NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Appraisal Consultation Document

Laparoscopic surgery for colorectal cancer

The Department of Health and the Welsh Assembly Government have asked the National Institute for Health and Clinical Excellence (NICE or the Institute) to review and update as necessary guidance to the NHS in England and Wales on the clinical and cost effectiveness of laparoscopic surgery for the treatment of colorectal cancer. This review considers whether any new evidence that has become available justifies a change to the original guidance issued in December 2000. The Appraisal Committee has had its first meeting to consider both the evidence submitted and the views put forward by the representatives nominated for this appraisal by professional organisations and patient/carer and service user organisations. The Committee has developed preliminary recommendations on the use of laparoscopic surgery for colorectal cancer.

This document has been prepared for consultation with the formal consultees. It summarises the evidence and views that have been considered and sets out the preliminary recommendations developed by the Committee. The Institute is now inviting comments from the formal consultees in the appraisal process (the consultees for this appraisal are listed on the NICE website, www.nice.org.uk).

Note that this document does not constitute the Institute's formal guidance on this technology. The recommendations made in section 1 are preliminary and may change after consultation.

The process the Institute will follow after the consultation period is summarised below. For further details, see the *Guide to the technology appraisal process* (this document is available on the Institute's website, www.nice.org.uk).

- The Appraisal Committee will meet again to consider the original evidence and this Appraisal Consultation Document in the light of the views of the formal consultees.
- At that meeting, the Committee will also consider comments made on the document by people who are not formal consultees in the appraisal process.
- After considering feedback from the consultation process, the Committee will prepare the Final Appraisal Determination (FAD) and submit it to the Institute.
- Subject to any appeal by consultees, the FAD may be used as the basis for the Institute's guidance on the use of the appraised technology in the NHS in England and Wales.

The key dates for this appraisal are:
Closing date for comments: 13 April 2006
Second Appraisal Committee meeting: 27 April 2006

Details of membership of the Appraisal Committee are given in appendix A and a list of the sources of evidence used in the preparation of this document is given in appendix B.

Note that this document does not constitute the Institute's formal guidance on this technology. The recommendations made in section 1 are preliminary and may change after consultation.

1 Appraisal Committee's preliminary recommendations

1.1 Laparoscopic (including laparoscopically assisted) resection should be considered as an alternative to open resection in individuals with colorectal cancer who are suitable for surgery.

1.2 Laparoscopic colorectal surgery should be performed only by surgeons who have completed appropriate training in the technique and who perform this procedure with sufficient frequency to maintain competence. These criteria should be determined by local cancer networks and the relevant professional bodies.

1.3 The decision about which of the procedures (open or laparoscopic) is undertaken should be made after informed discussion between the patient, the surgeon and members of the MDT. In particular, the following issues should be considered:

- the suitability of the lesion for laparoscopic resection
- the risks and benefits of the two procedures
- the experience of the surgeon in both procedures.

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2 Clinical need and practice

2.1 Colon cancer is a malignant neoplasm arising from the lining (mucosa) of the large intestine (colon). Colorectal cancer (cancer arising in the mucosa of the colon or rectum) is the third most common cancer in the UK. Almost 30,000 new cases were registered in England and Wales in 2002, representing over 12% of all new cancer cases. The incidence of colorectal

cancer increases with age. In people between the ages of 45 and 49 years, the incidence is about 20 per 100,000. In those aged 75 and older, the annual incidence is over 300 cases per 100,000 men and over 200 cases per 100,000 women.

2.2 Complete surgical excision of the tumour is the only potential cure. It is indicated in 70–80% of diagnosed individuals. The remaining 20–30% usually have disease that has advanced to the extent that surgical resection with curative intent is unlikely to be successful. Among those who undergo surgery, the majority will have a good prognosis while about 30% will go on to develop advanced disease and metastases despite having apparently complete initial resection. For those with advanced disease, treatment is mainly palliative, aiming to increase the duration and quality of the person's life while controlling symptoms.

