University of Aberdeen (CHaRT) ScotCap Evaluation

Evaluation
Protocol – Clinical component

Version 2, 27 August 2019

Contents

VERSION HISTORY

Amendment no.	**Protocol version no.**	**Description of changes (*incl. author(s) of changes*)**	**Date**
	1	New document	12 August 2019
	2.0	Correction of minor typographical errors	27 August 2019

1. SUMMARY

In April 2019, NHS National Services Scotland announced the successful bidder from a tender to identify an Innovation Partner to provide a CCE managed service integrated into the NHS with the aim of improving the patient journey, improving outcomes and reducing the requirement for traditional hospital-based optical colonoscopy procedures (https://www.tendersdirect.co.uk/Search/Tenders/Expired.aspx?ID=%20000000007260032&sect=E043&cat=27&Page=Categories). The successful Innovation Partner will provide colon endoscopy capsules alongside a delivery, reading and reporting service. The Innovation Partner will start to deliver Phase 1 by June 2019 across NHS Highland, NHS Western Isles and NHS Grampian. Phase 1 incorporates a Service Evaluation, which will inform Phase 2 (roll-out of the managed service across other Health Boards in Scotland in 2020). The evaluation incorporated in phase 1 is being undertaken in collaboration with the Universities of Aberdeen and Strathclyde.

This protocol was created to describe the clinical component of the service evaluation which will be completed University of Aberdeen (Centre for Healthcare Randomised Trials; CHaRT).

The qualitative component of the service evaluation is described in a protocol prepared by University of Strathclyde.

Both these protocols sit below the overarching document "A service evaluation of colon capsule endoscopy in patients with gastro-intestinal symptoms". The overarching document describes the background to the evaluation and the CCE managed service itself.

2. AIMS & OBJECTIVES

The overall aim of the service evaluation is to assess the performance and acceptability of CCE within a referral pathway for patients presenting to their GP with 'Red Flag' lower GI symptoms and for patients waiting for a surveillance colonoscopy.

Specifically, the clinical component of the evaluation has the following objectives:

- To determine the uptake of CCE
- To determine the rates of acceptable bowel preparation for CCE
- To determine the CCE completion rate
- To determine the need for further diagnostic tests
- To determine findings from CCE and findings and/or pathology from further diagnostic tests

3. OUTCOME MEASURES

The main outcome measures for the evaluation are clinical and related to the test process. These outcomes include uptake of CCE, bowel preparation success rates, CCE test completion rate, pathology found, need for further investigations because of a failed CCE test or because pathology has been found which needs biopsy or removal.

- Uptake of CCE

- Bowel preparation rates. Given a numerical score by clinical reporting team for three segments: right colon, transverse colon and left colon.

- CCE test completion rate. CCE traverses the entirety of the colon and sees the anal cushions and/or is excreted.

- Need for further investigations because of incomplete test. CTC, flexible sigmoidoscopy, colonoscopy.

- Need for further investigations because of the findings from CCE. Flexible sigmoidoscopy or colonoscopy.

- Findings from the CCE: Colorectal cancer; polyps less than/equal to 6mm in size; 7-9mm in size; equal or greater than 10mm in size; inflammation, vascular lesion, diverticular disease, other.

- Findings from further investigation (Colorectal cancer; polyps less than/equal to 6mm in size; 7-9mm in size; equal or greater than 10mm in size; inflammation, vascular lesion, diverticular disease, other) and pathology/final outcome.

