NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA105: Laparoscopic surgery for the treatment of colorectal cancer

This guidance was issued in August 2006 with a review date of September 2009.

Recommendation

- The guidance should be transferred to the 'static guidance list' and incorporated into the Colorectal Cancer Guideline, due to publish in 2011. That we consult on this proposal.

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	Longer term RCT data on the efficacy and safety of this procedure are now available. This data was deemed to be 'essential' in TA 105, and could help in producing a more accurate assessment of the cost per QALY gained associated with laparoscopic surgery. The Colorectal Cancer Guideline could incorporate TA105.
The decision to review the guidance should be deferred.	Following the publication of a significant amount of new evidence, we believe that a review at present would be more appropriate.
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	No appropriate technology review has been found.
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	No appropriate referred appraisals have been found.
A review of the guidance should be incorporated into an on-going clinical guideline.	A clinical guideline on the diagnosis and management of colorectal cancer is due for publication in 2011.
A review of the guidance should be updated into an on-going clinical guideline.	Given the above, we would expect the upcoming clinical guideline on colorectal cancer to signpost any review of TA105. The Colorectal Cancer Guideline could incorporate TA105.
A review of the guidance should be transferred to the 'static guidance list'.	**The Colorectal Cancer Guideline could incorporate TA105, it should move to the static list until the guideline publishes (expected 2011).**

Original remit(s)

"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 which was issued in December 2000 [TA17]".

Current 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.

Relevant Institute work

Published:

Improving outcomes in colorectal cancer. Cancer services guideline (2004)

Preoperative high dose rate brachytherapy for rectal cancer. Interventional procedure guideline. IPG 201 (2006)

Computed tomographic colonography (virtual colonoscopy) Interventional procedure guideline. IPG 129 (2003)

Radiofrequency ablation for the treatment of colorectal liver metastases. Interventional procedure guideline IPG 92 (2004)

Irinotecan, oxaliplatin and raltitrexed for advanced colorectal cancer. Technology Appraisal TA93. (2005)

Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer. Technology appraisal TA118 (2007)

Capecitabine and tegafur uracil for metastatic colorectal cancer. Technology appraisal TA 61 (2003)

Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer. Technology appraisal TA100 (2006)

In progress:

Diagnosis and management of colorectal cancer. Clinical guideline (publication expected July 2011).

Cetuximab for the first line treatment of metastatic colorectal cancer. Technology appraisal (publication expected August 2009).

Bevacizumab in combination with oxaliplatin and either 5FU or capecitabine for the treatment of metastatic colorectal cancer. Technology appraisal (publication expected May 2010).

Irinotecan for the adjuvant treatment of colon cancer. Technology appraisal (publication date TBC)

Terminated:

Cetuximab for the treatment of metastatic colorectal cancer following failure of oxaliplatin-containing chemotherapy. Technology appraisal TA150 (June 2008)

In topic selection:

On-going trials

Trial name and contact	Details
Laparoscopic-Assisted Resection or Open Resection in Treating Patients With Stage IIA, Stage IIIA, or Stage IIIB Rectal Cancer	Phase III Currently recruiting Estimated completion date: August

	2010
A Randomized Controlled Clinical Trial Comparing Oncological Results and Functional Recovery Between Laparoscopic and Open Method for the Treatment of Advanced Rectal Cancer After Concurrent Chemoradiation Therapy (CCRT)	Phase III Currently recruiting Estimated completion date: December 2007
Laparoscopic-Assisted Surgery Compared With Open Surgery in Treating Patients With Colon Cancer	Phase III Ongoing Estimated completion date: none stated
A Trial to Evaluate Laparoscopic Versus Open Surgery for Colorectal Cancer	Phase III Ongoing Estimated completion date: April 2014
Comparison of Laparoscopic Colectomy Versus Open Colectomy for Colorectal Cancer: … A Prospective Randomized Trial	Phase III Currently recruiting Estimated completion date: July 2005
Randomized Prospective Trial for Laparoscopic vs Open Resection for Rectal Cancer (CTS-179)	Phase III Currently recruiting Estimated completion date: December 2011
COLOR II: Laparoscopic Versus Open Rectal Cancer Removal	Phase III Currently recruiting Estimated primary completion date: December 2011
COlon Cancer Laparoscopic or Open Resection	Phase III Ongoing Estimated primary completion date: March 2008
Prospective Randomised Study Comparing Laparoscopic Versus Open Surgery in Patients With Rectal Cancer	Phase III Ongoing Estimated completion date: December 2010
Endolaparoscopic Versus Immediate Surgery for Obstructing Colorectal Cancers	Phase III Currently recruiting Estimated completion date: not given
Rectal Reconstruction in Treating Patients Who Are Undergoing Surgery for Rectal Cancer	Phase III Currently recruiting Estimated primary completion date: December 2012
Comparison of Two Types of Surgery in Treating Patients With Rectal Cancer	Phase III Currently recruiting Estimated primary completion date: not given.
Conventional versus laparoscopic surgery for colorectal cancer within an Enhanced Recovery program	Phase III Currently recruiting Anticipated end date: October 2009

