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Quality assurance, centralisation and outcomes in complex cancer surgery

Graeme Poston

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Chair

HPB Specialised Commissioning Clinical Reference Group, NHS England

Specialised Commissioning Internal Medicine Programme of Care, NHS England

NICE Colorectal Cancer Guideline Development Group

NICE Colorectal Cancer Quality Standards Development Group

UNIVERSITY OF LIVERPOOL

Aintree University Hospitals

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Drivers for improvement

- Our populations are getting older:
  - age is the greatest aetiological factor for disease in western society
- Healthcare inflation is 5% per year
- Patient expectation increases year on year
- Loss of medical manpower:
  - are we producing enough doctors?
    - impact of EWTD?
- Can we afford it?

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The surgeon as a prognostic factor in rectal cancer: variability among 13 consultant surgeons

	%
• Curative resection (R0)	40 – 76
• Anastomotic leakage	0 – 25
• Postoperative mortality	8 – 30
• Local recurrence	0 – 21
• 5 year survival	20 – 63

McArdle and Hole, *BMJ* 1991;302:1501-5

Specialised Surgery

"Some surgeons perform less than optimal surgery. Some are less competent technically than their colleagues; and some fail to supervise surgeons in training adequately.

… If by more meticulous attention to detail, the results of surgery could be improved, and our results suggest that this would not be difficult, the impact on survival might be greater than that of any of the adjuvant therapies currently under study."

McArdle and Hole, *BMJ* 1991;302:1501-5

Quality assurance

<u>Traditional Definition</u>

The complete set of systematic actions that is required to achieve a treatment result that meets a certain standard

Quality assurance

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- **Clinical Effectiveness** – quality care is care which is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes
- **Safety** – quality care is care which is delivered so as to avoid all avoidable harm and risks to the individual's safety
- **Patient Experience** – quality care is care which looks to give the individual as positive an experience of receiving and recovering from the care as possible, including being treated according to what that individual wants or needs, and with compassion, dignity and respect.

Quality assurance

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Definition of Quality

This definition of quality has now been enshrined in legislation through the Health and Social Care Act 2012.

Quality assurance

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Quality Assurance	Quality Improvement
To ensure quality requirements are being met	Supports immediate positive changes in delivering quality
Assesses compliance with standards	Uses standards as a basis for defining quality to improve practice
Uses data to compare actual with standards	Data used to drive improvement to achieve best practice
Actions intended to remedy variations from standards	Actions involve changing processes or systems to deliver improved practice
Repeated data collection required	Repeated data collection required

Quality assurance

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Quality Assurance is:

- An assessment of quality of care by an external body often in terms of comparison against agreed threshold standards, to determine whether the quality of care is acceptable
- This judgement leads to further discussion as to whether and where 'corrective actions' are required to maintain or improve quality
- Quality Assurance also ensures that these actions are implemented through monitoring and review of progress

Kings Fund 2011.

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Issues of quality assurance in cancer surgery

- Treatment decision making: MDT working
- Surgical technique
- Quality standards
- Centre and surgeon volumes
- Centralisation
- Clinical trials and outcomes
- Commissioning complex cancer surgery
- Measuring outcomes

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Issues of quality assurance in cancer surgery

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MDT WORKING?

Medical Oncologists

Pathologists

Surgeons

Radiation Oncologists

Radiologists

Multidisciplinary management of cancer

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- Controversial when first promoted
- Good evidence now exists that demonstrates overall long term survival benefits when patients are managed within MDTs
- But is it really necessary when dealing with early cancer (e.g. T1 N0 M0 breast carcinoma)?
- Legal requirement for all cancer patient management in many European countries

Zorbas H et al. Med J Aust 2003; 179: 528-31
Basler JW et al. Curr Urol Rep 2005; 6: 228-34
Houssami N, Sainsbury R. Eur J cancer 2008; 42: 2480-91
Wright FC et al. Eur J Cancer 2007; 43: 1002-10
Westin T, Stalfors J. Curr Opin Otolaryngol Head Neck Surg 2008; 16: 103-7

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Limitations on MDT working?

- Little high quality supportive evidence of efficacy until recently?
- Discordance of MDT decisions made and actions taken?
- Reasons for discordance:
  - unknown co-morbidity?
  - inadequate clinical information?
  - patient choice?
  - commoner for gastric and pancreatic cancers?

Blazeby JM et al. Ann Oncol 2006; 17: 457-60
Houssami N, Sainsbury R. Eur J cancer 2008; 42: 2480-91

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Limitations to MDT working?

- 149 (115 upper GI, 34 colorectal) consecutive cancer cases over 6 months at Roswell Park, Buffalo NY
- Reasons for discussion:
  - progression/metastases (44%)
  - case management (26%)
  - diagnosis (21%)
  - pathology (15%)
  - resectability (7%)
- Physicians certain of management plan pre-MDT 84%
- Change in management at MDT in 36%

Oxenberg J et al. Ann Surg Oncol 2015; 22: 1533-9

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Limitations to MDT working?

- Meta-analysis of literature on outcomes of MDTs for cancer 2005-2012
- Fifty one papers identified
- Better cancer outcomes identified:
  - colorectal
  - head and neck
  - breast
  - oesophageal
  - lung
- Associated with better clinical diagnostic and decision making

Prades J et al. Health Policy 2015; 119: 464-74

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MDTs for cancer result in

- Better patient care and survival outcomes
- Improved consistency of decision making and delivery of treatment
- Better continuity, coordination and cost-effectiveness of care
- Optimal, appropriate and standardised decision making on diagnosis, follow up and patient support
- Reduced over-referrals, interventions, length of stay, operative morbidity and mortality

Vasudevan SP et al. Colorectal Dis 2013; 15: 1253-6
Shah S et al. Surg Endosc 2014; 28: 2783-8
Prades J et al. Health Policy 2015; 119: 464-74

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Non-adherence to MDT decisions

- Results in trend towards lower survival in lung cancer
- Reasons:
  - unknown co-morbidity
  - patient choice
  - more clinical information becoming subsequently available

Blazeby JM et al. Ann Oncol 2006; 17: 457-60
Leo F et al. J Thorac Oncol 2007; 2: 69-72

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Impact of multidisciplinary team working on the management of colorectal cancer

- Same-centre multidisciplinary management has benefits over multi-centre referred management:
  - reduced number of interventions
  - shorter length of stay
  - shorter delays in delivering care
  - better and more appropriate use of chemotherapy
  - decreased operative morbidity and mortality
- Specialist Stage IV colorectal MDT outcomes are superior to generic colorectal cancer MDTs

Lordan JT et al. Eur J Surg Oncol 2010; 35: 302-6
Goyer P et al. Clin Res Hep Gastro 2013; 37: 47-55
Jones RP et al. Eur J Cancer 2014; 50: 1590-601
Jones RP et al. Br J Surg 2012; 99: 1263-9
Vigano L et al. Ann Surg Oncol 2013; 20: 938-45

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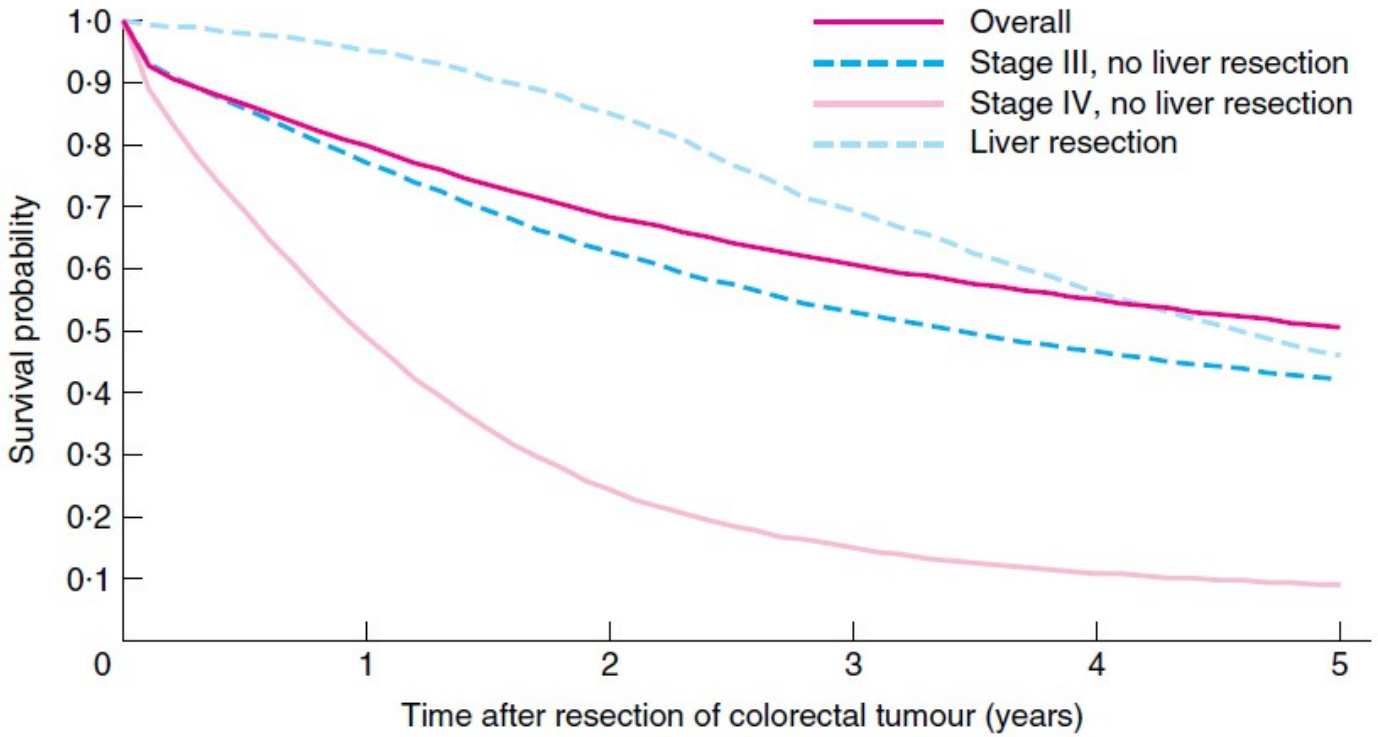
DECISION MAKING OUTSIDE OF A SPECIALISED MDT?

