NICE National Institute for Health and Care Excellence

NICE guidance

# Virtual chromoendoscopy to assess colorectal polyps during colonoscopy

HealthTech guidance
Published: 10 May 2017

www.nice.org.uk/guidance/htg438

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# Contents

This guidance replaces DG28.

# 1 Recommendation

1.1 Virtual chromoendoscopy using NBI, FICE or i-scan is recommended to assess polyps of 5 mm or less during colonoscopy, instead of histopathology, to determine whether they are adenomatous or hyperplastic, only if:

- high-definition enabled virtual chromoendoscopy equipment is used
- the endoscopist has been trained to use virtual chromoendoscopy, and accredited to use the technique under a national accreditation scheme
- the endoscopy service includes systems to audit endoscopists and provide ongoing feedback on their performance (see section 6.1) **and**
  - the assessment is made with high confidence.

# 2 Clinical need and practice

## The problem addressed

2.1 Colorectal polyps are small growths on the inner lining of the colon. Polyps are not usually cancerous; most are hyperplastic polyps with a low risk of cancer; but some (known as adenomatous polyps) will eventually turn into cancer if left untreated.

2.2 Detecting and removing adenomas during colonoscopy has been shown to decrease the later development of colorectal cancers. However, removal of any polyps by polypectomy may have adverse effects such as bleeding and perforation of the bowel. Also, as imaging technologies improve, more polyps may be found, which may in turn increase the number of polyps removed from a person and affect the workload of gastroenterologists and histopathologists.

2.3 It can take 3 weeks for a person to get the examination results for polyps that were removed during colonoscopy, and they may feel anxious during this waiting period.

2.4 Virtual chromoendoscopy technologies (Narrow Band Imaging [NBI], flexible spectral imaging colour enhancement [FICE] and i-scan), are intended to allow colour-enhanced visualisation of blood vessels and surface pattern compared with conventional colonoscopy, without using dyes.

2.5 Using virtual chromoendoscopy technologies may allow real-time differentiation of adenomas and hyperplastic colorectal polyps during colonoscopy, which could lead to: fewer resections of low-risk hyperplastic polyps (resulting in a reduction in complications); quicker results and management decisions; and reduced resource use through fewer histopathology examinations.

2.6 The purpose of this assessment is to evaluate the clinical and cost effectiveness of virtual chromoendoscopy (NBI, FICE and i-scan) for assessing diminutive (5 mm or less) colorectal polyps during colonoscopy to determine whether they are adenomatous or hyperplastic.

# The condition

## Colorectal polyps and colorectal cancer

2.7 Colorectal polyps are common, affecting 15% to 20% of the UK population. Most polyps produce no symptoms, but some larger polyps can cause a small amount of rectal bleeding, diarrhoea, constipation or abdominal pain.

2.8 Colorectal cancer is one of the most common cancers in the UK and is the second most common cause of cancer death. About 40,000 new cases are registered each year. Colorectal cancer is strongly related to age, with almost three-quarters of cases occurring in people aged 65 or over.

# The diagnostic and care pathways

## Diagnosis

2.9 Colonoscopy examinations may be done for several clinical reasons, including:

- further investigation of symptoms suggestive of colorectal cancer
- further investigation of a positive faecal occult blood test as part of the NHS bowel cancer screening programme **or**
- ongoing checks (surveillance) after removal of adenomatous polyps.

2.10 The NICE guideline on suspected cancer recommends that people should be referred for colorectal cancer investigations within 2 weeks if:

- they are aged 40 and over with unexplained weight loss and abdominal pain **or**
- they are aged 50 and over with unexplained rectal bleeding **or**
- they are aged 60 and over with iron-deficiency anaemia or changes in their bowel habit **or**

- tests show occult blood in their faeces.

2.11 The guideline also recommends that people should be considered for referral for colorectal cancer investigations if:

- they have a rectal or abdominal mass
- they are aged under 50 with rectal bleeding and have any of the following unexplained symptoms or findings:
  - abdominal pain
  - changes in bowel habit
  - weight loss **or**
  - iron deficiency anaemia.

2.12 The NHS bowel cancer screening programme offers screening every 2 years to men and women aged 60 to 74. The screening programme invites eligible adults to have a faecal occult blood test. This involves collecting 3 stool samples and posting them to the laboratory to be checked for the presence of blood, which could be an early sign of colorectal cancer. People with an abnormal faecal occult blood test result are offered a colonoscopy.

2.13 The NICE guideline on colonoscopic surveillance recommends that colonoscopies are offered to people:

- with inflammatory bowel disease whose symptoms started 10 years ago **or**
- who have had adenomas removed and are at intermediate or high risk of developing colorectal cancer.

  It also recommends that colonoscopic surveillance is considered for people who have had adenomas removed and are at low risk of developing colorectal cancer. The frequency of surveillance may be every 1, 3 or 5 years, depending on the level of risk of developing colorectal cancer.

2.14 For investigating possible colorectal cancer in secondary care, the NICE guideline on colorectal cancer recommends that:

- people without major comorbidity are offered colonoscopy
- people with major comorbidity are offered flexible sigmoidoscopy plus barium enema
- CT colonography is considered as an alternative to colonoscopy or flexible sigmoidoscopy plus barium enema, if the local radiology service can show competency in this technique
- people who have had an incomplete colonoscopy are offered repeat colonoscopy, CT colonography (if the local radiology service can show competency in this technique), or a barium enema.

2.15 If colorectal polyps are found during a colonoscopy they can be removed using cauterisation or a snare (polypectomy). Polyps removed by polypectomy are sent for histopathology to determine whether they are hyperplastic or adenomatous.

2.16 If colorectal cancer is suspected, biopsies are taken and sent to the laboratory to determine whether the sample contains benign or malignant cells. If colorectal cancer is confirmed, the NICE guideline on colorectal cancer recommends further imaging tests, such as CT or MRI, to stage the cancer and determine what treatment is needed.

2.17 Colonoscopy is usually done as an outpatient procedure with the person having sedation or painkillers. People having colonoscopy may be concerned about the adverse effects of the colonoscopy, such as heavy bleeding or perforation of the bowel. Colonoscopy with polypectomy also has an increased risk of bleeding and perforation compared with colonoscopy without polypectomy. Some people may also have a reaction to the sedative which could result in temporary breathing or heart problems.

## Care

2.18 If colorectal cancer is not diagnosed then surveillance colonoscopy is offered, and the length of time between assessments depends on the risk of cancer. The NICE guideline on colonoscopic surveillance recommends that people with:

- 1 or 2 small (less than 10 mm) adenomas are at low risk, and need either no, or 5-yearly, colonoscopic surveillance until they have 1 negative examination, after which surveillance stops
- 3 or 4 small adenomas of less than 10 mm or at least 1 adenoma that is 10 mm or more are at intermediate risk and should be screened 3-yearly until they have 2 consecutive negative examinations
- 5 or more adenomas smaller than 10 mm, or 3 or more adenomas at least one of which is 10 mm or more, are at high risk and should have an extra examination at 12 months before returning to 3-yearly surveillance.

