

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technologies Programme

Artificial intelligence software to help detect and characterise colorectal polyps

Final scope

August 2024

1 Introduction

The topic selection oversight panel identified artificial intelligence (AI) software to help detect and characterise colorectal polyps during colonoscopy as suitable for evaluation by the Health Technologies Programme based on a topic intelligence briefing.

The final scope was informed by discussions at the scoping workshop on 15 August 2024. A glossary of terms is provided in appendix A.

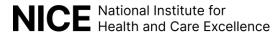
2 Description of the technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts and on information available in the public domain. NICE has not carried out an independent evaluation of these descriptions.

2.1 Purpose of the medical technologies

Al-assisted colonoscopy supports the detection of colorectal polyps during the colonoscopy procedure by detecting and flagging lesions of concern for the endoscopist to review. This function of Al technologies is known as Computer Aided Detection (CADe). CADe aims to help endoscopists detect polyps that may otherwise have been missed by endoscopist review alone. Al software technologies use machine learning and deep learning to analyse images and videos taken during a colonoscopy.

Some technologies also provide Al-based Computer Aided Diagnosis (CADx) in addition to the CADe function. CADx assists in the characterisation of the detected polyps based on features such as polyp size and histology (see section 3.1.1). The aim of CADx is to improve the optical diagnosis performed by endoscopists to help decisions about whether to remove a polyp or not. This could reduce unnecessary polypectomies (with a resulting reduction in complications such as bleeding and perforation of the bowel) and also improve recognition of polyps for resection. Using CADx to support optical diagnosis may also reduce variability due to different levels of endoscopist experience (see section 6.1).



2.2 Product properties

The level of detail in the following descriptions depends on the extent of information provided by manufacturers during topic scoping. Technologies will only be included in guidance if they are available to the NHS and have appropriate regulatory approval.

Al technologies are intended to be incorporated into usual colonoscopy procedure. An endoscopist makes a final decision on whether to remove any identified polyps. Technologies with CADe function are described below:

Technology	Regulatory status	Intended use
(manufacturer)		
Argus	Regulatory approval is in	A gastrointestinal lesion software detection system is a computer-assisted detection device
(Endosoft)	process	used in conjunction with endoscopy for the detection of abnormal lesions in the
		gastrointestinal tract. This device with advanced software algorithms brings attention to
		images to aid in the detection of lesions. The device has hardware components to support
		interfacing with an endoscope.
Discovery	CE class I	The product is intended to assist endoscopists in finding potential polyps during a
(Pentax		colonoscopy examination. The system is not intended to make or recommend any patient
Medical UK)		management, diagnosis or therapeutic decisions.
ENDO-AID	CE class I	The Endoscopy CAD system processes the electronic signals received from the endoscopy
(Olympus		video system center and overlays additional information on the observation monitor. The
		device directs the user's attention to areas of interest for further clinical assessment.
		device directs the user's attention to areas of interest for further cliffical assessment.

Medical		The device is intended to assist physicians in the detection of mucosal abnormalities such as
Systems Corp.)		potential colorectal polyps during colonoscopy. The device is an adjunctive tool, and the user
		should not rely solely on the device for detection of abnormalities.
ENDOANCEL	Danding alouification from	Internal adversariation and available addless time of finalising the course. The course available addless time of finalising the course of the
ENDOANGEL	Pending clarification from	Intended use statement not available at the time of finalising the scope. The company's
Lower	company	website (accessed 28 August 2024) indicates that ENDOANGEL is computer-aided polyp
Gastrointestinal		detection system powered by Al. It is used for polyp identification of lower digestive tract
Endoscope		during endoscopic operation. The identification results are only used as a reference for
Image Auxiliary		diagnosis and it is not intended to replace clinical decision making.
Diagnostic		
Equipment		
(Wuhan		
EndoAngel		
Medical		
Technology		
Co., Ltd.)		
Endoscopic	Regulatory approval is in	Intended use statement not available at the time of finalising the scope. Company have
Multimedia	process	indicated that the technology provides Al-based polyp detection.
Information		
System (EMIS;		
EndoMetric		
Corporation)		