3.1 Primary outcome measure

The primary outcome measure is the CCE test completion rate

3.2 Secondary outcome measures

- Uptake of CCE
- Successful bowel preparation rate
- Findings from CCE
- Need for further diagnostic bowel tests
- Findings and/or pathology found at further investigation

3.3 Contextualisation of outcomes

To help contextualise the outcomes of those who accept the CCE invitation, we will explore clinical outcomes in those patients who were eligible for CCE but who declined the invitation for CCE. Outcome measures in this group will include:

- Type of investigation(s) – flexible sigmoidoscopy, colonoscopy, CTC
- Findings and/or pathology from above investigations (colorectal cancer; polyps less than/equal to 6mm in size; 7-9mm; greater than 10mm in size; inflammation, vascular lesion, diverticular disease)

4. DATA COLLECTION AND TRANSFER

4.1 Data collection

The evaluation will use pseudo-anonymised routine patient-level data collected by CorporateHealth International as part of the managed service; supplemented by data collected by NHS Highland Research, Development and Innovation Departments (RD&I) acting on behalf of the NHS Health Boards. The data collected by NHS (Highland RD&I) and CorporateHealth International is detailed in appendix 1 of this document.

In summary, NHS RD&I collect data on patient invitation and uptake of the invitation for colon capsule. CorporateHealth International collect data (as part of their patient management software) on the patients who accept the invitation to have colon capsule, through their capsule journey to either report from the colon capsule or at the point where they fail capsule (for example are not able to proceed to have colon capsule, have inadequate bowel preparation, or the camera fails to excrete within its battery life). NHS RD&I will collect data from medical

records on patients who require further examination (for example because of failed colon capsule or because the report from the colon capsule has findings that require further investigation).

The numbers of patients screened in order to identify those to be invited will be made available by the Chief Investigator and his team.

The data required to contextualise the outcomes (section 3.3) will be available from EMS and provided by the Endoscopy Team – it is likely that this will be a single transfer of data.

4.2 Data transfer

The CorporateHealth International data is pseudoanonymised; using the EMS number. The EMS number is the number allocated to a patient on referral to CorporateHealth International for CCE. The data collected by NHS RD&I will include EMS number; all other identifiable information will be stripped from the file by NHS RD&I before being transferred to UoA for analysis.

Data from NHS RD&I (Castor system) will be accessible to UoA through password protected log-in.

Data transfer from CorporateHealth International and the Endoscopy Team to UoA will be via ZendTo (https://zendto.abdn.ac.uk/). ZendTo allows files to be transferred across the network in a securely encrypted format. All files uploaded and temporarily stored on ZendTo are held on equipment owned and operated at the University's own Data Centre and are subject to the Data Protection regulations and laws of the University and the country.

ZendTo is not a "cloud" service. Everything is stored (even temporarily) on equipment directly owned by the University, and managed by its own IT staff. All access to data is very tightly and strictly controlled by the University. All accesses to data on ZendTo are logged and can be easily checked if there are concerns that a third party might have gained access to data. Uploaded data is only held on ZendTo for a maximum of 14 days, after which time it is automatically deleted. There is no "undelete" facility available. No backups are taken of the uploaded data (it is only a transitory stopping point), so no uploaded data ever moves off ZendTo itself onto other equipment or media such as backup tapes. After an uploaded file has been deleted, there is no way of recovering the file.

5. SAMPLE SIZE

Phase 1 of the managed service includes the service evaluation. During this phase it is anticipated that 350 patients will undergo colon capsule endoscopy. With data on at least 350 participants we will be able to estimate proportions (for example CCE test completion) with a confidence interval of plus/minus 0.05 (or in percent terms plus/minus 5%).

6. STATISTICAL ANALYSIS

Statistical analysis will largely be descriptive. All baseline and outcome data will be summarised using appropriate descriptive measures and graphical tools. Estimates of outcomes will be presented with 95% confidence intervals. Dummy tables are presented in Appendix 2.

7. REPORTING

CHaRT will prepare a monthly report on the accruing data for the ScotCap Partners. A fortnightly report on uptake and number of procedures completed will be prepared by CHaRT.

8. GOVERNANCE

8.1 Confirmation of service evaluation

The substantive employer of the Chief Investigator (NHS Highland) has confirmed that this is a Service Evaluation and not a research project. Therefore, NHS REC and local R&D approvals are not required for the clinical component of the service evaluation.

8.2 Information governance and data protection

A data processing agreement will be in place between NHS Highland and University of Aberdeen. Similar agreements will be put in place between NHS Western Isles and Aberdeen, and between NHS Grampian and Aberdeen.

