National Endoscopy Programme Capsule Endoscopy Working Group

The Use of Colon Capsule Endoscopy (CCE) in a FIT-Stratified Symptomatic Patient Diagnostic Pathway

Irish Capsule Endoscopy Working Group White Paper

The Irish Capsule Endoscopy Working Group
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Contents

Executive Summary. P2-4

1. Current Challenges in the Symptomatic Patient Pathway. P5-6

2. Evidence Base for FIT and Colon Capsule Endoscopy (CCE). P7-14
2.1 FIT in Symptomatic Patients
2.2 Colon Capsule Endoscopy
2.3 The Combined FIT-CCE Approach

3. Proposed FIT-Stratified Diagnostic Pathway. P15-26
3.1 Patient Eligibility and Selection Criteria
3.2 FIT-Based Risk Stratification
3.3 Integration of CCE within the Diagnostic Pathway
3.4 Escalation to Colonoscopy and Other Investigations
3.5 Proposed National Algorithm

4. Operational Considerations. P27-38
4.1 Workforce Requirements
4.2 Role of Advanced Nurse Practitioners
4.3 Health Service Impact and Resource Implications

5. Community-Based CCE Services. P39-45
5.1 Rationale for Community Delivery
5.2 Delivering and Supporting Care Closer to Home
5.3 Integration with Primary Care and Hospital Services
5.4 Enhanced patient experience
5.5 Environmental assessment

6. Digital Infrastructure, Technology and Artificial Intelligence. P46-50
6.1 Digital Referral and FIT Management Platform
6.2 Integrated Patient Tracking and Navigation
6.3 Colon Capsule Image Management Infrastructure
6.4 National CCE Reporting Network
6.5 Artificial Intelligence for Capsule Interpretation

7. National Standards and Guideline Development. P51-58
7.1 Evidence Base for National Standards
7.2 Governance Structure and Leadership
7.3 Quality Indicators and Performance Measurement
7.4 National Data Collection and Benchmarking
7.5 Quality Assurance of Reporting and Workforce Competency
7.6 Continuous Quality Improvement
7.7 Patient Safety and Risk Management
7.8 Quality Assurance Recommendations

8. Education and Engagement. P59-68
8.1 Workforce Education and Competency Development
8.2 Education of Key Stakeholders Across the Healthcare System
8.3 Stakeholder Engagement Strategy for National Implementation
8.4 Potential Barriers to Adoption and Strategies to Overcome Resistance
8.5 Communication and Awareness Campaign
8.6 Patient and Public Awareness, Education and Engagement

9. Summary of Recommendations. P69-73
9.1 Strategic Recommendation
9.2 Key Recommendations

10. References. P74-77

11. Appendices. P78-79

Executive Summary

Demand for lower gastrointestinal diagnostic services in Ireland continues to increase, placing significant pressure on colonoscopy capacity and contributing to prolonged waiting times. Despite improvements in endoscopy quality and national investment in waiting-list reduction initiatives, more than 32,000 patients were waiting for GI endoscopy procedures in 2025, with many urgent referrals exceeding recommended timelines. A new diagnostic model is required to improve access while maintaining high standards of care.

This white paper proposes a FIT-stratified symptomatic lower GI diagnostic pathway that combines quantitative Faecal Immunochemical Testing (FIT), Colon Capsule Endoscopy (CCE), and targeted colonoscopy. The model aims to optimise resource utilisation by reserving colonoscopy for patients most likely to have significant pathology while directing lower-risk symptomatic patients towards CCE as a minimally invasive, highly accurate diagnostic alternative.

Evidence from international studies demonstrates that FIT is an effective risk-stratification tool with high sensitivity and negative predictive value for colorectal cancer (CRC). FIT enables prioritisation of patients at highest risk of cancer while reducing unnecessary colonoscopy demand. Emerging Irish and international data support its routine use within symptomatic referral pathways.

CCE has matured into a robust diagnostic modality with proven accuracy for the detection of colorectal neoplasia and other significant colonic disease. Irish Registry (ICaRe) data demonstrate a diagnostic yield of 55%, a polyp detection rate of 45% and a significant polyp detection rate of 25.7%, and avoidance of further endoscopic investigation in approximately 61% of patients. International programmes have reported comparable diagnostic performance, with sensitivity for significant polyps frequently exceeding 90%.

> ***"In practical terms, for every 100 appropriately selected low- or intermediate-risk FIT patients undergoing CCE, approximately 50 to 60 colonoscopy slots may be preserved for higher-priority activity."***

The proposed pathway incorporates FIT as the initial triage tool. Patients with high FIT values proceed directly to colonoscopy, while those with low or intermediate FIT levels are preferentially investigated using CCE. Colonoscopy is subsequently reserved for patients with significant findings on CCE, incomplete examinations, or ongoing clinical concern. This approach preserves valuable endoscopy capacity, improves diagnostic yield, and supports more timely access for higher-risk patients. In practical terms, for every 100 appropriately selected low- or intermediate-risk FIT patients undergoing CCE, approximately 50 to 60 colonoscopy slots may be preserved for higher-priority activity.

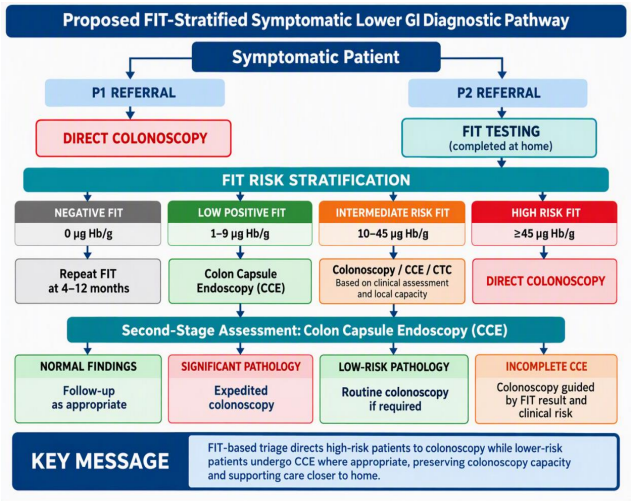
A key feature of the proposal is the delivery of CCE through community-based diagnostic services, supported by regional reporting hubs operating within a hub-and-spoke model. This aligns closely with Sláintecare principles by providing care closer to home, improving patient convenience, reducing hospital attendances, and supporting equitable access across geographic regions.

The pathway also supports significant workforce transformation. Advanced Nurse Practitioners (ANPs) would play a central role in patient assessment, pathway coordination, capsule administration, result communication, and escalation of positive findings. Consultant gastroenterologists and colorectal surgeons would be increasingly focused on therapeutic procedures, cancer pathways, and complex case management rather than low-yield diagnostic colonoscopy.

Digital infrastructure will be critical to successful implementation. The proposed model requires integrated electronic referral systems, FIT management platforms, cloud-based capsule reporting capabilities, national quality registries, and future integration with Ireland's developing electronic health record infrastructure. Artificial intelligence-assisted capsule

interpretation offers further opportunities to improve efficiency, consistency, and reporting productivity.

To ensure safe and effective implementation, the paper recommends the development of a national governance and quality-assurance framework under the National Endoscopy Governance Framework, supported by NEQI and the Irish Capsule Endoscopy Registry (ICaRe). Standardised performance measures, accreditation pathways, workforce training programmes, and continuous quality-improvement processes will be essential components of national rollout.



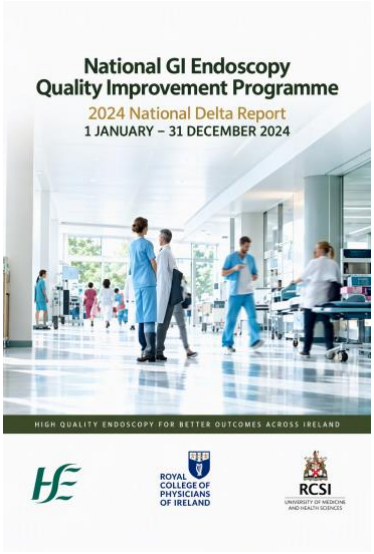
Overall, the proposed FIT-CCE-colonoscopy pathway represents a strategic service transformation rather than simply the introduction of a new diagnostic test. By combining evidence-based risk stratification, minimally invasive diagnostics, community-based delivery, and national quality oversight, Ireland has an opportunity to expand colorectal diagnostic capacity, reduce waiting-list pressures, improve patient experience, and create a more sustainable and patient-centred model of care for symptomatic lower GI investigation.

This paper is a culmination of consensus meetings of the CCE working group, tasked by the national endoscopy programme. A systematic analysis of Irish and international data was performed and a draft proposal developed which was refined and approved at a consensus meeting of the authors. The final draft was circulated to all CCE working group members prior to publication.

Current Challenges in the Symptomatic Patient Pathway

The NEQI programme, captures more than 94% of national endoscopy activity, it demonstrates a sustained increase in colonoscopy activity (120000 colonoscopies annually) in Ireland over the past decade (1).

A recent analysis of over 658,000 colonoscopies performed between 2016 and 2022 demonstrates sustained improvement in colonoscopy quality indicators at a national level, with high completion rates and strong polyp detection (2).



In line with this recent National Treatment Purchase Fund (NTPF) data demonstrates sustained pressure on Irish endoscopy services. In July 2025, 32,839 patients were waiting for a GI endoscopy procedure nationally, representing an increase from 28,663 patients in March 2025 (3). Concurrently, more than 2,700 patients exceeded the HSE target of 28 days for urgent colonoscopy between January and May 2025. Despite investment through the Waiting List Action Plan and expansion of FIT-based triage and capsule endoscopy services, demand for GI endoscopy continues to grow at approximately 4% annually, reflecting increasing referral volumes and ongoing capacity constraints within endoscopy services (4).

Endoscopy referrals in Ireland are typically clinically vetted based on symptoms into urgent (P1), routine (P2) and surveillance pathways. P1 referrals generally comprise patients with alarm symptoms or features suggestive of colorectal malignancy, including rectal bleeding with change in bowel habit, iron deficiency anaemia and unexplained weight loss. P2 referrals comprise symptomatic patients who do not meet urgent colorectal cancer referral criteria and are managed through a routine endoscopy pathway (5).

The NTPF national waiting-list protocol requires all GI endoscopy referrals to undergo clinical prioritisation and vetting before addition to a waiting list. Patients are prioritised according to clinical urgency, with urgent (P1) referrals scheduled ahead of routine (P2) referrals.

The protocol emphasises consultant-led clinical prioritisation, active waiting-list validation, and scheduling according to clinical need to ensure timely access for patients with suspected significant pathology while maintaining equitable access across the endoscopy service (6).

Urgent (P1) colonoscopy referrals should be undertaken within 28 days where significant pathology or malignancy is suspected. Routine (P2) referrals are managed through standard waiting-list pathways and the national key performance indicator require 65% to be undertaken within a twelve week target.

National waiting-list policy is increasingly based on clinical prioritisation categories rather than fixed P1/P2 timelines, and the current Sláintecare target for GI endoscopy is an average waiting time of 5.5 months. However as referenced above, in reality a significant proportion of referrals are not performed within this time frame and with an increasing colonoscopy demand, waiting times for all patient categories are predicted to increase without further intervention.

Evidence Base for FIT and Colon Capsule Endoscopy (CCE)

2.1 FIT (Faecal Immunological Test) in Symptomatic Patients

FIT Diagnostic Accuracy for Colorectal Cancer

Significant international evidence supports FIT as an excellent predictor of colorectal cancer (CRC). Applying a FIT threshold of 2- 10ug/g.

FIT Prediction of Significant Colonic Disease

Beyond CRC, FIT is also predictive of significant colonic pathology, including:

- Advanced adenomas
- Large polyps
- High-risk neoplasia
- Inflammatory bowel disease

International evidence of FIT in colorectal cancer

Study	Threshold	Sensitivity	Specificity
D'Souza et al. (NICE-FIT, 2021) [7]	2 µg/g	97.7%	Variable
D'Souza et al. (NICE-FIT, 2021)	10 µg/g	92.2%	Variable
Saw et al. (2022 Meta-analysis)[8]	2 µg/g	96.8%	65.6%
Saw et al. (2022 Meta-analysis)	10 µg/g	88.7%	80.5%
Monahan et al. (2022)[9]	10 µg/g	87.0%	84.4%
Westwood et al. (2017)[10]	10 µg/g	92.1%	85.8%

Studies consistently show that increasing faecal haemoglobin concentration correlates with a greater likelihood of significant pathology. Although FIT performs best for cancer detection, it also identifies populations at increased risk of advanced adenomas and clinically significant polyps requiring colonoscopic intervention.

FIT Clinical Application

Based on the growing body of evidence, FIT has now become a highly effective triage tool for colonoscopy vetting in symptomatic patients, allowing prioritisation of patients at highest risk of colorectal cancer (CRC) and significant colonic disease.

FIT and Colonoscopy Demand

Study	Design / Population	FIT Threshold (µg Hb/g)	Sensitivity (%)	Specificity (%)
Westwood et al. (2017) (NICE DG30 Evidence Review)[10]	Health technology assessment of low-risk symptomatic adults in UK primary care	10	92.1% (95% CI 84.5–96.3)	85.8% (95% CI 78.3–91.0)
Goddard et al. (2023)[12]	Prospective NHS cohort of symptomatic primary care referrals	10	90.2%	78.8%
Cole et al. (2024) [13]	Five-year real-world audit (56,202 FIT tests)	10	92.0%	Not reported

The UK's National Institute for Clinical Excellence (NICE) DG30 Guidance, recommends the use of quantitative FIT in primary care to guide referral decisions for patients with low-risk symptoms of colorectal cancer. The guidance concluded that FIT provides greater diagnostic accuracy than symptom assessment alone, allowing more effective risk stratification, reduction of unnecessary colonoscopies, and prioritisation of patients at highest risk of significant colorectal disease.

A threshold of 10 µg Hb/g faeces was recommended for urgent referral, while emphasising the need for clinical judgement and safety-netting in FIT-negative patients (11). FIT demonstrates very high sensitivity and negative predictive value (NPV) for CRC, making it particularly valuable as a "rule-out" test.

Recent analysis of the UK national endoscopy database highlights its value in combination with other clinical parameters including patient age and anaemia. Patients with negative FIT results have a very low probability of underlying CRC, allowing endoscopy resources to be focused on higher-risk individuals. This approach has also been endorsed by the British Society of Gastroenterology and several studies have demonstrated the impact of FIT on reducing colonoscopy demand.

In addition, current real world evidence from the UK also supports the routine use of FIT in patient triage. Beaton et al analysed data from 447,109 symptomatic colonoscopies in the UK National Endoscopy Database and found that colorectal cancer (CRC) yield was 3.8% in patients with a FIT ≥10 µg Hb/g compared with just 0.3% in those with a FIT <10 µg Hb/g. Iron deficiency anaemia (IDA) was the only symptom strongly associated with CRC risk, more than doubling the likelihood of cancer detection (aOR 2.14, 95% CI 1.97-2.33). Applying current FIT-based referral guidance (FIT ≥10 µg Hb/g and/or IDA) would have reduced colonoscopy demand by 16.2% while missing only 1% of CRC cases, supporting FIT as an effective triage tool for symptomatic patients (14).

Limitations

*False-negative CRCs occur at all thresholds, though infrequently.

*FIT performs less well for right-sided lesions and some advanced adenomas.

*Clinical judgement remains essential, particularly in patients with iron deficiency anaemia, palpable rectal or abdominal masses, persistent symptoms despite a negative FIT and strong family history of CRC

Despite excellent performance, FIT is not sufficiently sensitive to completely exclude significant disease.

