NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Laparoscopic surgery for colorectal cancer

Comments on ACD from consultees, commentators, non-consultees and non-commentators

1. Comments received from consultees (in alphabetical order)

Consultee	Comments received	Action/Response
Association of Coloproct-ology of Great Britain and Ireland (Highlighting refers to suggested changes from ACPGBI)	"We feel that all relevant evidence has been taken into account. The summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and the preliminary views on the resource impact and implications for the NHS are appropriate."	Comments noted. No action required.
	"The provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS with one or two suggested alterations (highlighted in the ACD attached)." 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."	Comments noted.

Consultee	Comments received	Action/Response
	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…"	Comments noted. Members of the multidisciplinary team are mentioned in Section 4.3.5 of the FAD. The difficulty in including the whole team in the guidance section means that the criteria for appropriate training and frequency of procedures (in 1.2) to be developed by the relevant national bodies would have to apply to the whole team. This would necessarily expand the number of relevant bodies and the number and nature of the criteria. This was not the Committee's intention.
Association of Coloproct-ology of Great Britain and Ireland (continued)	4.1.9 "…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."	Relevant figure amended from 5% to less than 10%.
	4.3.5 "…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."	Relevant figure amended from 5% to less than 10%.
	"We have also added a suggested section on audit - 7.3.3." 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.	See 5.6 in FAD

Consultee	Comments received	Action/Response
	"As there are relatively few surgeons fully trained in the technique at present we feel it should be considered as an alternative to open surgery rather than recommended at this stage."	Comments noted. Laparoscopic resection was recommended **only as an alternative** to open resection in the ACD Preliminary Recommendation 1.1
	"We also request that the technology is considered for review at the end of 2009 or early 2010 because we have just submitted a full application to cruk to fund a multicentre randomised trial of laparoscopic v open surgery within an enhanced recovery program. Results should be available towards the end of 2009 and will answer many of the questions about short term recovery when compared to open surgery and cost."	The guidance be considered for review in September 2009
	"In relation to the published ACD, I believe that the preliminary recommendations put forward by the Appraisal Committee are consistent with the evidence available and should allow for the safe wider introduction of this beneficial technology."	Comments noted. No action required.
Association of Laparoscopic Surgeons of Great Britain and Ireland (continued)	"Specifying a frequency of operation to maintain competence is admirable but is applicable to all types of surgery in all specialities – not just laparoscopic surgery. Surgeons will need to start somewhere and by definition will have an experience of zero with their first case. This has to be accepted as a fact of life and should not be a barrier to progression."	
	"There is currently no body accrediting surgeons for procedure specific tasks. The Royal Colleges accredit surgeons through their exam systems. It should be recognised that the preceptorship programme does not accredit surgeons but simply allows a mechanism for qualified surgeons to access expertise and training in a particular field."	
Association for	"AfPP are pleased an original AfPP recommendation to the Appraisal Committee from our original Consultation response have been accepted."	Comments noted. No action required.

Consultee	Comments received	Action/Response
Perioperative Practice	"'AfPP reported one element of training not considered was that of the theatre team rather than just the surgeon.' The guidance for implications to NHS training will be amended to take this into account."	
	1. **Whether we consider all relevant evidence has been taken into account?** "AfPP are confident the Appraisal Committee has utilised evidence where it is available. This includes the evidence and views of Consultees evaluated by the Assessment Group. AfPP have concerns with regard to the limited reliable evidence which is available to inform the Appraisal Committee of the clinical effectiveness of laparoscopic surgery for colorectal surgery. The Aberdeen Technology Assessment review Group conducting its own systematic review highlighted the quality of random controlled trials varied. The Appraisal Committee acknowledge quantifiable evidence is not available to suggest laparoscopic surgery may be associated with a slight decrease in the number of lymph nodes retrieved, an increase in anastomotic leakage and a slightly lower risk of operative and 30 day mortality. Evidence is also limited to suggest patients who are converted to open surgery have higher blood loss, longer surgery, longer hospital stay and higher risk of tumour recurrence. Reliable evidence is required for survival outcomes beyond 3 years to inform whether laparoscopic surgery is cost effective."	
Association for Perioperative Practice (continued)	2. **Whether we consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?** "AfPP are concerned there is not available a systematic review with regard to economic evaluations of utilising laparoscopic technology. Reliable data is required to assess long term outcomes of patients having laparoscopic surgery with those having open method. The Assessment group have used varying assumptions when formulating an economic model."	The Aberdeen Technology Assessment Group did conduct a systematic review of economic evaluation. Please see Assessment Report Chapter 4, available from http://www.nice.org.uk/page.aspx?o=297525. The Committee was mindful of the importance of collection of long-term outcome data. Relevant further research was therefore recommended in ACD section 5. Guidance will be reviewed in the future in light of available new data.

