National Institute for Clinical Excellence

Consultee comments on the draft scope for review of laparoscopic surgery for colorectal cancer (TA No 17)

Section	Consultees	Comments	Action
Background information	Association of Laparoscopic Surgeons of Great Britain and Ireland	Your comments upon the background are not entirely accurate and in your fourth paragraph concerning surgical resection of colon cancer you are right in saying that it may involve removal of the entire colon: this should be called total colectomy, Your comments about transverse resection of the colon (transverse colectomy) is an operation which is hardly ever performed now and any tumours of the transverse colon are usually rectified by what is called an extended right hemicolectomy. Your other definition as 'part of the colon' would be better described as right hemicolectomy, left hemicolectomy and sigmoid colectomy. This is much more accurate and accords with the common usage of the terms	Amended
		Your next paragraph which commences 'Tumours of the upper rectum' is again not fully accurate. For example, tumours of the lower rectum are not necessarily removed by abdomino-perineal resections. The only indication for abdomino-perineal resection is when the tumour is so low that it is near to the sphincters. You are correct in saying that after an abdomino-perineal resection a permanent colostomy is essential. A total mesorectal excision (TME) does not necessarily involve the removal of the whole rectum but does involve the removal of the so called mesorectum which is the surrounding fatty tissue. All operations involve removal of all the regional lymph nodes up to the origin of the inferior mesenteric artery from the aorta. After low TME it is common to perform a temporary ileostomy which is then closed several weeks later.	Amended – reworded in a similar way to the recommendation of the Association of Coloproctology of Great Britain and Ireland.

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	Association of Coloproctology of Great Britain and Ireland	Paragraphs 4 and 5 are not entirely accurate. Surgical resection of colon cancer rarely involves the removal of the entire colon and this should be referred to as a total colectomy rather than just colectomy. Tumours of the transverse colon are uncommon and it is most unusual to perform a transverse colectomy. More commonly an extended right hemicolectomy is performed under these circumstances. Other operations which are used for the removal of colon cancers include right hemicolectomy, left hemicolectomy and sigmoid colectomy. Paragraph 5 I believe should read: Tumours of the upper and mid rectum are removed by anterior resection. Tumours of the lower rectum are removed either by low anterior resection or by abdomino-perineal resection. The latter includes the removal of the whole rectum and anus so that patients always require a permanent colostomy. Total mestorectal excision (TME) involves the removal of the rectum and the surrounding fatty tissue known as the mesorectum which contains the draining lymph nodes. When an anastomosis is performed close to the anal verge it is common to perform a temporary stoma to reduce the serious consequences of an anastomotic leak.	Amended as suggested
	University of Aberdeen	Laparoscopic surgery for colorectal cancer can include laparoscopic, laparoscopically assisted and hand assisted procedures. The differences influence the size of incisions required to complete the procedure. Any of these procedures can be used to remove a segment of the colon, the rectum or the entire large bowel. The majority of “laparoscopic” procedures will be “laparoscopically assisted” with a component of the operation performed on the surface making use of the smallest incision possible to remove the resected specimen. In contrast, hand-assisted laparoscopic surgery is technically easier for surgeons who are not expert in laparoscopic surgery and permits a “reduced access” rather than “minimal access” approach.	Now refers to 2 types of procedure - laparoscopic colectomy (to include laparoscopically assisted) and hand port-assisted colectomy is considered separately.
	Welsh Assembly Government	In the background I would emphasise that tumours of the lower 3rd of the rectum are also treated by anterior resection as well as by abdomino perineal resection. It is only the very low tumours of the rectum which are now treated by abdomino-perineal excision	Amended