The literature therefore emphasises that FIT should be used alongside symptom assessment and safety-netting rather than as a standalone diagnostic test.

2.2 Colon Capsule Endoscopy (CCE)



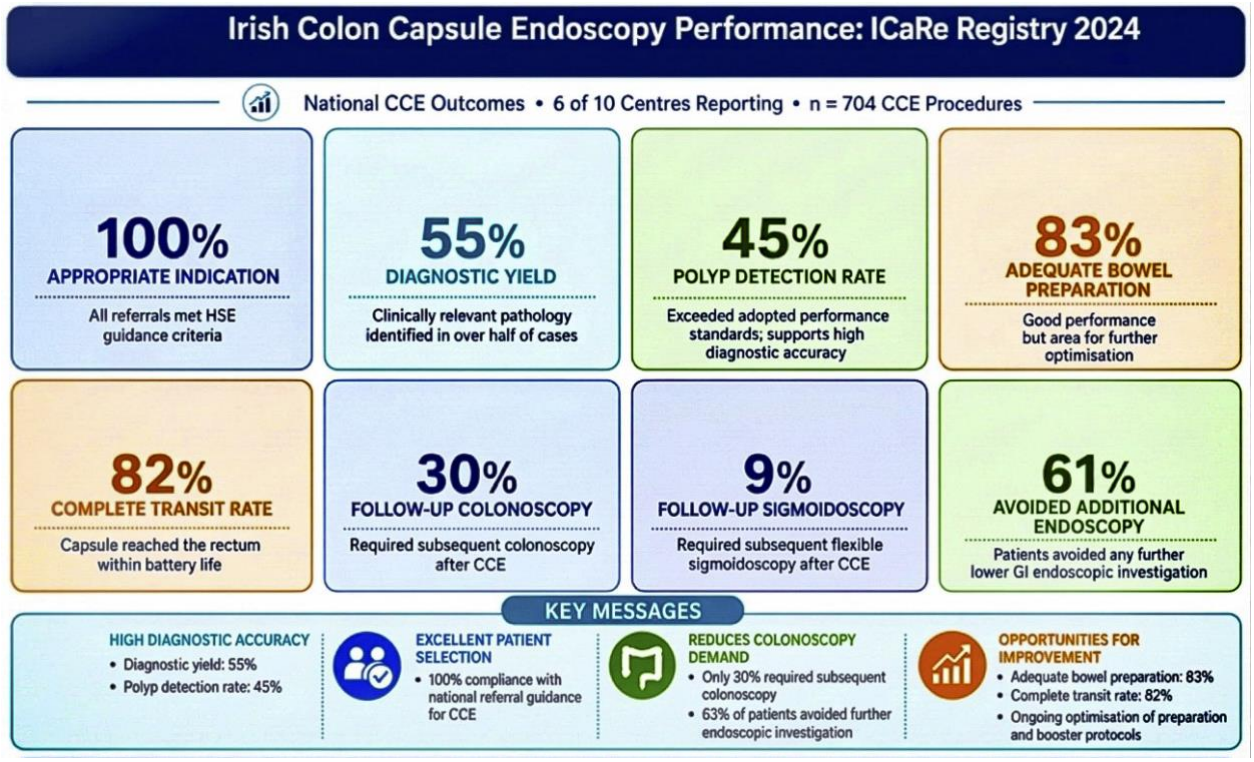
Irish Colon Capsule Endoscopy Performance Data

The Irish Capsule Endoscopy Registry (ICaRe) provides the first comprehensive national assessment of Colon Capsule Endoscopy (CCE) performance across Irish hospitals and offers valuable real-world evidence regarding the effectiveness, quality, and operational challenges associated with CCE implementation. During 2024, six of the ten designated capsule endoscopy centres contributed data, representing 704 CCE and pan-intestinal capsule procedures.

The registry demonstrates that CCE is an effective diagnostic modality with a high diagnostic yield and strong pathology detection rates. Overall diagnostic yield was 55%, indicating that clinically relevant pathology was identified in more than half of all examinations. Polyps were detected in 45% of procedures substantially exceeding the benchmark adopted from NEQI colonoscopy quality standards (20%). Moreover, significant polyps (≥ 3 polyps or any polyp ≥6mm) occurred in 25.7% in more recent ICaRe data (15). Both studies confirm CCE is highly accurate for the detection of colorectal neoplasia in Irish patients.

Appropriate patient selection was excellent, with 100% of examinations meeting HSE clinical guidance criteria for referral to CCE. This finding confirms successful integration of CCE into established clinical vetting pathways and demonstrates consistent adherence to national guidance across participating centres.

Technical performance indicators highlighted both strengths and opportunities for further optimisation. Adequate bowel preparation was achieved in 83% of procedures (range 79-94%), while complete capsule transit occurred in 82% of examinations (range 60-94%). Although both metrics fell below the aspirational target of 90%, the results compare favourably with published international experience and identify bowel preparation protocols and booster regimens as key quality-improvement priorities.



Importantly, ICaRe 2024 confirms that CCE can function effectively as a filter test within a symptomatic diagnostic pathway. Following CCE, 30% of patients required a subsequent colonoscopy and 9% underwent flexible sigmoidoscopy. Consequently, approximately 61% of patients avoided any further lower gastrointestinal endoscopic investigation. These findings suggest that careful patient selection can substantially reduce pressure on colonoscopy services while maintaining diagnostic accuracy.

Registry analysis also suggests that the greatest value of CCE lies in the investigation of symptomatic patients who are at lower risk of requiring therapeutic intervention. Patients undergoing surveillance investigations were significantly more likely to require subsequent colonoscopy than those undergoing investigation for new symptoms. These findings support the use of CCE within a FIT-stratified symptomatic pathway, reserving colonoscopy capacity for patients at highest risk of cancer or advanced neoplasia while directing lower-risk patients towards CCE as a first-line structural examination.

Overall, the ICaRe data demonstrate that CCE is a safe, accurate, and scalable diagnostic modality capable of supporting national efforts to improve access to lower gastrointestinal investigation. While ongoing work is required to optimise bowel preparation quality and capsule completion rates, the registry findings provide strong evidence for the incorporation of CCE into modern risk-stratified diagnostic pathways and support its continued expansion within both hospital and community-based services.

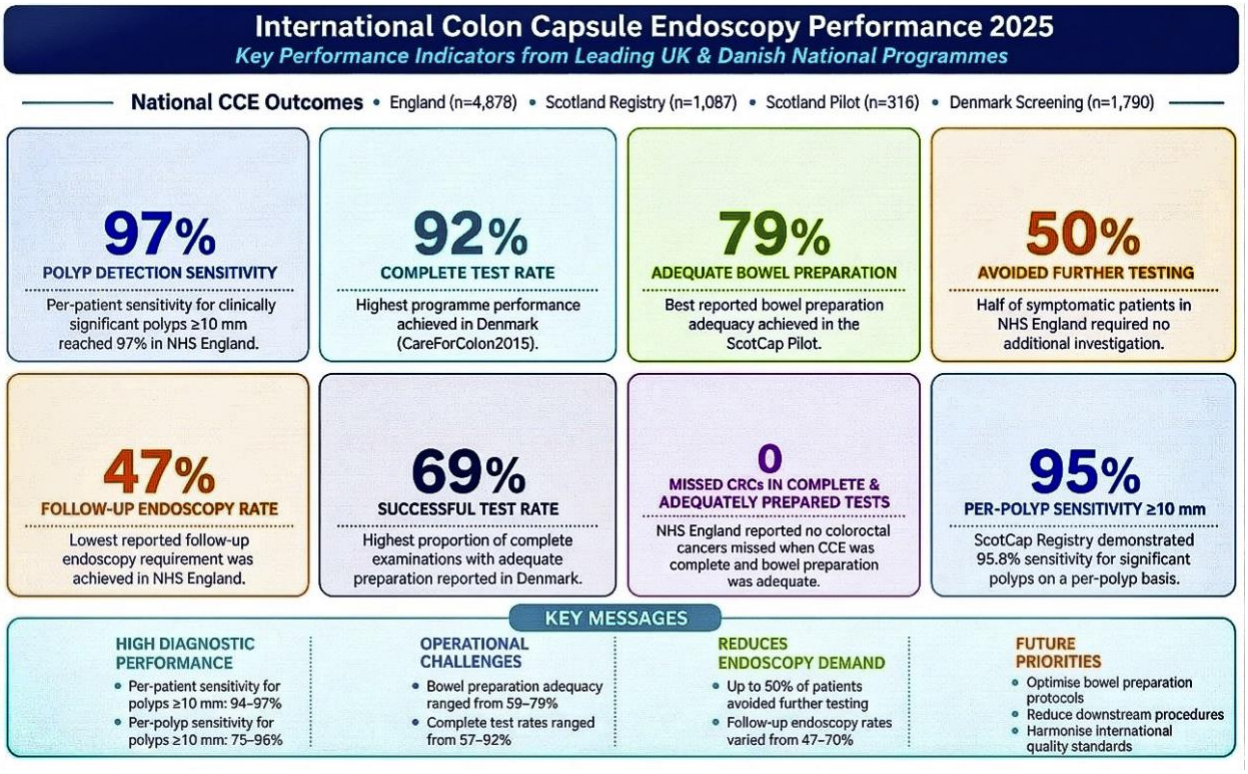
Summary of International Colon Capsule Endoscopy Performance Data

Substantial international evidence demonstrates that Colon Capsule Endoscopy (CCE) is a highly accurate, minimally invasive diagnostic test capable of supporting modern risk-stratified lower gastrointestinal investigation pathways. Large national programmes in England, Scotland, and Denmark have shown that CCE can identify clinically significant colorectal pathology with high sensitivity while reducing demand for conventional colonoscopy (16-20).

Across international programmes, bowel preparation quality and complete examination rates have continued to improve, although variability remains between healthcare systems. Adequate bowel preparation rates ranged from approximately 59% to 79% in Scottish programmes and 74% to 76% in English and Danish cohorts. Complete colon visualisation rates ranged from 57% in early registry experience to over 90% in the Danish CareForColon programme, demonstrating the importance of optimised preparation and booster protocols. The use of prokinetic agents such as prucalopride has been associated with improved completion rates and may be an important factor in future service development.

One of the most important observations from large-scale implementation studies is the ability of CCE to function as a filter test, reducing the requirement for downstream endoscopic investigation. Follow-up colonoscopy or sigmoidoscopy rates varied between programmes, reflecting differences in patient selection, referral indications and reporting thresholds. The NHS England programme reported one of the lowest rates of follow-up endoscopy, suggesting that careful patient selection can maximise the clinical and operational benefits of CCE.

The strongest evidence supporting CCE relates to its ability to detect clinically significant polyps. In large national symptomatic cohorts, per-patient sensitivity for polyps ≥10 mm ranged from 93.8% to 97.0%, while per-polyp sensitivity ranged from 75.0% to 95.8%. These figures are comparable to accepted standards for optical colonoscopy and support the role of CCE as a reliable diagnostic investigation for colorectal neoplasia. Several studies have suggested that CCE may detect lesions that are subsequently missed during colonoscopy, reinforcing its high diagnostic accuracy.



Importantly, no colorectal cancers were missed in complete, adequately prepared examinations in the NHS England programme. Reported missed cancers were predominantly associated with inadequate bowel preparation or incomplete examinations, highlighting the critical importance of test quality and complete colonic visualisation. These findings emphasise that bowel preparation quality and completion rates remain the most important performance indicators for ongoing quality improvement initiatives.

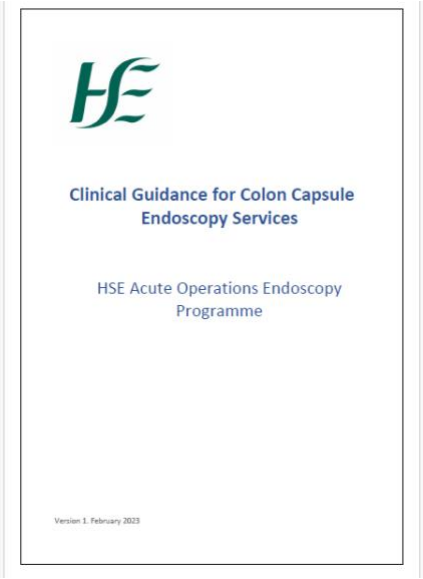
Overall, international experience demonstrates that CCE is a safe, accurate, and a scalable diagnostic technology that can expand diagnostic capacity, improve patient choice, and preserve colonoscopy resources for patients most likely to require therapeutic intervention.

Collectively, the international data support several key conclusions

- CCE is highly accurate for the detection of clinically significant colorectal pathology.
- Per-patient sensitivity for significant polyps consistently exceeds 90%.
- CCE can reduce demand for conventional colonoscopy when deployed in appropriately selected populations.
- Optimal bowel preparation and complete capsule transit are critical determinants of performance.
- Standardisation of quality indicators and preparation protocols remains an important priority for national programmes.
- Emerging evidence supports the use of CCE within FIT-stratified symptomatic pathways and other risk-based models of care.

Proposed FIT-Stratified Diagnostic Pathway

3.1 Patient Eligibility and Selection Criteria



Patient selection for CCE will be based on the National Endoscopy Programmes 2023 Guidance for Colon Capsule Endoscopy.

Similarly, CCE procedures will be performed uniformly following National recommendations, developed in accordance with National and International best practice.

Appropriate Patient Selection

Patients will be referred for CCE based on the proposed FIT based risk stratification as outlined in paragraph 3.5. Patient choice is a key foundation of the proposed pathway and as such all should be informed that a subsequent conventional colonoscopy may still be required if abnormalities such as polyps, inflammation or suspected cancer are identified. Similarly, CCE remains a valid option for patients who prefer a less invasive procedure and request CCE as an alternative to colonoscopy. In addition to the proposed symptomatic patient diagnostic pathway CCE remains indicated in a variety of other clinical settings including following an incomplete colonoscopy.

Contraindications

CCE should not be performed in patients with conditions that increase the risk of capsule retention or inability to swallow the capsule safely.

Predictors of Poor-Quality Examinations

Several factors may reduce the likelihood of a complete or high-quality study. These patients may benefit from enhanced counselling and closer preparation support.

Bowel Preparation Protocol

Successful CCE relies on excellent bowel preparation because the capsule cannot wash or suction debris during the examination. A standardised evidence based CCE bowel preparation regimen will be employed. However it is essential that future advantageous refinements to the protocol are adopted in a timely fashion. As such the preparation advice should be viewed as a living document.

