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Stapled haemorrhoidopexy for the treatment of haemorrhoids

NICE technology appraisal guidance 128 Stapled haemorrhoidopexy for the treatment of haemorrhoids

Ordering information

You can download the following documents from www.nice.org.uk/TA128

- The full guidance (this document).
- A quick reference guide for healthcare professionals.
- Information for people with haemorrhoids and their carers ('Understanding NICE guidance').
- Details of all the evidence that was looked at and other background information.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone the NHS Response Line on 0870 1555 455 and quote:

- N1334 (quick reference guide)
- N1335 ('Understanding NICE guidance').

This guidance is written in the following context

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

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1 Guidance

This technology appraisal examined the currently available devices for stapled haemorrhoidopexy. The evidence considered refers to the HCS33 circular stapler (models PPH01 and PPH03, Ethicon Endo-Surgery). At the time of the technology appraisal, there was no evidence to make recommendations for the Autosuture stapler with the STRAM kit adaptor.

- 1.1 Stapled haemorrhoidopexy, using a circular stapler specifically developed for haemorrhoidopexy, is recommended as an option for people in whom surgical intervention is considered appropriate for the treatment of prolapsed internal haemorrhoids.

2 Clinical need and practice

- 2.1 Haemorrhoidal tissue is a normal component of the anal canal and is composed predominantly of vascular tissue, supported by smooth muscle and connective tissue. It functions as a compressible lining that allows the anus to close completely. Internal haemorrhoids (also known as piles) are located beneath the lining of the anus and occur when the haemorrhoidal tissue of the distal rectum and anal canal prolapses. Internal haemorrhoids are usually classified according to the degree of prolapse, although this may not reflect the severity of the person's symptoms. First-degree haemorrhoids bleed but do not prolapse. Second-degree haemorrhoids prolapse on straining during bowel movements, and reduce spontaneously. Third-degree haemorrhoids prolapse on straining and require manual reduction. Fourth-degree haemorrhoids are prolapsed and cannot be manually reduced.
- 2.2 A number of factors are known to be associated with the development of haemorrhoids, including increasing age, pregnancy and childbirth, chronic constipation, chronic diarrhoea, and family history of haemorrhoids. Estimates of the proportion of the UK population affected range from 4.4% to 24.5%. In 2004–5,

approximately 23,000 haemorrhoidal procedures were carried out in England, of which approximately 8000 were excisional interventions.

2.3 Internal haemorrhoids may cause anal itching and irritation, bleeding during bowel movements and perianal pain. They sometimes protrude from the anus during bowel movements or may prolapse or extend outside the anus. External haemorrhoids can also occur. These are located near the anus and, although they cannot prolapse, may bleed if ruptured.

2.4 First- and second-degree internal haemorrhoids are generally treated by changing bowel habit, diet and lifestyle, and by using stool softeners or laxatives. For second-degree haemorrhoids, injection sclerotherapy, rubber-band ligation or infrared coagulation may also be used. Surgical haemorrhoidectomy is usually the treatment of choice for third- and fourth-degree haemorrhoids, prolapsed second-degree haemorrhoids that have not responded to non-surgical interventions and second-degree haemorrhoids with full circumferential involvement. Surgical haemorrhoidectomy is usually performed by the Milligan-Morgan (open) or Ferguson (closed) procedure. The Milligan-Morgan procedure involves dissection of the haemorrhoid and ligation of the vascular pedicle. The wounds are left open to heal naturally. The Milligan-Morgan procedure is thought to be relatively safe and effective for managing advanced haemorrhoidal disease, but because the anodermal wounds are left open healing is delayed, which may result in discomfort and prolonged postoperative morbidity. The Ferguson procedure is a modified version of the Milligan-Morgan technique, in which the wound is closed with a continuous suture to promote healing. A number of postoperative complications are associated with surgical haemorrhoidectomy. The short-term complications include pain, urinary retention, bleeding and perianal sepsis. Long-term complications may include anal fissure, anal

stenosis, incontinence, fistula, and the recurrence of haemorrhoidal symptoms.

