



Innovative Medical Technology Overview | February 2024

Colon capsule endoscopy (CCE) for the detection of colorectal polyps and cancer

Summary

Colon capsule endoscopy (CCE) is used to examine the colon lining to identify colorectal polyps and cancer.

The intended place of CCE in the care pathway is as a triage tool for people referred for a colonoscopy. In Scotland, people are referred for a colonoscopy if they have:

- signs or symptoms of colorectal polyps or cancer (symptomatic population)
- a history of positive findings on a previous colonoscopy (surveillance population)
- a family history of colorectal polyps or cancer (surveillance population).

New evidence published since the [SHTG recommendations](#) in 2020 includes five meta-analyses and a systematic review assessing the diagnostic accuracy of CCE, an evaluation of the ScotCap service in northern Scotland, and evidence on patient experiences and preferences around bowel screening. The new evidence on CCE reports:

- sensitivity of 84% to 88% and specificity of 87% to 94% for the detection of polyps >6mm
- low adverse event rates
- patient views on acceptability that are comparable with those of colonoscopy.

An update to the 2020 SHTG cost analysis found that CCE is marginally cost saving in the symptomatic population because the costs of providing CCE are offset by a reduction in colonoscopies. CCE was found to be cost incurring in the surveillance population.

The evidence within this IMTO should be considered alongside the [2020 SHTG recommendations](#). Updating the SHTG recommendation would require an appraisal of the new evidence, clarification of the degree of overlap in studies within the meta-analyses and more detailed exploration of uncertainties in the cost analysis.

The technology and its use

Colorectal (bowel) cancer begins in the inner lining of the colon or the rectum, often as a small growth called a polyp or adenoma.¹ Early detection and removal of precancerous polyps is very effective for preventing colorectal cancer.

In Scotland, people who have signs or symptoms of colorectal polyps or cancer, or who have a positive bowel screening test, are routinely referred for a colonoscopy.¹ Colonoscopy is the reference standard for examining the colon.

CCE is an alternative technique for examining the colon.¹ CCE involves three key components: a capsule endoscope that the patient swallows, a data recording device the patient wears during the procedure and image processing software.¹

Colonoscopy services are under considerable strain, with long waiting lists.² Using CCE as a triage tool could help reduce waiting lists and help prioritise patients for referral to colonoscopy.

What is innovative about CCE?

Compared with colonoscopy, CCE is a less invasive way of examining the colon. This means that, unlike colonoscopy which must be undertaken in a hospital, people can have a CCE procedure in a community setting or in their home.

Regulatory information

The PillCam® Endoscopy System is a CE-marked class IIa device.

Current care pathway in Scotland

People who have signs or symptoms of colorectal polyps or cancer, or who have a positive bowel screening test, are routinely referred for a colonoscopy.¹

People who have an incomplete colonoscopy, or who are unable to have a colonoscopy, may be offered a computed tomographic colonography (CTC).¹ This technique produces a 3D reconstruction of the colon lining using CT imaging.

In NHS Grampian, NHS Highland and NHS Western Isles, a CCE service has been trialled (known as the ScotCap programme) as an alternative to direct colonoscopy referral. People with symptoms of colorectal polyps or cancer, and people under surveillance because they had symptoms in the past, are offered CCE procedures as part of routine care. People with a positive result on CCE are referred for an urgent colonoscopy.

Population, setting and intended user

Colorectal cancer is the third most common cancer in Scotland.¹ In 2020, 19,087 people in Scotland received a new diagnosis of colorectal cancer.³

In 2019–2021, 72.9% of people who had a positive bowel screening test (faecal immunochemical test, FIT) went on to have a colonoscopy.⁴

The CCE procedure can be performed:

- in a primary care or community diagnostic centre
- at home with guidance from a nurse
- at home where the person completes the procedure alone*.²

The CCE procedure can be performed by gastroenterologists, nurses or the patient.² Examination and interpretation of images from CCE procedures needs to be done by an expert.¹

CCE may be suitable for people who:

- have a positive bowel screening test (FIT positive)
- have signs or symptoms of colorectal polyps or cancer
- are unwilling or unable to have a colonoscopy
- have had an incomplete colonoscopy
- are under surveillance after positive findings on a previous colonoscopy
- are under surveillance because of a family history of colorectal cancer.¹

Costs

The total cost per CCE procedure is £747 at list price, according to National Services Scotland micro-costing.

The total cost per colonoscopy is estimated at £900.¹

Equality considerations

Table 1 shows that colorectal cancer is slightly more common in people from the most deprived areas of Scotland compared with the least deprived areas.³

* Patients swallow the capsule in the presence of a clinician or nurse and then return home.