Management of Incomplete Studies

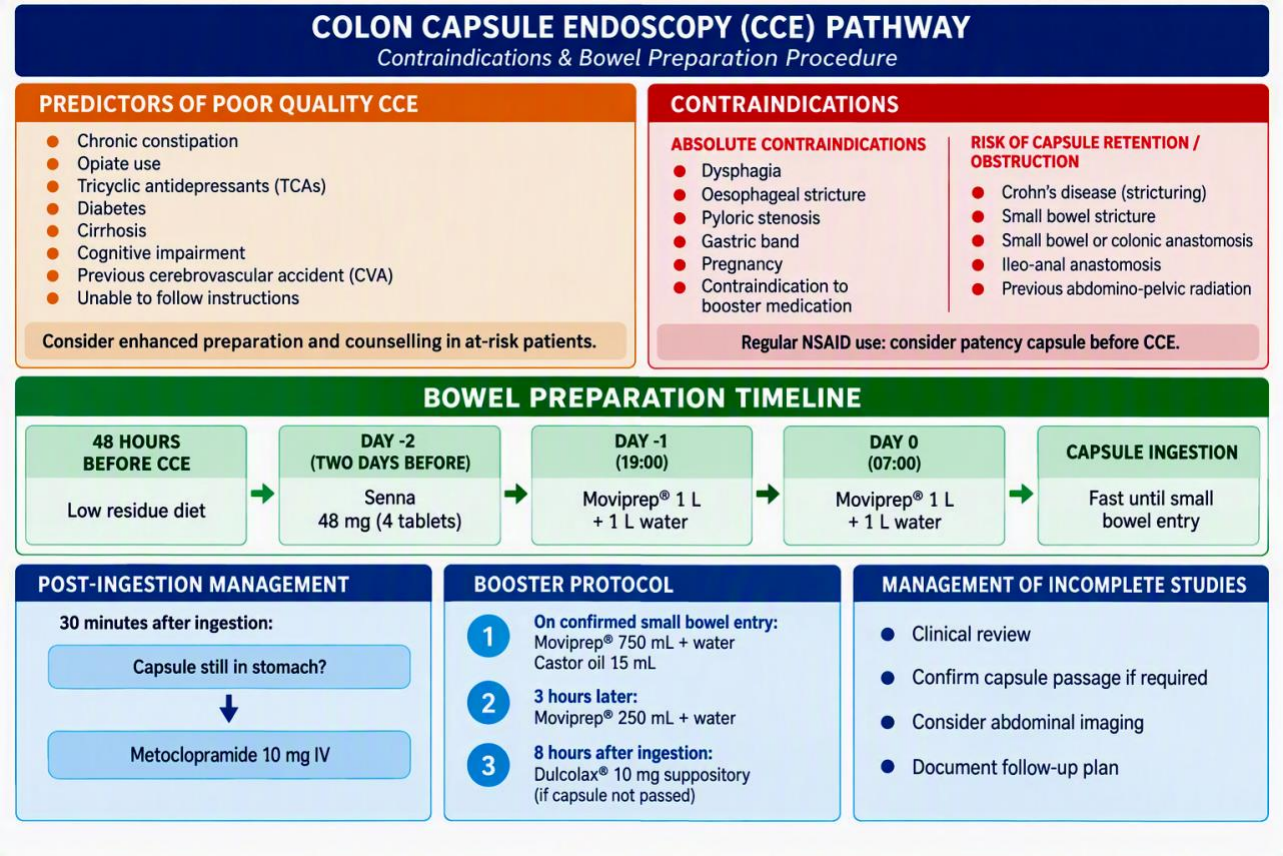
Patients with incomplete examinations require:

- Clinical review.
- Consideration of imaging to exclude capsule retention.
- A documented follow-up plan.
- Repeat CCE may be considered where bowel preparation or image quality was inadequate but capsule transit was satisfactory.

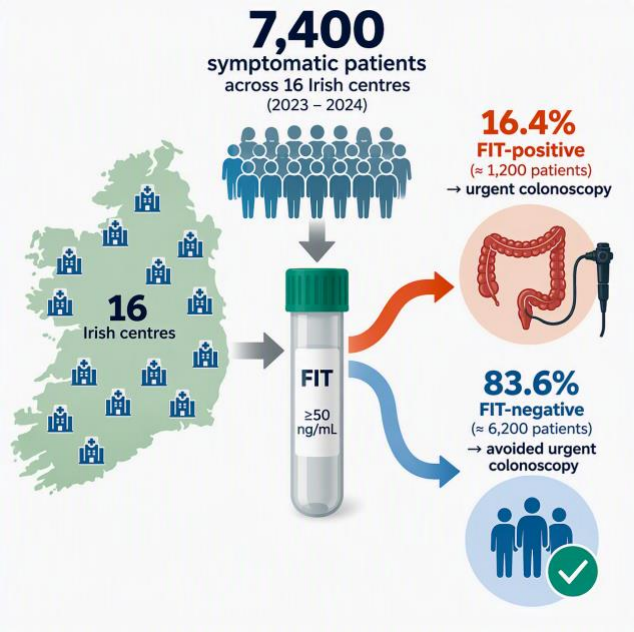
Technical Performance Indicators

As with all endoscopy CCE performance will be required to meet national and international performance measures. All units will regularly audit and report their performance metrics via the national registry. Further details on the format and structure of National CCE quality assurance is provided in section 5.5. The core quality principle emphasises that successful CCE depends on three factors: Appropriate patient selection, Excellent bowel preparation and Clear follow-up planning.

Appropriate patient selection + Excellent bowel preparation + Clear follow-up planning = High Quality CCE


COLON CAPSULE ENDOSCOPY (CCE) PATHWAY
Contraindications & Bowel Preparation Procedure
PREDICTORS OF POOR QUALITY CCE
Chronic constipation
Opiate use
Tricyclic antidepressants (TCAs)
Diabetes
Cirrhosis
Cognitive impairment
Previous cerebrovascular accident (CVA)
Unable to follow instructions
Consider enhanced preparation and counselling in at-risk patients.
CONTRAINDICATIONS
ABSOLUTE CONTRAINDICATIONS
Dysphagia
Oesophageal stricture
Pyloric stenosis
Gastric band
Pregnancy
Contraindication to booster medication
RISK OF CAPSULE RETENTION / OBSTRUCTION
Crohn's disease (stricturing)
Small bowel stricture
Small bowel or colonic anastomosis
Ileo-anal anastomosis
Previous abdomino-pelvic radiation
Regular NSAID use: consider patency capsule before CCE.
BOWEL PREPARATION TIMELINE
48 HOURS BEFORE CCE
Low residue diet
DAY -2 (TWO DAYS BEFORE)
Senna 48 mg (4 tablets)
DAY -1 (19:00)
Moviprep® 1 L + 1 L water
DAY 0 (07:00)
Moviprep® 1 L + 1 L water
CAPSULE INGESTION
Fast until small bowel entry
POST-INGESTION MANAGEMENT
30 minutes after ingestion:
Capsule still in stomach?
Metoclopramide 10 mg IV
BOOSTER PROTOCOL
1 On confirmed small bowel entry: Moviprep® 750 mL + water Castor oil 15 mL
2 3 hours later: Moviprep® 250 mL + water
3 8 hours after ingestion: Dulcolax® 10 mg suppository (if capsule not passed)
MANAGEMENT OF INCOMPLETE STUDIES
Clinical review
Confirm capsule passage if required
Consider abdominal imaging
Document follow-up plan

3.2 FIT-Based Risk Stratification in Ireland



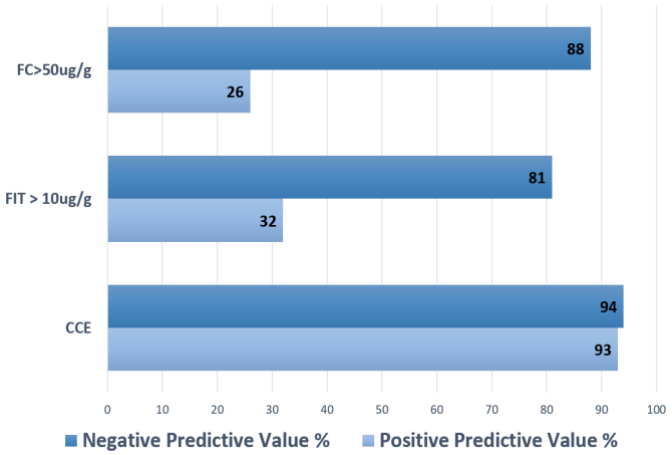
Irish experience supports the use of FIT as an effective risk stratification tool within symptomatic colorectal referral pathways. The strongest contemporary evidence comes from a national multicentre study presented in abstract form at the Irish Society of Gastroenterology, Summer Meeting 2025. Coordinated through the HSE Endoscopy Programme. The study evaluated 7,400 symptomatic patients across 16 Irish centres between 2023 and 2024.

Using a FIT threshold of ≥50 ng/mL, only 16.4% of patients tested positive, allowing the majority to avoid urgent colonoscopy.

Among FIT-negative patients who subsequently underwent colonoscopy, colorectal cancer was detected in only 0.2% and advanced adenomas in 2.7%, demonstrating a very low risk of significant pathology following a negative FIT result. These findings support the use of FIT-centred triage pathways to prioritise higher-risk patients for colonoscopy while safely reducing demand for endoscopic resources.

Irish evidence for FIT-based triage is strengthened by work from Tallaght University Hospital. During the COVID-19 recovery period, the Tallaght group evaluated a pathway combining FIT-based risk stratification with Colon Capsule Endoscopy (CCE) in symptomatic, average-risk patients referred for colorectal investigation (21). In their published work Ismail et al. demonstrated that colon capsule endoscopy accurately detected significant colorectal pathology compared to colonoscopy as a gold standard (sensitivity 81%, specificity 98%, NPV 94%).

Importantly, the authors examined the role of biomarkers alongside CCE. FIT and faecal calprotectin were frequently elevated in patients with colitis or high-risk adenomas, although neither biomarker alone was sufficiently accurate to reliably predict significant pathology.



The findings suggested that combining biomarker assessment with CCE could provide an enhanced diagnostic strategy. Evidence from screening populations further support this combined approach (see appendix). The advantage of a combined CCE and FIT strategy is enhanced detection, minimising the risk of missed cancers and other significant disease, while limiting the need for conventional endoscopy.

While much of the current Irish evidence derives from service evaluations and conference presentations rather than fully published peer-reviewed studies the Irish data does support a risk-stratified model in which FIT identifies patients requiring urgent colonoscopy while FIT-negative patients can be referred safely for CCE or no investigation based on biomarker levels.

3.3 Integration of CCE within the Diagnostic Pathway

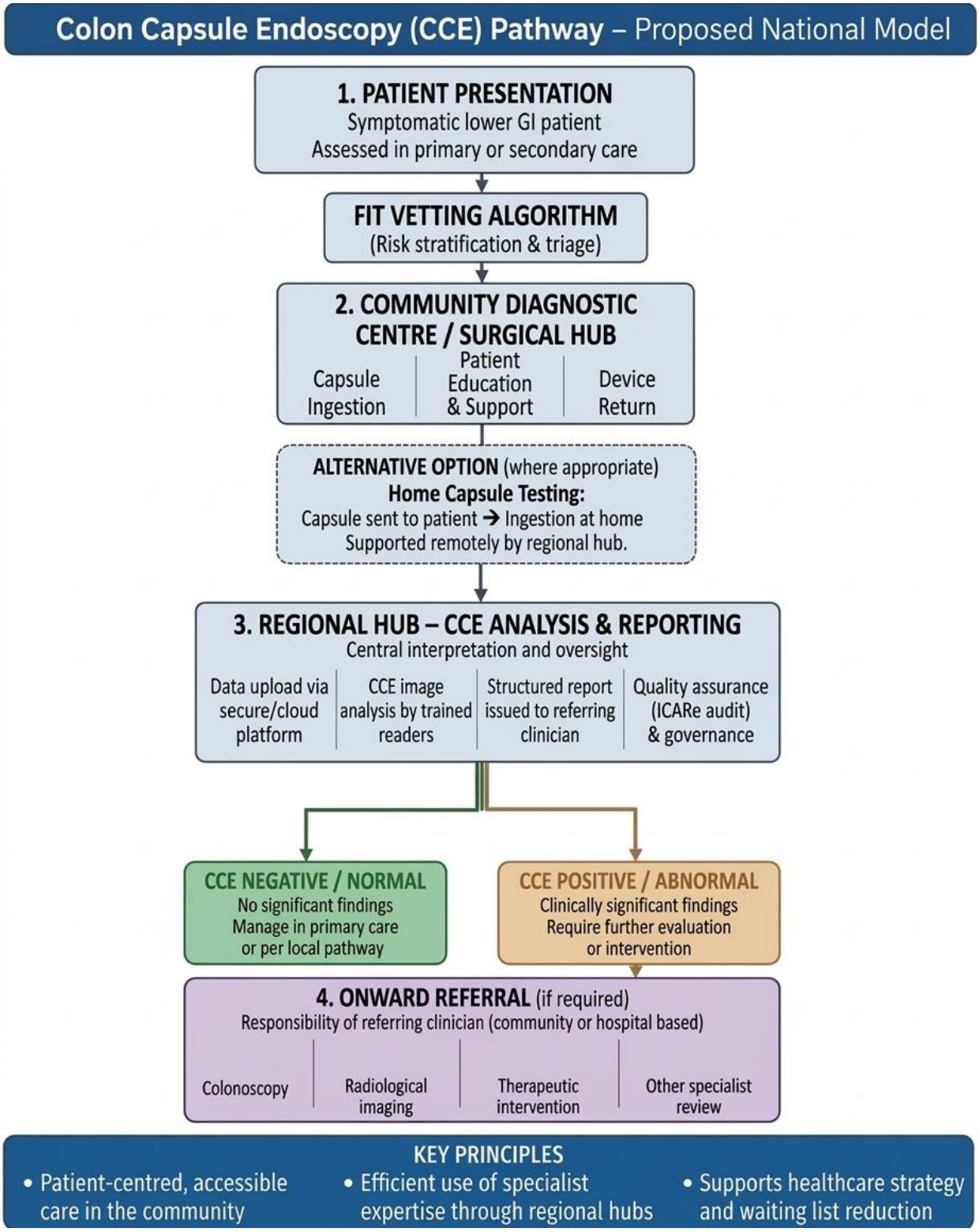
Ireland has established a growing network of ten CCE centres supported by the HSE Acute Operations Endoscopy Programme and the National Capsule Clinical Advisory Group. HSE guidance was published in 2023 to standardise service delivery and patient selection nationally. The guidance explicitly supports CCE for routine symptomatic patients, incomplete colonoscopy, patients declining colonoscopy, selected urgent patients where access delays exist, and surveillance populations. Despite recent advancements CCE is not yet embedded nationally as a routine component of a symptomatic lower GI pathway. Ireland already possesses the clinical expertise, governance structures and emerging service infrastructure necessary to support wider adoption of Colon Capsule Endoscopy. Building on the successful experience to date with CCE, a phased national expansion of services should be undertaken.



The proposed expansion aligns with key health strategic aims including: Sláintecare, waiting list action plans, HSE Endoscopy Programme objectives and community diagnostic hub development.

Implementation Considerations

While the clinical rational and proposed diagnostic pathway incorporating both FIT and CCE are covered elsewhere, it is important to consider the practical requirements around the proposed patient pathway which is depicted in the following figure.


Colon Capsule Endoscopy (CCE) Pathway – Proposed National Model
1. PATIENT PRESENTATION
Symptomatic lower GI patient
Assessed in primary or secondary care
FIT VETTING ALGORITHM
(Risk stratification & triage)
2. COMMUNITY DIAGNOSTIC CENTRE / SURGICAL HUB
Capsule Ingestion
Patient Education & Support
Device Return
ALTERNATIVE OPTION (where appropriate)
Home Capsule Testing:
Capsule sent to patient → Ingestion at home
Supported remotely by regional hub.
3. REGIONAL HUB – CCE ANALYSIS & REPORTING
Central interpretation and oversight
Data upload via secure/cloud platform
CCE image analysis by trained readers
Structured report issued to referring clinician
Quality assurance (ICARe audit) & governance
CCE NEGATIVE / NORMAL
No significant findings
Manage in primary care or per local pathway
CCE POSITIVE / ABNORMAL
Clinically significant findings
Require further evaluation or intervention
4. ONWARD REFERRAL (if required)
Responsibility of referring clinician (community or hospital based)
Colonoscopy
Radiological imaging
Therapeutic intervention
Other specialist review
KEY PRINCIPLES
• Patient-centred, accessible care in the community
• Efficient use of specialist expertise through regional hubs
• Supports healthcare strategy and waiting list reduction

Implementation Steps

A: Expand Existing Centers.