3 The technology

3.1 Stapled haemorrhoidopexy is a technique that reduces the prolapse of haemorrhoidal tissue by excising a band of the prolapsed anal mucosa membrane above the dentate line, using a specific circular stapling device. This interrupts the blood supply to the haemorrhoids and reduces the potential for available rectal mucosa to prolapse. The procedure is referred to as a 'pexy' because the haemorrhoidal tissue is not excised as in conventional haemorrhoidectomy. Stapled haemorrhoidopexy is also known as 'procedure for prolapse and haemorrhoids' (PPH), stapled anopexy, stapled prolapsectomy and stapled mucosectomy. It has been used in the UK for at least 2 to 3 years.

3.2 Two devices were identified in this appraisal: the HCS33 device (models PPH01 and PPH03, Ethicon Endo-Surgery) and the Autosuture stapler (Tyco Healthcare), which can be used in conjunction with the STRAM kit adaptor to perform haemorrhoidopexies.

3.3 The cost of the HCS33 PPH03 stapling device, the model currently in use, is £420 based on the submission from Ethicon Endo-Surgery. Costs may vary in different settings because of negotiated procurement discounts. The cost of the Autosuture stapler with the STRAM kit adaptor was not available.

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 The Assessment Group identified 27 randomised controlled trials (RCTs) of stapled haemorrhoidopexy, 19 of which were also included in the Ethicon Endo-Surgery submission. The Assessment Group included studies that compared stapled haemorrhoidopexy with the Milligan-Morgan, Ferguson, Anderson, Fransler and Parks surgical procedures. The studies identified by the Assessment Group all evaluated the HCS33 stapling device (PPH01 model). None was identified that evaluated the Autosuture device for stapled haemorrhoidopexy (Autosuture stapler in conjunction with the STRAM kit adapter). The Ethicon Endo-Surgery submission included studies of the PPH01 and the CDH33 device, which is for general colorectal surgery, and included studies that compared stapled haemorrhoidopexy with the Milligan-Morgan or Ferguson procedure.
- 4.1.2 The Assessment Group found that stapled haemorrhoidopexy, compared with conventional haemorrhoidectomy, was associated with less pain up to 14 days postoperatively in 95% of identified studies. There was significant statistical heterogeneity, so a meta-analysis was not carried out. Ethicon Endo-Surgery undertook two meta-analyses. The first, a meta-analysis of four studies measuring pain 24 hours postoperatively, identified a statistically significantly greater reduction in early postoperative pain with stapled haemorrhoidopexy compared with conventional Milligan-Morgan haemorrhoidectomy (weighted mean difference [WMD] in visual analogue scale [VAS] score -3.11 , 95% confidence interval [CI] -5.37 to -0.85). The second, a meta-analysis of two studies, showed a statistically significant reduction in early postoperative pain with stapled haemorrhoidopexy compared with the Ferguson haemorrhoidectomy (WMD in VAS score -2.77 , 95% CI -3.35 to -2.20).