Consultee	Comments received	Action/Response
	3. **Whether we consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?** "The provisional recommendations are open to challenge in the absence of validated systematic reviews. It is not clear what clinical effective best practice is. Especially with the absence of an economic model. AfPP support the Appraisal Committees findings there is a need for further research: • To establish long term clinical safety of the technology, especially beyond 3 years • To identify important sub group differences and establish patient selection criteria • To assess any differences in clinical and cost effectiveness among the different types of laparoscopic surgery • To assess costs of training of surgeons **and the non medical surgical team** to carry out laparoscopic colorectal surgery."	Comments noted. The Aberdeen Technology Assessment Group conducted a systematic review of the clinical and cost effectiveness of laparoscopic surgery for colorectal cancer. See Assessment Report Chapters 3 and 4, available from http://www.nice.org.uk/page.aspx?o=297525.
British Association of Surgical Oncology	"I have enjoyed the provisional report that I have been allowed to read. I think this represents a comprehensive review with sensible and appropriate recommendations. It has my full support."	Comments noted. No action required.
Department of Health	Para 1.2 – "Is there a issue that by leaving the mode and mechanisms for deciding on definitions of 'appropriate training' and 'sufficient frequency' to local networks and professional bodies. There might be high levels of local variation in practice?"	Comments noted. 1.2 was amended in the FAD light of results of ACD consultation.
Department of Health (continued)	Para 1.3 last bullet- "Would you please clarify whether this means surgeons are to be mandated to discuss with the patient their experience in both procedures and, if so, in what degree of detail? "	When the guidance is published, health professionals will be expected to take it into account, but it does not override the professional responsibility of the surgeon.

Consultee	Comments received	Action/Response
	Para 9.2 – "Clinical colleagues suggest it might be more appropriate if this guidance could be considered for review in September 2008."	The guidance be considered for review in September 2009 – see response to Association of Coloproctology of Great Britain and Ireland above
	Appendix C – "It would be helpful if you could consider making the recommendations more stronger on audit, particularly for conversion rates. If audit criteria is to be set locally, the resulting data might be difficult to compare. Clinical colleagues suggest that you might wish to consider allowing the criteria to be determined by some form of a joint sub committee of the Association of Coloproctolgy of Great Britain and Northern Ireland and the Association of Laparoscopic Surgeons."	Audit recommendations are provided to support the implementation of the guidance as stated in section 1. They are therefore limited to the scope of the guidance.
Ethicon Endo-Surgery	**1. <u>Whether the provisional recommendations are considered sound…</u>** "We consider the preliminary recommendation to be sound, and able to provide a suitable basis for guidance to the NHS. The committee has identified the key issues of training, patient selection and experience, and has been pragmatic in the recommendations around these. We only question the appropriateness of Local Cancer Networks in determining what is appropriate surgical training, and consider that the professional bodies are better positioned to determine this, as is current practice (**Paragraph 1.2**)."	FAD 1.2 amended

Consultee	Comments received	Action/Response
Ethicon Endo-Surgery (continued)	**2. <u>Whether the summaries ….. are reasonable interpretations of the evidence…</u>** "The clinical evidence reported in section 4 focuses on the long-term outcomes between the open and laparoscopic techniques, which are acknowledged to be equivalent. The only short-term measure reported is theatre time, presumably because it is used in the model. As reported in our submission, and it would appear (from 4.1.9) also by the experts at the meeting, the value of the laparoscopic approach is in the short term benefits realised by patients. We therefore request that Section 4 mention some of the short-term benefits. For example, this could be incorporated in to **Paragraph 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. **<u>In addition to reduced length of hospital stay, short-term benefits of laparoscopic surgery to the patient include the requirement for less analgesia; improvements in patient reported quality of life; less intra-operative blood loss; and faster return of normal GI and pulmonary function</u>**. *Paragraph continues…"*	The ACD and FAD do not include all endpoints covered by the assessment report. In general, the evidence for improvement in short-term outcomes with laparoscopic surgery is based on relatively few studies and could not be quantitatively synthesised. The potential for short term benefit was considered by the Committee (see 4.3.3 in FAD)
	3. <u>Whether all relevant evidence has been taken in to account</u> "With regard to the recommendation to short-term benefits above, we consider all evidence has been taken in to account."	Comments noted. No action required.
	"Furthermore, for your information, it is our understanding that the meta-analysis referred to in **paragraph 4.1.1** has now been accepted for publication in 'Archives of Surgery'."	Comments noted and thank you. At the time of the second committee discussion confirmation of release from academic in confidence status had not been received.
Karl Storz Endoscopy (UK) Ltd	Thank you for the above. We are naturally pleased with the overall outcome, which we see as a positive first step to more widespread use of laparoscopic techniques.	Comments noted. No action required.

