NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Assessment Programme

Virtual chromoendoscopy for real-time assessment of colorectal polyps during colonoscopy

Final scope

February 2016

1 Introduction

The Medical Technologies Advisory Committee identified virtual chromoendoscopy for real-time assessment of colorectal polyps during colonoscopy, as potentially suitable for evaluation by the Diagnostics Assessment Programme on the basis of a briefing note. This scope was informed by discussions at the scoping workshop held on 22 January 2016 and the assessment subgroup meeting held on 5 February 2016. A glossary of terms and a list of abbreviations are provided in appendices A and B.

2 Description of the technology

This section describes the properties of the virtual chromoendoscopy technologies based on information provided to NICE by companies and clinical experts. NICE has not carried out an independent evaluation of these descriptions.

2.1 Purpose of the medical technology

Colorectal polyps, that is, fleshy growths on the lining of the colon, may be detected during a colonoscopy. Polyps are not normally cancerous; however, some polyps (known as neoplastic polyps or adenomatous polyps) will eventually turn into cancer if left untreated. In current clinical practice, all detected colon polyps (except some polyps in the rectosigmoid area) are removed and their histopathology is examined to determine whether the polyp is neoplastic, and therefore at high risk of cancer, or non-neoplastic, and therefore at low risk of cancer. Conventional white light endoscopy is currently used to detect polyps and may be used in combination with dyes (chromoendoscopy). Virtual chromoendoscopy technologies aim to provide colour-enhanced visualisation of blood vessels and surface pattern compared with conventional endoscopy, but without the use of dyes. This may enable real-time differentiation of neoplastic and non-neoplastic colorectal polyps

during colonoscopy. This could lead to the need for fewer resections of low risk non-neoplastic polyps (with a resulting reduction in complications); the provision of quicker results and management decisions; and a reduction in resource use through fewer histopathology examinations.

2.2 Product properties

A conventional endoscopy system includes the following components: an endoscope, a light source, a video processor, and a monitor. The light source produces light which is transmitted to the endoscope's distal end. The video processor converts electrical signals into video signals and displays them on the monitor.

There are 2 types of virtual chromoendoscopy, optical chromoendoscopy and digital chromoendoscopy. Optical chromoendoscopy technologies have optical lenses integrated into the endoscope's light source, which selectively filter white light to give narrow band light, whereas digital chromoendoscopy technologies incorporate digital post-processing of endoscopic images which are produced in real-time by a video processor. Both methods are activated directly from an endoscope and are intended to enable high contrast imaging of the mucosal surface without the need for dyes and additional equipment.

2.2.1 Narrow band imaging (NBI)

Narrow Band Imaging (Olympus) is a technology feature of the Olympus 200 series video endoscopy systems. It is recommended for use only in models which feature high definition or high resolution imaging. NBI is a function of the light source and video processor. Optical lenses are used to filter the white light, resulting in narrow band light which consists of two wavelengths: 415 nm blue light and 540 nm green light. Narrow band light is absorbed by vessels but reflected by mucosa, therefore the contrast between the vessels and the surrounding mucosa is increased compared with use of standard white light. The NBI filter can be activated and deactivated as required by the endoscopist, to switch between standard white light and narrow band imaging.

The image quality achieved with NBI varies between the different video endoscopy systems. Olympus states that the highest image quality is offered by the EVIS LUCERA ELITE video processors (CV-290/CLV-290SL), which have the following advanced features, compared with the EVIS LUCERA SPECTRUM video processors (CV-260SL/CLV-260SL):

- Dual Focus, which allows the user to switch between two focus settings: 'near mode' for close mucosal observation or 'normal mode' for standard observation.

- Increased viewable distance compared with previous generations, which gives improved contrast and increased brightness.
- Improved image processing compared with previous generations, which gives reduced noise, reduced blurring and improved colour contrast.

In addition, Olympus states that the EVIS LUCERA ELITE 290HQ (high definition) endoscope offers the highest image quality, followed by the EVIS LUCERA ELITE 290H endoscope, then the 260H and the 260Q EVIS LUCERA SPECTRUM endoscopes.