Overall survival of patients in England (114,155) diagnosed with colorectal cancer between 1998-2004 according to stage at diagnosis

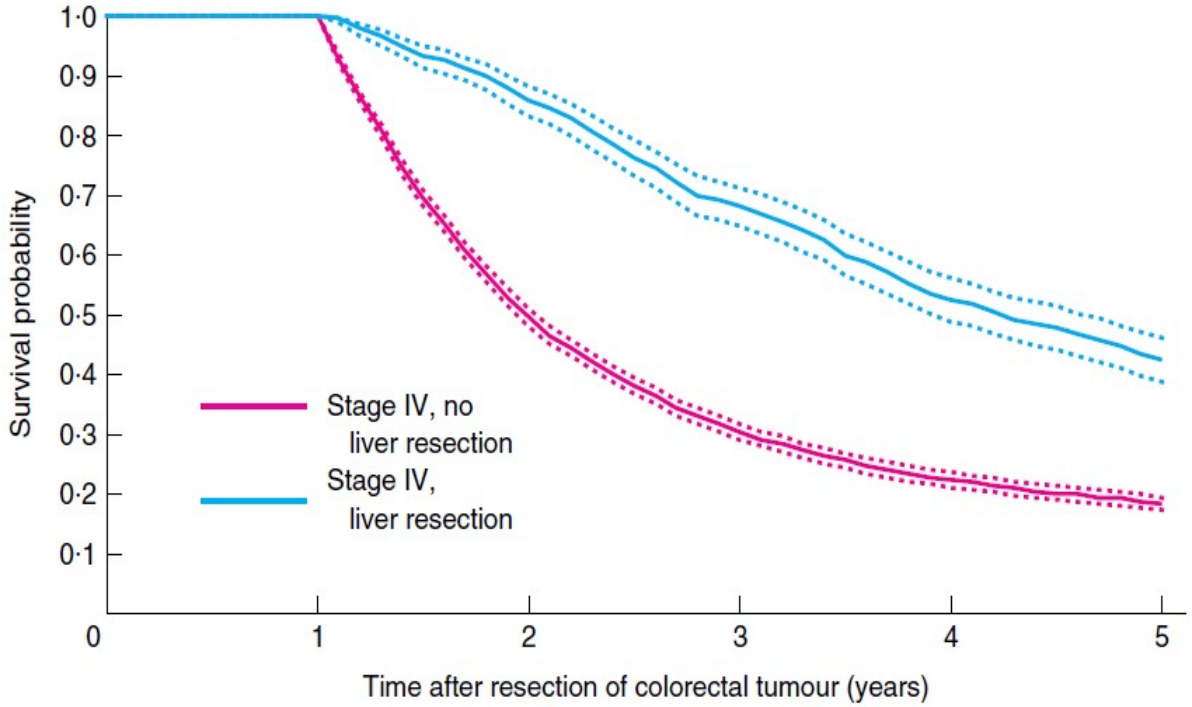
Morris E et al. Brit J Surg 2020; 97: 1110-8



No. at risk						
Overall	114 155	90 868	78 122	69 186	62 668	48 188
Stage III, no liver resection	34 805	26 846	21 803	18 413	16 210	12 241
Stage IV, no liver resection	9459	4613	2297	1398	1030	701
Liver resection	3116	2973	2657	2169	1748	1108

Landmark analysis of patients with Stage 4 at diagnosis who survived 1 year who did and did not undergo liver resection

Morris E et al. Brit J Surg 2010; 97: 1110-8



No. at risk						
Stage IV, no liver resection	9459	4613	2297	1398	1030	701
Stage IV, liver resection	821	761	657	520	401	257

Fig. 5 Landmark survival analysis of patients with stage IV disease at diagnosis who survived 1 year and did or did not undergo liver resection. Dotted lines represent 95 per cent confidence intervals

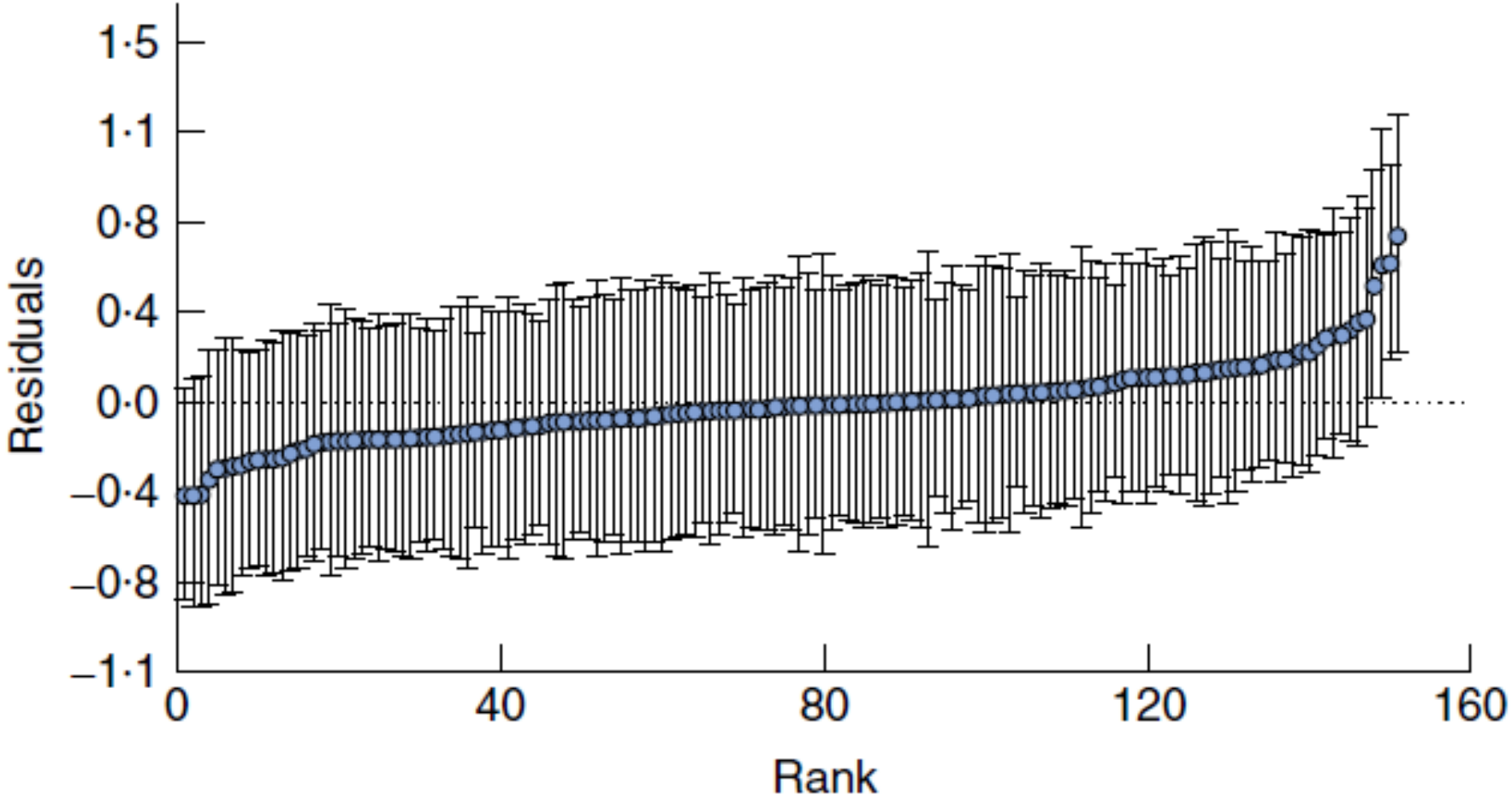
Use of liver resection in England for metastatic colorectal cancer: hospital by hospital analysis

197 individual hospitals in England

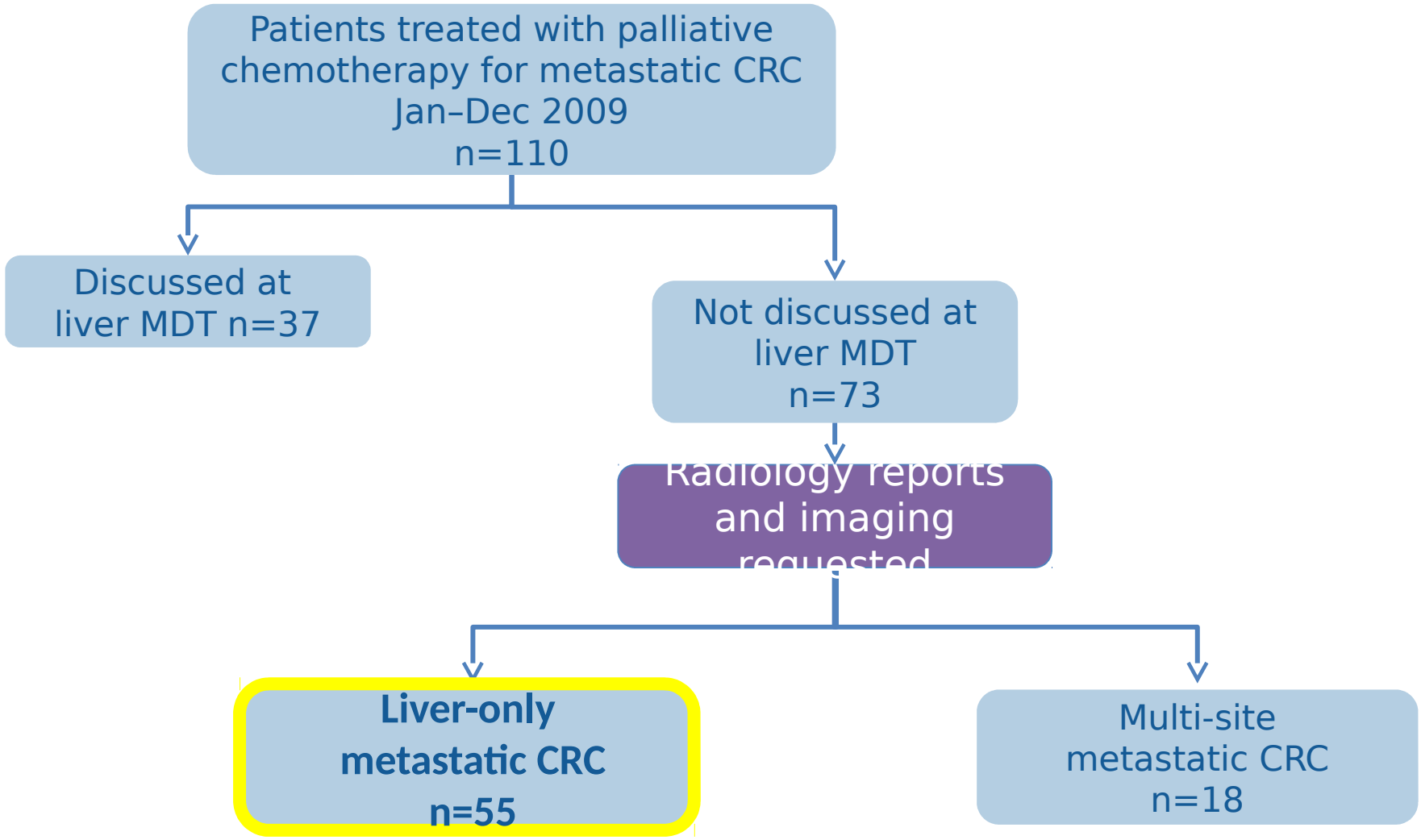
Morris EJA et al. Brit J Surg 2010; 97: 1110-8

Referral of colorectal cancer patients from all English hospitals for liver resection 1998-2004 (expressed as % of all CRC patients) adjusted for age, deprivation, year of diagnosis, stage and site of primary at diagnosis and co-morbidities (Charlson)

Morris E et al. Brit J Surg 2010; 97: 1110-8



Decision making:



Jones RP, et al. Br J Surg 2012; 99: 1263-9

Imaging reviewed by 7 liver surgeons at 5 centres

- Graeme Poston, Hassan Malik, Steve Fenwick - Aintree
- Dave Berry - Cardiff
- Merv Rees - Basingstoke
- René Adam - Hôpital Paul Brousse, Villejuif
- Nic Vauthey - M D Anderson, Houston

