Process Evaluation of a New Technology Enabled Colon Capsule Endoscopy (CCE) Service In North of Scotland

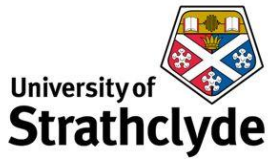
Digital Health and Wellness Group

Department of Computer and Information Science

University of Strathclyde

28th April 2020

V2.5 (Exec)



AUTHORS

Dr Marilyn Lennon

Principle Investigator

Reader in Human Computer Interaction and Digital Health and Care,

Dept. Computer and Information Sciences, University of Strathclyde.

Professor Roma Macguire

Co-Investigator

Professor in Digital Health and Care,

Dept. Computer and Information Sciences, University of Strathclyde.

Dr Sarah Horan

Research Associate, Dept. Computer and Information Sciences, University of Strathclyde.

Babis Kyfonidis

Research Assistant, Dept. Computer and Information Sciences, University of Strathclyde.

Rachel Munford

Research Assistant, Dept. Computer and Information Sciences, University of Strathclyde.

Matthew Jamieson

Research Associate, Dept. Computer and Information Sciences, University of Strathclyde (now at University of Glasgow, UK).

COLLABORATORS

Michelle Brogan

Service Development Manager, Digital Health and Care Institute

Angus Watson

Consultant General and Colorectal Surgeon and Director of Research, Development & Innovation at NHS Highland

Acknowledgements

This research was funded by Scottish Government and Highlands and Islands Enterprise. We would also like to thank interviewees for giving up their time to participate in our research and share their experiences to inform this service evaluation.

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The DHI was established as a collaboration between the University of Strathclyde and the Glasgow School of Art and is part of the Scottish Funding Council's Innovation Centre Programme. The DHI is also part-funded by Scottish Government. DHI supports innovation between academia, the public and third sectors, and businesses in the area of health and care.

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EXECUTIVE SUMMARY

Colon capsule Endoscopy (CCE) is a new medical procedure that uses a video capsule (which patients swallow) to examine the colon. CCE is a complementary investigation route and can avoid the need for optical colonoscopy in many cases. The underlying technology for CCE has a CE-mark and has been used successfully and documented in several previous clinical trials. Little is known however about its use and acceptance by both patients and clinicians as part of an innovative new service model in the live healthcare setting.

The aim of the SCOTCAP programme in Scotland is to remove the diagnostic bottleneck for Gastro Intestinal (GI) disease and bowel cancer risk assessment using CCE. By creating and evaluating a new clinical pathway at point of care within the community, SCOTCAP aims to create increased diagnostic capacity within the NHS, reduce waiting times, allow for saving in clinical time, minimize the impact on the daily life of patients, avoid complications, reduce specialist participation, reduce resource utilisation and make use of modern digital health technology – while maintaining the medical accuracy of existing procedures.

A CCE pathway was created in the North of Scotland to test the acceptability and feasibility of CCE with N=317 patients. The University of Aberdeen conducted a clinical feasibility trial for the CCE pathway, the Scottish Health Technologies Group (SHTG) conducted an economic evaluation, and the University of Strathclyde (UoS) conducted a qualitative evaluation which examined the process of implementation during the live Test of Change in NHS Highland, Western Isles and Grampian (Highland being the largest of these three recruitment sites).

The aims of the qualitative process evaluation reported here were to (i) capture patient acceptance and user experience of the new CCE pathway; (ii) capture experiences from health care professionals and other implementers involved in service planning, delivery and evaluation; and (iii) understand the potential barriers and facilitators to adopting this new pathway long term within NHS Highland and ultimately to help identify what factors need to be considered if this service were to scale more widely. Methods used included process mapping of the old and new pathways, a scoping review of the existing evidence for

acceptance of CCE, surveys of the NHS Highland patients experiencing CCE and a selection of interviews across the lifetime of the project with both patients and key stakeholders involved in the implementation of the new CCE pathway.

During June-Dec 2019 a total of 317 patients experienced the new CCE pathway in the three NHS health boards (Highland, Grampian and Western Isles). Of these 286 were from NHS Highland (the focus of the experience findings presented in this report). Two hundred and eleven (67%) of these NHS Highland patients completed a patient experience survey. Eighteen (6%) of the patients in NHS Highland also took part in a user experience interview with the University of Strathclyde Evaluation team. In addition, fourteen cross sectional interviews were conducted with key implementers involved in the realisation of the new pathway.

University of Strathclyde's evaluation revealed that clinicians and decision makers believe there are real benefits to both the patient (e.g. less invasive procedure, less travel) and to the existing clinical pathway (e.g. reducing waiting times). Patients reported that they could see value in CCE and there were no reported difficulties in swallowing the capsule. When asked if they would recommend this service to others most patients (162/195) responded that they would. Patient data also indicated several areas for continued improvement to the service including: the need to continually improve the comfort and wearability of the technology (e.g. the belt); the transparency of the new service and process (for example communicating anticipated timelines, and managing expectations around the bowel preparation). Implementation findings revealed several significant areas that others should address if implementing this (or similar) new innovative services. These included the need for: more agile health innovation project management strategies; resolving issues around data sharing and information governance; implementing supporting IT systems; innovative partnership working to accelerate service transformation; embedded service evaluation frameworks.

It is anticipated that this report will benefit policy makers in government, operational managers, clinical leads, service managers and IT/e-health managers by providing a practical checklist of what must be considered in planning and conducting the implementation of CCE (and other similar services) within health and care pathways.

Contents

The full University of Strathclyde SCOTCAP Evaluation report contains the following chapters and is available from University of Strathclyde or The Digital Health and Care Institute:

CHAPTER 1	**Background, context and motivation** for a new improved technology enabled pathway for colonoscopy in Scotland
CHAPTER 2	**Aims and objectives** of the evaluation
CHAPTER 3	**Evidence Review** for acceptance and uptake of CCE technology
CHAPTER 4	**Evaluation Methods**
CHAPTER 5	**Patient acceptance** and experience of the new CCE pathway
CHAPTER 6	**Professional and organisational acceptance** of the new CCE pathway
CHAPTER 7	**Recommendations for future work**

SCOTCAP

The Scottish Colon Capsule project (SCOTCAP) is a program sponsored by the Scottish Government to evaluate the use of Colon Capsule Endoscopy (CCE) technology as an important contribution to the delivery of gastroenterology diagnostic services. This involves moving from traditional approaches to gastrointestinal diagnostics towards an innovative service model that has the potential to enhance services for patients and may lead to many patients avoiding OCs.