2.3 The current standard procedure for the surgical resection of primary colorectal tumours uses the open approach, which involves open laparotomy and removal of the tumour via the abdominal incision. Either a part or the whole of the large intestine is removed, depending on the site and extent of the tumour. This procedure is associated with significant postoperative pain and usually involves a long hospital stay. While techniques such as epidural analgesia can effectively control postoperative pain, associated complications may require high-dependency care.

2.4 The original NICE guidance states that open rather than laparoscopic resection should be the preferred surgical procedure for colorectal cancer, and that laparoscopic surgery should only be undertaken as part of a randomised controlled clinical trial.

3 The technology

3.1 Laparoscopic colorectal surgery involves inserting laparoscopic instruments through a number of ports in the abdominal wall to dissect tissues around the

tumour. The tumour is then removed through an abdominal incision, the length of which depends on the size of the tumour.

3.2 Laparoscopically assisted surgery refers to laparoscopic surgery in which the incision is enlarged to complete the dissection before the tumour is removed. The difference between laparoscopic and laparoscopically assisted surgery is subtle, and both approaches have the advantage of requiring an abdominal incision smaller than that used in open resection. Hand-port-assisted laparoscopic surgery involves the use of a hand-port through which a gloved hand is inserted intracorporeally.

4 Evidence and interpretation

The Appraisal Committee considered evidence from a number of sources (see appendix B).

4.1 Clinical effectiveness

4.1.1 The independent systematic review identified 19 randomised controlled trials (RCTs) that were relevant to the appraisal and the results from these were included in the reviewed data. An unpublished meta-analysis based on individual patient data (IPD) from a subset of patients from four RCTs was also considered. This meta-analysis was submitted on an academic-in-confidence basis and the results are not presented in this document. Neither the Assessment Report nor the consultee submissions made a distinction between laparoscopic and laparoscopically assisted surgery in the assessments of evidence. The data available to assess the relative merits of hand-port-assisted laparoscopic surgery were very limited.

4.1.2 When compared with open surgery, laparoscopic surgery was associated with a statistically significant longer operating time (weighted mean difference [WMD] 40 minutes, 95% confidence interval [CI] 32 to 48 minutes, based on three RCTs) and shorter hospital stay (WMD 2.6 days, 95% CI 2.0 to 3.1 days, based on four RCTs) than open resection. The results with

laparoscopic resection also suggested a trend towards a decreased number of lymph nodes retrieved (WMD −0.4, 95% CI −1.4 to 0.6 nodes, based on three RCTs), an increased risk of anastomotic leakage (pooled relative risk [RR] 1.13, 95% CI 0.74 to 1.73, based on eight RCTs), and a decreased risk of operative and 30-day mortality (based on three RCTs) compared with open resection, although these differences did not reach statistical significance.

4.1.3 Seven RCTs and the IPD meta-analysis reported overall survival. Raw data were available from six RCTs and contributed to a meta-analysis that did not show a statistically significant difference in overall survival between laparoscopic and open resection (pooled RR 1.03, 95% CI 0.98 to 1.09). However, these RCTs had widely differing follow-up periods that ranged from 1 to 108 months, and proportion of events rather than time-to-event data were analysed. Three-year survival outcomes from the seventh RCT (the CLASICC trial) have not been published and only very limited information about these results was available. The results of the IPD meta-analysis were supplied on an academic-in-confidence basis and are not reported here.

4.1.4 Five RCTs and the IPD meta-analysis reported disease-free survival. Raw data were available from four RCTs – meta-analysis of these data did not show a statistically significant difference between laparoscopic and open surgery (pooled RR 1.01, 95% CI 0.95 to 1.07). Long-term survival outcomes in the fifth RCT (the CLASICC trial) have not been published and only very limited information about these results was available. The results of the IPD meta-analysis were supplied on an academic-in-confidence basis and are not reported here.

