .001
T2	1,029	14.6	8	5-12	
T3	4,091	57.9	11	7-16	
T4	1,535	21.7	11	7-17	
Unknown	49	0.7	8	4-13	
<b>Stage</b>					
I	1,131	16.0	7	4-11	< .001
II	3,030	42.9	10	6-15	
III	2,732	38.7	11	8-17	
Unknown	169	2.4	9	5-13	
<b>Year</b>					
1995	410	5.8	7	4-11	< .001
1996	828	11.7	7	4-12	
1997	892	12.6	8	5-13	
1998	843	11.9	11	7-15	
1999	882	12.5	10.5	7-15	
2000	903	12.8	11	7-16	
2001	798	11.3	11	7-16	
2002	808	11.4	11	7-18	
2003	698	9.9	13	8-19	
<b>Pathologist</b>					
General	2,622	37.1	9	6-14	< .001
MDT	4,440	62.9	12	8-18	
<b>Surgeon</b>					
General	4,808	68.1	9	5-13	< .001
MDT	2,254	31.9	11	7-16	
<b>Surgeon and pathologist</b>					
General	4,981	70.5	9	6-14	< .001
MDT	2,081	29.5	13	8-18	

Abbreviations: IQR, interquartile range; MDT, multidisciplinary team.





**Table 2.** Odds of Retrieving 12 or More Nodes From a Patient  
Multivariate Analysis

Characteristic	Odds Ratio	95% CI	<i>P</i>
Age, per year	0.98	0.98 to 0.99	< .01
Sex			
Male	1.00		
Female	1.19	1.07 to 1.33	< .01
Maximum tumour diameter, per cm	1.05	1.03 to 1.06	< .01
Local invasion			
T1	1.00		
T2	1.81	1.30 to 2.51	< .01
T3	3.49	2.58 to 4.71	< .01
T4	3.03	2.20 to 4.76	< .01
Unknown	1.54	0.71 to 3.35	.28
No. of positive nodes, per node	1.15	1.13 to 1.18	< .01
Year of diagnosis, per year	1.17	1.14 to 1.19	< .01
Pathologist			
General	1.00		
MDT	2.16	1.93 to 2.41	< .01
Surgeon			
General	1.00		
MDT	1.40	1.24 to 1.58	< .01

Abbreviation: MDT, multidisciplinary team.



# TNM5 (1997): 3-MM RULE

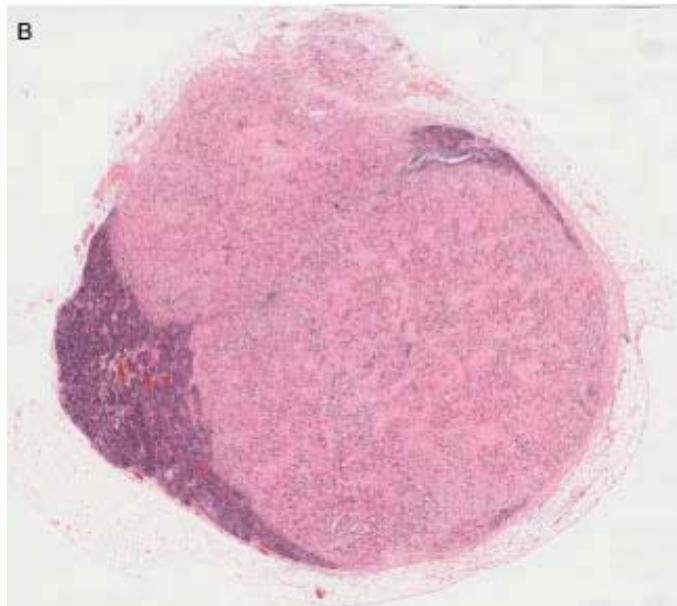
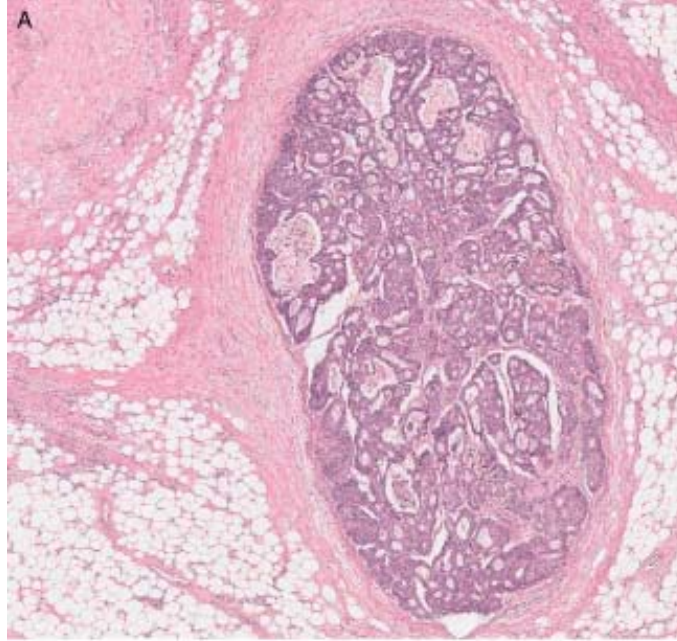
- Any mesocolic or mesorectal tumour deposit 3 mm in size or greater should be thought of as an involved lymph node



