NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: General

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
1	Pentax Medical	Diagnostic consultation document, pg. 1.	We feel that the Advisory Committee preformed an extensive and comprehensive literature review and that all relevant evidence has been taken into account.	Thank you for your comment which the committee considered.
2	NHS Professional	5.3 - 6.1	Virtual Chromoendoscopy is an attractive idea because of the potential for reducing costs and streamlining care. The new endoscopic system can better enhance and characterize gastrointestinal lesions and predict histology in real time.	Thank you for your comment which the committee considered.
3	British Society of Gastroenterology	General	We are writing on behalf of the British Society of Gastroenterology, the Joint Advisory Group on GI endoscopy and the Bowel Cancer Screening Programme accreditation panel to give our response to the NICE diagnostic consultation document on virtual chromoendoscopy to assess colorectal polyps during colonoscopy. The BSG, JAG and the BCSP have a need and responsibility to assess, and where appropriate adopt new technologies such as virtual chromoendoscopy. The membership of all 3 professional bodies have been actively involved with virtual chromoendoscopy in the UK over the last decade and have contributed significantly to research and understanding of this	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			area. On an International stage, we are fortunate to have some highly regarded experts in this field. All 3 bodies are committed to developing the correct role for virtual chromoendoscopy and delivering it safely into clinical practise once the evidence base and appropriate training, accreditation and Quality Assurance is clear. With this background we have the following observations in relation to the recent NICE consultation document.	
4	British Society of Gastroenterology	General	The BCSP does not currently have any established role for virtual chromo endoscopy.	Thank you for your comment which the committee considered.
5	Royal College of Physicians	General	We would like to endorse the response submitted by the British Society of Gastroenterology.	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Endoscopist expertise

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6	British Society of Gastroenterology	General	Virtual chromo endoscopy has been demonstrated to work in expert hands, but in a large UK community base study UK endoscopists were not able to safely distinguish between adenomatous and hyperplastic polyps (DISCARD 2 study).	Thank you for your comment which the committee considered. The committee consideration of the DISCARD 2 study is described in section 5.2 of the diagnostics guidance. The committee concluded that the diagnostic accuracy of virtual chromoendoscopy technologies reported in the NICE assessment reflects the accuracy that could be achieved by endoscopists with experience of using virtual chromoendoscopy and who work in specialist or academic settings. The committee concluded further that diagnostic accuracy results in the NICE assessment probably do not reflect the accuracy that would be achieved by endoscopists with limited experience of virtual chromoendoscopy and who work in community-based settings.
7	British Society of Gastroenterology	General	Whilst the study was not powered for these outcomes the DISCARD 2 study did not demonstrate any difference between high definition and standard definition endoscopes and nor did it demonstrate a difference between expert (Bowel Cancer Screening	Thank you for your comment which the committee considered. The committee consideration of the DISCARD 2 study is described in section 5.2 of the

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			Programme accredited) and non-expert endoscopists. Whilst these endoscopists were not necessarily experts in virtual chromoendoscopy they are expert colonoscopists.	diagnostics guidance. The committee concluded that the diagnostic accuracy of virtual chromoendoscopy technologies reported in the NICE assessment reflects the accuracy that could be achieved by endoscopists with experience of using virtual chromoendoscopy and who work in specialist or academic settings. The committee concluded further that diagnostic accuracy results in the NICE assessment probably do not reflect the accuracy that would be achieved by endoscopists with limited experience of virtual chromoendoscopy and who work in community-based settings.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Training

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8	British Society of Gastroenterology	General	There are many studies demonstrating that optical diagnosis can be performed by experts but studies are less convincing when applied to general gastroenterologists. The training modalities utilised in the various studies varied hugely and we currently do not have clear evidence regarding the optimal training package and the efficacy of such a package.	Thank you for your comment which the committee considered. The committee consideration on training is described in section 5.16 of the diagnostics guidance. Additional detail has been added to this section to note that the most effective forms of training should be determined, and that this could be done through a collaboration between manufacturers of virtual chromoendoscopy technologies and the specialist societies.
9	Pentax Medical	Diagnostic consultation document, Draft Recommendation. pg. 2.	We support the need for endoscopist training to use virtual chromoendoscopy (i/e., “diagnostic accuracy achieved is likely to depend on the experience level of the endoscopist and the level of confidence in the polyp characterisation - Section 5.3 pg. 29)”. We also support the need to be accredited by the Joint Advisory Group for Gastrointestinal Endoscopy (JAG). Industry should have educators available with the education and competencies necessary to deliver structured, measured and effective teaching	Thank you for your comment which the committee considered. The committee consideration on training is described in section 5.16 of the diagnostics guidance. Additional detail has been added to this section to note that the most effective forms of training should be determined, and that this could be done through a collaboration between manufacturers of virtual chromoendoscopy technologies and the specialist societies.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			strategies. Education should be easy to access and multimodal.	