New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline(R) In-Process and Embase. References from 2005 onwards were reviewed.

Implementation

A submission from Implementation is attached at the end of this paper.

Appraisals comment:

The current guidance recommends laparoscopic (including laparoscopically assisted) resection as an alternative to open resection for individuals with colorectal cancer in whom both laparoscopic and open surgery are considered suitable. Surgery should also be performed only by surgeons who have completed appropriate training in the technique and who perform this procedure with sufficient frequency to maintain competence.

This topic appears on the Technology Appraisals work programme as a legacy of NICE's pre-IP era. If new comparator procedures emerge they are likely to be dealt with as IPs. GE may wish to consider whether, for consistency's sake, responsibility for this topic should be transferred to the IP team at some point in the future, with the decision whether or not to review to be determined by the IP criteria

There were three recommendations for further research noted in the current guidance. The Committee recommended that data on the long-term effectiveness of the use of laparoscopic surgery in clinical practice be collected. The Committee were also aware that data on the long-term clinical outcomes of laparoscopic surgery would be reported when the results of the CLASICC trial were published. The Committee also requested that further research be conducted on any differences in clinical and cost effectiveness between different laparoscopic techniques, including hand-port-assisted laparoscopic surgery.

Literature searches identified 21 new, published clinical trials since the publication of the original guidance. 7 ongoing trials on the effectiveness of the laparoscopic surgery are due to complete between 2009 and April 2014, with a further 3 trials recorded in the clinical trials registeries that are currently recruiting or ongoing but have no stated completion date. The literature search also found 8 (post 2005) randomised control trials that collected long-term effectiveness and safety data specific to laparoscopic and open procedures that allow comparison of efficacy and safety outcomes, and 9 recent trials that have reported on differences in effectiveness of different laparoscopic techniques.

At the time of the current guidance, the results of the UK-based MRC funded multi-centre CLASICC trial on long-term clinical outcomes and economic evaluation were yet to be published. Long-term outcomes (3-year overall survival [OS], disease-free survival [DFS], local recurrence, and quality of life [QoL]) have now been determined on an intention-to-treat basis. The recent publication of these results may provide a more accurate estimate of QALYs for laparoscopic surgery. One Multicenter, prospective, randomized trial (Marcello et al 2008), reported a significantly shorter operative time while maintaining similar clinical outcomes for hand-assisted laparoscopic colorectal surgery compared to straight laparoscopic techniques. Such sub group analysis of different techniques may provide greater insight into the differences between different laparoscopic techniques.

Summary

In TA105 the Committee recognised the uncertainties and limitations in the existing evidence base. The original proposal, which was considered by GE on 25 August 2009, was that a review of the guidance should be planned into the appraisal work programme. This proposal was suggested as the publication of new evidence may help to reduce the uncertainties that were raised in the current guidance.

Following discussions at GE involving the team developing the Colorectal Cancer Guideline it has been agreed that this guideline will incorporate TA105. The proposal has consequently been amended.

GE paper sign off:

Nina Pinwill, Associate Director, CHTE
9 October 2009

Contributors to this paper:

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NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

IMPLEMENTATION DIRECTORATE

Guidance Executive Review

Technology appraisal 105: Guidance on colorectal cancer – laparoscopic surgery.