The Highland Capsule Project (HICAP) was a 'proof of concept' work for this innovation conducted in 2017 across two NHS sites in remote areas of Scotland (Ullapool and Broadford, Scotland, UK). Corporate Health International (CHI), a private healthcare company, provided staff (a specialist nurse) who travelled to patients' homes and health centres to help them take the bowel preparation and a CCE capsule (MedTronic PillCam). It was found that this innovative CCE could be feasibly introduced in these remote areas. However, due to its limited scope, HICAP was not able to demonstrate, or provide data to understand the issues that could impact on the scalability of this innovation. See Figures 1.2 and 1.3 for the CCE equipment. See Fig 2.2 for the mapping of the new CCE clinical pathway for SCOTCAP.

Figure 1.2 The Medtronic PillCam

Figure 1.3 The PillCam recording belt

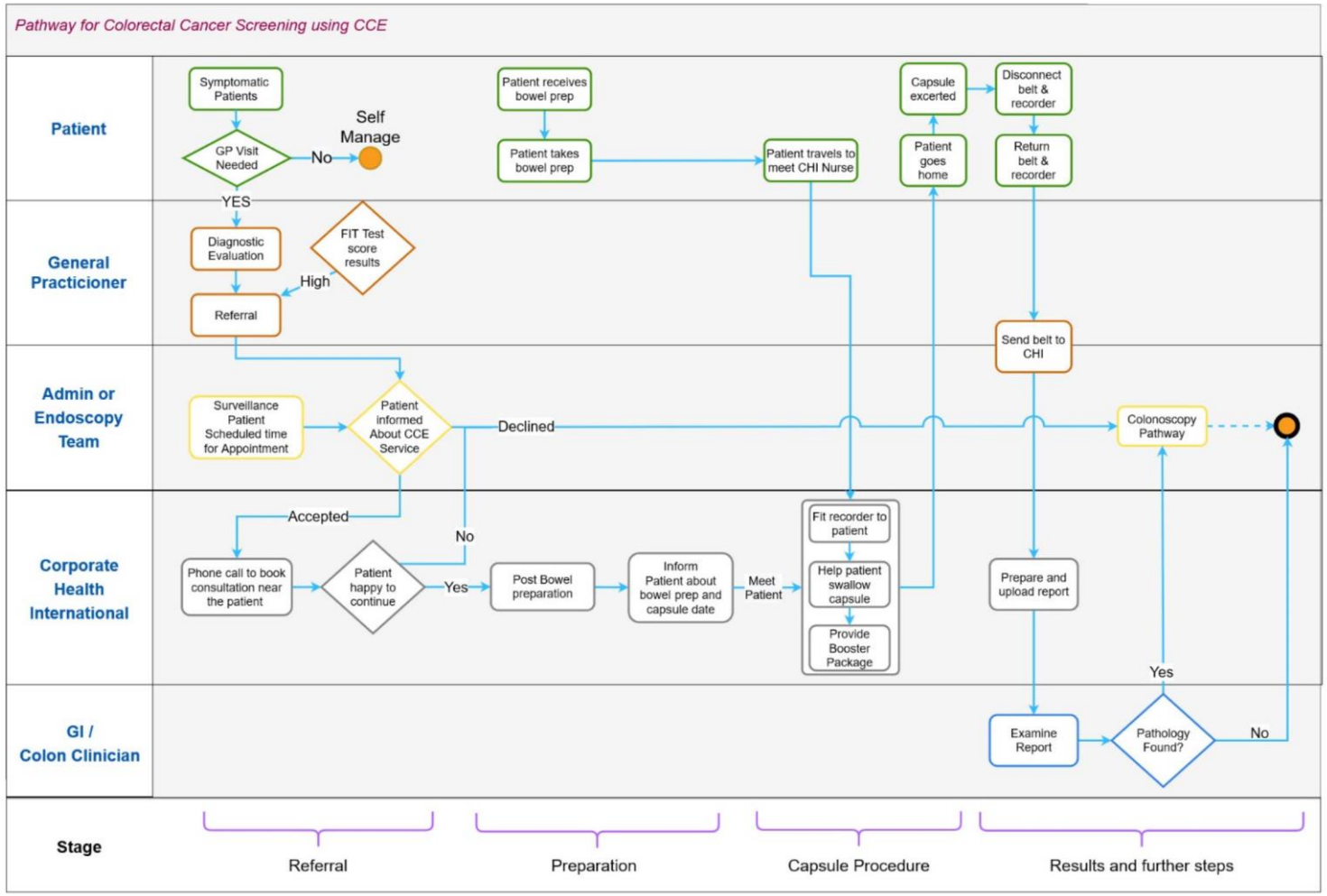

Fig 2.2 The new SCOTCAP CCE enabled pathway

Evaluation Aims

SCOTCAP aims to evaluate the implementation of CCE in a large-scale evaluation across a larger part of Scotland (the Highland and Islands, Western Isles and Grampian regions). The outcomes, evidence and learning associated with the SCOTCAP programme will be used to support the development of a business case exploring the potential for CCE to be more widely adopted across NHS Scotland.

The aims of the University of Strathclyde Process Evaluation were to:

1. Understand and map the new CCE clinical pathway in NHS Highland.
2. Conduct a scoping review of the literature to identify what evidence exists for the acceptance of CCE.
3. Qualitatively explore the patient experience and acceptance of the new CCE technology and pathway.
4. Qualitatively explore the professionals (clinical and organisational) readiness to accept and adopt a new technology enabled colonoscopy pathway involving a single use CCE in NHS Highland, NHS Grampian, and NHS Western Isles.

A survey was used to gather data on the patient journey and experiences of the CCE (before during and after the procedure). Qualitative data was also captured by interviews with patients and a variety of professionals (including clinicians, and other key decisions makers) involved in the test for change as it evolved. Expectations and experiences from involved in the service at set up, before and during recruitment. Patients were interviewed once they had experienced the new CCE pathway (see Figure 4.1).

All topic guides for interviews and the analysis of the qualitative data were based on the NASSS framework (Greenhalgh et al, 2017).

