

# **Laparoscopic surgery for inguinal hernia repair**

# Technology Appraisal Guidance 83

## Laparoscopic surgery for inguinal hernia repair

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

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NOTE: This guidance replaces Technology Appraisal Guidance No. 18 issued in January 2001.

The Institute reviews each piece of guidance it issues.

The review and re-appraisal of the use of laparoscopic surgery for inguinal hernia repair has resulted in changes in the guidance. Specifically there has been:

- a recommendation that laparoscopic surgery is one of the treatment options for the repair of inguinal hernia
- a recommendation that patients should be fully informed of all the risks and benefits of open and laparoscopic surgery by either the TAPP or TEP approaches, to enable them to choose between the procedures.

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# 1 Guidance

1.1 Laparoscopic surgery is recommended as one of the treatment options for the repair of inguinal hernia.

1.2 To enable patients to choose between open and laparoscopic surgery (either by the transabdominal preperitoneal [TAPP] or by the totally extraperitoneal [TEP] procedure), they should be fully informed of all of the risks (for example, immediate serious complications, postoperative pain/numbness and long-term recurrence rates) and benefits associated with each of the three procedures. In particular, the following points should be considered in discussions between the patient and the surgeon:

- the individual's suitability for general anaesthesia
- the nature of the presenting hernia (that is, primary repair, recurrent hernia or bilateral hernia)
- the suitability of the particular hernia for a laparoscopic or an open approach
- the experience of the surgeon in the three techniques.

1.3 Laparoscopic surgery for inguinal hernia repair by TAPP or TEP should only be performed by appropriately trained surgeons who regularly carry out the procedure.

# 2 Clinical need and practice

2.1 An inguinal hernia is a protrusion of a sac of peritoneum (often containing intestine or other abdominal contents) through a weakness in the abdominal wall in the groin. It usually presents as a lump, with or without some discomfort that may limit daily activities and the ability to work. Around 98% of inguinal hernias are found in men because of the vulnerability of the male anatomy to the formation of hernias in this region. Inguinal hernias can occasionally be life-threatening if the bowel within the peritoneal sac strangulates and/or becomes obstructed.

- 2.2 In England, there were approximately 70,000 surgical repairs of inguinal hernia in 2001/02, affecting 0.14% of the population and utilising over 100,000 NHS bed-days of hospital resources. Of these procedures, 62,969 were for the repair of primary hernias and 4939 for the repair of recurrent hernias.
- 2.3 Surgical repair (herniorraphy) is undertaken in most individuals presenting with inguinal hernia in order to close the defect, alleviate symptoms of discomfort, prevent serious complications (that is, obstruction or strangulation of the bowel) and reduce the risk of recurrence.
- 2.4 Most hernia repairs are undertaken as elective procedures. However, 4.8% of primary repairs and 8.6% of recurrent hernias present as an emergency with a complication. Some individuals present with bilateral hernias, which may be repaired during the same operation or at a later date, and up to 30% of people with a primary unilateral hernia subsequently develop a hernia on the opposite side.
- 2.5 Traditional methods of open repair (for example, the Bassini method), which repair the hernia defect by suturing, have not changed significantly since their introduction in the late 19th century. Recently, the availability of prosthetic meshes has led to an increase in the number of 'tension-free' methods of reinforcing the inguinal region. Open mesh methods of repair are classified as open flat mesh (OFM; for example, the Lichtenstein method), open preperitoneal mesh (OPPM; for example, the Stoppa and Nyhus methods) and open plug and mesh repair (OPM; for example, the Rutkow method). Open methods of hernia repair are associated with postoperative pain and numbness because of the large inguinal incision. OFM repairs are thought to be the principal surgical method of hernia repair in the UK.

### **3 The technology**

- 3.1 Laparoscopic surgery is a minimal-access technique that allows the hernia repair to be undertaken without the need to open the abdominal wall. Small incisions are made for the laparoscope and operating instruments, and

synthetic mesh is usually used to close the hernia and prevent recurrence. There are two main approaches for the laparoscopic repair of inguinal hernias.

- **Transabdominal preperitoneal (TAPP) repair** involves access to the hernia through the peritoneal cavity. Mesh is inserted through the peritoneum and placed over all potential hernia sites in the inguinal region. The peritoneum is then closed above the mesh.
- **Totally extraperitoneal (TEP) repair** is the newer laparoscopic technique, in which the hernia site is accessed via the preperitoneal plane without entering the peritoneal cavity. TEP repair is considered to be technically more difficult than the TAPP technique, but it may reduce the risk of damage to intra-abdominal organs.

3.2 The surgical approach to inguinal hernia repair is the main focus of this appraisal; other issues, such as comparisons between TAPP and TEP and the use of laparoscopic surgery in special subgroups (for example, bilateral or recurrent hernia), are subsidiary considerations.