- 4.1.3 The Assessment Group identified 10 studies that reported pain in the later postoperative period (between 10 and 15 days). All studies found that people experienced less pain with stapled haemorrhoidopexy compared with conventional haemorrhoidectomy. This difference was statistically significant in two of the three studies available that provided a measure of variance. The Assessment Group found that there was little difference between stapled haemorrhoidopexy and conventional haemorrhoidectomy in postoperative pain after 21 days and at 1 year or later.
- 4.1.4 The Assessment Group found that stapled haemorrhoidopexy was associated with shorter wound healing time (unhealed wounds at 3 to 8 weeks postoperatively, weighted odds ratio [OR] = 0.08, 95% CI 0.03 to 0.19; and at 12 weeks postoperatively, weighted OR = 0.15, 95% CI 0.002 to 1.28), and with shorter time to return to normal bowel function (WMD -0.33 days, 95% CI -0.48 to -0.17), operating time (WMD -13.71 minutes, 95% CI -14.41 to -13.00) and length of hospital stay (WMD -1.23 days, 95% CI -1.30 to -1.16). In addition, there was a reduction in time to return to normal activity (ranging from -2.70 to -45.70 days) with stapled haemorrhoidopexy in all 14 RCTs identified that reported this outcome.
- 4.1.5 The Assessment Group found that there was statistically significantly less bleeding at 14 days postoperatively with stapled haemorrhoidopexy compared with conventional haemorrhoidectomy (pooled OR = 0.43, 95% CI 0.24 to 0.76). At 6–8 weeks postoperatively there was a trend towards a greater odds of bleeding with stapled haemorrhoidopexy compared with conventional haemorrhoidectomy, but the difference was not statistically significant (pooled OR = 1.75, 95% CI 0.97 to 3.14). The Assessment Group carried out a series of meta-analyses to compare levels of postoperative bleeding at 12 weeks or more

between stapled haemorrhoidopexy and conventional haemorrhoidectomy. None of these analyses (and none of the individual studies) found a statistically significant difference between the surgical procedures.

4.1.6 The Assessment Group undertook a series of meta-analyses of studies reporting rates of recurrent prolapse at different time points after haemorrhoid surgery. Four of the analyses identified statistically significantly greater odds of recurrent prolapse between 1 and 8 weeks with stapled haemorrhoidopexy compared with conventional haemorrhoidectomy (OR = 5.18, 95% CI 1.73 to 15.50), between 3 months and less than 1 year (OR = 4.68, 95% CI 1.11 to 19.71), between 16 months and 2 years (OR = 6.25, 95% CI 1.53 to 25.54) and between 12 months and 3.8 years (OR = 4.34, 95% CI 1.67 to 11.28). A meta-analysis of seven studies did not identify a statistically significant difference in the rate of recurrent prolapse between stapled haemorrhoidopexy and conventional haemorrhoidectomy 12 months postoperatively (OR = 3.20, 95% CI 0.71 to 14.45). Two studies that examined rates of recurrent prolapse after 5 years reported no recurrence in either of the treatment arms.

4.1.7 The Assessment Group undertook a series of meta-analyses of studies that reported rates of re-intervention (surgery, rubber-band ligation, sclerotherapy, skin tag removal and unspecified medical intervention). Two of these meta-analyses identified statistically significantly greater odds of re-intervention with stapled haemorrhoidopexy compared with conventional haemorrhoidectomy at 12 or more months: re-intervention for recurrent prolapse (OR = 4.99, 95% CI 1.05 to 23.60), re-intervention for bleeding (OR = 7.44, 95% CI 1.27 to 43.43). One meta-analysis identified a trend towards greater odds of any non-excision surgery with stapled haemorrhoidopexy at 12–18 months, but the difference compared with conventional haemorrhoidectomy

was not statistically significant (OR = 1.52, 95% CI 0.43 to 5.34). A further meta-analysis of two studies identified a trend towards smaller odds of intervention for skin tag removal less than 12 months after stapled haemorrhoidopexy, but the difference compared with conventional haemorrhoidectomy was not statistically significant (OR = 0.99, 95% CI 0.14 to 7.15).

- 4.1.8 The Assessment Group examined the incidence of a range of other postoperative complications and itching at different time points but no statistically significant differences between stapled haemorrhoidopexy and conventional haemorrhoidectomy were identified. For faecal incontinence there was a trend favouring stapled haemorrhoidopexy over conventional haemorrhoidectomy, but the difference was not statistically significant.
- 4.1.9 The Ethicon Endo-Surgery submission identified three studies that measured the quality of life of people being treated for haemorrhoids. None of these studies identified a statistically significant difference between stapled haemorrhoidopexy and conventional haemorrhoidectomy. The Assessment Group identified 14 studies that reported patient preference or level of satisfaction. The majority of the studies did not identify a preference for either stapled haemorrhoidopexy or conventional haemorrhoidectomy, but five studies reported greater patient satisfaction with stapled haemorrhoidopexy within the first year after the procedure was carried out. One study reported greater patient satisfaction with conventional haemorrhoidectomy approximately 4 years postoperatively.
- 4.1.10 Statements from patient experts and clinical specialists asserted that stapled haemorrhoidopexy is considerably less painful postoperatively than conventional haemorrhoidectomy and that people can return to work and normal lifestyle sooner after stapled

haemorrhoidopexy compared with conventional haemorrhoidectomy.

