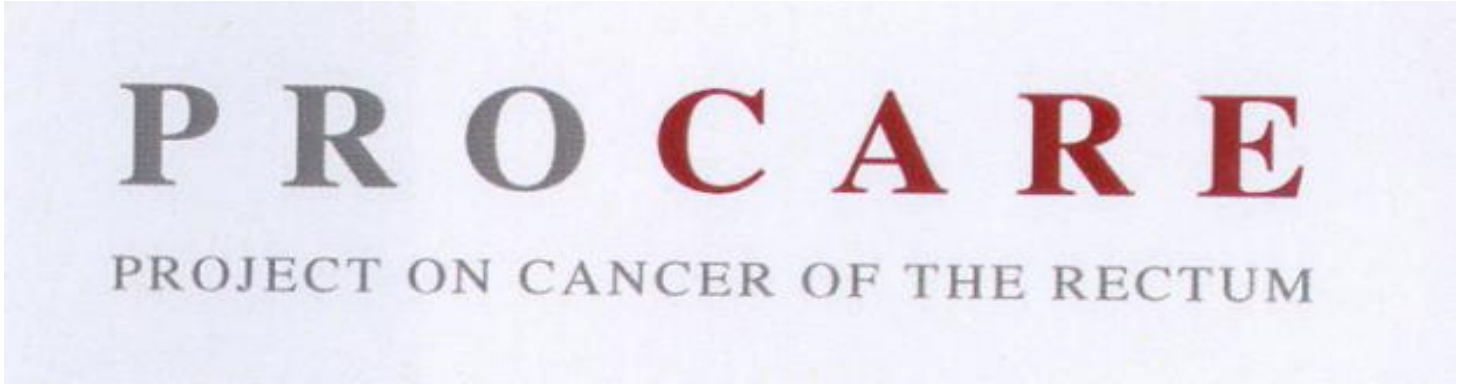
Lessons from PROCARE and proposal for the future



financial support for training (central review) and registration from the Stichting tegen Kanker (2006-2007) and the RIZIV / INAMI (2007-2012)

www.kankerregister.org

PROCARE
Achievements

Guidelines (KCE report 2007)

Implementation of guidelines through training

- TME surgery (2009-2011): 9 surgeons trained
- TME pathology (2007-2012): 444 evaluable TMEs reviewed
- radiotherapy (CTV) (2010-2012)
- CT/MRI staging (2010-2012)

Presentations at LOK/GLEM, regional, nat. and internat. meetings

Quality of Care Indicators (KCE report 2008)
Registration of > 5000 patients in a dedicated database (on line)
Risk-adjusted benchmarking (KCE report 2011)
Participation in European collaboration (EURCECCA)
Publications: 12

PROCARE
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PROCARE induced improvement (1)

5-yr OS	BCR 1997-1998	BCR 2004-2005	BCR 2004-2008	PROCARE < 12/2011
All patients	46.6	51.6	52.4	66
Stage I (all)	77	75.1	76.8	86
Stage II (all)	64.4	61.5	61.2	70
Stage III (all)	38.2	54.1	54.7	60
Stage IV (<75 yr) 2 yr OS	28	49.8	52	73

REMARKS

1. Overall a >10 % absolute increase of OS has been achieved
2. OS improvement achieved for all stages
3. Largest improvement for Stage III and IV
4. Cautions for Stages (pStage>cStage in BCR) and PROCARE registration bias