3.3 The potential benefits of using a laparoscopic approach include reduced postoperative pain, earlier return to normal activities and a reduction in long-term pain and numbness. The repair of bilateral hernias (including occult hernias detected during contralateral inspection at the time of a unilateral repair) may be undertaken during the same operation.

3.4 Laparoscopic surgery is associated with additional costs, for the endoscopy system (video unit, monitor, endoscope and CO<sub>2</sub> insufflator) and instruments (staplers, diathermy scissors or ports), although these may be reusable. The cost of laparoscopic surgery is highly dependent on whether disposable or reusable equipment is used.

## 4 Evidence and interpretation

The Appraisal Committee (Appendix A) considered evidence from a number of sources (Appendix B).

### 4.1 *Clinical effectiveness*

- 4.1.1 Outcomes of interest, against which the effectiveness of laparoscopic and open surgery were assessed, were primary outcomes of recurrence and persistent pain, and secondary outcomes of the rate of complications and persistent numbness, the duration of the operation, length of hospital stay, time to return to normal activities and quality of life.
- 4.1.2 A systematic review of the literature identified 37 randomised controlled trials (RCTs) that compared laparoscopic with open mesh repair of inguinal hernias in a total of 5560 participants. The effectiveness of laparoscopic surgery compared with different methods of open surgery (OFM, OPPM and OPM) was presented separately for the TAPP and TEP laparoscopic methods of repair. The best available data (individual patient data, or aggregate data from studies) were used to generate a meta-analysis of the effectiveness of TAPP and TEP procedures for different outcomes of effectiveness.
- 4.1.3 Laparoscopic surgery was associated with a statistically significant increase in operation time compared with open methods of hernia repair. Meta-analysis of 16 RCTs of TAPP repair demonstrated an overall increase of 13.33 minutes (95% CI 12.08 to 14.57) compared with open repair. Meta-analysis of eight RCTs of TEP repair demonstrated an overall increase of 7.89 minutes (95% CI 6.22 to 9.57) compared with open repair.
- 4.1.4 Laparoscopic surgery was associated with a significantly shorter time to return to usual activities in all of the studies that measured this outcome. Meta-analysis of seven RCTs of TAPP repair reported a hazard ratio (HR) of 0.66 (95% CI 0.58 to 0.75;  $p < 0.00001$ ), corresponding to a return to normal activities approximately 3 days earlier than after open repair. Meta-analysis

of five RCTs of TEP repair reported an HR of 0.49 (95% CI 0.42 to 0.56;  $p < 0.00001$ ), approximating to a return to usual activities 4 days earlier than after open repair.

- 4.1.5 Both TAPP and TEP procedures demonstrated a statistically significant reduction in persistent numbness compared with open repair. Meta-analysis of eight RCTs comparing TAPP and open repair reported a relative risk (RR) of numbness of 0.26 (95% CI 0.17 to 0.40;  $p < 0.00001$ ) in favour of TAPP repair. Meta-analysis of four RCTs comparing TEP with open repair reported an RR of 0.67 (95% CI 0.53 to 0.86;  $p < 0.002$ ) in favour of TEP. One trial ( $n = 160$ ) that randomised patients to TAPP or OFM repair reported no significant difference (RR 1.00, 95% CI 0.06 to 15.71 for TAPP) between the two techniques. Another trial that randomised 254 patients to TEP or OFM repair reported no significant difference (RR 2.57, 95% CI 0.11 to 62.38) between the two techniques. One RCT of TAPP compared with open repair showed that the reduction in numbness was maintained at 5-year follow-up (3% persistent numbness with TAPP compared with 23% with OFM repair).
- 4.1.6 Overall, there were fewer cases of persistent pain at 1 year post-operation after laparoscopic repair, compared with open repair, in both TAPP and TEP studies. Meta-analysis of eight RCTs of TAPP repair reported an RR of 0.72 (95% CI 0.58 to 0.88;  $p = 0.001$ ) in favour of TAPP. Meta-analysis of four RCTs of TEP repair reported an RR of 0.77 (95% CI 0.64 to 0.92;  $p = 0.004$ ) in favour of TEP repair. One RCT of TAPP compared with open repair showed that the reduction in pain was maintained at 5-year follow-up (2% persistent pain with TAPP compared with 10% with OFM repair).
- 4.1.7 The rates of recurrence were similar for laparoscopic and open repair. Meta-analysis of 15 TAPP RCTs reported a total of 26 recurrences out of 1052 TAPP procedures (2.5%) compared with 22 recurrences out of 1062 open repair procedures (2.1%; RR 1.18, 95% CI 0.69 to 2.02). Thirteen RCTs of TEP repair reported a total of 23 recurrences out of 1007 TEP repairs

(2.3%), compared with 13 recurrences out of 1002 open repair procedures (1.3%; RR 1.61, 95% CI 0.87 to 2.98).