4.2 Cost effectiveness

- 4.2.1 No published economic evaluations were identified by Ethicon Endo-Surgery or the Assessment Group.
- 4.2.2 Ethicon Endo-Surgery submitted a cost–utility analysis comparing stapled haemorrhoidopexy with Milligan-Morgan haemorrhoidectomy, using a cohort-based probabilistic model. This model included people with third- and fourth-degree haemorrhoids, and the analysis was based on the following health states: full recovery without recurrent prolapse, recurrent prolapse that can be self-treated and recurrent prolapse requiring re-surgery (the latter of which may be followed by no further prolapse or a second recurrent prolapse). Complications or symptoms other than prolapse were not included. The average time from initial surgery to recurrence of prolapse was assumed to be 120 days and the waiting time from recurrence with severe symptoms to re-intervention was assumed to be 10 days. The model followed a 1-year time horizon and it was assumed that there was no difference in treatment effect beyond 12 months. The economic evaluation was undertaken from a UK NHS perspective. Because there were no RCTs that recorded utility in the crucial early postoperative period, utility weights were estimated indirectly by converting VAS pain scores from one RCT and matching SF-36 health survey dimensions to utility using a cross-sectional dataset of people aged 39 to 67 who were registered with a general practitioner in Sheffield. The SF-36 data were then converted into utility values.
- 4.2.3 The Ethicon Endo-Surgery base-case resulted in an incremental cost of £191 and 0.009 incremental quality adjusted life years (QALY) for stapled haemorrhoidopexy compared with conventional

haemorrhoidectomy, with an incremental cost-effectiveness ratio (ICER) of £22,416 per QALY. At a willingness to pay of £30,000 per QALY there was a greater than 70% probability that stapled haemorrhoidopexy was cost effective.

- 4.2.4 The Assessment Group undertook a cost–utility analysis comparing stapled haemorrhoidopexy with conventional haemorrhoidectomy. The structure of the Assessment Group’s model was broadly similar to the Ethicon Endo-Surgery model, but it included a wider definition of symptoms, complications of surgery and both surgical and non-surgical re-interventions, and it considered a 3-year time horizon. As in the Ethicon Endo-Surgery model, utility weights were estimated indirectly. This was done by converting VAS pain scores from ten RCTs to SF-36 data. The SF-36 data were then converted into utility values, but using a different methodology from that used by the manufacturer. The Assessment Group used the pain dimension of the SF-36 to calculate utility values, but the manufacturer included pain and physical functioning SF-36 dimensions. The difference between the utility with stapled haemorrhoidopexy and conventional haemorrhoidectomy was smaller in the Assessment Group’s model than in the Ethicon Endo-Surgery model.
- 4.2.5 The Assessment Group’s base-case resulted in an incremental cost of £19 and 0.001 fewer QALYs for stapled haemorrhoidopexy compared with conventional haemorrhoidectomy over 3 years. Stapled haemorrhoidopexy was therefore dominated by conventional haemorrhoidectomy. In the range of willingness to pay of £20,000 to £30,000 per QALY there was a 45% probability that stapled haemorrhoidopexy was cost effective.
- 4.2.6 The Assessment Group carried out a number of one-way sensitivity analyses using both its own model and the Ethicon Endo-Surgery model, and found that the ICER was extremely sensitive to the

assumptions used, with very small differences in the benefits resulting in large differences in the ICERs. Only when the Assessment Group's model was run with the Ethicon Endo-Surgery utility values was an ICER of less than £30,000 per QALY produced. Alternatively, when the Ethicon Endo-Surgery model was run with the Assessment Group's utility values, this gave an ICER of £383,985. When the price of the device was set at the 2006 price of £420 rather than the estimated 2007 price of £437, the total cost difference in the Assessment Group's model decreased to approximately £2.