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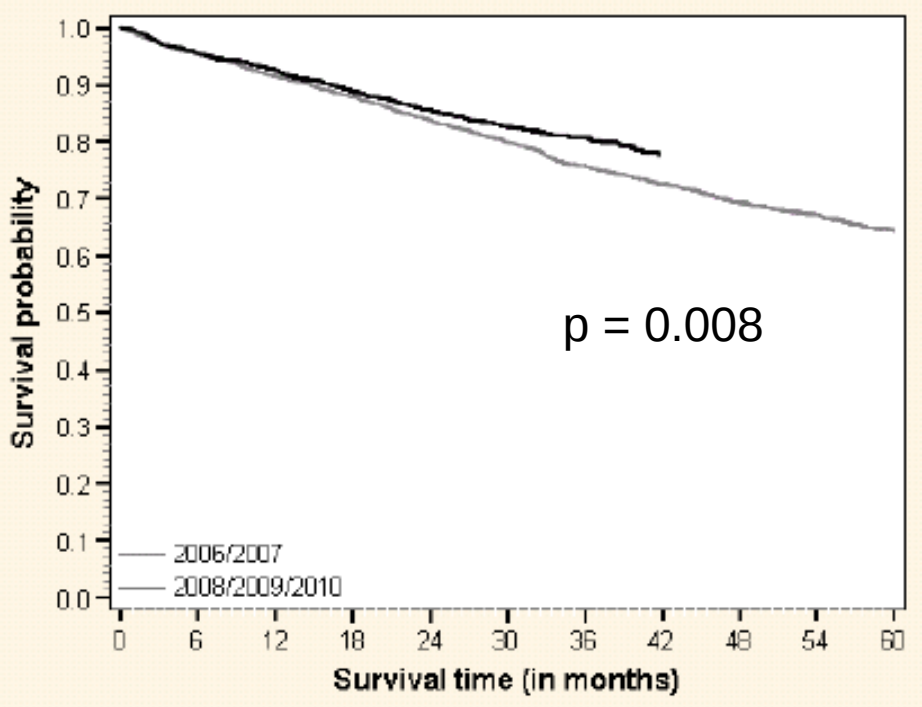
PROCARE induced improvement (2)

OBSERVED SURVIVAL by incidence date



p = 0.008

N pts 2006/2007 = 1706
N pts 2008-2010 = 2046

REMARKS

1. OS seems to further improve during the project
2. Registration bias cannot be excluded and should be analysed

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PROCARE induced improvement (3)

Feedback	BCR 1997-1998 (N=3079)	PROCARE 10/2009 (N=1249)	PROCARE 12/2011 (N=4583)
EUS for cT1-2		48.8	89.3
MRI for cT3-4		40.5	93.3
R(C)T for cStage II-III	54.8	75.8	76.6
R0 resection		76.1	77.4
APE + HR overall		24.4	23.9
APE + HR lower third		47.7	47.4
In hospital mortality		2.9	1.9
(y)pCRM positive overall		18.4	18.1
ypStage 0		4.4	8.6

REMARKS
1. RC management (staging methods, use of neoadj RT) (further) improved
2. Type of surgery remained constant, but postop mortality decreased
3. Registration bias cannot be excluded

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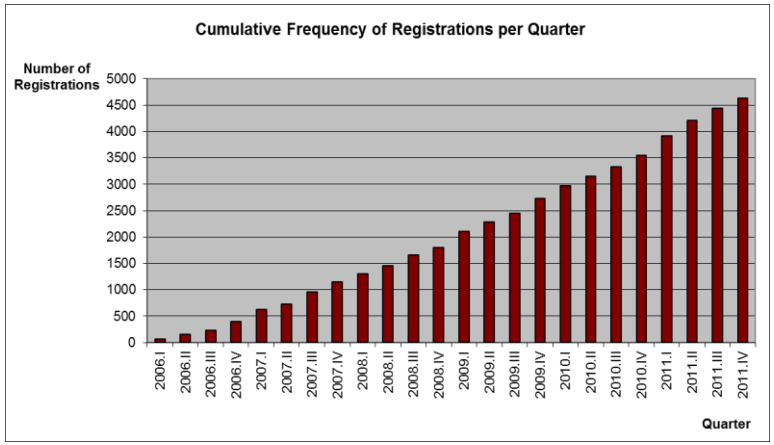
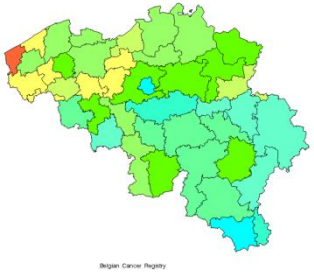
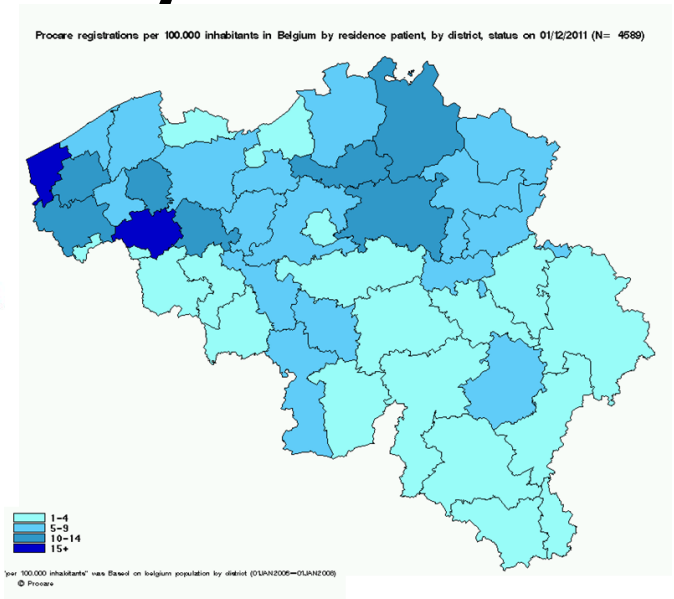
Lesson 1
Participation on a voluntary basis