Consultee	Comments received	Action/Response
Karl Storz Endoscopy (UK) Ltd (continued)	It is not unreasonable to suggest that with a wider take-up of the procedure: • Surgeon experience will develop with a consequent reduction in operating times and in reversion to open surgery. • Patient-led demand for the laparoscopic approach will increase. • Laparoscopic operating costs will significantly diminish with the introduction of reusable apparatus. On this latter point, I very much hope that reusable product costings are being considered by the Costing Unit alongside those of single-use devices. If they require assistance with this, we would be happy to co-operate and provide comparative data.	For consideration by costing unit
	Alternatively, given the omission of such a fundamental point regarding the cost of the procedure from the ACD are we to assume that equipment cost is now no longer an issue given the weight of evidence in support of the procedure?	

2. Comments received from commentators

Commentator	Comments received	Action/Response
Aberdeen Technology Assessment Group	Paragraph 3.1. "It is stated that the tumour is removed through an abdominal incision. This is not always the case because the tumour may sometimes be removed rectally. It is perhaps more appropriate to say that it is usually removed through an abdominal incision."	"usually" added in 3.1

Commentator	Comments received	Action/Response
	Paragraph 4.1.6. “In this paragraph outcomes for patients converted from laparoscopic to open surgery are reported. It may be worth noting that these results may be biased, as it is not known whether the reason for the conversion was the nature of the patients’ underlying condition or caused by some aspect of the laparoscopic surgery. In the former case, patients converted are more severe cases than the majority of laparoscopic patients and as a result would be expected to fair worse, therefore initial choice of laparoscopic surgery does not reflect outcome (although it may affect cost). Differences caused by the latter situation would however be relevant to record. In both situations the risk of conversion may be reduced with experience. In the former case this would be due to improvements in pre-operative assessment and in the latter, it would be due to improvements in operative technique.”	Covered in section 4.3 (see FAD 4.3.4)
Aberdeen Technology Assessment Group Continued	Paragraph 4.1.7. “The sub-group analysis by location of disease referred to in this paragraph did not formally compare risks for the different sub-groups. Any conclusions about the similarity or otherwise of the risks between the different locations of cancer are based on essentially indirect comparisons.”	
	Paragraph 4.1.7. “No mention is made of the number of studies contributing data on risk of anastomotic leakage by location of the cancer.”	
	Paragraph 4.1.8. “In this paragraph no reference is made to the meta-analysis by Bonjer and colleagues. In this meta-analysis information on overall survival and disease free survival by stage of the cancer is presented.”	
	Paragraph 4.2.2. “In this paragraph reference is made to the unpublished data. These data were provided as academic in confidence (AiC). It might be useful to state that the results of this study are not reported in the ACD.”	

Commentator	Comments received		Action/Response
	Paragraph 4.2.4. "In this paragraph reference is made to the threshold analysis conducted on length of stay. The ACD quotes the assessment report which stated "*this magnitude of difference was not observed in any of the studies included in the systematic review."* This is a mistake in the assessment report as two non-UK studies reported a difference of this magnitude. We of course regret this mistake and suggest that the text is revised to: "*this magnitude of difference was <u>rarely</u> observed in any of the studies included in the systematic review.""*"		Comments noted. Relevant section amended as recommended.
	Paragraph 4.2.5. "In this paragraph the results of the economic analysis conducted as part of the Assessment Report is summarised. No mention is made of the probabilistic analysis. This is perhaps inappropriate, as the text does not reflect the statistical imprecision surrounding the results, nor the fact that the decisions about dominance are made using a very strict decision rule."		
	Paragraph 5.1. "The CLASICC Trial has collected data on the short-term benefits of the treatments. These data would be suitable for the assessment of QALYs however they have not been made available even as AiC. It may be worth mentioning that such short-term data along with long-term data may also become publicly available."		
Aberdeen Technology Assessment Group Continued	Appendix B. "The authorship of the assessment report quoted is incorrect. The authorship should read: Alison Murray, Tania Lourenco and Robyn de Verteuil *et al.*"		Relevant section in the FAD is amended.
NHS Quality Improvement Scotland	*Whether all the relevant evidence has been taken into account.*		
	Reviewer 1	"I believe that all relevant evidence has been taken into account in this document."	Comment noted. No action required.

Commentator	Comments received		Action/Response
	Reviewer 2	"The ACD does not give details of the search strategy that was used to conduct the systematic review. The criteria for including trials in the review are not provided. However the evidence presented in the ACD reflects my personal understanding of the current literature regarding laparoscopic surgery for colorectal cancer."	
	Reviewer 3	"Yes it has."	Comment noted. No action required.
	Whether the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate.		
	Reviewer 1	"I believe that the summary of clinical effectiveness is a reasonable interpretation of the evidence but I believe that the data available on cost effectiveness are inadequate to allow a reasonable conclusion to be reached. This is evidenced by the enormous confidence incidence around the estimated cost difference (paragraph 4.2.4)."	Comment noted. No action required.