2.19 If colorectal cancer is diagnosed, it may be treated with surgery, chemotherapy or radiotherapy, or sometimes with biological agents such as cetuximab. Treatment depends on the stage of the cancer and is described in more detail in the NICE guideline on colorectal cancer.

# 3 The diagnostic tests

The assessment compared 3 intervention tests with 1 comparator.

## The interventions

3.1 A conventional endoscopy system includes an endoscope, a light source, a video processor and a monitor. The light source produces light which is sent to the end of the endoscope. The video processor converts electrical signals into video signals and shows them on the monitor.

3.2 There are 2 types of virtual chromoendoscopy: optical chromoendoscopy and digital chromoendoscopy. Optical chromoendoscopy technologies have optical lenses, built into the endoscope's light source, which selectively filter white light to give narrow-band light. Digital chromoendoscopy technologies include digital processing of endoscopic images, which are produced in real-time by a video processor. Both methods can be switched on directly from an endoscope and are intended to allow high-contrast imaging of the mucosal surface without the need for dyes and additional equipment.

### Narrow Band Imaging

3.3 Narrow Band Imaging (NBI; Olympus) is a feature of recent Olympus 200 series video endoscopy systems. The company states that NBI should only be used in models with high-definition or high-resolution imaging. NBI is produced by the light source and displayed through the video processor and monitor. Optical filters are used on white light, resulting in narrow-band light, which consists of 2 wavelengths: 415 nm blue light and 540 nm green light. Narrow-band light is absorbed by vessels but reflected by mucosa, which increases the contrast between the vessels and the surrounding mucosa compared with using standard white light. The endoscopist can turn the NBI filter on or off as needed, to switch between standard white light and narrow-band imaging.

## Flexible spectral imaging colour enhancement

3.4 Flexible spectral imaging colour enhancement (FICE; manufactured by FujiFilm and distributed by Aquilant Endoscopy) is a software-based feature of Fuji endoscopy systems. Standard white light is directed at the tissue and the reflected light is captured and processed. Software turns conventional images into reconstructed spectral images by limiting the wavelengths of the light; the images are then shown in real-time. The image can be viewed in 10 different colour combinations. The pre-set wavelength patterns can also be changed manually. The endoscopist can move between the conventional image and the FICE image using a switch on the endoscope.

## i-scan

3.5 i-scan (Pentax Medical) is a software-based image enhancement technology for use with Pentax endoscopy systems. Images from standard white light endoscopy can be processed using 3 algorithms:

- surface enhancement, which improves the contrast between light and dark regions
- contrast enhancement, which adds blue colour to relatively dark areas to show mucosal surface detail
- tone enhancement, which changes the colour contrast to improve visibility of mucosal structure and blood vessels.

3.6 The 3 algorithms are used in different combinations to give 3 modes for detecting, characterising and demarcating lesions. The endoscopist can move between the conventional image and the different i-scan image modes by pushing a button on the endoscope.

# The comparator

## Histopathology

3.7 The comparator for this assessment is histopathology. It is assumed that in current practice all detected polyps are removed and sent to the laboratory for histopathology assessment. Polyps are examined to determine whether they are adenomatous, and therefore at high risk of cancer, or hyperplastic, and so at low risk.

# 4 Evidence

The diagnostics advisory committee considered evidence on virtual chromoendoscopy for real-time assessment of colorectal polyps during colonoscopy from several sources. Full details of all the evidence are in the committee papers.

## Clinical effectiveness

4.1 In total, 30 studies were included in the systematic review. There were 24 studies on Narrow Band Imaging (NBI), 3 studies on flexible spectral imaging colour enhancement (FICE) and 5 studies on i-scan. Two studies included more than 1 technology (1 study on NBI and FICE; and 1 study on NBI and i-scan). Fourteen studies were done in the US, 11 in Europe (of which, 4 were in the UK), 4 in Asia and 1 in Australia. Most of the studies were carried out in specialist centres. The QUADAS assessment found that all studies were at low risk of bias.

4.2 None of the included studies reported on health-related quality of life, mortality, incidence of colorectal cancer, or number of outpatient appointments.

### Virtual chromoendoscopy using Narrow Band Imaging

4.3 Twenty-four studies reported on the use of NBI. Most were done in a single centre and the results might not be generalisable to other centres. The endoscopists' levels of experience of using NBI varied: all endoscopists were experienced in 8 studies, some had experience in 4 studies, none had experience in 4 studies, and the experience levels were unclear for 8 studies.

#### Accuracy of Narrow Band Imaging for characterising diminutive colorectal polyps in the whole colon

4.4 Seventeen studies reported on the sensitivity of NBI and 16 studies reported on the specificity of NBI for characterisations of polyps made with any level of confidence. The sensitivity ranged from 0.55 to 0.97 and the specificity ranged

from 0.62 to 0.95. Bivariate meta-analysis of the 16 studies reporting on both sensitivity and specificity produced summary values of 0.88 (95% confidence interval [CI] 0.83 to 0.92) for sensitivity and 0.81 (95% CI 0.75 to 0.85) for specificity.

4.5 The sensitivity and specificity of NBI was higher for polyps diagnosed with high confidence, compared with those diagnosed with any level of confidence (that is, those assessed with low and high confidence). Eleven studies reported on the sensitivity and specificity of NBI for assessing polyps that were characterised with high confidence. Bivariate meta-analysis produced summary values of 0.91 (95% CI 0.85 to 0.95) for sensitivity and 0.82 (95% CI 0.76 to 0.87) for specificity.

4.6 A post-hoc bivariate meta-analysis was run for high-confidence characterisations, which only included studies with endoscopists who were experienced in using NBI (4 studies). The analysis produced summary values of 0.92 (95% CI 0.89 to 0.94) for sensitivity and 0.82 (95% CI 0.72 to 0.89) for specificity. Compared with the analysis for endoscopists with different levels of experience, the point estimate for sensitivity increased slightly from 0.91 to 0.92 and the specificity did not change. The confidence interval for sensitivity narrowed for experienced endoscopists compared with that for endoscopists with a variety of experience. The confidence interval for specificity for experienced endoscopists widened (0.72 to 0.89) compared with endoscopists with different levels of experience (0.76 to 0.87).

4.7 Sixteen studies reported on the negative predictive value of NBI for characterising diminutive polyps in the whole colon, made with any level of confidence. The negative predictive value ranged from 43% to 96%. The lower bound of the 95% confidence interval fell below 90% in all studies, apart from Patel et al. (2016).