- Each patient scored*

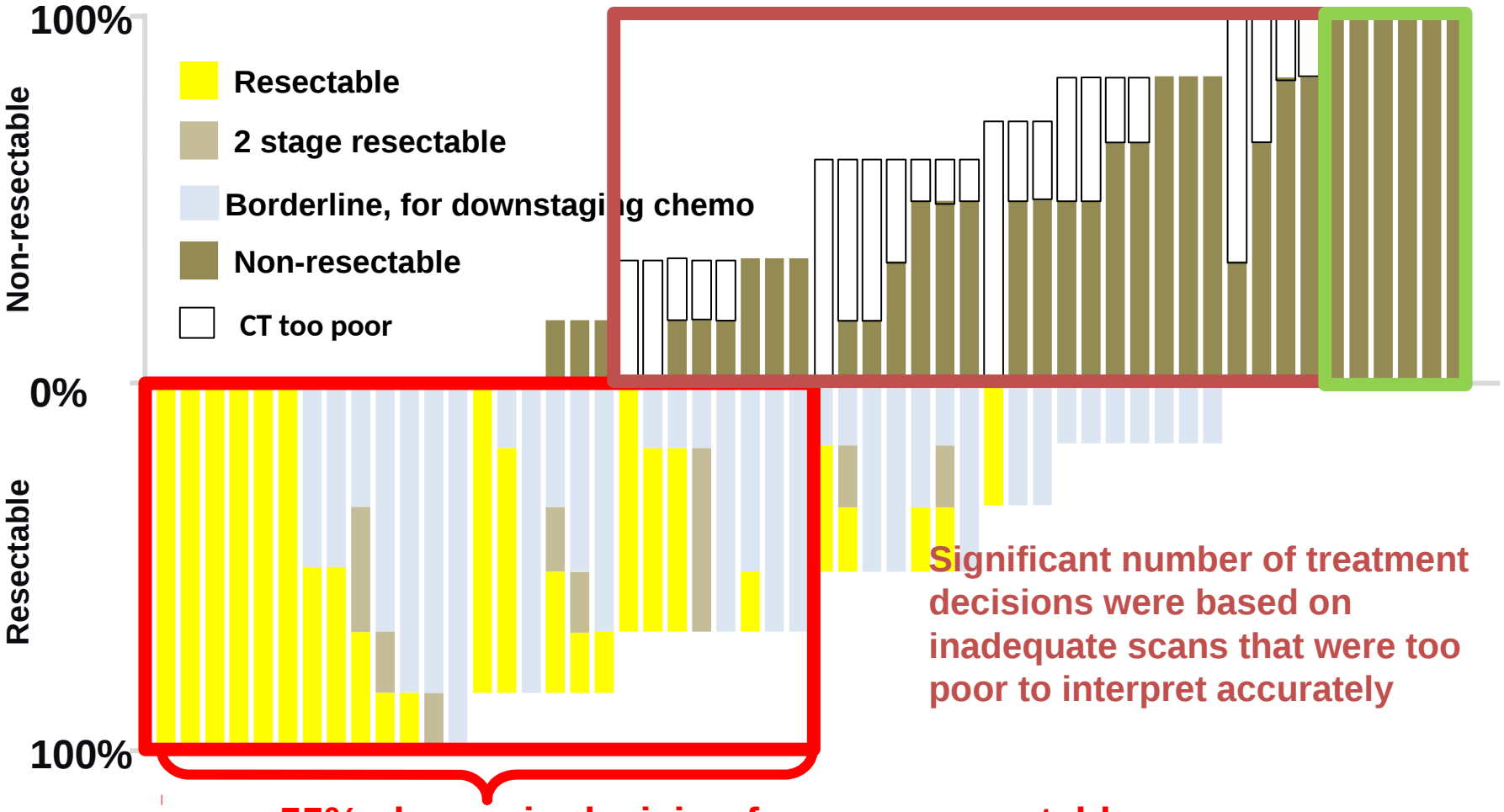
1. Easily resectable
2. Complex resectable
3. Borderline resectable
4. Irresectable
5. Unable to comment on scan

Results expressed as waterfall plots

Jones RP, et al. Br J Surg 2012; 99: 1263-9

Experts' opinions on resectability

Only 10% complete concordance
Between experts and non-experts



Significant number of treatment decisions were based on inadequate scans that were too poor to interpret accurately

55% change in decision from non-resectable to resectable/borderline

Kappa score = 0.577

Jones RP, et al. Br J Surg 2012; 99: 1263-9

NICE National Institute for Health and Care Excellence

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NICE Clinical Guideline:

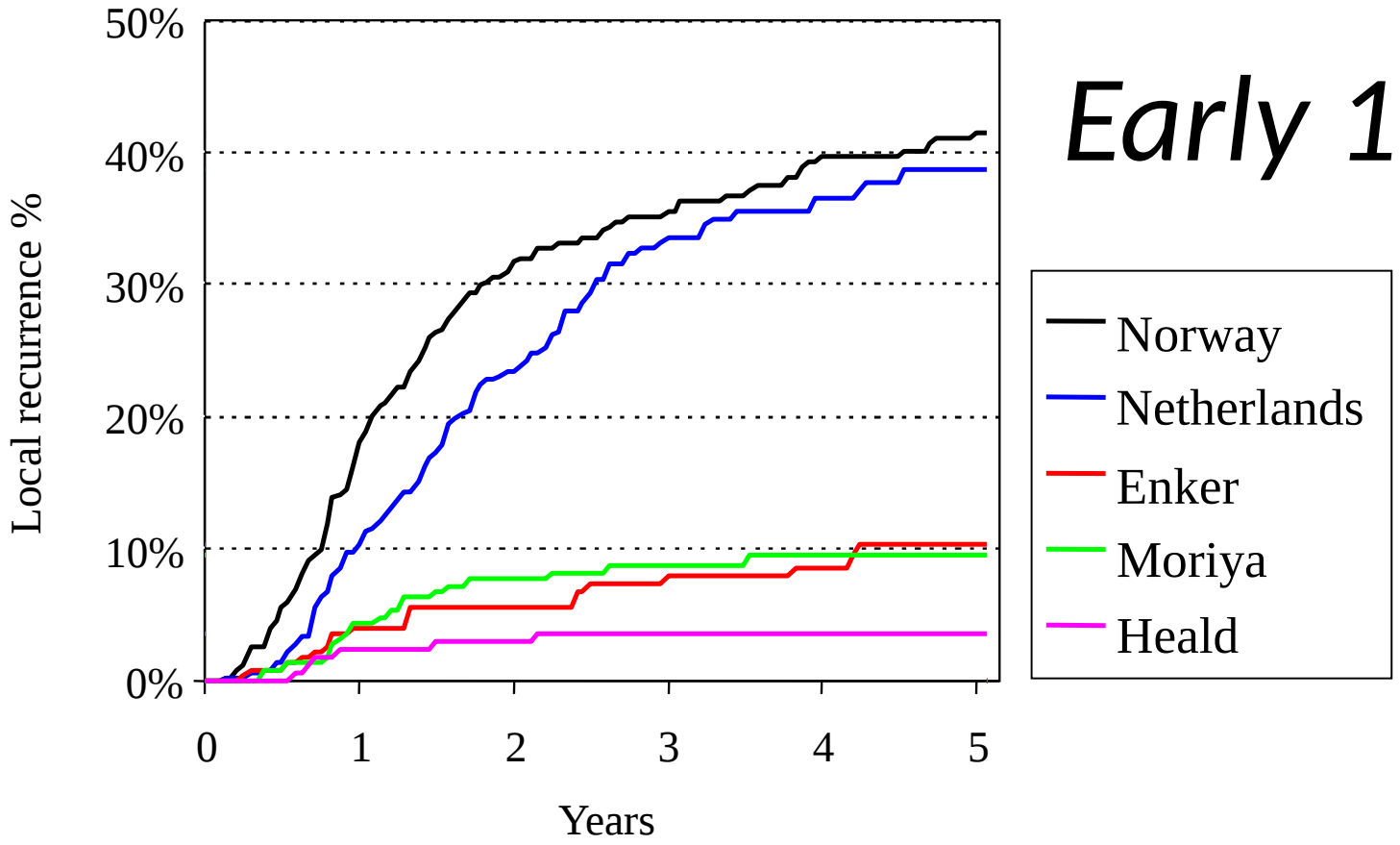
CG131: Colorectal Cancer, November 2011
Revised December 2014

- **Imaging hepatic metastases**
- 7. If the CT scan shows metastatic disease only in the liver and the patient has no contraindications to further treatment, a specialist hepatobiliary MDT should decide if further imaging to confirm surgery is suitable for the patient - or potentially suitable after further treatment - is needed.

SURGICAL TECHNIQUE?