8.3 Archiving

All essential data and documents (electronic and hard copy) are retained for a period of at least 5 years after the evaluation is complete, according to the CHaRT archiving policy.

APPENDIX 1: Data collection

Symptomatic patients

Referred to colorectal team with patient details, blood tests. E-Vetting against inclusion criteria in TRAKCARE (by the colorectal team) to Scotcap or standard care. The ScotCap referred patients are notified to NHS RD&I team (via TRAKCARE) who enter onto the RD&I CASPER data management system and send out letters to patients.

% of symptomatic patients eligible for ScotCap: • Number eligible (from RD&I) • Number screened (from the colorectal team)

Surveillance patients

Surveillance patients are recorded on Yellow cards held in Inverness and Wick. Vetting/review against inclusion criteria. Those who meet the inclusion criteria are entered onto the RD&I excel sheet and transferred to the RD&I CASPER data management system.

% Surveillance patients eligible for ScotCap: • Number eligible (from RD&I) • Number screened (from the colorectal team)

Thereafter – all patients

The RD&I CASTOR data management system includes ScotCap participant number (e.g. H001, H002, W001, W002), whether symptomatic or surveillance and, for surveillance patients, results of previous colonoscopy (normal, abnormal). In a separate system, they will hold contact details of participants and chi-number.

- Patient emails / phones to AGREE – RD&I team add details to EMS; record EMS number and date of entry onto EMS onto the RD&I CASTOR data management system. Those patients who agree to ScotCap will be picked-up by CHI via EMS.
- Patient emails / phones to DECLINE – RD&I team refer back to consultant; record date of referral back to consultant and any reasons for declining on RD&I excel sheet. Initially capture free text. Once we have some free text available, we can look to code these and potentially move to recording the reason from a pre-defined list.
- No contact from patient – NHS team telephone after 1 week to confirm whether they want to agree to ScotCap or remain in routine care.

% of patients who agree to ScotCap (analyse separately by symptomatic and surveillance): • Number accepted (from RD&I) • Number eligible (from RD&I; as above) • Reasons for declining (from RD&I) • For those who agree, time from screening to acceptance • For those who decline, time from screening to return to routine care

Data transfer to CHaRT:

From the colorectal team: (actual numbers; not patient level data)	Numbers of symptomatic and surveillance patients screened	Monthly
From CHI (patient level data)	Data from that collected on the dashboard, as described on following pages; including EMS number	Fortnightly
From RD&I (patient level data)	Data from that recorded on the NHS RD&I Castor data management system, as described on following pages, including EMS number (where relevant) and ScotCap study number. No personal identifiable information to be transferred.	Available in real time