4.1.5 Seven RCTs and the IPD meta-analysis contained relevant information on tumour recurrence. Two of the RCTs reported zero event rates in both surgery groups. In a meta-analysis of the remaining five studies, there was no statistically significant difference between the two types of surgery (pooled RR

0.92, 95% CI 0.74 to 1.14). Eight RCTs contained information on port-site recurrence. There were only three reported events.

4.1.6 Some patients who were originally randomised to undergo laparoscopic surgery were converted intra-operatively to open resection. Eleven RCTs reported conversion rates, the mean overall rate being 20%. Three RCTs recorded separate outcome data for converted patients: they appeared to have higher blood loss, require a longer hospital stay and have a greater risk of tumour recurrence than patients who underwent the laparoscopic or open procedure as planned.

4.1.7 Anastomotic leakage was the only outcome for which there were sufficient data to conduct a stratified meta-analysis by location of cancer (that is, to establish differences in clinical effectiveness for cancers of the colon and rectum). The increased risk of anastomotic leakage with laparoscopic resection compared with open resection was similar for colon and rectal cancers (pooled RR 1.27, 95% CI 0.70 to 2.31 for colon cancer; pooled RR 1.25, 95% CI 0.63 to 2.46 for rectal cancer).

4.1.8 Only two RCTs reported subgroup analyses by stage of cancer for overall survival. Both reported that there was no statistically significant difference between the overall survival of patients undergoing laparoscopic surgery and those undergoing open surgery for cancer stages I, II or III.

4.1.9 Submissions from manufacturer and professional consultees contended that long-term clinical outcomes between open and laparoscopic colorectal surgery are equivalent, while short-term clinical outcomes favour the laparoscopic approach. The Committee heard from the professional experts who provided evidence at the Appraisal Committee meeting that the consensus among clinicians is that there is no difference in long-term outcomes between laparoscopic and open colorectal surgery provided that the laparoscopic procedure is performed by adequately trained surgeons. The

professional experts also informed the Committee that for experienced surgeons, the mode of access can be the only difference between the two types of surgery and single figure conversion rates from laparoscopic to open resection can be achieved.

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4.2 *Cost effectiveness*

4.2.1 The Assessment Group conducted a systematic review of economic evaluations published from 2000 to 2005 and performed an independent economic evaluation. The consultees did not submit any formal economic evaluation of the technology. Instead, key issues were identified and highlighted in the submissions.

4.2.2 The Assessment Group identified five relevant primary studies. Two were UK studies: an unpublished draft paper on the short-term economic evaluation of a subset of patients in the CLASICC trial, and a small study in the context of an enhanced recovery programme. When compared with open surgery, the mean cost for laparoscopic surgery was higher in all of the studies except one. There was considerable variation in the reported differences in mean costs of laparoscopic and open surgery in the studies.

4.2.3 The principal issues raised in a submission by a manufacturer were: (a) the conversion rate of laparoscopic to open surgery and the length of hospital stay are the two key drivers of total cost; (b) laparoscopic surgery shortens hospital stay; (c) conversion rates could be lowered to a single-digit percentage through appropriate training, mentoring and case selection; and (d) with the control of conversion rates, the cost of laparoscopic surgery should be similar to or lower than that of open surgery. As there is no difference in long-term clinical outcomes between laparoscopic and open surgery, and short-term outcomes favour laparoscopic surgery, it was concluded that laparoscopic surgery should be a cost-effective alternative for patients within the NHS. The Assessment Group's report cautioned that while it is likely that the total cost of laparoscopic surgery decreases as conversion

rate is lowered, direct evidence is limited. In addition, it is not clear how a reduction in conversion rate would affect the cost difference between laparoscopic and open surgery.