# TNM6 (2002): CONTOUR RULE

- Smooth metastatic nodules in the pericolic or perirect fat should be considered as lymph node metastases
- Irregularly contoured metastatic nodules should be staged as an extension of the T category





## TNM7 (2009): STANDARDISATION IMPOSSIBLE

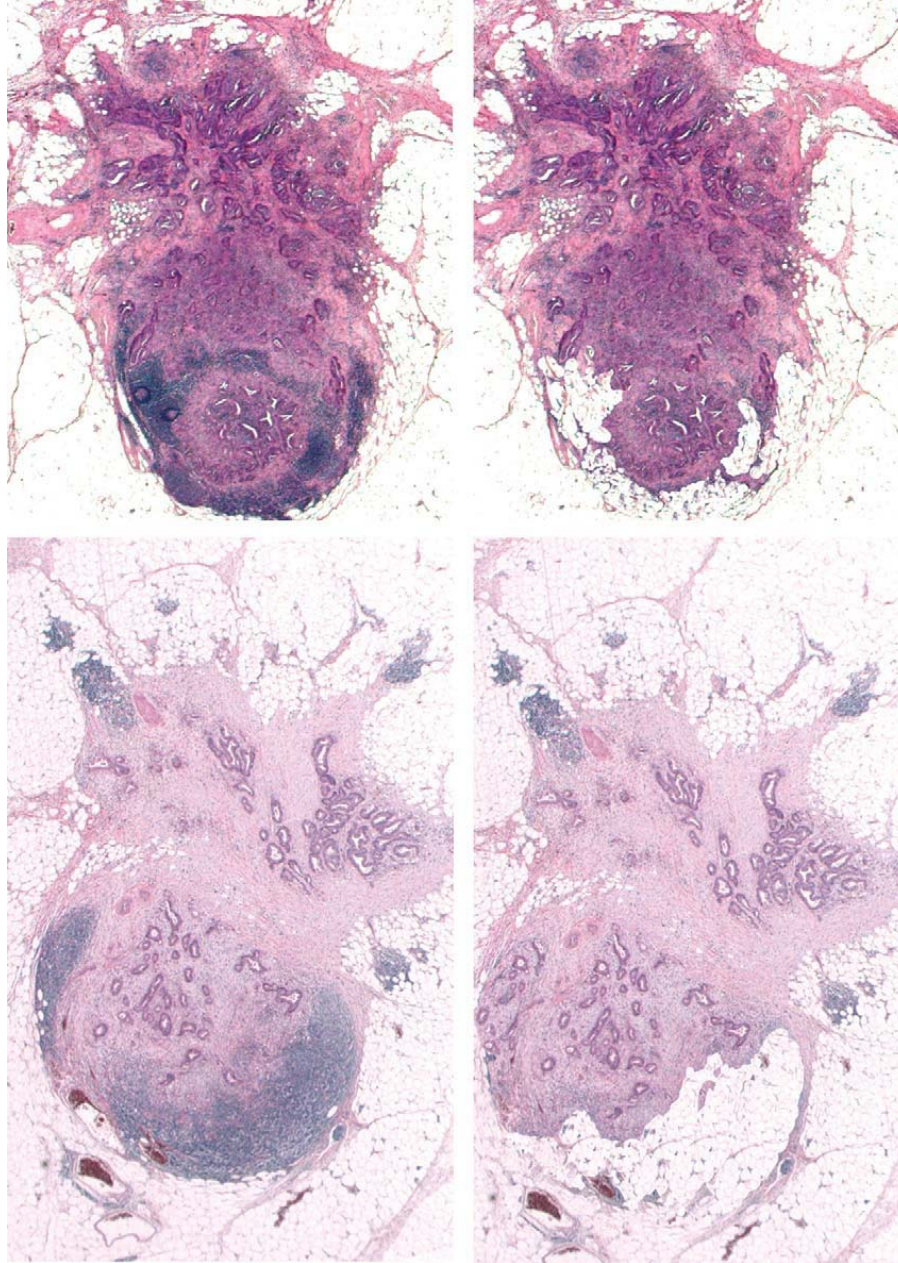
- *“Discrete foci of tumour found in the pericolic or perirectal fat or in adjacent mesentery (mesocolic fat) away from the leading edge of the tumour and showing no evidence of residual lymph node tissue but within the lymph drainage area of the primary carcinoma are considered to be peritumoural deposits or satellite nodules, and their number should be recorded in the site-specific prognostic markers on the staging form as tumour deposits. Such tumour deposits may represent discontinuous spread, venous invasion with extravascular spread, or a totally replaced lymph node”.*