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Patient characteristics					
EMS number	NA	RDI	Both	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
ScotCap Number	NA	RDI/CHI	Both	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS: PA
Age	Actual	RDI	Both	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS:PA
Gender	M / F	RDI	Both	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS:PA
Type of patient	Symptomatic / surveillance	RDI	Both	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS:PA
Reason why on surveillance	Family history Colorectal cancer surgery follow up Hereditary Non Polyposis Colorectal Cancer gene history (without family history of gastric cancer Previous polyps with less than 5 polyps on previous colonoscopy Other	RDI	Surveillance patients only	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS:PA
Urgency of referral	Routine / Urgent	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS:PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Referral symptoms *(select all that apply)*	Change in bowel habit Weight loss Rectal bleeding Abdominal mass Diarrhoea Constipation Microcytic anaemia Other	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA/UoS	EMS/RDI/CHI:P UoA:PA UoS:PA
FBC	Results	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
Serum biochemistry eGFR	Results	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
FIT	Results	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
Examination	Mass felt / no mass felt / no examination	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
Postcode (sector level – eg AB51 3)	Postcode (partial)	RDI	Both	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
Pre CCE					
Date of GP referral	Date	RDI	Symptomatic patients only	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
Date of vetting	Date	RDI	Both	EMS/RDI	EMS/RDI:P
Date surveillance colonoscopy initially scheduled	Date	Colorectal team	Surveillance patients only (will be first day of 3 month window when colonoscopy initially scheduled; colorectal team to record on RD&I excel sheet when adding the surveillance patients)	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Date of referral to RDI	Date	RDI	Both	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA:PA
Date of Invitation Letter sent by RDI	Date	RDI	Both	EMS/RDI/CHI	EMS/RDI/CHI:P
1 week contact date	Date	RDI	Both	EMS/RDI/CHI	EMS/RDI/CHI:P
Follow up tel contact date #1	Date	RDI	Both	EMS/RDI/CHI	EMS/RDI/CHI:P
Follow up tel contact date #2	Date	RDI	Both	EMS/RDI/CHI	EMS/RDI/CHI:P
Follow up tel contact date #3	Date	RDI	Both	EMS/RDI/CHI	EMS/RDI/CHI:P
Outcome of invitation	Agree to CCE / decline CCE	RDI	Both	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA: PA
If decline CCE, reasons for this	Free text	RDI	Both	EMS/RDI/CHI/UoA UoS (if qualitative)	EMS/RDI/CHI:P UoA: PA UoS: A
Date of referral to CHI from RDI	Date	RDI	Both	EMS/RDI/CHI/UoA	EMS/RDI/CHI:P UoA: PA
Date of initial CHI contact (Julie)	Date	CHI	Both	CHI/UoA	CHI: P UoA: PA
If decline CCE, reasons for this	Free text	CHI	Both	EMS/RDI/CHI/UoA UoS (if qualitative)	EMS/RDI/CHI: P UoA: PA UoS: A
Date of nurse follow-up (Lesley)	Date	CHI	Both	CHI/UoA	CHI: P UoA: PA
If decline CCE, reasons for this	Free text	CHI	Both	EMS/RDI/CHI/UoA UoS if qualitative	EMS/RDI/CHI: P UoA: PA UoS: A
Stop the clock (Stop the clock will be used if for example patients are on holiday).	Number of days	CHI	Both	CHI/UoA	CHI: P UoA: PA
Stop the clock (reason)	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Blacklist conditions	Insulin dependent diabetic Other: detail	CHI	Both	CHI/UoA	CHI: P UoA: PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
If yes, proceed with CCE	Yes / no	CHI	Both	CHI/UoA	CHI: P UoA: PA
Compliance doubts	Yes / no	CHI	Both	CHI/UoA	CHI: P UoA: PA
Compliance doubts reasons	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
If yes, proceed with CCE	Yes / no	CHI	Both	CHI/UoA	CHI: P UoA: PA
Outcome of readiness call	As planned, delay 1 hour, abandon	CHI	Both	CHI/UoA	CHI: P UoA:PA
If outcome of readiness call is to abandon, reason for this	Consider possible reasons: Bowel preparation not complete Illness Weather Transport Other	CHI	Both	CHI/UoA	CHI:P UoA: PA
If outcome of readiness call is to abandon, date the CCE should have taken place	Date	CHI	Both	CHI/UoA	CHI: P UoA: PA
DNA for CCE	Yes / no	CHI	Both	CHI/UoA	CHI: P UoA: PA
If DNA, any reason for this	Free text initially	CHI	Both	CHI/UoA	CHI: P UoA: PA
If DNA, date the CCE should have taken place	Date	CHI	Both	CHI/UoA	CHI: P UoA: PA
CCE					
CCE date	Date	CHI	Both	CHI/UoA	CHI: P UoA: PA
CCE location	Elgin, Inverness, Ullapool, Skye, Stornoway, Thurso	CHI	Both	CHI/UoA	CHI: P UoA: PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Bowel preparation	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Booster	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Any problems with bowel prep	Yes/no	CHI	Both	CHI/UoA	CHI: P UoA: PA
