National Institute for Health and Clinical Excellence

Colonoscopic surveillance – 2nd consultation
Guideline Consultation Comments Table
10 December 2010– 21 January 2011

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	ACPGBI	13.00	Full	General	General	Clear and well documented evidence based guidelines	Thank you.
SH	ACPGBI	13.01	Full	1.1.2	General	It would be helpful in terms of clarity to define what 'appropriate biopsy' means. The BSG definition of 'pancolonic dye spraying with targeted biopsy of abnormal areas' is appropriate. Subsequent statements referring to chromoscopy eg 1.1.4 should add 'and targeted biopsy'	Thank you. We have now amended recommendation 1.1.2 to include the suggested wording.
SH	ACPGBI	13.02	Full	Table 1	6 line 13	Accurate	Thank you.
SH	ACPGBI	13.03	Full	1.1.3	7 line 1 to 6	Clear	Thank you.
SH	ACPGBI	13.04	Full	Table 2	8	Accurate	Thank you.
SH	ACPGBI	13.05	Full	1.1.9	8 to 9	Clear	Thank you.
SH	ACPGBI	13.06	Full	1.1.15	9-10 and general	Another important part of informed consent is the fact that every test has a miss rate even in the most experienced hands.	Recommendation 1.1.14/15 covers risks/benefits of the procedure.
SH	ACPGBI	13.07	Full and appendix 4	2.4.7	48 Appendix 4 page 58	The Cochrane review has been updated with data from one more study (Stoffel 2008) which adds to the conclusion that chromoscopy detects more neoplasia. If the literature search was done in Oct 2009 surprised this paper was not picked up. It seems to meet your criteria. Not done the stats to see if (even after	Thank you for this information. Although we had not noted the update (due to the timing of publication Oct 2010) we had identified the Stoffel 2008 study which was excluded for this guideline as the participants included people who had previously had colorectal cancer (so people who are outside the Scope of this guideline).

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						exclusion of the Hurlstone paper) this makes the result more statistically significant but I suspect it does. Whilst we do not dispute the conclusion of the GDC in that chromoscopy should not be recommended routinely the question is how much more evidence is required before it does become reasonable? Should this and the cost implications (particularly the extra time required for chromoscopy) be an area of future research?	Re the research recommendation, the GDG noted the lack of evidence in this population and the need for the evidence to show a significant benefit. However, no research recommendation was considered necessary.
SH	ACPGBI	13.08	Full	2.5.9	86 lines 26 to 28	Cross referencing of NICE guidelines to BSG/ACPGBI guidelines 2010 – Cairns et al (Gut 2010;**59**:666-690) – should be clarified that this refers to a future piece of data to come rather than the reference to the data itself	Thank you and clarification has been added.
SH	ACPGBI	13.09	Full	7.1	106	Should be Le Rhun M not Le RM	Thank you. This has been corrected.
SH	ACPGBI	13.10	Full	7.2	General	The glossary is a little inconsistent. On the one hand it is written for a lay person (for instance defines mucosa in basic terms) on the other hand some definitions are complex medical jargon (for instance definition of inflammation). Would recommend a consistent style.	Thank you. We have now updated our definitions.
SH	ACPGBI	13.11	Full	7.2	110	Definition of adenoma is weak – needs to be specific to colon and rectum	Thank you. We have now updated our definitions.
SH	ACPGBI	13.12	Full	7.2	111	This is an incorrect definition of chromoscopy. Better 'application of dyes onto the surface of the mucosal lining to enhance abnormal morphology (or mucosal irregularities if using lay person's terms)'.	Thank you. We have now updated our definitions.
SH	ACPGBI	13.13	Full	7.2	111	Better definition of Crohn's can be given. Eg. Chronic inflammation that can involve	Thank you. We have now updated our definitions.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						any part of the gut but typically involves the distal portion of the small intestine and/ or colon and is characterised by diarrhoea, cramping, loss of appetite and weight and local abscesses and scarring.	
SH	ACPGBI	13.14	Full	7.2	112	The definition of index colonoscopy is confusing. Better ' the first or base line colonoscopy of a series'	Thank you. We have now updated our definitions.