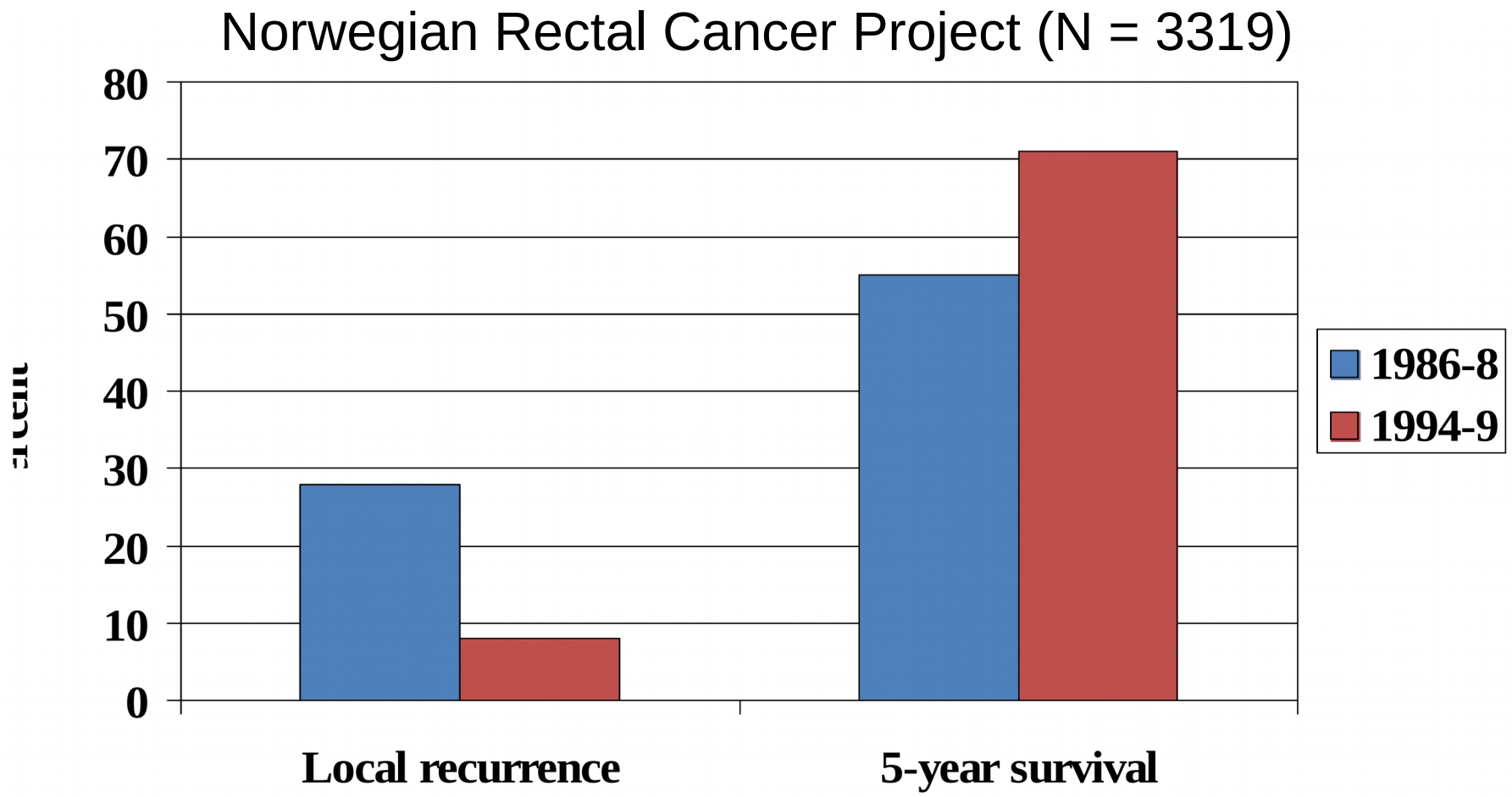
Rectal Cancer: How it was

Eur J Surg Oncol 1999; 25: 368-374



Early 1990's

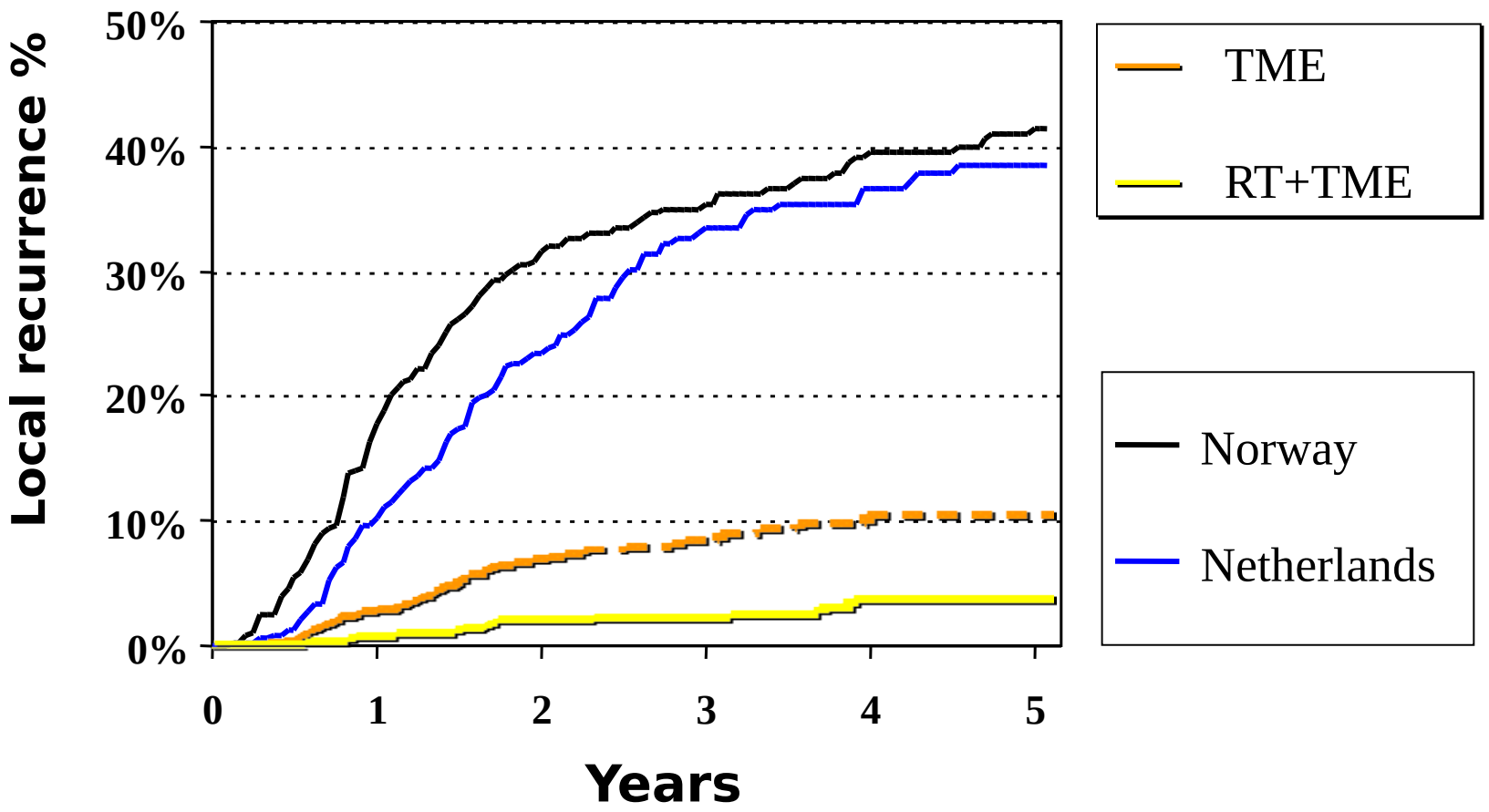
Results of the Norwegian programme to introduce TME



Wibe et al. *Dis Colon Rectum* 2002;**45**:857-66

Rectal Cancer: How it now is

DCRCG, N Engl J Med 2001;345:638-646



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QUALITY STANDARDS?

NICE National Institute for Health and Care Excellence

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What are Quality Standards?

- A **quality standard** is a set of specific, concise statements that:
  - act as markers of high-quality, cost-effective patient care across a pathway / clinical area;
  - are derived from the best available evidence such as NICE guidance or other accredited sources
  - are produced collaboratively along with partners, service users and carers

What is the purpose of a Quality Standard?

- To make it clear what high quality care is by providing definitions of clinical and cost-effective care
- To support benchmarking of performance
- To provide information to patients, carers and the public about the quality of care they can expect

NICE National Institute for Health and Care Excellence

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NICE Quality Standards:

QS20: Colorectal Cancer, August 2012

- Quality statement 6
- *People with a contrast-enhanced computed tomography (CT) of the chest, abdomen and pelvis suggesting liver metastatic colorectal cancer have their scans reviewed by the hepatobiliary multidisciplinary team to decide whether further imaging is needed to confirm suitability for surgery*
- Incorporated into NHS contracts April 2014
- Failure to comply will result in financial penalties

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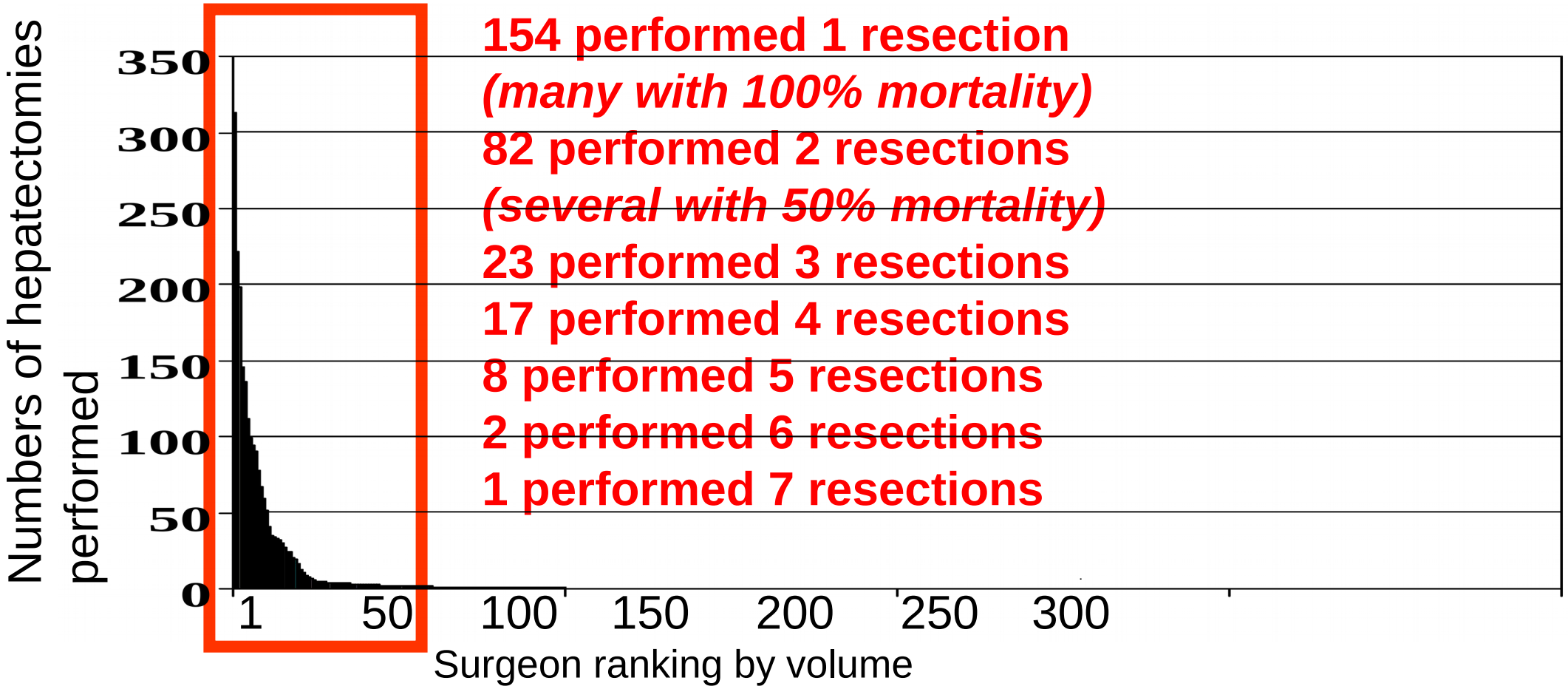
SURGEON AND CENTRE VOLUMES: CENTRALISATION?