4.2.4 The Assessment Group conducted its own economic evaluation using first a balance-sheet approach and then a modelling approach. Laparoscopic surgery was associated with a higher estimated cost than open surgery with an estimated cost difference of £265 (95% CI –£3829 to £4405). Assuming that the long-term outcomes are equivalent, a judgment is then required as to whether the short-term benefits associated with earlier recovery merit the extra cost of laparoscopic resection. Difference in length of hospital stay was identified as one of the key determinants of this cost difference. Threshold analysis suggested that the cost difference would decrease to zero if laparoscopic surgery decreased the average length of hospital stay by just over 4 days when compared with open surgery. However, this magnitude of difference was not observed in any of the studies included in the systematic review. In addition, if the difference in length of stay between the two types of surgery decreases to as little as 1 day (for example, in an enhanced recovery programme), the incremental cost of laparoscopic surgery compared to the open procedure would increase to over £500.

4.2.5 The Assessment Group used a Markov model to estimate the long-term costs and benefits in a hypothetical cohort of 65-year-old patients with colorectal cancer undergoing surgical resection of tumour. Laparoscopic surgery was dominated (that is, it was associated with higher costs but was no more effective) by open surgery in the base-case analysis and in almost all of the sensitivity analyses.

4.2.6 The Assessment Group acknowledged that these results did not capture the quality-of-life benefits that might be associated with an earlier recovery, for which little data were available. The Group concluded that, taking £30,000 as a theoretical value for the maximum acceptable cost of an additional quality-

adjusted life-year (QALY) and the mean incremental cost for laparoscopic surgery as estimated at £263 (base-case analysis) and £290 (equal mortality and disease-free survival), then in order for laparoscopic surgery to be considered cost effective, the QALY gain associated with laparoscopic surgery would have to be 0.009 in the base case and 0.010 in the case of equal overall and disease-free survival.

4.3 *Consideration of the evidence*

4.3.1 The Committee noted that more evidence has become available since the original guidance was issued by the Institute in 2000. The Committee reviewed the new data available on the clinical and cost effectiveness of laparoscopic surgery for the treatment of colorectal cancer, having considered evidence on the nature of the condition and the value placed on the benefits of laparoscopic surgery by people with surgically resectable colorectal cancer, those who represent them, and clinical experts. It was also mindful of the need to take account of the effective use of NHS resources.

4.3.2 The Committee considered that there is evidence that laparoscopic surgery is associated with a longer operating time and a shorter hospital stay. The evidence base, though limited, did not show a difference between laparoscopic and open surgery in terms of tumour recurrence, or in disease-free or overall survival at 3 years.

4.3.3 While the Committee recognised the uncertainties and limitations in the existing evidence base, the Committee was persuaded that laparoscopic colorectal surgery and open colorectal surgery are likely to have similar long-term outcomes with appropriate patient selection and when performed by surgeons with the appropriate experience and skills. ***[Recommendation 1.3, part]***

4.3.4 The Committee was also persuaded that there are important differences between the laparoscopic and open approaches regarding both the length of

hospital stay for patients and their ability to return to normal activities after the operation. The Committee considered that although there was little direct evidence of quality-of-life benefits associated with the laparoscopic procedure over the open procedure, it was likely that such benefits exist and are significant in the short term, at least for the first 6 weeks after the operation. On this basis, the Committee concluded that the quality-of-life benefits would make the laparoscopic procedure cost effective and an appropriate use of resources for the NHS providing it was undertaken by surgical teams fully trained and experienced in performing it. ***[Recommendation 1.1]***

4.3.5 The Committee was aware that, on average, 20% of individuals scheduled for laparoscopic surgery were converted to open surgery in clinical trials, and there was some evidence that these individuals had poorer outcomes than those who had laparoscopic or open surgery as planned. The Committee heard from the professional experts that poorer outcomes in converted patients tend to be a result of the individual's condition, which influences the decision to convert, rather than a direct result of the conversion itself. The Committee also heard that appropriate patient selection and development of surgical skills through experience would be expected to lower the conversion rate and that currently, for experienced surgeons, single figure conversion rates are achievable.