- 4.1.8 A number of studies reported the incidence of adverse events (complications such as haematoma, seroma, wound-related infection, mesh infection, vascular or visceral injuries and port-site hernia). Laparoscopic repair (both TAPP and TEP) was associated with fewer cases of wound-related infection and haematoma. However, TAPP repair was associated with a higher incidence of vascular and visceral injuries compared with open repair (0.13% vascular injuries with TAPP compared with 0% with TEP and open repair; 0.79% visceral injuries with TAPP compared with 0.16% with TEP and 0.14% with open repair).
- 4.1.9 One RCT randomised 52 patients with unilateral inguinal hernia to TAPP (n=28) or TEP (n=24) repair. There were no statistically significant differences between the procedures in terms of the duration of operation, intra-operative complications, incidence of haematoma, recurrence at 3-month follow-up, or time to return to usual activities.
- 4.1.10 There were no direct comparisons of TAPP and TEP methods of laparoscopic repair in patients with bilateral or recurrent hernia. Trials that evaluated the effectiveness of laparoscopic surgery compared with various forms of open surgery (OFM, OPPM and OPM) in the repair of recurrent inguinal hernias (six trials of TAPP and five trials of TEP) and bilateral inguinal hernias (six trials of TAPP and six trials of TEP) were consistent with the overall results for primary surgery of unilateral inguinal hernias.
- 4.1.11 The Assessment Group evaluated the effect of surgeons' experience on the duration of operation for laparoscopic repair (the 'learning effect'). Inexperienced surgeons (up to 20 procedures) were estimated to perform TAPP procedures in 70 minutes and TEP procedures in 95 minutes, compared with experienced surgeons, who were estimated to perform TAPP procedures in 40 minutes and TEP procedures in 55 minutes.

4.1.12 A recent study, published after the Assessment Group's initial review, randomised 2164 patients to laparoscopic surgery (10% TAPP, 90% TEP) or to OFM repair. Many of the results of this study were broadly consistent with the findings of the systematic review and did not affect the pooled results when they were incorporated into meta-analysis. This study reported a statistically significant increase in the recurrence rate with laparoscopic surgery (10.1% for TAPP and TEP combined compared with 4.9% after open repair at 2-year follow up, odds ratio [OR] 2.2, 95% CI 1.5 to 3.2). When the recurrence rates from the recent study were incorporated into meta-analysis of TEP compared with OFM repair, the RR of recurrence associated with laparoscopic surgery was increased from 1.61 (95% CI 0.57 to 4.60), in the original report, to 2.0 (95% CI 1.43 to 2.81). The incidence of serious complications was also significantly higher with laparoscopic repair (1.1%; TAPP and TEP combined) compared with open repair (0.1%; OR 11.2, 95% CI 1.3 to 1.7), although this had little effect on the results when incorporated into the meta-analysis. This study also reported a reduction in persistent pain after laparoscopic compared with open repairs (9.8% after laparoscopic surgery compared with 14.3% after open repair).

## **4.2 Cost effectiveness**

- 4.2.1 The literature review identified seven economic evaluations of laparoscopic surgery for inguinal hernia repair – three based on economic models and four based on primary studies. Only two studies (submitted by Ethicon Endo-Surgery and BARD Ltd) were relevant to the UK setting.
- 4.2.2 Ethicon Endo-Surgery provided a re-analysis of data from the MRC Laparoscopic Groin Hernia Trial, taking into consideration the repair of occult bilateral hernias. This model was based on the assumption that bilateral repairs in 30% of people with occult hernias would prevent the need for subsequent operation, and reduced the incremental cost effectiveness ratio (ICER) for laparoscopic surgery from £55,549 per quality-adjusted life year (QALY), as reported in the MRC Laparoscopic Groin Hernia Trial, to

£15,000 per QALY. However, the model did not take into account the possibility that some people with occult hernias would not develop a clinically significant hernia.

- 4.2.3 The BARD submission compared the cost effectiveness of the Perfix plug (used in OPM repairs) with that of laparoscopic surgery on the basis of data presented in the previous guidance, issued in 2001 (see Section 8). BARD estimated that open plug and mesh repairs may be cost saving on the basis of assumptions that the additional device cost may be offset by reductions in the recurrence rate (0.5% Perfix plug compared with 2.2% with laparoscopic surgery reported in the previous guidance) and an increase in the number of perfix plug repairs undertaken as less costly day cases (91% perfix plug and 60% laparoscopic repairs undertaken as day cases).
- 4.2.4 The Assessment Group developed a Markov model that updates the paper by Vale I, Grant A and McCormack K (unpublished data 2003). The cost and outcome of various laparoscopic (TAPP and TEP) and open (OFM, OPPM and OPM) techniques were assessed in 1-year cycles over 5- and 25-year time horizons. All individuals entered the model at the point of initial hernia repair. In the first year, survivors were assumed to undergo a 3-month period of convalescence and then to return to full health. In subsequent years, individuals could be in a health state of no recurrence (with or without persistent pain or numbness), recurrent hernia proceeding to re-operation, recurrence without re-operation (at risk of emergency surgery for complications), or death (operative and all-cause mortality).
- 4.2.5 Inputs to the economic model on the costs and EQ5D utility estimates for the different health states were based on data from the MRC Laparoscopic Groin Hernia Trial. Theatre costs (£6.40 per minute) and in-hospital costs (£236 per day) were similar for open and laparoscopic procedures. The additional equipment and consumable costs of laparoscopic surgery were £167 per procedure when using predominantly reusable equipment (assuming all reusable devices are used on average 250 times a year for