Volume

"Patients can often improve their chances of survival substantially, even at high volume hospitals, by selecting surgeons who perform the operations frequently"

Birkmeyer *et al*. *N Engl J Med* 2003; 349: 2117-27

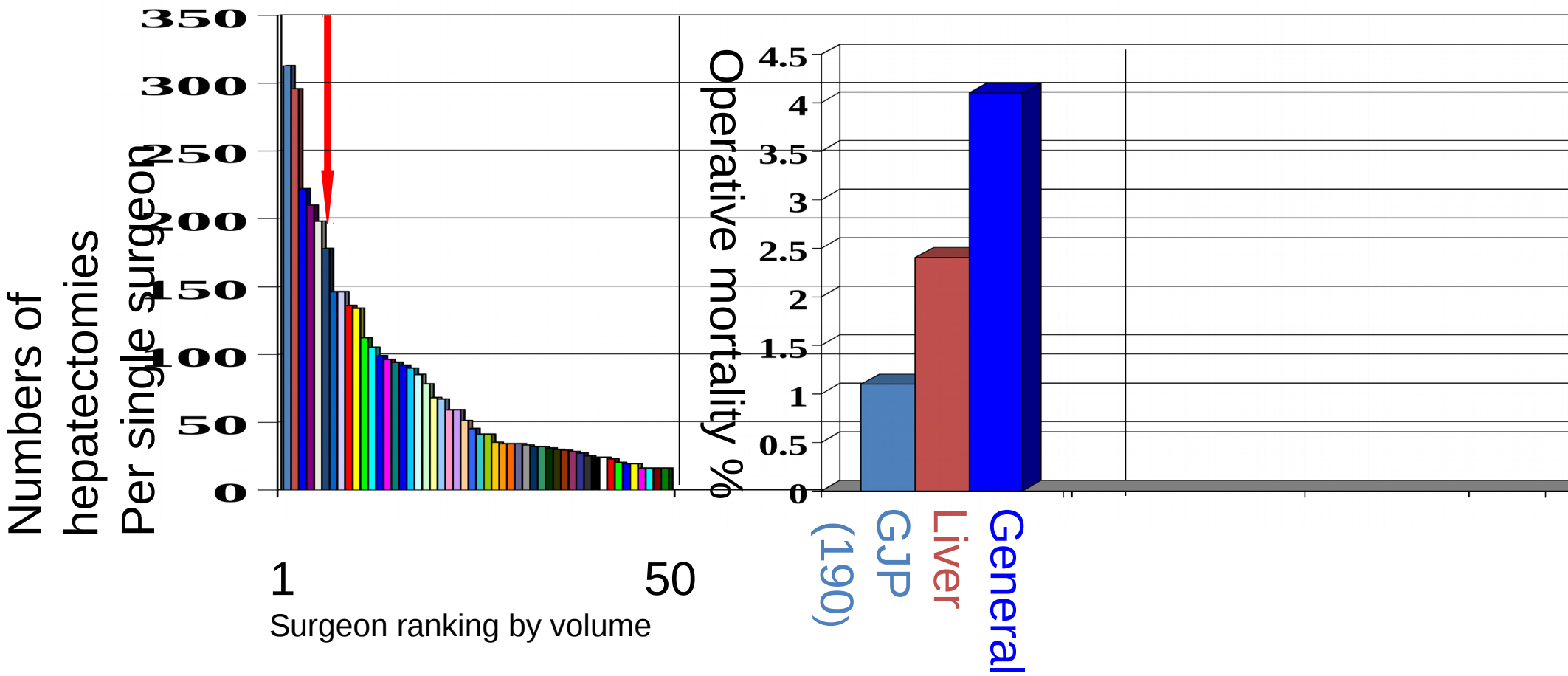
Detailed activity analysis 1999-2003:
3116 liver resections for CRC metastases performed by ***305*** surgeons in England!



154 performed 1 resection
(many with 100% mortality)
82 performed 2 resections
(several with 50% mortality)
23 performed 3 resections
17 performed 4 resections
8 performed 5 resections
2 performed 6 resections
1 performed 7 resections

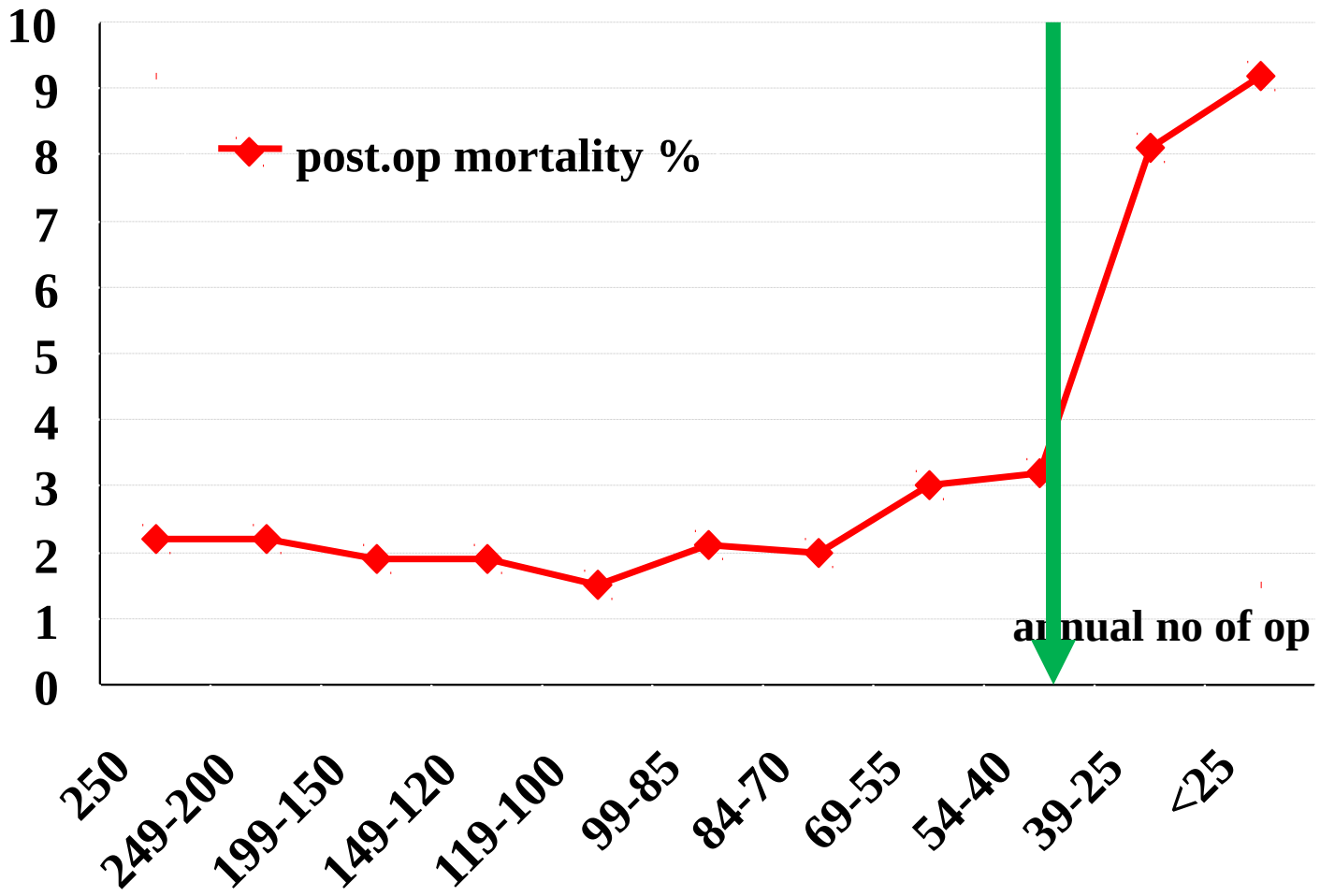
Morris EJA et al. Brit J Surg 2010; 97: 1110-8

Detailed activity analysis 1999-2003:
2679/3116 liver resections for CRC metastases performed by 50 highest volume surgeons
(42 liver trained and 8 non-liver trained)



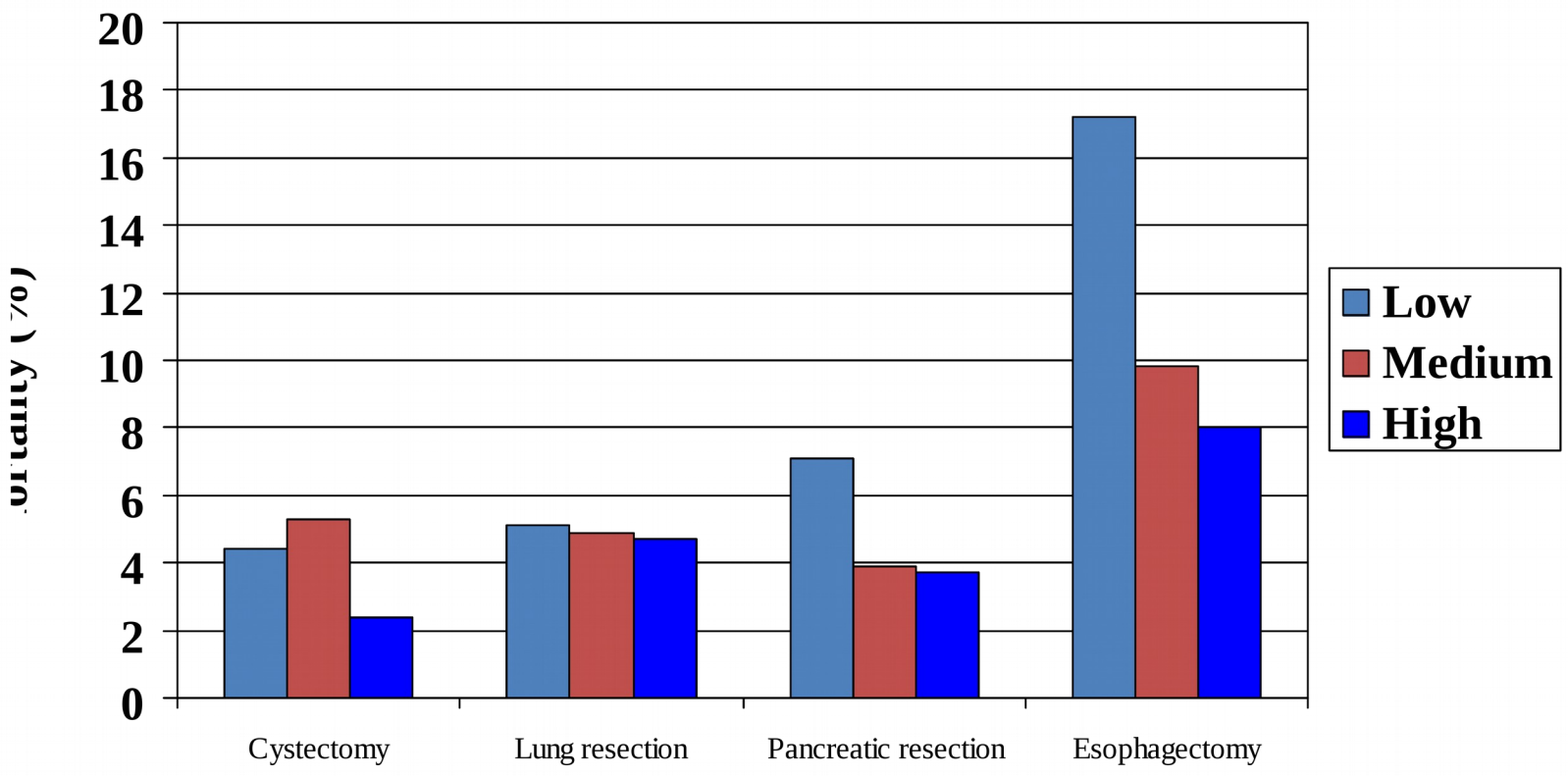
Morris EJA et al. Brit J Surg 2010; 97: 1110-8

Impact of hospital volume on the outcome of rectal cancer surgery (1995-2003)