Endoscreener	CE class II	Intended use statement not available at the time of finalising the scope. The company's
(Wision AI)		website (accessed 23 August 2024) indicates that EndoScreener is a computer-assisted
		detection device for colorectal polyps. EndoScreener takes as input colonoscopy video stream
		from an endoscopy device, which is analyzed in real-time. The device output consists of blue
		boxes overlaid onto the colonoscopy images to highlight regions of potential polyp.

Technologies that perform CADe and CADx functions are described below:

Technology	Regulatory	Intended use
(manufacturer)	status	
CAD EYE (Fujifilm Healthcare UK Ltd)	CE class IIa	This software detects and characterises an area suspected to be a colonic polyp in an endoscopic video image outputted from an endoscopic video processor. The software superimposes the result of Detection Mode or Characterisation Mode onto the endoscopic video image and displays on the monitor in real-time. This software is intended to be used to support diagnosis during colonoscopy under the supervision of medical professionals. Characterisation mode displays a suggestion about whether a suspected colonic polyp is neoplastic or
		hyperplastic.

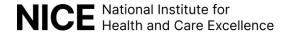
CADDIE (Odin	Company	Intended use statement not available at the time of finalising the scope. The product brochure, available
Vision)	website	on the company's website (accessed 23 August 2024), indicates that the product supports endoscopists
	indicates CE	to detect and characterise colorectal polyps in real-time during colonoscopy procedures.
	/UKCA	
	marked	
	product	
	(accessed 23	
	August 2024)	
GI Genius	GI Genius	The GI Genius software is an artificial intelligence-based medical device that has been trained to
(Medtronic)	Software: CE	process colonoscopy images containing regions consistent with colorectal lesions like polyps, including
	class IIb	those with flat (non-polypoid) morphology. The GI Genius software is intended to be used by trained
		clinicians as an adjunct to white-light colonoscopy for the purpose of highlighting regions suspected to
		have visual characteristics consistent with different types of mucosal abnormalities (e.g., colorectal
		polyps). The target population is represented by persons undergoing colonoscopy procedures.
		If characterisation support is enabled, a polyp detected and highlighted by the GI Genius software is
		consistently framed in white-light video colonoscopy, based on the visual characteristics of the detected
		polyp, the GI Genius software provides an estimation of the possible polyp histology. The following tags
		are shown: adenoma (when the system predicts a possible adenoma histology), non-adenoma (when
		the system predicts a possible non-adenoma histology) or no prediction (when the system is not
		confident enough to provide a possible histology prediction).

ded to replace endoscopist assessment or histopathological sampling. ME-APDS (Magentiq Eye Automatic Polyp Detection System) is intended to be used by scopists as an adjunct to the common video colonoscopy procedure, aiming to assist the scopist in identifying lesions during colonoscopy procedure by highlighting regions with visual acteristics consistent with different types of mucosal abnormalities that appear in the colonoscopy during the procedure. Highlighted regions can be independently assessed by the endoscopist and opriate action taken according to standard clinical practice.
scopists as an adjunct to the common video colonoscopy procedure, aiming to assist the scopist in identifying lesions during colonoscopy procedure by highlighting regions with visual acteristics consistent with different types of mucosal abnormalities that appear in the colonoscopy during the procedure. Highlighted regions can be independently assessed by the endoscopist and
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during the procedure. Highlighted regions can be independently assessed by the endoscopist and
priate action taken according to standard clinical practice.
ME-APDS is trained to process video images which may contain regions consistent with polyps.
ME-APDS is intended to be used as an adjunct to endoscopy procedures and is not intended to
ce histopathological sampling as means of diagnosis.
company's website (accessed 28 August 2024) indicates that the technology aides the
penterologist detect polyps with additional information (size category and type), on the consistency
e detected lesion.
Detection (Ce3.0): This product analyses video signals from endoscopic equipment and provides
scopists with the location of potential colorectal polyps. It aims to invite endoscopists' attention to

Polyp Characterization (Cx3.0): This product analyses video signals from endoscopic equipment to categorize the colorectal polyps detected by the endoscopists as neoplastic or non-neoplastic polyps. It aims to support the endoscopists to make an optical diagnosis during colonoscopy.