1. NICE Implementation uptake report

NICE implementation uptake reports provide information on national trends and activity associated with technologies recommended in NICE guidance.

Overview

The number and percentage of colorectal resections performed using laparoscopic surgery is increasing in NHS hospitals in England (figure 1). In the 12 months to March 2007, the percentage of colorectal resections recorded as performed using the laparoscopic approach was 8.82% (table 1). The level of uptake at March 2007 is consistent with future forecasts made in the NICE cost impact analysis produced for this guidance (figure 2). Local organisations should consider referring to the NICE audit criteria to assess their performance in this area.

Laparoscopic surgery for colorectal cancer (surgical procedures)

'Laparoscopic surgery for colorectal cancer' NICE technology appraisal 105 (August 2006). The current NICE guidance recommends laparoscopic surgery (including laparoscopically assisted surgery) as an alternative to open surgery for people with colorectal cancer.

This guidance replaces NICE technology appraisal 17 (December 2000). The previous guidance recommended that for colorectal cancer, open rather than laparoscopic resection should be the preferred surgical procedure.

Surgical procedures: England

This report provides information on surgical procedures for colorectal resections carried out in hospitals in England. The figures are obtained from the Hospital Episode Statistics (HES) national data warehouse which is maintained by the NHS Information Centre. Table 1

shows the number of Finished Consultant Episodes (FCEs) for colorectal resections in England in 2006/2007.

Table 1 Finished Consultant Episodes for colorectal resections and % with laparoscopic surgery in 2006/2007

OPCS-4 Classification		Number of procedures	Number of procedures with laparoscopic surgery	% with laparoscopic surgery
H04	Total excision of colon and rectum	167	6	3.59%
H05	Total excision of colon	196	6	3.06%
H06	Extended excision of right hemicolon	1,372	58	4.23%
H07	Other excision of right hemicolon	5,411	562	10.39%
H08	Excision of transverse colon	164	10	6.10%
H09	Excision of left hemicolon	1,210	91	7.52%
H10	Excision of sigmoid colon	1,545	186	12.04%
H11	Other excision of colon	359	15	4.18%
H33	Excision of rectum	8,625	746	8.65%
		19,059	**1,680**	**8.82%**

Source: Hospital Episode Statistics (HES), The Information Centre for Health & Social Care

1. Colorectal resections are defined where ICD-10 diagnosis codes C18, C19, and C20 appeared as the primary diagnosis and OPCS procedure codes H04-H11, H33 appeared as the main operation.

   C18 is malignant neoplasm of colon, C19 is malignant neoplasm of rectosigmoid junction and C20 is malignant neoplasm of rectum.
2. Laparoscopic surgery is identified where OPCS subsidiary classification code Y508, Y751, Y752, Y753, Y754, Y755, Y758 and Y759 appeared in any of the secondary procedure codes (see appendix 1 for further information).