SH	ACPGBI	13.15	Full	7.2	115	Advise removal or justification of the statement 'Flexible sigmoidoscopy is generally the preferred procedure'. It is not necessarily the preferred procedure for instance in a surgical outpatient clinic or in defining the height of a polyp from the anal verge.	Thank you. We have now updated our definitions.
SH	ACPGBI	13.16	Full	General	General	The introduction does draw attention to the BSG guidelines as does appendix 1. They say that updated guidelines are being prepared. These were published in 2010 and are very similar (but broader that the NICE guidance in that they include other moderate/high risk groups). Is this not reinventing the wheel?	The Department of Health asked NICE in 2009 to produce a short clinical guideline on Colonoscopic surveillance for patients with ulcerative colitis Crohn's disease and polyps to prevent colorectal cancer.
SH	ACPGBI	13.17	Full	General	General	There is no mention of surveillance for pouch patients. This group is relevant to the title. Also what about polyp cancers?	Pouch patients are outside the scope of this guideline. Polyp cancers would be treated according to colorectal cancer guidelines currently under development.
SH	ACPGBI	13.18	Appendix 3		16-17	The statement based on the results from the questionnaires (questions 1 and 2) suggest all at risk sub-groups will be considered. This includes family history patients and yet these are excluded from the document. This needs clarifying.	Thank you for your comment. We do take family history into account in defining the risk categories for adenomas but the guideline is not about screening or surveillance for people with a family history of colorectal cancer unless this presents with non-familial non-hereditary polyposis.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	ACPGBI	13.19	Full	1.1.15	25	The 'incomplete' examination rates (preferably local) should be conveyed to the patient. Examination failure may result in the need for a further colonoscopy or alternative radiological examination. In addition, some polyps may be missed. This may depend on the experience of the colonoscopist. Some assurance of colonoscopy competency should be conveyed to the patient also. JAG competency offers quality assurance in colonoscopy. There are however no such equivalents in radiology (i.e. for CTC or barium enema surveillance) to my knowledge.	Recommendation 1.1.14/15 covers risks/benefits of the procedure
SH	ACPGBI	13.20	Full	1.1.2	9	Watanabe et al, J Gastroenterol 2011 – in a recent paper these authors question the need for step biopsies or rather to use target biopsies in areas of suspected neoplasia. Will some clarification on the issue of what constitutes an appropriate method to surveillance biopsy in IBD be required in the guideline?	Recommendation 1.1.2 had now been updated to clarify appropriate biopsies.
SH	ACPGBI	13.21	Full	1.1.1	8	In a recent study comparing presentations of UC and CD related CRC – Kiran et al, (Ann Surg 2010) found that only 26% of those with CD-CRC had pancolitis (vs 68% for UC-CRC). How certain can one be of the significance of more than one segment inflammation in CD.	Thank you. The GDG came to the conclusion, based on all the evidence, that the risk of colorectal cancer in Crohn's disease was comparable to that in people with ulcerative colitis and therefore we have treated them as of equivalent risk.
SH	ACPGBI	13.22	Full	General		Although not a common situation the guidance does not offer recommendations on the surveillance of the defunctioned rectum in patients who have undergone	This population is outside the scope of this guideline.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						subtotal colectomy for IBD and still retain the rectum. Surveillance can be difficult due to the coexisting inflammatory change brought about through diversion of faecal contents. Presumably patients with ileorectal anastomoses with their rectum in continuity follow the guidelines according to their preoperative disease distribution. Does this, as well as guidance for pouchoscopy in ileal pouch cases need explicity definition in the guidance?	
SH	ACPGBI	13.23	Full	2,2,4		The economic model has been based largely upon a UC population for derivation of transition states and costs (Rutter 2006 Tappenden 2004). However the utilities used employed a time trade off technique applied to a Crohns population. We acknowledge that the group felt that this was acceptable but are the findings from UC and Crohns in these exact circumstances similar? Is inclusion of this IBD health economic model desirable – it seems that it was associated with significant uncertainty.Similar uncertainty within the adenoma health economic model is acknowledged in 2.2.9 – and again we question whether this should be included.	Comments noted. The GDG considered appropriate using data related to Crohn's disease because the relevant data on ulcerative colitis is very limited. Economic models were developed to explore uncertainties based on the available evidence to help inform decision making. It is fully acknowledged that the models were exploratory, therefore results needs to be interpreted with caution.
