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## **Laparoscopic surgery for colorectal cancer**

**Review of NICE technology appraisal 17**

## **NICE technology appraisal guidance 105 Laparoscopic surgery for colorectal cancer (review)**

### **Ordering information**

You can download the following documents from [www.nice.org.uk/TA105](http://www.nice.org.uk/TA105)

- The full guidance (this document).
- A quick reference guide for healthcare professionals.
- Information for people with colorectal cancer and their carers ('Understanding NICE guidance').
- Details of all the evidence that was looked at and other background information.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone the NHS Response Line on 0870 1555 455 and quote:

- N1097 (quick reference guide)
- N1098 ('Understanding NICE guidance').

### **This guidance is written in the following context**

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

### **National Institute for Health and Clinical Excellence**

MidCity Place  
71 High Holborn  
London  
WC1V 6NA

[www.nice.org.uk](http://www.nice.org.uk)

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NOTE: This guidance replaces *NICE technology appraisal guidance* no. 17 issued in December 2000.

The Institute reviews each piece of guidance it issues.

The review and re-appraisal of the use of laparoscopic surgery for colorectal cancer has resulted in a change in the guidance. Specifically, laparoscopic (including laparoscopically assisted) resection is now recommended as an alternative to open surgery in people with colorectal cancer in whom both laparoscopic and open surgery are considered suitable and under the circumstances outlined in section 1.

## 1 Guidance

- 1.1 Laparoscopic (including laparoscopically assisted) resection is recommended as an alternative to open resection for individuals with colorectal cancer in whom both laparoscopic and open surgery are considered suitable.
- 1.2 Laparoscopic colorectal surgery should be performed only by surgeons who have completed appropriate training in the technique and who perform this procedure often enough to maintain competence. The exact criteria to be used should be determined by the relevant national professional bodies. Cancer networks and constituent Trusts should ensure that any local laparoscopic colorectal surgical practice meets these criteria as part of their clinical governance arrangements.
- 1.3 The decision about which of the procedures (open or laparoscopic) is undertaken should be made after informed discussion between the patient and the surgeon. In particular, they should consider:
  - the suitability of the lesion for laparoscopic resection
  - the risks and benefits of the two procedures
  - the experience of the surgeon in both procedures.

## **2 Clinical need and practice**

- 2.1 Colorectal cancer (cancer arising in the lining 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 and is indicated in 70% to 80% of diagnosed individuals. The remaining 20% to 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 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. Part or all 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.

## **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 usually 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 minor, 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 (appendix A) considered evidence from a number of sources (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 (n = 1536) from four RCTs was also considered. This independent meta-analysis was submitted by a manufacturer consultee before publication 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. No data were identified comparing hand-port-assisted laparoscopic surgery with open surgery.
- 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). 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.
- 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.
- 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 was 20%. Three RCTs

recorded separate outcome data for converted patients who 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 for colon cancer 1.27, 95% CI 0.70 to 2.31, four studies; pooled RR for rectal cancer 1.25, 95% CI 0.63 to 2.46, two studies).
- 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 in overall survival between 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.

## 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 arguments used by a manufacturer in its submission were as follows: (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 can be lowered to under 10% 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. On the basis of these arguments, the manufacturer concluded that as there is no difference in long-term clinical outcomes between laparoscopic and open surgery, and short-term outcomes favour laparoscopic surgery, laparoscopic surgery should therefore be a cost-effective alternative for patients within the NHS.
- 4.2.4 The assessment report cautioned that while it is likely that the total cost of laparoscopic surgery decreases as the 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.
- 4.2.5 The Assessment Group conducted its own economic evaluation using a balance-sheet approach in addition to a modelling approach. Laparoscopic surgery was associated with higher estimated cost than open surgery with an estimated 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 rarely 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 with the open procedure would increase to over £500.

4.2.6 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.

4.2.7 The Assessment Group acknowledged that these results did not capture the quality-of-life benefits that might be associated with 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 estimated mean incremental cost for laparoscopic surgery as £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 NICE issued the original guidance (NICE technology appraisal no. 17) 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 the evidence that laparoscopic surgery is associated with a longer operating time and a shorter hospital stay. The evidence from RCTs did not show a difference between laparoscopic and open surgery in terms of tumour recurrence, disease-free or overall survival at 3 years. Professional experts at the Appraisal Committee meeting reported 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 Committee was therefore 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.
- 4.3.3 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. These differences favoured laparoscopic procedures. 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 be sufficient to make the laparoscopic procedure cost effective and an appropriate use of resources for the NHS providing it was undertaken by surgical teams who are fully trained and experienced in performing the procedure.
- 4.3.4 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 result from the individual's condition, which influences the decision to convert, rather than as a direct result of the conversion itself. The

Committee also heard from the professional experts that appropriate patient selection and development of surgical skills through experience would be expected to lower the conversion rate and that for an experienced surgeon, a conversion rate of less than 10% is achievable.

4.3.5 The Committee considered the appropriate training of surgeons and surgical teams to be essential to ensure the clinical effectiveness and safety of the technique as an alternative to open surgery. The Committee therefore concluded that laparoscopic colorectal surgery should be performed only by surgeons who: (a) have completed appropriate training in the technique and; (b) perform the procedure often enough to maintain competence. The Committee considered that these criteria should be determined by the relevant national professional bodies. Cancer networks and constituent Trusts should ensure that any local laparoscopic colorectal surgical practice meets these criteria as part of their clinical governance arrangements. 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.