Polyp Sizing (Cs3.0): This product analyses video signals from endoscopic equipment to categorize the colorectal polyps detected by the endoscopists as diminutive ("5 mm or less") or non-diminutive ("6 mm or more"). It aims to support the endoscopists in sizing of polyps during colonoscopy.

The intended population is people who have been determined to be eligible for colonoscopy. All ages, weights, and health conditions are acceptable, however patients with following conditions are excluded: bowel inflammation (Ulcerative colitis or GVHD–related bowel inflammation); familial adenomatous polyposis; or have a history of chemotherapy or radiation therapy for targeted colorectal cancer.



3 Target conditions

3.1 Colorectal polyps

Colorectal polyps are small growths on the lining of the colon. Most colorectal polyps do not cause any symptoms, so people are unaware that they have them. However, some can cause rectal bleeding, mucus in stool, diarrhoea or constipation, and abdominal pain.

Risk factors for colorectal polyps include older age, genetics and family history of bowel polyps or bowel cancer, dietary and lifestyle factors and conditions that affect the gut such as inflammatory bowel disease (IBD).

3.1.1 Classification of colorectal polyps

Polyps can be described in terms of their shape, size, location and histology.

The Association of Coloproctology of Great Britain and Ireland (ACPGBI) recommends the <u>Paris endoscopic classification</u> to describe polyps on the basis of their shape:

- Type 0-lp: protruded, pedunculated (on a stalk)
- Type 0-ls: protruded, sessile (flat against the surface, slightly raised)
- Type 0-IIa: superficial, elevated
- Type 0-IIb: flat
- Type 0-IIc: superficial shallow, depressed
- Type 0-III: excavated (depressed)

The <u>European Society of Gastrointestinal Endoscopy (ESGE) (2024) guideline on colorectal polypectomy and endoscopic mucosal resection (EMR)</u> defines colorectal polyps by size:

- Diminutive size: 5 mm or less
- Small size: 6 to 9 mm
- Intermediate size: 10 to 19 mm
- Large size: 20 mm or more

A premalignant polyp, as defined by British Society of Gastroenterology (BSG)/ ACPGBI <u>guideline</u>, includes both serrated polyps (excluding diminutive [1–5 mm] rectal hyperplastic polyps) and adenomatous polyps, but not other polyps such as post-inflammatory polyps.

3.1.2 High risk colorectal polyps

The BSG / Public Health England (PHE) / ACPGBI post-polypectomy and post-colorectal cancer resection surveillance guidelines (2020) defines criteria for high-risk polyps as either:

- 2 or more pre-malignant polyps including at least 1 advanced colorectal polyp; or
- or 5 or more pre-malignant polyps

The guideline defines advanced colorectal polyps as either:

- A serrated polyp of at least 10 mm in size or containing any grade of dysplasia, or
- An adenoma of at least 10 mm in size or containing high-grade dysplasia.

3.2 Diagnostic and care pathway

Colonoscopy is often used for people without major comorbidities. It can visualise the entire colon and tissue samples can be taken and examined histologically to confirm a diagnosis, unless this is contraindicated. Colonoscopy is most frequently performed as an outpatient procedure with the person having sedation or painkillers.

