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NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Stapled Haemorrhoidopexy for the treatment of haemorrhoids

Comments from Consultees and Commentators on the ACD

Organisation	Section	Comment	Institute's Response
Association of Coloproctology of Great Britain & Ireland	Whether all the relevant evidence has been taken into account	I confirm that in my opinion i) all the relevant evidence has been considered	Comment noted.
Association of Coloproctology of Great Britain & Ireland	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	ii) the summaries of clinical and cost effectiveness are reasonable and appropriate, and iii) the recommendations are sound and constitute a suitable basis for guidance to the NHS.	Comment noted.
Department of Health		I wish to confirm that the Department of Health has no substantive comments to make, regarding this	

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		consultation.	
Royal College of Nursing		The document is comprehensive and is welcomed.	Comment noted.
The Continence Foundation		The Continence Foundation is happy with all aspects of the ACD and evaluation report for the appraisal of Stapled Haemorrhoidectomy. Indeed, would you please pass on to David Bartlett that I commend the committee for the clarity of their determination.	Comment noted.
Welsh Assembly Government	Whether all the relevant evidence has been taken into account	We are content with the technical detail of the evidence supporting the consultation and have no further comments to make at this stage.	Comment noted.
NHS QIS Reviewer 1	Whether all the relevant evidence has been taken into account	On whole I felt that all of the relevant evidence had been taken into account. With regard to the summaries of clinic and cost effectiveness my opinion would be that the evidence has been interpreted reasonably and the preliminary views on the resource impact and implications for the NHS are appropriate. I see no reason why this should be different within Scotland but would wish to highlight training as an issue that must be addressed.	Comment noted.
NHS QIS Reviewer 1	Whether all the relevant evidence has been taken into account	Corman et al authored a consensus group, which was published in Colorectal Disease in 2003. This was attended by the main proponents of the technique, from around the world. They proposed several position statements regarding the procedure and technique. The	The procedure was referred to as stapled hemorrhoidopexy in the ACD.

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		<p>first being that it should be called a stapled haemorrhoidopexy rather than a haemorrhoidectomy as it best captured the nature of the procedure. They also indicated the patient groups best suited to the procedure. Outlining instances where caution was to be advised and when it was contra indicated. They also discussed informed consent and at the summation of the article made recommendations for surgeons planning to perform stapled haemorrhoidopexy independently.</p>	
NHS QIS Reviewer 1	Whether all the relevant evidence has been taken into account	<p>They outlined that experience within rectal surgery and the understanding of anorectal anatomy was requisite. One had to have experience with circular stapling devices and attendance at a formal course such as the one held at Ninewell's Hospital in Dundee should be mandatory. Following the course it should initially be performed whilst being observed by an experienced surgeon. For any guideline to be complete one has to include the issues of training. In my opinion this is essential. Any Scottish NICE documentation must take account of this otherwise what is a worthwhile technique may become discredited.</p>	Comment noted.
NHS QIS Reviewer 1	Whether the provisional recommendations of the Appraisal Committee are sound and	<p>Overall the provisional recommendations of the Appraisal Committee were sound and constituted a suitable basis for the preparation of guidance to the NHS but I cannot emphasise too strongly that the training issue has to be addressed.</p>	Comment noted.

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	constitute a suitable basis for the preparation of guidance to the NHS		
NHS QIS Reviewer 2		Absent on annual leave until 29 May 2007.	Comment noted.
NHS QIS Reviewer 3	Whether all the relevant evidence has been taken into account	Yes with one caveat – the report notes the use of procedure in the UK for 2 – 3 years – has it been through the IPP process or does it not need to go?	NICE Interventional Procedure Guidance 34 “Circular stapled haemorrhoidectomy” was published in 2003. Available from www.nice.org.uk/IPG034 (see FAD section 7)
NHS QIS Reviewer 3	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	Appeared a reasonable summation as far as I can tell.	Comment noted.