The EVIS EXERA II and the EVIS EXERA III endoscopy systems are available in the US and parts of Europe, but are not available in the UK for use in gastroenterology. Olympus states that the EVIS EXERA and the EVIS LUCERA are comparable in terms of their diagnostic performance.

2.2.2 Flexible Spectral Imaging Colour Enhancement (FICE)

FICE (Aquilant Endoscopy/FujiFilm) is a technology feature of Fuji endoscopy systems. Standard white light is directed at the tissue and the reflected light is captured and processed using software. The software turns conventional images into reconstructed spectral images by limiting the wavelengths of the light, and the images are then displayed in real-time. The image can be displayed in 10 different colour combinations. The pre-set wavelength patterns can also be manually altered. The endoscopist can switch between the conventional image and the FICE image using a switch on the endoscope.

FICE is a feature on the EPX-4450HD, EPX-3500HD and EPX-4400 endoscopy systems, and Aquilant Endoscopy states that image quality on the EPX-4450HD and EPX-3500HD systems is higher than on the EPX-4400 system. Additionally, the 500 series and 600 series endoscopes can use FICE, however image quality varies between the different scopes. Aquilant Endoscopy states that the 600 series CMOS endoscopes give the best image quality. Further, FICE can be used in combination with magnifying endoscopes, which Aquilant Endoscopy claims can provide more detailed information on the micro surface and vascular pattern.

2.2.3 i-scan

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

- surface enhancement – improves the contrast between light and dark regions to give a sharper image
- contrast enhancement – adds blue colour to relatively dark areas to show mucosal surface detail
- tone enhancement – modifies the colour contrast to improve visibility of mucosal structure and blood vessels

The 3 different algorithms are used in different combinations to give 3 recommended modes: i-scan 1 for detection of lesions; i-scan 2 for characterisation of lesions; and i-scan 3 for demarcation of lesions. The endoscopist can switch between the conventional image and the 3 different i-scan modes image by pushing a button on the endoscope.

The EPK i5000, the EPK i7000 and the EPK i7010 high-definition video processors feature i-scan enhanced visualisation technology. These processors can be connected to i10, 90i and 90K endoscopes.

2.2.4 Product summary

Table 1 summarises the different versions of high definition and high resolution processors and endoscopes that have NBI, FICE or i-scan and are available for use in clinical practice in the NHS.

Table 1: Summary of the high definition and high resolution video processors and endoscopes that have NBI, FICE or i-scan, and are available in the NHS

Company	Technology	Video processors	Endoscopes
Olympus	NBI	EVIS LUCERA ELITE (CV-290/CLV-290SL) EVIS LUCERA SPECTRUM (CV-260SL/CLV-260SL)	EVIS LUCERA ELITE (290HQ/290H) EVIS LUCERA SPECTRUM (260Q/260H)
FujiFilm /Aquilant	FICE	EPX-4450HD, EPX-3500HD, EPX-4400	500 series / 600 series / 600 CMOS
Pentax	i-scan	EPK i5000, EPK i7000 and EPK i7010	i10, 90i and 90K

3 Target condition: colorectal polyps and colorectal cancer

3.1 Background

Colorectal polyps are small growths on the inner lining of the colon that carry a small risk of becoming cancerous. Colorectal polyps are common, affecting

15-20% of the UK population. Most polyps produce no symptoms, however, some larger polyps can cause:

- a small amount of rectal bleeding
- diarrhoea or constipation
- abdominal pain.

3.1.1 Classification of colorectal polyps

Polyps can be described in terms of their shape, size and location. The shape of a polyp can be defined according to the Paris endoscopic classification:

- Type 0-Ip: protruded, pedunculated (on a stalk)
- Type 0-Is: protruded, sessile
- Type 0-IIa: superficial, elevated
- Type 0-IIb: flat
- Type 0-IIc: superficial shallow, depressed
- Type 0-III: excavated

Colorectal polyps can be further classified according to their histology, for example, hyperplastic polyps, adenomatous polyps, or deep submucosal invasive cancer. Hyperplastic polyps usually do not carry a risk of developing into cancer. However, a subgroup of hyperplastic polyps called sessile serrated polyps, do have the potential to develop into cancer. Similarly, adenomas or adenomatous polyps have the potential to develop into cancer if left alone. Adenomas can be further divided into 3 subtypes based on histological features: tubular, tubulovillous, and villous. Deep submucosal invasive cancer is likely to require surgical resection.