Standard colonoscopy uses conventional high-definition white-light endoscopy (WLE) to detect colorectal polyps and may be used in combination with dyes (chromoendoscopy). Virtual chromoendoscopy (VCE) technologies provide colourenhanced visualisation of blood vessels and surface pattern compared with conventional endoscopy, but without the use of dyes. This helps endoscopists to assess colorectal polyps in real-time during colonoscopy, instead of through later histopathology (known as optical diagnosis). MICE guideline DG28 (2017) recommends that endoscopists assess diminutive polyps (polyps 5 mm or less in size) during colonoscopy by performing optical diagnosis using VCE technologies, instead of histopathology. Clinical experts commented that VCE is used in the NHS,

but the extent of use is not known. They also stated that VCE has a greater role in the characterisation, rather than detection, of polyps.

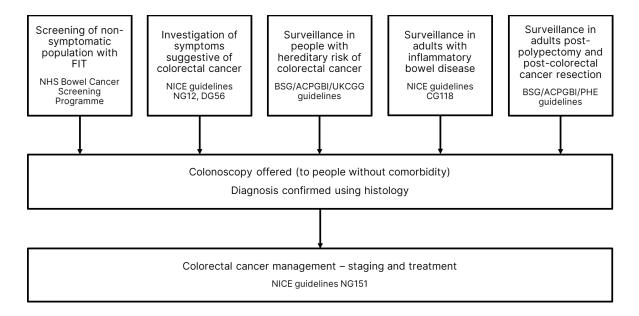
The ESGE (2019) guideline on advanced imaging for detection and differentiation of colorectal neoplasia recommends the use of high-definition white-light endoscopy in combination with VCE to predict the presence and depth of any submucosal invasion in non-pedunculated colorectal polyps prior to any treatment.

Experts also highlighted that Endocuff Vision is used in the NHS. This is a disposable sleeve that fits over the end of most colonoscopes and may be used to improve visualisation of the bowel during colonoscopy. The NICE guideline MTG45 (2019) recommends use of Endocuff Vision to improve adenoma detection for people having a colonoscopy as part of bowel cancer screening following a positive stool test.

The <u>Gastroenterology Get It Right First Time (GIRFT) Programme national specialty</u> report highlights the need to support earlier diagnoses of colorectal cancer and identify areas for improvement in the quality of colonoscopy services.

An overview of the care pathway is presented in figure 1 and described in sections 3.2.1 to 3.2.4.

Figure 1: Overview of the care pathway (adapted from NICE DG28 scope)



3.2.1 Screening of non-symptomatic population with FIT

The NHS bowel cancer screening programme (BCSP) invites people in the UK to return a faecal immunochemical test (FIT) kit every 2 years to detect the presence of blood in the stool. The age groups invited for bowel cancer screening, and the detection threshold for an abnormal test (above or at the FIT threshold) result differs for each UK country. The BCSP for each UK country is described further in the NICE CKS for Bowel screening (2024). Colonoscopy is offered to people if they have an abnormal test result.

3.2.2 Investigation of symptoms suggestive of colorectal cancer

A person referred on the suspected colorectal cancer pathway should receive a diagnosis or ruling out of cancer within 28 days of being referred. For further details, see NHS England's webpage on <u>faster diagnosis of cancer</u>. <u>Section 1.3 of the NG12 NICE guideline</u> on suspected cancer describes the criteria to make a referral through this pathway for colorectal cancer. These recommendations are adapted from <u>sections 1.1 to 1.4 of NICE guideline DG56</u> for the use of quantitative FIT. The <u>ACPGBI/BSG (2022) guideline on FIT in patients with signs or symptoms of suspected CRC</u> recommends that a FIT threshold of at least 10 micrograms of haemoglobin per gram of faeces should be used in primary care to select patients to the suspected cancer pathway for colorectal cancer investigation. It also recommends that people should not be excluded from referral from primary care on Artificial intelligence software to help detect and characterise colorectal polyps Final scope August 2024

the basis of FIT alone. <u>Section 1.3 of NG12</u> states that people with a rectal mass, an unexplained anal mass or unexplained anal ulceration do not need to be offered FIT before referral is considered.