SH	ACPGBI	13.24	Full	2.3.9		Health economic modelling in this situation (i.e. colonoscopy versus other modalities (namely CTC) for adenoma) would have been highly useful in my opinion – although we acknowledge that evidence is scant on costs and effectiveness of CTC. The excess of hyperplastic and muscosal tag polyps in	Thank you for your comment.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						the colonoscopy group may render it less cost-effective than CTC. This would be an important question to answer although I accept that this is acknowledged in 2,3.10.	
SH	ACPGBI	13.25	Full	2.4.10		It seems at odds that given the acknowledged enhanced polyp detection identified in the evidence that a recommendation to use dye spray has not been issued. The difference in neoplastic detection rates however represents the important question as dye spray may yield an excess of non clinically relevant findings e.g. hyperplastic polyps. Is there sufficient evidence that the included studies were sufficiently powered to address differences in genuine neoplasia (benign and malignant) rather than polyp rates?	The GDG noted chromoscopy does improve recognition of polyps; it is uncertain whether it improves identification of adenomas and, on balance, the GDG felt that it didn't add enough to justify the additional costs and time involved.
SH	ACPGBI	13.26	Full	2.4.7		There is no mention on the use of dye spray for polyposis syndroms such as FAP. The inclusion/exclusion of this group should be stated clearly in the guidelines. This in fact relates to the entire guideline.	Genetic syndromes are outside the scope of this guideline
SH	ACPGBI	13.27	Full	1.1.16		The guideline suggests that ongoing surveillance should be discussed with patients at the time of examinations. This can be difficult due to use of sedation. The guideline should perhaps reflect this.	Thank you. We have now amended recommendation 1.1.16 to make this clearer.
SH	ACPGBI	13.28	Full	1.1.15		A very minor point – often there is a time delay between examination and being able to convey findings to patient – either because 1) biopsy results take time to return and 2) sedation may impede discussion (above)	Thank you. We have now amended recommendation 1.1.16 to make this clearer.
SH	Bowel Cancer Screening	14.00	Gener			When the recommendations of the	Thank you for your comments. In relation to

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Programme		al			guideline depend so much on expert opinion why not just endorse the current guideline from the BSG/ACP? Does it have to be a shade different? It will be confusing for the service to have a second guideline, presented in a different style with a slightly different message. The affordability issue, and opportunity cost, of the guideline has not been addressed fully. In the context of limited capacity in the service should the guideline recommend that for low risk groups colonoscopy can be 'considered', especially given we have an average risk screening programme in place. The guideline should recommend 'auditable outcomes' of the recommendations such as cancer detected in surveillance programmes and the extent of adherence to guidelines.	your first point NICE where given the remit from the Department of Health to produce a short clinical guideline on Colonoscopic surveillance for patients with ulcerative colitis Crohn's disease and polyps to prevent colorectal cancer. We produce our guidelines using the methodology outlined in the guidelines manual. In relation to your second and third points NICE produce implementation slide sets which address cost impact and help with auditoutcomes.
SH	Bowel Screening Wales	8.00	Full - Summary	1.1.6	7	BSW are currently not offering surveillance to the low risk adenoma group, other than standard FOB recall. We believe this is a contentious issue, as it is clear that there are benefits to be gained from surveillance in the intermediate and high risk groups but not the low risk individuals, who have a similar risk to the general population. We believe that NICE were correct in the original version and were more dissuasive	Recommendation 1.1.9 states that clinicians can consider to offer surveillance for the low risk group.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						of surveillance in this group.	
SH	Bowel Screening Wales	8.01	Full – Summary	1.1.1	6	The colitis surveillance algorithm is similar to the BSG Guideline and we have been doing this for some time in Wales.	Thank you.
SH	Bowel Screening Wales	8.02	Full	General		BSW are satisfied with the draft guidelines apart from low risk adenoma surveillance as described above.	Thank you.