Commentator	Comments received		Action/Response
NHS Quality Improvement Scotland (continued)	Reviewer 2	"The ACD contains reasonable interpretations of the evidence. The principal finding regarding clinical effectiveness is that laparoscopic colorectal cancer surgery is associated with reduced hospital admission duration when compared with open surgery. For all other clinical parameters, laparoscopic colorectal cancer surgery is at least equivalent to open surgery. The ACD acknowledges that cost effectiveness is related to conversion rates and admission duration. It is debatable whether sufficiently low conversion rates and short admission durations can be achieved to render laparoscopic colorectal cancer surgery as cost effective as open surgery. Section 6 of the appraisal document states that the NICE costing unit is currently developing preliminary views on the resource impact and implications for the NHS. The costing unit should recognise that only a minority of British colorectal surgeons are currently trained in laparoscopic colorectal surgery (Harinath et al. Laparoscopic colorectal surgery in Great Britain and Ireland – where are we now? *Colorectal Disease* 2005; 7:86-89)."	
	Reviewer 3	"From the information given, I have no reason to question the summaries given."	Comment noted. No action required.
	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.		

Commentator	Comments received		Action/Response
NHS Quality Improvement Scotland (continued)	Reviewer 1	"I believe that the provisional recommendations of the Appraisal Committee are sound but I think it is important to stress two areas: 1. It is very important that all laparoscopic colorectal surgery carried out in this country is subjected to a rigorous audit process. I am concerned the results of laparoscopic surgery outside randomised trials may not match up to the published evidence. 2. I believe that the guidance should stress the importance of further research into techniques of laparoscopic colorectal surgery with a view to standardization."	

Commentator	Comments received		Action/Response
NHS Quality Improvement Scotland (continued)	Reviewer 2	"In general the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS. Three specific points might merit revision. a) Laparoscopic colorectal cancer surgery has been appraised by a national institution (i.e. NICE). In my personal opinion "*appropriate training*" and "*sufficient frequency to maintain competence*" would be better determined by relevant national professional bodies (e.g. the Association of Coloproctology of Great Britain and Ireland) rather than by local cancer networks (ACD section 1.2). b) Given the uncertainty of cost effectiveness and long-term clinical outcomes, it may be preferable to recommend audit of laparoscopic colorectal cancer surgery as "*essential*" rather than "*useful*" (ACD section 5.2). c) The Committee recommends that the "*suitability of the lesion for laparoscopic resection*" should be considered. However a definition of such "*suitable*" lesions is not provided. Defining suitable lesions would help surgeons and patients make an informed decision regarding laparoscopic colorectal cancer surgery (ACD section 1.3)."	1.2 in FAD has been amended.
	Reviewer 3	"On the evidence given, yes."	Comment noted. No action required.

Commentator	Comments received	Action/Response
NHS Quality Improvement Scotland (reviewer 4)	"This is a comprehensive and thoughtful review of the changes in practice and evidence that have taken place since NICE first pronounced on laparoscopic surgery for colorectal cancer. The conclusions reached reflect my understanding of current practice, that the two procedures have equivalent outcomes in similar cases and that quality of life may well be better with laparoscopic surgery. The cost increments are not substantial. The conclusions reached would be equally valid in Scotland."	Comment noted. No action required.

3. Comments received from non-consultees and non-commentators

Comment from	Comments received	Action/Response
Cancer Information Framework Wales & National Bowel Cancer Audit	Section 7: "The National Bowel Cancer Audit is commissioned by the Healthcare Commission and run jointly by the Association of Coloproctology of GB&I and the National Clinical Audit Support Programme. (www.icservices.nhs.uk/ncasp/bowelcancer & www.nbocap.org.uk). The dataset contains items relevant to both laparoscopic and non-laparoscopic surgery for bowel cancer, providing the facility for short and long-term audit on a National, comparative, basis. Participation in this audit will enable the effect of widespread introduction of laparoscopic bowel resection to be closely monitored."	Information added (see FAD 4.3.6 and 5.6)

