National Institute for Health and Clinical Excellence

Barrett's Oesophagus
Scope Consultation Table
13 March – 09 April 2009

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Association of Educational Psychologists	1		Organisations that were approached but did not respond	
SH	Association of the British Pharmaceuticals Industry (ABPI)	2		Organisations that were approached but did not respond	
SH	Barrx Medical Inc	57.00	4.1.1	The Scope draft dated February 2009 that was circulated prior to the Feb 26th Workshop stated, "adults with Barrett's oesophagus" in the "groups that will be covered" section (4.1.1), whereas the subsequent draft, in the same section, alternatively stated, "adults with a diagnosis of Barrett's oesophagus with high-grade dysplasia or intramucosal cancer." Such a change is unfortunate as it may dissuade those with low-grade dysplasia (LGD) from seeking/receiving endoscopic ablative therapy. There is ample research suggesting tangible benefits of radiofrequency ablation (RFA) for those with LGD as outlined below.	The issue of whether the guideline scope should be extended to include all grades of dysplasia was discussed at the scoping workshop with experts in the field. The consensus from the scoping workshop was that for this topic to progress as a viable short clinical guideline it should focus on the population for which there is both greatest need for guidance (those with high grade dysplasia or intramucosal cancer). There is a definite need to determine if ablative therapy is both clinically and cost effective when compared with other more invasive therapy for high grade BO such as oesophagectomy. Extending the population to include low or no dysplasia BO will make for a much larger guideline. This would not be possible to address within a short clinical guideline.
SH	Barrx Medical Inc	57.01	4.1.1	The safety and efficacy of RFA for LGD has been established. The AIM-LGD Trial by Sharma, et al. reported a complete response (CR) for dysplasia (CR-D) of 100% and a CR-IM of 90% without strictures or buried glands (Endoscopy 2008;40:380-7). Further, the AIM Dysplasia Trial by Shaheen, et	Thank you for this additional information

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				al. concluded from a randomized, sham-controlled study of RFA vs. surveillance alone (which included a LGD cohort) that RFA was superior to sham for CR-IM and CR-D for those with LGD and was associated with a favorable safety profile (2008 DDW AGA Presidential Plenary Session & Gastroenterology 2008;134:A37).	
SH	Barrx Medical Inc	57.02	4.1.1	Recent studies demonstrate a significant progression rate of LGD to HGD and cancer. The AIM Dysplasia Trial investigators found that 16% of the LGD cohort progressed to HGD in one year. Skacel, et al. learned that if 2 GI pathologists independently concurred on a diagnosis of LGD, then the risk for progression to cancer was the same as that for an HGD patient (Am J Gastroenterol 2000;95:3383–7). Further, Srivastava, et al. discovered that the extent of LGD within a set of biopsies was a predictive factor for progression to cancer (Am J Gastroenterol 2007;102:483–93). Lastly, Sharma, et al. found a 2.7% per patient per year progression rate from LGD to HGD (Clin Gastroenterol Hepatol 2006;4:566-72).	Thank you for this additional information
SH	Barrx Medical Inc	57.03	4.1.1	A high level of pathologic disconcordance exists when attempting to diagnose LGD. In the AIM Dysplasia Trial, 4% of patients receiving an expert home institution diagnosis of LGD were upgraded to HGD and cancer by the independent expert Cleveland Clinic GI pathologists.	Thank you for this additional information
SH	Barrx Medical Inc	57.04	4.1.1	Lifelong surveillance, particularly at regular intervals can be disruptive to patients' lives as well as costly for the NHS. The most recent (August 2005) British Society of Gastroenterology "Guidelines for the diagnosis and management of Barrett's columnar-lined oesophagus" recommends that those with a	Noted.