SH	British Society of Gastroenterology & Royal College of Physicians	11.00	Full	General		The title should be changed to make it clear the guidance refers to colonic adenomatous polyps and not all colonic	Thank you for your comment our title refers to ulcerative colitis, Crohn's disease or adenomas.
SH	British Society of Gastroenterology & Royal College of Physicians	11.01	Full	General		The document is wordy and should be shortened.	We produce our guidelines based on a template as outlined in the guidelines manual (http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/theguidelinesmanual2006/the_guidelines_manual_2006.jsp). We provide a summary version of our guideline called the quick reference guide which includes the algorithms and summary of recommendations.
SH	British Society of Gastroenterology & Royal College of Physicians	11.02	Full		21	The Health Economic IBD modality poorly serves the document because of lack of interpretable data. The Health Economic discussion should be abbreviated to reflect this lack of interpretable data.	Thank you for your comment. To enable transparency and understanding of what is done a full explanation is required.
SH	British Society of Gastroenterology & Royal College of Physicians	11.03	Full		25	Line 29 describes results as 'exploratory' which is inappropriate since the analysis but not the results could be described in this way.	Thank you for your comment however; the exploratory results were derived from exploratory analysis. It was emphasised that the results were speculative rather than definitive due to lack of available data.
SH	British Society of Gastroenterology &	11.04	Full		31	Line 13 again uses the word exploratory when describing results and again this is an	Thank you for your comment however; the exploratory results were derived from

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Royal College of Physicians					inappropriate use of the word.	exploratory analysis. It was emphasised that the results were speculative rather than definitive due to lack of available data
SH	British Society of Gastroenterology & Royal College of Physicians	11.05	Full		72	Table 1. The terms quiescent UC/Crohn's needs defining as is defined in the BSG/ACPGBI guidance from which the table is derived. The BSG/ACPGBI guidance defines quiescent as no active endoscopic or histological inflammation.	Thank you. We have now updated this in the guideline
SH	British Society of Gastroenterology & Royal College of Physicians	11.06	Full	General		Recommend use of the BSG/ACPGBI algorithms for adenoma and IBD surveillance which are much clearer than those algorithms provided by NICE.	Our algorithms have now been updated to make them clearer.
SH	British Society of Gastroenterology & Royal College of Physicians	11.07	Full	General		The NICE draft guidance comes very soon after UK Guidance was provided by BSG and ACPGBI (May 2010) the acknowledged expert societies for such guidance. However this draft more closely follows the BSG/ACPGBI guidance. There is a need for more careful editing to make the guidance clearer for clinicians and patients.	In regards to the timing of the guidance the department of health asked NICE to produce a short clinical guideline on Colonoscopic surveillance for patients with ulcerative colitis Crohn's disease and polyps to prevent colorectal cancer. Our guideline will be edited before publication and the understanding NICE guidance document which is intended for patients and carers will be published along with the guideline.
SH	British Society of Gastroenterology & Royal College of Physicians	11.08	Full	General		The title on the document does state adenoma rather than polyp it is the link which uses the word polyp.	Thank you. We will amend this on the web page.
SH	British Society of Gastroenterology & Royal College of Physicians	11.09	Full	General		Tables 1 and 2 and the statements 1.1.3 and 1.1.9 are clear	Thank you.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	British Society of Gastroenterology & Royal College of Physicians	11.10	Full	General		The guidelines specify inflammation has to be confirmed histologically. Due to sampling error inflammation which is clearly visible may not be confirmed histologically and it would be better to allow inflammation to be judged as present endoscopically OR histologically.	Thank you. We have now amended recommendation 1.1.2 table 2 to reflect this.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition	10.00	Full	General		Although this excellent and informative guideline (and Appendix 1) specifically states that it applies only to adults (specifically excluding anyone under 18y of age), there is clearly an important risk group missing from this advice. A significant minority of young adults / adolescents will have had extensive colitis (phenotype of UC in children is 80% pancolitis) for over 10 years by the time they appear in adult services aged 16-18 years. A significant proportion of children (12% in the 2003 census) are diagnosed with IBD under the age of 5y every year. Appropriate surveillance should clearly be discussed in these children before a formal 'handover' of care occurs to adult services. We feel that, at very least, a statement should be added that optimal care of this 'lost' population should lie within an established 'transition' service, where surveillance expertise can be provided in an age-appropriate setting, at a disease-appropriate time. No paediatric gastroenterologist has sufficient expertise in surveillance to competently assess these young adults, many of whom are likely to become some of the highest risk patients of	Thank you for your comment. We acknowledge the concerns you raise here however our scope specifically refers to adults 18 years or older.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						all.	