5 years), or £788 per procedure when predominantly disposable equipment is used. Baseline estimates for operation length, hospital stay, operative mortality, recurrence, re-operation, persistent pain and numbness, time away from usual activities and health state utilities were taken from the best available data identified during this systematic review. Relative differences in the effectiveness of the different methods of open and laparoscopic repair were based on the meta-analysis results for the various outcomes, which were applied to these baseline parameters. Probabilities, costs and utilities were not considered to be fixed but were assigned a probability distribution to reflect uncertainty about their values. The same annual risk of recurrence, pain, numbness and relative effect sizes was used for primary and subsequent procedures. A constant annual risk for persistent pain, numbness and recurrence was assumed when extrapolating from years 6 to 25 of the model.

- 4.2.6 The results from the model showed that laparoscopic surgery (using reusable equipment) was associated with an increased cost of between £100 and £400 per procedure. Also, QALY differences between all of the techniques were small. Incremental analysis found the OPM method to be the most cost-effective method of open repair, driven by the duration of operation and hospital stay, which was the shortest with this procedure. However, when the same duration of operation and of hospital stay were assumed for all open procedures, the costs of OPM and OPPM techniques increased compared with OFM, and OFM became the most cost-effective method of open repair. TEP dominated TAPP, as it was less costly and more effective than the TAPP method of repair. The incremental cost of laparoscopic surgery compared with OFM was between £5000 and £12,000 per QALY at 5 years and between £2000 and £5000 per QALY at 25 years for TEP and TAPP, respectively. When the cost effectiveness of laparoscopic surgery was compared with OPM repair, laparoscopic surgery was not cost effective (with an ICER of £46,000–£606,000), and TEP was only cost effective (£20,000 per QALY) if the benefits extended for 25 years.

- 4.2.7 Sensitivity analysis for differences in the costs, utility and relative effectiveness of different methods of open and laparoscopic repair was undertaken to evaluate the effect of uncertainty in these areas; most of these had little effect on the cost effectiveness of laparoscopic surgery. However, the cost effectiveness of laparoscopic repair was shown to be highly dependent on the cost of the open repair comparator.
- 4.2.8 Sensitivity analysis that assumed that laparoscopic surgery did not improve the level of persistent numbness compared with OFM, increased the ICER of TEP from £2000 per QALY at baseline to £4000 per QALY at 25 years. Sensitivity analysis that assumed that laparoscopic surgery did not improve the level of persistent pain, increased the ICER of TEP from £2000 per QALY at baseline to £8000 per QALY at 25 years. Assumptions that laparoscopic surgery did not confer any benefits of reduced persistent pain or numbness increased the ICER of TEP to approximately £100,000 per QALY at 25 years. The use of reusable (approximately £170 per procedure) or disposable (approximately £790 per procedure) equipment in laparoscopic surgery had a huge impact on the cost effectiveness of surgery. Laparoscopic surgery using disposable equipment increased the ICER of TEP from £2000 per QALY at baseline to £14,000 per QALY at 25 years. In a separate analysis, the Assessment Group modelled the effect of repairing occult bilateral hernias on the cost effectiveness of laparoscopic surgery. This led to an increase in the cost of laparoscopic surgery compared with OFM, and a reduction in the probability of recurrence (as it has already been repaired) in the first year, increasing the ICER of TEP from £5000 per QALY at baseline to up to £10,000 per QALY at 5 years, depending on the prevalence and rate of progression of occult hernia.
- 4.2.9 A supplementary analysis was undertaken by the Assessment Team in order to evaluate the effect of inclusion of new data from the study published after completion of the original report (4.1.12). This also incorporated a number of sensitivity analyses evaluating the cost effectiveness of laparoscopic surgery, using data from the most recent trial, which led to

more conservative estimates of the reduction in persistent pain and an increased RR of hernia recurrence with laparoscopic repair. Thus when the baseline recurrence rate for all laparoscopic surgery was increased from a cumulative rate of approximately 3% in the original base-case analysis to 10% at 2 years (based on the recent paper), the ICER of TEP compared with OFM was £6500 per QALY at a 25-year time horizon. When the RR of persistent pain was reduced from 0.77 in the original model, to 0.69 based on the results of the recent study, the ICER of TEP compared with OFM repair was £4000 per QALY at a 25-year time horizon. With these scenarios TAPP and TEP were associated with costs and effects that were increasingly similar.