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<p>NHS QIS Reviewer 3</p>	<p>Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?</p>	<p>Yes, if the above comment re IPP is resolved. No other advice from surgical advisers</p>	<p>NICE Interventional Procedure Guidance 34 “Circular stapled haemorrhoidectomy” was published in 2003. Available from www.nice.org.uk/IPG034 (see FAD section 7)</p>
<p>Ethicon Endo Surgery</p>	<p>Whether all the relevant evidence has been taken into account</p>	<p>all relevant evidence has been taken in to account</p>	<p>Comment noted</p>
<p>Ethicon Endo Surgery</p>	<p>Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the</p>	<p>II. The summaries are reasonable interpretations of the evidence, and III. The recommendations constitute a sound basis for guidance to the NHS</p>	<p>Comment noted</p>

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	preparation of guidance to the NHS		
Ethicon Endo Surgery	Whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS	We concur with the wording of Section 1. We believe this to be a positive outcome for patients and surgeons.	Comment noted
Ethicon Endo Surgery		We appreciate that the procedure name has now been recognised; being ‘-pexy’ recognising haemorrhoidal tissue is conserved, rather than the traditional method of complete removal, or ‘-ectomy’.	Comment noted
Ethicon Endo Surgery		•We support the comments in paragraph 4.3.10. We recognise the principal recommendation is related to the procedure, however we appreciate that the committee has recognised that the success of the general procedure is in part determined by the specific devices used, and these therefore require	Comment noted

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		<p>their own evidence base.</p> <ul style="list-style-type: none"> • That the Committee recognised the value of our utility estimates (4.3.7). 	
Ethicon Endo Surgery		<p>We have one textual change to suggest for paragraph 3.2, clarifying the device currently available. Only PPH03 is currently marketed for this procedure in the UK, as implied in Paragraph 3.3. A suggested amendment is attached in the Annex, Section A</p> <p><u>Annex: Section A</u></p> <p><u>Suggested amendment to Paragraph 3.2 & 3.3</u></p> <p>3.2 Two devices were listed in the scope for this appraisal: the HCS33 device, of which the <u>(models PPH01 and PPH03)</u> models are currently in use, developed by Ethicon Endo-Surgery (<u>a Johnson & Johnson company</u>); and the Autosure stapler, developed by Tyco Healthcare, which can be used in conjunction with the STAM kit adaptor to perform haemorrhoidopexies.</p> <p>3.3 The cost of the HCS33 PPH03 stapling device, <u>the model currently in use</u>, is £420.00, based on the submission from Ethicon Endo-Surgery. Costs may vary in different settings because of negotiated procurement discounts. The cost of the Autosure stapler with the STAM kit adaptor was not available.</p> <p>.</p>	Comment noted. Sections 3.2 and 3.3 have been amended.
Ethicon Endo		Finally, we have one comment on the response to our	Comment noted

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Surgery		<p>comments on the Assessment Report. We recognise these do not impact the ACD, so they are in the Annex, Section B. However they are included as they may be relevant to any subsequent monograph produced, and request they be passed to the Assessment Team. We thank the Assessment Group for their responses to our comments. We consider one of our comments may not have been well communicated as it appears to have been misunderstood in the comments. We are flagging it at this time as it might warrant comment in any future monograph or publication. Our comment relates to the use of the HODaR data to estimate the quality of life impact, and hence QALYs. Our key issue was that the HODaR data based on the SF36 elicits responses from patients over their experiences during weeks 3 to 6 post surgery (it has a four week recall period, and is asked after week 6). It therefore does not include any contribution from weeks 1 and 2 – when the pain from the traditional haemorrhoidectomy is at its greatest. Therefore, using SF36 data from HODaR as the baseline estimate under-estimates the impact of pain following conventional haemorrhoidectomy. This is important as the Assessment Team then use a relative reduction for the benefit of the stapled procedure. Applying a relative reduction to a baseline that already under-estimates the actual impact of the traditional surgical approach can only under-estimate the relative benefit of the stapled procedure.</p> <p>This issue is not recognised in the Assessment Report or in their follow up comments. We request that the group consider at least mentioning this issue qualitatively if not</p>	
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		quantitatively in the discussion of any future publication.	
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