SH	Department of Health	6.00	General			We wish to confirm that the Department of Health has no substantive comments to make regarding this consultation	Thank you.
SH	Ferring Pharmaceutical	12.00	General			We have reviewed the draft guidance and have no comments	Thank you.
PR	NETSCC, Health Technology Assessment	15.00	Full	General		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** No comments	Thank you.
PR	NETSCC, Health Technology Assessment	15.01	Full	General		**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).** Comments regarding the health economic analyses are listed below. In summary, the overall methodological approach to assessing cost-effectiveness appears consistent with NICE guidance for economic evaluations albeit the □odelling was constrained by a lack of primary data and perhaps limited time to develop more comprehensive models. Some of the assumptions in the models are open to criticism on clinical grounds but the authors acknowledge the speculative nature of the analyses. The methods applied to the limited available data do appear appropriate in terms of developing Markov analyses and	Thank you.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						in presenting base-case results and sensitivity analysis. Some relevant source data appears to have been missed in the literature review and there are some minor errors in describing aspects of the existing health economics literature but this is unlikely to have influenced the findings or added significantly to the strength of the □odelling.	
PR	NETSCC, Health Technology Assessment	15.02	Full	2.2.4	21	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** Line 17: The model for IBD is focused only on a "high risk group" since the authors report a lack of natural history data to support more extensive modeling. Hence, no modeling was undertaken to simulate progression from inflamed mucosa to *de novo* dysplasia in patients with longstanding IBD. Instead, the model considers a highly selective group of patients who "had flat dyplastic lesions who had declined surgery". Hence, patients in the model had dysplastic lesions diagnosed at their first screening colonoscopy and the model is actually looking at progression to cancer to serve as the trigger for intervention (surgery) during ongoing yearly surveillance. The comparator of "no surveillance" in this situation appears to imply that a patient with known dysplasia would be offered no subsequent repeat colonoscopy but rather undergo further evaluation only on	Thank you for your comments. The major component of the health economic model for IBD was the natural history of dysplasia because dysplasia is precancerous marker for colorectal cancer. This was considered appropriate by GDG. Due to limited data and resource availability, hypothetical population in the model was restricted to people with IBD and with confirmed dysplasia (low or high grade) to help decision making within the given timelines.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						symptomatic presentation of cancer – not a clinically realistic scenario for high grade dysplasia.	
PR	NETSCC, Health Technology Assessment	15.03	Full	2.2.4	21	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** Line 17: The model further assumes that a patient who declined surgery at the stage of high grade dysplasia (where there's a significant chance of invasive cancer being present already) would opt for surgery on subsequent diagnosis of invasive cancer at a repeat surveillance colonoscopy. This atypical scenario has limited relevance to assessing the overall cost-effectiveness of a screening program for detecting the development of dysplasia and cancer in longstanding IBD. Instead, the model considers a very narrow question of the cost-effectiveness of offering ongoing surveillance to patients who decline to commit to surgery on discovery of dysplastic lesions at first screening colonoscopy. The cost-effectiveness of surveillance for dysplasia/cancer in IBD in general remains uncertain.	Thank you for your comments however, screening of the IBD population is outside the remit
PR	NETSCC, Health Technology Assessment	15.04	Full	General	23	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** Line 7: "The model assumed there were no complications from colonoscopy – although perforation and bleeding are serious risks, they occur infrequently and were assumed	Thank you.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						to be negligible." This may be a reasonable assumption for the selected patient group in the model (see comments above), but any risk of morbidity/mortality arising from the procedure would be an important consideration for lower risk patient groups where the likelihood of dysplasia development is equally very small. However, □odelling was not performed for the lower risk groups. The quality and relative scarcity of the research evidence clearly presented difficulties for the health economics team and limited time is also cited as a barrier to producing a model that could shed light on the likely cost-effectiveness of screening in IBD in general.	