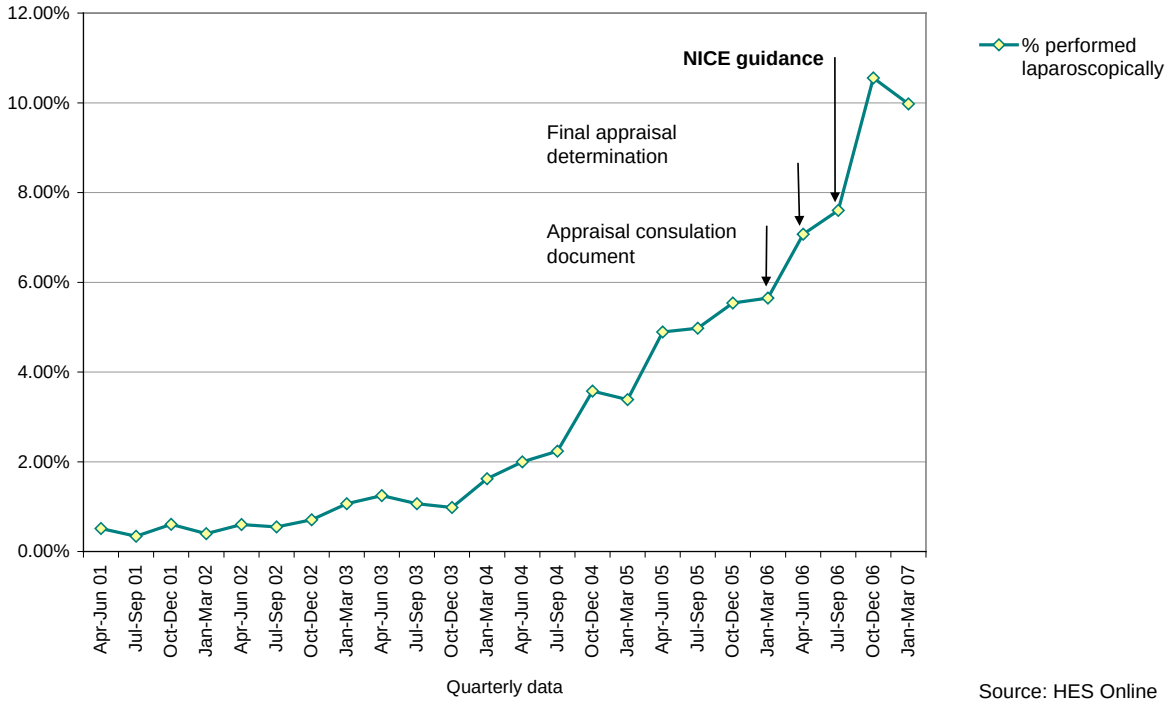
ICD-10 (International Statistical Classification of Diseases and Related Health Problems, 10th Revision) – is used to classify diseases and other health problems recorded on many types of health records including hospital records.

OPCS-4 (Office of Population, Censuses and Surveys: Classification of Surgical Operations and Procedures, 4th Revision) - records details of any operations performed, e.g. hip replacement, inguinal hernia repair, colorectal resection.

A total of 19,049 FCEs were recorded where the main operation was a colorectal resection. Of these, 8.82% were identified as being performed using the laparoscopic approach. The number and percentage of repairs recorded as being done laparoscopically is increasing, as shown from the quarterly trend in figure 1. The publication of the NICE guidance appears

to correspond with a further increase in the rate of uptake. It is too early to confirm a statistical link between guidance publication and change in uptake.

Figure 1 percentage (%) of colorectal resections performed laparoscopically



Source: HES Online

Uptake trajectory

The NICE guidance recommends that laparoscopic surgery for colorectal cancer should only be performed by surgeons who have completed appropriate training in the technique, and who perform this procedure often enough to maintain competence.