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4.3.6 The Committee recognised the importance of appropriate patient selection in determining the outcomes of laparoscopic surgery and considered the appropriate training of surgeons to be essential to ensure the clinical effectiveness and safety of the technique as an alternative for the resection of colorectal cancer. The Committee therefore concluded that laparoscopic colorectal surgery should be performed only by surgeons (a) who have completed appropriate training in the technique, and (b) who perform the procedure with sufficient frequency to maintain competence. The Committee considered that these criteria should be determined by local cancer networks and the relevant professional bodies. The professional experts informed the

Committee that there are many existing training courses in laparoscopic colorectal surgery in the UK, including the preceptorship programme set up by the Association of Laparoscopic Surgeons of Great Britain and Ireland and the Association of Coloproctology of Great Britain and Ireland in 2004. ***[Recommendation 1.2]***

5 Proposed recommendations for further research

5.1 The UK-based MRC-funded multi-centre CLASICC trial is now closed and is expected to publish results regarding long-term clinical outcomes and economic evaluation.

5.2 Further data on the long-term effectiveness and safety of these procedures in clinical practice should be collected. The Committee heard from the professional experts that there are ongoing clinical audit projects for bowel cancer. Collection of data specific to laparoscopic and open procedures that allow comparison of long-term efficacy and safety outcomes would be useful.

5.3 Further research may be required to assess any differences in clinical and cost effectiveness between different laparoscopic techniques, including hand-port-assisted laparoscopic surgery.

6 Preliminary views on the resource impact for the NHS

The NICE Costing Unit is currently developing this section. A costing template and report will be available at the time of publication of the final guidance.

7 Proposals for implementation and audit

This section presents proposals for implementation and audit based on the preliminary recommendations for guidance in section 1.

7.1 Surgeons who operate on people with colorectal cancer, and their NHS organisations, should review current practice and policies to take account of the guidance set out in section 1.

7.2 Local guidelines, protocols or care pathways that refer to the surgical treatment of people with colorectal cancer should incorporate the guidance.

7.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in appendix C.

7.3.1 The option of laparoscopic resection (including laparoscopically assisted resection), as an alternative to open resection, is discussed with a person with colorectal cancer considered to be suitable for surgery.

7.3.2 Laparoscopic colorectal surgery is performed only by a surgeon who has completed appropriate training in the technique and who performs this procedure with sufficient frequency to maintain competence.

7.3.3 In order to monitor results of laparoscopic colorectal resection and ensure that its introduction does not cause an increase in complications when compared to current outcomes following open surgery, all provider units should ensure that data is collected and submitted to The National Bowel Cancer Audit Project (nbocap). Postoperative anastomotic leakage, hospital stay and postoperative mortality, should be compared to accepted national benchmarks.

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7.3.4 The decision as to which of the procedures (open or laparoscopic) is undertaken is made after fully informed discussion between the patient and the surgeon.

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7.4 Local clinical audits on the management of colorectal cancer could also include measurement of compliance with accepted clinical guidelines or protocols or the NICE recommendations for services for people with colorectal cancer.

8 Related guidance

8.1 NICE has issued the following related technology appraisals:

The clinical effectiveness and cost effectiveness of capecitabine and tegafur uracil for colorectal cancer. *NICE technology appraisal* no. 61 (May 2003). Available from: www.nice.org.uk/TA061.

Irinotecan, oxaliplatin and raltitrexed for advanced colorectal cancer (review of no. 33). *NICE technology appraisal* no. 93 (August 2005). Available from: www.nice.org.uk/TA093.

8.2 NICE has issued guidance on services for people with colorectal cancer:

Improving outcomes in colorectal cancer. *NICE Cancer Service Guidance* (June 2004). Available from: www.nice.org.uk/csgcc.

8.3 NICE is in the process of producing the following technology appraisals:

Oxaliplatin and capecitabine for the adjuvant treatment of colorectal cancer. Expected date of issue: April 2006.

Bevacizumab and cetuximab for advanced colorectal cancer. Expected date of issue: November 2006.

9 Proposed date for review of guidance

9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider whether the technology should be reviewed. This decision will be taken in the light of information gathered by the Institute, and in consultation with consultees and commentators.