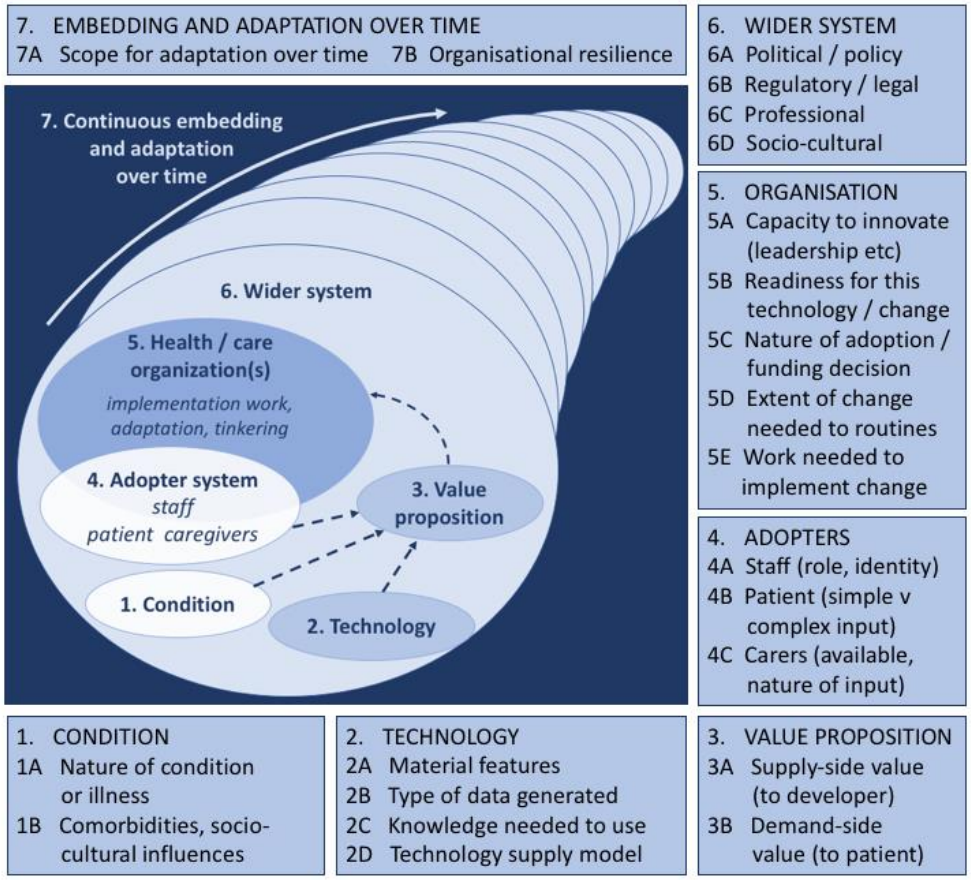

Figure 4.2: NASSS framework's constructs

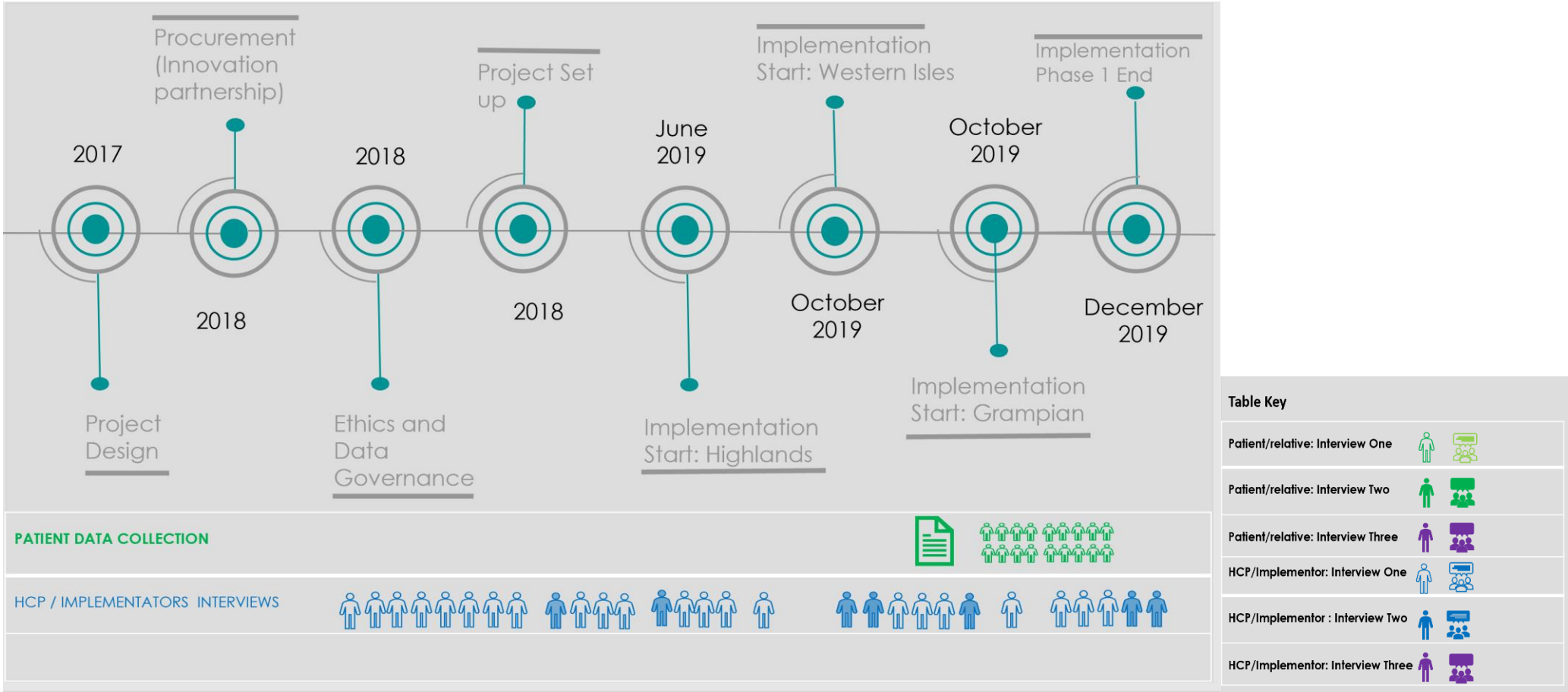

Figure 4.1. Timeline overview diagram

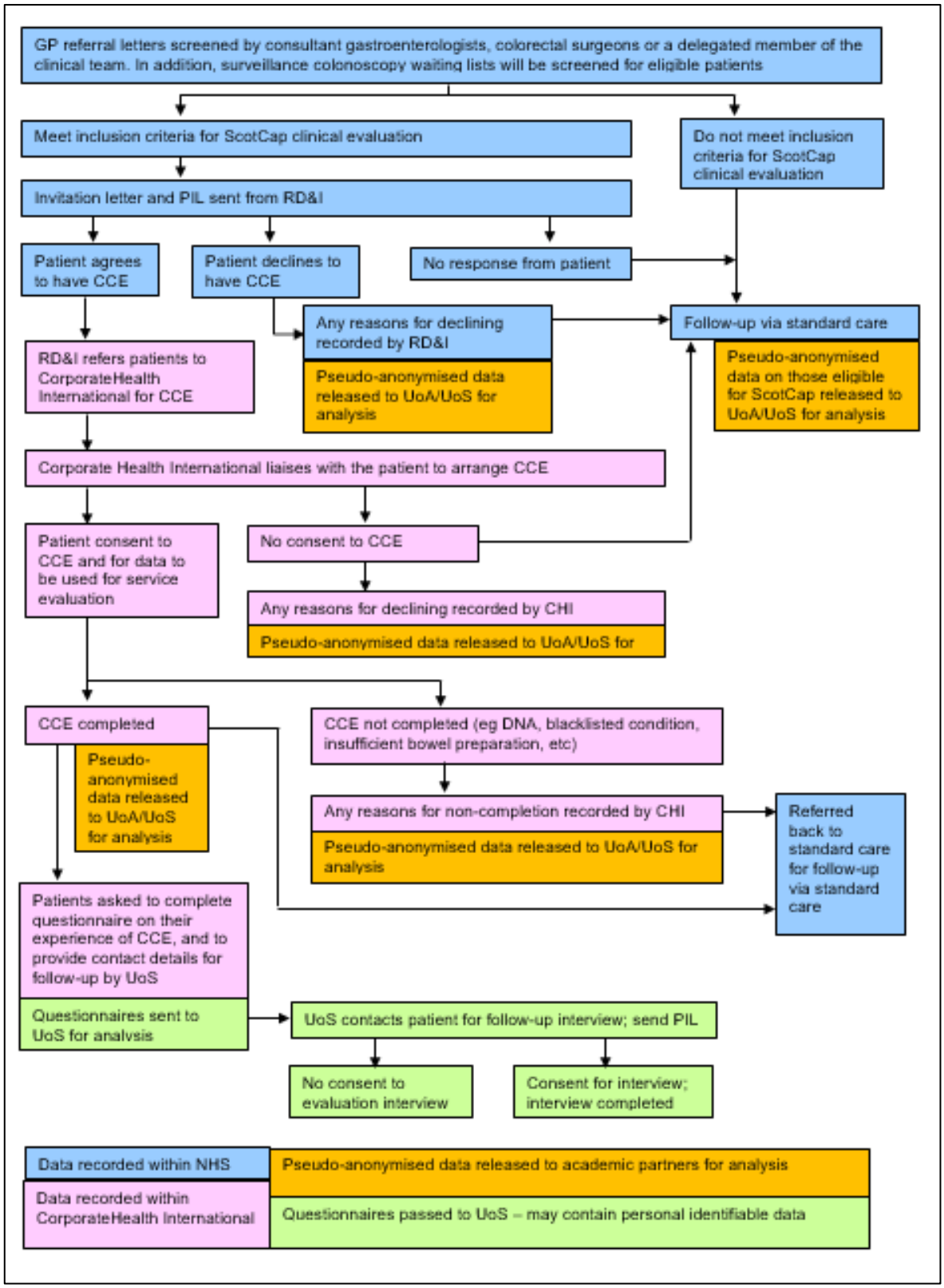

Figure 4.3. Overview SCOTCAP Evaluation Process

Findings: Patient Acceptance

1. **Patients** **N=317 received CCE**
2. **Patient Surveys Completed** **N=211** (67% return rate)
3. **Patient Interviews** **N=18** (8.5% of those surveyed)

N=317 patients in total completed the CCE pathway in NHS Highland, Grampian, and Western Isles during June-Dec 2019. 286 of these patients were from the initial SCOTCAP site in NHS Highland. N=211 patient surveys were returned and analysed from the N= 286 NHS Highland cohort of patients (74% return rate from that site). N=18 interviews with patients from NHS Highland (6% total; 8.5% of those returning the survey) were conducted during Oct-Dec 2019 once the patients had experiences the CCE in NHS Highland.

Sex	Male	93
	Female	90
Groups	Surveillance	82
	Symptomatic	101
Reason for surveillance	Previous polyps	49
	NA	101
	CRC follow-up	23
	HNPCC	5
	Family history	5
Referral urgency	NA	82
	USC	41
	Urgent	30
	Routine	30
Age	Average age	64.8 years
	Oldest age	83 years
	Youngest age	34 years

Table 5.1 Overview of demographic details of SCOTCAP participants

The qualitative data (free text from the surveys and interview responses) were analysed and grouped into themes outlined in Table 5.2.

NASSS Domain	UoS Theme	Sub Themes
Condition	**Participation**	5.1.1 Referral 5.1.2 Choosing CCE
Technology	**Technology and Process**	5.2.1 Bowel Cleansing 5.2.2 Belt and Recorder 5.2.3 CCE capsule
Value Proposition	**Managed Service**	5.3.1 Information & Communication 5.3.2 Staff 5.3.3 Travel 5.3.4 Private company managed service
Technology Value Proposition	**Procedure and Results**	5.4.1 Procedure 5.4.2 Results
Value Proposition	**Overall Impressions**	5.5.1 Meeting expectations 5.5.2 Comparing to OC 5.5.3 Impact on daily life 5.5.4 Recommending to others

Table 5.2 Key themes from patient experience (survey and interviews)

