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Dear Alana,

**Response to Assessment Report:  
Laparoscopic surgery for the treatment of colorectal cancer**

Thank you for the opportunity to respond to the above Assessment Report (AR). The report is extensive and summarises the available evidence fairly. Our response focuses therefore on the key issues that we feel could inform the Committee's discussion most productively in considering the value of laparoscopic (Lap) surgery for this indication.

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**Cost of Laparoscopic Surgery**

- We accept the costs presented in the assessment report, but suggest the cost difference highlighted within the report be considered to be towards the maximum end of the scale. The most relevant primary costing study undertaken within the UK demonstrated equal costs for Lap and open surgery (King *et al*).
- Similar variations in cost (i.e. £200 - £300) are likely to be evident between the best and worst performing Trusts that are currently only performing open surgery, simply driven by the results of their current clinical practice (e.g. regarding variations in length of stay and operating room occupancy).

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**Benefits of Laparoscopic Surgery**

- The main claims made for laparoscopic surgery concern the realisation of short-term benefits to the patient.
- These benefits are realised within the first month post surgery, and are listed in our original submission.
- The economic model, as it stands, explicitly excludes these short-term benefits, as they are difficult to quantify in QALY terms due to current limitations of evidence – as acknowledged within the Assessment Report.
- Even though the short-term benefits of Lap surgery are not included within the model, the assessment group still conclude that there is a 40% likelihood of Lap surgery being cost effective.

**Training**

- The assessment report recognises the current lack of trained laparoscopic surgeons within the UK.

- This is in part, a consequence of the existing NICE guidance. Sufficient numbers of surgeons will not be trained in this technique until NICE alters its existing guidance. It would be perverse for NICE to wait for sufficient surgeon availability before recommending Lap surgery for colorectal cancer.
- Training is rightly recognised as a critical issue for this appraisal by all stakeholders, an issue of lesser concern with many pharmaceutical appraisals undertaken by NICE. A detailed training programme for laparoscopic colorectal cancer surgery is in place, driven by the two key professional groups (The Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI)). The programme provides training, preceptorship and continuing mentoring for all surgeons enrolled.
- In addition, the UK training programme reinforces the need for appropriate patient selection for each procedure, which is matched to the surgeon's current position on the learning curve. This minimises the risk of a conversion to an open procedure, and focuses the surgeon on treating manageable cases at the appropriate time (e.g., mastering colon cases before attempting the arguably more difficult rectal cases). Implementation of any positive guidance within the UK would therefore be controlled and supported by the key professional groups.

### **Long-Term Clinical Outcomes**

- The three-year data presented within the assessment report demonstrates there is no clinical, or statistical, difference in overall survival or disease free survival between the Lap and Open approaches to surgery.
- It is therefore questionable whether numerically different survival times should be used within the economic model, when on the contrary no clinically and statistically meaningful short-term benefits have been included.

### **Other Clinical Considerations**

#### Conversion rates

- Appropriate patient selection, resulting from the co-ordinated training programme, should minimise conversion rates.

#### Incisional Hernia rates

- The evidence considered by the assessment group on incidence of incisional hernias is considered to be too narrow. The studies considered are limited in scope, for example dropout rates are not reported.
- Reviews of published evidence have reported that the determinant of incisional hernia rates is the length of the incision, not the surgical procedure<sup>1,2</sup>. A review of evidence from all abdominal surgery, not solely colorectal cancer, would therefore provide a better evidence base to inform the model, as suggested in our

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<sup>1</sup> Van't Riet M, Steyerberg WE et al., Meta-analysis of techniques for closure of midline abdominal incisions, British Journal of Surgery 2002, 89:1350-1356

<sup>2</sup> Rucinski J, Margolis M et al., Closure of the abdominal midline fascia:meta-analysis delineates the optimal technique, American Surgeon 2001, Vol 67:421-426

initial submission. A rapid review of available data has provided the following overview. The reference list is provided in Appendix 1:

<b>Hernia types</b>	<b>Y1</b>	<b>Y2</b>	<b>Y3</b>	<b>Note</b>
Incisional hernia after Open Surgery	0.066	0.088	0.095	Pooled data from 29 studies
Port site hernia after Lap Surgery	0.0028	0.0041	0.0068	Pooled data from 7 studies

## Summary

The short-term benefits of laparoscopic surgery to the patient are numerous. These have not been considered in the economic model, though they are undoubtedly meaningful and of value. We believe the evidence demonstrates that Lap surgery can be delivered for the same or little additional overall cost to the NHS. If the committee is minded to accept the Assessment Group's incremental cost estimate, then the decision is whether the short-term benefits are worth the additional cost. We believe they are even though direct utility evidence is lacking. If however the Committee requires further quantitative evidence, we suggest that the assessment group be requested to review their evidence on incisional hernia rates as discussed above. It is considered that the present parameters do not adequately represent the true clinical picture. If a higher incidence rate in open patients were incorporated in to the model, greater cost offsets would be observed. The cost of surgery to treat incisional hernia is between £1,300 and £2,000, and there were over 7,600 incisional hernia repairs undertaken in England alone during 2004. Incisional hernias are not a hypothetical issue.

A recommendation from NICE that laparoscopic surgery should be a treatment option for patients with colorectal cancer would allow provider Trusts the freedom to decide whether or not to develop a laparoscopic service, just as whether or not to implement an enhanced recovery programme, or some combination of both. This would also support the Patient Choice agenda. The Trust's ability to attract patients under the Patient Choice agenda, and deliver care within tariff under Payment by Results, should then decide which services, Lap and open, succeed or fail.

Yours sincerely

Adrian Griffin  
**Director of Health Outcomes**

## **Appendix 1**

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