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Audit, accreditation and quality assurance

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
10	British Society of Gastroenterology	General	The Joint advisory group on GI endoscopy (JAG) in the UK does not have accreditation standards for optical diagnosis and is not currently able to develop those standards. JAG accreditation in colonoscopy (including screening colonoscopy) does not equate to endoscopists being able to undertake optical diagnosis, current accreditation does not assess this.	Thank you for your comment which the committee considered. The committee consideration on quality assurance is described in section 5.17 of the diagnostics guidance. This section was changed to highlight that quality assurance measures should be in place before virtual chromoendoscopy for assessment of polyps during colonoscopy can be used in clinical practice. Further changes highlighted that quality assurance measures, such as accreditation and monitoring of practice, are needed to ensure that only endoscopists who can meet the PIVI criteria can use virtual chromoendoscopy for making optical diagnoses, and to maintain high levels of diagnostic accuracy over time. The committee concluded that a national accreditation scheme on virtual chromoendoscopy for making optical diagnoses should be developed.
11	British Society of Gastroenterology	General	Neither JAG nor any other relevant UK specialist organisations (such as BSG or BCSP) has a system to audit endoscopists' use of optical diagnosis. JAG unit	Thank you for your comment which the committee considered.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			accreditation therefore cannot reassure that appropriate Quality Assurance will be undertaken.	Section 1.1 of the diagnostics guidance states that virtual chromoendoscopy is recommended only if the endoscopy service includes systems to audit endoscopists. The committee consideration on quality assurance is described in section 5.17 of the diagnostics guidance. This section was changed to highlight that quality assurance measures should be in place before virtual chromoendoscopy for assessment of polyps during colonoscopy can be used in clinical practice. Further changes highlighted that quality assurance measures, such as accreditation and monitoring of practice, are needed to ensure that only endoscopists who can meet the PIVI criteria can use virtual chromoendoscopy for making optical diagnoses, and to maintain high levels of diagnostic accuracy over time. The committee made a recommendation for further research (section 6.1 of the diagnostics guidance) that specified audit to monitor whether

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Audit, accreditation and quality assurance

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
				endoscopists using virtual chromoendoscopy (NBI, FICE and i-scan) are correctly assessing polyps as adenomatous and hyperplastic during colonoscopy.
12	British Society of Gastroenterology	General	Quality Assurance measures for lower gastroenterology endoscopic practice rely heavily on pathological confirmation of adenomas. The health economics of the screening program require the QA relating to ADR detection for individual endoscopists to ensure long term outcomes match the modelling used for the screening programme.	Thank you for your comment which the committee considered. The committee consideration on quality assurance is described in section 5.17 of the diagnostics guidance. This section was changed to highlight that quality assurance measures should be in place before virtual chromoendoscopy for assessment of polyps during colonoscopy can be used in clinical practice. Further changes highlighted that monitoring of practice is needed to ensure that only endoscopists who can meet the PIVI criteria can use virtual chromoendoscopy for making optical diagnoses, and to maintain high levels of diagnostic accuracy over time. The committee made a recommendation for further research (section 6.1 of the diagnostics

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Audit, accreditation and quality assurance

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				guidance) that specified audit to monitor whether endoscopists using virtual chromoendoscopy (NBI, FICE and i-scan) are correctly assessing polyps as adenomatous and hyperplastic during colonoscopy. The committee noted that annual audit of colonoscopists using virtual chromoendoscopy, for example where a fixed number of diminutive polyps that have been assessed consecutively with optical diagnosis are sent for analysis by histopathology, should enable adenomas detection rate to be checked.
13	British Society of Gastroenterology	General	The suggestion for a discard practice cannot currently be developed until the case for optical diagnosis is more robustly demonstrated and a validated alternative QA measure is developed to replace the need for pathological confirmation.	Thank you for your comment which the committee considered. The committee concluded that the assessment of diminutive colorectal polyps with virtual chromoendoscopy technologies is cost effective compared with assessment of diminutive colorectal polyps using histopathology (see sections 5.12 and 5.13 of the diagnostics guidance).