4.3 Consideration of the evidence

- 4.3.1 The Appraisal Committee reviewed the data available on the clinical and cost effectiveness of stapled haemorrhoidopexy, having considered evidence on the nature of the condition and the value placed on the benefits of stapled haemorrhoidopexy by people with haemorrhoids, those who represent them, and clinical specialists. It was also mindful of the need to take account of the effective use of NHS resources.
- 4.3.2 The Committee was persuaded on the basis of the RCT evidence and advice from patient experts and clinical specialists that stapled haemorrhoidopexy offered benefits compared with conventional haemorrhoidectomy in the reduction of short- and medium-term postoperative pain. The Committee heard from the clinical specialist and the patient expert that people are often deterred from seeking treatment because of a fear of postoperative pain and the long recovery period associated with conventional haemorrhoidectomy. The Committee also heard that people who have undergone conventional haemorrhoidectomy are more likely to require support for postoperative pain management in primary care, including community nursing support, and may be at greater risk of hospital readmission because of postoperative problems.

The Committee was persuaded that such interventions are required less often following stapled haemorrhoidopexy.

- 4.3.3 The Committee also noted that the available RCT evidence suggested that people experience a shorter wound-healing time, less time in hospital and earlier return to normal activities with stapled haemorrhoidopexy than with conventional haemorrhoidectomy. The committee recognised that these factors were of great importance to people being treated for haemorrhoids.
- 4.3.4 The Committee noted that RCT evidence suggests that stapled haemorrhoidopexy is associated with a higher rate of recurrent prolapse than conventional haemorrhoidectomy. However the Committee heard from the clinical specialist that the recurrence of prolapse after haemorrhoidopexy varied on a case by case basis and in his experience of clinical practice recurrent prolapse was uncommon after stapled haemorrhoidopexy. The Committee heard from the clinical specialist and patient expert that a possible increased need for re-intervention is a less important factor than the expectation of a high level of post-operative pain for patients and clinicians when choosing between stapled haemorrhoidopexy or conventional haemorrhoidectomy. The Committee also heard that recurrent prolapse does not affect the prospects of further successful intervention. The Committee noted that the available RCT evidence indicated that stapled haemorrhoidopexy was associated with a higher rate of re-intervention compared with conventional haemorrhoidectomy, but it was persuaded by the clinical specialist and the patient expert that the level of postoperative pain and the length of the recovery period would be the deciding factors in their choice of procedure rather than any increased risk of prolapse or need for re-intervention. The Committee also heard from the clinical specialist that re-intervention for prolapse after stapled haemorrhoidopexy did not pose a greater risk than re-intervention after conventional

haemorrhoidectomy. The Committee also noted that the available RCT evidence did not identify a statistically significant difference between stapled haemorrhoidopexy and conventional haemorrhoidectomy in terms of other postoperative complications, such as faecal incontinence.

- 4.3.5 The Committee heard from the clinical specialist that stapled haemorrhoidopexy was appropriate in most people with third-degree haemorrhoids, and also in people with fourth-degree haemorrhoids for whom residual external prolapse or skin tags would not be a concern. It was suggested that stapled haemorrhoidopexy may also be considered a clinically appropriate procedure for people with second-degree haemorrhoids with full circumferential mucosal prolapse where banding either would not be possible (because of the number of bands required) or would be considered likely to be less effective. The Committee considered that the evidence from RCTs for the use of stapled haemorrhoidopexy for people with second-degree haemorrhoids was limited. However, the Committee concluded that there were circumstances in which conventional haemorrhoidectomy might be considered in people with second-degree haemorrhoids, and in those cases stapled haemorrhoidopexy would be an appropriate alternative.
- 4.3.6 The Committee considered the cost-effectiveness analyses from the Ethicon Endo-Surgery model indicating an ICER of £22,416 per QALY for stapled haemorrhoidopexy compared with conventional haemorrhoidectomy, and the Assessment Group model showing that conventional haemorrhoidectomy dominates stapled haemorrhoidopexy. The Committee noted that in both models the differences in cost and utilities between stapled haemorrhoidopexy and conventional haemorrhoidectomy were small, and therefore the ICERs were sensitive to minor changes in the assumptions made about costs and benefits.