Classification systems aim to help clinical judgement to distinguish benign polyps from pre-cancerous polyps and invasive cancer. Several classification systems are available, including:

- The NBI International Colorectal Endoscopic (NICE) classification system uses 3 criteria to assess polyp histology: colour, vessels and surface pattern (Hewett et al. 2012). Polyps are classified as hyperplastic (type 1), adenomas (type 2) or deep submucosal invasive cancer (type 3).
- The Kudo classification uses pit patterns to classify polyps as normal (type I), hyperplastic (type II), tubular adenoma (type III), tubulovillous or villous adenoma (type IV) or high grade or invasive (type V).
- The Showa classification considers the microvessel pattern surrounding the pit

- The NAC (novel classification system) has been developed for use with FICE and uses vascular and surface patterns to predict histology

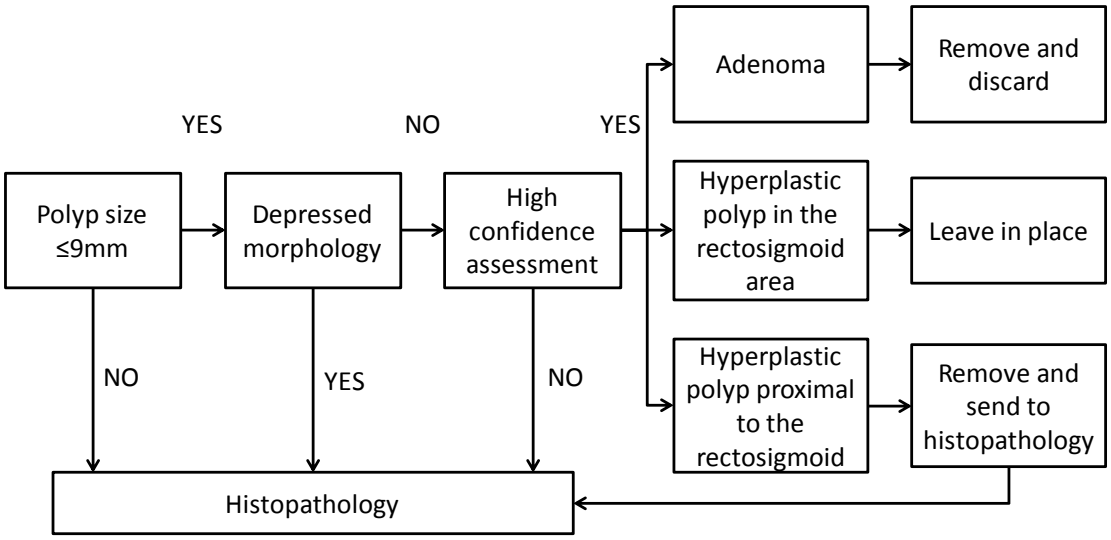
Recently, a new classification system has been developed for endoscopic differentiation of adenomas, hyperplastic polyps and sessile serrated polyps: the Workgroup serrAted polypS and Polyposis (WASP) classification (IJspeert et al. 2015).

3.1.2 Diagnostic approaches to colorectal polyps

Most colorectal cancers are thought to arise in adenomatous polyps through the adenoma-carcinoma sequence, that is, a stepwise pattern of mutational activation of oncogenes and inactivation of tumour suppressor genes. The detection and removal of adenomatous polyps during colonoscopy has been shown to decrease the subsequent development of colorectal cancers. However, removal of any polyps by polypectomy may result in adverse effects such as bleeding and perforation of the bowel. Further, as imaging technologies improve, more polyps may be detected, which may increase the number of polyps removed from a patient. This could impact on the workload of gastroenterologists and histopathologists.