4.8 Thirteen studies reported on the negative predictive value for high-confidence characterisations of polyps in the whole colon. The negative predictive value was higher for characterisations made with high confidence compared with those made with all levels of confidence. The range was 48% to 98%. When reported, the lower bound of the 95% confidence interval fell below 90% in all but 2 studies.

4.9 One study looked at the difference between the negative predictive value of characterisations done by specialists in colonoscopy and general endoscopists. The study found that specialists achieved a higher negative predictive value (90.9%; CI 70.8 to 98.9) than generalists (71.4%; 95% CI 47.8 to 88.8). However, the difference was not statistically significant.

## Accuracy of Narrow Band Imaging for characterising polyps in the rectosigmoid colon

4.10 Four studies reported on the sensitivity and specificity of NBI for assessing polyps in the rectosigmoid colon with high confidence and 3 studies reported data for assessing polyps in the rectosigmoid colon with any level of confidence. Bivariate meta-analysis for characterisations made with any level of confidence produced summary values of 0.85 (95% CI 0.75 to 0.91) for sensitivity and 0.87 (95% CI 0.74 to 0.94) for specificity. For characterisations made with high confidence, summary values were 0.87 (95% CI 0.80 to 0.92) for sensitivity and 0.95 (95% CI 0.87 to 0.98) for specificity.

4.11 A post-hoc bivariate meta-analysis was run for the 2 studies that included endoscopists who were experienced in using NBI. For high-confidence characterisations, it produced summary values of 0.90 (95% CI 0.71 to 0.97) for sensitivity and 0.98 (95% CI 0.91 to 1.00) for specificity. When compared with the bivariate analysis for endoscopists with different levels of experience, the point estimate for sensitivity increased from 0.87 to 0.90 and the point estimate for specificity increased from 0.95 to 0.98. The confidence interval for sensitivity widened for experienced endoscopists (0.71 to 0.97) compared with that for endoscopists with different levels of experience (0.80 to 0.92). The confidence interval for specificity narrowed slightly for experienced endoscopists (0.91 to 1.00) compared with that for endoscopists with different levels of experience (0.87 to 0.98).

## Other outcomes for Narrow Band Imaging

4.12 Thirteen studies reported on the agreement between surveillance intervals set when using NBI compared with those set by histopathology; agreement ranged

from 84% to 99%.

## Virtual chromoendoscopy using flexible spectral imaging colour enhancement

4.13 Three studies reported on the use of FICE. All studies were carried out in single centres and none reported on high-confidence characterisations of diminutive polyps or on a specific part of the colon. One study reported that the endoscopists did not have any experience of using FICE. In the remaining 2 studies, it was unclear whether the endoscopists had any experience.

### Accuracy of flexible spectral imaging colour enhancement for characterising diminutive colorectal polyps in the whole colon

4.14 All 3 studies reported the sensitivity and specificity of FICE for characterising polyps in any part of the colon. The sensitivity ranged from 0.74 to 0.88 and the specificity ranged from 0.82 to 0.88. Bivariate meta-analysis using all 3 studies produced summary values of 0.81 (95% CI 0.73 to 0.88) for sensitivity and 0.85 (95% CI 0.79 to 0.90) for specificity. The negative predictive values ranged from 70% to 84%.

## Virtual chromoendoscopy using i-scan

4.15 Five studies reported on the use of i-scan. Most of the studies were done in a specialist endoscopy centre by 1 endoscopist. So, it is unclear how generalisable the results are to different settings. Three studies reported that the endoscopists had experience of using i-scan. The remaining 2 studies did not report on level of experience.

### Accuracy of i-scan for characterising colorectal polyps in the whole colon

4.16 Two studies reported on high-confidence characterisations of polyps in the whole colon. Bivariate meta-analysis produced summary values of 0.96 (95% CI

0.92 to 0.98) for sensitivity and 0.91 (95% CI 0.84 to 0.95) for specificity.

4.17 Two studies reported that the negative predictive value of i-scan for detecting colorectal polyps in the whole colon was above 90%. But, the lower bound of the confidence interval for both studies was below 90%.

### Accuracy of i-scan for characterising polyps in the distal or rectosigmoid colon

4.18 Two studies reported that the negative predictive value of i-scan for detecting colorectal polyps in the distal or rectosigmoid colon was above 90%. But, the lower bounds of the confidence interval were below 90%.

# Cost effectiveness

## Review of economic evidence

4.19 Two studies were found that reported full economic evaluations comparing virtual chromoendoscopy with histopathology. Hassan et al. (2010) found no difference in life expectancy between the 2 strategies and therefore could not calculate a cost per life year gained. Kessler et al. (2011) found that the cost per life year gained for sending all polyps detected during colonoscopy for histological analysis, compared with a resect and discard strategy using virtual chromoendoscopy, was US $377,460. It is unclear how generalisable the results are to the NHS, because non-UK resource costs were used and health outcomes were not valued in quality-adjusted life years (QALYs).

## Modelling approach

4.20 The external assessment group (EAG) developed a de novo economic model to assess the cost effectiveness of virtual chromoendoscopy (NBI, FICE and i-scan) compared with histopathology for assessing colorectal polyps. The model took the perspective of the NHS and personal social services and all costs and QALYs were discounted at a rate of 3.5% per year. The model consisted of 2 parts. The

first part was a decision tree that estimated the short-term costs and outcomes of the first colonoscopy. In this model, polyps are assessed and a surveillance interval is assigned. The second part was an existing model used to estimate the long-term costs and QALYs for each surveillance classification, including incorrect surveillance classifications. The second model was a state transition model developed by the School of Health and Related Research (ScHARR), at the University of Sheffield, for the NHS bowel cancer screening programme. The model was chosen because it is a long-standing model that has been validated and was used to inform the introduction of the screening programme. The model was run independently and the cost and QALY estimates were entered as parameters at the end points of the decision tree model.

## Model structure

4.21 The decision tree compared the virtual chromoendoscopy strategies with a histopathology strategy. It had 4 main arms, 1 for each test that was assessed: NBI, FICE, i-scan and standard endoscopy with histopathology. The comparator arm of the decision tree assumed that all polyps are resected and sent to histopathology and everyone is given the correct surveillance interval.

4.22 Firstly, the cohort was divided into 4 risk categories based on the number of adenomas that they have:

- no adenomas
- low risk (1 to 2 adenomas)
- intermediate risk (3 to 4 adenomas)
- high risk (5 or more adenomas).

4.23 The model then calculated the proportion of patients in each category expected to have a correct surveillance interval assigned and the proportions expected to have an incorrect surveillance interval assigned.

4.24 With a virtual chromoendoscopy strategy, the following errors could lead to an incorrect surveillance interval (too long or too short) being assigned in the model:

- 1 or more hyperplastic polyps might be misclassified as an adenoma and so be unnecessarily resected
- 1 or more adenomas might be misclassified as a hyperplastic polyp and left in place.

