Health & Social Care: Colon Capsule Endoscopy Project: Q1-Q4 2022

End of Project Report

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The colon capsule endoscopy (CCE) project set out to develop a home-delivered solution to enable patients to carry out a capsule endoscopy in their own home whilst connected to a nurse-led virtual clinic. Phase 1 produced a minimal viable product that was tested with 20 'dummy' patients who were segmented into pre-testers (n=5), influences (n=5), customers (n=4) and citizens (n=6). Early tester focused on basic functions of the box , interaction with the onboard 5G router and tablet and instruction materials. Alongside technological testing the tracking solution and connectivity, and refinement of instructions, the focus of later testers was on the IntelliGI's potential to benefits patients and to address the huge waiting list for endoscopy procedures. The results of phase 1 fed directly into Phase 2 which products 7 commercial Smartboxes, improved tracking, a video guide for patients and updated standard operating procedures for clinicians.

Introduction

Background

Experience in Scotland has demonstrated that it is both possible and beneficial to deliver an at-scale managed capsule endoscopy service through local hubs. SCOTCAP is currently delivering at a run rate of 12,000 patients a year using capsule as an effective triage tool for symptomatic patients

However, CCE is a complex procedure that requires careful patient management as well as expert analysis. It is being delivered in the patient's community through a GP practice or health centre. See below for a description of the patient journey.

Description of CCE in a community (clinical) setting

After referral by an NHS consultant, experienced nurse staff inform the patient about the procedure with a special emphasis on correct bowel preparation. The patient is provided with detailed instructions, necessary medication and an appointment at the most convenient or next available delivery site.

After successful preparation the patient needs to put on a belt (antenna) and recorder and pair these with the capsule. Once completed, the patient can swallow the capsule with some water and possibly some medication. They then need to follow a regimen of drinking further bowel prep as alarms indicate key procedure points.

Once the capsule is excreted or runs out of battery, the belt and recorder are taken off.

Finally the equipment needs to be returned for disinfection, data download and preparation for the next patient. The data is translated into a video that gets centrally analysed and a report is prepared for the referring gastroenterologist.

The process described in above reduces the bottleneck of hospital-delivered procedures by moving service delivery closer to the patient. However, that can be reduced even further by allowing the patient to self-administer the test at home by using advanced communications and connected devices and nursing staff support remaining in central offices.

The main advantages for the patient are the increase in flexibility and avoidance of travel. These are mirrored on the service delivery side where travel from nurse staff to a clinic becomes unnecessary and clinic capacity constraints are removed. Together this promises to increase patient satisfaction while decreasing total cost.
Therefore, self-administration can close a critical gap in the strategy to scale CCE across the whole country. However, it can also provide a platform and case-for-change for adjacent technologies to rapidly conduct tests in the home of the patient, such as IBD assessments, infection measurements or SARS-CoV-2 tests. 5G becomes the critical enabler to conduct patient friendly medical test efficiently, effectively, and safely at scale starting with one of the most important ones to detect a deadly cancer

Key objectives
WM5G commissioned the development of a colon capsule endoscopy (CCE) Smartbox to contribute to the provision of a home-delivered capsule endoscopy service. As a first step on this important journey WM5G commissioned Corporate Health International (CHI) to build and test an initial Smartbox demonstrating the value of 5G and broader advanced connectivity in the provision of the service.
WM5G supported delivery through overall project management and worked with NHS Arden and GEM Commissioning Support Unit who provided day-to-day management of CHI and pathway design expertise to ensure relevance to the NHS. WM5G secured input from Vodafone as the potential operator to engage with CHI.

It was CHI's responsibility to meet all the requirements against the milestones with some components subcontracted to ensure flexibility and innovation in delivery. The original aims of the project were to:

- Build at least one minimal viable product (MVP) CCE Smartbox which can be delivered to 'dummy' patients to ensure they can be guided through the process of preparing to swallow a capsule. This MVP was to include all the clinical and connectivity components necessary to undertake a home endoscopy.
- Ensure, working with Vodafone and/or other specialist connectivity partners, that the Smartbox can be used effectively and independently of patients' own connectivity solutions and demonstrate the added value which 5G brings. The effective use requires inclusion of guidance content (e.g. video) to support the patient procedure.
- Demonstrate this added value and the operation of the Smartbox by delivering the CCE Smartbox to up to 20 'dummy' patients.
- Demonstrate effective tracking of the Smartbox to and from the 'dummy' patient so that the expensive equipment contained in the Smartbox is well-managed.
- Agree the target 'dummy' patients and locations suitable for the required trials considering, where possible, the desire to achieve strong publicity with NHS budget

holders. Specifically, this meant agreeing to utilise senior NHS staff as 'dummy' patients.
- Support the reporting and publicity of the project trials to encourage further investment and support for home-delivered endoscopy.