The DISCARD (Detect, InSpect, ChAracterize, Resect, and Discard) strategy is an approach to diminutive and small polyps (9 mm or less) which aims to allow endoscopists to make an assessment of the histopathology of a polyp during the colonoscopy (Ignjatovic et al. 2009; Figure 1). Small or diminutive polyps confidently identified as adenomatous can be removed and discarded, that is, not sent for histological examination. Small and diminutive polyps in the rectosigmoid area confidently identified (high confidence) as hyperplastic polyps can be left in place. However, all small or diminutive polyps that the endoscopist cannot make a confident assessment of (low confidence) should be removed and sent for histological examination. In addition, flat depressed polyps, polyps with a distorted shape, and hyperplastic polyps proximal to the rectosigmoid area should all be removed and sent for histological examination, irrespective of size. All polyps larger than 9 mm would continue to be removed and sent for histological examination. The DISCARD strategy is not currently used in clinical practice in the NHS, however, in some centres diminutive polyps in the rectosigmoid area are optically diagnosed using white light or virtual chromoendoscopy and left in place if there is high confidence the polyps are hyperplastic.

Figure 1: Flow chart for application of the DISCARD strategy for colorectal polyps (adapted from Wang and East 2015)



The potential problems with adopting the DISCARD strategy are that:

- assessment of diminutive polyps during a colonoscopy by endoscopists with less expertise and experience in the optical assessment of polyps is less accurate and often insufficient to meet accepted diagnostic accuracy thresholds (PIVI criteria; see section 3.1.3)
- sessile serrated polyps may be incorrectly identified as hyperplastic polyps and left in place, which may result in the development of cancer
- diminutive polyps cancers may be incorrectly identified as adenomas, resected and discarded, which may result in the development of cancer.

These potential problems give rise to medicolegal concerns because a patient may develop colorectal cancer after an endoscopist chose to resect and discard a polyp or leave a polyp in place.

The following practices may help address some of the concerns:

- an accreditation system to ensure endoscopists using virtual chromoendoscopy to make an assessment of polyp histology have received relevant training
- a quality assurance programme to ensure robust methods are used to make an assessment of polyp histology with virtual chromoendoscopy

- use of endoscopes and monitors with high definition
- capture of high quality still images to keep on file.

3.1.3 Diagnostic thresholds for optical diagnosis

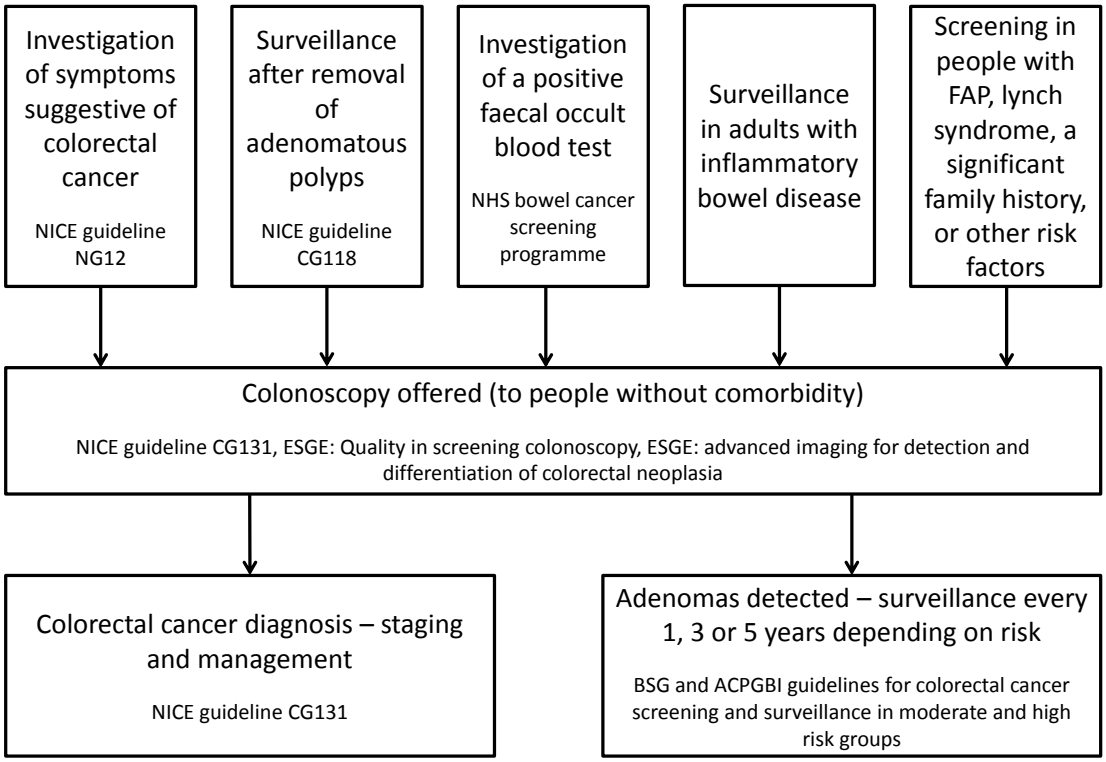
The PIVI (Preservation and Incorporation of Valuable endoscopic Innovations) initiative is an American Society for Gastrointestinal Endoscopy programme whose objectives are to identify important clinical questions related to endoscopy and to establish diagnostic or therapeutic thresholds for endoscopic technologies designed to resolve these clinical questions. PIVI has produced 2 statements on real-time optical diagnosis of the histology of diminutive colorectal polyps:

- in order for colorectal polyps 5 mm or less in size to be removed and discarded without pathologic assessment, the endoscopic technology used should provide a ≥90% agreement in assignment of post-polypectomy surveillance intervals when compared to decisions based on pathology assessment of all identified polyps.
- in order for a technology to be used to guide the decision to leave suspected rectosigmoid hyperplastic polyps 5 mm or less in place, the technology should provide a negative predictive value >90% for adenomatous polyp histology.

3.2 Care pathway

An overview of the care pathway is presented in figure 2 and described in sections 3.2.1 to 3.2.5.

Figure 2: Overview of the care pathway



3.2.1 Referral for colonoscopy

Colonoscopy examinations may be done for a number of clinical reasons, for example:

- 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
- Surveillance in adults with inflammatory bowel disease
- Surveillance after removal of adenomatous polyps
- Screening in people with familial adenomatous polyposis, lynch syndrome, a significant family history of colorectal cancer, or other risk factors for colorectal cancer.

The NICE guideline on suspected cancer: recognition and referral (2015) recommends that people should be referred for colorectal cancer investigations 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.

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 any of the following unexplained symptoms or findings: abdominal pain, changes in bowel habit, weight loss, or iron deficiency anaemia.

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 carry out a faecal occult blood test. This involves collecting a stool sample and posting it 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.

The NICE guideline on colonoscopic surveillance (2011) recommends that the following groups are offered colonoscopic surveillance:

- people with inflammatory bowel disease whose symptoms started 10 years ago
- people 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 colonoscopic surveillance may be every 1 year, 3 years or 5 years, depending on the level of risk of developing colorectal cancer.

3.2.2 Investigations for colorectal cancer and management of polyps

For investigating possible colorectal cancer, the NICE guideline on colorectal cancer (2014) recommends that:

- people without major comorbidity are offered colonoscopy.
- people with major comorbidity are offered flexible sigmoidoscopy then barium enema.
- CT colonography is considered as an alternative to colonoscopy or flexible sigmoidoscopy then barium enema, if the local radiology service can demonstrate competency in this technique.

- people who have had an incomplete colonoscopy are offered repeat colonoscopy, CT colonography (if the local radiology service can demonstrate competency in this technique), or barium enema.

A guide to colonoscopy has been produced in a position statement by the European Society of Gastrointestinal Endoscopy: Quality in screening colonoscopy. This statement highlights important aspects to achieve optimal performance of screening colonoscopy, and proposes standards to allow for audit.

- the consent process should include a clear explanation of the procedure and of the preparation required, and should have a realistic discussion of discomforts, risks, and benefits
- effective bowel cleansing is fundamental for high quality colonoscopy. Poor bowel preparation is associated with prolonged procedures and failure to detect disease
- sedation practices, including average doses and patient comfort scores should be audited
- a complete examination of the colon and rectum is fundamental
- the number of adenomas and cancers should be recorded for all examinations
- the withdrawal time should be a minimum of 6 minutes in diagnostic examinations
- at least 90% of resected polyps should be retrieved for histological analysis
- the size, appearance, location and histology of all polyps larger than 1cm should be recorded.