Crude incidence in Belgium





89/111 hospitals have participated between 2006 – 2011
62 hospitals registered patients in 2011

REMARK

1. A major effort has been made by professionals on a voluntary basis
2. **Many (most) professionals are willing to contribute and to know**
3. **Collaboration with BCR and RIZIV/INAMI was optimal**
4. Participation has been incomplete and variable

Lesson 2
Participation on a voluntary basis is incomplete

	2006	2007	Mid 2008	GLOBAL
ICD C20 in BCR	2208	2164	1132	5504
Radical resection in IMA	1795	1715	880	4391
Rad. resection in PROCARE (%)	852 (48)	739 (43)	397 (45)	1989 (**45**)
Chemo without rad. resect. in IMA	160	170	101	431
Chemo only in PROCARE (%)	21 (13)	24 (14)	10 (10)	55 (**13**)

REMARK
1. Registration in PROCARE is incomplete and may have (has) registration bias
2. Registration on voluntary basis did not increase with time
3. Complete registration of all patients is required for survey/audit
4. Registration should be obligatory for all items relevant for adjusted benchmarking

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Lesson 3
Registration bias ? (PROCARE vs BCR + IMA)

Period 2006-mid 2008	Registered during participation in PROCARE	*Not registered before/during/after participation in PROCARE*	Non-participating centres
R(C)T for cStage II-III	845/1020 (83%)	*367/669 (55%)*	247/343 (72%)
APE+HR rate if rad resection	504/1987 (25%)	*412/1476 (28%)*	265/927 (29%)
3-yr OS/RS for (y)pStage 0-II after rad resection	86.4 / 94.7	*80.7 / 89.5*	80.2 / 89.1
3-yr OS/RS for (y)pStage III after rad resection	76.1 / 82.8	*69.4 / 76.7*	65.5 / 71.1

REMARKS
1. Participation is related to improved management and outcome QCIs
2. Registration bias cannot be excluded based on these data; further analysis is required.

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Lesson 4
The problem of missing relevant data

	BCR 2006-mid 2008	PROCARE 2006-2011
cStage known	3105 / 5504 (56%)	3795/4583 (83%)
(y)pStage known	3830/5504 (70%)	3595/4003 (90%)

cStage 0, X or missing and (y)pStage X or missing excluded from nominators

REMARK

1. BCR does not provide all items for benchmarking (only these 2 + age, sex)
2. The obligation to register at BCR does not result in complete data
3. Registration of all items for adjusted benchmarking should be controlled and ‘forced’ for its completeness

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Lesson 4 The problem of missing relevant data
Top 10 in PROCARE (in %)

Percentages of missing data	GLOBAL 2011	2008	2009	2010
Adj chemo for (y)pStage III, R0	94.3			94.2
Follow-Up at 1, 2 and 5 yr	65 / 74 / 82			
Lower limit	12.5	3.7	7.3	9.6
cStage	13.9	9.8	12.5	11.7
ASA class	11.4	14.9	11	10.4
Neoadj RT or RCT total dose	16.8	14.4	18	13.4
(y)pCRM positivity if rad resection ?	25.7	29.9	33.3	27.3
(y)pStage	6.8	19.5	8.8	5.3