4.25 The ScHARR bowel cancer screening (SBCS) model was designed to assess the cost effectiveness of different screening strategies for colorectal cancer for a lifetime time horizon. The model simulated the progression of colorectal cancer in people who are eligible for the bowel cancer screening programme in England.

## Population

4.26 The population in the base-case analysis was people taking part in the bowel cancer screening programme who had been referred for colonoscopy. Patients were included if they had at least 1 diminutive polyp (5 mm or less), and were excluded if they had 1 or more non-diminutive polyps (more than 5 mm). In addition, scenario analyses looked at:

- people offered colonoscopy as surveillance because they previously had adenomas removed **and**
- people referred to colonoscopy by a GP because of symptoms of colorectal cancer.

## Diagnostic strategy

4.27 Two different diagnostic strategies were explored in the economic analyses, the virtual chromoendoscopy strategy (used in the base case) and the DISCARD strategy (Detect, InSpect, ChAracterise, Resect, and Discard; used in some scenario analyses). The criteria common to both strategies were that diminutive polyps:

- in the whole colon are optically characterised using virtual chromoendoscopy
- diagnosed with high confidence as adenomas are resected and discarded

- diagnosed with low confidence are resected and sent to histopathology.

4.28 The characteristic unique to the virtual chromoendoscopy strategy was that diminutive polyps, in the whole of the colon, diagnosed with high confidence as hyperplastic are left in place.

4.29 The characteristics unique to the DISCARD strategy were that diminutive polyps:

- in the proximal colon, characterised with high confidence as hyperplastic, are resected and discarded.
- in the rectosigmoid colon, diagnosed with high confidence as hyperplastic, are left in place.

## Model inputs of the decision tree

4.30 The model inputs were taken from various sources, including routine sources of cost data, published literature, and the clinical-effectiveness review and meta-analyses.

4.31 The prevalence of adenomas was estimated for 3 populations: the screening population (base case), the surveillance population (scenario analysis) and the symptomatic population (scenario analysis). For the base-case analysis on the screening population, the prevalence of adenomas was taken from a published study by Raju et al. (2013) that retrospectively analysed data from a US colon cancer screening programme. The distributions of adenomas and the data sources for each population are reported in table 1.

**Table 1 Proportion of people by risk category for screening, surveillance and symptomatic population**

| Risk category | Screening population (Raju et al. 2013) | Surveillance population (Martinez et al. 2009) | Symptomatic population (McDonald et al. 2013) |
|---|---|---|---|
| No adenoma | 0.302 | 0.533 | 0.782 |
| Low risk | 0.535 | 0.358 | 0.125 |

| Risk category | Screening population (Raju et al. 2013) | Surveillance population (Martinez et al. 2009) | Symptomatic population (McDonald et al. 2013) |
|---|---|---|---|
| Intermediate risk | 0.107 | 0.072 | 0.061 |
| High risk | 0.056 | 0.037 | 0.032 |

4.32 Data on diagnostic accuracy were taken from the clinical-effectiveness review and meta-analysis for NBI, FICE and i-scan, as shown in table 2. Data were used for polyps in the whole colon that were characterised with high confidence in the base-case analysis for NBI and i-scan. Data were used for polyps in the whole colon that were characterised with any level of confidence in the base-case analysis for FICE. It was assumed that the proportion of low-confidence characterisations was the same for all 3 technologies, and was calculated using data from 12 NBI studies, because data were not available for FICE and i-scan. The comparator, histopathology, was assumed to be 100% accurate.

**Table 2 Sensitivity and specificity for virtual chromoendoscopy technologies**

| Parameter | Value | Lower 95% CI | Upper 95% CI | Source |
|---|---|---|---|---|
| NBI sensitivity | 0.910 | 0.855 | 0.945 | Meta-analysis |
| NBI specificity | 0.819 | 0.760 | 0.866 | Meta-analysis |
| FICE sensitivity | 0.814 | 0.732 | 0.875 | Meta-analysis |
| FICE specificity | 0.850 | 0.786 | 0.898 | Meta-analysis |
| i-scan sensitivity | 0.962 | 0.917 | 0.983 | Meta-analysis |
| i-scan specificity | 0.906 | 0.842 | 0.946 | Meta-analysis |
| Proportion of polyp characterisations made with low confidence | 0.214 | 0.21 | 0.22 | EAG literature review (the average value from 12 NBI studies that were included in the literature review; data were not available on the proportion of polyp characterisations made with low confidence for FICE and i scan) |

Abbreviations: CI, confidence interval; EAG, external assessment group; FICE, flexible spectral imaging colour enhancement; NBI, Narrow Band Imaging.

4.33 The probabilities of adverse events occurring during colonoscopy were assumed to be 0.003 for hospitalisation for bleeding with polypectomy, 0.003 for perforation with polypectomy, and 0.052 for death of patients with perforation during polypectomy. These values were taken from published values used in the SBCS model.

4.34 For the base-case analysis, the costs of colonoscopy, polypectomy, adverse events and histopathology were taken from the NHS reference costs for 2014/15 (see table 3). Training costs were assumed to be £14.72 per patient, based on the assumption that endoscopists complete 150 endoscopies per year and that training costs are equivalent to 2 days of pay (£1,104) per year.

**Table 3 Unit costs for colonoscopy and treating adverse events**

| Parameter | Value | Lower 95% confidence interval | Upper 95% confidence interval |
|---|---|---|---|
| Cost of colonoscopy without polypectomy | £518.36 | £340.89 | £695.83 |
| Cost of colonoscopy with polypectomy | £600.16 | £406.24 | £794.08 |
| Cost of treating bowel perforation (major surgery) | £2,152.77 | £902.21 | £3,403.33 |
| Cost of admission for bleeding (overnight stay on medical ward) | £475.54 | £327.69 | £623.39 |
| Pathology cost per polyp examination | £28.82 | £6.78 | £50.86 |

4.35 The cost of upgrading equipment was not included in the model. It was assumed that most hospitals already had equipment with virtual-chromoendoscopy-enabled technology in place, and hospitals that do not have this equipment will get it in the future as part of standard procurement. Therefore, the base-case analysis assumes that the cost of maintaining and purchasing equipment is included in the Healthcare Resource Group (HRG) cost of colonoscopy.

4.36 Health-related quality of life was calculated in the SBCS model. The base-case analysis used utility values taken from a study by Ara and Brazier (2011). The model assumes a utility of 0.697 for people with cancer and a utility of 0.798 for people without cancer.

4.37 A scenario analysis was done using utility values from a study identified by the EAG through a targeted search (Farkkila et al. 2013). For the scenario analysis, it was assumed that the utility for people with cancer was 0.761 and for people without cancer was 0.798.