# TNM7 (2009): STANDARDISATION IMPOSSIBLE

- *“If a nodule is considered by the pathologist to be a totally replaced lymph node (generally having a smooth contour), it should be recorded as a positive lymph node and counted as such”.*





**PRO CARE**

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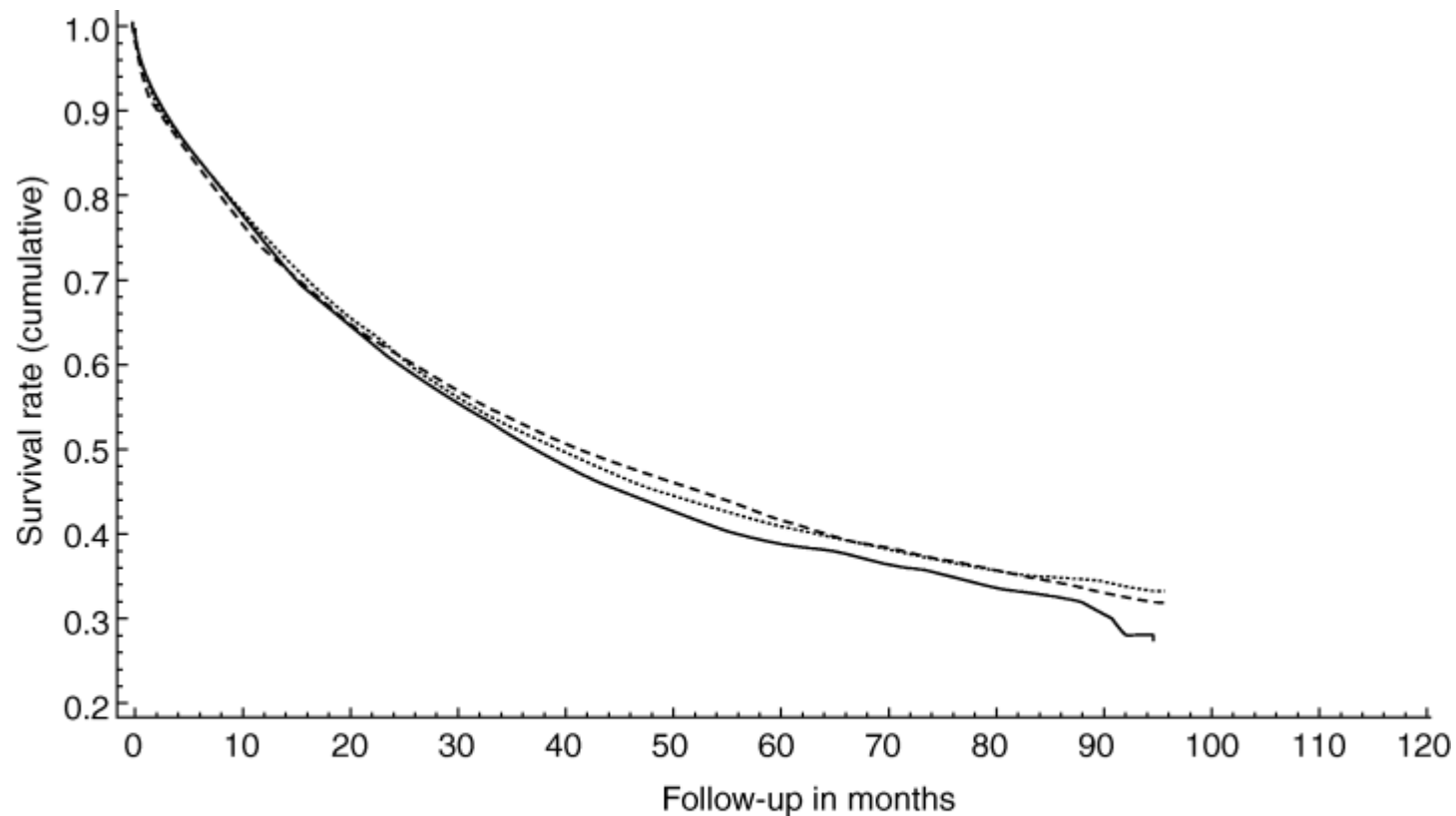
Quirke P, *Lancet Oncol* 2007



# International experiences with quality measurement of rectal cancer care

- Population-based databases
  - Sweden
  - Norway
  - Denmark
  - United Kingdom
  - Spain
- Regional databases
  - France
  - Germany
  - The Netherlands





	0	12 months	24 months	36 months	48 months	60 months
<15/year	1043	774	626	524	452	397
15-30/year	1390	1034	851	718	618	565
>30/year	2588	1895	1571	1365	1190	1056

*“The question of how to identify the ‘best’ hospitals is complex. (...) it seems that the only meaningful answer is to ensure that every hospital performs within the range of the standards set up in national guidelines, and to react if this should not be the case, rather than focusing on rigid volume standards”.*