Table 1: Colorectal cancer incidence in Scotland (2020) by Scottish Index of Multiple Deprivation (SIMD)³

	Age standardised incidence per 100,000 person years at risk (95% confidence interval, CI)
SIMD 5 (least deprived)	60.6 (56.0 to 65.3)
SIMD 1 (most deprived)	65.2 (60.0 to 70.6)

A National Institute for Health and Care Excellence (NICE) scoping document identified several potential inequalities relating to colorectal cancer and CCE:²

- people from Black African, Black Caribbean, Jewish or eastern European family backgrounds are more likely to develop colorectal polyps
- colorectal cancer is more common among people from low socioeconomic backgrounds
- people who do not speak or understand English, or for whom English is a second language, may be harder to reach and less likely to participate in bowel screening programmes
- CCE completion rates are lower among people with a learning disability or reduced mobility
- colonoscopy may be less acceptable in some cultures.

Summary of clinical evidence

In 2020, SHTG published recommendations on using CCE for the detection of colorectal polyps and cancer in adults.¹ The most robust evidence in the recommendations is a meta-analysis of five prospective studies (n=361). The [2020 recommendations](#) state:

‘CCE should not replace optical colonoscopy, but should be available as a diagnostic option in the current pathway for patients who present with lower gastrointestinal signs and symptoms suggestive of colorectal cancer and have a positive faecal immunochemical test (FIT). Evidence on clinical effectiveness and economic analysis indicate that CCE should be reserved for patients at lower risk of colorectal cancer.

Communication with patients needs to be very clear in setting out why they are being offered CCE. Shared patient decision-making should take into account the relative risks of incorrect diagnoses in each available investigative procedure, and should acknowledge that a substantial proportion – approximately half – of CCE recipients will require a follow up procedure.

Support should be provided to patients undergoing bowel cleansing to ensure the efficacy of CCE, recognising the increased requirements surrounding the CCE bowel preparation regimen compared with colonoscopy and computed tomographic colonography.

The full cost effectiveness of CCE remains unknown. Based on the SHTG cost analyses, CCE appears to increase financial cost for the health and care system.

SHTG supports the introduction of a registry to continuously and consistently collect relevant patient outcome and cost data, and this should inform future service delivery.¹

Since the 2020 SHTG recommendations, six meta-analyses and one narrative systematic review have been published.⁵⁻¹¹ *Table 2* presents an overview of the diagnostic performance of CCE reported in these systematic reviews and meta-analyses. Sensitivity and specificity of CCE for the detection of polyps >6mm were consistently reported as 84–88% and 87–94% respectively.

There is a degree of overlap in the studies included in the meta-analyses. The narrative systematic review includes similar studies to the meta-analyses. Four out of seven primary studies described in the 2020 SHTG recommendations are included in the recent meta-analyses.

Table 2: Summary of the diagnostic accuracy of CCE for detecting colorectal polyps reported in meta-analyses and systematic reviews published between 2020 and 2023

Study	Tests	Population	n studies	n patients	Polyps >6mm		Polyps >10mm	
					Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Sulbaran et al (2022) ¹⁰	CCE, colonoscopy	Average risk screening population	8	1,602	88% (84% to 91%)	94% (92% to 95%)	88% (82% to 93%)	95.5% (94% to 97%)
Mollers et al (2021) ⁹	CCE, colonoscopy	Average risk screening population, positive screening test, first-degree relatives of people with colorectal cancer, mixed indications	13	2,328	87% (83% to 90%)	87% (76% to 93%)	87% (83% to 90%)	95% (92% to 97%)
Kjølhede et al (2021) ⁸	CCE, colonoscopy	Screening population, history of polyps or cancer, positive FIT test, first-degree relatives of people with colorectal cancer	12	1,898	87% (83% to 90%)	88% (75% to 95%)	87% (82% to 90%)	95% (92% to 97%)
Ali et al (2021) ^{5*}	CCE, colonoscopy	Screening population, history of polyps or cancer, first-degree relatives of people with colorectal cancer	5	1,305	86% (82% to 91%)	88% (72% to 96%)	86% (80% to 91%)	96% (92% to 98%)

Vuik et al (2021) ^{11**}	CCE, colonoscopy	Average risk screening population	13	2,485	Range 79% to 96%	Range 66% to 97%	Range 77% to 97%	Range 91% to 99%
Alihosseini et al (2020) ^{6*}	CCE, colonoscopy	Screening in people with suspected colorectal polyps	8	1,238	84% (80% to 88%)	88% (85% to 90%)	84% (76% to 89%)	96% (94% to 97%)
Deding et al (2020) ^{7***}	CCE, CTC, both	People with an incomplete colonoscopy	26	2,423	NR	NR	NR	NR

**All included studies are also present in more recent meta-analyses by Sulbaran, Mollers or Kjolhede⁸⁻¹⁰*

***Narrative systematic review only*

****Diagnostic accuracy of CCE for detecting polyps >5mm and >9mm. Only reports diagnostic yield.*

ScotCap

Three primary studies and two evaluation reports describe the ScotCap CCE service in the north of Scotland (NHS Highland, NHS Grampian, NHS Western Isles).¹²⁻¹⁶ These studies and reports focus on CCE completion rates, patient and staff experiences, and barriers and facilitators to scaling up the ScotCap service to national level (*Table 3*).