PR	NETSCC, Health Technology Assessment	15.05	Full	General	23	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** Line 11: Although it is true that IBD-Q scores do not translate into utility weights, there are published algorithms to assist this process (Buxton et al, Value Health. 2007 May-Jun;10(3):214-20). Given the fact that "dysplasia" *per se* is essentially a microscopic finding, it is difficult to accept that global HRQoL (utilities) are likely to be *different* between patients with LGD and HGD. Perhaps, on average, those with more dysplasia will have experienced more disease activity *in the past* but it's uncertain whether a patient's *current* overall symptom status would vary significantly according to	It was not appropriate to link quality of life to IBD based on Buxton et al. (2007) as no data was available on linking CDAI to levels of dysplasia. Therefore, it was considered appropriate to use Gregor et al. (1997) as it explicitly linked the health states in the model to utility values. This was explained in Appendix page 25. *"Uncertainty remains about the appropriate method to account for quality of life associated with dysplasia because it is asymptomatic, whereas other risk factors such as inflammation are symptomatic. The patient experts and clinical specialists in the GDG considered that the psychological burden of being diagnosed with dysplasia and the grade of dysplasia could be very*

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						the presence or absence HGD lesions at colonoscopy. It is the severity of overall colonic inflammation that dictates QoL in IBD rather than degrees of focal dysplasia. In the appendix 7.6, it appears that utility scores for patients with LGD were taken as equivalent to "mild Crohn's disease' and for HGD taken as 'moderate Crohn's disease' – this assumption lacks clinical validity. A sensitivity analysis in which utility inputs for LGD and HGD states were the same value would be of interest.	*high. The approach taken to address the uncertainty was to conduct both a one-way sensitivity analysis and a probabilistic sensitivity analysis, varying the utility values."* In the Appendix part 2, 7.3 it reads; *"The utility value for mild Crohn's disease was used as a proxy for low-grade dysplasia and the utility value for moderate Crohn's disease was used as a proxy for high-grade dysplasia. This approach seemed acceptable because the patient experts on the GDG felt that a person with low-grade dysplasia has a lower quality of life than a person in the general population and a person with high-grade dysplasia has a lower quality of life than a person with low-grade dysplasia."*
PR	NETSCC, Health Technology Assessment	15.06	Full	2.2.9		**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The □odelling for surveillance in adenoma patients is more relevant to the main decision question s for this patient group than the somewhat limited model for IBD. A 50-year Markov model identifies an appropriate base-case patient, incorporates relevant disease states and obtains transition probability and survival data from selected available literature (albeit without a complete systematic review of evidence). It appears that surveillance continues until	Thank you.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						death and the model does not explore any "stopping rule" based on age criteria – many patients would be de-selected from surveillance as they reach advanced age owing to co-morbidity or diminishing perceived benefit of detecting cancer. Furthermore, sensitivity/specificity of colonoscopy was assumed to be 100%, whereas in reality there is a finite "miss rate" of adenomas. However, □odelling for missed pathology would have added significantly to the complexity of the model. Results need to be interpreted accordingly.	
PR	NETSCC, Health Technology Assessment	15.07	Full	7.1	14	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The literature search appears to have been incomplete as the "Gregor et al, 1997" paper is *not* the only publication reporting utility values in IBD patients (e.g. Buxton, 2007). There are some more recent publications but these may have appeared after the original literature search.	GDG considered the use of utility values from Gregor et al. (1997) appropriate as it was directly relevant to the health states in the model and the clinical data available to the technical team.
PR	NETSCC, Health Technology Assessment	15.08	Full	7.3	15	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** See previous comments regarding assigning differing utility values according to grades of microscopic dysplasia	GDG considered the use of utility values from Gregor et al. (1997) appropriate as it was directly relevant to the health states in the model and the clinical data available to the technical team.