Support current CCE units to: increase capacity, provide regional access and support community based diagnostic centres, participate in quality assurance measures (ICaRe audit)

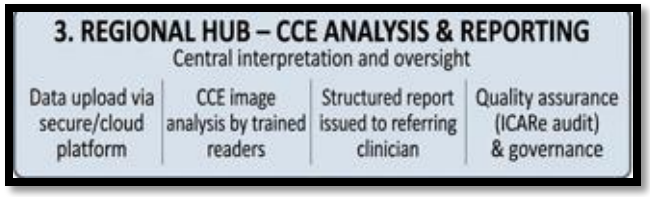
B: CCE Service Development Model: Regional Hub-and-Spoke Network

A hub model could be established across regions employing current established CCE centres as shown.

Capsule administration should occur locally in the community, in line with strategic aims for health care delivery.

Image interpretation will occur centrally at the regional hubs. CCE analysis at regional hubs can be undertaken through a variety of measures including cloud based reading platforms, remote access to local reading platforms as well as on local platforms, with home CCE designed packages (22).

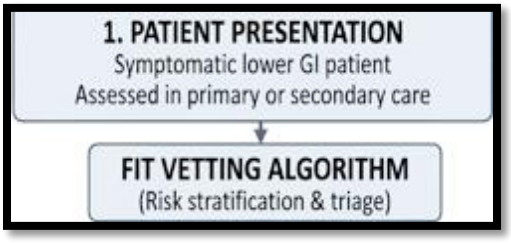
Region	Potential Hub
East, North East & Midlands	Tallaght University Hospital Connolly Hospital St Vincent's University Hospital Mater Misericordiae University Hospital St James's Hospital Beaumont Hospital
South	Mercy University Hospital Cork University Hospital University Hospital Limerick
West & North West	University Hospital Galway Letterkenny University Hospital



C: Community Diagnostic Centers

In keeping with Sláintecare principles: capsule ingestion, patient education and device return would occur within Community Diagnostic Centres or Surgical Hubs rather than acute hospitals. While awaiting full deployment of community diagnostic capacity, the potential for near patient "Home Capsule Testing" as discussed in section 6.2, supported by the regional hubs can be considered as a viable alternative, which requires little or no additional infrastructure to deliver.

D: FIT Testing Capacity



Laboratory FIT analysis is relatively inexpensive, automated and scalable. Capacity and demand mapping repeatedly identify downstream diagnostic capacity rather than FIT analysis itself as the primary constraint in delivering timely lower gastrointestinal diagnostics. A FIT-stratified pathway such as the one proposed could likely be implemented using existing laboratory infrastructure because: FIT testing is already performed at national scale (>190,000 tests/year); FIT assays are automated and highly scalable; The incremental cost of additional FIT testing is modest.

While access to FIT testing is now readily available in most acute settings and is planned for community settings, it is not currently a requirement for triage. This will require education and an implementation strategy to ensure all symptomatic patients undergo FIT testing as part of their triage process.

E. Onward referral



While regional hubs will provide CCE oversight, analysis and reporting, onward referral for positive cases requiring additional endoscopic , radiological or other intervention will be the responsibility of the referring community or hospital based clinician.

While it is envisaged that the proposed diagnostic pathway will reduce the overall requirement for colonoscopy it is essential that patients in need of onward referral are prioritised appropriately and receive timely access to care based on the CCE findings. The process for onward referral is covered in more detail later.

3.4 Escalation to Colonoscopy and Other Investigations

Following FIT-based triage, CCE should constitute a second-stage risk stratification test within the symptomatic lower GI pathway. Colonoscopy prioritisation should be determined primarily by CCE findings when available, with FIT results remaining the principal prioritisation tool only in cases where CCE is incomplete or non-diagnostic. This approach ensures that patients with significant pathology identified on CCE are not disadvantaged by an initially low or intermediate FIT result, while also supporting efficient use of colonoscopy capacity through prioritisation based on the most accurate available assessment of colonic pathology.

Specifically, patients with CCE findings suggestive of high-risk or serious colonic pathology, including suspected colorectal cancer, advanced adenomas, significant polyp burden, inflammatory bowel disease, or other findings requiring tissue diagnosis or therapeutic intervention, should be referred directly to colonoscopy through an expedited pathway with priority equivalent to other high-risk endoscopy referrals.

Patients with low-risk pathology identified on complete CCE may be referred for routine colonoscopy only where endoscopic confirmation, surveillance, or therapeutic intervention is required, with prioritisation again informed by the capsule findings.

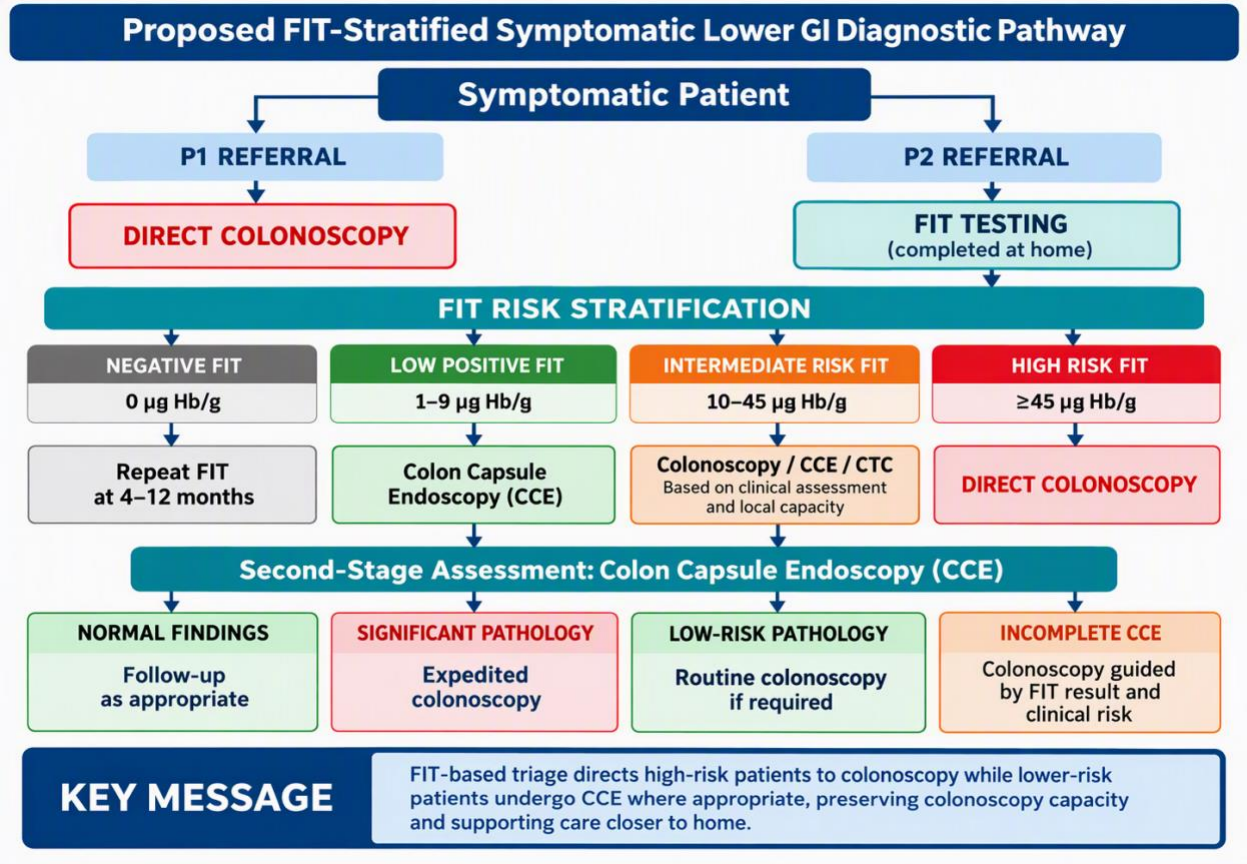
Where CCE is incomplete, technically inadequate, or fails to visualise the entire colon, patients should proceed directly to colonoscopy, with urgency determined by the highest available risk indicator, including CCE findings where present and FIT level.

To avoid unnecessary delays and duplication of triage, CCE reports should be accepted as a definitive risk-stratification tool within the endoscopy referral pathway, enabling direct allocation to urgent, routine, or surveillance colonoscopy lists without requiring repeat vetting or reassessment unless new clinical concerns arises.

3.5 Proposed National Algorithm

The proposed FIT-stratified symptomatic lower gastrointestinal diagnostic pathway is designed to optimise the use of available endoscopy resources while maintaining timely access to definitive investigation for patients at highest risk of colorectal cancer and advanced colorectal neoplasia. The pathway combines established clinical prioritisation categories (P1 and P2), faecal immunochemical testing (FIT), and Colon Capsule Endoscopy (CCE) to support a risk-based approach to investigation and resource allocation.

The Pathway: Patients triaged as Priority 1 (P1) continue to undergo direct colonoscopy in accordance with current clinical practice. For Priority 2 (P2) symptomatic patients, FIT is used as an initial risk stratification tool. Patients with high FIT concentrations (≥45 µg Hb/g; equivalent to ≥225 ng/ml) proceed directly to colonoscopy because of the increased probability of significant pathology. Patients with intermediate FIT values (10-45 µg Hb/g; 50-224 ng/ml) may be offered colonoscopy, Colon Capsule Endoscopy (CCE), or CT colonography (CTC), with the choice informed by local capacity, patient preference, and clinical assessment. Patients with low positive FIT levels (1-9 µg Hb/g; 1-49 ng/ml) are directed to CCE as the preferred first-line structural investigation. Patients with a negative or undetectable FIT result enter an interval surveillance pathway with repeat FIT testing at 4-12 months, if deemed clinically necessary, including the persistence of symptoms. This pathway seeks to reserve colonoscopy capacity for patients most likely to benefit from invasive investigation while utilising CCE as a sensitive, minimally invasive diagnostic modality for lower-risk symptomatic patients. The model is intended to support timely diagnosis, reduce waiting list pressures, enhance patient choice, and facilitate delivery of diagnostic services closer to home.



Operational Considerations

4.1 Workforce Requirements

"In practical terms, for every 100 appropriately selected low- or intermediate-risk FIT patients undergoing CCE, approximately 50 to 60 colonoscopy slots may be preserved for higher-priority activity."

The proposed pathway is expected to have a favorable impact on endoscopy workforce requirements by ensuring that colonoscopy resources are increasingly directed towards patients with confirmed or highly suspected pathology rather than all patients with intermediate-risk symptomatic presentations. Based on the international and Irish CCE performance data presented, Colon Capsule Endoscopy (CCE) functions as an effective second-stage triage test that can substantially reduce demand for conventional colonoscopy while maintaining high diagnostic performance.

The most significant workforce benefit arises from the reduction in colonoscopy demand. International programmes report that approximately 50% of symptomatic patients can avoid further endoscopic investigation following CCE, while Irish registry data suggest an even greater reduction, with 61% of patients avoiding additional endoscopy after CCE. This translates into a substantial release of colonoscopy capacity which can be redirected towards urgent cancer referrals, bowel screening and surveillance programmes, complex therapeutic procedures and patients requiring intervention. In practical terms, for every 100 appropriately selected low- or intermediate-risk FIT patients undergoing CCE, approximately 50 to 60 colonoscopy slots may be preserved for higher-priority activity.

The proposed pathway would alter the composition of colonoscopy waiting lists rather than simply reducing their size. Colonoscopy services would receive a more concentrated cohort of patients requiring intervention, including those with high-risk pathology identified on CCE, patients requiring biopsy confirmation, therapeutic polypectomy, inflammatory bowel disease assessment or completion of a non-diagnostic capsule examination. Consequently, the diagnostic yield of colonoscopy would be expected to increase, improving the efficiency of endoscopy sessions and potentially reducing the number of low-yield procedures performed.

Medical Workforce



From a medical workforce perspective, the pathway reduces pressure on consultant gastroenterologists and colorectal surgeons performing routine diagnostic colonoscopies. Vetting activity would increasingly shift towards review of structured CCE reports, allowing clinicians to prioritise patients on the basis of demonstrated pathology rather than symptom-based risk estimation alone. This creates opportunities for more streamlined triage processes and greater use of standardised reporting and prioritisation protocols. While also reserving specialist time for procedures requiring intervention.

The pathway would require investment in a dedicated CCE workforce. Staff would be required for patient selection, capsule administration, bowel preparation management, report generation and result communication. Experience from the Irish CCE Registry demonstrates that high levels of appropriate indication (100%) and clinically relevant diagnostic yield (55%) can be achieved through structured programme delivery. Workforce planning should therefore include specialist nursing, advanced nurse practitioners, endoscopy coordinators and trained capsule readers operating within agreed governance frameworks.

An important consideration is the management of follow-up procedures. International data suggest follow-up colonoscopy rates of approximately 47%, whereas Irish registry data report substantially lower rates of approximately 30%. The difference likely reflects increasing programme maturity and improved patient selection. Under the proposed pathway, follow-up colonoscopy demand would become more predictable and focused on patients with clinically significant findings, enabling more accurate workforce and capacity planning. A proposed integration pathway has been outlined in section 3.3.

The proposed pathway also has implications for administrative and scheduling staff. Direct progression from CCE findings to an appropriately prioritised colonoscopy list avoids repeated referral cycles, duplicate vetting and additional outpatient appointments. Patients with high-risk CCE findings can be transferred immediately to urgent colonoscopy pathways, while low-risk findings can enter routine pathways without requiring re-referral. This reduction in administrative duplication would improve overall pathway efficiency and reduce non-clinical workload.

Strategic Workforce Impact

Overall, the proposed integrated pathway represents a shift from a colonoscopy-led diagnostic model to a risk-stratified diagnostic model in which CCE acts as a secondary triage investigation. The workforce consequences are expected to include:

- Reduced demand for diagnostic colonoscopy capacity (approximately 50-60% of selected patients avoiding further endoscopy).
- Increased availability of colonoscopy appointments for urgent and therapeutic cases.
- Higher diagnostic yield per colonoscopy performed.
- Greater reliance on specialist CCE reporting capabilities.
- Reduced administrative burden arising from repeat vetting and re-referral.
- Improved alignment of workforce resources with clinical need.

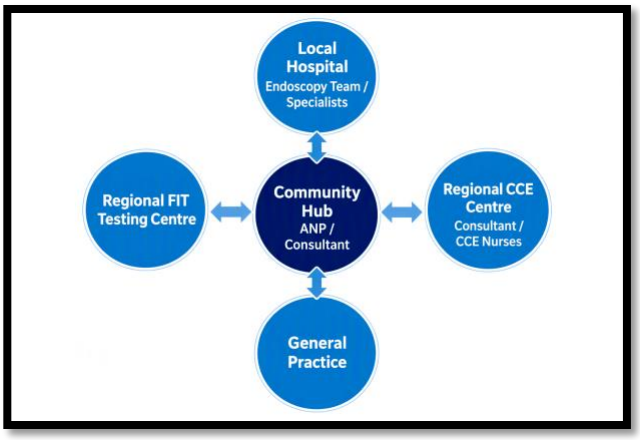
The proposed pathway is unlikely to reduce the overall requirement for gastrointestinal diagnostic staff, but it would enable a more efficient deployment of existing workforce resources by reserving colonoscopy capacity for patients with demonstrated pathology while expanding the role of CCE-based assessment within symptomatic lower gastrointestinal services.