3.2.3 Surveillance intervals

The British Society of Gastroenterology and the Association of Coloproctology for Great Britain and Ireland guidelines for colorectal cancer screening and surveillance in moderate and high risk groups (Cairns et al. 2010) and the NICE guideline on colonoscopic surveillance (2011) make the following recommendations:

- people with 1 or 2 small (less than 1 cm) adenomas are at low risk, and need no colonoscopic surveillance or 5-yearly until one negative examination then cease surveillance
- people with 3 or 4 small adenomas or at least 1 adenoma 1 cm or larger are at intermediate risk and should be screened 3-yearly until two consecutive examinations are negative
- people with 5 or more adenomas, or 3 or more adenomas at least one of which is 1 cm or bigger, are at high risk and an extra

examination should be undertaken at 12 months before returning to 3-yearly surveillance.

3.2.4 Current guidance on virtual chromoendoscopy

Specific recommendations on dye-based and virtual chromoendoscopy are made in the European Society of Gastrointestinal Endoscopy guideline on advanced imaging for detection and differentiation of colorectal neoplasia (2014):

- Routine use of high definition white-light endoscopy systems for detecting colorectal neoplasia in average risk populations.
- Routine use of high definition systems and pancolonic conventional or virtual (NBI, i-scan) chromoendoscopy in patients with known or suspected Lynch syndrome.
- Routine use of high definition systems and pancolonic conventional or virtual (NBI) chromoendoscopy in patients with known or suspected serrated polyposis syndrome.
- Virtual chromoendoscopy (NBI, FICE, i-scan) and conventional chromoendoscopy can be used, under strictly controlled conditions, for real-time optical diagnosis of diminutive (5 mm or less) colorectal polyps to replace histopathological diagnosis. The optical diagnosis has to be reported using validated scales, must be adequately photo-documented, and can be performed only by experienced endoscopists who are adequately trained and audited.
- Use of conventional or virtual (NBI) magnified chromoendoscopy to predict the risk of invasive cancer and deep submucosal invasion in lesions such as those with a depressed component or non-granular or mixed-type laterally spreading tumours.

3.2.5 Management of colorectal cancer

The staging and management of colorectal cancer is described in the NICE pathway on colorectal cancer, which is based on the NICE clinical guideline on the diagnosis and management of colorectal cancer (CG131, 2011).

3.3 Patient issues and preferences

The preparation for a colonoscopy involves completely emptying the bowel by following dietary restrictions and taking a strong laxative the day before the colonoscopy. This causes diarrhoea and therefore the person will need to stay close to the toilet and avoid travelling or going to work. Before the colonoscopy the person is given a sedative, which may make them feel drowsy and will mean that they cannot drive themselves home after the

procedure. During the colonoscopy some air is pumped into the colon which may cause bloating or a feeling of cramping in the abdomen. Some people find having a colonoscopy uncomfortable, but most people do not report that it is painful. If polyps are removed during the colonoscopy, the person will have to wait for the samples to be examined before they receive the results, which can take 3 weeks and may cause anxiety.

People having colonoscopy may also be concerned about the adverse effects of the colonoscopy, such as heavy bleeding or perforation of the bowel. Further, colonoscopy with polypectomy has an 11 times increased risk of bleeding and a 3 times increased risk of perforation compared with colonoscopy without polypectomy (Rutter 2014). Some people may also have a reaction to the sedative which could result in temporary breathing or heart problems.

Potential advantages for patients of virtual chromoendoscopy used to make an optical diagnosis of a colorectal polyp may be the need for fewer polypectomies, as some polyps could be left in place. This could lead to a reduced risk of adverse effects of polypectomy such as bleeding and perforated bowel. It may also reduce anxiety in some people because they won't have to wait 3 weeks for the histopathology results. In contrast, some patients may prefer all polyps to be removed if they perceive there to be a risk of an incorrect optical diagnosis of a polyp being made and an incorrect management decision taken.