9.2 It is proposed that the guidance on this technology is considered for review in September 2009. This date has been set in view of the likely timing of publication of the long-term clinical outcomes and economic analysis of the

CLASICC trial as well as the anticipated availability of safety data from the national audit. The Institute particularly welcomes comment on this proposed date.

David Barnett
Chair, Appraisal Committee
March 2006

Appendix A. Appraisal Committee members and NICE project team.

A. Appraisal Committee members

The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month except in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Dr Jane Adam
Radiologist, St George's Hospital, London

Professor A E Ades
MRC Senior Scientist, MRC Health Services Research Collaboration, Department of Social Medicine, University of Bristol

Dr Tom Aslan
General Practitioner, Stockwell, London

Professor David Barnett (Chair)
Professor of Clinical Pharmacology, University of Leicester

Mrs Elizabeth Brain
Lay Representative

Dr Karl Claxton
Health Economist, University of York

Dr Richard Cookson
Senior Lecturer in Health Economics, School of Medicine Health Policy and Practice, University of East Anglia

Mrs Fiona Duncan
Clinical Nurse Specialist, Anaesthetic Department, Blackpool Victoria Hospital, Blackpool

Professor Christopher Eccleston
Director Pain Management Unit, University of Bath

Dr Paul Ewings
Statistician, Taunton & Somerset NHS Trust, Taunton

Professor John Geddes
Professor of Epidemiological Psychiatry, University of Oxford

Mr John Goulston
Director of Finance, Barts and the London NHS Trust

Ms Linda Hands

Consultant Surgeon, John Radcliffe Hospital

Dr Elizabeth Haxby
Lead Clinician in Clinical Risk Management, Royal Brompton Hospital

Dr Rowan Hillson

Consultant Physician, Diabeticare, The Hillingdon Hospital

Dr Catherine Jackson

Clinical Senior Lecturer in Primary Care Medicine, University of Dundee

Professor Richard Lilford

Professor of Clinical Epidemiology, Department of Public Health and Epidemiology, University of Birmingham

Dr Simon Mitchell

Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester

Ms Judith Paget

Chief Executive, Caerphilly Local Health Board, Wales

Dr Katherine Payne

Health Economist, The North West Genetics Knowledge Park, The University of Manchester

Dr Ann Richardson

Lay Representative

Dr Stephen Saltissi

Consultant Cardiologist, Royal Liverpool University Hospital

Mr Mike Spencer

General Manager, Clinical Support Services, Cardiff and Vale NHS Trust

Dr Debbie Stephenson

Head of HTA Strategy, Eli Lilly and Company

Professor Andrew Stevens (Vice Chair)

Professor of Public Health, University of Birmingham

Dr Cathryn Thomas

General Practitioner, & Associate Professor, Department of Primary Care & General Practice, University of Birmingham

Dr Norman Vetter

Reader, Department of Epidemiology, Statistics and Public Health, College of Medicine, University of Wales, Cardiff

Professor Mary Watkins

Professor of Nursing, University of Plymouth

Dr Paul Watson

Medical Director, Essex Strategic Health Authority

B. NICE Project Team

Each appraisal of a technology is assigned to a Health Technology Analyst and a Technology Appraisal Project Manager within the Institute.

Elizabeth Seil

Technical Lead, NICE project team

Janet Robertson

Technical Advisor, NICE project team

Alana Miller

Project Manager, NICE project team

Appendix B. Sources of evidence considered by the Committee

A The assessment report for this appraisal was prepared by Aberdeen Health Technology Assessment Group:

I Alison Murray, Aileen McKinley, Luke Vale et al, Systematic review of the clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer, November 2005.