Impact on Consultant Workforce

The pathway does not eliminate consultant involvement but changes where consultant time is spent. Instead of large volumes of low-yield diagnostic colonoscopy, consultants focus on:

- Interpretation of complex CCE findings.
- Therapeutic colonoscopy.
- Cancer diagnosis and staging.
- Complex polypectomy.
- Inflammatory bowel disease management.
- Clinical governance and quality assurance.

This represents a more efficient use of scarce specialist expertise.



The proposed FIT-stratified CCE pathway supports a significant shift in workforce deployment from hospital-based diagnostic endoscopy towards community-based advanced practice. Community Diagnostic Centres and Surgical Hubs could provide capsule administration, patient education, bowel preparation support and pathway coordination through Advanced Nurse Practitioners (ANPs) and specialist nurses, while image interpretation and quality assurance are delivered through regional reporting hubs. This hub-and-spoke model enables a large proportion of symptomatic patients to undergo investigation without requiring hospital endoscopy resources, with Irish registry data demonstrating that 61% of patients avoided further endoscopy following CCE. ANPs are well positioned to provide autonomous assessment, pathway navigation and result management, escalating patients with high-risk capsule findings directly to expedited colonoscopy while facilitating discharge or routine follow-up for low-risk findings. Consequently, consultant gastroenterologist and colorectal surgery resources can be increasingly directed towards therapeutic endoscopy, cancer pathways and complex disease management, improving both workforce efficiency and access to timely diagnostic investigation.

4.2 Role of Advanced Nurse Practitioners

A major advantage of the proposed FIT-CCE-colonoscopy pathway is that it redistributes diagnostic activity away from acute hospital endoscopy units and towards a community-based, ANP-supported model. Rather than simply substituting one investigation for another, the pathway creates an opportunity to redesign workforce deployment so that specialist endoscopy capacity is reserved for patients who genuinely require invasive investigation or therapy.

Expanded role of Advanced Nurse Practitioners

ANP Central Role in Patient Journey

- Review of FIT-positive referrals against agreed eligibility criteria.
- Patient assessment and education prior to capsule administration.
- Consent processes and explanation of bowel preparation requirements.
- Capsule administration and device management.
- Monitoring patient progress during the examination period.
- Management of incomplete studies according to predefined protocols.
- Communication of normal and low-risk results.
- Coordination of onward referral pathways when significant pathology is identified.

The proposed pathway is particularly well suited to delivery by ANPs working within Community Diagnostic Centres (CDCs) or Surgical Hubs. Under this model, ANPs could assume responsibility for much of the patient journey and act as the key coordinator of patient care.

This represents a significant expansion of advanced practice roles from procedural support to autonomous management of a substantial proportion of the symptomatic lower GI diagnostic pathway. By shifting these activities from consultant-led outpatient and endoscopy services into ANP-led community settings, specialist medical time can be redirected towards complex diagnostics, therapeutic endoscopy, cancer pathways and multidisciplinary care.

A New Role for ANPs in Pathway Coordination

Perhaps the greatest workforce benefit lies in pathway navigation. ANPs could become the principal coordinators of the diagnostic pathway by:

1. Identifying suitable FIT-positive patients.
2. Arranging CCE.
3. Reviewing reports.
4. Escalating high-risk pathology directly to urgent colonoscopy.
5. Arranging routine colonoscopy where indicated.
6. Supporting discharge or surveillance pathways following normal examinations.

This reduces multiple hand-offs between primary care, outpatient clinics, endoscopy services and specialist teams.

A Community Hub ANP vision commits Advanced Nurse Practitioners to providing expert, autonomous, patient-centred care across the integrated colorectal diagnostics pathway.

Through clinical leadership, multidisciplinary collaboration, education, service development, and quality improvement, ANPs will facilitate timely access to diagnostics, specialist assessment, treatment coordination, and follow-up care.

Ensuring patients receive the right care, in the right place, at the right time.

4.3 Health Service Impact, Infrastructure and Financial Resource Implications

The implementation of a FIT-stratified Colon Capsule Endoscopy (CCE) pathway has the potential to deliver significant benefits for the Irish health service by increasing diagnostic capacity, improving waiting list performance, enhancing patient experience, and optimising utilisation of specialist endoscopy resources. However, successful implementation will require targeted investment in infrastructure, workforce development, digital systems, governance arrangements, and quality assurance mechanisms.

Health Services Impact

- Increase overall diagnostic capacity without proportional expansion of endoscopy infrastructure.
- Reduce waiting times for symptomatic patients.
- Improve compliance with access targets.
- Prioritise colonoscopy resources for patients at highest risk of colorectal cancer.
- Improve patient choice and acceptability.
- Facilitate delivery of care closer to home through Community Diagnostic Centres and Surgical Hubs.
- Support more efficient use of consultant, nursing and

Health Service Impact

Demand for lower gastrointestinal diagnostic services continues to increase due to population growth, ageing demographics, expanding bowel screen and surveillance requirements, and increased awareness of colorectal cancer symptoms. Colonoscopy remains the gold standard investigation; however, current capacity constraints have resulted in substantial waiting lists across many services. The introduction of FIT-guided triage combined with CCE offers an opportunity to reserve conventional colonoscopy capacity for higher-risk patients while providing a safe and effective diagnostic alternative for appropriately selected symptomatic individuals.

International and Irish experience suggests that CCE can reduce pressure on endoscopy services by decreasing demand for diagnostic colonoscopy among lower-risk populations whilst maintaining high levels of diagnostic accuracy. The hub-and-spoke model proposed within this white paper further enables scaling of services while maintaining consistent quality standards through centralised reporting and governance.

Infrastructure Requirements

A national FIT-CCE programme will require investment in both physical and digital infrastructure.

Community Diagnostic Centres and Surgical Hubs should be equipped to provide:

Compared with colonoscopy services, CCE requires significantly less procedural infrastructure. Dedicated endoscopy rooms, decontamination facilities, recovery areas, and sedation support are not required

- Patient assessment and education
- Capsule administration and monitoring
- Support for bowel preparation protocols
- Data capture and communication systems
- Escalation pathways for technical failures & urgent findings

Additional Infrastructure Requirements

Regional Hub Reporting Infrastructure	Digital Infrastructure
• Capsule reading workstations. • Secure image storage systems. • Reporting software and structured reporting templates. • Access to specialist clinical expertise. • Governance, audit, and peer review processes.	• Digital integration will be essential to pathway success and should include: • Electronic FIT requesting and reporting. • Referral management systems. • Capsule reporting platforms. • Connectivity with national electronic health records. • Registry and audit systems. • Integration with ICaRe and existing national quality reporting structures (NEQIS).
Centralisation of reporting expertise to provide economies of scale while supporting quality assurance and workforce sustainability.	**In line with HSE's Technology and Transformation (T&T) function is to create a patient-centred, digitally connected health service**

Financial Resource Implications

Although relatively few formal economic evaluations of CCE have been undertaken, the available international evidence provides useful benchmarks for assessing potential costs and benefits within an Irish FIT-stratified symptomatic pathway. A consistent finding across economic studies is that the cost-effectiveness of CCE is highly dependent on three variables:

- Capsule acquisition cost
- The proportion of patients requiring follow-up colonoscopy
- The value assigned to increased diagnostic capacity, reduced waiting times, and improved patient acceptability**.**

Screening-Based Economic Evaluations

Recent European modelling studies have examined CCE within colorectal cancer screening programmes. A multi-country analysis conducted in Denmark, Scotland, and Spain found that replacing colonoscopy with CCE after a positive FIT result produced slightly improved health outcomes and marginally higher colorectal cancer detection, but at increased cost. Incremental cost-effectiveness ratios ranged from approximately €43,500 per additional cancer detected in Spain to €136,900 in Denmark, with capsule cost identified as the major determinant of cost-effectiveness. The authors concluded that reducing capsule costs and incorporating AI-supported reading would substantially improve economic performance (36).

Similarly, a Dutch microsimulation study evaluating multiple screening strategies found that while CCE produced favourable cancer detection and mortality outcomes, it was generally not cost-effective as a primary screening strategy when compared with established FIT screening or colonoscopy-based screening programmes. However, the authors noted that economic outcomes were strongly influenced by assumptions regarding capsule price, adherence, and downstream colonoscopy utilisation (37).

Symptomatic Patient Evaluations

> "The economic value of CCE may be greatest when used as a capacity-enhancing intervention rather than as a direct replacement for colonoscopy."

The most relevant evidence for the proposed Irish pathway comes from recent NHS economic modelling undertaken alongside the NHS England CCE Pilot Programme. This evaluation assessed second-generation CCE in a mixed cohort of symptomatic and surveillance populations and compared CCE with both colonoscopy and CT colonography. Among patients suitable for colonoscopy, CCE was generally associated with higher costs and small losses in quality-adjusted life years (QALYs) when compared with direct colonoscopy. However, the analysis was conducted from a conventional health economic perspective and did not fully account for the system-level benefits of increased diagnostic capacity, reduced waiting times, and improved access during periods of severe colonoscopy constraint (38).

Significantly, these assessments include patients undergoing screening, with a high likelihood of having significant disease. As such, a substantial proportion would have required a follow up colonoscopy after the CCE to manage pathology, with obvious financial disadvantages. This is the opposite of the proposed FIT- CCE model, whereby FIT is used to identify patients with a small risk of significant disease and therefore a low likelihood of requiring a subsequent endoscopy.

Importantly, these findings also highlight that the economic value of CCE may be greatest when used as a capacity-enhancing intervention rather than as a direct replacement for colonoscopy. This is particularly relevant in healthcare systems such as Ireland where endoscopy demand exceeds available capacity.

National Endoscopy Quality Improvement Programme

"National colonoscopy volumes increased year-on-year by an average of 10.5% between 2016"

Service-Level Economic Benefits

International experience suggests several areas where indirect financial benefits may accrue. These broader system benefits are not always captured in traditional health economic models but may be particularly important in evaluating CCE within the Irish healthcare context.

Implications for Ireland

The available evidence suggests that an Irish economic evaluation should extend beyond a simple comparison of the per-test costs of CCE and colonoscopy. Instead, modelling should consider both capital and operational costs of CCE services.

Given Ireland's current endoscopy capacity challenges, the most relevant economic question may not be whether CCE is cheaper than colonoscopy on a per-case basis, but whether a FIT-CCE pathway represents a cost-effective strategy for increasing national diagnostic capacity while maintaining quality and improving access to care.

This broader system perspective should form the basis of any future Irish health technology assessment and business case for national implementation.

Indirect Benefits

- Reduced utilisation of endoscopy suites.
- Reduced need for procedural sedation and recovery facilities.
- Lower staffing requirements during capsule administration.
- Delivery through community settings rather than acute hospitals.
- Improved waiting-list management.
- Prioritisation of colonoscopy for higher-risk patients.
- Potential earlier diagnosis through improved access to investigation.
- Reduced patient travel and productivity losses.

Implementation Considerations

A phased implementation strategy is likely to represent the most cost-effective and operationally feasible approach. Early deployment through existing high-volume capsule centres and established reporting hubs would allow for refinement of clinical pathways, training programmes, governance arrangements, and quality standards before wider national rollout. Investment decisions should be linked to defined performance indicators and monitored through national governance structures. Integration with ICaRe, NEQI, and existing HSE reporting infrastructure will maximise value from current investments while minimising duplication of systems and processes.

Recommendation

Investment in a national FIT-stratified CCE pathway should be viewed as a strategic service transformation initiative rather than a stand-alone diagnostic intervention. By combining FIT-based risk stratification, community-based capsule delivery, regional reporting expertise, and national quality assurance oversight, Ireland has the opportunity to increase colorectal diagnostic capacity, improve patient access, reduce pressure on conventional endoscopy services, and deliver a more sustainable, patient-centred model of care.

"Investment in a national FIT-stratified CCE pathway should be viewed as a strategic service transformation initiative rather than a stand-alone diagnostic intervention."

Community-Based CCE Services

5.1 Rationale for Community Delivery

A community-based Colon Capsule Endoscopy service represents a practical and scalable innovation that supports Sláintecare objectives by delivering timely, patient-centred diagnostics closer to home. Through FIT-guided risk stratification, regional hub-and-spoke reporting networks, and integration within Community Diagnostic Centres, CCE can expand lower GI diagnostic capacity, reduce reliance on hospital colonoscopy services, improve patient experience, and support earlier detection of colorectal cancer. The model aligns with national priorities for integrated care, efficient resource utilisation, waiting-list reduction, and equitable access to diagnostics across all regions of Ireland.

5.2 . Delivering and Supporting Care Closer to Home

A core principle of Sláintecare is that patients should receive the right care, in the right place, at the right time, with a shift away from unnecessary hospital-based care. This approach enhances patient convenience while reducing travel, waiting times and pressure on acute hospital services. The HSE is already investing in Community Diagnostic Centres as part of healthcare reform. CCE can therefore become a flagship diagnostic service within community hubs.

Sláintecare- Right Care , Right Place, Right Time	
CCE supports this objective	CCE fits a community environment
• **Allowing assessment of appropriate symptomatic lower GI patients in community diagnostic hubs.** • **Reducing the need for hospital attendance for diagnostic colonoscopy.** • **Providing a less invasive investigation option for many patients.** • **Improving accessibility for rural and underserved populations through a hub-and-spoke model.**	• Limited physical infrastructure. • Minimal procedural facilities. • Lower staffing requirements than conventional endoscopy. • Integration with existing diagnostics including laboratory, radiology and cancer pathways.

Near Patient Testing

More recently fully remote near patient colon capsule delivery systems have been introduced. Emerging evidence supports the feasibility of these home-based CCE systems. In the UK 5G-SUCCEEDS programme, patients reported high levels of satisfaction with remotely supported home CCE services. Participants highlighted the convenience of avoiding hospital attendance, the ability to continue normal activities during testing, and the reassurance provided through remote clinical support. Most patients were able to complete the investigation independently without requiring assistance from family members or healthcare staff (22).

5.3 Integration with Primary Care and Hospital Services

Successful implementation of a FIT-stratified Colon Capsule Endoscopy (CCE) pathway requires seamless integration between primary care, community diagnostic services and hospital-based specialist care. The pathway should operate as a single, coordinated diagnostic network rather than as separate referral streams.

Primary Care as the Entry Point

General Practitioners (GPs) play a central role in identifying symptomatic patients requiring lower GI investigation and initiating FIT testing as the first diagnostic step for routine referrals. Within the proposed pathway:

- Patients fulfilling criteria for routine symptomatic assessment undergo FIT testing in the community.
- FIT kits can be distributed and returned directly from home, minimising barriers to participation.
- FIT results inform risk stratification and subsequent investigation.
- GPs receive clear referral guidance aligned with national pathways and local diagnostic capacity.

This approach supports more consistent referral practices and ensures colonoscopy resources are prioritised for patients at greatest risk. As covered in section 5 the coordination of subsequent care will be undertaken by Community Based ANP's and Consultants in accordance with the proposed Algorithm. They play an essential role in integrating primary, community and acute hospital care.

Integration with Hospital Endoscopy Services

Hospital endoscopy services remain essential for patients requiring therapeutic intervention or further diagnostic assessment.

The pathway enables more targeted use of colonoscopy by reserving capacity for:

- High-risk FIT-positive patients.
- Significant pathology identified on CCE.
- Patients requiring biopsy or polypectomy.
- Incomplete or non-diagnostic CCE examinations.

Importantly, CCE findings should supersede initial FIT-based risk stratification once available, allowing prioritisation of colonoscopy according to demonstrated pathology rather than referral category alone.