Patient successfully swallowed capsule	Yes/no	CHI	Both	CHI/UoA	CHI: P UoA: PA
Reason for no success in swallow	Free text initially	CHI	Both	CHI/UoA	CHI: P UoA: PA
Capsule excreted within battery life of capsule	Yes/no	CHI	Both	CHI/UoA	CHI: P UoA: PA
Reason capsule not excreted within battery life of capsule	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Any AEs	Yes/no	CHI	Both	CHI/UoA	CHI: P UoA: PA
If yes, details (free text)	Details	CHI	Both	CHI/UoA	CHI: P UoA: PA
Any SAEs	Yes/no	CHI	Both	CHI/UoA	CHI: P UoA: PA
If yes, details (free text)	Details	CHI	Both	CHI/UoA	CHI: P UoA: PA
Outcome of CCE (from report)					
Quality of preparation of the bowel – right colon	Score	CHI	Both	CHI/UoA	CHI: P UoA: PA
Quality of preparation of the bowel – transverse colon	Score	CHI	Both	CHI/UoA/	CHI: P UoA: PA
Quality of preparation of the bowel – left colon	Score	CHI	Both	CHI/UoA	CHI: P UoA: PA
Most distal part of bowel reached	Stomach, small intestine, right colon, transverse colon, left colon, rectum/anal cushion	CHI	Both	CHI/UoA	CHI: P UoA: PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Technical difficulties	None / minimal / severe	CHI	Both	CHI/UoA	CHI: P UoA: PA
Technical difficulties (details)	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Successful CCE test completion	Yes / No	CHI	Both	CHI/UoA	CHI: P UoA: PA
Reason why CCE not completed successfully (unless captured elsewhere)	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Findings – colorectal cancer	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – polyps	Yes / No	CHI	Both	CHI/UoA	CHI: P UoA: PA
If polyps found, number of polyps	Number	CHI	Both	CHI/UoA	CHI: P UoA: PA
If polyps found, size of largest polyp	≤6mm, 7-9mm, ≥10mm	CHI	Both	CHI/UoA	CHI: P UoA: PA
Findings – inflammation	Yes / No	CHI	Both	CHI/UoA	CHI: P UoA: PA
Findings – Vascular Lesion	Yes / No	CHI	Both	CHI/UoA	CHI: P UoA: PA
Findings – diverticular disease	Yes / No	CHI	Both	CHI/UoA	CHI: P UoA: PA
Findings – other	Free text	CHI	Both	CHI/UoA	CHI: P UoA: PA
Date report available to NHS	Date	CHI	Both	CHI/UoA	EMS / RDI /CHI: P UoA: PA
Date report signed off by clinician	Date	CHI	Both	CHI/UoA	EMS / RDI /CHI: P UoA: PA
Further examination required	Yes/no	CHI / RDI	Both	CHI/UoA	EMS / RDI /CHI: P UoA: PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Date clinic gives RDI results letter	Date	RDI	Both	CHI/UoA	EMS / RDI /CHI: P UoA: PA
Date patient sent results	Date	RDI	Both	CHI/UoA	EMS / RDI /CHI: P UoA: PA
Further examination : Flexible Sigmoidoscopy					
Flexible sigmoidoscopy	Yes/no	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Date of flexible sigmoidoscopy	Date	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – colorectal cancer	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – location of colorectal cancer	Right colon / transverse colon / left colon, rectum	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – polyps	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
If polyps found, number of polyps	Number	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
If polyps found, size of largest polyp	≤6mm, 7-9mm, ≥10mm	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – inflammation	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – Vascular Lesion	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – diverticular disease	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – other	Free text	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Further examination : Colonoscopy					EMS/RDI/CHI/UoA
Colonoscopy	Yes/no	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Date of colonoscopy	Date	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
Findings – colorectal cancer	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – location of colorectal cancer	Right colon / transverse colon / left colon, rectum	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – polyps	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
If polyps found, number of polyps	Number	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
If polyps found, size of largest polyp	≤6mm, 7-9mm, ≥10mm	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – inflammation	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – Vascular Lesion	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – diverticular disease	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – other	Free text	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Further examination : CTC					
CTC (Computed Tomography Colonography)	Yes/no	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Date of CTC	Date	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – colorectal cancer	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – location of colorectal cancer	Right colon / transverse colon / left colon, rectum	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – polyps	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
If polyps found, number of polyps	Number	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA

Data Point	Response Options (from Participants)	Source/ responsibility (Which Organisation)	Type of Patient (Symptomatic / Surveillance)	Data Required by Which Partner	Data Status (Personal / Pseudo-Anonymised / Anonymised)
If polyps found, size of largest polyp	≤6mm, 7-9mm, ≥10mm	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – inflammation	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – Vascular Lesion	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – diverticular disease	Yes / No	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Findings – other	Free text	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Pathology & final outcome					
Biopsies taken	Yes/no	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Pathology from biopsies	CRC, Benign polyp, IBD Other…….	RDI	Both	EMS/RDI/CHI/UoA	EMS / RDI /CHI: P UoA: PA
Final outcome	Discharged / Further surveillance / operation or further treatment	RDI	Both	EMS/RDI/UoA	EMS / RDI /CHI: P UoA: PA
Patient Satisfaction Evaluation					
See questionnaire from UoS	Includes how referral took place How patient made decision to participate Experience of the procedure (CCE) Overall satisfaction	UoS	Both	UoS	UoS:PA

APPENDIX 2 - Draft report

Table 1: Demographics of patients who accept ScotCap invitation [*includes all patients referred to ScotCap*]

Symptomatic patients	
Age; mean (SD)	
Gender; % male	
Urgency of referral, % urgent	
Referral symptoms, n, % Change in bowel habit Weight loss Rectal bleeding Abdominal mass Diarrhoea Constipation Microcytic anaemia Other	
FBC, mean (SD)	
FIT, mean (SD)	
Serum biochemistry eGRF, mean (SD)	
Examination, n, % Mass felt No mass felt No examination	
Surveillance patients	
Age; mean (SD)	
Gender; % male	
Reason why on surveillance Previous cancer, last colonoscopy negative Previous cancer, last colonoscopy positive Family history, no previous colonoscopy	