Comment from	Comments received	Action/Response
National Cancer Audit	Section 7: "The National Clinical Audit Support Programme wishes to ensure that NICE and the authors of the recommendations within this document relating to clinical audit are aware of the existence of the National Bowel Cancer Audit. This audit is commissioned by the Healthcare Commission, managed jointly by the NHS Health and Social Care Information Centre and the Association of Coloproctology of Great Britain and Ireland and is fully supported by the National Cancer Director. The audit already has the ability to compare treatments undertaken by both open and laparoscopic surgery and measures performance against national standards. We also have the potential to develop the audit to encompass recommendations contained within the guidance on laparoscopic surgery for colorectal cancer and would welcome the opportunity to engage in discussions on the recommended approach to clinical audit."	Information added (see FAD 4.3.6 and 5.6)
National Lead Clinician for Colorectal Cancer	"My general view of the NICE Overview Document and the Appraisal Consultation Document is that whereas neither is strictly "neutral" (in my view both are slanted by the enthusiasts in favour of laparoscopic surgery), I think that NICE has come up with the correct conclusions about laparoscopic colorectal cancer surgery, and consequently the previous restriction in the NUCE Guidance that these operations should only be done in the context of a randomised controlled trial (RCT) can, and should, be withdrawn."	Comments noted. No action required.
	"On the other hand, there are sufficient doubts within the colorectal fraternity (which are somewhat played down in both of the NICE papers), to make a determined, ongoing but reasonably simple, audit *compulsory* and the criteria **MUST** be laid down nationally rather than locally if there is to be any hope of a general interpretation of its results in the future."	
	"I should like to make the following points:- 1. Laparoscopic surgery is almost certainly equivalent to open surgery for colorectal cancer of the colon, the evidence is less clear for cancer of the rectum (anterior resection and abdominoperineal resection) where the surgery is generally regarded as being even more difficult."	Comments noted.

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	"2. Laparoscopic surgery is definitely better than open with regard to post-operative pain (three to five 1cm puncture incisions for the port site and a greatly reduced "main incision" for actual removal of the specimen). Laparoscopic surgery is very likely to be better than open in terms of reduced length of hospital stay. The Overview overstates this: page-3, 1.2 para-3 "open surgery has a long hospital stay". Page-14, table-3, third row: open surgery length of stay > 17 days, but same table, row-4: open surgery for colonic resection, mean 7.4 days. Why are these figures so very different? I believe there is a selection bias and a mathematical explanation, which relates to the CLASICC trial being the work of *enthusiasts* doing selected favourable cases, and they have used the arithmetical mean for hospital stay rather than the median. I would imagine that if the raw data are consulted that in both sets of data, 90% of the patients would have stayed between five and twelve days for the open surgery and four and eight days for the laparoscopic colonic surgery. Since all the patients in the laparoscopic trial will have had to have fulfilled the (stringent) requirements for laparoscopic surgery (in general terms the "easy" cases), there are unlikely to be any who stayed a great length of time due to extensive co-morbidity. Thus the two durations of stay quoted in the CLASICC Trial are entirely reasonable. The seventeen day figure will result from "all comers" and will include some patients with extensive co-morbidity who are likely to have stayed in hospital up to six months. It only takes one or two such patients to raise the arithmetic mean to seventeen days, whereas the median will still be somewhere around about ten days. This is what I mean by saying that both of the NICE papers are somewhat slanted in favour of the laparoscopic option."	These comments refer to the overview rather than the ACD.

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	"3. Laparoscopic surgery is probably worse than open for cases that are "converted" (i.e. they start laparoscopic but because of operative difficulties have to be converted into open procedures). They are possibly worse for local recurrence (particularly of the rectum) and finally, there are persistent anecdotal accounts of "dreadful complications" most often associated with consultants' learning curves which seldom reach the published literature. The only way to refute the allegation of occasional "dreadful complications" is by the use of a thorough compulsory audit. (The analogy with laparoscopic cholecystectomy is pretty obvious. It is universally agreed that the laparoscopic method is the operation of choice for the generality of patients will gallstones but it is well known that the "price" for this is an increased incidence of serious damage to the common bile duct, Sir Anthony Eden etc., etc.) The increased "harm" caused by conversion is an interesting matter that highlights (to my mind) the somewhat simplistic interpretation common to both NICE papers. The figures show, (and I am pretty sure they are right) that when a case has to be converted there is definitely an increased blood loss (exactly as you would expect because it is one of the reasons you convert in the first place), possibly an increased incidence of inadequate tumour removal (because it is difficult), and possibly a reduced long-term survival (perhaps due to the local recurrence issue). The assumption is made in both NICE papers that if one can reduce the conversion rate then these cases would have the standard outcome for all three variables. It seems to me that whereas this may be true, it is equally possible that it is not true, and that "conversion" is merely a surrogate for an operation that is going to be difficult whether open or laparoscopic, where there is an increased chance of incomplete excision and where the long-term outcome may therefore be less good. Putting it another way, there is no guarantee that reducing the conversion rate will improve the local and systemic outcomes for this cohort of patient, although "common sense" would suggest that this is quite likely to be the case. Again, only rigorous audit will show where the truth actually lies."	Comments noted