Theme	**Example quotes.**
Indicated *Other* *(*Reasons not listed in the surveys)	N= 99
• A good alternative for colonoscopy	*"The technology also fascinated me" Ps181.*
▪ More convenient	*"Something new, hopefully pain free, a lot more convenient" Ps133.*
▪ Seemed easier	*"Timescale, thought the capsule would be the easier option" Ps154.*
▪ Less invasive	*"I preferred this option for ease of procedure. I have not had a colonoscopy but heard it is unpleasant." Ps135.*
▪ Less painful	"Mainly because colonoscopy was excruciatingly painful in past." Ps199.
• Efficiency of the process	*"I thought it would be better, more photos more info" Ps49.*
• Seemed more effective	*"I believe the camera investigation takes more detailed images" Ps23.*
• Less risky	*"No fear of perforation of bowel" Ps210.*
• No sedation	*"…Thought it would be less invasive. Did not have to get sedated and would reduce pressure on surgeons in NHS etc." Ps98.*
• Can do it unaccompanied	*"On my own so did not have to get anyone to me up." Ps98.*
• Help NHS and other patients	"My original, traditional colonoscopy went off without a hitch. I really just wanted to volunteer to give something back to NHS" Ps36.
• Try a new alternative	"I actually thought the detail of the picture (all the way from stomach) would be more detailed than a colonoscopy. Although the colonoscopy would have been more painful/uncomfortable, it would have been over quicker. I fully understood the need for a full, clear picture of my colon all the way. Detail was paramount to my decision. But time will tell pending results" Ps163.
• Advice from clinician	*"I received a letter from …[the]…Hospital advising I had to go the CCE procedure, so I just went with that procedure" Ps86.*
• Due to comorbidities	"To avoid need for anaesthetic, as I cannot have Opioids" Ps80.

Table 5.3 Table outlining factors influencing the choice of CCE.

Theme	Examples of quotes from surveys.
• **Positives - Clarity and adequacy of information**	N=111
○ **Due to helpful and friendly staff**	"Nurse explained all aspects of the CCE and answered my questions in language I understood" Ps88.
○ **Due to quality of written information**	"Was phoned beforehand and was told and given plenty of information all the team were excellent from phone calls to having the procedure." Ps13.
○ **Due to calls**	*"The procedure was explained well over the phone and documented in leaflets." Ps50.*
• **Negatives / challenges to the service**	N=46
○ **Inadequate information**	"A couple of things on consent form was not been fully explained prior to insertion day" Ps39.
○ **Not clear about what happens after swallowing**	"Whole procedure could be better explained. Info supplied somewhat confusing in places. Need more info on actual recorder" Ps93.
○ **What happens after procedure**	"Slightly confusing information. Could be better edited / presented" Ps93.
○ **Risks not explained**	*"Although I was not informed of the risks until the morning of taking the capsule" Ps79.*
○ **Verbal information covering less than written**	"Full information at the start would be better. Information given by the nurses was excellent but a bit late. Nearly pulled out" Ps44.
• **Improvements on information**	N=48
○ **Clearer procedure**	"Keep in mind that patients can be quite nervous on day. So, more time and less rushing through" Ps39.
○ **Receiver Signals**	"I thought I would swallow a capsule, put on the receiver, then wait for the capsule to exit. I did not realise I would have to take follow up medicine at regular intervals" Ps36.
○ **Disadvantages and risks of CCE**	*"Let people know the unpleasant side of it so they can be mentally prepared. Maybe give something for haemorrhoids that may follow (as they did for me)" Ps123.*
○ **All information in one document**	"… to find out which button to press on the monitor for info as to what stage I was at (1), (2) … This was not online. I just pressed the 'obvious' button but was wrong! May have powered the machine down! A basic patient 'user' guide…with only "This is the only button you need to press throughout the procedure" with an arrowed/highlighted diagram, I am not sure I was told but generally couldn't remember" Ps163.

Table 5.4 Table outlining factors related to service set-up and delivery and supporting quotes from the surveys.

Theme	Example quotes from the surveys.
Overall Impressions of CCE	N=116
• **Negatives**	N=64
○ **Bowel preparation (cleanser and booster)**	"Found the bowel prep and after painful and exhausting.: Ps24
○ **Belt and holster design**	"…the belt and monitor were constantly need to be adjusted" Ps11.
○ **Length of the procedure**	"From start to finish involved 5 days. Rather than the 3 of the endoscopy" Ps18.
○ **Unclear or missing information**	"I thought I would swallow a capsule, put on the receiver, then wait for the capsule to exit. I did not realise I would have to take follow up medicine at regular intervals" Ps36.
○ **Travel distance/time**	"Had to travel to [hospital]l to give blood, because my own medical practice would not do this as they said they needed a signed letter explaining why they are taking blood. I then took the SCOTCAP letter to them and still they did not take my blood" Ps48.
• **Positives**	N=51
○ **Ease of the procedure**	"Plenty information given before phone calls also to explain things very friendly and made you feel relaxed" Ps13.
○ **Professionalism of the staff**	"Staff were superb. Clear instructions and friendly support. It did involve a fair bit of travelling but perhaps that may reduce if the system is fully rolled out..." Ps80.
○ **Adequacy and clarity of information**	"Quickly done Well documented instructions" Ps81.

Table 5.5 Table showing the results of surveys and example of quotes from the surveys.

Theme	*Example quotes.*
• **CCE versus Colonoscopy**	*N=143*
○ **CCE**	*N=103*
▪ **Less invasive/embarrassing**	"Less invasive for people nervous of medical procedures and less embarrassing." Ps22.
▪ **Easier option**	*"A lot easier to get a clearer picture of any problems. Painless" Ps138.*
▪ **Less pain and discomfort**	"No pain - have had 3 colonoscopies 2 were painful" Ps13.
▪ **Quicker - time efficient**	*"No waiting list, very quick from Dr to the actual procedure a big incentive" Ps62.*
▪ **Less stressful**	*"A lot easier and less stressful. No long hospital appointment" Ps50.*
▪ **More effective**	*"To give more information of any problems" Ps102.*
▪ **Better for the NHS**	*"Can be done at home. Saves travelling to hospital…Saves NHS costs. Less invasive" Ps103.*
• **Colonoscopy**	*N= 19*
○ **Colonoscopies efficiency (time needed and ability to find and treat pathology)**	*"…During colonoscopy you can view screen and get more immediate results" Ps110.*
○ **Colonoscopy might still be needed**	"Colonoscopy over at once and results given. With CCE if something is found you still a colonoscopy" – Ps42
○ **Easier bowel preparation**	*"Too much bowel preparation - especially after taking the capsule… I had a lot of discomfort" Ps24.*
○ **Pain and discomfort of CCE**	*"My experience was too long and exhausting with the capsule" Ps115.*
• **Not Sure**	*N=21*
○ **Cannot decide without the results first**	"… Need to ask me once I get test results" – Ps14
○ **CCE equally effective to colonoscopy**	*"Both have issues" Ps54.*
○ **CCE equally hard as colonoscopy**	*"CCE minimal risk but restricted activity for capsule to exit. Colonoscopy procedure over very quickly" Ps148.*

Table 5.6 Table showing the results of surveys and example of quotes from the surveys.