Table 3: Summary of studies relating to the ScotCap CCE service in northern Scotland

Study	Study design and participants	Key outcomes
Bond et al (2023) ¹² Lennon et al (2020) ¹⁶	211 survey responses from patients 47 interviews	<ul style="list-style-type: none"> Patients reported benefits including reduced travel time, reduced waiting times, and completing the procedure at home. Patients and other stakeholders described the importance of clear and accessible information. Most patients (162/195) would recommend CCE to others.
MacLeod et al (2023) ¹⁴	Prospective cohort 401 patients	<ul style="list-style-type: none"> In symptomatic patients, age is associated with a successful CCE (odds ratio OR 0.97, 95% CI 0.95 to 0.99) and needing a follow up procedure (OR 1.04, 95% CI 1.02 to 1.06). In surveillance patients, needing a follow up procedure was associated with previous cancer (OR 0.42, 95% CI 0.18 to 0.97), previous bowel surgery (OR 0.43, 95% CI 0.19 to 0.98) or taking a beta blocker (OR 0.32, 95% CI 0.11 to 0.88).
MacLeod et al (2022) ¹⁵	Prospective cohort 509 patients	<ul style="list-style-type: none"> 72% of symptomatic patients and 71% of surveillance patients had a complete test. 63% of symptomatic patients and 72% of surveillance patients needed a follow up test. Two patients experienced serious adverse events.
Brogan et al (2020) ¹³	Three workshops with clinical staff (n=23) 7 interviews with clinical staff	<p>Recommendations for successful service implementation include:</p> <ul style="list-style-type: none"> needing a culture of change introducing an electronic endoscopy management system streamlining communication channels and systems increasing interactivity between primary and secondary care introducing a new digital vetting system to review, sort and identify the most appropriate pathway for patients centralising dispensing and distribution of bowel preparation and equipment.

Summary of safety evidence

Two systematic reviews with meta-analysis reporting safety outcomes have been published since the 2020 SHTG recommendations (*Table 4*).^{17, 18} Both analyses include studies on multiple types of capsule endoscopy. It is likely that there is a high degree of overlap in the studies included in the two meta-analyses.

Table 4: Summary of CCE related adverse events reported in two meta-analyses

Study	n studies	n patients	Key outcomes
Cortegoso Valvidia et al (2022) ¹⁷	328 (42 on CCE)	86,930 total	Capsule retention rate across all patients of 1% (95% CI 0% to 1%).
Wang et al (2020) ¹⁸	402 (43 on CCE)	91,069 total (5,918 CCE)	Capsule retention rate of 0.26%. Swallow disorder in 0.04% of patients. No instances of aspiration. Technical failure rate of 1.76%. Incidence of procedural adverse events 0.81%.

Summary of economic evidence

No health economic evidence has been published since the [2020 SHTG recommendations](#).¹

Evidence from the ScotCap programme

SHTG analysed data from the CCE registry established as part of the ScotCap programme. Data are for patients who had CCE after a new bowel preparation regimen (addition of prucalopride) was introduced to improve procedure completion rates.¹⁹ Seven health boards contributed data for at least one patient population of interest: surveillance, symptomatic FIT negative or symptomatic FIT positive. ScotCap data were collected from the rollout of the new bowel preparation (May to October 2023) to the data cutoff (end November 2023).

The 2020 SHTG cost analysis was updated using the ScotCap data from 2023 and new prices for CCE. *Tables 5–7* present the results of the updated analysis.

The analysis found that CCE remains cost incurring in the surveillance population. The total cost associated with the CCE pathway in this patient population is £3,728,121 compared with £3,496,251 for the current pathway, resulting in an incremental cost of £231,870 per year or £64.75 per patient.

The CCE pathway was found to be marginally cost saving in the symptomatic population. For the symptomatic FIT positive population, the CCE pathway cost £15,757,159 compared with £15,867,817 for the current pathway, resulting in a cost saving of £110,658 per year or £6.71 per patient. In the symptomatic FIT negative population, the CCE pathway cost £28,702,395 compared with £28,713,192 for the current pathway, resulting in a cost saving of £10,979 per year or £0.36 per patient.

The cost savings in the symptomatic populations are driven by a reduction in the number of colonoscopies needed by patients in the CCE pathway compared with the current pathway. Since most of the resources related to colonoscopy, such as staff and colonoscopy equipment costs, are likely to be fixed in the short term, these cost savings are unlikely to be cash releasing.