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The technology/ intervention	Association of Laparoscopic Surgeons of Great Britain and Ireland	The techniques you describe under this heading are not accurate and are not useful. There is no such thing as a pure laparoscopic colectomy because at some point the specimen needs to be pulled out through the abdominal wall and the proximal end of the colon is pulled out so that the anvil of the stapling device can be inserted into the colon prior to it being put back into the abdomen for anastomosis. A laparoscopically assisted colectomy is a valid term and most operations fall into this group as I have just indicated. Hand port assisted colectomy is relatively unusual in this country. The techniques do not vary in the way you describe in the sense that a proportion of the procedure is performed laparoscopically but more relate to the method in which the bowel is to be reanastomosed. In most cases, the whole dissection is performed laparoscopically and hence your definition of a 'laparoscopic colectomy' applies to most of these methods apart from the hand port	Amended – laparaoscopic and laparoscopically assisted have been grouped together. Hand port-assisted will be considered separately.
	Association of Coloproctology of Great Britain and Ireland	The 3 techniques described rather confuse the issue. Strictly speaking all laparoscopic colorectal surgery is laparoscopically assisted as it involves making an incision to remove the specimen. Whether the anastomosis is performed outside the abdominal cavity or inside the abdominal cavity has no influence on the size of the incision. It may be simpler to reduce it to 2 techniques, laparoscopic colorectal resection and laparoscopically assisted colorectal resection, the latter would include hand assisted laparoscopic surgery. Laparoscopic colorectal resection is where all of the dissection is carried out laparoscopically and the size of the incision is dictated by the size of the specimen to be removed. Laparoscopically assisted colorectal resection is where the incision has to be enlarged to complete the dissection, the difference between the two is obviously subtle and either approach has the potential to benefit the patient with a smaller incision.	Amended – now refer to laparoscopic colectomy (to include laparoscopically assisted). Hand port-assisted colectomy is considered separately.
	Department of Health	Would it be possible to consider laparoscopic surgery in the context of 'Enhanced Recovery Programmes' as we believe these may have a substantial impact on the length of stay?	Have added under new 'Other considerations' section to be considered if the evidence allows.

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	J&J	1. The descriptions of the procedures carried out in clinical papers may not be clear enough to categorise them against the three laparoscopic techniques described in the scope i.e laparoscopic colectomy; laparoscopic assisted colectomy and hand assisted colectomy. 2. Clinical papers may not define the level of experience of the surgeon(s) involved in the study but this is an important artefact of economic and clinical effectiveness. 3. Further clarity is probably needed between a closed and lap assisted procedure	1. Now reduced to 2 categories. Hand port assisted should be easily distinguished from the others. 2. Not sure of the relevance of this to the scope 3. See 1 above
	Royal College of Nursing	There is no mention of laparoscopic surgery training for either medical or nursing staff – shouldn't the scope of the appraisal include this?	Training programmes may affect the implementation of the intervention – but not the clinical and cost effectiveness.
	University of Aberdeen	Our suggestion is that for the purposes of this appraisal laparoscopic and laparoscopically assisted colectomy are grouped together under the heading laparoscopic colectomy but hand assisted laparoscopic procedures also be included where possible as a separate intervention.	Laparoscopic and laparoscopically assisted colectomy will be considered together
	Welsh Assembly Government	There are other laparoscopic techniques such as robotic assisted surgery which are available to surgeons although not widely available in the UK.	Not specifically excluded in scope. For discussion with assessment group when developing protocol
Population	University of Aberdeen	We suggest that where possible the population is stratified according to the site of the primary tumour viz: colonic or rectal cancer.	Have added in a new "other considerations" section
Outcomes	Association of Laparoscopic Surgeons of Great Britain and Ireland	In the column on 'Outcomes' there are additional important parameters particularly the circumferential distance of margin of tumour clearance and also distal margins. Also it is not only the instance of port site metastases but this should be compared with the incidence of wound metastasis in open surgery. Finally, in this section it is not only health related quality of life but also the utilization of healthcare after discharge, This is particularly relevant in laparoscopic procedures where the patient usually requires very little in the way of help once leaving hospital and they will also leave hospital much earlier.	Margins of tumour clearance would appear to be surrogate outcomes and have not been added. Wound metastasis added. Health care utilisation after discharge should be included in the economic analysis without the need to specify in the scope