Swedish cancer registry 2006

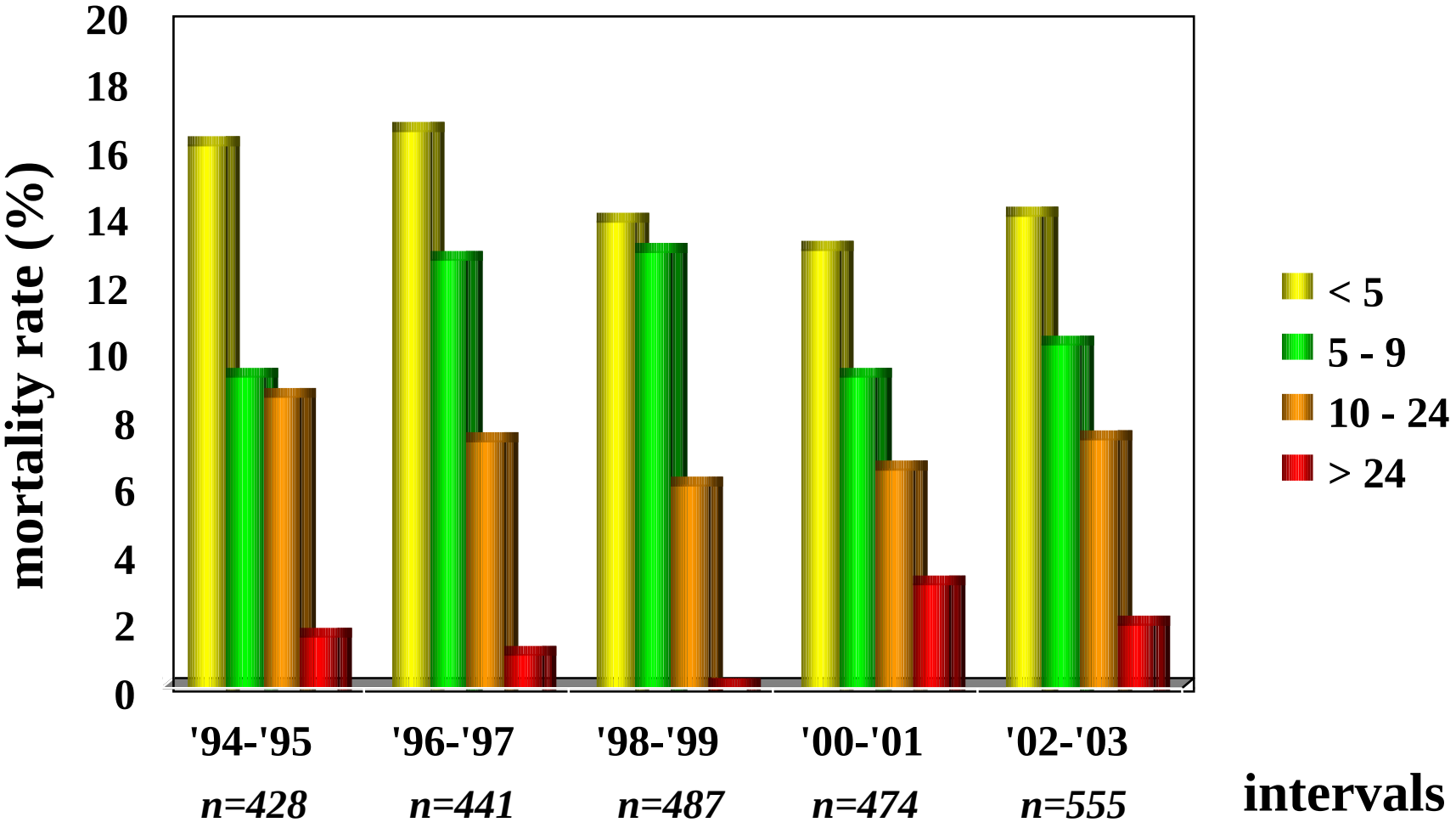
Role of surgeon volume at high-volume hospitals



1998-9 Medicare population, from Birkmeyer et al., *NEJM*, 2003

Results after pancreatico-duodenectomy: hospital mortality per cluster

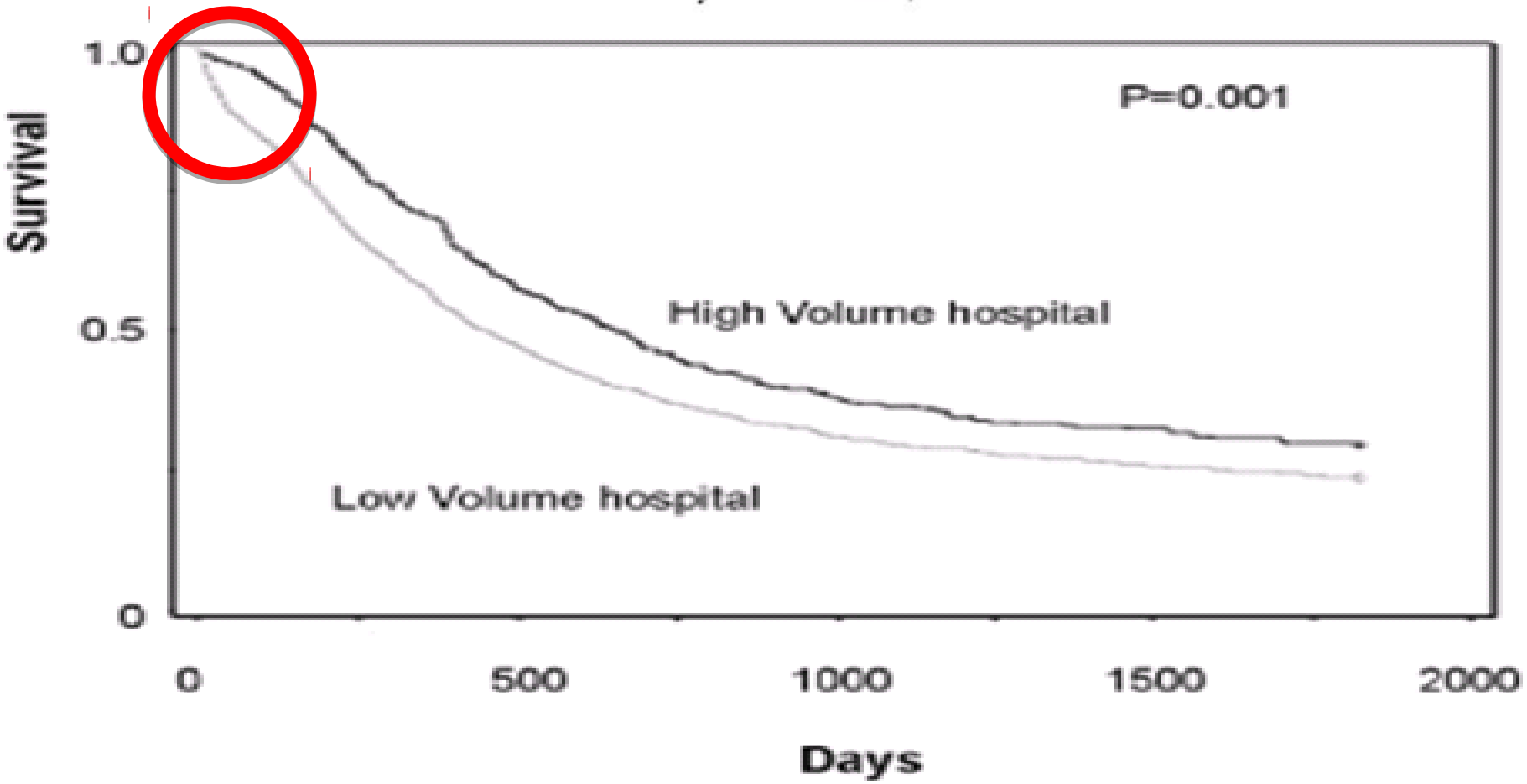
van Heek et al. Ann Surg 2005; 242:781-790



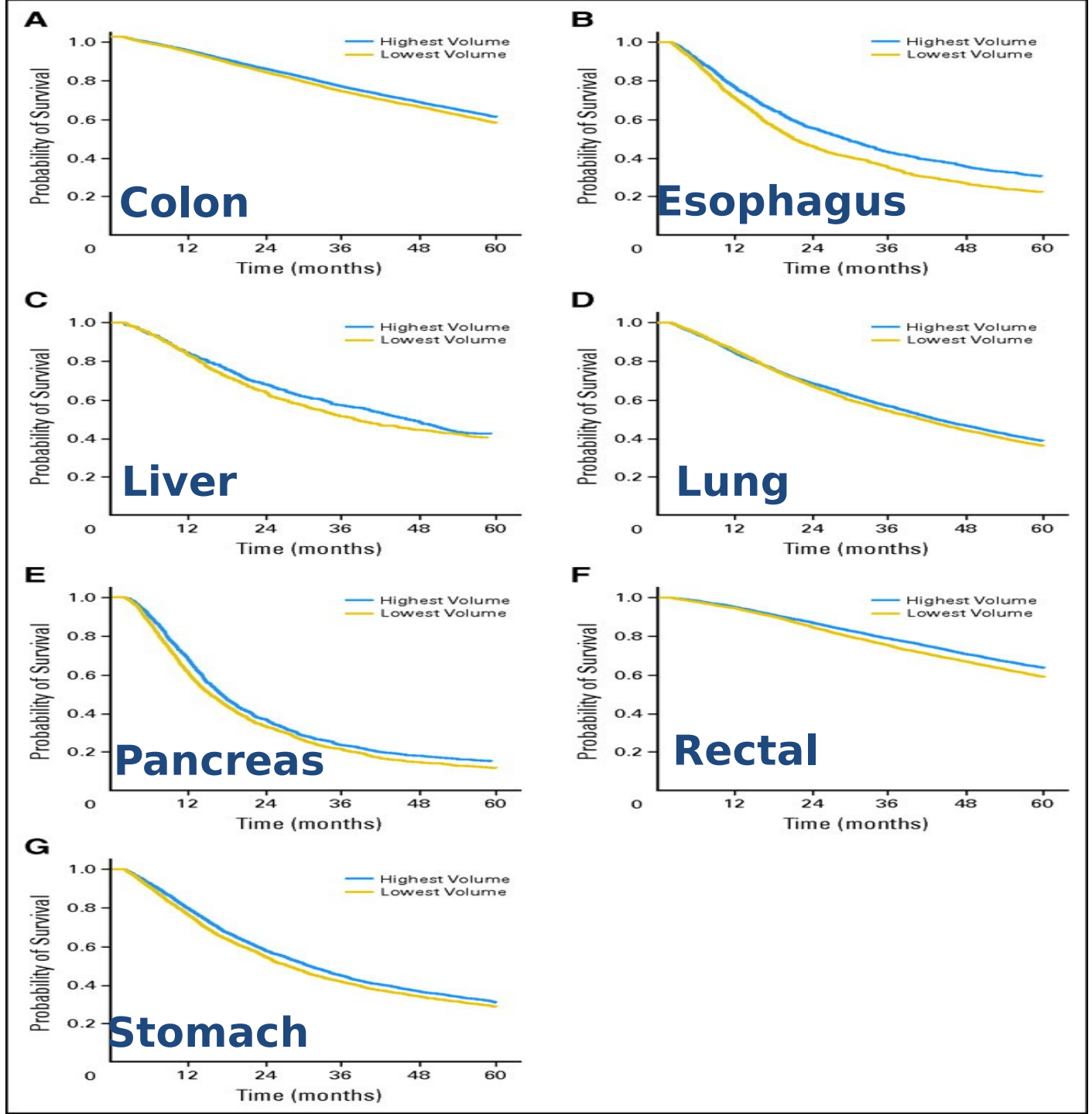
Long-Term Survival Is Superior After Resection for Cancer in High-Volume Centers