3.2.3 Surveillance colonoscopy

3.2.3.1 Surveillance colonoscopy for people with hereditary risk of colorectal cancer

Some people have genetic factors which increase their risk of getting colorectal cancer. The BSG/ACPBGI/UKCGG (2019) guideline for the management of hereditary colorectal cancer provides recommendations on colonoscopic surveillance for people with increased hereditary risk of colorectal cancer. This includes people with:

- Lynch syndrome
- polyposis syndromes (conditions where there are more than 10 polyps in the colon)
- significant family history of colorectal cancer
- a diagnosis of bowel cancer under the 50 years of age.

3.2.3.2 Surveillance colonoscopy for adults with IBD

NICE guideline CG118 (sections 1.1.1 to 1.1.5) recommends using colonoscopic surveillance to check for signs of colorectal cancer in people aged 18 and over with IBD.

BSG (2019) guidelines on the management of IBD in adults recommends stratifying IBD patients' colorectal cancer risk to determine the frequency of surveillance colonoscopy. Experts noted that there is also a guideline currently in development by the BSG which will update this recommendation.

3.2.3.3 Surveillance colonoscopy post polypectomy and post colorectal cancer resection

The <u>BSG/ACPBGI/PHE (2019) guideline</u> on post-polypectomy and post-colorectal cancer resection surveillance recommends colonoscopic surveillance for people who have undergone removal of either adenomatous polyps, serrated polyps, or colorectal cancer.

3.2.4 Management of colorectal polyps and cancer

The ESGE (2024) guideline on colorectal polypectomy and endoscopic mucosal resection (EMR) recommends resection of all polyps with the exception of diminutive rectosigmoid polyps that are predicted to be non-adenomatous with high confidence. Hyperplastic polyps located in the rectosigmoid have an even lower risk of advanced histology and a negligible risk of progression, therefore the guideline states that a diagnose-and-leave-behind strategy is appropriate to reduce polypectomy risks, pathology workload, and costs.

The ESGE guidance further recommends retrieval and histopathologic analysis of resected polyps. A resect-and-discard strategy using real-time optical diagnosis with virtual or dye-based chromoendoscopy for diminutive colorectal polyps should be reserved for experts only.

Clinical experts advised that typically in current practice resected polyps have histopathologic analysis. However, they highlighted that a resect-and-discard strategy is starting to be used within the BCSP. An accreditation process is in place to ensure that endoscopists are fully trained to use the resect-and-discard strategy effectively.

Clinical experts stated that the <u>BSG/ACPBGI/PHE</u> (2019) <u>guideline</u> is used in current clinical practice in the NHS for the surveillance in people who have had colorectal polyps removed. This guideline highlights the need for a careful polypectomy to be performed for a high-quality index colonoscopy (initial colonoscopy), to ensure complete and safe excision of the polyp. The need for subsequent surveillance colonoscopy is determined based on the individual's age and whether they meet high-risk surveillance criteria (see table 1 in <u>BSG/ACPBGI/PHE</u> (2019) <u>guideline</u>).

NICE guideline IPG503 on combined endoscopic and laparoscopic removal of colonic polyps has recommendations on the use of combined endoscopic and laparoscopic removal of colonic polyps to excise polyps that are unsuitable or high-risk for endoscopic removal.

If colorectal cancer is confirmed, <u>NICE guideline NG151 on colorectal cancer</u> recommends further imaging tests, such as CT and/or MRI, to stage the cancer and determine what treatment is needed. A PET-CT may also be indicated in some cases.

Management of malignant polyps

Experts highlighted that the <u>Management of the malignant colorectal polyp: ACPGBI</u> <u>position statement</u> is a key piece of guidance for practice.