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	"4. Neither NICE paper lays sufficient emphasis on the fact that laparoscopic colorectal surgery is technically extremely demanding and difficult, and this has major consequences for any recommendation/implication that it should be introduced either widely or universally (Appraisal Document page-23, Table: row-1 says that 100% of people with colorectal cancer that are considered suitable for surgery should be offered laparoscopic surgery – a completely unworkable proposition at present!). As a guide to the non-surgeon, I would say that if the operation of laparoscopic appendicectomy counts for 1/10 in terms of difficulty, this would place laparoscopic cholecystectomy at 3/10, laparoscopic colonic resection 7/10, and laparoscopic rectal excision at 10/10. The Appraisal Overview (page-4, para-3) seriously underplays the situation when it says "a recently published survey reported that only 45 of the existing members of the Association of Coloproctology of Great Britain and Ireland perform laparoscopic colorectal surgery." What it should have said is that only 45 out of the 400 existing consultant members of the Association of Coloproctology of GBI do this operation i.e. 10%. Thus there are very major training issues here. Firstly, there are not the training opportunities in the UK to train the other 355 consultants in laparoscopic colorectal surgery over a short period of time (say three years). Even if this could be done, there are not sufficient trainers in laparoscopic surgery who could act as their mentors for the early part of each surgeon's learning curve. Furthermore, it is highly unlikely that without a major abandonment of the government's targets for both cancer and non-cancer surgery Trusts could find the increased operating time needed to accommodate these learning curves. And finally, it is likely that a significant proportion of the 355 consultant surgeons would not be "very good" at this technically demanding and difficult procedure that requires a spacial appreciation and orientation which is not universal, and has not in the past been a selection criterion for training related to this particular cohort of practitioners.	

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	(If you look at this in a urological concept I would say the following. It just so happens that for a historical reason I am dually accredited as both a pure urologist and general surgeon. For this reason, I have direct personal experience of both sets of training. Use of the urological resectoscope is very similar to use of the laparoscope. My experience teaching urological SHO's was that approximately a quarter of trainees take to the resectoscope with consummate ease, half have difficulty but can be trained, and the remaining quarter are no good at it and are best doing something else, i.e. not urology. It therefore follows that consultant urologists are a pre-selected group who have good spacial and optical skills. This kind of selection has, for obvious reasons, never taken place with colorectal trainees and therefore it is, in my view, highly likely that an appreciable proportion of established consultant colorectal surgeons will not be able to convert to laparoscopic surgery even if the personal "will" were present.) This training problem does not seem to have been addressed in either of the two NICE papers.	

Comment from	Comments received	Action/Response
	"5. Once trained, the generality of colorectal surgeons are very unlikely to be as good, quick, and slick as the laparoscopic enthusiasts who have produced the early papers that are quoted. Such a reduction to "the common denominator" is a universal dilemma with the introduction of new techniques when they are overtly more difficult than the standard procedure. Although the enthusiasts write, maintain and aver that after their learning curve has been traversed, their operation time is not enormously different from the time they take for open surgery, I believe it is highly unlikely that this would apply to the generality of retrained colorectal surgeons, and one ought to reckon on these operations taking 1.5 times the time the current operation required. Again Trusts are going to need to make significant alterations to the schedules to cope with this. (In Leicester we have approximately 400 new cases of colorectal cancer a year, spread among six surgeons, 98% patients get some kind of operation even if it is not curative, so that is approximately 60 for each surgeon, which, allowing for holidays, time off etc., etc., is one to two operations a week. For open surgery, colonic resection takes approximately two hours (anaesthetic time, start of operation, procedure, cleaning the theatre etc.) and rectal resection three and a half hours. Operating lists usually last three and half to four hours. The difficulties are obvious."	
National Lead Clinician for Colorectal Cancer (continued)	"6. If laparoscopic colorectal surgery is to be "rolled out" so that it becomes a widespread option, if not exactly "the norm," then there will need to be some reasonably generous funded pilot scheme involving whole hospitals to see if it can be made to work for "all comers" in a locality, coupled with a sensible audit (see below), this should produce a workable way forward."	

Comment from	Comments received	Action/Response
	"7. The audit proposals in the Appraisal Document (pages 22-24 are to my mind weak to the extent of pusillanimous! At best they could be described as "not thought through," at worst they are "unworkable". The table on page 23 says it all. Row-1, number-1, columns 2 & 3 are mutually exclusive. How can you offer an operation to 100% of suitable patients if it is either not available at all, or only available to [let us say] one quarter of the patients going through the hospital). I am deeply worried where it says that the criteria should be arranged locally (row-1, column-4; row-3, column-4). If everybody is allowed to set their own criteria locally we will end up with a series of data that are difficult to compare, and quite possibly uninterpretable! To my way of thinking it is absolutely essential that the criteria for audit are determined **nationally** by some form of joint sub-committee of the Association of Coloproctology GBI and the Association of Laparoscopic Surgeons. Such an audit should be compulsory which means that on the one hand all surgeons should be compelled to take part, and on the other all Trusts should be compelled to provide the infrastructure for data collection. To my way of thinking it might well be possible to organise implementation on a regional basis (which might be less unwieldy than a full national audit) and there are some good precedents for this, such as the (very successful and much quoted) Wessex audit of colorectal cancer, and the Trent and South Wales audit of colorectal cancer (in which we took part in Leicester)."	