4 Scope of the evaluation

Table 2: Scope of the evaluation

Decision question	Does virtual chromoendoscopy for real-time assessment of diminutive (1 to 5 mm) colorectal polyps during colonoscopy represent a cost-effective use of NHS resources?
Populations	• People with symptoms suggestive of colorectal cancer who are referred for colonoscopy by a GP • People offered colonoscopic surveillance because they have had adenomas removed • People referred for colonoscopy through the NHS bowel cancer screening programme
Interventions	• Narrow Band Imaging (Olympus Medical Systems) • FICE (Fujinon/Aquilant Endoscopy) • i-scan (Pentax Medical) (Used with high definition or high resolution monitors and

	endoscopes without the use of magnification) The following factors should also be considered in addition to the different interventions: • level of expertise and experience in optical assessment of polyps • level of confidence in polyp assessment • location of polyp • use of different classification criteria
Comparator	Histopathology
Healthcare setting	Secondary and tertiary care
Outcomes	Intermediate measures for consideration may include: • Accuracy of assessment of polyp histopathology • Number of polyps left in place • Number of polyps removed and discarded • Number of polyps removed and sent for histological examination • Recommended surveillance interval • Length of time to perform the colonoscopy • Number of outpatient appointments/telephone consultations
	Patient-reported outcomes for consideration may include: • Health related quality of life including anxiety
	Clinical outcomes for consideration may include: • Adverse effects of polypectomy • Colorectal cancer • Mortality
	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: • Endoscopy system costs • Colonoscopy and related outpatient appointments/telephone consultations • Training • Histopathology • Colorectal cancer treatment • Treatment of adverse effects of polypectomy
	The cost-effectiveness of interventions should be expressed in terms of incremental cost per quality-adjusted life year.

Time horizon	The time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

5 Modelling approach

5.1 Existing models

One published study and 2 conference abstracts were identified which all aimed to assess the cost-effectiveness of using virtual chromoendoscopy to make a real-time optical assessment of colorectal polyp tissue. All studies focused on colorectal cancer screening rather than assessment in a symptomatic or surveillance population.

Hassan et al. (2010) used a Markov model to compare the cost-effectiveness of universal pathology examinations with a 'resect and discard' policy using NBI, for colonoscopy screening in a US population. Results show that universal pathology examination costs an estimated $3222 per person. Adoption of a 'resect and discard' policy for eligible diminutive polyps resulted in savings of $25 per person, without any meaningful impact on screening efficacy. Authors note that projection of these cost savings onto the US population would result in undiscounted annual savings of $33 million.

McGill et al. (2013) presented a conference abstract of an analysis which modelled a cohort of 50 year olds undergoing a first screening colonoscopy. Results showed that optical diagnosis with NBI to inform a 'resect and discard' strategy saved $28.47 per person per lifetime as compared with a strategy in which there is universal resection and histological examination, with no change in quality adjusted life years. The authors report that these cost savings projected onto the population of the US would result in annual savings of $30 million.

Longcroft-Wheaton et al. (2011) presented a conference abstract which evaluated the cost effectiveness of real-time histology prediction using white light, FICE and indigo carmine dye spray in the bowel cancer screening programme in the UK. The results showed that when using high definition endoscopes for adenoma detection, sensitivities of 76% and 93% using white light and FICE, respectively, were achieved. The surveillance interval would have been correct in 97% of cases using FICE and a potential cost saving of £109 per person could be made.

5.2 Modelling possibilities

It is likely that diagnostic accuracy data and polyp management decisions will need to be linked through modelling to clinical outcomes such as adverse effects of polypectomy, occurrence of colorectal cancer and death.

6 Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

All people with cancer are covered under the disability provision of the Equality Act (2010) from the point of diagnosis. Colorectal cancer is more common in older men and women. In the UK between 2010 and 2012, an average 43% of bowel cancer cases were diagnosed in people aged 75 years and over, and 95% were diagnosed in those aged 50 and over.

7 Implementation issues

7.1 Pathway

Adoption of this technology into routine clinical practice with the intention of reducing the number of unnecessary polypectomies and the number of polyps sent for histopathological assessment would be a significant change to the current patient pathway. There are concerns about the responsibility of diagnosing potentially cancerous polyps moving from histopathology laboratories to clinicians in non-specialist care, and the risk and implications if cancers are missed.

7.2 Patient confidence

A move away from all polyps being removed and undergoing histopathological assessment will require patients to be confident in the experience and performance of the endoscopist. Some patients may have concerns and may not agree to this.