They also noted that there is a guideline currently in development by the <u>European Society of Coloproctology (ESCP) on T1 cancer.</u>

3.3 Patient issues and preferences

Patient understanding of AI and their experiences of encountering AI in healthcare can be varied. They may come with concerns particularly when it is involved as part of their care.

Potential advantages for patients if AI technology improves colorectal polyp detection may be fewer pre-malignant polyps missed during colonoscopy. This could mean reduced risk of colorectal cancer and may also reduce anxiety in some people, particularly those from a high-risk group, if the use of the technology alongside healthcare professional review gives greater reassurance that polyps are not being missed.

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 so a need to stay close to the toilet and this process can be very unpleasant. A person undergoing the procedure would also need to 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. Some people may experience difficulties with requiring time off from work or other activities, both before and after the procedure, and this may have financial implications. Any impact of the tests on the need for further colonoscopy will impact patients.

If polyps are removed during a colonoscopy, there may be a wait for the samples to be examined before receiving the results, which can take 3 weeks and may cause anxiety.

Colonoscopy with polypectomy has an increased risk of bleeding and risk of perforation compared with colonoscopy without polypectomy. If the tests are able to result in fewer unnecessary polypectomies being done, this will have benefits for patients and reduce risk of adverse effects related to polypectomy.

Clinical experts noted that AI technologies that improve optical diagnosis may also reduce the need for histopathology and associated wait times for results from this. AI technologies that improve polyp detection may increase the number of people going for surveillance colonoscopy.

4 Comparator

The comparator is colonoscopy done without use of the Al-supported technologies. This can be with use of other technologies used in the NHS such as virtual chromoendoscopy, dye-based chromoendoscopy, or Endocuff Vision (see section 3.2).

5 Scope of the assessment

Table 1: Scope of the assessment

Decision question	Does the addition of Al-supported colonoscopy technologies to colonoscopy represent a clinically- and cost-effective use of NHS resources?
Populations	People having a colonoscopy because they have been:
	Referred for colonoscopy through the NHS bowel cancer screening programme
	Referred for colonoscopy for investigation of symptoms suggestive of colorectal cancer
	 Referred for surveillance colonoscopy because of a hereditary risk of colorectal cancer
	Referred for surveillance colonoscopy because of IBD
	 Referred for surveillance colonoscopy post polypectomy or post colorectal cancer resection.

	Where data permits, subgroups based on these sub-populations	
	should be considered (see section 6.2).	
Intervention	Colonoscopy done with Al-supported colonoscopy technologies incorporated to support decision making:	
Comparator	Colonoscopy done without Al supported colonoscopy technologies.	
Healthcare setting	Secondary care	
Outcomes: intermediate measures	 Intermediate measures for consideration may include: Measures of ability or accuracy to detect polyps or cancer Measures of ability to characterise identified polyps Measures related to healthcare resource use (such as time to do colonoscopy, need for repeat colonoscopy to be done, need for a second observer) Time to colonoscopy and impact on waiting lists Number of polyp removal procedures Incidences that the technology does not function Impact on decision making Ease of use/acceptability of the technologies to healthcare professionals 	
Outcomes: clinical	Clinical outcomes for consideration may include: Morbidity (including outcomes related to colonoscopy procedure and cancer, including incidence of post-colonoscopy colorectal cancer) Mortality	
Outcomes: patient- reported	Patient-reported outcomes for consideration may include: • Health-related quality of life (including anxiety)	

	Acceptability of tests to patients
Outcomes: costs	Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:
	Costs of AI systems (including any software, hardware, consumables, maintenance, and service costs)
	Cost of training
	Costs related to colonoscopy and polyp removal
	Costs of histopathology
	Cost of treatment for colorectal cancer
	Costs of adverse events from the procedure or further diagnostic work up
Measuring cost-effectiveness	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.