The difference in cost outcomes for symptomatic and surveillance populations is driven by a higher proportion of patients in the symptomatic population who need a subsequent procedure having the less costly flexible sigmoidoscopy. This was calculated based on relative procedure rates in the ScotCap 2023 data.

Further analysis should be undertaken to assess the robustness of the results. For example, exploring the uncertainty around the cost of a colonoscopy in NHSScotland.

Table 5: Aggregate and incremental per person cost analysis in the surveillance population

	Annual cost (£)	Resource use	
		n colonoscopies	n flexible sigmoidoscopies
Current pathway	3,496,251	3,851	0
CCE pathway	3,728,121	2,359	37
Net vs current pathway (aggregate)	231,870	-1,493	37
Net vs current pathway (per patient)	64.75	–	–

Table 6: Aggregate and incremental per person cost analysis in the symptomatic FIT positive population

	Annual cost (£)	Resource use	
		n colonoscopies	n flexible sigmoidoscopies
Current pathway	15,867,817	17,418	0
CCE pathway	15,757,159	13,826	533
Net vs current pathway (aggregate)	-110,658	-3,592	533
Net vs current pathway (per patient)	-6.71	–	–

Table 7: Aggregate and incremental per person cost analysis in the symptomatic FIT negative population

	Annual cost (£)	Resource use	
		n colonoscopies	n flexible sigmoidoscopies
Current pathway	28,713,192	31,518	0
CCE pathway	28,702,395	25,265	890
Net vs current pathway (aggregate)	-10,979	-6,253	890
Net vs current pathway (per patient)	-0.36	–	–

User experience

A systematic review and a systematic review with meta-analysis explored patient aspects relating to CCE.^{20, 21} Two primary studies, one from England and the other from Ireland, explored experiences and preferences around CCE.^{22, 23} Findings are summarised in *Table 8*.

Table 8: Summary of study findings relating to patient aspects of CCE

Study	Tests	n patients	Key outcomes
Ali et al (2023) ²⁰ Systematic review	CCE, colonoscopy, CTC, flexible sigmoidoscopy, FIT or blood test	12 studies (n patients not reported)	No significant differences in uptake, screening test preference or willingness to repeat a test.
Ismail et al (2022) ²² Retrospective cohort	CCE, colonoscopy	40	CCE was more comfortable than colonoscopy (p<0.0001). Satisfaction scores were comparable (p=0.28). 77.5% of patients preferred CCE.
Deding et al (2021) ²¹ Meta-analysis	CCE, colonoscopy	12 studies (n patients not reported)	Pooled patient preference was 52% for CCE and 45% for colonoscopy. Tolerability was high for both CCE and colonoscopy.
Kaushal et al (2020) ²³ Randomised vignettes	CCE, colonoscopy, CTC	953	No significant differences in participants' intention to have CCE or colonoscopy procedures. For people who did not intend to have the test they were offered, CCE or no investigation was preferable to colonoscopy or CTC.

One primary study, not described in *Table 8*, reported patient experiences with a different colon imaging technique called C-scan.²⁴ This technology uses a capsule to construct x-ray based models of the colon lining. No bowel preparation is required for using this technology. Evidence for C-scan is limited to two small observational studies.

Conclusions

Since the 2020 SHTG recommendations, five meta-analyses and a systematic review have reported diagnostic accuracy measures for CCE. Sensitivities of 84% to 88% and specificities of 87% to 94% are consistently reported for the detection of polyps >6mm using CCE. This is a higher estimated specificity than the meta-analysis cited in the 2020 recommendations (76%).

Two meta-analyses report low adverse event rates for CCE procedures. With the exception of technical failure (1.76%), all adverse event rates affected less than 1% of patients. Technical failures include battery life expiring before the capsule has reached the end of the colon.

Two systematic reviews and two primary studies provide evidence that patient preferences and acceptability of CCE are comparable with colonoscopy (the current standard of care).

Three primary studies and two reports describe findings from an evaluation of the ScotCap service in NHS Highland, NHS Grampian and NHS Western Isles. These studies report CCE completion rates of around 70% and patient acceptability of the service within NHSScotland.

The updated SHTG cost analysis found that CCE is marginally cost saving in the symptomatic population. Annual cost savings of £110,658 (£6.71 per patient) and £10,979 (£0.36 per patient) were calculated for the symptomatic population with a positive or negative FIT test, respectively. CCE remains cost incurring in the surveillance population.

Any change to the SHTG recommendations will require a more in-depth assessment of the new literature.

What is an IMTO?

An IMTO provides a high level summary of a health and care innovations. IMTOs include a clear description of the technology and its potential use in Scotland, and an overview of the evidence, to help gauge the potential impact of the technology on people and health and care services.

References

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