7.3 Training

Clinical experts note that achieving competency in real-time optical diagnosis using virtual chromoendocopy is subject to previous experience, motivation and enthusiasm for this technology. They report that it can take up to 6 months to achieve competency and consistently high performance. Further, over time performance may decrease, particularly with regards to specificity, therefore training should be ongoing to maintain performance.

7.4 Quality assurance and governance

Clinical experts consider that clinicians using virtual chromoendoscopy would need to be accredited and performing at least 150 colonoscopies with real-time optical assessment of colorectal polyps per year to maintain competency. The experts advise that accreditation for the use of virtual chromoendoscopy could be easily included in the current endoscopic accreditation programme.

7.5 Quality of images recorded and stored

Clinical experts have noted that the quality of the images stored is suboptimal when compared with the image the clinician sees on the screen at the time of assessment. There will need to be an accurate process for storing and linking the images to patient files and the ability to recall specific images to enable re-evaluation.

Appendix A Glossary of terms

Chromoendoscopy
Dyes are used in the gastrointestinal tract during endoscopy to enhance visualisation of the tissue

Colonoscopy
A procedure which allows a clinician to look at the inner lining of the large intestine using a thin flexible tube called a colonoscope

Colorectal polyps
A fleshy growth occurring on the lining of the colon or rectum

Diminutive polyps
Polyps between 1 and 5 mm in size

Faecal occult blood test
A test which detect small amounts of blood in faeces

Histopathology
The study of diseased tissue, including examination under the microscope

Lynch syndrome
An inherited disorder that increases the risk of many types of cancer, particularly colorectal cancer

Neoplastic polyps
Benign polyps which have the potential to become cancerous (also called adenomas or adenomatous polyps)

Non-neoplastic polyps
Hyperplastic polyps which do not have the potential to become cancerous

Polypectomy
Removal of polyps

Proximal colon
The first and middle parts of the colon, which includes the cecum (where the small intestine joins the colon), the ascending colon (the right side) and the traverse colon (the part that goes across the body connecting right and left)

Rectosigmoid
The lower part of the sigmoid colon (the S-shaped part of the colon that connects the descending colon [left side] to the rectum) and the upper part of the rectum

Appendix B Abbreviations

CT	Computed tomography
FICE	Flexible spectral imaging colour enhancement
NBI	Narrow Band Imaging
NICE	National Institute for Health and Care Excellence
NICE	NBI International Colorectal Endoscopic
PIVI	Preservation and Incorporation of Valuable endoscopic Innovations

Appendix C Related NICE guidance and pathways

Related NICE guidance

Suspected cancer: recognition and referral (2015) NICE guideline NG12

Combined endoscopic and laparoscopic removal of colonic polyps (2014) NICE interventional procedure guidance IPG503

Aflibercept in combination with irinotecan and fluorouracil-based therapy for treating metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy (2014) NICE technology appraisal guidance TA307

Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer after first-line chemotherapy (2012) NICE technology appraisal guidance TA242

Colorectal cancer: diagnosis and management (2011) NICE guideline CG131

Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas (2011) NICE guideline CG118

Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer (2010) NICE technology appraisal guidance TA212

Endoscopic submucosal dissection of lower gastrointestinal lesions (2010) NICE interventional procedure guidance IPG335

Cetuximab for the first-line treatment of metastatic colorectal cancer (2009) NICE technology appraisal guidance TA176

Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer (2007) NICE technology appraisal guidance TA118

Laparoscopic surgery for colorectal cancer (2006) NICE technology appraisal guidance TA105

Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer (2006) NICE technology appraisal guidance TA100

Computed tomographic colonography (virtual colonoscopy) (2005) NICE interventional procedure guidance IPG129

Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer (2003) NICE technology appraisal guidance TA61

Related pathways

The virtual chromoendoscopy guidance will be included in several NICE pathways, for example: colonoscopic surveillance and colorectal cancer. In some of these pathways, it may be appropriate to include the full recommendations of the guidance, in others it will only be necessary to give a link to the guidance.

Relevant guidance from other organisations

The Paris endoscopic classification of superficial neoplastic lesions: esophagus, stomach, and colon: November 30 to December 1, 2002. Gastrointest Endosc. 2003 Dec;58(6 Suppl):S3-43.

Quality in screening colonoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE). Rembacken B, Hassan C, Riemann JF, et al. Endoscopy 2012; 44: 957–968

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