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				confirmed diagnosis of LGD undergo surveillance endoscopy with biopsy on a frequent basis (every 12 months).	
SH	Barrx Medical Inc	57.05	4.1.1	Bergman, et al. have shown that genetic abnormalities are associated with LGD and can be completely eliminated with RFA when the remaining neosquamous epithelium is studied (Gut 2008;57:A82 & Am J Gastroenterol in press).	Thank you for this additional information
SH	Barrx Medical Inc	57.06	4.1.1	Ablation of LGD has been shown to be cost-effective in the US using very conservative assumptions. Inadomi, et al. reported that RFA was a preferred strategy for LGD compared to other interventions including natural history and surveillance (Gastroenterology epub on 6 March 2009 ahead of print, DOI 10.1053/j.gastro.2009.02.062).	Thank you for this additional information
SH	British National Formulary (BNF)	3		Organisations that were approached but did not respond	
SH	British Society of Gastroenterology/AUGIS/ Gloucestershire Hospital NHS Foundation Trust	4	General	There is some data arriving on the management of low grade dysplasia and it might be worth considering this within the remit. The crucial area is high Grade and intramucosal cancer	Noted. We consider that the focus of this short clinical guideline, as set out in the scope, should be on patients with high-grade dysplasia or intramucosal cancer.
SH	British Society of Gastrointestinal and Abdominal Radiology (BSGAR)	5		Organisations that were approached but did not respond	
SH	Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)	6		Organisations that were approached but did not respond	
SH	Commission for Social Care Inspection	7		Organisations that were approached but did not respond	
SH	Connecting for Health	8		Organisations that were approached but did not respond	
SH	Cook Medical	9		Organisations that were approached but did not respond	
SH	Department for Communities and	10		Organisations that were approached but did not	

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	Local Government			respond	
SH	Department of Health	11		Organisations that were approached but did not respond	
SH	Department of Health, Social Security and Public Safety of Northern Ireland	12		Organisations that were approached but did not respond	
SH	Healthcare Commission	13		Organisations that were approached but did not respond	
SH	Leicester Royal Infirmary	14		Organisations that were approached but did not respond	
SH	Luton & Dunstable Hospital NHS Foundation Trust	15		Organisations that were approached but did not respond	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	16		Organisations that were approached but did not respond	
SH	National Patient Safety Agency (NPSA)	17		Organisations that were approached but did not respond	
SH	National Public Health Service - Wales	18		Organisations that were approached but did not respond	
SH	National Treatment Agency for Substance Misuse	19		Organisations that were approached but did not respond	
SH	NCCHTA	27		Organisations that were approached but did not respond	
SH	NHS Plus	28		Organisations that were approached but did not respond	
SH	NHS Purchasing & Supply Agency	29		Organisations that were approached but did not respond	
SH	NHS Quality Improvement Scotland	30		Organisations that were approached but did not respond	
SH	PERIGON Healthcare Ltd	31		Organisations that were approached but did not respond	
SH	Primary Care Society for Gastroenterology (PCSG)	32	General	If EMR is found to be worthwhile then greater diligence will be required to diagnose Barrett's in the first place. The Nice dyspepsia guidelines do no	The NICE dyspepsia guideline will be considered for updating in line with the process outlined in the 2009 Guidelines Manual. The developers will need to

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				encourage endoscopy for reflux symptoms and therefore if followed closely would be against making a diagnosis of Barrett's and the selection of those cases which would benefit from EMR. The Dyspspsia guidelines may need to be changed in the light of a positive outcome to this treatment	consider other relevant published NICE guidance when making their decision on which aspects of the guideline need updating.
SH	Queen Alexandra Hospital	33		Organisations that were approached but did not respond	
SH	Royal College of General Practitioners	34		Organisations that were approached but did not respond	
SH	Royal College of Nursing	35	General	The RCN welcomes proposals to develop this guideline. The scope is clear and comprehensive.	Thank you
SH	Royal College of Paediatrics and Child Health	36		Organisations that were approached but did not respond	
SH	Royal College of Pathologists	37		Organisations that were approached but did not respond	
SH	Royal College of Physicians London	38.00	3.1	'Often the patient has no outward symptoms'. Most patients do have symptoms. The sentence should be rephrased 'the patient may have no outward symptoms'	We agree and have deleted this sentence as it does not add to the point made in this paragraph. We have reworded section to make it clear that Barrett's is commonly found at endoscopy of those with chronic GOR symptoms.
SH	Royal College of Physicians London	38.01	3.2b	'There is uncertainty as to whether a) ablative therapy for Barrett's is clinically and cost effective…' This sentence is ambiguous. Do you mean clinically effective as well as cost effective?	We have amended slightly (inserted "both"). It is important to determine if ablative therapy as a whole is both clinically effective and cost effective compared to other treatment options and also whether any one of the ablative therapies is more clinically effective and cost effective than other ablative therapies.
SH	Royal College of Physicians London	38.02	4.1.2	There is much discussion in the field about ablation for low grade dysplasia and non-dysplastic Barrett's. If this is outside of the scope of this document this would be better to be clearly stated	To emphasise this point we have added this group to section 4.1.2 of the scope.