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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				The committee consideration on quality assurance is described in section 5.17 of the diagnostics guidance. This section was changed to highlight that quality assurance measures should be in place before virtual chromoendoscopy for assessment of polyps during colonoscopy can be used in clinical practice. Further changes highlighted that monitoring of practice is needed to ensure that only endoscopists who can meet the PIVI criteria can use virtual chromoendoscopy for making optical diagnoses, and to maintain high levels of diagnostic accuracy over time.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Economic modelling

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
14	British Society of Gastroenterology	General	Until the clinical validity of a virtual chromoendoscopy is established health economic analysis seems redundant.	Thank you for your comment which the committee considered. The committee decided that the levels of evidence on the clinical validity of virtual chromoendoscopy were sufficient to enable health economic evaluation.
15	OLYMPUS	4.20	A modelling approach incorporating QALYs is inappropriate for optical diagnosis of colorectal polyps where the key value driver is related to reducing the number of steps in the diagnostic process without compromising the ability to identify adenomas (i.e. an efficiency driver). The inappropriateness of this approach is indicated by the majority of existing literature on economic evaluations of colorectal polyp diagnosis which do not incorporate QALYs, including: • Hassan *et al.* Clinical Gastroenterology & Hepatology 2010;8(10):865-9 • Kessler *et al.* Endoscopy 2011;43(8):683-91 • Solon *et al.* Journal of Medical Economics 2016;19(11):1040-8	Thank you for your comment which the committee considered. The committee noted that the lack of published economic evaluations on virtual chromoendoscopy that incorporated QALYs does not mean that a cost-utility analysis approach is incorrect. It noted further that cost-utility analysis can capture changes in efficiencies and therefore the methodology used in the assessment was appropriate and in accordance with the reference case outlined in the diagnostics assessment programme manual. The committee decided that no changes to the diagnostics guidance were needed.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			• Longcroft-Wheaton et al. European Journal of Gastroenterology and Hepatology 2011;23(10):903-11 • Ignjatovic et al. Lancet Oncology 2009;10(12):1171-8 • Chandran et al. Internal Medicine Journal 2015;45(12):1293-9 • Longcroft-Wheaton and Bhandari. Gut 2011;60:A30 • Patel et al. Gastrointestinal Endoscopy 2016;AB421 Furthermore, an additional study which explored cost per QALY found that there was no difference in QALYs between optical diagnosis with NBI vs pathology: • McGill et al. Gastrointestinal Endoscopy 2013;AB168 This concept of efficiency and the potential limitations of an approach centred around QALYs are not sufficiently addressed in the final report and should be better	The committee noted that the endoscopist's level of experience would affect how many diminutive polyps are assessed with high confidence, and therefore how many polyps are sent to histopathology. For example, risk-averse practice (in which polyps that are likely to be hyperplastic are removed and sent to histopathology) is probably more common in endoscopists with less experience. Therefore, cost savings through avoiding histopathology assessment may not be as large in this group compared with experienced endoscopists, who are likely to assess more polyps with high confidence and send fewer to histopathology. The committee therefore decided that efficiency gains in endoscopy and histopathology services should be monitored through data collection and analysis (see section 6.3 of the diagnostics guidance).

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			emphasised throughout – specifically it should be made clearer that: • Efficiency gains are the biggest economic driver of virtual chromoendoscopy • The majority of published economic evaluations did not use a cost per QALY approach • A cost per QALY approach may not be the optimal economic assessment for virtual chromoendoscopy techniques in this context, given quality of life improvements are not a key value driver of their use To achieve this, we recommend either creating a new sub-section (5.14) or adding the following statements to: • Section 4.19: *"It should be noted that the majority of published economic evaluations for virtual chromoendoscopy techniques do not adopt a cost per QALY approach, reflecting that efficiency and not quality of life improvements are the key value driver of their use"* • Section 4.44: *"When interpreting these results, however, it is important to note that the key value driver of virtual chromoendoscopy techniques is*	

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			optimising the efficiency of diagnosis, so cost per QALY may not be the optimal economic evaluation approach given its reliance on quality of life to demonstrate meaningful differences between comparators"	
16	OLYMPUS	5.7	Although uncertainty of the appropriateness of the ScHARR model is alluded to in the final report, it does not sufficiently highlight the full limitations of its use – specifically: • It is driven by surveillance intervals and does not factor in the performance of virtual chromoendoscopy techniques o The authors themselves highlight that there is "considerable uncertainty surrounding the modelling of surveillance" due to transition rate data post polypectomy being very limited Our recommendation is, therefore, that the following text is incorporated into section 5.7 of the report: *"The committee therefore concluded that there was uncertainty about the SBCS model's results and the*	Thank you for your comment which the committee considered. The committee consideration on the suitability of the ScHARR model is discussed in section 5.7 of the diagnostic guidance. The committee decided that the key points relating to the uncertainties in the model had been adequately captured and no changes were needed in the diagnostics guidance.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

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			corresponding long-term cost and QALY estimates should be interpreted with caution. However, despite these uncertainties, in the absence of an alternative data source it was considered to be the most appropriate model for the assessment".	