Ann Surg 2005; 242: 540-4

Yuman Fong, MD, Mithat Gonen, PhD, David Rubin, MS, Mark Radzyner, MBA, JD, and Murray F. Brennan, MD

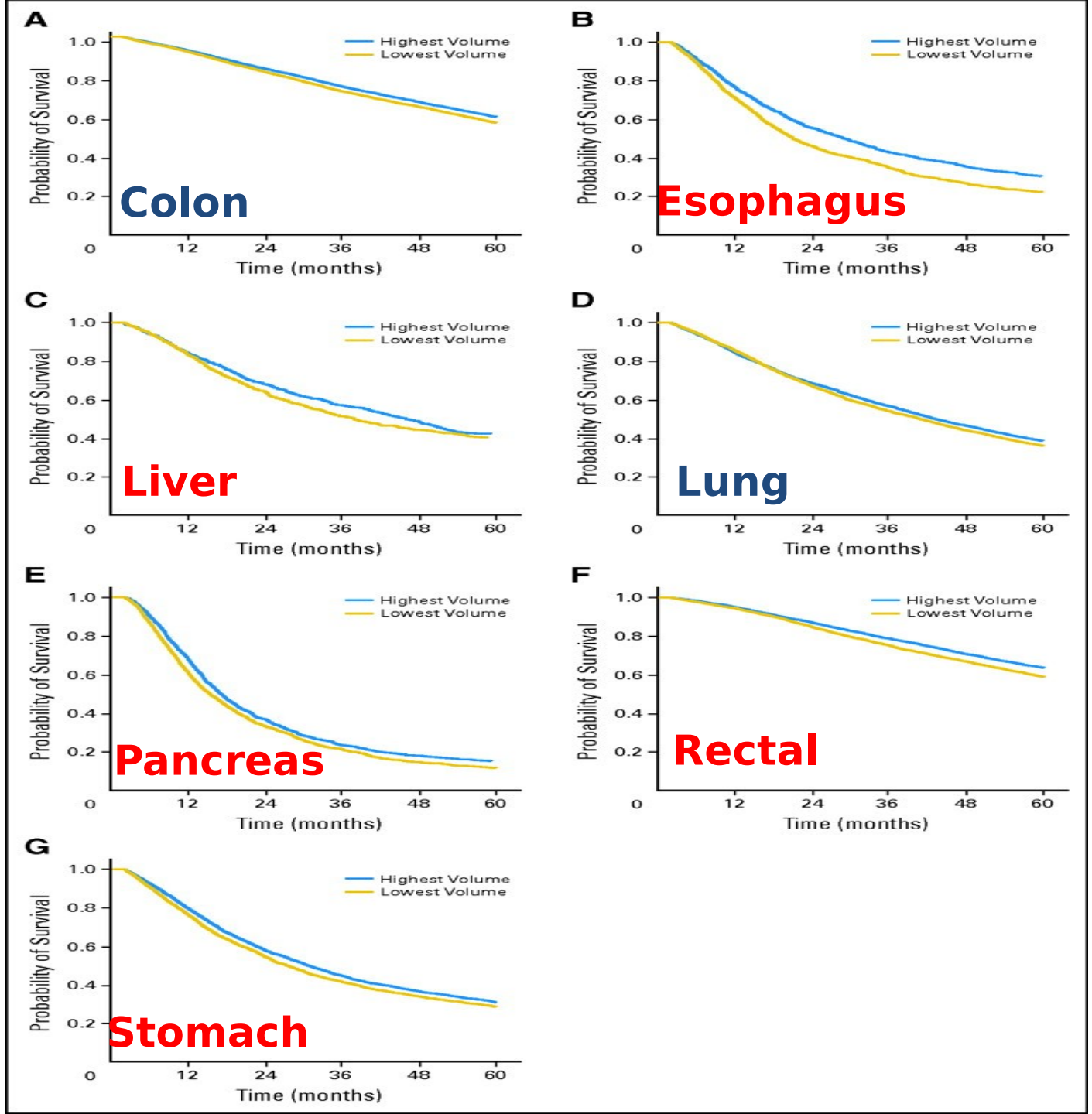


Survival of patients subjected to pancreatic resection for cancer



Five-year conditional survival comparing patients undergoing resection at highest-volume and lowest-volume quintile hospitals (adjusted for all covariates in the Cox model)

Bilimoria, K. Y. et al.
J Clin Oncol 2008; 26:4626-4633



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Bilimoria, K. Y. et al.
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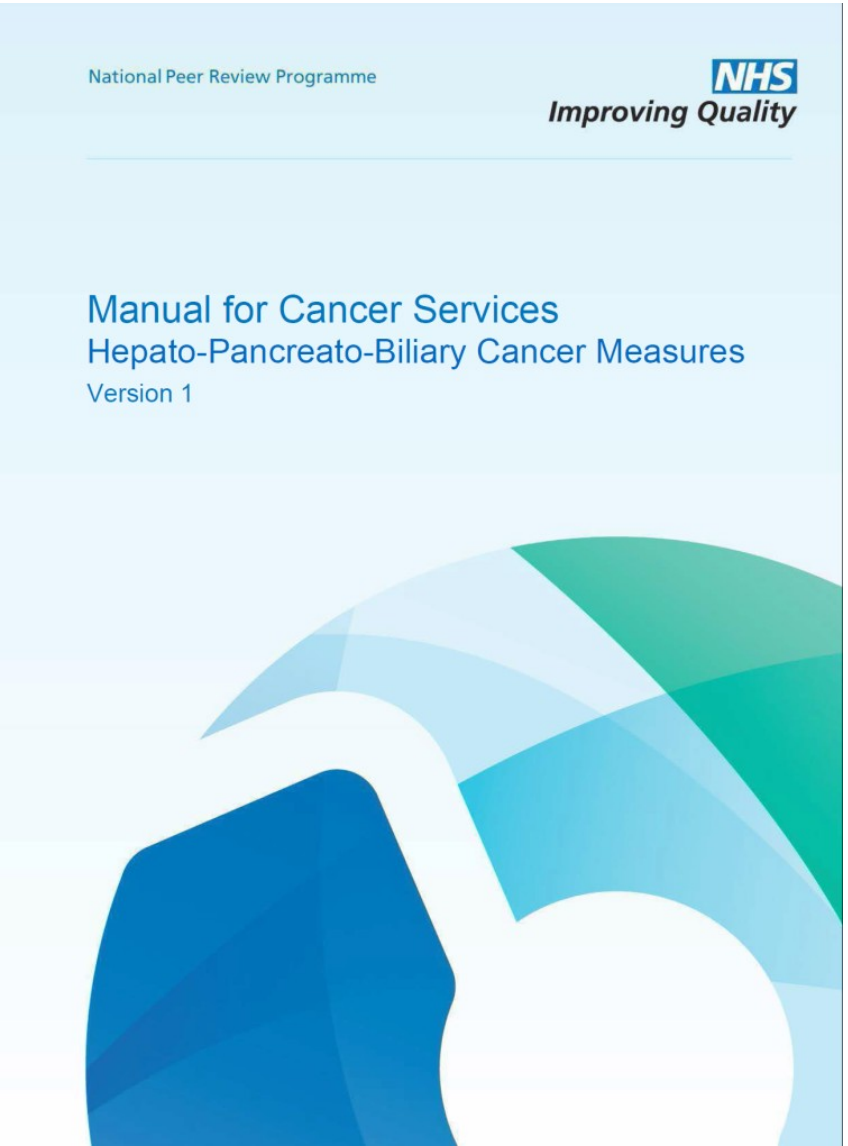
COMMISSIONING HIGH QUALITY SURGERY?

English National Cancer Plan: Improving Outcomes Guidance

- First published in 2001: Relates to the management of all common cancers
- Specifies core membership of each MDT
- Common cancers (breast, primary colorectal, skin etc.) managed by every general hospital
- Complex cancer surgery (lung, oesophagus, stomach, pancreas, liver, bladder, sarcoma) centralised to regional centres
- HPB updated in 2013
- www.cquins.nhs.uk/download.php?d=resources/measures/HPB



English National Cancer Plan:
2013 Hepato-Pancreato-Biliary Cancer Measures

Key Clinical Indicators (numerators) measured against documented incidence (denominator):

- *Number of cases with confirmed histology*
- *Number patients having surgical resection*
- *One, two and five year survival (rate)*

www.cquins.nhs.uk/download.php?d=resources/measures/HPB

AUGIS

The Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

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- **Provision of specialised HPB surgical services (2012):**
  - minimum population of 2 (ideally 3) million
  - based at major university hospitals
  - 5-7 HPB surgeons with 24/7 HPB surgical cover
  - weekly specialised HPB MDTs
- **HPB Surgeon volumes (2011):**
  - minimum surgeon annual liver volume 15-25 (10-15 major) resections
  - minimum centre annual volume 150 (75 major) resections
- **25 of 197 English general hospitals reimbursed for HPB surgery**

AUGIS.org

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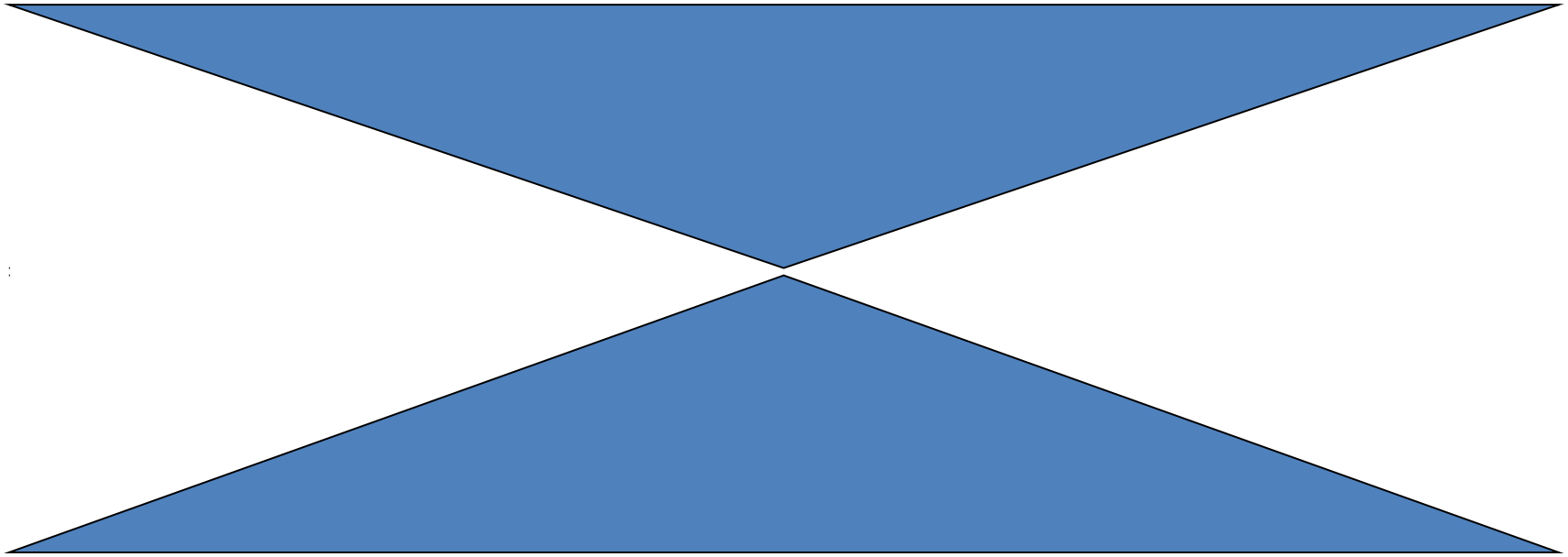
MEASURING OUTCOMES?