REMARK
1. Chemotherapy and follow-up data are major problems
2. Solutions should be found, e.g. Follow-Up if event and/or treatment
3. % missing data does not decrease ‘spontaneously’ (exc. (y)pStage

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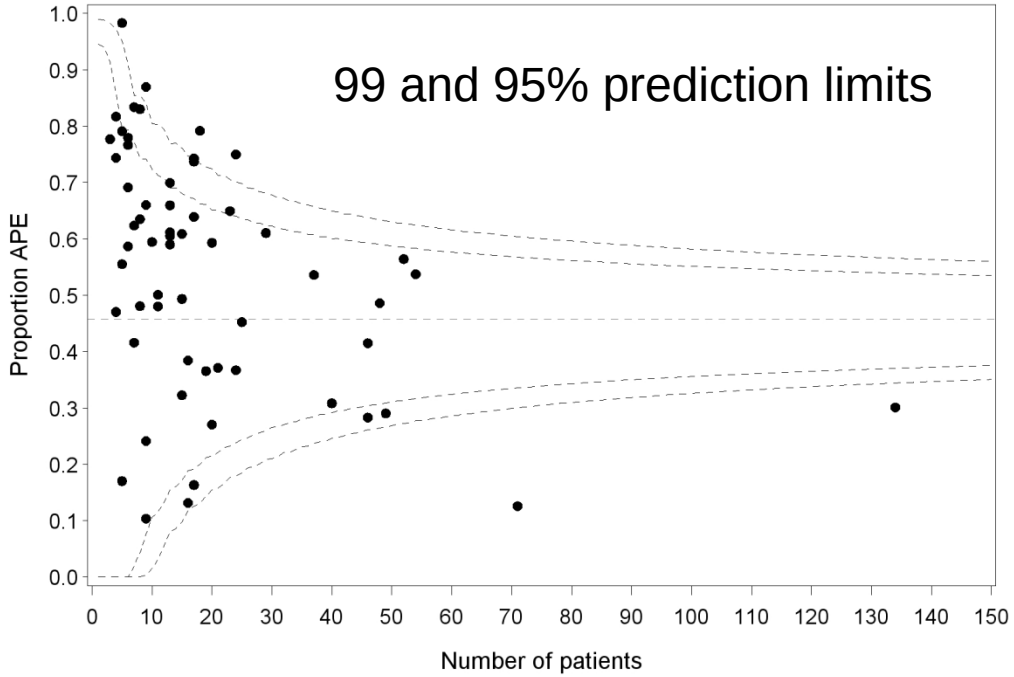
Lesson 5 Adjustment is relevant
Effect on abdominoperineal excision rate for low RC

Gut 2012, accepted



adjustment for (level)
age, sex, ASA, cT4, preop incontinence

Before adjustment: 14 centres > upper 95% prediction limit.

After adjustment: 10 (8 of these 14 centres) + another 2 centres as ‘outliers’.

REMARK
1. Adjustment for relevant factors is essential for identification of outlier(s)
2. Experts have to determine the relevant confounding factors (for adjustment)
3. Outliers should improve under ‘supervision’ by peers