### **4.3 Consideration of the evidence**

- 4.3.1 The Committee reviewed the data available on the clinical and cost effectiveness of laparoscopic surgery for inguinal hernia repair, having considered evidence on the nature of the condition and the value placed on the benefits of laparoscopic surgery for inguinal hernia repair by people with the condition, those who represent them, and clinical experts. It was also mindful of the need to take account of the effective use of NHS resources.
- 4.3.2 The Committee heard evidence from experts that the incision resulting from open hernia repair may cause damage to the tissues and nerves, leaving some people with long-term pain and numbness. Experts further advised that all the open methods of repair (OFM, OPPM and OPM) would be expected to have similar incidences of persistent pain and numbness.
- 4.3.3 The Committee considered carefully the evidence from the RCTs on the potentially higher incidences of visceral and vascular injuries associated with laparoscopic hernia repair compared with open procedures. In addition, the evidence from the RCTs suggests that the incidences of these important adverse events may be different between the two laparoscopic procedures. Experts advised that this may have been a result of the relative lack of experience of surgeons in some of these early studies, and advised that

there is currently no significant difference in the rate of adverse events between the two laparoscopic procedures when performed by experienced surgeons. The Committee considered carefully the recent study (4.1.12), which reported a significantly higher incidence of serious complications with laparoscopic repair compared with open repair (although this was not reported separately for TAPP and TEP repairs). Many of the adverse events may have been related to the effects of the general anaesthetic used in the patients undergoing laparoscopic repair coupled with the relatively poorer general health of patients recruited into this study (that is, two-thirds in ASA groups II and III) compared with patients included in the original systematic review. However, the Committee were persuaded that the patients in this trial were probably representative of the unselected patients undergoing operations for inguinal hernia in the NHS and therefore considered that inclusion of the data from this study in the overall analysis was appropriate.

4.3.4 The Committee appreciated that differences in the outcomes and adverse events of laparoscopic surgery, which may occur in practice and are apparent in the recent study (4.1.12), could result from differences in surgical experience. The Committee were persuaded that ongoing evaluation and review of the results of laparoscopic hernia repair was important and that this should be established at a national level to ensure that potentially serious events are identified and recorded in individual centres.

4.3.5 The Committee considered the uncertainty over the recurrence rate associated with laparoscopic surgery, which was statistically significantly higher than that associated with open repair when data from the recent study were incorporated. The Committee concluded that the risk of recurrence which was relatively low with both procedures, and that the increased risk of recurrence with laparoscopic surgery may be acceptable for some patients when the benefits (reduced pain and numbness, and earlier return to normal activities) are taken into consideration.

- 4.3.6 In summary, the Committee considered that laparoscopic repair of inguinal hernia was likely to result in considerably less postoperative pain and numbness than open repair. However, there was uncertainty over the rates of recurrence and of serious complications associated with laparoscopic surgery for primary repairs, which may be higher than those associated with the open procedure. On balance, the Committee concluded that laparoscopic surgery would be the preferred technique for the repair of recurrent hernias (as scar tissue from previous open repairs may be avoided) and bilateral hernias (repaired during the same operation and should also be an option for primary repair of unilateral hernias because of the reduced incidence of long-term pain and numbness and the potential for earlier return to normal activities).
- 4.3.7 The Committee considered that current evidence did not suggest which of the two available laparoscopic methods should be preferred for routine surgery, and noted the importance of the individual surgeon's experience in each method as a factor in determining the best choice. The Committee was advised that the TAPP approach enabled the surgeon to both view, and if required, effect a repair of an occult hernia on the contralateral side during a primary repair procedure. The TEP approach also allowed an occult hernia on the contralateral side to be seen, but required more dissection to facilitate repair.
- 4.3.8 The Committee was aware that laparoscopic (TAPP and TEP) methods of repair are technically more demanding than open repair, and that the clinical and the cost effectiveness of laparoscopic hernia repair are closely linked to the experience of the surgeon in the technique. The Committee heard evidence from experts that whilst surgeons are being trained in laparoscopic surgery, there is likely to be an increase in the duration of the operation, but were persuaded that this would not affect the overall longer-term cost effectiveness of the procedure. The Committee was persuaded of the importance of ensuring appropriate standards of training for laparoscopic hernia repair. They considered that, in light of the relatively small number of

surgeons currently proficient in laparoscopic techniques (as compared with those undertaking open repair procedures), further training of surgeons in laparoscopic methods of repair will be required before this procedure can be more widely adopted.