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Patient acceptability

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
17	British Society of Gastroenterology	General	Until the clinical validity of virtual chromoendoscopy is established it is impossible to gauge patient views on the acceptability of such a policy. We cannot approach patients and ask them if an un validated form of practice would be acceptable to them.	Thank you for your comment which the committee considered. The committee decided that the levels of evidence on the clinical validity of virtual chromoendoscopy were sufficient to enable patient acceptability to be studied. It noted that UK based evidence on patient acceptability would contribute to the wider evidence base on virtual chromoendoscopy for use in the NHS. The committee decided to keep the recommendation for further research on patient acceptability of virtual chromoendoscopy (section 6.2 of the diagnostics guidance).

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Differences between the technologies

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
18	OLYMPUS	5.3	The final statement of this section is misleading as it implies all three technologies are similar, which contradicts the rest of the guidance which explores the differences in clinical and economic outcomes between the three. For clarity, we recommend this is reworded to better highlight the importance of appropriate training: *"Provided the endoscopists have undergone appropriate training and can make high confidence predictions, the committee concluded that NBI, FICE and i-scan were likely to perform similarly in clinical practice. This is because, in this context, the diagnostic accuracy achieved is likely to depend on the endoscopist experience level and level of confidence in polyp characterisation rather than the virtual chromoendoscopy technology used."*	Thank you for your comment which the committee considered. The committee discussed how the 3 technologies are likely to perform in clinical practice and noted that no direct comparative data is available. The committee concluded that it is unclear whether one virtual chromoendoscopy technology is superior to others. This consideration has been highlighted in section 5.3 of the diagnostics guidance.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Recommendations

Comment number	Name and organisation	Section number	Comment	NICE/EAG considerations
19	OLYMPUS	1.1	The draft recommendation makes no reference to confidence levels, despite current literature demonstrating confidence levels have an impact on the accuracy of diagnosis with high confidence predictions being the optimal standard. We recommend the draft recommendation is revised to indicate that virtual chromoendoscopy is recommended to assess polyps less than 5mm high only if they can be made with high confidence (i.e. low confidence predictions should not be recommended). It is suggested to add the following bullet point: *"Characterisation of polyps can be made with high confidence"*	Thank you for your comment which the committee considered. The committee decided to add in the requirement for polyps to be assessed with high confidence into the section 1 recommendation in the diagnostics guidance.
20	British Society of Gastroenterology	General	The view of the British Society of Gastroenterology, the Joint Advisory Group on GI endoscopy and the Chair of the Bowel Cancer Screening Programme accreditation panel is that virtual chromo endoscopy cannot yet be adopted into routine clinical practice. The British Society of Gastroenterology, the Joint Advisory Group on GI endoscopy and the Bowel Cancer Screening Programme Accreditation panel are unable to support the	Thank you for your comment which the committee considered. NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice. In addition NICE will support this guidance through a range of activities to promote the recommendations for further research.

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Recommendations

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			current NICE diagnostic advisory panel recommendations on virtual chromoendoscopy to assess colorectal polyps during colonoscopy. We would be very enthusiastic however in working with NICE and other stakeholders to develop an implementation plan as to how we might virtual chromoendoscopy forward into clinical practice.	

DIAGNOSTICS ASSESSMENT PROGRAMME

Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 15 February 2017

THEME: Further research

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21	British Society of Gastroenterology	General	Further research is required to establish: • If training in chromoendoscopy can result in individuals with the competence to use this technology with confidence and safety in a NHS service delivery setting. • The training requirements required in order for endoscopists to be sufficiently trained to be able to undertake virtual chromoendoscopy • Determine and assess quality assurance measures to monitor and audit the ability of individual endoscopists to undertake virtual chromoendoscopy • Whether there is a role for additional computer assisted diagnostics to aid clinician decision making in virtual chromoendoscopy • Once the clinical validity of virtual chromoendoscopy is established, the health economics aspects and patient acceptability aspects should be studied	Thank you for your comment which the committee considered.