

The
National Bowel Cancer Audit Project.

(NBOCAP)

**The Association of Coloproctology of Great Britain & Ireland,
The NHS Information Authority and the Healthcare Commission.**

Consultation Document June 2004

Contents

1. Introduction
2. Organisations involved in national bowel cancer audit
3. Priority issues in bowel cancer addressed by NBOCAP
4. Development and implementation
5. IT infrastructure
6. Participation.

- Appendix I making bowel cancer outcome data available to the general public –
available as a separate download
- Appendix II project group membership
- Appendix III reference group membership
- Appendix IV priority outputs in bowel cancer
- Appendix V data items for centres not using the ACPGBI database

Introduction

The aim of this project is to improve the quality of care and survival of patients with bowel cancer by means of a National Audit.

The place of audit in achieving these aims is set out in the recommendations of The Report of the Bristol Royal Infirmary Inquiry (http://www.bristol-inquiry.org.uk/final_report). Specific reference should be made to sections on the provision of care of an appropriate standard, the responsibilities of NHS organisations and Staff in this respect and the process of validation and revalidation of Trusts.

1. Background

1.1 The NHS requires services to monitor the quality of the care they deliver in a systematic way and all clinicians are required to participate in clinical audit as part of clinical governance. This document sets out the means by which audit, on a national basis, can be used to measure and compare the quality of clinical care, informing local action to improve patient experience and outcomes.

1.2 If quality in bowel cancer care is to be measured on the basis of a national clinical audit, it is important to develop:

- i. public involvement in determining the issues which determine the quality of care for patients with bowel cancer.
- ii. a dataset to meet the needs of the quality of care agenda.
- iii. methods by which data may be a) collected and stored locally, at a Unit level
b) transferred electronically to a central facility for analysis.
- iv. a system of data validation using a combination of internal checks and external, independent, review.
- v. clearly defined and timely outcome measures.
- vi. a robust statistical tool for risk adjustment so that meaningful comparison of outcomes can be made between units, networks, regions and countries
- vii. ways in which outcome information can be fed back to providers and recipients of care to stimulate appropriate change.
- viii. linkage to Office of National Statistics (ONS)
- ix. an audit that is sensitive to and addresses confidentiality issues.

1.3 Participation in national audit will be a visible, key component of clinical governance at the local, clinician level. The output of the clinical audit will contribute to the monitoring of the Unit's performance by the Healthcare Commission and professional bodies, including the Association of Coloproctology of Great Britain & Ireland.

1.4 Understanding and interpreting observed differences in outcomes requires an understanding of those effects due to variations in performance of individual units, as well as those due to patient-related variables such as differing disease stage at presentation, co-morbidity and socio-economic status. A key part of this study is the development of analytical models that allow for these variables.

2 Organisation of National Bowel Cancer Audit.

2.1 The **Healthcare Commission** (the Commission for Healthcare Audit and Inspection) is an independent body formed by the Health and Social Care (Community Health and Standards) Act 2003 and launched on April 1st 2004. The Healthcare Commission exists to promote improvement in the quality of the NHS, private and voluntary healthcare across England and Wales. It is committed to sharing information with the public, patients, doctors, nurses and managers about how their local services are doing.

(Kennedy. www.healthcarecommission.org.uk/Homepage/fs/en)

2.2 The **NHS Information Authority** (NHSIA) is charged by the Healthcare Commission to work with professional groups, such as the Association of Coloproctology of Great Britain and Ireland, to develop national audit.

2.3 The **National Clinical Audit Support Programme** is the clinical audit and information resource, managed by the NHSIA, which supports the monitoring of clinical performance against standards identified within national service frameworks (NSFs) and other documents produced from time to time by the DoH, NICE, and other professional and governmental bodies. The Government is committed to introducing national comparative clinical audit for lung, breast bowel and head and neck cancers. NCASP has a central role in this objective, working in partnership with professional bodies.

2.4 The **Association of Coloproctology of Great Britain and Ireland** (ACPGBI) is the multidisciplinary, multi-professional body whose membership are the clinical specialists responsible for the treatment of patients with bowel cancer in the UK. It has experience of national audit in bowel cancer in three studies

1998-1999	A national audit of the emergency treatment of bowel cancer in more than 1,000 patients, using a small, purpose designed database
2000-2001	The first national audit of bowel cancer, which included over 8,000 patients.
2001-2002	The second national audit which accrued 10,500 patients

Data from these audits have been used to develop risk adjustment models for post-operative mortality, lymph node harvest, length of stay, and the effects of social deprivation. Lessons learned from these studies will be used to assist in the development of the National Bowel Cancer Audit.