The project scope was extended in January 2022 to include new deliverables enhancing the capability of the CCE Smartbox, adding in RPA/AI to support larger adoption and defining commercial models. Phase 1 aimed to move from TRL2 to TRL4 and phase 2 we aimed to raise the TRL to 5/6.

Specifically, the aims of phase 2 were to:

- Design and produce 7 prototype products (IntelliGI)
- Create educational material for General Practitioners
- Create a guidance video for patients
- Develop an IT software solution specification and integrate into IntelliGI
- Update Standard Operating Procedures
- Complete 20 trials with (professional) volunteers.

3. Description of the results

3.1. Phase 1 trials tested development of the MVP between September and December 2021. 90% of trials were conducted in the West Midlands. The Smartbox's capabilities were tested through targeted segmentation: pre-testers (n=5), influences (n=5), customers (n=4), citizens (n=6). Testing resulted in improvements to the stability of the box in transit, set-up/close down and interaction with the onboard technology (i.e. tablet and router) and clinical interface and content of instructions.

3.2. Specific problems identified during testing included: 5G router and tablet detached from the fixings during transit, scrolling issues when entering the VC set-up and additional windows opening on booting the tablet, clearer instructions regarding location of power on button on the tablet and 'accepting cookies' on the browser.

3.3. Testing also included the performance of the battery life of onboard devices, (up to) 5G connectivity and tracking of the Smartbox.
- Results showed battery life of the router and tablet was sufficient to support transition to and from the tester's location and completion of the video call with the clinician.
- Connectivity was achieved with all testers to a level that was sufficient to complete a video call; however, in most cases 5G connectivity was not achieved. This was due to 5G coverage where the tester was located either due to lack of service coverage or signal strength within parts of the home/building.
- Testing of the tracking units deployed in phase 1 were insufficient at 30 minute pings. Furthermore, results were fed back to the third-party company in order to improve the effectiveness of the tracking solution. This included: the need to enhance the signal strength to provide a better indoor/outdoor performance, reduce the power consumption to achieve better battery life, fix the charging

LED in the tracker and the 'lose part' in the box, and change the location coordinate to region name in the associated dashboard.

3.4. Phase 2 focused initially on implementing the results of Phase 1 trials. Then moved on to adapting and improving the box design to create a more commercial and streamlined product, deploying and testing these improvements, including to the tracking solution, together with updating SOPs for clinicians and guidance for patients. The IntelliGI system was demonstrated on 16th December 2021 to an audience of clinicians, commissions and policy makers in the West Midlands and online to clinicians in Denmark and Germany.

- A box schematic was produced and 7 boxes were manufactured. The design is 40% lighter than similar products on the market and made with lightweight HPX™ (Peli UK) resin which rebounds without breaking. It is certified dustproof, crushproof, waterproof with reliable watertight properties.
- The tracking system within the boxes was modified (see 3.2.3). The systems battery life in outdoor and indoor environments, ping transmission rate (5 pings every hour) and the battery capacity (3000mAh) were all successfully tested. Results showed battery life of 35 days outdoor and 20 days indoor. Transmission rate was set at 11-12 minute pings for Phase 2 and was tracked for a total of 1,124 pings. Of these, 98.1% (n=1,103) pings were received within 1 hour. The reasons for an unknown (or at least unconfirmed) location was the lack of pings during transport via rail and when the Smartbox was located inside a large building.
- Phase 2 also resulted in production of e-learning materials for General Practitioners and guidance video for patients. The e-learning materials were reviewed and endorsed by GP. One GP said "This is life changing for rural patients".

  A workshop was held with patients on 27th January 2022. Participants had recently undergone the CCE procedure in a clinic setting. All felt the video instructions and box labelling were clear and felt confident to undertake the procedure at home (including fitting the belt themselves) with the support of the nurse via virtual clinic. Standard Operating Procedures were updated to incorporate the results of changes made during testing and were endorsed by a GI Clinician at University Hospitals of Coventry and Warwickshire.