6 Other issues for consideration

6.1 Impact of endoscopist skill and experience

Clinical experts noted that endoscopist training is standardised across the UK but Bowel Cancer Screener Accreditation (BSCA) differs between the UK nations. England and Wales have national BCSP accreditation and quality standards, but in Scotland screening colonoscopists are approved locally. Health Education England and Health Education and Improvement Wales (HEE and HEIW) have also introduced an accelerated programme to train suitably qualified registered health professionals to perform colonoscopies. Experts commented that this means that there may be variations in the experience levels of endoscopists trained through different programmes.

Clinical experts also noted that there are differences in the surveillance programmes offered to different populations. For example, the BCSP in England includes a surveillance programme for Lynch syndrome, but people with Lynch syndrome in other UK nations may not always have screening accredited colonoscopists performing their procedures. Further, not all hereditary high-risk (such as polyposis) conditions are handled by screening-accredited colonoscopists in England.

Experts noted that AI technologies may offer greater benefit for less experienced endoscopists. The extent that the AI technologies improve endoscopist performance when added to current colonoscopy procedures may depend on the skill and experience of the endoscopist. Analysis of data showing technology performance should take into account the skill and experience of the health care professional performing the colonoscopy.

6.2 Performance variation by reason for colonoscopy

Clinical experts commented that the Al algorithms may not be developed, trained, or validated on data from people with IBD or hereditary risk factors. They raised concern about the performance of the technologies when used for these populations. Evidence levels on performance may also differ between groups. For example, people with IBD have been excluded from studies. The availability of evidence for the difference subpopulations having colonoscopy, and how appropriate it is to generalise data between these subpopulations, should be considered in the assessment. The requirements for the healthcare professional doing the colonoscopy can also vary by reason for colonoscopy (see section 6.1).

6.3 Workforce and capacity issues

Increase in polyp detection could increase the need for polypectomies, increasing workload of gastroenterologists and histopathologists. These changes could exacerbate capacity challenges further and increase existing wait times for colonoscopies. The assessment should consider potential implications of increases in the need for colonoscopy resulting from use of the technologies. Outputs of modelling should include an indication of the estimated change in numbers of colonoscopies, as well as other healthcare procedures such as polypectomies and those related to histopathology.

6.4 Existing guidance on the use of computer-assisted detection and diagnosis in colonoscopy

The <u>Health Technology Wales (HTW) (2024) guidance on Al-assisted endoscopy in the detection of gastrointestinal cancer and pre-cancerous lesions</u> recommends routine adoption of computer aided detection (CADe) colonoscopy for the detection of lower gastrointestinal cancer and pre-cancerous lesions.

The <u>ESGE (2022) position statement on the expected value of AI in gastrointestinal</u> endoscopy has recommendations on the use of CADe and CADx.

6.5 Impact of CADx function of tests

For technologies with CADx functionality, the impact of this on decisions about identified polyps may depend on how resect-and-discard and diagnose-and-leave strategies are used in the NHS, and on how much health care professionals use CADx results in their assessment of identified polyps. The <u>ESGE (2022) position</u> statement on the expected value of Al in gastrointestinal endoscopy recommends that for acceptance of Al optical diagnosis (computer-aided diagnosis [CADx]) of diminutive polyps (≤5 mm), Al-assisted characterization should match performance standards for implementing resect-and-discard and diagnose-and-leave strategies. As described in the <u>section 3.2.4</u>, experts have advised that in current NHS practice use of a resect-and-discard strategy may be limited, but this has recently begun to be used by bowel cancer screening colonoscopists within the BCSP.

If data allows, exploratory analysis investigating the use of the Al-based software to enable greater use of a resect-and-discard strategy should also be considered. This may help to identify the potential impacts of this and help identify areas of uncertainty that would benefit from further data collection.

7 Potential 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.

Risk of lower gastrointestinal cancer increases with the number and size of polyps and this is related to older age, people who are overweight, people who smoke, and people with significant family history of colorectal polyps or colorectal cancer, conditions such as IBD, acromegaly and with certain genetic conditions such as Lynch syndrome or familial adenomatous polyposis (<u>Cancer Research UK, 2022</u>).