2.5 The ACPGBI developed a bowel cancer data set to underpin the above studies. This is based on regional audits, which were held in Wales, Trent, Wessex and Lothian in the 1990s. The database program, was developed by the Centre for Clinical Oncology, Clatterbridge and is available, free, at: www.canceruk.net/products.htm?productindex=1.

2.6 The remit of the **National Cancer Dataset Project** is to develop a generic dataset to fulfil the needs of clinical audit, assist in the production of National Performance Indicators, allow outcome assessment and provide clinical information for Cancer Registries. Version 4 of the Generic dataset, with bowel specific fields is available at: <http://www.nhsia.nhs.uk/cancer/pages/dataset/datamanuals.asp>. The fields and supporting data dictionary are emulated by the ACPGBI database.

2.7 Primary responsibility for the organisation and conduct of the national bowel cancer audit will be through a multi-professional project group, with membership drawn from the ACPGBI, the public, The National Cancer Services Analysis Team, the United Kingdom Association of Cancer Registries, the NHSIA and the Healthcare Commission, as set out in Appendix II.

2.8 To ensure the national clinical audit is as relevant as possible to all interested parties, there will be a larger Reference Group, with multi-professional, multi-disciplinary membership, who will advise the Project Group on specific issues, the proposed membership of this group is given in Appendix III.

2.9 The Project Group has identified priority outputs for the initial phase of the audit, which address appropriate, timely referral, investigation, treatment and outcomes. (Appendix IV).

2.10 Items in the ACPGBI and NCDS required to derive the audit outputs are given in Appendix V.

3 Priority issues in bowel cancer addressed by NBOCAP.

3.1 Bowel cancer was the commonest cancer diagnosed in the European Union in 2000, with an estimated total of 258,000 cases (Ann Oncol **14**, 2003 p974). Survival rates for bowel cancer in the UK compare poorly with other European countries and the USA. One of the key commitments of the NHS Cancer Plan is to bring survival rates in the UK up to the best in Europe. NBOCAP will support this objective by measuring and comparing the quality of clinical care, providing feedback to providers to stimulate local change where necessary.

3.2 There are four main areas relating to bowel cancer, which, if properly addressed, would be likely to have a major impact on the incidence and outcomes of the disease. These can be summarised as follows:

- i. **Prevention**; i.e. “5 fruits & veg a day” high fibre diet and chemo- prophylaxis.
- ii. **Earlier diagnosis** by screening and by rapid access of symptomatic patients to specialist teams.
- iii. Emphasis on timely and appropriate **investigations** to provide efficient diagnosis and optimal pre-treatment staging.
- iv. **Treatment** according to national guidelines.

3.3 Prevention and screening are beyond the scope of this project. Attention to the remaining areas should ensure that patients receive the optimal treatment package for their cancer, delivered by an appropriate specialist team in a measured time.

3.4 A fundamental part of the national clinical audit of bowel cancer is to develop statistical models to calculate risk-adjusted outcomes. This will allow the results from different Units to be compared, suggest reasons for any differences and indicate appropriate change in practice. Observed differences may be due to:

- i. Differing standards of clinical practice.
- ii. Differing levels of patient co-morbidity.
- iii. Differences in stage of disease at presentation.
- iv. Variations in access to specialist treatment services.
- v. Artefacts of statistical analysis.

3.5 The role of statistical methods in monitoring clinical performance has been highlighted elsewhere (Commissioned analysis of surgical performance using routine data: lessons from the Bristol enquiry. Spiegelhalter et al J R Statist Soc (2002) **165** 191-231) and appropriate statistical analysis is a critical part of this project.

3.6 Data from previous ACPGBI audits have been used to develop a model for risk adjusting postoperative mortality rate. The model has been peer reviewed (Tekkis et al BMJ (2003), **327**; 1196-1201) and is available in an easy-to-use form at: www.riskprediction.org.uk.

3.7 Collection and analysis of clinical data is a major part of this project, but processing and disseminating the information is of equal importance. Kennedy highlights that:

“Bristol was awash with data..... Little, if any of this information was available to the parents or to the public”... (Report of the Public Inquiry into Children’s Cardiac Surgery at the Bristol Royal Infirmary)

It is important to ensure that the public have access to outcome information, specifically about their hospital, which will inform on the treatment risks they may face. It is also important that the public should be aware that their hospital takes part in National Audit and that the results are subject to external review. A detailed proposal for making outcomes available to the public has been produced by the public and patient subcommittee of NBOCAP and is set out in appendix I.