- 4.3.9 The Committee considered it important that individuals be advised of the potential risk of complications associated with laparoscopic surgery. Laparoscopic surgery would not be appropriate for all, particularly those people unable to undergo or at higher risk from general anaesthesia, or in situations where the size or location of the hernia defect does not lend itself to laparoscopic surgery. Experts advised that individual surgeons tend to have a favoured method of open or laparoscopic repair. The Committee concluded that individuals should be given impartial advice as to the relative risks and benefits of laparoscopic repair compared with open repair during discussions with the surgeon at the time of referral, in order to facilitate an informed choice.
- 4.3.10 The Committee reviewed the data on the cost effectiveness of laparoscopic repair compared with the different methods of open repair, and considered the OFM technique to be the most clinically relevant comparator because it is the most common method of open repair and because of the absence of long-term data on the costs and outcomes of newer techniques (OPPM and OPM). The Committee considered that, taking all data reviewed into account, laparoscopic surgery (TAPP and TEP) is a cost-effective alternative to OFM repair. However, they noted that the choice of disposable or reusable equipment for use in laparoscopic hernia repairs had a significant effect on the ICER of the procedure. The Committee were therefore persuaded that, wherever possible, the use of reusable equipment was to be preferred.

## **5 Recommendations for further research**

- 5.1 The Institute recommends that further trials be undertaken to evaluate the utility of individuals undergoing laparoscopic surgery at 1 year and longer follow-up (where possible, up to 25 years) to provide long-term data on the cost effectiveness of this technique.
- 5.2 The issue of chronic pain and numbness after inguinal hernia repair should be addressed prospectively in future studies, using standard definitions to allow for assessment of the degree of pain.
- 5.3 It is recommended that a registry be set up to monitor the incidence of serious adverse events (specifically the rates of visceral and vascular injury) associated with laparoscopic hernia repair and recurrence rates.

## **6 Implications for the NHS**

- 6.1 Approximately 70,000 surgical inguinal hernia repairs are performed in England each year, at a cost to the NHS of £56 million a year. In the year 2001/02, 95.9% of mesh repairs were performed by open surgery, and 4.1% of repairs were performed by laparoscopic surgery.
- 6.2 The anticipated costs of adopting laparoscopic surgery are based on the degree of diffusion of this technique. However, experts advised that, for the foreseeable future, it is unlikely that the uptake of laparoscopic surgery would exceed 40% of all surgical hernia repairs. If the annual percentage of laparoscopic repairs increased to 20%, the additional cost to the NHS in England would be approximately £1 million (based on the number and cost of hernia repairs in 2001/02 of £1078 for laparoscopic and £987 for open mesh repairs).
- 6.3 The cost effectiveness of laparoscopic surgery for inguinal hernia repair is influenced by:

- the number of laparoscopic procedures performed per annum and the experience of the operating surgeon
- the use of disposable or reusable laparoscopic equipment
- the rates of hernia recurrence, serious complications and persistent pain (and its severity).

6.4 The duration of surgery is directly linked to the experience of the surgeon: the duration of laparoscopic surgery decreases as the operating surgeon's experience increases, and this should reduce the costs attributable to theatre time. Operating costs for open and laparoscopic repairs done by experienced surgeons are likely to be similar.

6.5 Hospital policy as to the use of reusable or disposable consumables will also have a significant impact on the cost of laparoscopic surgery. Reusable equipment for laparoscopic surgery costs about £170 per procedure compared with disposable equipment, which costs about £790 per procedure.

6.6 Regional variations in the implementation costs of this guidance are likely, depending on the degree to which laparoscopic surgery is taken up locally, and on variations in hospital policy towards, for example, the use of reusable or disposable equipment.

## **7 Implementation and audit**

7.1 Surgical services in NHS organisations should review their current practice and policies relating to repair of inguinal hernia to take account of the guidance set out in Section 1.

7.2 Local guidelines or care pathways for people who undergo surgery for repair of inguinal hernia should incorporate the guidance, considering the availability of a surgeon who is trained and experienced in laparoscopic surgery for the repair of inguinal hernia.

7.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C.

7.3.1 Laparoscopic surgery is considered as one of the treatment options for the repair of inguinal hernia. In choosing between open and laparoscopic surgery (either the TEP or TAPP procedures), the following are considered:

- the suitability of the individual for general anaesthesia
- the nature of the presenting hernia
- the suitability of the particular hernia for a laparoscopic or open approach
- the experience of the surgeon in the three techniques.

7.3.2 The individual undergoing repair of inguinal hernia is fully informed of all the risks and benefits associated with open surgery and laparoscopic surgery by both the TEP and TAPP procedures as part of the informed consent process.

7.3.3 Laparoscopic surgery for inguinal hernia repair by TAPP or TEP is performed only by a surgeon who has received appropriate training and regularly carries out the procedure.