4.3.6 The Committee was aware of the existence of the National Bowel Cancer Audit Project commissioned by the Healthcare Commission and managed jointly by the National Clinical Audit Support Programme and the Association of Coloproctology of Great Britain and Ireland. The Committee understood that this audit has the potential to be developed to encompass the recommendations in this guidance. The Committee was also persuaded that relevant data collection on a national basis is of paramount importance in closely monitoring the introduction of the laparoscopic procedure.

## 5 Implementation

- 5.1 The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health', issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by NICE technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- 5.2 'Healthcare Standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- 5.3 NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website ([www.nice.org.uk/TA105](http://www.nice.org.uk/TA105)).
- Costing report and costing template to estimate the savings and costs associated with implementation.
  - Audit criteria (see appendix C).

## 6 Recommendations for further research

- 6.1 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.
- 6.2 Further data on the long-term effectiveness and safety of the laparoscopic procedure 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 was deemed to be essential. The Committee therefore strongly recommended collaboration of the relevant professional bodies and relevant local NHS bodies to facilitate collection of relevant data.
- 6.3 Further research may be required to assess any differences in clinical and cost effectiveness between different laparoscopic techniques, including hand-port-assisted laparoscopic surgery.

## 7 Related guidance

- 7.1 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 (2003).

Available from: [www.nice.org.uk/TA061](http://www.nice.org.uk/TA061).

Irinotecan, oxaliplatin and raltitrexed for advanced colorectal cancer (review of *NICE technology appraisal* no. 33). *NICE technology appraisal* no. 93 (2005).

Available from: [www.nice.org.uk/TA093](http://www.nice.org.uk/TA093).

Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. *NICE technology appraisal* no. 100 (2006). Available from:

[www.nice.org.uk/TA100](http://www.nice.org.uk/TA100).

7.2 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](http://www.nice.org.uk/csgcc).

7.3 NICE is in the process of producing the following technology appraisal:

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

## **8 Review of guidance**

8.1 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.

8.2 The guidance on this technology will be considered for review in September 2009.

Andrew Dillon  
Chief Executive  
August 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 Member

**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 and Somerset NHS Trust, Taunton

**Professor Terry Feest**

Professor of Clinical Nephrology, Southmead Hospital

**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, Oxford

**Dr Elizabeth Haxby**

Lead Clinician in Clinical Risk Management, Royal Brompton Hospital, London

**Dr Rowan Hillson**

Consultant Physician, Diabeticare, The Hillingdon Hospital, Middlesex

**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**

Independent Research Consultant

**Professor Philip Routledge**

Professor of Clinical Pharmacology, College of Medicine, University of Wales, Cardiff

**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, and Associate Professor, Department of Primary Care and 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(s) and a Technology Appraisal Project Manager within the Institute. The project team for this appraisal was:

**Elizabeth Seil**

Technical Lead, NICE project team

**Janet Robertson**

Technical Adviser, 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 (Health Services Research Unit, and Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen).

I Murray A, Lourenco T, de Verteuil R 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, assessment report and the Appraisal Consultation Document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination.

I Manufacturer/sponsors:

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

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 were also invited to comment on the ACD.

- Mr Mark Gudgeon, Consultant Surgeon, Frimley Park Hospital Foundation Trust – clinical expert nominated by the 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 the 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**

The National Bowel Cancer Audit Project collects data that enable clinicians to examine the management of patients with colorectal cancer in their hospitals in comparison with others. This national audit includes collection of data on both laparoscopic and non-laparoscopic surgery for colorectal cancer. The audit is commissioned by the Healthcare Commission and run jointly by the Association of Coloproctology of Great Britain and Ireland and the National Clinical Audit Support Programme. For more information on the audit, see [www.icservices.nhs.uk/ncasp/bowelcancer](http://www.icservices.nhs.uk/ncasp/bowelcancer) and [www.nbocap.org.uk](http://www.nbocap.org.uk).

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.

### ***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 of people with colorectal cancer who undergo laparoscopic and laparoscopically assisted resection or people with colorectal cancer that is considered to be suitable for both laparoscopic and open surgery, who are seen over a suitable time period for audit, for example, 6 months. Both measures that follow could be applied to the first group, and only measure 2 could be applied to the second group.

### ***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.

<b>Criterion</b>	<b>Standard</b>	<b>Exception</b>	<b>Definition of terms</b>
<p>1. Laparoscopic colorectal surgery is performed by a surgeon who:</p> <p>a. has completed appropriate training in the technique <b>and</b></p> <p>b. performs this procedure often enough to maintain competence</p>	<p>100% of laparoscopic colorectal surgical procedures carried out for people with colorectal cancer</p>	<p>None</p>	<p>‘Appropriate training’ and ‘often enough to maintain competence’ are as determined by the relevant national professional bodies. Cancer networks and constituent Trusts should ensure that any local laparoscopic colorectal surgical practice meets these criteria as part of their clinical governance arrangements. Clinicians will need to agree locally on how training and frequency of performance of the technique will be documented for audit purposes.</p>
<p>2. The decision as to which procedure is undertaken is made after fully informed discussion between the patient and the surgeon</p>	<p>100% of people with colorectal cancer that is considered to be suitable for surgery</p>	<p>None</p>	<p>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 fully informed discussion with the patient is documented for audit purposes.</p>

### ***Calculation of compliance***

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

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

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.