4. Development and implementation.

4.1 The most recent ACPGBI bowel cancer audit is based on data of patients diagnosed in the financial year 2001-2. A report will be available for the ACPGBI Annual Meeting June 28 – July 1 and posted on the NBOCAP website for wider dissemination. Audit for patients diagnosed between April 2004 and March 2005 will continue to be based on the ACPGBI database, with additional fields to take account of changes in imaging and laparoscopy. Units, details of the data fields and their appropriate format are available for Units that use commercial (eg Infoflex, Dendrite)

or local databases, so that relevant information can be extracted and sent to Clatterbridge (see Appendix VI).

4.2 Although participation in the National Bowel Cancer Audit will remain voluntary attention is drawn to two of the recommendations of the Bristol Inquiry:

Clinical Audit must be fully supported by Trusts. They should ensure that Healthcare Professionals have access to the necessary time, facilities, advice and expertise in order to conduct audit effectively.

Clinical Audit should be compulsory for all Healthcare Professionals providing clinical care and the requirement to participate in it should be included as part of the contract of employment.

Cancer network leads will also be contacted with details of the project and there is now a web site with detailed information. Communications and recruitment will also be supported through NCASP and the Healthcare Commission.

4.3 The audit web site, <http://www.nbocap.org.uk/>, has been developed by Jason Smith, a member of the project group and will have links to the ACPGBI, NCASP, Healthcare Commission, The Centre for Clinical Oncology at Clatterbridge and the United Kingdom Association of Cancer Registries.

4.4 All current NCASP audits have been granted support by the Patient Information Advisory Subgroup, under Section 60 of the Health & Social Care Act (2001), so that two patient identifiers, NHS number and postcode, may be included in the dataset in the immediate future.

4.5 This support is critical in allowing links with other organisations, specifically the Office for National Statistics. The major advantage of this will be the ability to determine whether or not individual patients have died, without which a National Bowel Cancer Audit cannot fulfil its potential of changing outcomes. Links to cancer registries will provide an additional source for their registration and clinical information, particularly stage of disease at diagnosis.

4.6 For the current audit, data cleaning and merging will be done, as in previous years, by Helen Forbes and her colleagues in The National Cancer Services Analysis Team at Clatterbridge (www.canceruk.net) and analysis will continue to be carried out by the ACPGBI.

4.7 The annual audit report in June 2004 will be published by the ACPGBI and include sections on the conduct of the audit, data quality, unit demographics and outcomes, and the effect of deprivation, based on postcode and 2001 census data. There will also be an update of the mortality risk model and a new model for lymph node harvest. The report will feedback information to all participating units and will also be available on the NBOCAP website. Future publications will be in association with NCASP and the Healthcare Commission.

4.8 Data from the National Audit Report will be of use in:

- i. Refining the statistical model for more accurately measuring risk adjusted outcomes.
- ii. Setting national standards and comparing performance against these.
- iii. Stimulating research on measuring clinical performance.
- iv. Identifying different local and regional characteristics of bowel cancer so that resources and efforts to improve outcomes can be targeted.

5 IT infrastructure

5.1 The ACPGBI bowel cancer database (www.canceruk.net) is currently being upgraded to include relevant fields in imaging and laparoscopy. This upgraded version will be available by the Annual Meeting in June 2004.

5.2 Technical infrastructure after 2004-05 will change. The current method of data collection is based on populating a local, unit based, Access database, which, when complete, is uploaded to Clatterbridge for cleaning and merging. Although this process has been adequate in past studies, it is not practical in the long-term due to the limitations inherent in Access and the long time interval required to merge data and produce reports.

5.3 NCASP currently provides the IT infrastructure for two national cancer audits (Lung and Head and Neck). These use secure audit systems, which are being developed to provide patient linkage between providers along the care pathway. They will accept either direct data entry or files from third party systems and have integral reporting and feedback mechanisms. Both are currently being reviewed by the National Bowel Cancer Audit Steering group with the intention of recommending that Data for the 2005 National Audit, cases diagnosed in the financial year 2005-06, will also use a web-based system.

5.4 The NHSIA have also commissioned an independent group to write a specification for the technical infrastructure to underpin a national bowel cancer audit. The specification will be reviewed by NBOCAP in May 2004. The broad outline of the specification and principals on which the conduct of the audit will be based includes:

- i. Web-based data collection, uploading and feedback.
- ii. The highest levels of security and a complete audit trail.
- iii. User-friendly interfaces and navigation, including the production of blank proformas and printed records.
- iv. A high level of internal data validation with regular data-quality reports to units.
- v. Linkage to the Office for National Statistics
- vi. The production of regular reports to individual Units, which will include standard queries and advanced statistical analysis (CUSUM chart and Mortality Control Chart). The latter are the means by which a unit might monitor its outcomes.

vii. Statistical analysis to be carried out by the ACPGBI

viii. An annual summary publication of reports jointly by the ACPGBI, the Healthcare Commission and the NHSIA.

ix. Mechanism for the Management of outlying units as proposed in the report of the Public and Patient's Subcommittee of NBOCAP (Appendix I).