Integration with Colorectal Cancer Pathways

The pathway must provide rapid escalation for patients with suspected significant pathology. Patients with suspected colorectal cancer should be referred directly into established hospital colorectal pathways with expedited access to colonoscopy, biopsy, imaging and multidisciplinary team review where required. This ensures that the use of CCE does not delay definitive diagnosis or treatment.

Digital Connectivity and Shared Care

An Effective pathway delivery depends on robust digital integration across care settings. Shared access to diagnostic information supports continuity of care and reduces duplication of investigations.

Electronic referral systems are required to enable:

- FIT result availability to primary and secondary care.
- Direct booking of CCE investigations.
- Secure transfer of capsule studies.
- Standardised reporting.
- Automated communication of results and recommendations.

Benefits of an Integrated Model

An integrated FIT and CCE pathway delivers:

- Earlier risk stratification of symptomatic patients.
- More efficient use of colonoscopy capacity.
- Reduced hospital attendances.
- Improved patient experience.
- Faster access to diagnostics.
- Enhanced collaboration between community and hospital services.
- Better alignment with Sláintecare objectives for integrated, person-centred care.

By combining FIT testing, community-based CCE delivery, regional reporting networks and rapid access to hospital endoscopy when required, the pathway creates a coordinated lower GI diagnostic service that supports both improved patient outcomes and more sustainable use of healthcare resources.

5.4 Enhancing Patient Experience

Patient experience is an important consideration in the design of symptomatic colorectal diagnostic pathways. Evidence from recent studies suggests that Colon Capsule Endoscopy (CCE) is highly acceptable to many patients and is generally associated with a more favourable procedural experience than conventional colonoscopy. A systematic review of patient-reported outcomes found that patients frequently preferred CCE to colonoscopy because it is less invasive, does not require sedation, and avoids the discomfort and perceived loss of dignity associated with endoscopic intubation (23).

The largest contemporary assessment of patient experience comes from the NHS England CCE programme, involving 927 patients who underwent CCE, colonoscopy or CT colonography. Only 2% of patients undergoing CCE reported procedural pain compared with 21% for colonoscopy and 12% for CT colonography ($p<0.001$). Overall, CCE was found to be similarly or better tolerated than alternative investigations across most stages of the patient journey (24).

Patients particularly value the non-invasive nature of the test, the absence of sedation, and the ability to remain mobile and maintain normal daily activities during the examination. Similarly qualitative studies from the NHS pilot programme found that most participants regarded CCE positively, appreciated its convenience, and indicated they would choose the investigation again if required (25).

However, studies consistently identify bowel preparation as the principal determinant of patient satisfaction. Although discomfort associated with bowel preparation is broadly similar to that experienced before colonoscopy, some patients perceive the preparation regimen as burdensome and this can reduce willingness to undergo repeat testing. Evidence suggests that clear patient information, effective preparation support, and achieving a definitive diagnostic outcome are key factors influencing overall satisfaction with CCE (24).

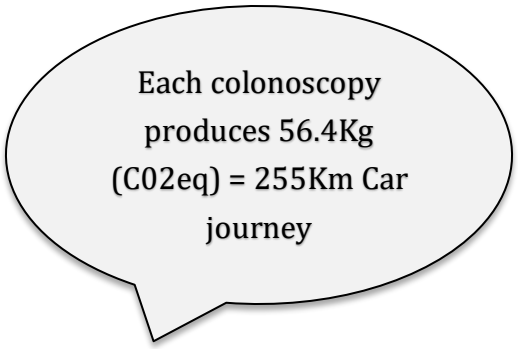
Similarly, Irish patient experience data support the acceptability of Colon Capsule Endoscopy as an alternative diagnostic investigation for selected symptomatic patients (26, 27). A prospective study from Tallaght University Hospital and Trinity College Dublin comparing patient experiences of both CCE and colonoscopy found significantly higher comfort scores with CCE (9.2 vs 6.7 out of 10; p<0.0001), with more than three-quarters of patients (77.5%) expressing a preference for CCE should future investigation be required.

> "Overall, 77.5% (n = 31/40) of patients would prefer CCE if they required a further lower GI investigation in the future. Of these, 77.4% (n = 24/31) still preferred CCE despite the potential need for a follow-up colonoscopy. 70.6% (12/17) of males and 82.6% of females prefer CCE over colonoscopy and gender does not seem to affect this preference (p = 0.37)."

Notably, most patients continued to prefer CCE even when informed that a subsequent colonoscopy might still be necessary. The principal advantage cited was improved procedural comfort, while bowel preparation remained the main limitation.

For the proposed new symptomatic pathways, these findings suggest that CCE has the potential to improve patient engagement with colorectal investigation, particularly among individuals who are reluctant to undergo conventional colonoscopy. By offering a minimally invasive, sedation-free diagnostic option closer to home, community-based CCE services may enhance patient-centred care, improve pathway compliance, and support earlier diagnosis while maintaining high levels of patient satisfaction.

5.5 . Environmental Assessment



The proposed FIT-stratified CCE pathway has the potential to support the HSE's sustainability objectives by reducing reliance on resource-intensive hospital-based colonoscopy services. Conventional colonoscopy requires dedicated endoscopy facilities, energy-intensive equipment reprocessing, water consumption, chemical disinfectants and significant quantities of single-use consumables. The British Society of Gastroenterology Green Endoscopy Consensus identifies GI endoscopy as a significant contributor to healthcare greenhouse-gas emissions and waste generation (28). Published studies identify patient travel, equipment use and endoscope reprocessing as major contributors to endoscopy-related carbon emissions and waste generation.

In contrast, CCE eliminates the need for endoscope reprocessing and can be delivered within community diagnostic hubs or, in future, through home-based models. By combining home FIT testing, community-based CCE services and targeted use of colonoscopy for higher-risk patients, the proposed pathway has the potential to reduce unnecessary hospital visits, decrease healthcare-associated travel emissions and improve utilisation of endoscopy resources. Emerging evidence from UK home-based CCE programmes further suggests that community and remote diagnostic models may substantially reduce travel-related carbon emissions while maintaining high levels of patient satisfaction.

As with small bowel capsule endoscopy, the advantages of colon capsule are mostly attributable to reduced need to travel. Where there is a need for subsequent colonoscopy or CCE services are not located in the community the beneficial effects are significantly reduced (29, 30).

The environmental benefits of the pathway are likely to be greatest where FIT-directed patient selection, community based testing, high CCE completion rates and low conversion rates to colonoscopy are achieved.

Digital Infrastructure, Technology and Artificial Intelligence

The FIT-CCE diagnostic pathway is fundamentally a digitally enabled model**.** Its success will depend as much on information systems, interoperability and AI-supported workflow as on the clinical pathway itself. The HSE is currently progressing towards a fully integrated digital healthcare system through the HSE Digital for Care strategy, the National Shared Care Record programme and the planned One Health Record national electronic health record. While healthcare records remain fragmented across multiple systems and care settings at present, substantial investment is underway to create a unified digital health infrastructure.

The proposed FIT-stratified Colon Capsule Endoscopy pathway should be designed to align with these developments, supporting electronic referral, digital FIT management, structured capsule reporting and future interoperability with national shared-care and electronic health record platforms. In doing so, the pathway could serve as a model for digitally enabled community diagnostics within Sláintecare.

6.1 Digital Referral and FIT Management Platform

The pathway begins in primary care and requires a fully electronic referral process.

Core capabilities should include:

- Electronic GP referral.
- Automated FIT kit ordering and tracking.
- Recording of FIT results in a shared clinical system.
- Automated risk stratification based on FIT thresholds.
- Electronic triage to CCE, colonoscopy or interval FIT pathways.
- Clinical decision support aligned with national referral criteria.

The objective is to minimise paper-based administration and ensure that FIT results trigger the correct next step automatically. Ideally, in a fully integrated IT enabled system, FIT results should populate:

- GP electronic health records.
- Community Diagnostic Centre systems.
- Hospital electronic patient records.
- National colorectal diagnostic dashboards.

6.2 Integrated Patient Tracking and Navigation

The proposed pathway contains multiple possible routes:

- FIT negative.
- Low-positive FIT.
- Intermediate-risk FIT.
- High-risk FIT.
- Complete normal CCE.
- Significant CCE pathology.
- Incomplete CCE.
- Follow-on colonoscopy.
-

A digital pathway management platform should therefore provide:

Real-time patient tracking	Status monitoring	Automatic alerts for pathway breaches.
Waiting-time monitoring.	Escalation for urgent findings	This creates a "single source of truth" across primary and secondary care.

6.3 Colon Capsule Image Management Infrastructure

CCE generates large volumes of image data.

The service would require:

- Secure upload and storage of capsule studies.
- Cloud or regional server infrastructure.
- Remote review capabilities.
- Structured reporting.
- Long-term image archiving.

This is particularly important for a hub-and-spoke model where, capsule acquisition occurs in community sites and image interpretation occurs in regional specialist centres.

The benefits of a image management infrastructure would include:

▪ Supports national reporting networks.	▪ Enables cross-cover between centres
▪ Improves service resilience	▪ Facilitates quality assurance

*100% Success Upload / Download

*0 Encryption/ Decryption Errors

*100% Reported Ease of Use

*86% Said It Improved Departmental Efficiency

An Irish feasibility study has evaluated a cloud-based capsule endoscopy reporting platform across 377 capsule studies, including 59 colon capsule examinations. The system achieved 100% reporting completion with no encryption or data-transfer failures. Readers reported improved efficiency, while remote reporting and multisite collaboration were identified as major advantages. These findings support the role of a cloud reading platform to support a hub-and-spoke Capsule Endoscopy reporting network, enabling image acquisition in Community Diagnostic Centres with expert interpretation performed remotely by accredited capsule readers (31).

6.4 National CCE Reporting Network

The Irish ICaRe initiative already provides a foundation for national data collection and benchmarking. However in its current iteration is not automated and complete data capture is not guaranteed. Future infrastructure should support:

▪ Standardised Reports	▪ National KPI's	▪ Reader Accreditation.
▪ Unit Benchmarking	▪ Audit Tools	▪ Research & Development

This would mirror successful networked radiology and pathology models.

6.5 Artificial Intelligence for Capsule Interpretation

AI is likely to become one of the most important developments in capsule endoscopy. Current AI systems are being developed to:

▪ Detect polyps	▪ Identify cancers	▪ Flag bleeding.
▪ Identify inflammation	▪ Prioritise images.	▪ Reduce Reading Time

Potential Benefits of AI enabled capsule systems include:

- Faster reporting.
- Improved productivity.
- Reduced inter-observer variation.
- Better consistency across centres.
- Support for less experienced readers.

Importantly, AI should be viewed as: "Decision support for accredited capsule readers rather than replacement of clinical judgement." AI enabled systems should be at the core of any technical considerations for any future national capsule tendering process.

6.6 AI-Supported Triage and Risk Stratification

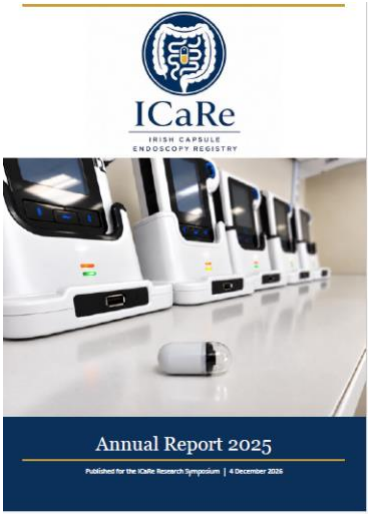
In addition to capsule AI features, future AI enabled patient administration systems could be employed to further enhance the efficiency and durability of the service.

For example in future AI enabled risk stratification could rapidly and automatically combine several factors to generate more sophisticated risk scores.

Thereby enabling:

▪ Dynamic prioritization	▪ Better colonoscopy allocation
▪ Earlier identification of high-risk patients	▪ Further reduction in unnecessary investigation

National Standards and Guideline Development



The success of a FIT and Colon Capsule Endoscopy (CCE) symptomatic pathway is dependent on the consistent delivery of high-quality care across all participating centres. Quality within a modern diagnostic pathway encompasses timely access to investigation, diagnostic accuracy, patient safety, service effectiveness, patient-centred care, and a culture of transparency, accountability, and continuous improvement.

As FIT and CCE become increasingly integrated into colorectal diagnostic pathways, particularly for symptomatic patients at low to intermediate risk of colorectal cancer, the development of nationally agreed standards is essential to ensure equitable and evidence-based care. Variations in referral thresholds, patient selection, bowel preparation protocols, capsule completion rates, reporting standards, and follow-up pathways can lead to significant differences in clinical outcomes and service efficiency.

A standardised national framework would reduce unwarranted variation and support consistent delivery of high-quality care.

7.1 Evidence Base for National Standards

European evidence supports the establishment of robust quality frameworks for CCE services. The European Society of Gastrointestinal Endoscopy (ESGE) recognises CCE as a safe and effective diagnostic modality in appropriately selected patients and recommends the development of structured pathways, quality assurance processes, and standardised reporting systems to optimise clinical performance (32).

The European Society of Gastrointestinal Endoscopy Quality Improvement Initiatives emphasise that capsule endoscopy services should be routinely assessed using predefined performance measures encompassing patient selection, bowel preparation quality, complete examination rates, diagnostic yield, reporting quality, timeliness, and safety outcomes.

Measurement of these indicators enables benchmarking, identifies unwarranted variation in practice, supports continuous quality improvement, and ensures that capsule services deliver safe, effective, and accountable patient care (33).

7.2 Governance Structure and Leadership

Ireland has considerable experience in the delivery of nationally coordinated quality improvement programmes in endoscopy. The National Gastrointestinal Endoscopy Quality Improvement (NEQI) Programme has established a culture of performance measurement, audit, benchmarking, governance, and continuous quality improvement across Irish endoscopy services and provides an ideal model on which a national CCE quality framework can be built. Similarly, the Irish Capsule Endoscopy Registry (ICaRe) has demonstrated the feasibility and value of prospective national data collection for capsule endoscopy. Early registry data have confirmed strong performance across Irish centres while highlighting the importance of systematic measurement and quality improvement as services continue to expand nationally.

The pathway should operate within a formally defined governance structure comprising:

▪ Local service leadership within community diagnostic centres, surgical hubs, and participating hospitals
▪ Regional capsule reporting hubs responsible for specialist interpretation and quality assurance
▪ National oversight through the national endoscopy governance framework and the National GI Endoscopy Quality Improvement Programme (NEQI)

A dedicated multidisciplinary FIT and CCE Standards Working Group should be established to oversee the development, implementation, and ongoing review of national standards.

Membership should include:

▪ Consultants with capsule expertise	▪ National and regional endoscopy clinical leads	▪ Advanced Nurse Practitioners / CCE Nurses
▪ National diagnostics and cancer programme stakeholders	▪ Health service management and data specialist representatives	▪ Patient representatives

Working Group Responsibilities

- Developing national technical and clinical standards for CCE delivery
- Develop standardised, pre-assessment, procedure and post procedure documentation and consent forms
- Defining key performance indicators (KPIs)
- Establishing reporting standards and terminology
- Producing guidance on patient selection and FIT-based risk stratification
- Monitoring service performance through national audit and benchmarking
- Recommending quality improvement interventions
- Supporting workforce training, accreditation, and competency

7.3 Quality Indicators and Performance Measurement

National guidance should define agreed quality indicators, including both minimum acceptable standards and aspirational performance targets. Consistent with ESGE recommendations, these measures should assess the entire patient pathway from referral through to definitive diagnosis and follow-up. These indicators should be monitored at local, regional, and national levels to facilitate benchmarking and continuous service improvement.