4.38 No disutility values for adverse events during polypectomy, such as bowel perforation and bleeding, were found. Therefore, the values were taken from studies that reported on similar events. A QALY loss of 0.006 was taken from Dorian et al. (2014) for the disutility of a major gastrointestinal bleed and a QALY loss of 0.010 was taken from Ara and Brazier (2011) for the disutility of bowel perforation.

4.39 The costs and QALYs for the end points of the decision tree were calculated by running the SBCS model with a cohort of patients aged 65.

### Bowel cancer screening model inputs

4.40 The following changes were made to the SBCS model for this assessment:

- Colonoscopy and adverse-event costs were updated to 2014/15 costs.
- The screening costs were updated.
- Adenoma recurrence rates were adjusted to model people with higher-disease risk and people with adenomas left in the body.

## Base-case results

4.41 The following assumptions were applied in the base-case analysis:

- The long-term cost and QALY outcomes were estimated using the SBCS model, which assumed that standard colonoscopy with histopathology assessment of all polyps was used for follow-up surveillance. Therefore, diagnostic accuracy data and training costs associated with virtual chromoendoscopy were not included in the long-term results.
- Studies did not report on the relationship between diagnostic accuracy and

assigning people to the correct surveillance intervals, therefore the following was assumed:

  - diagnostic accuracy data were applied to individual polyps
  - the adenoma-to-hyperplastic-polyp ratio was assumed to be the same for each risk category.

- Only diminutive polyps were assessed, people with polyps larger than 5 mm were not included in the model.
- The proportion of polyps assessed with low confidence (21%) was assumed to be the same for NBI, FICE and i-scan.
- The disutility for bleeding was assumed to be similar to a major gastrointestinal bleed.
- The disutility for perforation was assumed to be the same as for a stomach ulcer, abdominal hernia or rupture.

4.42 The results of the base-case analysis can be seen in table 4a and table 4b. Pairwise analyses compared each of the 3 technologies in turn (NBI, FICE and i-scan) with histopathology. Results showed that NBI and i-scan dominated histopathology, that is, they were cheaper and more effective than histopathology. FICE was cost saving and less effective than histopathology, with an incremental cost-effectiveness ratio (ICER) of £671,383 saved per QALY lost.

4.43 The differences in incremental QALYs ranged from −0.0001 when FICE was compared with histopathology to 0.0007 when i-scan was compared with histopathology. The differences in costs ranged from −£87.70 when FICE was compared with histopathology to −£73.10 when NBI was compared with histopathology.

4.44 The lifetime risk of colorectal cancer according to the method of assessing polyps, calculated from the model, was:

- 3.025% for histopathology
- 3.020% for NBI

- 3.045% for FICE
- 3.021% for i-scan.

4.45 The fully incremental analyses show that histopathology was dominated by NBI and i-scan; and NBI was dominated by i-scan. When i-scan was compared with FICE it had an ICER of £10,466 per QALY gained.

**Table 4a Cost-effectiveness results from the lifetime economic model: full incremental results**

| Assessment | Costs | Inc | QALYs | Inc | ICER (£ per QALY) |
|---|---|---|---|---|---|
| Histopathology | £988.95 | – | 11.2703 | – | Dominated |
| FICE | £901.25 | −£87.70 | 11.2701 | −0.0001 | – |
| i-scan | £909.74 | £8.49 | 11.2709 | 0.0008 | £10,465.74 |
| NBI | £915.85 | £6.11 | 11.2708 | −0.0001 | Dominated |

**Table 4b Cost-effectiveness results from the lifetime economic model: pairwise comparisons**

| Assessment | Costs | Inc | QALYs | Inc | ICER (£ per QALY) |
|---|---|---|---|---|---|
| Histopathology | £988.95 | – | 11.2703 | – | – |
| NBI | £915.85 | −£73.10 | 11.2708 | 0.0005 | Dominates |
| Histopathology | £988.95 | – | 11.2703 | – | – |
| FICE | £901.25 | −£87.70 | 11.2701 | −0.0001 | £671,383 (incremental cost saving per QALY lost) |
| Histopathology | £988.95 | – | 11.2703 | – | – |
| i-scan | £909.74 | −£79.21 | 11.2709 | 0.0007 | Dominates |

Abbreviations: FICE, flexible spectral imaging colour enhancement; ICER, incremental cost-effectiveness ratio; Inc, incremental; NBI, Narrow Band Imaging; QALY, quality-adjusted life year.

## Analyses of alternative scenarios

4.46 The EAG did 12 scenario analyses, and a further 2 scenario analyses were done as an addendum to the assessment report. Fewer scenario analyses were done for FICE, because data were unavailable. Results of the scenario analyses show that NBI and i-scan were dominant in all scenario analyses when compared with histopathology.

4.47 When FICE was compared with histopathology, it was cost effective in all scenario analyses. FICE was cheaper and more effective than histopathology and therefore was dominant when:

- the risk-category distributions for the cohort were changed to reflect a population that was having surveillance colonoscopy
- the risk-category distributions for the cohort were changed to reflect a cohort with symptoms **and**
- the discard strategy was applied and diagnostic accuracy data were used for all levels of confidence for characterisations in the whole colon.

4.48 When alternative utility values were used from Farkkila et al. (2013), FICE was cheaper and slightly less effective compared with histopathology and had an ICER of £1,273,941 saved per QALY lost.

4.49 When diagnostic accuracy data were used from studies that reported data for endoscopists experienced in using NBI for the whole colon and the rectosigmoid colon, the results were similar to the base-case analyses for virtual chromoendoscopy and NBI dominated histopathology.

4.50 The effect of using virtual chromoendoscopy (NBI) for surveillance was explored and found to be small; it was estimated to increase cost savings by £20 and increase QALYs gained by 0.0003.

4.51 The EAG produced an addendum with 2 scenario analyses on adverse events. The first analysis varied the rate of perforation during colonoscopy using ratios from the data in Rutter et al. (2014), and found that cost savings for all 3 technologies decreased slightly in relative and absolute terms, and the QALYs decreased slightly in absolute terms, whereas the relative change was large (see

table 5). NBI and i-scan still dominated histopathology and the ICER for FICE increased to £126,229 saved per QALY lost. The second analysis included the risk of an adverse event happening during all colonoscopies, as well as for colonoscopies with polypectomy. This analysis also used data from Rutter et al. and found that cost savings for all 3 technologies decreased slightly in relative and absolute terms, and the QALYs decreased slightly in absolute terms, whereas the relative change was large (see table 6). NBI and i-scan still dominated histopathology and the ICER for FICE increased to £342,438 saved per QALY lost.