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SH	Royal College of Physicians London	38.03	4.3.1	We believe that clinical effectiveness should be considered first and as a separate issue to cost effectiveness. These are both important but need to be clearly addressed in turn.	We can confirm that the evidence for both clinical and cost effectiveness will be separately reviewed and presented in turn.
SH	Royal College of Physicians London	38.04	4.3.1	Some of these questions are likely to be difficult to address due to lack of evidence e.g. 'depth of tissue destruction required'.	Noted.
SH	Royal College of Physicians London	38.05	4.3.1	The surgical comparison will need to include different forms of surgery such as laparoscopic oesophagectomy	Noted.
SH	Royal College of Physicians London	38.06	4.3.1	Endoscopic Mucosal Resection may be needed in combination with ablation therapies not just as an alternative	Noted. The need to consider this combination therapy will be discussed with the Guideline Development Group.
SH	Royal College of Physicians London	38.07	4.4	Risk of recurrence of high grade dysplasia should also be included.	This has been added to section 4.4b).
SH	Royal Society of Medicine	39		Organisations that were approached but did not respond	
SH	SACAR	40		Organisations that were approached but did not respond	
SH	Scottish Intercollegiate Guidelines Network (SIGN)	41.00		There is increasing and substantive evidence now from clinical trials that Radiofrequency ablation (RFA) is a very safe and effective therapy for Barretts oesophagus. I feel strongly that this treatment should be considered as the primary ablative therapy in the forthcoming NICE review	Thank you, RFA ablation is one of the ablative therapies which will be reviewed in this guideline
SH	Scottish Intercollegiate Guidelines Network (SIGN)	41.01		I was a reviewer for NICE (British Soc of Gastroenterology) when this was first assessed	Noted.
SH	Scottish Intercollegiate Guidelines Network (SIGN)	41.02		I feel the treatment group to be considered should include all dysplastic Barretts cases as we frequently see cases with field changes where cancers have developed without High grade dysplasia being identified.	The issue of whether the guideline scope should be extended to include all grades of dysplasia was discussed at the scoping workshop with experts in the field. The consensus from the scoping workshop was that for this topic to progress as a viable short clinical guideline it should focus on the population for which there is both greatest need for guidance

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					(those with high grade dysplasia or intramucosal cancer). There is a definite need to determine if ablative therapy is both clinically and cost effective when compared with other more invasive therapy for high grade BO such as oesophagectomy. Extending the population to include low or no dysplasia BO will make for a much larger guideline. This would not be possible to address within a short clinical guideline.
SH	Sheffield PCT	43		Organisations that were approached but did not respond	
SH	Sheffield Teaching Hospitals NHS Foundation Trust	44		Organisations that were approached but did not respond	
SH	Social Care Institute for Excellence (SCIE)	45		Organisations that were approached but did not respond	
SH	Social Exclusion Task Force	46		Organisations that were approached but did not respond	
SH	Synectics Medical	47		Organisations that were approached but did not respond	
SH	Teva UK Limited	49		Organisations that were approached but did not respond	
SH	Welsh Assembly Government	50		Organisations that were approached but did not respond	
SH	Welsh Scientific Advisory Committee (WSAC)	51		Organisations that were approached but did not respond	
SH	Western Health and Social Care Trust	52		Organisations that were approached but did not respond	
SH	York NHS Foundation Trust	53		Organisations that were approached but did not respond	