6. Participation in the National Bowel Cancer Audit

6.1 The voluntary return of bowel cancer audit data from members of the ACPGBI has facilitated the development of risk-adjustment models, which can be used to estimate risks for an individual patient, and risk-adjusted comparison of hospital outcomes.

6.2 Previous audits have been multi-centre and in order to develop a true National Audit, wider participation by members of the Association will be a necessity. Benefits of contributing include the quality of feedback, which will have clear relevance to contemporary practice. Participation in designated national audit is also an issue of clinical governance and a public expectation.

6.3 In some Units there are resource or IT issues, which may make participation difficult. The NBOCAP project team wishes to be contacted by clinicians who experience such local problems.

6.4 There are a number of well-established regional, cancer centre and local audits of bowel cancer which currently support the ACPGBI studies. These centres can continue to use their established methods of audit, although the full benefit of NBOCAP, in particular all of the on-line reports, will not be available.

6.5 NBOCAP also has the option of using routinely collected NHS data (Hospital Episode Statistics, HES), which is available in the public domain, for those units, which do not participate in the national audit. This option is under consideration.

Appendix I

Making bowel cancer outcome data available to the general public: a report from the Patient and Public Subcommittee.

Due to the importance of this section of the document this has been removed and made available as a separate download from the NBOCAP website.

Appendix II

NBOCAP Group Membership

Association of Coloproctology of GB&I

Mr Jason Smith (webmaster@nbocap.org.uk)

Mr Jeff Stamatakis* (jeff@nbocap.org.uk)

Mr Paris Tekkis (ptekkis@nbocap.org.uk)

Mr Mike Thompson (mike@nbocap.org.uk)

Healthcare Commission

Ms Helen Laing

National Cancer Services Analysis Team

Ms Helen Forbes

NHSIA

Mr Steve Dean

Mr Steve Wise

Public representation

Ms Maria Shortis

Ms Lynn Faulds-Wood

Statistical Advisor

Dr Jan Poloniecki

United Kingdom Association of Cancer Registries

Mr Chris Carrigan

* current chair

Appendix III

NBOCAP Reference Group

It is proposed that invitations for Reference Group representation will be sent to:

- Association of Surgeons of Great Britain & Ireland
- British Association of Surgical Oncology
- Cancer Services Co-ordinating Group for Wales
- British Society of Gastroenterology
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Radiologists
- Royal College of Radiologists (Faculty of Clinical Oncology)
- Scottish Cancer Therapy Network

Appendix IV

Audit Outputs. The detail of these will be influenced by the NICE Guidance on Bowel Cancer, to be published imminently. The following outputs are supported by the current ACPGBI dataset.

PROCESS of CARE:

Waiting times:	to be seen by specialist to be diagnosed to first staging investigation to first treatment
Specialist care	Referred to MDT Seen by nurse specialist Operation by colorectal surgeon
Quality of investigations	accuracy of barium enema Quality of colonoscopy (CT and MRI data from 2004)

<u>CLINICAL OUTCOMES</u>	adjusted using the ACPGBI risk model for bowel cancer
early, postoperative:	anastomotic leak rate other major morbidity permanent stoma rate postoperative mortality* length of hospital stay*
late:	2, 3 & 5 year survival* local recurrence following curative surgery for rectal cancer*
Quality of histopathology	% cases where resection margin involvement is recorded nodal harvest* cases where Dukes' & TNM are recorded
Quality of surgery & Histopathology	positive resection margin after curative rectal resection* nodal harvest*

DEMOGRAPHICS

Regional and Unit variation plus effect of socio economic status on:

- Presentation
- Comorbidity
- Stage of disease
- Resection rates
- Presentation as emergency
- Operation as emergency
- Length of stay
- Postoperative mortality
- 5 year survival

Appendix V Data items for non-ACPGBI database centres.

List of the core database fields and format for the National Bowel Cancer Audit, for use by centres that do not use the ACPBGI database. The fields below should be copied from your database and sent by e-mail, as a password protected file, to the Centre for Clinical Oncology, Clatterbridge (karenjones27@btinternet.com). Karen will then contact your centre personally for password confirmation. Further details on the definitions of the data fields can be found either on the nbocap or canceruk web sites or by email to acpgbi@asgbi.org.uk

Users of the ACPGBI database should download the extraction file from the <http://www.cancernw.org.uk>. If help is required with transmission of data please contact Karen Jones.