- 4.3.7 The Committee noted that in both economic models the main influence on the ICERs was the utility estimates used. Furthermore, the Committee understood that, because there was little direct evidence, there remains uncertainty over the precise utility values associated with pain and the overall benefits of stapled haemorrhoidopexy. However, the Committee was persuaded that a clear utility benefit in favour of stapled haemorrhoidopexy is likely to exist, particularly in the early postoperative period, and therefore on balance the utility estimates used in the Ethicon Endo-Surgery model were plausible.
- 4.3.8 The Committee heard from the clinical specialist that people undergoing conventional haemorrhoidectomy are likely to require postoperative pain management in primary care more often than people undergoing stapled haemorrhoidopexy. The Committee noted that the costs of such pain management had not been included in the Assessment Group's economic model. It concluded that including the costs of such postoperative pain management would favour stapled haemorrhoidopexy in the economic model.
- 4.3.9 In summary, the Committee agreed that stapled haemorrhoidopexy was likely to be as effective as conventional haemorrhoidectomy when used appropriately (see section 4.3.5) and offered immediate benefit in terms of postoperative pain. In addition, taking into account the requirements for postoperative pain management and other support during inpatient stay and after discharge, stapled haemorrhoidopexy might lead to modest cost savings. The Committee therefore concluded that carrying out stapled haemorrhoidopexy would be an appropriate use of NHS resources and that stapled haemorrhoidopexy should be recommended as a treatment option for people in whom surgical intervention is considered appropriate for the treatment of prolapsed internal haemorrhoids. The Committee was persuaded that patient choice

was important in deciding between the two options for surgical intervention.

- 4.3.10 The Committee noted that the RCT evidence almost exclusively involved interventions using the PPH01 stapling device. The Committee heard from the clinical expert that there was no major difference between the PPH01 and the newer PPH03 device. It therefore concluded that the results of the RCTs would be applicable to the PPH03 device. However, the Committee concluded that the evidence could not be generalised to the other available stapling device, the Autosuture stapler with STRAM kit adapter, and that therefore no recommendations could be made for the Autosuture stapler. The Committee also heard that devices other than the PPH models were rarely used in UK clinical practice.

5 Implementation

- 5.1 The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by NICE technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- 5.2 'Healthcare Standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a

Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.

5.3 NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA128).

- Audit criteria to monitor local practice.
- A costing statement explaining the resource impact of this guidance.

6 Recommendations for further research

6.1 The Appraisal Committee recommends further research to evaluate the clinical and cost effectiveness of stapled haemorrhoidopexy in people with full circumferential second degree haemorrhoids.

7 Related NICE guidance

7.1 NICE has issued the following related interventional procedure guidance.

- Circular stapled haemorrhoidectomy. NICE interventional procedure guidance 34 (2003). Available from www.nice.org.uk/IPG034

8 Review of guidance

8.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider whether the technology should be reviewed. This decision will be taken in the light of information gathered by the Institute, and in consultation with consultees and commentators.

8.2 The guidance on this technology will be considered for review in August 2010.

Andrew Dillon

Chief executive

September 2007

Appendix A. Appraisal Committee members and NICE project team

A. Appraisal Committee members

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 twice 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 attending meetings of the three 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.