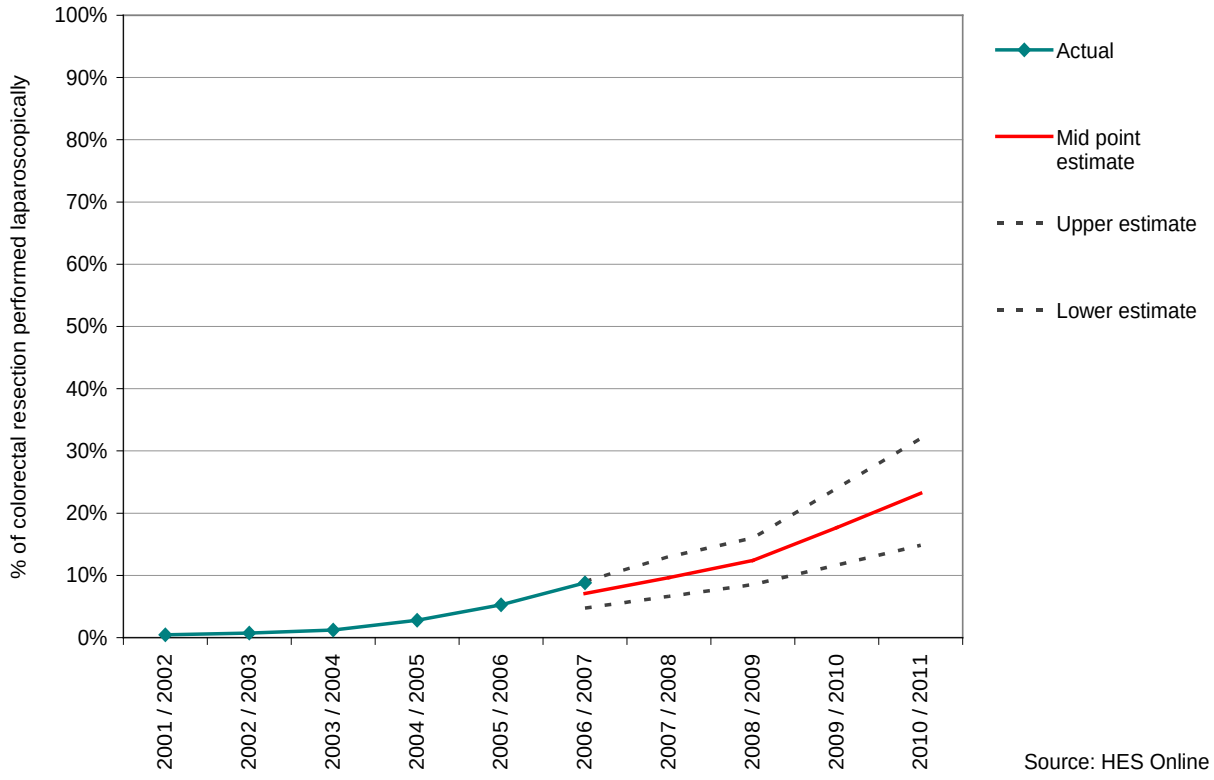
The main rate limiting factor in uptake is a recognised shortage of surgeons skilled in this technique. Another factor to take into account is patient choice; the NICE guidance recommends that patients should be fully informed about the risks of each of the types of surgery.

The NICE costing template, produced to support implementation of this guidance, provides possible scenarios for future uptake depending on the number of trained surgeons.[1] The future forecasts are shown in figure 2 alongside the actual uptake based on HES data from

[1] The costing template is available from: http://www.nice.org.uk/guidance/index.jsp?action=download&o=33501.

2001/02 to 2006/07. The rate of uptake, based on HES data, is already at the higher end of the trajectory produced by NICE in August 2006.

Figure 2 NICE trajectory for % of colorectal resections performed laparoscopically



Source: HES Online

Analysis by NICE Implementation Team

Appendix 1: change to OPCS4 coding for laparoscopic surgery via abdominal cavity

A new version of OPCS codes was developed by NHS Connecting for Health to reflect changing clinical practice and this was implemented in April 2006 - this new version is called OPCS4.3. All existing codes will remain. When using HES, care should therefore be taken when looking at procedures and interventions, in particular when using groups of codes as new codes and interventions have been introduced. More information on the change in classification of operations is available from: www.connectingforhealth.nhs.uk. Note that further developments have been made to the OPCS codes used in 2007-08 and quarterly 2007-08 data uses OPCS4.4.

List of OPCS4 codes for laparoscopic surgery relating to colorectal resections

OPCS 4.2	OPCS 4.3	OPCS 4.4	Description
Y50.8	Y50.8	Y50.8	Other specified approach through abdominal cavity
Y50.8	Y75.1	Y75.1	Laparoscopically assisted approach to abdominal cavity
Y50.8	Y75.2	Y75.2	Laparoscopic approach to abdominal cavity NEC
Y50.8	Y75.3	Y75.3	Robotic minimal access approach to abdominal cavity
Y50.8	Y75.4	Y75.4	Hand assisted minimal access approach to abdominal cavity
Y50.8	Y75.5	Y75.5	Laparoscopic ultrasonic approach to abdominal cavity
Y50.8	Y75.8	Y75.8	Other specified minimal access to abdominal cavity
Y50.8	Y75.9	Y75.9	Unspecified minimal access to abdominal cavity

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Appendix 2: uptake trajectory (upper and lower estimate)

This trajectory is adapted from a model provided in the NICE costing impact analysis produced to support implementation of this guidance. The model is based on 19,000 annual finished consultant episodes in England where the main operation was a colorectal resection.

Additional note: It is suggested that between 10 and 20 per cent of operations for colorectal resection started using the laparoscopic technique are converted to open surgery, depending on the experience of the surgeon. This conversion rate is not reflected these scenarios.