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	"**Conclusions:** It is my view that a) Laparoscopic surgery is likely to be equivalent to open surgery in all the main outcome measures. b) This view is only an "educated guess" and needs to be backed up by a rigorous compulsory ongoing audit that must be adequately funded. c) Both the Overview and the Appraisal Documents need a degree of reworking and "tightening up" which, in my opinion, will make them genuinely excellent, producing arguments that the sceptical will find difficult to refute d) Implementation is likely to be an enormous logistic problem both in terms of training of established colorectal surgeons already in post, and even more so in implementation of this change of practice, which will replace difficult and demanding but inherently straightforward procedures (open surgery) with extremely difficult technically demanding, time-consuming new options (laparoscopic surgery)."	Implementation issues have been noted and will be considered by the implementation team.
	Additional detailed comments and critique of the Overview….	Comments noted.
	"Page 4, 2.3 "…the open procedure involves a long hospital stay". The concept of a "long hospital stay" varies with discipline. Thus after bony trauma, an orthopaedic surgeon would regard a duration of more than six weeks to be a "long stay," whereas a breast surgeon would regard a ten day stay after a standard procedure as "long." Among the colorectal fraternity, most of us would regard a duration of longer than three weeks as a "long stay". "	Comments noted.
	"In my own practice the vast majority of patients undergoing colonic resection stay somewhere between five and ten days and for rectal resection, I put them down for a twelve day stay, and I am pleased when they go home earlier. It would make more sense if the analysis in the overview had used the median rather than the arithmetic mean."	Comments noted.

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	"On pages 4 & 5, Section 4.1.2, in these various sets of figures, you mention only the mean differences and confidence intervals for longer operative time, lymph node retrieval and anastomotic leak. In order to interpret these figures in a sensible fashion you need to provide the actual mean numbers as well as the mean differences. In other words there is a world of difference between an operation whose mean is one hour taking an additional forty minutes, and an operation whose mean duration is four hours taking an additional forty minutes, etc."	Comments noted. ACD section 4.1.2 reported the results of quantitative syntheses of various study data by the independent Assessment Group. The actual study data used in the quantitative syntheses for duration of operation, lymph node retrieval and anastomotic leak for laparoscopic and open surgery can be read in detail in the Assessment Report Appendix 9, Outcomes 01, 04 and 02 respectively.
	"Page-6, 4.1.5, one of these "zero rated effects" is death and you should say so. In other words in one of the RCT's quoted in the overview, page-14, Table-2, there were no deaths in either the laparoscopic or the open colonic resection. (Our figure last year in Leicester for all of our patients for all comers having elective colorectal cancer surgery was 2% at thirty days)."	Overall survival is discussed in paragraph 4.1.3.
	"Page-7, 4.1.6, you say that those patients whose laparoscopic operation is converted to open have increased blood loss, a longer hospital stay and possibly increased local recurrence. You need to say that these observations accord with "common sense" and might reasonably been expected."	It is not usual to comment on whether results might or might not have been expected in the evidence section of the FAD (4.1 and 4.2). See section 4.3 for consideration of the evidence
	"One of the major reasons for conversion is that the presence of blood greatly affects the laparoscopic cameras vision (red out), and if you cannot see adequately you have to "open up". Once you have "opened up" you are looking at an operation of longer duration, more morbidity and therefore an increased length of stay is to be expected. Furthermore, it is likely that at least to some extent, conversion is due to the tumour being unexpectedly more advanced, more adherent, larger etc., and therefore is intrinsically in a less good prognosis group."	

Comment from	Comments received	Action/Response
	"Finally there is the implication that if only one can reduce the conversion rate, one can avoid the increased length of stay and the local recurrence rate. An alternative explanation is that it is perfectly possible that this is a cohort of patients with significantly worse pathology who are going to have a less good outcome whichever kind of operation they receive."	
National Lead Clinician for Colorectal Cancer (continued)	"Page-8, 4.2.3, I must confess that I find the economic arguments that attempt to relate a reduced duration of stay with cost savings to be very superficial. To my way of thinking the problem comes in confusing unit cost of a patient episode with the global cost to the service as a whole (see my letter to the Times of 17th March 2006, copy enclosed). Since the overheads for a surgical bed remain the same, whether it contains a patient or whether it doesn't (nursing staff, hotel costs etc.) reducing the length of stay of patients by two days each, hardly saves any money if for these sets of two days the bed is empty. Furthermore, if an additional patient is processed through the bed in order to meet "targets," then it actually costs the organisation more. By the same token, opponents of laparoscopic surgery should not argue that increased operation time costs any more, unless the staff stay late and are paid extra money in overtime. It is true that laparoscopic operations cost more than open operations because the laparoscopic instruments are largely disposable and tend to be of significantly higher cost. So putting all this together, the introduction of laparoscopic surgery is likely to increase the cost of running a hospital surgical department by a modest amount, rather than decrease it."	There is an opportunity cost associated with longer hospital stays and longer operating times.
	"Introduction of widespread laparoscopic surgery that frees up a significant number of bed days, is likely to cost the hospital quite a bit more because of the additional operations that at least theoretically can be put through the system during the same time provided it can be arranged that the theatre will not be "blocked" by the additional time needed to undertake the laparoscopic surgery."	
	"Page-9, 4.2.4, the same considerations apply here."	