PR	NETSCC, Health Technology Assessment	15.09	Full	8.1	16	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.**	Thank you for your comment. This has been corrected.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						An error in the referencing of source literature ("Bodger et al, 2002") – this citation is a review article and the original cost-of-illness paper was "Bassi et al 2004". This has been used widely as a source of UK costings in some other published □odelling studies. The review authors suggest that the study did not provide a breakdown of costs (relative contribution of cost items was included) and that the results were reported in US dollars (incorrect; the study was reported in £ sterling).	
PR	NETSCC, Health Technology Assessment	15.10	Full	General		**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? B) Complete? i.e. are all the important aspects of the evidence reflected?** The available clinical evidence-base is limited and the topic presents major challenges in designing studies to resolve uncertainties. The guidelines appear to represent a pragmatic, well-considered consensus that draws on the available data and acknowledges the gaps in knowledge. The recommendations and are largely consistent with the British Society of Gastroenterology guidelines.	Thank you.
PR	NETSCC, Health Technology Assessment	15.11	Full	General		**3.2 Are any important limitations of the evidence clearly described and discussed?**	Thank you.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Yes	
PR	NETSCC, Health Technology Assessment	15.12	Full	General		**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Yes	Thank you.
SH	Royal College of Nursing	7.00	Full	General		It is a big document to get through but it is unclear what to do with distal or rectosigmoid disease patients. The most recent BSG guidelines on surveillance in moderate to high risk groups suggest left sided UC or greater. Does this mean rectosigmoid patients but not proctitis patients should be offered surveillance? We understand that this refers to full left sided rather than degrees of left sided disease per se. But consider that probably this could be made clearer in the guidelines.	Thank you for your comment. Left sided disease includes recto-sigmoid disease which is distinct from proctitis alone. [Recommendation 1.1.2 - table 1]
SH	Royal College of Nursing	7.01	Full	General		Also what about when to discontinue? Also though we consider that discontinuation is a matter to discuss with the patient and their individual condition including fitness to undergo colonoscopy also bearing in mind action to take i.e. any surgical procedure according to the findings rather than this being simply an age issue.	Recommendation 1.1.16 includes discussing discontinuation with the patient. The GDG noted that it is not appropriate to recommend a specific age to stop surveillance due to the range of factors involved in the decision specific to the patient.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						A recommendation on when to discontinue would be helpful.	
SH	Royal College of Pathologists	5.00	General			Please note that the Royal College of Pathologists has no comments to submit at this stage of the development	Thank you.
SH	UK National Screening Committee	4.00	Full	General		We welcome the document and note that it relates to high risk groups not whole population screening. It does however have an obvious link with an existing population screening programme: the bowel cancer screening programme (BCSP). We would be most concerned if the guidance in here did not closely match (or indeed was identical) to that of the BSCP. Policy and guidance dissonance at this level will mean that potentially clinicians may not follow either arguing that there is uncertainty.	Thank you for your comment. Our guidance is produced using the methodology outlined in the guidelines manual (http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/theguidelinesmanual2006/the_guidelines_manual_2006.jsp) and our recommendations are consistent with that of the British society for gastroenterology.
SH	UK National Screening Committee	4.01	Full	2.2.8		We were struck by evidence statement "there was no evidence for or against colonoscopic surveillance for the prevention and early detection of colorectal cancer after adenoma removal" This seems to fly in the face of the recommendations of your document which is to do surveillance on almost everyone but also in the face of the recent RCT in the Lancet that found flexisig and consequent treatments and follow ups (including colonoscopic surveillance) saved lives (lots of them). This needs more explanation (or perhaps the literature update was	Thank you. We have now updated the evidence statement to say "there was no high quality evidence" The RCT evaluated the screening of people with no known risk factors, not the surveillance of people known to be at high risk.

Type	Stakeholder	Order No	Document	Section No	Page No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						completed before the Lancet publication. Given that the proposed roll out of flexisig screwing is predicated on this trial this is an important policy area that needs to be consistent at national level.	
SH	UKCPA	9.00	General			UKCPA have no comments to make on this consultation	Thank you.

These stakeholder organisations were approached but did not respond