7.4 National Data Collection and Benchmarking

A core principle of governance should be mandatory participation in a national quality registry. The ICaRe Registry has already demonstrated the value of a centralised, anonymised, web-based system capable of benchmarking services against national and international standards while facilitating clinical audit, service evaluation, and quality improvement.

Expansion of a FIT-CCE pathway should therefore be accompanied by:

Standardised national data capture across all participating centres	Integration of CCE metrics into existing national quality reporting structures	Quarterly performance reporting
Centre-level benchmarking against national standards	Identification of variation and performance outliers	Annual national quality reports

As demonstrated by both NEQI and ESGE quality frameworks, transparency of performance data should be viewed primarily as a mechanism for learning and improvement rather than performance management alone

7.5 Quality Assurance of Reporting and Workforce Competency

Diagnostic accuracy is fundamental to the success of a CCE-based pathway. Standardised reporting, competency-based training, and ongoing professional development are therefore essential governance requirements. All capsule readers should undergo formal training and accreditation.

Training, Accreditation and Workforce Development

The successful scale-up of a national FIT-stratified Colon Capsule Endoscopy (CCE) pathway will require a sustainable workforce with recognised competencies in capsule administration, image interpretation, reporting, and clinical decision-making. Ireland is well positioned to develop a national training programme given the establishment of multiple high-volume capsule endoscopy centres, the success of the Irish Capsule Endoscopy Registry (ICaRe), and the growing body of national expertise in capsule endoscopy practice. Building on this foundation, a standardised Irish CCE curriculum could be developed and delivered by local experts, while remaining aligned with established European and international training recommendations (34).

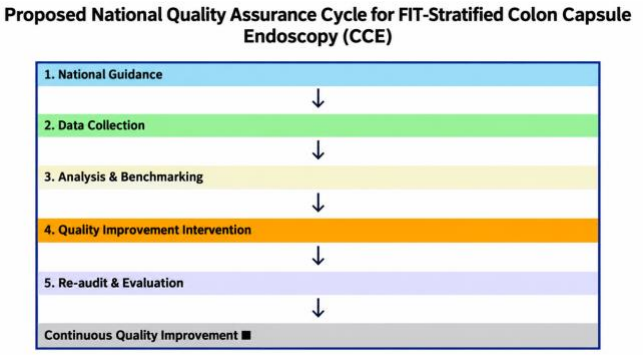
For Ireland, a national CCE training programme could be delivered through a hub-and-spoke model coordinated by established capsule centres and supported by ICaRe and the National GI Endoscopy Quality Improvement (NEQI) Programme. Such a programme should incorporate training in patient selection, capsule technology, bowel preparation, lesion recognition, examination quality assessment, structured reporting, and clinical decision-making. Training should combine formal teaching, supervised case review, hands-on learning, and competency-based assessment to ensure consistent reporting, accurate lesion detection, and safe patient care. International guidance recommends that training be delivered through experienced centres performing a minimum of 75-100 capsule endoscopy procedures annually, ensuring sufficient case volume to support skill acquisition, supervision, and maintenance of expertise (35). National certification should be provided for both training centres and trainers as well as providing evidence of competency for all capsule providers.

Competency assessment should include direct observation, structured case review, image interpretation exercises, and objective performance assessment. ESGE recommends assessment following supervised review of a minimum of 30 capsule examinations, complemented by structured competency assessment tools.
An Irish CCE competency framework could be developed through the National Endoscopy Training Programme and aligned with the educational principles underpinning the STEPS (Simulation Training for Endoscopy Programmes) initiative, thereby ensuring consistency with existing Irish approaches to endoscopy training, assessment, and accreditation tools.

Developing an Irish CCE curriculum would provide several strategic benefits. It would support service expansion, facilitate standardisation across centres, improve diagnostic quality, reduce reporting variability, strengthen governance arrangements, and create a sustainable workforce capable of supporting increasing demand for community-based diagnostic services. Furthermore, a nationally accredited training programme would reinforce Ireland's position as a European leader in capsule endoscopy innovation and quality assurance.

7.6 Continuous Quality Improvement

The FIT-CCE pathway should operate within a formal continuous quality improvement cycle consistent with established NEQI methodology and Irish and European Society of Gastroenterology quality standards.



This audit-improvement-reaudit methodology proposed mirrors the successful approach employed within the Irish NEQI Programme and represents the most effective mechanism for maintaining high standards while supporting service expansion.

7.7 Patient Safety and Risk Management

Patient safety should remain the primary objective of governance arrangements. Formal systems should be established for:

- Management of incomplete examinations.
- Escalation of high-risk findings.
- Monitoring and reporting of adverse events.
- Capsule retention surveillance.
- Incident reporting and review.
- Clinical review of delayed diagnoses.
- Interval colorectal cancer monitoring.
- Assurance of timely access to subsequent colonoscopy where indicated.

Clear clinical accountability should be maintained throughout the pathway, particularly where care is delivered across multiple settings including community diagnostic centres, regional reporting hubs, and hospital-based endoscopy services.

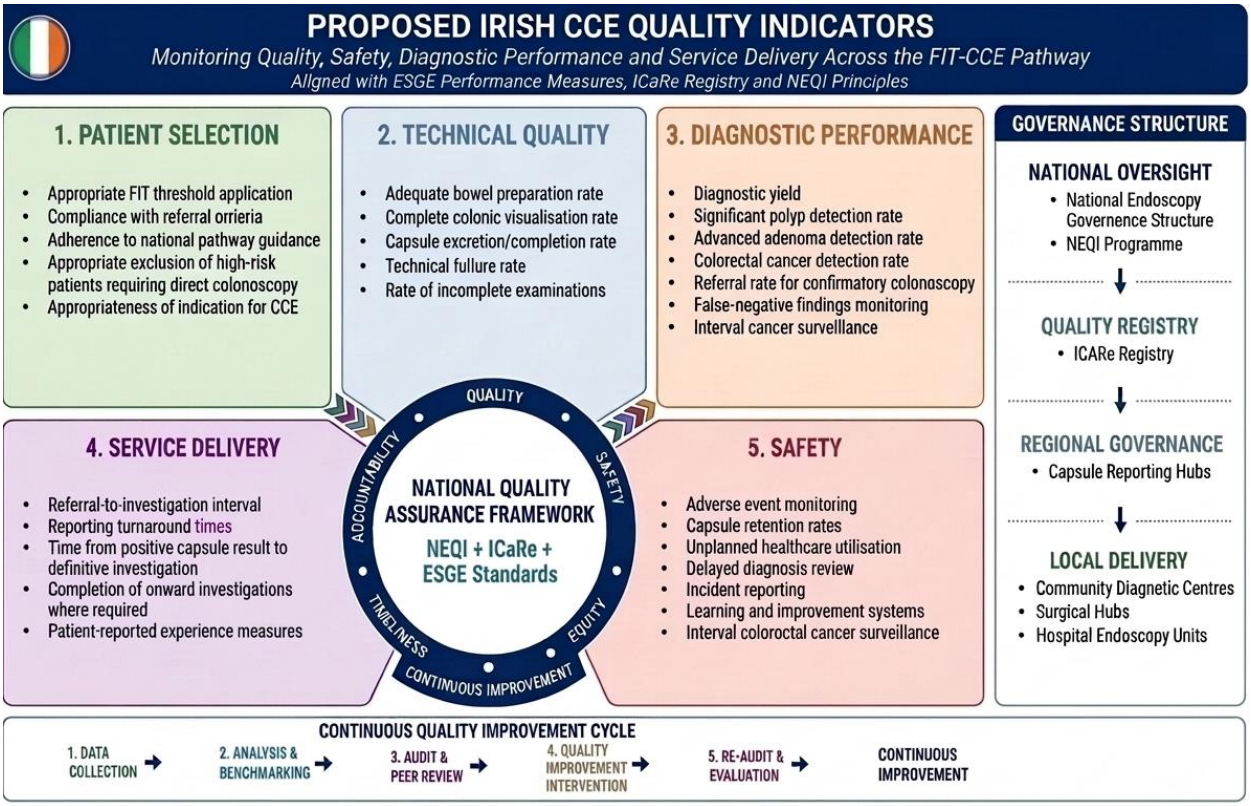
7.8 Recommendations

The establishment of a national standards, governance, and quality assurance framework as outlined will be fundamental to ensuring that FIT-stratified CCE pathways deliver safe, equitable, and high-quality diagnostic care.

By integrating community-based capsule delivery with national oversight, benchmarking, and continuous quality improvement, Ireland can develop a scalable diagnostic model that maintains the same quality expectations applied to conventional endoscopy while addressing increasing demand for colorectal cancer diagnostics.

National Standards and Guideline Key recommendations

- Establish a National FIT and CCE Standards Working Group under the National Endoscopy Governance Framework and NEQI.
- Develop comprehensive national guidance covering patient selection, technical delivery, reporting standards, governance, and quality assurance.
- Define a standardised set of national performance indicators aligned with international recommendations.
- Mandate participation in a national capsule endoscopy quality systems.
- Integrate CCE quality metrics into existing national endoscopy quality monitoring structures.
- Support the ongoing development of the Irish Capsule Endoscopy Audit (ICaRe) as a national quality improvement resource.
- Implement regional reporting hubs with formal governance and quality assurance responsibilities.
- Embed continuous audit, benchmarking, intervention, and re-audit within all participating services.
- Ensure structured accreditation, training, and competency assessment for all capsule readers.
- Incorporate emerging evidence, artificial intelligence-assisted capsule reading technologies, and future International updates into ongoing guideline development.



Education and Engagement

8.1 Workforce Education and Competency Development

The successful implementation of a national FIT-stratified symptomatic lower gastrointestinal diagnostic pathway will depend not only on the education and competency of staff directly delivering Colon Capsule Endoscopy (CCE), but also on the understanding and engagement of the wider healthcare workforce. Section 7.5 outlined the governance, accreditation and competency requirements for capsule readers, Advanced Nurse Practitioners (ANPs), trainers and reporting centres. These governance structures should form the foundation of a broader national educational strategy.

Clinical personnel directly involved in pathway delivery, including gastroenterologists, colorectal surgeons, ANPs, specialist nurses, capsule readers, endoscopy staff and programme managers, should complete nationally standardised training covering patient selection, FIT interpretation, CCE administration, reporting standards, escalation pathways, quality indicators, data collection requirements and governance processes. Training should be competency-based, supported through regional centres of excellence, and linked to ongoing continuing professional development (CPD), audit participation and national accreditation frameworks.

However, experience from other service transformation programmes demonstrates that education of the wider healthcare community is equally important. The pathway will fundamentally change referral behaviour, investigation sequencing and patient expectations. Consequently, healthcare professionals who do not directly perform FIT, CCE or colonoscopy must still understand the rationale, evidence base and operational aspects of the pathway to ensure consistent implementation.

8.2 Education of Key Stakeholders Across the Healthcare System

Implementation should include a structured stakeholder education programme targeting healthcare professionals involved in patient identification, referral, investigation, treatment and follow-up.

General Practitioners

General practitioners will be the primary entry point into the pathway and therefore represent the most important stakeholder group outside specialist gastroenterology services. Education programmes should focus on:

- Appropriate use and interpretation of FIT.
- Understanding FIT thresholds and referral criteria.
- Safety-netting of symptomatic FIT-negative patients.
- Indications for direct urgent referral for colonoscopy.
- Referral pathways to community-based CCE services.
- Interpretation of CCE reports and subsequent management recommendations.
- Patient counselling regarding the advantages and limitations of CCE.

Delivery methods may include:

ICGP-accredited educational modules	National webinars	Clinical guidance documents
Electronic decision-support tools integrated into GP software	Regional educational meetings	Case-based learning sessions

Acute Care and Hospital Physicians

Physicians working in emergency medicine, general medicine, geriatrics, oncology, surgery and internal medicine frequently encounter patients with lower GI symptoms and often generate endoscopy referrals.

Educational initiatives should ensure understanding of:

- The role of FIT in symptomatic assessment.
- Appropriate prioritisation of referrals.
- Escalation criteria for direct colonoscopy.
- Interpretation of CCE findings.
- Referral pathways following positive capsule investigations.
- Management of patients with persistent symptoms despite negative investigations.

Allied Health Professionals

Allied health professionals, including dietitians, physiotherapists, occupational therapists, pharmacists and community healthcare teams, often provide ongoing care for patients undergoing diagnostic investigation. Educational activities should highlight:

- The purpose and patient benefits of FIT-based pathways.
- Preparation requirements for CCE.
- Common patient concerns and misconceptions.
- Navigation of community diagnostic services.
- Support available for vulnerable or disadvantaged patient groups.

Hospital and Community Nursing Staff

As providers of healthcare across the entire system and key influencers of patient care, nurses working across primary care, community intervention teams, outpatient services, surgical hubs and hospital services should be educated regarding:

- FIT sampling processes.
- CCE preparation requirements.
- Patient education approaches.
- Follow-up procedures.
- Escalation pathways.
- Communication of results.
- Troubleshooting common patient concerns.

Healthcare Managers and Service Leaders

Those focused on strategic aims and delivery of healthcare strategy, healthcare managers, operational leads and service planners, require specific education focused on:

- Strategic rationale for pathway redesign.
- Expected impact on endoscopy waiting lists.
- Resource requirements.
- Workforce implications.
- Quality assurance structures.
- Performance indicators and service evaluation metrics.

This will be essential to securing organisational support and ensuring alignment of operational planning with national objectives.

8.3 Stakeholder Engagement Strategy for National Implementation

The introduction of a FIT-stratified CCE pathway represents a significant service redesign rather than the introduction of a single diagnostic test. As with any major healthcare transformation, successful implementation will require proactive engagement with all affected stakeholders. A structured engagement strategy should be established at national, regional and local levels. The objectives should include building consensus, promoting awareness, supporting standardisation and ensuring alignment with broader Sláintecare objectives. While early engagement of local clinical champions will be particularly important in promoting acceptance and supporting change management.

National Engagement

National engagement should involve:

- Office of the Chief Clinical Officer
- National Endoscopy Programme.
- National Cancer Control Programme.
- National Clinical Programmes.
- Irish College of General Practitioners.
- Royal College of Physicians of Ireland
- Royal College of Surgeons.
- Nursing and Midwifery leaders.
- Patient advocacy organisations.
- Health Technology Assessment bodies.
- Community diagnostic service leadership.

Regional and Local Engagement

Regional implementation groups should be established to support local adoption and facilitate communication between:

- Primary care.
- Community diagnostic centres.
- Surgical hubs.
- Regional CCE reporting hubs.
- Acute hospitals.
- Laboratory services.
- Management teams.

8.4 Potential Barriers to Adoption and Strategies to Overcome Resistance

Implementation of new pathways inevitably encounters resistance. Anticipating concerns and actively addressing them will be critical for successful national adoption.

Concern Regarding Diagnostic Accuracy

Some clinicians may perceive CCE as inferior to conventional colonoscopy.

Mitigation strategies include**:**

▪ Dissemination and Publication of regional and national performance data	▪ Presentation of international evidence demonstrating high sensitivity for significant lesions.
▪ Regular audit and benchmarking.	▪ Transparent reporting of quality indicators

Established Colonoscopy-Centred Practice

Many clinicians have developed referral practices based on direct access to colonoscopy and may be reluctant to adopt an alternative pathway.

Mitigation strategies include**:**

▪ Demonstrating improved access for high-risk patients	▪ Showing impact on waiting-list reduction
▪ Highlighting preservation of therapeutic endoscopy capacity	▪ Engagement of respected clinical leaders and early adopters

Concerns Regarding Additional Workflows

GPs and hospital staff may perceive FIT testing and CCE referral processes as additional administrative burden.