DEMOGRAPHICS:

1. **Unit ID:** name main unit treating patient
2. **Region ID:** 1= Eastern, 2= Greater London, 3= N Ireland, 4=North West, 5= Northern, 6 =R Ireland, 7=Scotland, 8= South East, 9= South West, 10= Trent, 11= Wales, 12= West Midlands.
3. **Patient NHS number:** 10 digit new format NHS number
please note that audits in England & Wales, carried out under the auspices of NCASP, have PIAG approval for exemption from Section 60 of the Health & Social Care Act 2001, this means that patient identification by means of the NHS number& postcode is permitted.
4. **Patient ID:** please also include a locally generated number by which the referring institution can identify the patient if we have any data query. *This is essential for centres in Scotland, Northern Ireland and The Republic of Ireland from where we are unable to accept patient identifiable data.*
5. **Age at the time of diagnosis:** yrs
6. **Gender:** 1 = male, 2 = female.
7. **Full postcode:**

PRESENTATION DETAILS

8. **Referral type:** 1 GP: elective any route , 2 Emergency: any source, 3 Internal: elective from another consultant
9. **Urgent outpatient referral (2-week rule):** 1= YES 2 = NO
10. **Date of receipt of OP referral by unit:** dd/mm/yyyy
11. **date of first OP attendance** dd/mm/yyyy
12. **Was this the first appointment offered?** 1 = yes, 2 = no.
13. **Was referral to member of colorectal MDT?** 1 = YES 2 = NO
14. **Date of diagnosis:** date on which the cancer was first diagnosed at operation, histology, colonoscopy, Ba enema or any other means dd/mm/yyyy
15. **Was the patient seen by a nurse specialist?** 1 = YES 2 = NO

TUMOUR / OPERATION DETAILS:

15. **Date of first definitive treatment:** dd/mm/yyyy
16. **Tumour site:** as per ICD10 (caecum=18.0, appendix=18.1, ascending=18.2, hepatic flexure=18.3, transverse=18.4, Splenic=18.5, Descending=18.6,

Sigmoid=18.7, Rectosigmoid=19, Rectum=20, Anus=21.9) if synchronous tumour only register the main site.

17. **Operation done:** 1 = YES, 2 = NO

18. **Operation method:** 1 = open, 2 = laparoscopic converted to open, 3 = laparoscopic completed.

19. **Cancer resected** 1= YES 2= NO

20. **Date of surgery.** dd/mm/yyyy

21. **Time of surgery** 1= 08:00-17:00, 2= 1700:2400, 3= 2400-08:00.

22. **Mode of surgery** (as per NCEPOD 1=elective 2= scheduled, 3= urgent, 4= emergency).

23. **ASA grade** 1,2,3,4,5.

24. **Operation** 1. Right Hemicolectomy H07.9: 2. Extended right hemicolectomy H06:

3. Transverse colectomy H08.9: 4. Left Hemicolectomy H09.9 5. Sigmoid colectomy

H10.9: 6. Anterior Resection H33.4: 7. APER H33.1: 8. Hartmann's procedure H33.5:

9. Trans Anal Resection of Tumour H41.9: 10 Total excision of colon and rectum

H04.1 or H04.2: 11. TEMS H41.2: 12. Stent H24.3: 13. Polypectomy H20.1: or H23.9:

14. EUA H44.4: 15 laparotomy only T30.9. 16 laparoscopy only T43.9: 17. Stoma

only colostomy G74.9, ileostomy H15.9: 18. OTHER state OPCS4 Code(s).

25. **Preoperative radiotherapy for rectal cancer**, 1 = yes short course, 2 = yes long course (include neoadjuvant therapy), 3 = none.

PATHOLOGY:

27. **Dukes Stage** A,B,C1, C2, D (D = all non-curative cases due to either local or metastatic disease).

28. **T stage** 1 - 4

29. **N stage** 0 - 2

30. **M stage** 0 - 1

31. **number of nodes +ve.** N=

32. **total number of nodes examined.** N=

33. **lateral margin involvement (rectal cancer only).** 1 = YES, 2 = NO, 3 = N/A

34. **distance of tumour from radial margin (rectal cancer):** mm

ENDPOINTS:

35. **Stoma** 1 = YES temporary 2 = YES permanent 3 = NO

36. **Death in hospital** 1 = YES 2 = NO.

37. **Date of Death or discharge.** Day / month / year (dd/mm/yyyy)

38. **Complications:** record all complications that required re-operation, interventional radiology, ITU/HDU care or delayed discharge by more than