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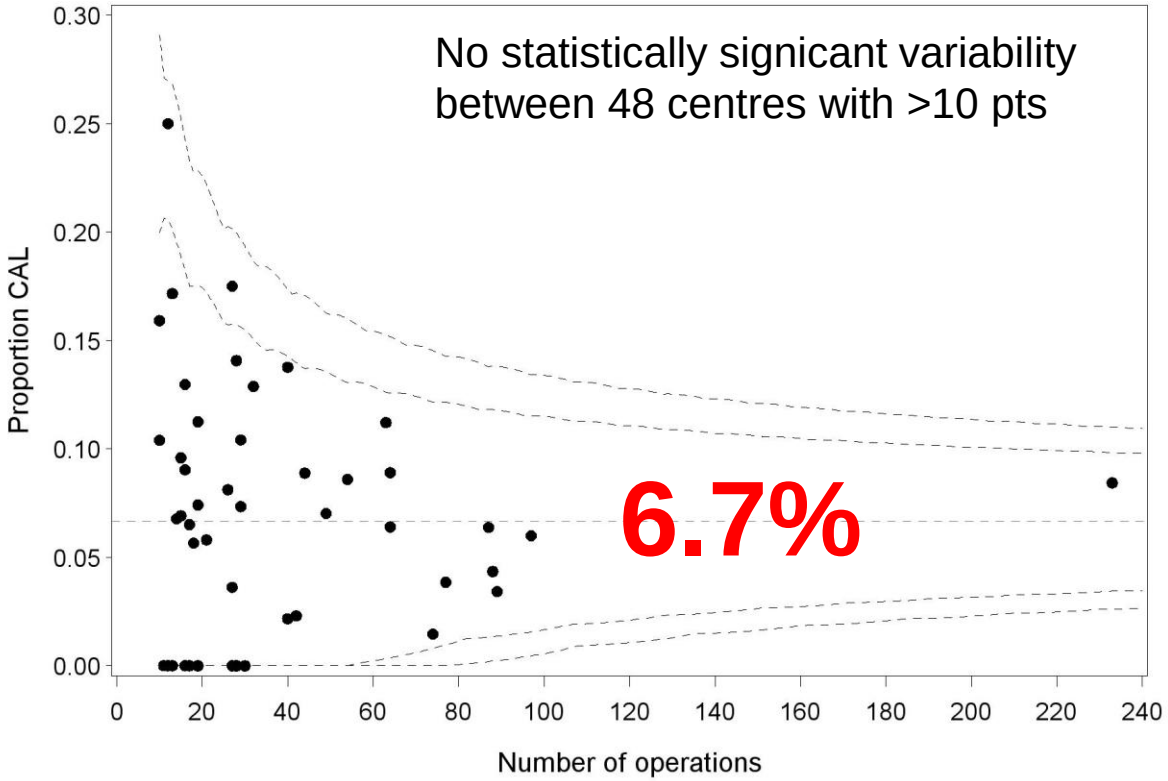
Lesson 6a
Risk-adjusted leak rate after TME + SSO

Colorectal Dis 2012

Adjusted for gender, age (>60 yr), ASA 3 or more, BMI > 25



NOT ADJUSTED FOR:

- neoadj (C)RT
- T diameter
- distal margin
- duration oper.
- oper. adverse ev.
- oper. Bleeding
- **defunctioning stoma**
- N of staplers if lap
- CPAA
- drains
- subspecialization
- volume of surg/hosp

REMARK
No significant variability, BUT room for improvement

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Lesson 6b
Leak after SSO: how to adjust practice?

Colorectal Dis 2012, Acta Chir Belg 2012

	P < 50 centres	P > 75 centres (12 centres)
Mobilisation splenic flexure	90%	80%
Primary defunct. stoma	74%	45%

REMARK

1. Detailed information can indicate how practice could/should be adapted
2. For appropriate benchmarking all centres would have to provide all data resulting in a too high burden of registration

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Lesson 7 a

Detailed information is useful for improvement …

e.g. Pathology

central review of TME ‘forces’ centres to improve methodology

e.g. Neoadjuvant radiotherapy

central review indicated correction of CTV in >70%

instructions followed in >70%

e.g.Surgery

leak rate after sphincter sparing operation (SSO)

BUT results in a burden of registration

(not felt as such by RTs and surgeons)

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Lesson 7 b

Time for collection and registration per setting

Acta Chir Belg 2011

Time in hours:minutes:seconds	MINIMUM	MAXIMUM
Early RC	0:34:13	1:01:52
cStage II-III short RT	1:03:05	1:42:40
cStage II-III long RCT	1:19:57	2:04:08
Metastatic RC palliative	0:24:40	0:58:29
Follow-up	0:07:39	0:19:36

70% physician time – 30% datanurse time

REMARKS

1. PROCARE has a **burden of registration** (related to improvement)
2. N of data should be limited if registration is made obligatory
3. A **minimum dataset** is to be determined by professionals
4. The minimum dataset **should allow adjusted benchmarking**

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Proposed principles

- Professionals + health authorities should assure quality of care (and improvement, as appropriate)
- All centres should participate and a minimum set of relevant data should be registrered for all patients
- Everyone can learn and improve
- Outlier should re-act and improve
- Centralisation is not a realistic option for rectal cancer (about 2000/yr), possibly except for subgroups of patients
- Confidentiality needs to be guaranteed/discussed

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Principles of proposals
Why to measure and to know ?