Figure 1: Participant flow

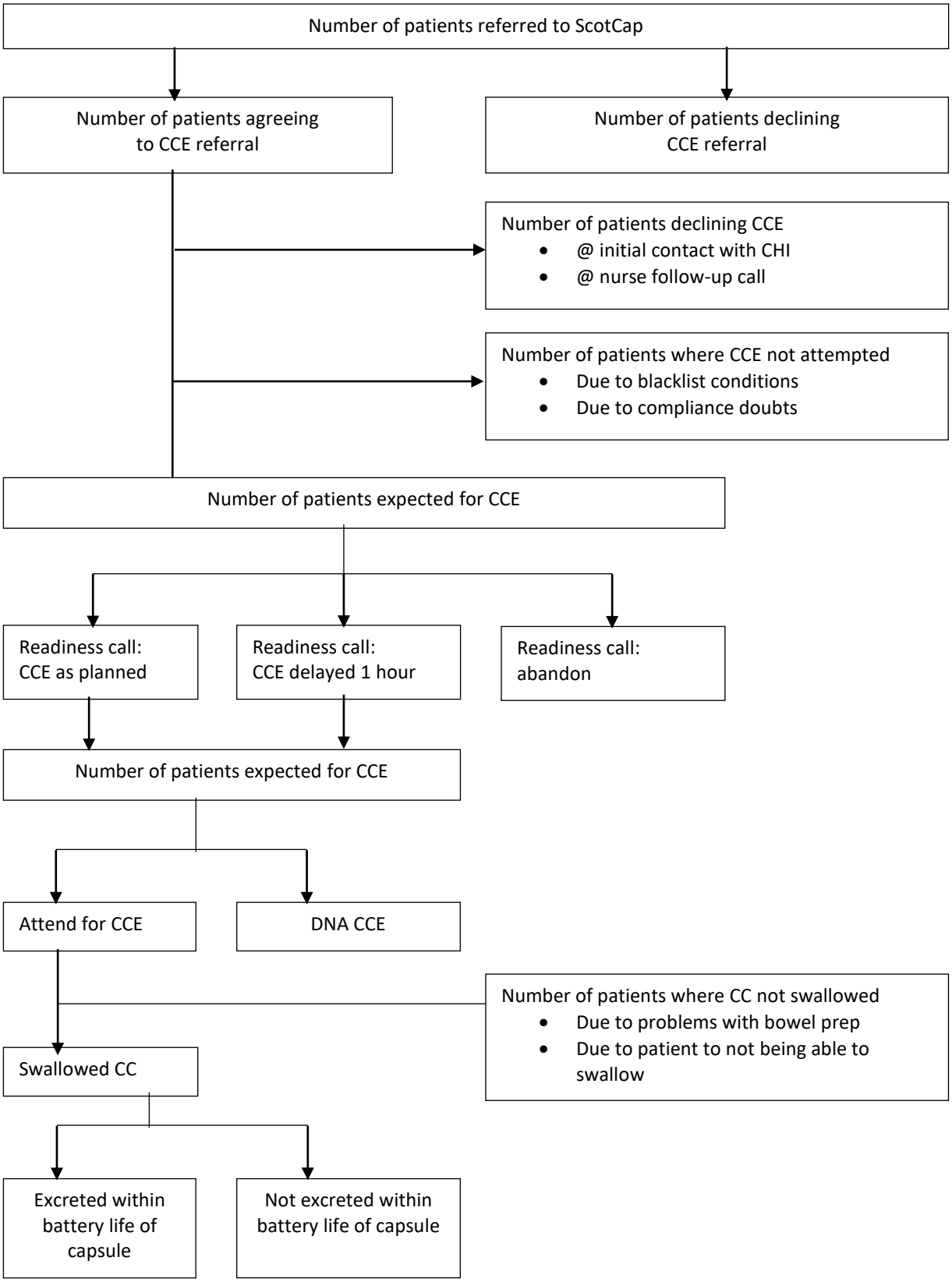

Table 2: CCE journey & timelines

	Symptomatic patients	Surveillance patients
Days from GP referral to patient invitation		
Days from anticipated surveillance colonoscopy date to patient invitation		
Days from GP referral to CCE		
Days from anticipated surveillance colonoscopy date to CCE		
Days from CCE to report being available to NHS		
Days from CCE to report being signed off by NHS		
Patients breaching 31 day target (date referral to CHI to date report available to NHS *(see footnote to table in Appendix 2, KPI report)*		
Patients breaching 42 day target (date of GP referral to date report signed off by clinician) *(see footnote to table in Appendix 2, KPI report)*		

Table 3: Outcome of CCE [include those who swallow CC]

	Symptomatic patients	Surveillance patients
Quality of bowel preparation – right colon		
Quality of bowel preparation – transverse colon		
Quality of bowel preparation – left colon		
Acceptable bowel preparation, n, % *(see footnote to table in Appendix 2, KPI report)*		
Most distal part of dowel reached, n, % Stomach Small intestine Right colon Transverse colon Left colon		
Colorectal cancer, n, %		
Polyps found, n, %		
Number of polyps found,		
Size of largest polyp ≤6mm 7-9mm ≥10mm		
Inflammation, n, %		
Lesion, n, %		
Further examination required, n, %		

Table 4: Further examination and final outcome [include those who swallow CC]

	Symptomatic patients	Surveillance patients
Further examination required, n, %		
Type of further examination completed, n, % Flexible sigmoidoscopy Colonoscopy CTC		
Colorectal cancer, n, %		
Polyps found, n, %		
Number of polyps found,		
Size of largest polyp ≤6mm 7-9mm ≥10mm		
Inflammation, n, %		
Vascular lesion, n, %		
Biopsies taken, n, %		
Pathology from biopsies Benign polyp IBD CRC		
Final outcome Discharged Further surveillance Operation/further treatment		

Table 5: Adverse events and serious adverse events

	Symptomatic patients	Surveillance patients
AEs reported (n (%) of patients experiencing)		
SAEs reported (n (%) of patients experiencing)		
Description of SAEs reported		