Upper estimate

Surgeons trained each year	30
Increase in training capacity per year	5
Lap resections per experienced surgeon per year	40
Lap resections per inexperienced surgeon per year	20
Years before trained surgeons become experienced	2

	2006/07	2007/08	2008/09	2009/10	2010/11
Finished consultant episodes where the main operation was a colorectal resection Source: based on HES data for 2006/2007	19,000	19,000	19,000	19,000	19,000
Experienced surgeons performing laps	45	45	45	75	105
Recently trained surgeons performing laps	-	30	65	75	90
Total laps by experienced surgeons	1,800	1,800	1,800	3,000	4,200
Total laps by inexperienced surgeons	-	600	1,300	1,500	1,800
Total resections performed laparoscopically	1,620	2,100	2,660	3,900	5,220
TRAJECTORY (proportion of all resections performed laparoscopically)	9.00%	13.00%	16.00%	24.00%	32.00%
ACTUAL	**8.82%**	**-**	**-**	**-**	**-**

Lower estimate

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Surgeons trained each year	30
Increase in training capacity per year	0
Lap resections per experienced surgeon per year	20
Lap resections per inexperienced surgeon per year	12
Years before trained surgeons become experienced	2

	2006/07	2007/08	2008/09	2009/10	2010/11
Finished consultant episodes where the main operation was a colorectal resection Source: based on HES data for 2006/2007	19,000	19,000	19,000	19,000	19,000
Experienced surgeons performing laps	45	45	45	75	105
Recently trained surgeons performing laps	-	30	60	60	60
Total laps by experienced surgeons	900	900	900	1,500	2,100
Total laps by inexperienced surgeons	-	360	720	720	720
Total resections performed laparoscopically	810	1,098	1,386	1,926	2,466
TRAJECTORY (proportion of all resections performed laparoscopically)	5.00%	7.00%	9.00%	12.00%	15.00%
ACTUAL	**8.82%**	-	-	-	-

Definitions of data used in this report

Hospital episode statistics

Hospital Episode Statistics (HES) is the national statistical data warehouse for England of the care provided by NHS hospitals and for NHS hospital patients treated elsewhere. HES is the data source for a wide range of healthcare analysis. It contains admitted patient care data from 1989 onwards.

The information in this uptake report comes from the HES Interrogation System which is an online version of the data. The NHS Information Centre maintains the system.

Finished Consultant Episode (FCE): The FCE is a period of admitted patient care under one consultant within one healthcare provider. The figures do not represent the number of patients, as a person may have more than one episode of care within the year.

Primary Diagnosis: The Primary Diagnosis is the first of up to 14 diagnosis fields in the Hospital Episode Statistics (HES) data set and provides the main reason why the patient was in hospital.

Main operation: The main operation is the first recorded operation in the HES data set and is usually the most resource intensive procedure performed during the episode.

Secondary operation: As well as the main operative procedure, there are up to 11 secondary operation fields in Hospital Episode Statistics (HES) that show secondary or additional procedures performed on the patient during the episode of care.

2. External literature

2.1 Cullum N, Dawson D, Lankshear A et al. (2004) The Evaluation of the Dissemination, Implementation and Impact of NICE Guidance.

HES data were used to identify patients diagnosed with cancer and were analysed for the years January 1992 to December 2001, for finished consultant episodes with ICD codes of:

- C18 Malignant neoplasm of colon
- C19 Malignant neoplasm of rectosigmoid junction
- C20 Malignant neoplasm of rectum
- C21 Malignant neoplasm of anus and anal canal