## **8 Related guidance**

8.1 The Institute issued the original guidance on the use of laparoscopic repair of inguinal hernia in January 2001.

National Institute for Clinical Excellence (2001) Guidance on the use of laparoscopic surgery for inguinal hernia. *NICE Technology Appraisal Guidance* No. 18. London: National Institute for Clinical Excellence. Available from [www.nice.org.uk/cat.asp?c=20663](http://www.nice.org.uk/cat.asp?c=20663)

## **9 Review of guidance**

9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of an updated Assessment Report, and decide whether the technology should be referred to the Appraisal Committee for review.

9.2 The guidance on this technology will be reviewed in September 2007.

Andrew Dillon  
Chief Executive  
September 2004

## **Appendix A. Appraisal Committee members and NICE project team**

### **A. Appraisal Committee members**

**NOTE** The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets three times a month except in December, when there are no meetings. The Committee membership is split into three branches, with the chair, vice-chair and a number of other members between them attending meetings of all branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

#### **Dr Darren Ashcroft**

Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences,  
University of Manchester

#### **Professor David Barnett (Chair)**

Professor of Clinical Pharmacology, University of Leicester

#### **Dr Peter Barry**

Consultant in Paediatric Intensive Care and Honorary Senior Lecturer, Department  
of Child Health, Leicester Royal Infirmary

**Mr Brian Buckley**

Vice Chairman, InContact

**Professor Mike Campbell**

Statistician, Institute of General Practice & Primary Care, Sheffield

**Dr Mark Chakravarty**

Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK) Ltd, Egham, Surrey

**Dr Peter I Clark**

Consultant Medical Oncologist, Clatterbridge Centre for Oncology, Wirral, Merseyside

**Dr Mike Davies**

Consultant Physician, University Department of Medicine & Metabolism, Manchester Royal Infirmary

**Mr Richard Devereaux-Phillips**

Public Affairs Manager, Medtronic Ltd

**Professor Cam Donaldson**

PPP Foundation Professor of Health Economics, School of Population and Health Sciences & Business School, Business School – Economics, University of Newcastle upon Tyne

**Professor Jack Dowie**

Health Economist, London School of Hygiene

**Professor Gary A Ford (Vice Chair)**

Professor of Pharmacology of Old Age/Consultant Physician, Newcastle upon Tyne Hospitals NHS Trust

**Dr Fergus Gleeson**

Consultant Radiologist, The Churchill Hospital, Oxford

**Ms Sally Gooch**

Director of Nursing, Mid-Essex Hospital Services NHS Trust, Chelmsford

**Professor Trisha Greenhalgh**

Professor of Primary Health Care, University College London

**Miss Linda Hands**

Clinical Reader in Surgery, University of Oxford

**Professor Peter Jones**

Professor of Statistics and Dean, Faculty of Natural Sciences, Keele University

**Professor Robert Kerwin**

Professor of Psychiatry and Clinical Pharmacology, Institute of Psychiatry, London

**Ms Joy Leavesley**

Senior Clinical Governance Manager, Guy's and St Thomas' NHS Trust

**Ms Ruth Lesirge**

Previously Director, Mental Health Foundation, London

**Ms Rachel Lewis**

Staff Nurse (Nephrology), Hull Royal Infirmary

**Dr Ruairidh Milne**

Senior Lecturer in Public Health, National Coordinating Centre for Health Technology Assessment, University of Southampton

**Dr Neil Milner**

General Medical Practitioner, Sheffield

**Dr Rubin Minhas**

General Practitioner with a Special Interest in Coronary Heart Disease, Primary Care CHD Lead, Medway PCT & Swale PCT

**Mr Muntzer Mughal**

Consultant Surgeon, Lancashire Teaching Hospitals NHS Trust

**Professor Mark Sculpher**

Professor of Health Economics, University of York

**Dr Ken Stein**

Senior Lecturer, Peninsula Technology Assessment Group (PenTAG), University of Exeter

**Professor Andrew Stevens (Chair)**

Professor of Public Health, University of Birmingham

**B. NICE Project Team**

Each appraisal of a technology is assigned to a Health Technology Analyst and a Technology Appraisal Project Manager within the Institute.

**Eleanor Donegan**

Technical Lead, NICE project team

**Dr Sarah Cumbers**

Project Manager, NICE project team

## Appendix B. Sources of evidence considered by the Committee

A The Assessment Report for this appraisal was prepared by the Health Services Research Unit and the Health Economics Research Unit, University of Aberdeen.

- McCormack K, Wake B, Perez J et al. *Systematic review of the effectiveness and cost-effectiveness of laparoscopic surgery for inguinal hernia repair*, December 2003.
- McCormack K, Vale L, Grant A. *Supplement to the systematic review of the clinical effectiveness and cost-effectiveness of laparoscopic surgery for inguinal hernia repair*, May 2004

B The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination.