Table 6: Outcomes for participants who were eligible but decline CCE

	Symptomatic patients	Surveillance patients
Further examination completed, n, %		
Type of further examination completed, n, % Flexible sigmoidoscopy Colonoscopy CTC		
Colorectal cancer		
Polyps found, n, %		
Number of polyps found,		
Size of largest polyp ≤6mm 7-9mm ≥10mm		
Inflammation, n, %		
Lesion, n, %		
Diverticular disease, n, %		
Biopsies taken, n, %		
Pathology from biopsies Benign polyp IBD CRC		

APPENDIX 2 – KPI report

Number of patients invited to participate in SCOTCAP (KPI1)	
Highland	
Grampian	
Western Isles	
Outcome of invitations to participate in SCOTCAP (N agreeing to participate, % of invited; KPI1)	
Highland	
Grampian	
Western Isles	
Number of CCE procedures completed (KPI2)	
Highland	
Grampian	
Western Isles	
Total (N, % of 350 target)	
Number of patients who DNA for CCE (KPI5)	
Number of appointments cancelled by CHI (KPI6)	
Number of appointments cancelled by patient after initial consultation with CHI (KPI7)	
Number (%) where CCE procedure is delivered to the NHS within 31 days (date referral to CHI to date report available to NHS; KPI8)*	
Number (%) where CCE procedure is delivered to the NHS within 42 days – new patients only (date referral to date report available to NHS; KPI13)*	
Number of adverse events (KPI11)	
Number of serious adverse events (KPI12)	
Number (% of 350) of patients with complete Clinical CCE Data Set (KPI14)*	
Number (%) with Successful bowel preparation rate (KPI15)*	
Number (%) with CCE completion (KPI 16)	
Findings during CCE (KPI 17) N (%) with no findings (normal) N (%) with polyps Polyps less than/equal to <6mm in size 7-9mm in size equal or greater than 10mm in size N (%) with Colorectal cancer N (%) with Inflammatory bowel disease N (%) with vascular lesions N (%) with diverticular disease N (%) with other findings	

Number who need further investigation because of incomplete CCE (KPI18) Flexible sigmoidoscopy Colonoscopy CTC	
Number who need further investigation because of findings on CCE (KPI19) Flexible sigmoidoscopy Colonoscopy CTC	
Findings from further investigation (KPI 20) N (%) with no findings (normal) N (%) with polyps Polyps less than/equal to <6mm in size 7-9mm in size equal or greater than 10mm in size N (%) with Colorectal cancer N (%) with Inflammatory bowel disease N (%) with vascular lesions N (%) with diverticular disease N (%) with other findings	

*** Working definitions at the time of writing:**

Number (%) where CCE procedure is delivered to the NHS within 31 days (date referral to CHI to date report available to NHS; KPI8)	Date of referral to CHI defined as: • Symptomatic patients ➢ Initial workaround - date of email referral to CHI ➢ EMS solution – date added to EMS by RD&I • Surveillance patients ➢ Initial workaround - date of first contact call by CHI ➢ EMS solution – date added to EMS by CHI Date report available defined as: ➢ Initial workaround – when CHI have linked the chi-number and name to the report ➢ EMS solution – when the report is available in EMS
Number (%) where CCE procedure is delivered to the NHS within 42 days – new patients only (date referral to date report available to NHS; KPI13)	Date of referral defined as: Date of GP referral Date report available defined as: ➢ Initial workaround – when CHI have linked the chi-number and name to the report ➢ EMS solution – when the report is available in EMS
Number (% of 350) of patients with complete Clinical CCE Data Set (KPI14)	Complete clinical CCE data is defined as the patient diagnostic journey completed (e.g. if further investigation is required, this has been completed and findings/pathology known)
Number (%) with Successful bowel preparation rate (KPI15)	Using the Boston bowel preparation score; “excellent”, “good” and “fair” are defined as acceptable; “poor” is defined as unacceptable. Successful bowel preparation is defined as acceptable in all three segments.