With OPCS code which identified the laparoscopic approach of

- Y508 Approach through abdominal cavity – other specified

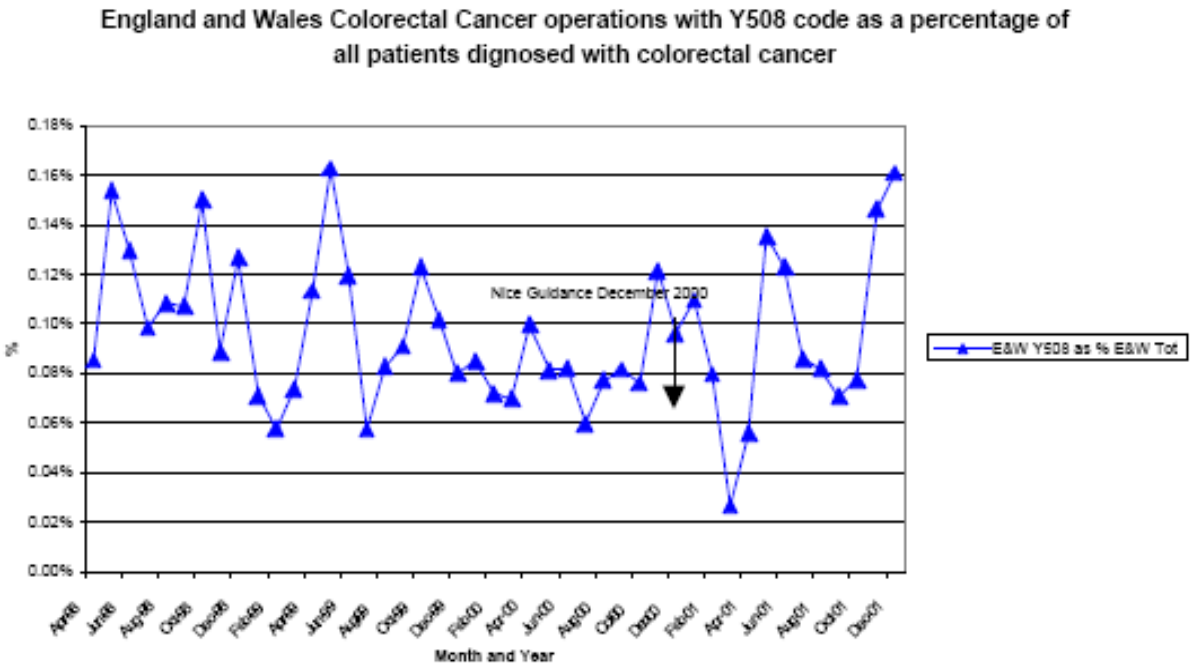
Table one show's that the total number of cases treated with laparoscopic surgery rose slightly from a total of 163 in 1998 to 189 in 2001, and that the percentage of cases of colorectal cancer having laparoscopic surgery remained stable at around 0.10%.

Table 1. Cases of colorectal cancer treated with laparoscopic surgery

		1998	1999	2000	2001	Total
England	No of cases	121,159	171,355	183,500	181,149	657,163
	No with Lap surgery	137	155	149	165	606
	% with lap surgery	0.11%	0.09%	0.08%	0.09%	0.09%
Wales	No of cases	12,066	14,300	15,751	14,954	57,071
	No with Lap surgery	26	21	17	24	88
	% with lap surgery	0.2%	0.1%	0.1%	0.2%	0.2%
Total	% with lap surgery	0.12%	0.09%	0.08%	0.10%	0.10%

Figure one shows the number of laparoscopic operations as a percentage of all patients diagnosed with colorectal cancer, on a monthly basis.

Figure 1. Percentage of colorectal cancer patients having laparoscopic surgery.



No evidence was found of changes in the numbers of laparoscopic colorectal cancer operations, which continued to be low.

Caveats on the data analysis

It is unclear whether coding of the laparoscopic approach is accurate in HES data. This suspicion is compounded by the apparent lack of patients coded in HES who are understood to have been treated at centres participating in the MRC funded CLASICC trial. However, the total number of patients over 2000-2002, with coding for laparoscopic surgery is in line with the total number of patients recruited into experimental arm of the trial.

Evidence from the audit

The guidance was unequivocal in its recommendations with no indications for appropriate use; therefore, an audit of patient notes was not undertaken. Also the use of the technology is rare and would have required a much larger sample of notes to estimate compliance rates. Although clinicians were not interviewed on this topic (because it was not included in our audit schedule), one respondent volunteered the view that the advice on colorectal cancer was contrary to common surgical opinion and also that it had very significant implications for training. This respondent claimed that trust figures demonstrated superior

results for a right hemi-colectomy conducted laparoscopically in respect of both the length of stay and complication rates.