Theme	Example of quotes from the surveys.
• **Recommend to others**	N= 195
○ **Yes**	"I'd go for CCE way before any 'scope'" Ps128.
▪ **Recommend by explaining personal experience**	"A lot easier and less stressful. No long hospital appointment" Ps50.
▪ **Recommend by explaining procedure**	*"It may be less invasive for people nervous of medical procedures and less embarrassing. Could also save travelling and medical time." Ps22.*
○ **No**	*N=2*
○ **Not Sure**	N=29
▪ **Not sure about the effectiveness of CCE**	"I haven't seen the results, but at the moment I wouldn't necessarily advise CCE over traditional colonoscopy" Ps28.
▪ **Due to difficult fasting and bowel preparation**	*"Obviously everyone reacts differently to many laxatives. I would recommend it if they felt they could manage ok" Ps24.*
▪ **Because colonoscopy might still be needed**	"Fasting procedure is more complex - spread over 3 days and through day of swallowing capsule … anything be found through CCE then a follow-up colonoscopy is required." Ps28.
▪ **Did not want to influence others**	*"I would discuss my experience but would not make a recommendation either way" –Ps40.*

Table 5.7 Table showing the results of surveys and example of quotes from the surveys.

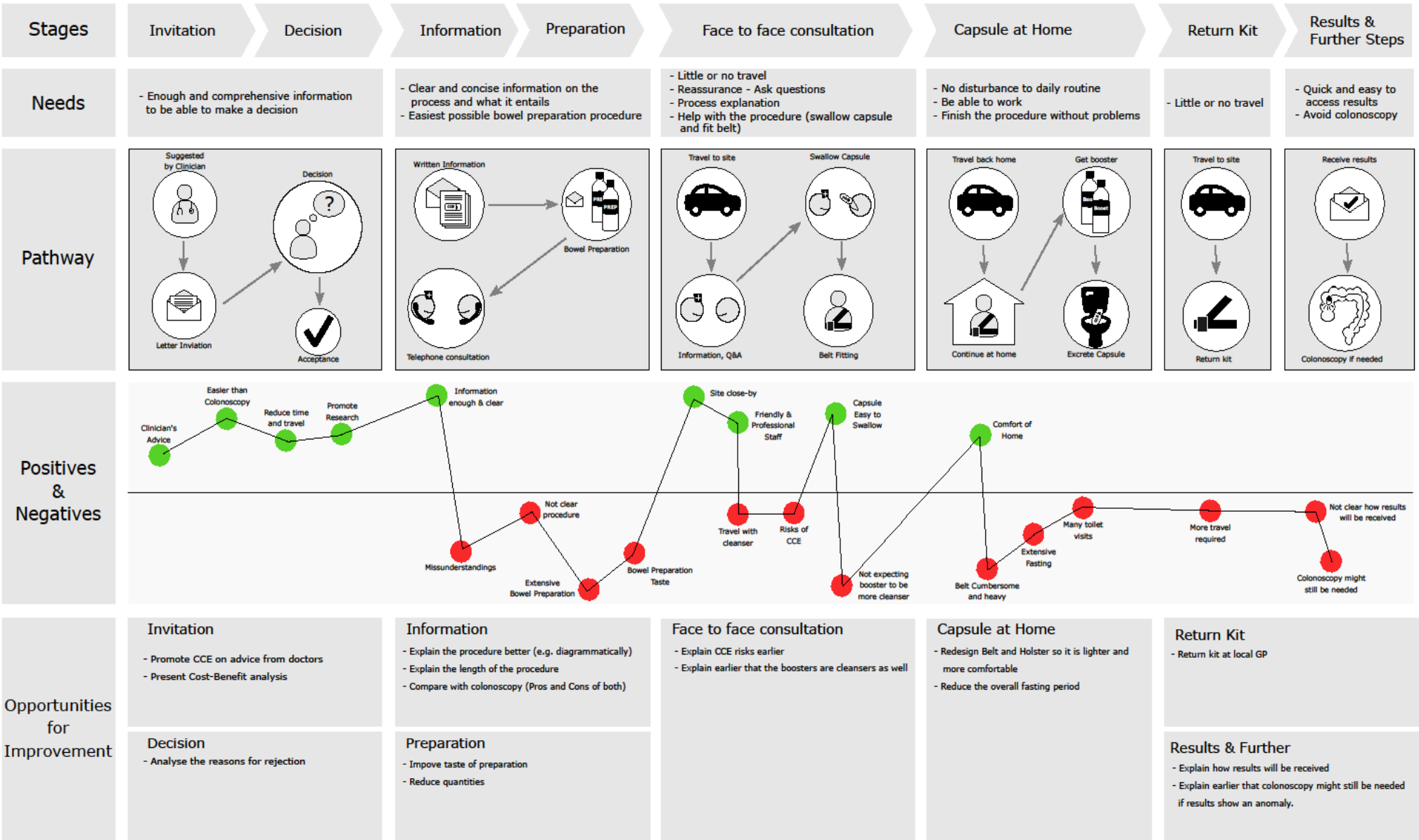

Figure 5.2: Patients' Journey Map

Findings: Implementation

A variety of data collection activities occurred across the implementation process. These methods included semi-structured interviews and also analysis of meeting notes. In total, twenty-nine interviews or meetings took place with key stakeholders (see Table 6.2).