AUDIT

identify outliers
discrimination

↓

sanction

SURVEY (audit)
+ IMPROVEMENT

identify variability
+ aspects to be
improved/trained

↓

improve (all) + correct

↓

intervention strategy
if no improvement

REMARKS

1. audit/survey is required and ‘outliers’ should improve/correct
2. Professionals should set **criteria for ‘outliers’** (definition: domain, QCI, ...)
3. Health insurrer(s) to finance quality control (benchmarking) and improvement

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Proposal 1
Datasets

For audit

↓

Minimum dataset

↓

Obligatory for all

For survey (audit)
+ improvement

↓

Extended dataset

↓

1. Obligatory for outliers
2. Obligatory for low volume centres
3. Voluntary (optional) for all others

in database at Belgian Cancer Registry

- existing cancer registration
- privacy, confidentiality, confidence

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Proposal 2
Criteria pre-set by professionals

> P95 = outlier
extended dataset obligatory for 2 consecutive years
with feedback from peers (initial, after every year)
central review of staging, RT plan, pathology (as appropriate)
N.B. per domain or overall? 'trigger' = 1 QCI or several?

> P50 = could improve
suggested to use extended dataset (not obligatory)
suggested to use central review (as appropriate)

Low volume = <10 new patients per year
extended dataset obligatory
.../...

to be elaborated at clinical workshop planned for April 2012

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Proposal 3
Judgement by panel of professionals

On anonymised data

Specific panel per discipline for each type of cancer
in the College of Oncology
with delegates from the scientific societies
academic and non-academic

What intervention strategy if no improvement?

to be elaborated at clinical workshop planned for April 2012

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Financial balance

- Global budget 7/2006 – 6/2012 = 1 175 500 €

- Status on 10/12/2011:
  - 613 416 € costs paid
  - 562 084 € saldo
  - costs in 2012 estimated at 200 000 € (as in 2011)
  - estimated saldo of 362 084 € in 7/2012

cfr infra for proposed use of remaining saldo

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Proposal 4
Prolongation of contract at no supplementary cost with use of remaining saldo until end 2014

- In 7/2012 a saldo of about 362 000 € is estimated
- It is proposed to keep this saldo available until end 2014 for:
  - registration & datamanagers at BCR (200 000)
  - BCR working costs (50 000)
  - maintenance of database/server (50 000)
  - costs of statistical analysis and reporting (60 000)
- Any residual sum on 31/12/2014 will be reimbursed

Proposals of the PROCARE Steering Group

- Registration for survey (audit)
  for all centres
- 'Training' (extended registration ± central review)
  for 'outliers' >P95)
  for low volume centres
  for those who want to improve on a voluntary basis
  (suggested for those >P50)
- Intervention strategy if no improvement

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“To dos”

- Compulsory registration of minimum dataset of all patients at BCR for adjusted benchmarking. Hospital management should be (more) supportive.
  - **Minimum dataset** for rectal cancer management (PROCARE 1/5/2012)
  - **Templates** per discipline (PROCARE 1/5/2012)
  - **Compulsory registration** of minimal dataset (from 1/1/2013?) before remuneration (and for specific accreditation of the team/centre ?)
- Adjusted benchmarking should be available per year (no delay of 2-3 years).
  - obligation to use online registration and **maintenance of online database**
  - Software, manpower (statistician, datamanager, experts) for **adjusted benchmarking** (at BCR)
- Professional involvement is essential for definition of criteria and judgment after adjusted benchmarking.
  - **Definition of ‘outlier’** (workshop 4/2012; PROCARE Steering Group 5/2012)
  - Judgment on anonymous data. Check of plan for improvement if applicable.
  - To decide who (**dedicated subgroup of College of Oncology**).
- Extended dataset + central review for ‘outlier-centres’ during 2 years and for low volume centres (and optional for other centres: improvement)
  - **Extended dataset** (PROCARE 1/5/2012)
  - **Intervention strategy** if no improvement within 2 years (to be developed)