**Table 5 Cost-effectiveness results with the revised rate of perforation during colonoscopy using data from Rutter et al. (2014)**

| Assessment comparison | Base-case inc cost | Revised inc cost | Relative change in cost compared with base case | Base-case inc QALYs | Revised inc QALYs | Relative change in QALYs compared with base case |
|---|---|---|---|---|---|---|
| Histopathology versus NBI | −£73.10 | −£72.47 | −0.9% | 0.0005 | 0.0001 | −80% |
| Histopathology versus FICE | −£87.70 | −£86.92 | −0.9% | −0.0001 | −0.0007 | −600% |
| Histopathology versus i-scan | −£79.21 | −£78.60 | −0.8% | 0.0007 | 0.0002 | −71% |

Abbreviations: FICE, flexible spectral imaging colour enhancement; Inc, incremental; NBI, Narrow Band Imaging; QALY, quality-adjusted life year.

**Table 6 Cost-effectiveness results with risk of perforation and increased bleeding in all colonoscopies including those without polypectomy**

| Assessment comparison | Base-case inc cost | Revised inc cost | Relative change in cost compared with base case | Base-case inc QALYs | Revised inc QALYs | Relative change in QALYs compared with base case |
|---|---|---|---|---|---|---|
| Histopathology versus NBI | −£73.10 | −£73.06 | −0.05% | 0.0005 | 0.0004 | −20% |
| Histopathology versus FICE | −£87.70 | −£87.65 | −0.06% | −0.0001 | −0.0003 | −200% |
| Histopathology versus i-scan | −£79.21 | −£79.16 | −0.06% | 0.0007 | 0.0006 | −15% |

Abbreviations: FICE, flexible spectral imaging colour enhancement; inc, incremental; NBI, narrow band imaging; QALY, quality-adjusted life year.

## One-way deterministic sensitivity analyses results

4.52 The one-way deterministic sensitivity analyses found that the parameters with the most influence on the cost effectiveness of the tests were pathology cost, the probability of perforation with polypectomy, and the proportion of patients who die from perforation. All one-way sensitivity analyses showed that NBI, FICE and i-scan were cost effective compared with histopathology at a maximum acceptable ICER of £30,000 per QALY gained.

## Probabilistic sensitivity analysis results

4.53 The EAG did a probabilistic sensitivity analysis by varying the base-case inputs for the decision tree. The analysis was done by running the model 5,000 times. Each time it was run, the inputs were varied according to the distribution of the input.

4.54 The probabilistic sensitivity analysis found that i-scan was more likely to be cost effective than NBI and FICE. At a maximum acceptable ICER of £20,000 per QALY gained, i-scan was cost effective in 85.2% of the analyses, and at a maximum acceptable ICER of £30,000 per QALY gained i-scan was cost effective in 99.5% of the analyses.

# 5 Committee discussion

5.1 The committee considered the potential benefits of using virtual chromoendoscopy technologies for real-time assessment of diminutive polyps during colonoscopy. The committee heard from a clinical expert that the purpose of colonoscopy with polypectomy is to protect against developing colorectal cancer. The committee also heard that if virtual chromoendoscopy was used to characterise diminutive polyps (5 mm or less), fewer hyperplastic polyps would be resected which may reduce adverse events and costs for histopathology. The committee noted that a large proportion of people assessed in the bowel cancer screening programme only have diminutive polyps, and that an analysis of the data from the bowel cancer screening programme has shown that only 0.19% of diminutive polyps were cancerous. The committee concluded that the risk of colorectal cancer in people who only have diminutive polyps is low.

## Clinical effectiveness

5.2 The committee considered the generalisability of the evidence base to clinical practice in the NHS. The committee noted that most of the endoscopies in the studies included in the assessment were done by experienced endoscopists in single academic centres, most of which were outside of the UK. The committee also noted that the UK-based DISCARD 2 study was excluded from the assessment because only 22% of the participating centres had high-definition equipment. The committee heard from clinical experts that DISCARD 2 was a multicentre community-based study, with 28 endoscopists, which compared Narrow Band Imaging (NBI) with histopathology and was considered to reflect clinical practice in the NHS. The results of this study showed that the sensitivity of NBI for real-time assessment of diminutive polyps was lower than the accuracy estimated in this assessment (0.76 compared with 0.87 to 0.92). The committee concluded that the diagnostic accuracy of virtual chromoendoscopy technologies reported in this assessment reflect 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 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.

5.3 The committee considered the differences between the 3 virtual chromoendoscopy technologies (NBI, flexible spectral imaging colour enhancement [FICE] and i-scan). The committee heard from clinical experts that FICE and i-scan work differently to NBI; they are software-based image enhancement technologies, whereas NBI uses optical filters on white light, resulting in narrow-band light which enhances the contrast between the vessels and the surrounding mucosa. The committee also heard that the type of technology in place in centres is likely to vary, and equipment is replaced every 5 to 8 years. The committee then considered the different levels of evidence available for NBI, FICE and i-scan. It noted that most studies were on NBI and very few studies were on FICE and i-scan. It also noted that most of the studies on i-scan were done in academic centres, by 1 endoscopist experienced in using virtual chromoendoscopy, and this resulted in higher accuracy results for i-scan compared with NBI. It noted also that none of the studies on FICE limited the accuracy data to high-confidence characterisations of polyps, and this resulted in lower accuracy results for FICE compared with NBI. The committee concluded that, without direct comparative data, it is unclear whether one virtual chromoendoscopy technology is superior to others. It concluded further that NBI, FICE and i-scan will probably perform similarly in clinical practice, because the diagnostic accuracy achieved is likely to depend on the experience level of the endoscopist and the level of confidence in the polyp characterisation more than on the virtual chromoendoscopy technology used.

5.4 The committee considered the diagnostic accuracy of virtual chromoendoscopy technologies for real-time assessment of diminutive polyps. The committee noted that the American Society for Gastrointestinal Endoscopy has developed criteria on diagnostic accuracy that endoscopic technologies must meet before being considered appropriate for use in US clinical practice (the Preservation and incorporation of valuable endoscopic innovations [PIVI] criteria). The PIVI criteria on real-time assessment of diminutive colorectal polyps guides decisions on resecting and discarding polyps without histopathologic assessment. These criteria are:

- technologies should have an agreement of 90% or more with the surveillance intervals set by histopathology

- the negative predictive value of the technology for assessing adenomatous polyp histology should be 90% or more.

  The committee heard from clinical experts that the PIVI criteria, which are used in US clinical practice, were widely accepted in the UK gastrointestinal community. The committee concluded that the diagnostic accuracy of NBI, FICE and i-scan were likely to meet the PIVI criteria if used by endoscopists with experience of virtual chromoendoscopy technologies.

5.5 The committee discussed the accuracy of the comparator test, histopathology. The committee heard from clinical experts that histopathology is considered to be the gold standard in current practice, but it is actually an imperfect reference standard for diagnosing polyps. The committee also heard from clinical experts that currently about 8% to 10% of diminutive polyps do not have histopathology assessment because they are lost or destroyed before they reach the histopathologist and they are therefore assumed to be adenomatous. It heard further that polyp characterisation using histopathology assessment is 90% to 95% correct. The committee concluded that given the limitations of histopathological assessment of polyps, the diagnostic accuracy of the virtual chromoendoscopy technologies is likely to be more accurate than data from the studies suggests.