Comment from	Comments received	Action/Response
	"In addition there needs to be a reworking in a far more sophisticated way to take into account the financial consequences of the disruption to the routine service caused by taking 350 consultant colorectal surgeons out of it to receive dedicated one-to-one training, (during which time they cannot be doing their own routine work) This then has to be followed by the costs of the additional time required for consultant one-to-one mentoring of these newly retrained consultants during the first part of their learning curve. (In essence this involves two surgeons being present for what are quite lengthy operations instead of one, so not only is the retrained surgeon taking longer, but the mentor is not doing his/her work at all)."	
National Lead Clinician for Colorectal Cancer (continued)	"Page-11, 4.3.5 There is an assumption here that all (or at least most) of the 350 existing colorectal surgeons can relatively easily be converted into laparoscopic surgeons who then, within a reasonable learning curve, become fast laparoscopic surgeons with the low conversion rates of the real enthusiasts (5%). In the CLASICC trial (which itself encompassed enthusiasts), the initial conversion rate was 20%, so one may reasonably expect that in the generality of colorectal surgeons, many of whom (perhaps most of whom) will not be enthusiasts, the conversion rate is likely to be far higher."	
	"Page-12, item-7 implementation and audit. 7.3 – this refers to Appendix-C which is to my way of thinking deeply flawed and inadequate because the issue of capacity, supply and demand is crucial, and is not adequately addressed. " 7.3.1 discussion of the pro's and con's of laparoscopic surgery is pointless if it is not available locally either at all, or in sufficient numbers to cope with demand."	

Comment from	Comments received	Action/Response
	"7.4 I believe that the criteria for audit must be agreed and laid down **nationally** (and not locally) otherwise nobody will subsequently be able to interpret the results if we have a whole string of audits done according to different criteria. Once national criteria are agreed, then it might well be possible to have regional audits, which might be more manageable, but using these national criteria (e.g. the Wessex Colorectal Cancer Audit and the Trent Wales Colorectal Cancer Audits of the past)."	
	"Page-14, 9.2, David Barnett specifically asks whether consideration for review should commence in September 2009. It seems to me that this is too late, and that discussions ought to start in September 2008, with a view to publication of a draft rather like this one in September 2009."	
	"Appendix-A: Appraisal Committee Members, page-15. I noticed that on your Appraisal Committee there are twenty-nine members of whom only one is a surgeon, Miss Hands, and she is a vascular surgeon. The role of laparoscopy in vascular surgery is minimal and I suggest that both of your NICE documents have suffered through a paucity of informed surgical input."	

Comment from	Comments received	Action/Response
National Lead Clinician for Colorectal Cancer (continued)	"Page-23, Appendix-C, Audit Proposals. It seems to me that these proposals encapsulated very succinctly in this table are a recipe for a communications disaster for NICE because they are completely unworkable. Row-1 is the main problem, in that it requires (under "Standard") 100% patients with colorectal cancer that are considered suitable for laparoscopic surgery (which is at least 60%) must have a discussion about whether they wish to have laparoscopic surgery, presumably with a view to offering them this option, whereas the fact is that only 10% (45/400 consultant members of ACPGBI) are currently offering it! This is like offering all the passengers on an aeroplane equal chance of a first-class seat when only 10% of the seats are in the first-class cabin! We are all having enough trouble at present with the NICE Guideline that says that hernia patients should be offered the option of laparoscopic hernia surgery, when that too is only available for a minority of patients. With hernia surgery there is at least a substantial major article in the New England Journal of Medicine that suggests that the long-term results are very decidedly inferior to conventional operation, and I certainly would not wish to have a laparoscopic hernia repair for myself. There is no such easy "let-out clause" for laparoscopic colorectal cancer surgeons. In addition in "definition of terms" row-1, in my view clinicians should agree nationally on how the surgery is documented, what the criteria are etc., likewise under row-3 "definition of terms", in my view clinicians need to agree nationally on how decision-making on an individual basis etc., is documented for audit purposes."	The audit appendix has now been amended.
NHS Professional	Section 2: "Enhanced recovery programmes have drastically reduced post-operative pain and length of stay for open surgery. The same major complications will occur as frequently with either technique in reference to HDU care."	
	Section 3: "Many surgeons are now increasingly utilising smaller transverse incisions routinely for open colorectal cancer resections."	