I Manufacturer/sponsors:

- Atrium Medical Corporation
- BARD Ltd
- Conmed Corporation
- Cory Brothers (Hosp Contracts) Co. Ltd
- Ethicon Endo-Surgery
- Eurosurgical Ltd
- Gyrus Medical Limited
- Karl Storz Endoscopy (UK) Ltd

- Keymed (Medical & Industrial Equipment) Ltd
- Mantis Surgical Ltd
- Medical Innovations (Service Centre) Ltd
- Nikomed Limited
- Optec (UK) Ltd
- Pentax UK Ltd
- Richard Wolf UK Ltd
- Rimmer Bros/RB Endoscopy
- Rocket Medical Plc
- Skymed Ltd
- Smith & Nephew Healthcare Ltd
- Tyco Ltd
- W. L. Gore & Associates

II Professional/specialist and patient/carer groups:

- ABHI
- Association of Endoscopic Surgeons of Great Britain and Ireland
- Association of Operating Department Practitioners
- Association of Surgeons of Great Britain and Ireland
- British Association of Day Surgery
- Department of Health
- EUCOMED
- Men's Health Forum
- National Association of Theatre Nurses
- Royal College of Nursing

- Royal College of Surgeons
- South Manchester PCT
- South Worcestershire PCT
- Welsh Assembly Government

III Commentator organisations (without the right of appeal):

- British Medical Association
- Health Services Research Unit, University of Aberdeen
- National Coordinating Centre for Health Technology Appraisals (NCCHTA)
- NHS Confederation
- NHS Information Authority
- NHS Purchasing and Supplies Agency
- NHS Quality Improvement Scotland

C The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on laparoscopic surgery for inguinal hernia repair by attending the initial Committee discussion and/or providing written evidence to the Committee. They were also invited to comment on the ACD.

- Professor M Bailey, President, Association of Endoscopic Surgeons of Great Britain & Ireland, representing the Association of Endoscopic Surgeons of Great Britain & Ireland.
- Mr DJ McCormack, Vice President, Association of Operating Department Practitioners, representing the Association of Operating Department Practitioners.

## **Appendix C. Detail on criteria for audit of the use of laparoscopic surgery for inguinal hernia repair**

### ***Possible objectives for an audit***

An audit could be carried out on the appropriateness of the use of laparoscopic surgery for inguinal hernia to ensure the following.

- Laparoscopic surgery is considered as one of the treatment options for the repair of inguinal hernia.
- Individuals are fully informed of the risks and benefits of alternative procedures.
- Surgeons carry out laparoscopic surgery for the repair of inguinal hernia only after receiving appropriate training and experience.

### ***Possible patients to be included in the audit***

An audit could be carried out on all people referred for repair of inguinal hernia in a reasonable time period for audit, for example, 6 months or 1 year.

### ***Measures that could be used as a basis for an audit***

The measures that could be used in an audit of laparoscopic surgery for inguinal hernia are as follows.

<b>Criterion</b>	<b>Standard</b>	<b>Exception</b>	<b>Definition of terms</b>
1. Laparoscopic surgery is considered as one of the treatment options for the repair of inguinal hernia	100% of the people referred for repair of inguinal hernia	None	Surgeons will need to agree locally on how consideration of laparoscopic surgery as a treatment option is recorded for audit purposes. In choosing between open and laparoscopic surgery, the following are considered: (a) the individual's suitability for general anaesthesia; (b) the nature of the presenting hernia; (c) the suitability of the particular hernia for laparoscopic or open approach; (d) the experience of the surgeon in open and laparoscopic procedures. 'Laparoscopic surgery' means the TEP or the TAPP procedure. 'Nature of the presenting hernia' means primary repair, recurrent hernia or bilateral hernias. 'Experience of the surgeon' refers to all three techniques, open surgery and the TEP or TAPP laparoscopic procedures.
2. The individual undergoing repair of inguinal hernia is fully informed of all the risks and benefits associated with open and laparoscopic surgery through the informed consent process	100% of people referred for repair of inguinal hernia	None	'Risks' include immediate serious complications, post-operative pain or numbness and long-term recurrence. 'Laparoscopic surgery' means either the TEP or the TAPP procedure. Clinicians will need to agree locally on how an individual is determined to be 'fully informed' of risks and benefits for audit purposes.
3. Laparoscopic repair of inguinal hernia is	100% of people having laparoscopic	None	Clinicians will need to agree locally on what constitutes 'appropriate

performed only by a surgeon who: a. has received appropriate training <b>and</b> b. regularly carries out the procedure	repair of inguinal hernia		training' and how many procedures are needed in a given time period to count as 'regularly' carrying out the procedure.
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### ***Calculation of compliance***

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

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

Clinicians should review the findings of measurement, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.