Data collection activity	**Role of person interviewed**	**Interview/ meeting/surveys.**
1	Clinician (first interview).	Meeting notes & Transcription.
2	General Practitioner (GP).	Transcription.
3	Funder (first meeting).	Transcription.
4*	Two members of the Health and Social Care Alliance.	Meeting notes.
5	2 Government Representatives.	Transcription.
6	NHS representative.	Transcription.
7	Future implementor: GP.	Transcription.
8	Procurement personnel (first meeting).	Meeting notes.
9	Clinician (second interview).	Transcription.
10	Employee of implementation company (first interview).	Transcription.
11	GP involved in previous study.	Transcription.
12	NHS Clinician.	Transcription.
13	Procurement personnel (second meeting).	Meeting notes.
14	Government: project management personnel.	Meeting notes.
15	Funder senior level manager.	Transcription.
16	Funder senior level manager.	Transcription.
17	Government Representative of the Modern Outpatient Programme.	Transcription.
18	Procurement personnel.	Transcription.
19	Employee of implementation company (second interview).	Transcription.
20	Employee of implementation service company (service company).	Transcription.
21	Employee of company (device).	Transcription.
22	Government: project management personnel.	Transcription.
23	Funder.	Transcription.
24	NHS administrator.	Transcription.
25	Facilitator.	Transcription.

26	Clinician.	Transcription.
27	Clinician.	Transcription.
28	Project Manager (NHS).	Transcription.
29	Clinician (third interview)	Transcription.
30	**Patient Interviews (n=18).**	**Transcription.**
31	**Patient surveys (n=211).**	**Surveys.**

Table 6.2 Full data collection

The five overall emerging themes from the data captured during the implementation process interviews will be presented with quotes to support the statements in the following five sections:

1. **Implementation planning**
2. **Project management**
3. **Resources**
4. **Implementation (barriers and facilitators)**
5. **Wider adoption and scale**

Conclusions and Recommendations

The service evaluation of SCOTCAP enabled the capture of both patient acceptance of CCE and also further understanding of the barriers and facilitators to the adoption and uptake of a new innovative service model and clinical pathway for CCE. This is something that was missing in the evidence and literature to date.

One of the main outcomes of SCOTCAP is that patients are now potentially being placed more appropriately on the waiting list for colonoscopy. An important additional finding revealed through the process evaluation however and equally important is that the majority of patients reported seeing value in CCE as a way to avoid unnecessary colonoscopy and cited benefits such as being able to be closer to home or work or avoiding unnecessary travel.

The guided bowel preparation, use of the belt recorder and handheld feedback device, and reading of the data to create a diagnosis are all crucial elements to consider during the scaling of this innovation. This evaluation helped to identify that patients reported almost no problems with swallowing the capsule itself. We also found that patient acceptance issues that need further explored include looking at ways to further improve the bowel cleansing process and also including additional information and guidance to manage expectations around this part of the CCE procedure/pathway. Patients reported that additional improvements could also be made regarding the weight and form factor of the accompanying belt that is required to be worn to transfer data (something that is already being considered by the provider).

Systems to procure, run and maintain these parts of the service will need to be well established. Companies providing the CCE service will be able to improve their performance in this market (competing against other CCE service providers and against alternative methods of bowel investigation) by improving the success and usability of bowel preparation solutions and procedure to administer this solution.

What was really being tested in SCOTCAP was the innovative service delivery model. Patients reported feeling mostly well informed and well looked after through the process of opting for CCE and experiencing CCE (information and support from the staff was reported on many occasions as being very good). The evaluation showed that additional improvements could be made around clarity of timelines for patients opting for CCE (in terms of receiving results) and making clear what the likelihood is that a patient might still need to be referred for colonoscopy after CCE. Presenting future patients with patient journey maps and/or case studies might prove a useful tool to increase patient understanding and acceptance of the procedure moving forward.

Clinicians and implementers reported perceived value in the CCE service model as a way to potentially reduce waiting times. Further work should explore what patients stand to benefit most from this alternative route rather than considering CCE as a replacement (which was never the intention in SCOTCAP). Further work needs to be done around helping other sites to set up similar service pathways and make this option part of routine service delivery.

The recommendations provided in Tables 1-4 below could contribute to making the path to implementing CCE in other areas much smoother in order to realise the benefits at scale much more quickly.

1. Clinical Practice (service delivery)
2. Research
3. Implementation
4. Policy

1. Clinical Practice – Service Delivery Recommendations	Recommendations.	Checklist:	Has this been achieved to a satisfactory level? Indicate with a Y/N
1.1 Update patient information.	To prevent misunderstandings, improvements on (and regular updating of) clarity of patient information (e.g. verbal and/or written) so they know what to expect prior to the procedure and what the patient's role is within the procedure. *For example (in SCOTCAP),* - *boosters being laxatives,* - *risks,* - *size and* - *weight of belt, results,* - *length of the procedure,* - *amount of bowel preparation.* - *how and when patients will receive results* - *what happens if a follow up procedure is required* - *consideration to measure service levels through patient experience*	<u>Prior*/during*/after* to the procedure,</u> Has the patient been given: - Understandable written information (diagram if appropriate)? - Understandable verbal information? - Opportunity to ask questions? (*Whichever most appropriate). Build this into the implementation plan.	
1.2 Ensure waiting list position for those still needing colonoscopy.	To avoid undue delay, ensure that those patients in need of [*a colonoscopy in SCOTCAP]* will keep their position at the relevant list and provide clarity to patients regarding the pathway.	Has a position been maintained for a [*colonoscopy]?* Build this into the implementation plan.	
1.3 Consider the implementation of a new improved belt design	If CCE is to be implemented, new improved belts should be implemented and patients asked about the improvements in design. *It is understood a new belt has been designed since the trial.*	Has the current belt and recorder technology been improved/accepted/tested by patients? Build this into the implementation plan.	
1.4 Integrate CCE service with existing electronic management systems in NHS.	Health Boards should actively consider the adoption of EMS. If Scottish Government/Health Boards pursue CCE then EMS ought to be considered as part of the implementation model.	Can the service be integrated into existing electronic management systems? Build this into the implementation plan.	

Table. 7.1 Table outlining key recommendations for the service delivery team.