Age and race are protected characteristics. Older people, people from Black African or Caribbean family backgrounds and Jewish people of central and eastern European family origin are thought to be at an increased risk of colorectal cancer, Artificial intelligence software to help detect and characterise colorectal polyps Final scope August 2024

whereas east Asian populations have a lower prevalence of colorectal cancer. People with cancer are protected under the Equality Act 2010 from the point of diagnosis.

8 Potential implementation issues

Training novice endoscopists

HTW guidance states that the learning curve in using CADe is thought to be minimal with experienced endoscopists and training may be provided free of charge.

However, there is potential for CADe to impact the training pathway for novice endoscopists and achievement of key performance indicators.

Integration of the technologies into existing colonoscopy systems

Manufacturers commented there is extensive variability in NHS IT infrastructure specification, performance and reliability which can potentially inhibit or limit AI software adoption. This may be because of installation connectivity and IT compatibility requirements for specific AI technologies. The different AI-based systems vary in which colonoscopy systems they can be used with. So, the colonoscopy system a centre currently uses may impact which of the AI-based technologies it can implement.

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Appendix A Glossary of terms

Familial adenomatous polyposis (FAP)

FAP is a genetic condition where a large number of polyps develop in the lining of the colon and rectum.

Inflammatory bowel disease (IBD)

IBD is a chronic condition which causes inflammation of the digestive system. It can cause severe stomach pain and diarrhoea. The main types of IBD are Crohn's disease and ulcerative colitis.

Lynch syndrome

Lynch syndrome is an inherited condition that causes an increased risk of bowel cancer. People with Lynch syndrome are more likely to develop cancer at younger ages and may get cancer more than once.

Serrated polyps

Serrated polyps are a class of colorectal polyps that have a 'saw-toothed' appearance under a microscope. These are mostly hyperplastic polyps.

Sessile serrated polyps (SSL)

About 20% of serrated polyps are sessile serrated polyps. These are a sub-type of serrated polyps which are more likely to develop into cancer if not removed.

Appendix B References

Advanced imaging for detection and differentiation of colorectal neoplasia (2019 update) ESGE guideline

Artificial Intelligence (AI)-assisted endoscopy in the detection of gastrointestinal cancer and pre-cancerous lesions (2024) Health Technology Wales guideline

Cancer Research UK <u>Risks and causes of bowel cancer 2021</u> [online; accessed 7 August 2024]

Bowel screening (2024) NICE Clinical Knowledge Summaries

Colorectal Cancer (2021) NICE guideline NG151

Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas (2022) NICE guideline CG118

<u>Colorectal polypectomy and endoscopic mucosal resection</u> (2024 update) ESGE guideline

Consensus guidelines on the management of inflammatory bowel disease in adults (2019) British Society of Gastroenterology

Endocuff Vision for assisting visualisation during colonoscopy (2019) NICE guideline MTG45

<u>FIT in patients with signs or symptoms of suspected CRC</u> (2022) British Society of Gastroenterology/Association of Coloproctology of Great Britain

<u>Guidelines for the management of hereditary colorectal cancer</u> (2019) British Society of Gastroenterology/Association of Coloproctology of Great Britain/ United Kingdom Cancer Genetics Group

<u>Position statement on serrated polyps in the colon and rectum</u> (2017) British Society of Gastroenterology

<u>Post-polypectomy and post-colorectal cancer resection surveillance</u> (2020) British Society of Gastroenterology/Association of Coloproctology of Great Britain and Ireland/Public Health England guideline

Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care (2023) NICE guideline DG56

Suspected cancer: recognition and referral (2023) NICE guideline NG12

T1 cancer guideline (in development) (2024) European Society of Coloproctology

<u>Virtual chromoendoscopy to assess colorectal polyps during colonoscopy</u> (2017) NICE guideline DG28