Professor Keith Abrams

Professor of Medical Statistics, University of Leicester

Dr Jeff Aronson

Reader in Clinical Pharmacology, University of Oxford

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, Leicester Royal Infirmary
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Professor Stirling Bryan

Director of the Health Economics Facility, University of Birmingham

Professor John Cairns

Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Mark Charkravarty

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

Professor Jack Dowie

Health Economist, London School of Hygiene and Tropical Medicine

Lynn Field

Nurse Director, Pan Birmingham Cancer Network

Professor Christopher Fowler

Professor of Surgical Education, University of London

Dr Fergus Gleeson

Consultant Radiologist, Churchill Hospital

Ms Sally Gooch

Former Director of Nursing and Workforce Development, Mid Essex Hospitals
Services NHS Trust

Mrs Barbara Greggains

Lay member

Mr Sanjay Gupta

Former Stroke Services Manager, Basildon and Thurrock Universities
Hospitals NHS Trust

Dr Mike Laker

Medical Director, Newcastle Hospitals NHS Trust

Mr Terence Lewis

Mental Health Consultant, National Institute for Mental Health in England
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Professor Gary McVeigh

Professor of Cardiovascular Medicine, Queens University, Belfast

Dr Ruairidh Milne

Senior Lecturer in Health Technology Assessment, National Coordinating Centre for Health Technology

Dr Neil Milner

General Medical Practitioner, Tramways Medical Centre, Sheffield

Dr Rubin Minhas

General Practitioner, CHD Clinical Lead, Medway PCT

Dr John Pounsford

Consultant Physician, North Bristol NHS Trust

Dr Rosalind Ramsay

Consultant Psychiatrist, Adult Mental Health Services, Maudsley Hospital

Dr Christa Roberts

UK Country Manager, Abbott Vascular

Dr Stephen Saltissi

Consultant Cardiologist, Royal Liverpool University Hospital

Dr Lindsay Smith

General Practitioner, East Somerset Research Consortium

Mr Roderick Smith

Director of Finance, West Kent Primary Care Trust

Mr Cliff Snelling

Lay member

Dr Ken Stein

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

Professor Andrew Stevens

Professor of Public Health, University of Birmingham

Dr Rod Taylor

Associate Professor in Health Services Research, Peninsula Medical School, Universities of Exeter and Plymouth.

B. NICE project team

Each technology appraisal is assigned to a team consisting of one or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Helen Tucker

Technical Lead

Dr Elisabeth George

Technical Adviser

Reetan Patel

Project Manager

Appendix B. Sources of evidence considered by the Committee

A The assessment report for this appraisal was prepared by NHS Centre for Reviews and Dissemination and Centre for Health Economics, University of York.

Baba -Akbari A, Burch J, Epstein D et al. Stapled haemorrhoidectomy (haemorrhoidopexy) for the treatment of haemorrhoids, February 2007.

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 Manufacturers/sponsors:

- Ethicon Endo-Surgery, Johnson & Johnson Medical Ltd
- Tyco Healthcare UK Ltd

II Professional/specialist, patient/carer and other groups:

- Association of Coloproctology of Great Britain and Ireland
- Association of Perioperative Practice
- Royal College of Nursing
- Continence Foundation
- Department of Health
- South Leeds PCT
- Welsh Assembly Government

III Commentator organisations (without the right of appeal):

- Department of Health, Social Services and Public Safety for Northern Ireland
- NHS Quality Improvement Scotland

- National Coordinating Centre for Health Technology Assessment
- Centre for Reviews and Dissemination and Centre for Health Economics, University of York

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 Stapled haemorrhoidopexy for the treatment of haemorrhoids by attending the initial Committee discussion and/or providing written evidence to the Committee. They were also invited to comment on the ACD.

- Mr Michael Parker, Consultant Surgeon, Darent Valley Hospital. Nominated as a clinical expert by the Association of Coloproctology of Great Britain and Ireland
- Dr Judith Wardle, Director, Continence Foundation. Nominated as patient expert by the Continence Foundation.