2 Research	Recommendation.	Checklist	Has this been achieved to a satisfactory level? Indicate with a Y/N
2.1 Consider NHS research ethics Vs service evaluation.	Discuss with the implementation team and Health Board whether the project is considered research or a service evaluation. Attain regulatory approvals/permission from relevant ethics committee if necessary. Consider input of key stakeholders at early stages of protocol development. Both require equal amounts of consideration for data governance and so one should not be seen as quicker or easier than the other.	Have discussions taken place with implementation team whether the project is considered research or service implementation? Has input of key stakeholders at early stages been considered?	
2.2 Identify and agree scope of evaluation.	The scope of the evaluation should be agreed before the commencement of the implementation process and this should be aligned with any existing or potentially future business case.	Has the scope of the evaluation been agreed?	
2.3 Conduct a stakeholder analysis.	Conduct a stakeholder analysis and consider how to involve each in the evaluation design and implementation.	Have key stakeholders been identified and involved in evaluation design and implementation?	
2.4 Communicate and agree timescales with implementation team.	Time scales should be assessed at early stages and revaluated throughout the project. This should be communicated clearly to the dedicated project manager, implementation team and business case team.	Have time scales of each task been assessed? Will these be re-evaluated at regular stages? Will this be communicated to the relevant person(s).	
2.5 Embed patient experience evaluation into service delivery.	Embed patient experience evaluation into service delivery and use this to continually improve service experience and inform business case.	Consider integrating use of evaluation tools e.g. questionnaires into the service delivery model.	

Table. 7.2 Table outlining key recommendations for the research implementation team.

3.Implementation Recommendations	Recommendation	Checklist	Has this been achieved to a satisfactory level? Indicate with a Y/N
3.1 Use dedicated project manager(s).	Identify dedicated project managers for the initial implementation and evaluation of the project. Provide experience and training if necessary. Identify how this will be managed when the service becomes routine practice. *Introduction of a project manager for SCOTCAP significantly improved the implementation process and partnership working.*	Has a dedicated project manager been identified? Have training/experiences needs been identified? If appropriate, provide project managers with change management and implementation experience.	
3.2 Early engagement with the stakeholders	Prior to commencement of a project relevant stakeholders (e.g. clinicians) need to be identified informed and engaged at an early stage.	Have key stake holders been identified at an early stage? Informed at an early stage? Engaged at an early stage?	
3.3 Create and use Data Sharing Agreements at procurement and preplanning stages	Data sharing agreements should be created at early stages for all relevant partners (including research teams).	Has a data sharing agreement been created? Will this be finalised prior to Go Live date?	
3.4 Identify service design, delivery, implementation, and evaluation leads and create a working group to identify roles and responsibilities. Consider division into subgroups.	Identify implementation team. Identify roles of individuals/teams. Consider appropriate division of implementation team into subgroups to reduce attendance of irrelevant meetings/tasks.	Has the implementation team been identified? Have roles been outlined? Could the implementation team be subdivided?	
3.5 Identify key clinical champion(s).	Identify key clinical champions. The project manager should be key contact. *The role of a key clinical champion and driver in SCOTCAP proved integral to making this innovative test for change take place and progress to the stage that it did.*	Has a key clinical champion(s) been identified? Have training/experiences needs been identified?	
3.6 Conduct workforce planning prior to implementation.	Ensure budget and resource covers adequate time and financial costs. Ensure clinical champion and implementation team receive	Has the clinical champion(s)and or implementation team received a reduced workload?	

	time or financial reimbursement or reduced workload.	Has the clinical champion(s)and or implementation team received financial/time reimbursement?	
3.7 Involve R&D early and form a partnership between them and the implementation and evaluation teams.	The research and development team of the local NHS board should be introduced to the relevant stakeholders (e.g. evaluation team) from as early as possible. *The evaluation team engaging later with R+D in SCOTCAP caused significant delays for example in establishing data sharing agreements.*	Has R&D been identified? Has R&D been contacted about involvement? Has the implementation team been given contact details of the relevant individuals?	
3.8 Involve local IT and form a partnership between them, the tech service provider, and the implementation and evaluation teams.	Identify relevant local IT teams and involve at early stages. The project manager/clinical champions should facilitate this working relationship (between the implementation team and IT)	Has local IT been contacted about involvement? Has the implementation team been given contact details of the relevant individuals?	
1.9 Run small scale pilot studies. Embed evaluation and implementation throughout.	Small-scale pilot studies (*like HICAP*) can quickly and cheaply provide insights on the process and the needs for implementing the service at a larger scale.	Has a small-scale pilot been implemented? Has an evaluation been embedded in this pilot?	
1.10 Ensure route to market is understood.	Ensure process is understood as to how the innovation can be scaled to the appropriate NHS Board(s).	Is there a route to market for the innovation activity?	
1.11 Ensure appropriate Governance for decision making of innovation	Ensure appropriate Governance exists for the delivery of the project and possible implementation of the outcome.	Are there appropriate Governance mechanisms for the project and its subsequent implementation?	

Table. 7.3 Table outlining key recommendations for the implementation team.

2. Policy	Recommendation.	Checklist	Has this been achieved to a satisfactory level? Indicate with a Y/N
4.1 Prioritise outcomes linked to national policy.	Identify relevant outcomes and identify how the project could link to improving healthcare in this outcome.	Have the outcomes been identified and linked to national policy? Examples include clinical, cost-benefit, patient acceptance, clinical acceptance, feasibility, scalability.	
4.2 Identify audience for outputs of the implementation.	Identify the audience of the outputs of the implementation? Examples may include; healthcare providers, patients, policy makers.	Has the audience been identified for the output of the implementation?	
4.3 Identify clear purpose for business case.	Identify what is needed for the business case both locally and in the wider scale up environment.	Is a business case needed? Have the requirements for the business case been outlined (both locally and in the wider scale up environment)? Can these requirements be linked to National strategies?	
4.4 Promote "innovation partnership" model.	Innovation partnership was found to be very helpful in setting a flexible and effective way for promoting research and development in the NHS. Such initiates can bring change to NHS by making procurement and collaborations with the industry more flexible and easier to access.	Has an innovation partnership been considered?	
4.5 Technical integration before implementation.	Before implementing a service with a potential to scale-up nationally, the IT infrastructure needs to be in place. Different IT systems or practices are resource consuming and can generate errors.	Have IT infrastructure needs been identified?	

Table 7.4 Table outlining key recommendations for policy

Process Evaluation of a New Technology Enabled Colon Capsule Endoscopy (CCE) Service In North of Scotland

Digital Health and Wellness Group

Department of Computer and Information Science

University of Strathclyde

28th April 2020

V2.5 (Exec)