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	Association of Coloproctology of Great Britain and Ireland	It is important that lymph node retrieval laparoscopically is compared with lymph node retrieval at open surgery within the same institution as lymph node yields vary significantly between pathologists, not just surgeons. The incidence of port site metastasis must be compared with the incidence of wound metastasis in open surgery.	Wound metastasis added. Issue with regard to lymph node retrieval is a matter for interpretation of the evidence found by the assessment group rather than for the scope.
	BSG?	Having just briefly perused the draft the only thing that is glaringly missing is in the outcome assessments as there does not seem to be recording of wound site metastases in the open surgery group. This can occur in up to 1% of patients in some reported series and clearly needs to be looked at.	Wound metastasis added
	J&J	Outcomes that we would like to see reviewed: a. Return to normal bowel function b. Level of mucus discharge c. Continence d. Blood loss and use of blood products e. Adhesions f. Small bowel obstruction g. Anastomotic leaks h. Impotence i. Costs associated with the complications above	Most of these outcomes will be incorporated under short-term/long-term complications and health-related quality of life
	Royal College of Pathologists	Under "outcomes", I believe that an additional relevant outcome could be "completeness of resection / margin involvement by tumour".	Added

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	University of Aberdeen	We would like to suggest the following additional outcomes are also considered: a. The number of ports used for laparoscopic repair, as this is likely to have an impact on the costs of the laparoscopic procedure as well as indicating the number of wounds that an individual might receive in the course of their operation. b. In addition to the incidence of port site metastasis we feel that it would also be important to consider the incidence of wound metastasis. c. The incidence of complications might be helpfully separated into short-term and long-term complications. Short-term complications include wound infection, anastomotic leakage and abdominal wound breakdown requiring re-operation. A major long-term complication that should be considered is the risk of incisional hernia which results in morbidity as well as treatment costs.	a. This is a technical decision rather than an outcome b. Added wound metastasis c. Have amended as suggested
Other considerations	University of Aberdeen	The appropriate selection of people for laparoscopic resection requires better pre-operative staging of the disease. This may lead to increased requirement for sophisticated imaging techniques such as positron emission tomography (PET), magnetic resonance imaging (MRI) and computerised tomography (CT). The cost of these imaging services along with the cost of the multidisciplinary team required to assess which patients are suitable for surgery may also need to be considered. However it is recognised that MDT meetings are now increasingly available to discuss complex imaging issues particularly for rectal cancer and this may be an increased cost only for colonic lesions.	See Cancer Service guidance

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	Welsh Assembly Government	Related to the NICE recommendations, current NICE guidance for colorectal cancer. I would argue that things have now changed and that laparoscopic resection for colorectal cancer should be considered. The Association of Coloproctology made it clear that is not necessary for these patients to be part of a randomised controlled trial but surgeons undertaking this technique should ensure that their results are subject to rigorous audit. The Association also suggested that as there is no structured training programme for established Consultants to undertake lapararoscopic colorectal surgery training that Consultants attend appropriate courses and are preceptioned by experienced laparoscopic surgeons or possible have secondment for sabbatical training at centres which currently practice laparoscopic colorectal resection. There are several centres within the UK where this is now becoming the standard treatment for many cases."	Committee to consider.

The following consultees/commentators indicated that they had no comments on the draft scope

Beating Bowel Cancer
Board of CHCs
Cancer Research
Colon Cancer Concern
Eurosurgical Limited
Long-term Medical Conditions Alliance
Marie Curie Cancer Care
NHS Purchasing and Supply Agency
NHS Quality Improvement Scotland
North Warwickshire PCT
OPTEC International Ltd
RB Medical
Rocket Medical plc
Royal College of General Practitioners
Royal College of Surgeons
Smith & Nephew Endoscopy