5.6 The committee discussed the consequences of misdiagnosing diminutive polyps using virtual chromoendoscopy. The committee noted that if virtual chromoendoscopy is used for real-time assessment of polyps, 3% to 6% of the surveillance intervals are likely to be incorrectly assigned. The committee heard from clinical experts that if virtual chromoendoscopy is used, over-surveillance would be slightly more common than under-surveillance. The committee noted that the effect on clinical outcomes from incorrectly leaving diminutive adenomatous polyps in place and incorrectly assigning a surveillance interval that is too long is uncertain. The committee heard from the external assessment group (EAG), however, that the lifetime risk of colorectal cancer calculated from the model was similar for the 3 virtual chromoendoscopy technologies and histopathology (3.025% for histopathology, 3.020% for NBI, 3.045% for FICE and 3.021% for i-scan; see section 4.44). It concluded that although there was some uncertainty over how the diagnostic accuracy data would translate into clinical outcomes, it was aware that an end-to-end study on clinical outcomes would

need to be done on a large cohort over a long period of time and so may not be feasible.

# Cost effectiveness

5.7 The committee discussed the uncertainties around using the School of Health and Related Research's (ScHARR) bowel cancer screening (SBCS) model for the assessment. The committee was aware that ScHARR ran the SBCS model on behalf of the EAG, and therefore the EAG was unable to internally validate the model results. However, it noted that the model had previously been validated for use to inform the NHS bowel cancer screening programme strategy, and that the costs in the model had been updated to reflect current costs. The committee heard from the EAG that there were structural uncertainties in the model, for example, the accuracy of virtual chromoendoscopy was not used for ongoing surveillance. However, the committee noted that it would not have been possible for the EAG to build a de novo model because of the level of resource needed to develop such a complex model. The committee therefore concluded that although there was some uncertainty about the SBCS model's results, it was considered to be the most appropriate model for the assessment.

5.8 The committee considered the cost of histopathology assessment of polyps used in the model. It heard from the EAG that in the base-case analysis, the cost of histopathology per polyp was based on the NHS reference cost for direct access pathology for 2014/15, which lists the cost of histopathology and histology as £28.82 (DAPS02). The committee noted that this reference cost is likely to include requests from community services, such as GPs, for histopathology and that there is no stratification by sample type (for example, type of specimen or tissue preparation), which may affect the cost. The committee noted further that the true cost of histopathology assessment of colorectal polyps was probably more than £50 per polyp. The committee concluded that the cost of histopathology was likely to be underestimated in the model, and so the cost savings for virtual chromoendoscopy technologies were likely to be greater than the model suggested.

5.9 The committee discussed the proportion of hospitals that already have high-definition enabled virtual chromoendoscopy equipment in place. The committee

heard from the EAG that the economic model assumed that the cost of upgrading colonoscopy equipment would be included in the NHS reference costs for colonoscopy (see table 3). The committee heard from clinical experts that most endoscopes were replaced every 5 to 8 years and the video system is likely to be replaced every 10 years because repairs after this period are often not supported. The committee heard further that most centres will have at least 1 virtual-chromoendoscopy-enabled machine. The committee concluded that the assumption made in the economic model was reasonable.

5.10 The committee discussed the assumption used in the model that histopathology is 100% accurate when assigning surveillance intervals. It heard from clinical experts that although histopathology is considered to be the gold standard, the diagnostic accuracy is likely to be below 100% (see section 5.5). The committee concluded that the clinical effectiveness of histopathology was likely to have been overestimated in the model, and therefore the difference in clinical effectiveness between histopathology and the virtual chromoendoscopy technologies was likely to be smaller than the results suggested.

5.11 The committee considered the implications for histopathology laboratories of adopting virtual chromoendoscopy for real-time assessment of colorectal polyps. The committee heard from clinical experts that histopathology laboratories are under considerable strain because of high workloads, and that diminutive colorectal polyp assessment is an important cause of this overload. The committee discussed whether using virtual chromoendoscopy for real-time assessment of diminutive polyps rather than sending all of these to histopathology could reduce this workload and result in cost savings or free histopathologists for other priorities. 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 concluded that virtual chromoendoscopy used by experienced endoscopists could reduce the number of diminutive polyps sent to histopathology laboratories, therefore

freeing histopathology resources.

5.12 The committee discussed the results of the cost-effectiveness analysis and noted that in the base case, the NBI and i-scan dominated histopathology, that is, they were cheaper and more clinically effective than histopathology. The committee also noted that in the base case, FICE could be considered cost effective with an incremental cost-effectiveness ratio (ICER) of £671,000 saved per quality-adjusted life year (QALY) lost (see section 4.42). However, the committee noted that the base-case analysis only included adverse events for colonoscopy with polypectomy. The committee heard from a clinical expert that there is also a risk of adverse events from a colonoscopy even without a polypectomy. It heard from the EAG that an analysis was done which included the risks of adverse events from all colonoscopies as well as for colonoscopy with polypectomy (see section 4.51). The committee noted that in this analysis, NBI and i-scan still dominated histopathology and the ICER for FICE decreased to £342,000 saved per QALY lost. The committee concluded that the most plausible results came from the scenario analysis that included a risk for adverse events for colonoscopy without polypectomy. The committee further concluded that NBI, FICE and i-scan could be cost-effective options for assessing diminutive polyps.

5.13 The committee discussed the robustness of the results of the economic model. It noted that results of the sensitivity and scenario analyses showed that NBI and i-scan were dominant compared with histopathology in all scenario analyses. It noted further that FICE dominated histopathology in some analyses and was considered cost effective in other analyses, with ICERs ranging from £126,000 to £1,270,000 saved per QALY lost. The committee considered that although there were limitations and uncertainties in the economic assessment (see section 5.7), the sensitivity analyses showed that the results were robust to changes. The committee concluded that the results of the economic model could be considered to be fairly robust.

5.14 The committee considered all its discussions on virtual chromoendoscopy, and noted its conclusions that:

- optical diagnosis using virtual chromoendoscopy technologies was likely to meet the PIVI criteria if used by endoscopists with experience of virtual chromoendoscopy technologies (see section 5.4)

- the lifetime risk of colorectal cancer was estimated to be similar when diminutive polyps were assessed and surveillance intervals were set using virtual chromoendoscopy technologies or histopathology (see section 5.6)
- 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)
- the virtual chromoendoscopy technologies are cost saving when they are used to implement a management strategy which reduces the number of diminutive polyps sent for histopathological analysis (see section 5.11).