Comparative audit of outcomes

Top down (numerator based): registry data

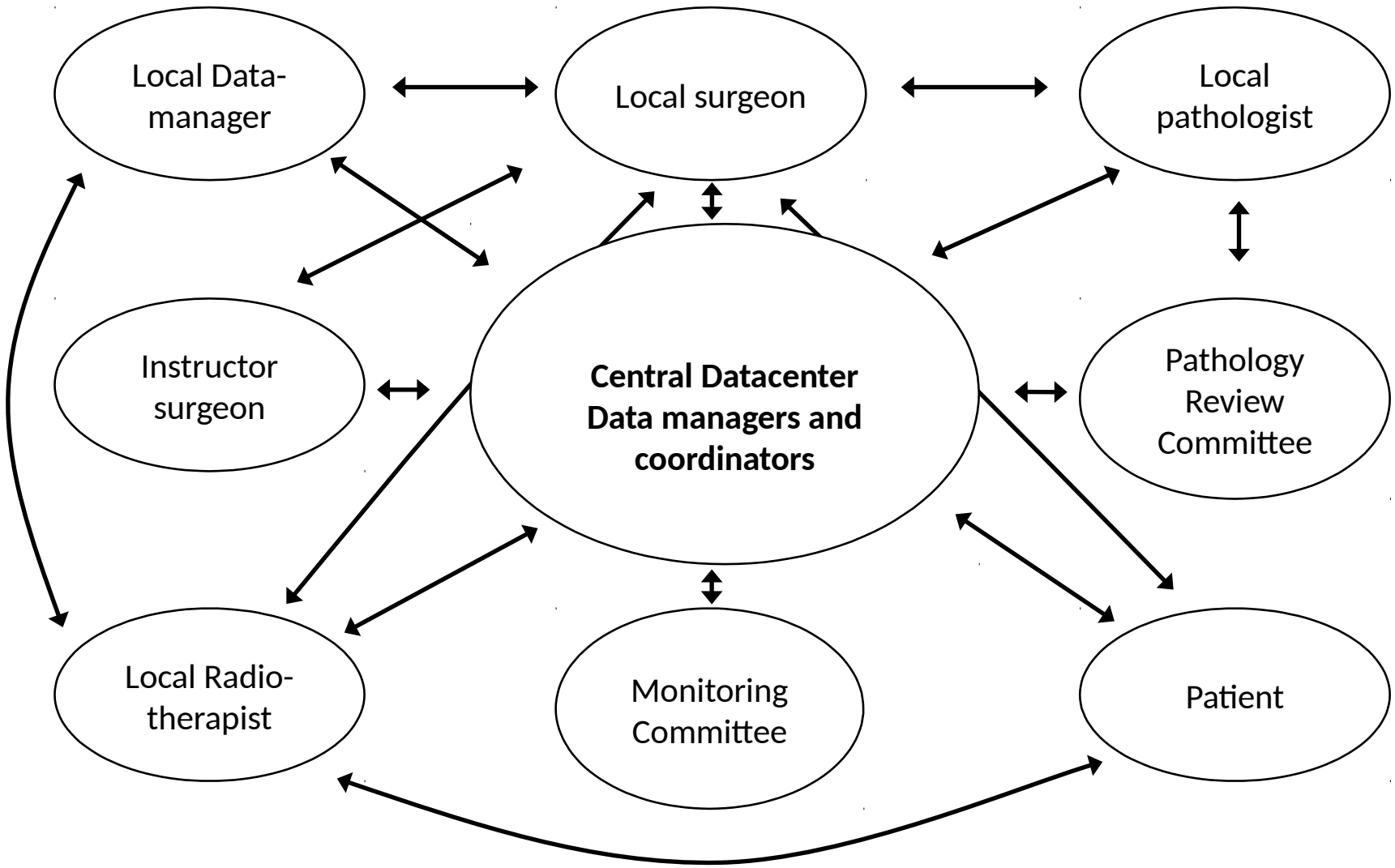


Bottom up (denominator based): population data

Basic concept of registries

- Outcomes registry
- Concurrent assessments of structure and process of care
  - Registry-based, site visits
- Analyses aimed at identifying best practices
- Broad implementation of such practices
- Outcomes tracking to confirm improvements

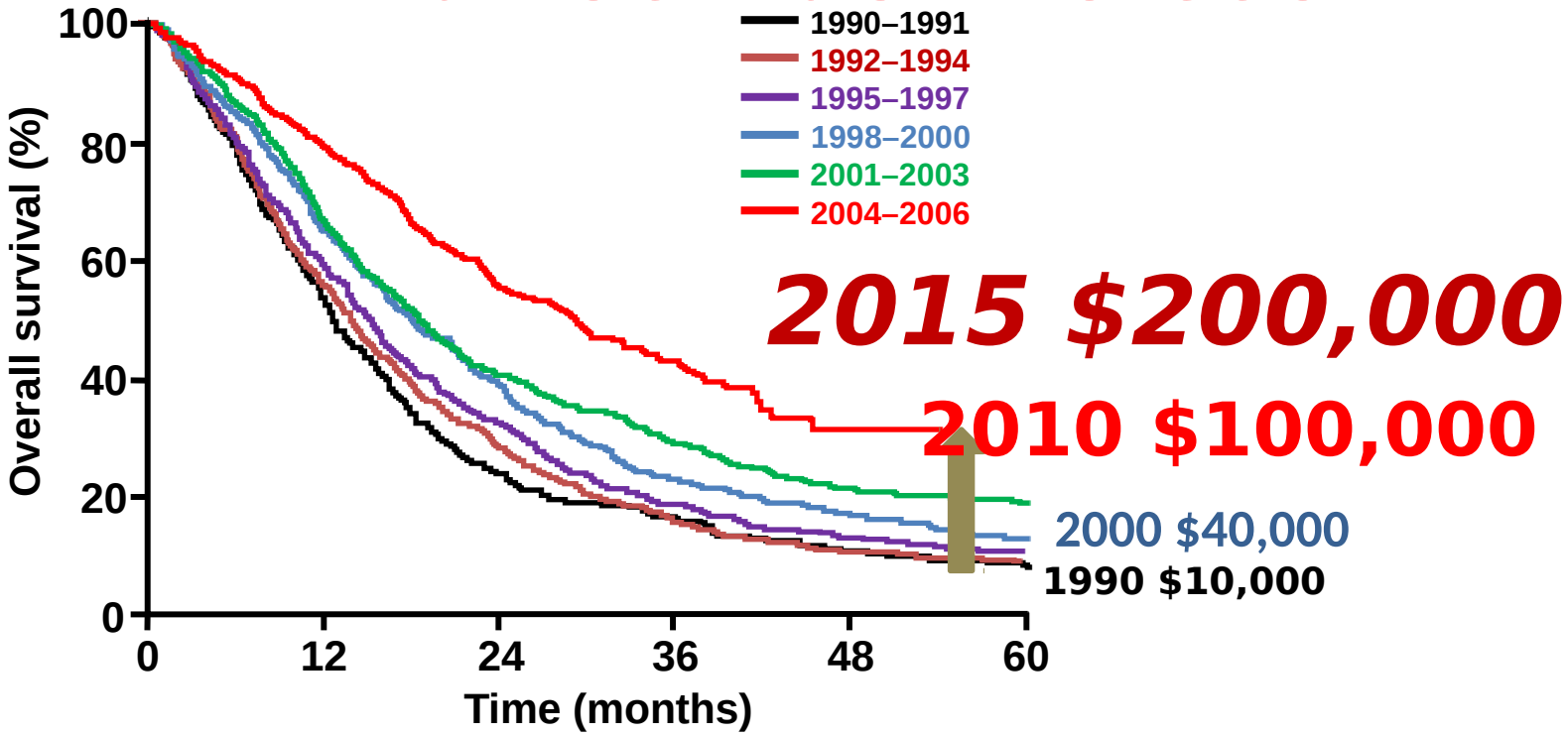
Logistics for quality assurance



mCRC treated at MD Anderson and Mayo clinics by year of diagnosis: OS

OS has improved substantially over the past 25 years

But so has the cost!!!!



2,470 patients from two highly specialized centers

Kopetz S, et al. J Clin Oncol 2009;27:3677–3683

Because……

- Metastatic colorectal cancer is now becoming a chronic condition rather than a terminal illness
- These patients are now becoming very expensive to treat if we are going to achieve long term survival like this, regardless of disease free status
- We don’t know the ideal treatment sequencing strategy to achieve optimal survival

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CLIMB 1409
A Prospective ***C***olorectal ***Li***ver ***M***etastasis Data***b***ase with an Integrated Quality Assurance Program

A Collaboration Project with the

EUROPEAN SOCIETY OF SURGICAL ONCOLOGY

esso
The European Society of Surgical Oncology

EORTC
European Organisation for Research and Treatment of Cancer

Can we compare outcomes? QIPP

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- ***Q***uality, ***I***nnovation, ***P***roductivity, and ***P***revention
- HPB surgery 2015-2016:

  - universal enhanced recovery programme

    - reimburse for maximum of 5 days in patient stay liver resection and 12 days for pancreas resection

  - procurement of both drugs and devices
- HPB surgery 2016-2017:

  - use of cross matching and blood transfusion

Can we compare outcomes?
CQUIN

- ***C***ommissioning for ***Qu***ality and ***In***novation
- Takes 2 years to implement
- Capacity planning: don't unnecessarily duplicate services
- Set national tariff for reimbursement
- Performance monitoring
- Quality dashboards

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Recommendations

- Centers of Excellence in an ideal world
  - *Best for procedures which are uncommon, high risk, expensive and have wide variation in outcomes*
- Delivery of care closer to home by appropriately trained surgeons working in cancer networks
- Multidisciplinary team meetings pre- and postoperatively
- Outcomes-based quality improvement
  - *Greatest promise for really improving quality, but will require major investments*

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Conclusions

- Quality assurance is mandatory
- Multidisciplinary working improves outcomes
- Centralisation increases volumes
- Increased centre and surgeon volumes improve outcomes
- Quality standards can be set
- Outcomes can be measured and compared