B The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope and assessment report. They are also invited to comment on the ACD and consultee organisations are provided with the opportunity to appeal against the FAD:

I Manufacturer/sponsors:

- Ethicon Endo-Surgery
- Karl Storz Endoscopy (UK) Ltd
- KeyMed (Medical & Industrial Equipment) Limited
- Medical Innovations (Service Centre) Ltd

II Professional/specialist and patient/carer group:

- Association for Perioperative Practice (formerly national Association of Theatre Nurses)
- Association of Cancer Physicians
- Association of Coloproctology of Great Britain and Ireland
- Association of Laparoscopic Surgeons of Great Britain and Ireland

- Association of Operating Department Practitioners
- Association of Surgeons of great Britain and Ireland
- Beating Bowel Cancer
- British Association of Surgical Oncology
- Cancer Research UK
- CancerBACUP
- Department of Health
- Lynn's Bowel Cancer Campaign
- Royal College of Nursing
- Royal College of Physicians' Medical Oncology Joint Special Committee
- Royal College of Surgeons
- Teenage Cancer Trust
- Welsh Assembly Government
- Welsh Cancer Networks

III Commentator organisations (without the right of appeal):

- Aberdeen Health Technology Assessment Group
- EUCOMED
- MRC Clinical Trials Unit
- National Coordinating Centre for Health and technology Assessment
- NHS Purchasing and Supplies Agency
- NHS Quality Improvement Scotland

C The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and

provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on laparoscopic surgery for colorectal cancer by attending the initial Committee discussion and/or providing written evidence to the Committee. They are invited to comment on the ACD:

- Mr Mark Gudgeon, Consultant Surgeon, Frimley Park Hospital Foundation Trust – clinical expert nominated by Association of Coloproctology for Great Britain and Ireland
- Mr David Howe - patient expert nominated by Cancer Voices
- Professor Timothy Rockall, professor of Surgery, Royal Surrey County Hospital - clinical expert nominated by Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI)

Appendix C. Detail on criteria for audit of the use of laparoscopic surgery for colorectal cancer

Possible objectives for an audit

An audit on the surgical treatment of people with colorectal cancer could be carried out to ensure that laparoscopic and laparoscopically assisted resection is used appropriately.

Possible patients to be included in the audit

An audit could be carried out on people with colorectal cancer that is considered to be suitable for surgery who are seen over a suitable time period for audit, for example, 6 months.

Measures that could be used as a basis for an audit

The measures that could be used in an audit of laparoscopic surgery for colorectal cancer are as follows.

Criterion	Standard	Exception	Definition of terms
1. The option of laparoscopic resection, as an alternative to open resection, is discussed with a person with colorectal cancer that is considered to be suitable for surgery.	100% of people with colorectal cancer that are considered to be suitable for surgery	A. The service does not have a surgeon who has completed appropriate training in the technique (see criterion 2)	Laparoscopic resection includes laparoscopically assisted resection. Clinicians will need to agree locally on how the suitability of the lesion for surgery is documented, for audit purposes.
2. Laparoscopic colorectal surgery is performed by a surgeon who meets both of the following: a. has completed appropriate training in the technique **and** b. performs this procedure with sufficient frequency to maintain competence	100% of laparoscopic colorectal surgical procedures carried out for people with colorectal cancer	None	'Appropriate training' and 'sufficient frequency to maintain competence' are as determined by a local cancer network and the relevant professional bodies. Clinicians will need to agree locally on how training and sufficient frequency to maintain competence will be documented for audit purposes.
3. The decision as to which procedure is undertaken is made after fully informed discussion between the patient and the surgeon	100% of people with colorectal cancer that is considered to be suitable for surgery	None	The decision includes consideration of the following issues: the suitability of the lesion for laparoscopic resection, the risks and benefits of the two procedures and the experience of the surgeon in both procedures. Clinicians will need to agree locally on how the decision being made on an individual basis and the fully informed discussion with the patient are documented for audit purposes.

Calculation of compliance

Compliance (%) with each measure described in the table above is calculated as follows.

$$\frac{\text{Number of patients whose care is consistent with the } \textbf{criterion} \textit{ plus } \text{number of patients who meet any } \textbf{exception} \text{ listed}}{\text{Number of patients to whom the } \textbf{measure} \text{ applies}} \times 100$$

Clinicians should review the findings of measurement, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.