Mitigation strategies include:

▪ Simplified referral processes	▪ Electronic decision-support systems
▪ Automated triage where possible	▪ Clear referral criteria
▪ Integration into existing digital platforms	

Workforce Anxiety

Some staff may be concerned that service redesign could alter professional roles or reduce procedural activity.

Mitigation strategies include:

▪ Emphasising expanded professional opportunities	▪ Development of accredited training pathways
▪ Career advancement opportunities for ANPs and specialist nurses	▪ Demonstrating that consultant expertise will increasingly focus on high-value therapeutic and complex care

Patient Misunderstanding

Patients may mistakenly interpret FIT negativity as absolute reassurance or may not fully understand the role of CCE. Mitigation strategies include:

▪ Standardised education resources.	▪ Consistent messaging across healthcare settings
▪ Strong safety-netting processes	▪ Clear communication regarding benefits and limitations of each investigation

8.5 Communication and Awareness Campaign

A coordinated national communication campaign should accompany implementation.

Potential communication channels	Key messages should emphasise
• National clinical guidance. • Professional society communications. • Educational webinars. • Conferences and scientific meetings. • HSE information platforms. • Digital newsletters. • Social media and professional networks. • Community diagnostic centre engagement events.	• Earlier diagnosis • Better patient access • Improved use of colonoscopy capacity • High diagnostic accuracy • Care closer to home • Enhanced patient choice • Alignment with Sláintecare principles

Success stories from early adopter sites should be actively shared to demonstrate practical benefits and build confidence across the healthcare system.

8.6 Patient and Public Awareness, Education and Engagement

Patient engagement should be considered a core component of pathway implementation rather than an adjunct activity. Public understanding of colorectal symptoms, FIT testing and CCE remains limited, and awareness will significantly influence pathway uptake and effectiveness.

A national patient engagement strategy

A national patient engagement strategy should be developed with direct involvement from patient representatives and advocacy groups.

Key Educational Themes

Public information materials should explain:

- The purpose of FIT testing.
- When FIT is used.
- What FIT results mean.
- The role of Colon Capsule Endoscopy.
- Differences between CCE and colonoscopy.
- Why some patients require follow-up colonoscopy.
- The importance of bowel preparation.
- Safety-netting and follow-up arrangements.
- The benefits of earlier investigation.

Methods of Patient Education

- Printed information posters.
- Online patient information portals.
- Educational videos.
- Community information events.
- GP waiting-room resources.
- Community pharmacy engagement.
- HSE and hospital websites.
- National awareness campaigns.

All materials should use plain language and be accessible to people with varying levels of health literacy. Particular emphasis should be placed on culturally appropriate communication and ensuring accessibility for underserved populations, older adults and those with limited digital literacy.

Patient Partnership and Co-Design

Patients should be involved in:

▪ Development of educational materials	▪ Pathway design	▪ Evaluation of patient experience
▪ Service improvement initiatives	▪ National governance structures	▪ Quality assurance programmes

Patient representatives should participate in the proposed National FIT and CCE Standards Working Group to ensure that service development remains person-centred.

Building Public Confidence

Public confidence will be strengthened through transparent communication regarding outcomes, quality standards and safety. Publication of national quality indicators, patient experience data and pathway performance metrics will provide reassurance that the pathway maintains the same commitment to quality and safety expected of conventional colonoscopy services.

Ultimately, effective patient and public engagement will help improve FIT participation, increase acceptance of CCE, support informed patient choice and contribute to the successful delivery of a modern, community-based, risk-stratified lower gastrointestinal diagnostic service for Ireland.

Recommendations

9.1 Strategic Recommendation

The overarching recommendation is that Ireland should adopt a **national FIT-stratified, CCE-supported symptomatic lower GI diagnostic pathway**, delivered through community-based services, supported by regional reporting hubs, governed through national quality standards, and integrated with digital and AI-enabled infrastructure. This would increase diagnostic capacity, reduce colonoscopy demand, improve patient experience, and support earlier diagnosis of colorectal disease

9.2 Key Recommendations

1. Implement a National FIT-Stratified Diagnostic Pathway

- Introduce FIT as the standard first-line risk stratification test for symptomatic lower GI referrals.
- Use FIT results to prioritise patients according to risk of colorectal cancer and significant colonic disease.
- Reserve direct colonoscopy primarily for patients with high-risk FIT results or alarm features.
- Incorporate CCE as a first-line structural investigation for low- and intermediate-risk symptomatic patients.
- Establish a national algorithm linking FIT results to appropriate investigation and follow-up pathways.
-

2. Expand Colon Capsule Endoscopy (CCE) Nationally

- Integrate CCE as a routine component of symptomatic lower GI diagnostics.
- Expand access beyond current pilot and regional services.
- Use CCE as a "filter test" to reduce unnecessary colonoscopy while maintaining diagnostic accuracy.
- Support phased national roll-out through existing centers of excellence.

3. Preserve Colonoscopy Capacity for Higher-Risk Patients

- Patients with high FIT levels.
- Alarm features suggestive of colorectal cancer.
- Significant pathology identified on CCE.
- Patients requiring biopsy, polypectomy, or therapeutic intervention.
- Incomplete or non-diagnostic CCE examinations.

4. Develop Community-Based CCE Services

- Deliver capsule administration through Community Diagnostic Centres and Surgical Hubs.
- Move diagnostic activity closer to patients' homes, consistent with Sláintecare principles.
- Reduce unnecessary hospital attendance.
- Explore future home-based capsule testing models where appropriate.

5. Establish a Regional Hub-and-Spoke Model

- Develop regional reporting hubs centred on existing experienced CCE centres.
- Allow capsule ingestion locally while maintaining expert centralised reporting.
- Provide regional quality assurance, education, governance and service support.
- Facilitate equitable access across all regions of Ireland.

6. Expand the Role of Advanced Nurse Practitioners (ANPs)

- Create ANP-led community diagnostic pathways.
- Enable ANPs to:
    - Assess and educate patients.
    - Coordinate FIT and CCE pathways.
    - Administer capsules.
    - Communicate normal results.
    - Escalate high-risk findings.
    - Facilitate onward referral.
    - Position ANPs as key pathway navigators across primary, community and acute care.

7. Invest in Digital Infrastructure

Develop an integrated digital platform supporting:

- Electronic GP referral.
- FIT ordering, tracking and reporting.
- Automated triage pathways.
- National patient tracking and waiting-list management.
- Cloud-based capsule image review.
- Structured CCE reporting.
- Integration with future HSE electronic health records.

8. Establish a National CCE Reporting Network

- Develop standardised national reporting systems.
- Support remote reporting and cross-site collaboration.
- Benchmark performance nationally.
- Ensure consistent reporting quality and service resilience.

9. Prepare for AI-Assisted Capsule Endoscopy

- Incorporate AI-enabled technologies into future procurement and service planning.
- Use AI to:
- Detect polyps and cancer.
- Identify inflammatory changes and bleeding.
- Prioritise important images.
- Improve reader productivity and consistency.
- Utilise AI as decision support rather than replacement for clinical judgement.

10. Create National Standards and Governance Structures

- Establish a National FIT and CCE Standards Working Group.
- Develop national guidance covering:
    - Patient selection.
    - FIT thresholds.
    - CCE delivery and reporting.
    - Reporting standards.
    - Escalation pathways.
    - Quality assurance.
    - Align governance with NEQI and the National Endoscopy Governance Framework.

11. Mandate National Quality Monitoring

- Require participation in the Irish Capsule Endoscopy Registry (ICaRe).
- Define national Key Performance Indicators (KPIs).
- Monitor:
    - Completion rates.
    - Bowel preparation quality.
    - Diagnostic yield.
    - Capsule retention rates.
    - Follow-up colonoscopy rates.
    - Publish national benchmarking and quality reports.

12. Develop a National Training and Accreditation Programme

- Create a standardised Irish CCE curriculum.
- Establish accreditation for: capsule readers, trainers and training centres.
- Support competency-based assessment and ongoing professional development.
- Align training with ESGE and Irish endoscopy education frameworks.

13. Undertake a Phased National Roll-Out

- Begin implementation through established high-volume centres.
- Refine operational pathways before wider expansion.
- Link investment to measurable outcomes and performance indicators.
- Integrate developments with existing HSE, ICaRe and NEQI infrastructure.
- Provide an educational and strategic information programme for medical practitioners and patients

Area	Key Recommendation	Expected Benefit
1. National FIT-Based Triage	Implement FIT as the standard first-line risk stratification tool for symptomatic lower GI referrals and use defined FIT thresholds to guide investigation pathways.	Improves prioritisation of higher-risk patients and reduces unnecessary colonoscopy demand.
2. National Adoption of CCE	Embed Colon Capsule Endoscopy (CCE) as a routine investigation for low- and intermediate-risk symptomatic patients.	Expands diagnostic capacity while maintaining high diagnostic accuracy.
3. Protect Colonoscopy Capacity	Reserve colonoscopy primarily for patients with high FIT levels, significant CCE findings, incomplete CCE examinations, or those requiring biopsy/polypectomy	Improves access to colonoscopy for patients most likely to benefit from therapeutic intervention.
4. Community-Based Service Delivery	Deliver capsule administration, patient education and pathway coordination through Community Diagnostic Centres and Surgical Hubs.	Supports Sláintecare objectives by delivering care closer to home.
5. Regional Hub-and-Spoke Network	Develop regional CCE reporting hubs linked to community-based capsule delivery sites.	Ensures equitable access, efficient reporting and robust governance.
6. Expanded Role for ANPs	Enable Advanced Nurse Practitioners to lead patient assessment, capsule administration, result communication and pathway navigation.	Enhances workforce efficiency and reduces reliance on consultant-led diagnostic pathways.
7. Integrated Digital Infrastructure	Implement electronic FIT management, referral systems, patient tracking, reporting platforms and integration with future electronic health records.	Improves pathway coordination, reduces administrative burden and supports real-time monitoring.
8. National CCE Reporting Network	Establish standardised national reporting systems and cloud-enabled remote review capabilities.	Improves consistency, efficiency and service resilience.
9. Adoption of Artificial Intelligence	Incorporate AI-supported capsule reading technologies into future service development and procurement strategies.	Enhances productivity, reporting consistency and lesion detection.
10. National Governance Framework	Establish a National FIT and CCE Standards Working Group under the National Endoscopy Governance Framework and NEQI.	Ensures standardisation, oversight and accountability.
11. National Quality Assurance Programme	Mandate participation in ICaRe and monitor nationally agreed quality indicators and performance benchmarks.	Supports quality improvement, transparency and patient safety.
12. Training and Accreditation	Develop a national training curriculum and competency-based accreditation programme for CCE providers and readers.	Creates a sustainable, high-quality workforce.
13. Phased National Roll-Out	Expand services initially through existing high-volume centres before wider national deployment.	Facilitates safe implementation and service refinement.

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Appendices

Irish Capsule Endoscopy Working Group Membership and White Paper Contributions.

The Irish Capsule Endoscopy Working Group was convened to develop evidence-based recommendations for the integration of Faecal Immunochemical Testing (FIT) and Colon Capsule Endoscopy (CCE) into symptomatic lower gastrointestinal diagnostic pathways in Ireland. The White Paper was authored by Prof. Deirdre McNamara (Lead Author), Dr Gráinne Holleran, Dr Mary Hussey, Dr Carol Goulding, Prof. Glen Doherty, Dr Jan Leyden and Dr Edric Leung. The remaining Working Group members provided expert clinical input, review, and strategic guidance during the development of the recommendations at capsule endoscopy working group meetings.

Member	Current Roles
Prof. Deirdre McNamara **Lead Author & Chairperson**	Professor In Clinical Medicine, Trinity College Dublin; Consultant Gastroenterologist, Tallaght University Hospital; Director, Trinity Academic Gastroenterology Group (TAGG) Research Centre
Dr Gráinne Holleran **Author & CCE working group member**	Consultant Gastroenterologist, Blackrock Clinic
Dr Mary Hussey **Author & CCE working group member**	Consultant Gastroenterologist, University Hospital Galway
Dr Carol Goulding **Author & CCE working group member**	Consultant Gastroenterologist, University Hospital Galway
Prof. Glen Doherty **Author & CCE working group member**	Clinical Full Professor of Gastroenterology, University College Dublin; Consultant Gastroenterologist, St Vincent's University Hospital; National Endoscopy Training Lead, HSE Endoscopy Programme
Dr Jan Leyden **Author & CCE working group member**	Consultant Gastroenterologist, Mater Misericordiae University Hospital; Clinical Lead, National Clinical Programme for Endoscopy
Dr Edric Leung **Author & CCE working group member**	Clinical Research Fellow and Temporary Consultant Gastroenterologist, Tallaght University Hospital
Dr Barry Hall **CCE working group member**	Consultant Gastroenterologist, Connolly Hospital Blanchardstown; National Referral Centre for Capsule Endoscopy and Device-Assisted Enteroscopy
Dr Mohd Syafiq Ismail **CCE working group member**	Consultant Gastroenterologist, Cavan General Hospital, Monaghan General Hospital and Beaumont Hospital
Dr Vikrant Parihar **CCE working group member**	Consultant Gastroenterologist, Letterkenny University Hospital
Prof. Martin Buckley **CCE working group member**	Consultant Gastroenterologist, Mercy University Hospital, Cork
Dr John O'Grady **CCE working group member**	Consultant Gastroenterologist, Cork University Hospital

Evidence for FIT and CCE in screening populations

Study (year)	Population & setting	FIT threshold / criteria	CCE comparator	Key metrics	Key notes
González-Suárez et al. (VICOCA) 2020	FIT-positive screening participants randomized to CCE vs CTC(Spain)	FIT-positive screening participants (program-specific threshold)	CTC; OC as ref	High sensitivity for neoplastic lesions; CCE more sensitive than CTC for any neoplastic lesion	Prospective RCT; supports CCE as effective filter test after positive FIT
Pioche et al. 2018	Patients with positive FOBT/FIT who refused colonoscopy	Positive fecal test (gFOBT/FIT depending on program)	CTC compared participation and detection	CCE detected significant lesions; useful alternative in colonoscopy-refusers	Randomized trial in FIT/FOBT-positive individuals who would not undergo colonoscopy
Holleran et al. 2014	FIT-positive CRC screening cohort	FIT-positive participants from screening program	OC	Correlation: r=0.62 for any lesion; r=0.84 for significant lesions	Early study showing good correlation between CCE and colonoscopy in FIT-positive subjects
Sulbaran et al. 2022 (Systematic review)	Multiple studies of CCE in screening/FIT-positive cohorts	Varied across included studies	OC/CTC	Polyp detection rate 24–74%; sensitivity for polyps >6 mm: 79–96%; CRC detection ~93% for completed CCEs	Systematic review summarizing CCE performance in FIT-positive and screening populations
Gibbons et al. 2023 (Review)	Review of CCE use including FIT-positive filter studies	Varied	OC/CTC	For polyps ≥10 mm sensitivity 84–97%; supports CCE as filter after positive FIT	Narrative review highlighting CCE as promising post-FIT triage tool but noting back-referral rates
TOPAZ / various pilot cohort studies	FIT-positive cohorts and pilot programs using CCE as filter test	Program-specific FIT thresholds (commonly 10 µg/g in studies)	OC	CCE sensitivity for clinically significant polyps generally high; good correlation with colonoscopy in FIT-positive groups	Multiple cohort and pilot studies; CCE reduces colonoscopy demand but some patients still require follow-up colonoscopy

The ICaRe Annual Reports and the Irish Capsule Endoscopy Working Group White Paper are available on the TAGG Research Centre website , TCD.

Access them using the QR code below.