The committee therefore concluded that virtual chromoendoscopy using NBI, FICE or i-scan to assess diminutive polyps during colonoscopy, instead of sending polyps to histopathology, could be considered clinically effective and cost effective if done by a specialist group, that is, endoscopists with expertise in optical diagnosis using virtual chromoendoscopy technologies.

# Other considerations

5.15 The committee considered whether using virtual chromoendoscopy for real-time assessment of diminutive polyps and using a discard strategy was acceptable to people. The committee heard from a clinical expert that there were no UK-based studies that looked at patient acceptability, but 2 studies from the US and 1 study from Australia with data on patient acceptability were available. In the US study, many patients stated that they would pay $150 from their own pocket to have polyps removed and assessed by histopathology, instead of using real-time assessment of polyps with a discard strategy (Vu et al. 2015). The committee concluded that further research on patient acceptability of virtual chromoendoscopy for real-time assessment of diminutive polyps and use of a discard strategy would be valuable.

5.16 The committee considered the effect of training for endoscopists on the diagnostic accuracy of NBI, FICE and i-scan. The committee heard from clinical experts that the DISCARD 2 study had implemented a programme consisting of a 1-hour training session using PowerPoint images followed by a test. The

committee noted that the results of the study suggested that training and monitoring for endoscopists needed to be more rigorous to maintain high levels of diagnostic accuracy for virtual chromoendoscopy technologies. The committee heard that the manufacturers of the technologies offer 2 forms of training for endoscopists, both developed with experts: peer-to-peer training at centres of excellence; and online training for self-study. The committee also heard that general experience in diagnosing polyps and familiarity with polyp classification systems, combined with acting on feedback from peers, were important factors in improving the skill levels of endoscopists. It concluded that the most effective forms of training should be determined, and that this could be done through collaboration between manufacturers of virtual chromoendoscopy technologies and professional organisations.

5.17 The committee discussed the need for quality assurance measures to be in place before virtual chromoendoscopy for assessment of polyps during colonoscopy can be used in clinical practice. It heard from clinical experts that the skills of endoscopists who do colonoscopies are known to vary. The committee heard further that quality assurance measures, such as accreditation and monitoring of practice, were needed to ensure that virtual chromoendoscopy for making optical diagnoses is only used by endoscopists who can meet the PIVI criteria, and to maintain high levels of diagnostic accuracy over time. The committee also noted that there was currently no accreditation or monitoring system in place for virtual chromoendoscopy and heard that any accreditation and monitoring scheme would need to be rolled out to both clinicians and nurse-endoscopists. The committee concluded that a national accreditation scheme for using virtual chromoendoscopy to make optical diagnoses should be developed. It concluded further that when virtual chromoendoscopy technologies are used, intermediate measures should be monitored for quality assurance and to give endoscopists ongoing feedback.

# 6 Recommendations for further research

6.1 Audit is recommended to monitor whether endoscopists using virtual chromoendoscopy (Narrow Band Imaging [NBI], flexible spectral imaging colour enhancement [FICE] and i-scan) are correctly assessing polyps as adenomatous and hyperplastic during colonoscopy. Measures may include:

- the diagnostic accuracy of polyp characterisation achieved **and**
- agreement with the surveillance interval for colonoscopy set by histopathology.

6.2 Further research is recommended on patient acceptability of using virtual chromoendoscopy for real-time assessment of diminutive polyps compared with assessment using histopathology.

6.3 Data collection and analysis are recommended to monitor the effect on endoscopy and histopathology services of using virtual chromoendoscopy instead of histopathology to assess diminutive polyps. Measures may include:

- the length of time to do colonoscopies
- the number of polyps sent for histopathology analysis
- cost savings or workload reductions associated with reductions in histopathology.

# 7 Implementation

NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for the development of specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 6 into its guidance research recommendations database (available on the NICE website) and highlight these recommendations to public research bodies.

# 8 Diagnostics advisory committee members and NICE project team

## Diagnostics advisory committee

The diagnostics advisory committee is an independent committee consisting of 22 standing members and additional specialist members. A list of the committee members who participated in this assessment appears below.

### Standing committee members

**Professor Adrian Newland**
Chair, diagnostics advisory committee and Professor of Haematology, Barts Health NHS Trust

**Dr Mark Kroese**
Vice Chair, diagnostics advisory committee and Consultant in Public Health Medicine, PHG Foundation, Cambridge and UK Genetic Testing Network

**Professor Ron Akehurst**
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

**Mr John Bagshaw**
Industry Representative, IVD Consultant

**Dr Sue Crawford**
GP Principal, Chillington Health Centre

**Dr Steve Edwards**
Head of Health Technology Assessment, BMJ Evidence Centre

**Dr Simon Fleming**
Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital

**Dr James Gray**
Consultant Microbiologist, Birmingham Children's Hospital

**Professor Steve Halligan**
Professor of Radiology, University College London

**Mr John Hitchman**
Lay Member

**Professor Chris Hyde**
Professor of Public Health and Clinical Epidemiology, Peninsula Technology Assessment Group (PenTAG)

**Mr Patrick McGinley**
Head of Costing and Service Line Reporting, Maidstone and Tunbridge Wells NHS Trust

**Dr Michael Messenger**
Deputy Director and Scientific Manager NIHR Diagnostic Evidence Co-operative, Leeds

**Mrs Alexandria Moseley**
Lay Member

**Dr Peter Naylor**
GP, Chair Wirral Health Commissioning Consortia

**Dr Dermot Neely**
Consultant in Clinical Biochemistry and Metabolic Medicine, Newcastle upon Tyne NHS Trust

**Dr Simon Richards**
Vice President Regulatory Affairs, Europe and Middle East, Alere Inc

**Professor Mark Sculpher**
Professor of Health Economics, Centre for Health Economics, University of York

**Professor Matt Stevenson**
Professor of Health Technology Assessment, School of Health and Related Research (ScHARR), University of Sheffield

**Professor Anthony Wierzbicki**
Consultant in Metabolic Medicine/Chemical Pathology, St Thomas' Hospital

## Specialist committee members

**Dr James East**
Consultant Gastroenterologist and Endoscopist, John Radcliffe Hospital

**Mrs Susan McConnell**
Nurse Endoscopist, County Durham and Darlington Foundation Trust

**Dr Morgan Moorghen**
Consultant Histopathologist, Northwick Park Hospital

**Dr Venkat Subramanian**
Clinical Associate Professor and Consultant Gastroenterologist, Leeds Institute of Biomedical and Clinical Sciences

# NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

**Jessica Maloney**
Topic Lead (to December 2016)

**Frances Nixon**
Technical Adviser (to December 2016) and Topic Lead (from January 2017)

**Rebecca Albrow**
Technical Adviser (from January 2017)

**Robert Fernley**
Project Manager

# Update information

**Minor changes since publication**

**December 2025:** Diagnostics guidance 28 has been migrated to HealthTech guidance 438. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-7371-2