4. Impact of the results including Benefits (in line with BR sheets – include KPI dashboard)

4.1. Key impacts and benefits of the trial in phase 1 was to develop and test a MVP for a CCE Smartbox (branded as IntelliGI) to facilitate the delivery of endoscopy at home. The MVP was presented to NHS England leads and a full range of stakeholders from across the UK on 24 September 2021. The response was overwhelmingly positive and several Trusts expressed a desire to engage further in development of the offer. University Hospital Coventry and Warwickshire NHS Trust (UHCW) was the clinical lead for the project and has secured internal and NHS funding to lead a full clinical trial of the solution. This should lead to wide acceptance of the solution into clinical pathways. The ultimate goal is to eradicate bowel cancer by providing a scalable

solution that can deliver early detection of the polyp pre-cursors to cancer. Whilst CCE technology exists and is used in a clinical setting in Scotland, there is no home-delivered CCE solution with integrated virtual clinic on the market.

4.2. The impact of Phase 1 led to a widening of scope of the project (Phase 2) to include integration and testing of extra components to underpin the scaling and also to 'pump-prime' the adoption by releasing a small number of IntelliGI prototypes into the professional community. This included updating the MVP and testing it with volunteers from this community, ensuring they could be guided through the process of CCE at home (i.e., preparing them to but not actually swallowing a capsule) and returning the IntelliGI box. The process was independent of the connectivity in volunteers' homes as 5G connectivity is integral to IntelliGi. Phase 2 also enabled further R&D testing of the tracking solutions building on the outcomes of phase 1 which showed adaptions are required to ensure tracking is fit for purpose; and other components to ensure IntelliGI is ready to embed within NHS clinical pathways (i.e., IT integration, standard operating procedures, GP and patient-facing materials).

4.3. The initiatives funded in Phase 2 supported the ability to scale the solution by demonstrating to clinicians and their Trusts the ability of IntelliGI to scale rapidly and be operated safely and effectively. Prior to this, there was no home-delivery solution available to the NHS therefore reducing in-clinic endoscopy waiting lists was an ambition that had little chance of being realised.

4.4. As a result of Phase 2 the tracker firmware was updated ensuring it is more reliable and longer battery life. If the box goes missing, the tracker will work for 35 days which would be sufficient time for investigation. Furthermore, the location history can help trace the location of the Smartbox even it is in an indoor environment.

- Focusing on professional volunteer testers in Phase 2 supported the aim to spread information about the IntelliGI system at varies levels, from local primary care organisations in similar settings (e.g. signposting other rural practices for a demonstration) to medical professionals in the UK and EU.
- Engagement with patient representatives showed they were reassured about not having to travel after taking bowel preparation. Some patients travel long distances (e.g. from rural areas) or rely on public transport to attend a clinic both scenarios are removed by using the IntelliGI system.
- Clinicians (e.g. GPs and Senior Community Nurse) were impressed by the quality of the interaction between the Smartbox and the virtual clinic.

4.5. The wider role health initiatives play in an integrated, urban connected community approach are pivotal. Health, mobility and transport are bound closely together with transport choices affecting healthy lifestyles and transport pollution having a direct impact on health conditions. Similarly, health and economic growth go hand in hand since a mentally and physically well workforce is more productive. Funding the development of a colon capsule endoscopy Smartbox capable of allowing a patient to self-administer the CCE procedure in their home, with remote nurse-led clinical support through integrated connectivity, and meeting the IT requirements of the NHS, fits neatly with broader urban connected themes as well as aligning with the WMCA ambition to place diagnostic capacity and capability into the community. There are key benefits of an endoscopy at home solution:

- Reduces unnecessary travel while simultaneously expanding diagnostic capacity.
- Onboard (up to) 5G capability ensures the best possible coverage irrespective of the box's location and/or the network / Wi-Fi speeds available in patient's homes.
- Onboard 5G capability strengthens security to handle the sensitive patient data
- Onboard 5G capability reduces the risk of service interruption during a clinical procedure.

4.6. As a result of the work completed in Phases 1 and 2 to produce a commercial product, a test of change clinical trial has been funded. A 20 patient trial funded by and being conducted at University Hospitals Coventry and Warwickshire NHS Foundation Trust is underway and will be a pre-cursor to a larger rollout of the trial following separate funding from the NHS (£840,000).

4.7. Sale from Danish General Practitioner is expected following an international online event.

4. Key lessons learned captured to date

1. The tracking solution in the MVP and prototypes use 2G technology. Whilst this technology provides the best coverage in the UK at the moment, it was acknowledged that IoT technology within the tracker will be needed beyond 2024. CHI are working with their third-party supplier to create an IoT version of the tracker in order to exchange the part in a Smartbox to conduct further testing. This will ensure the box is functional once IoT coverage is improved and 2G is no longer available.
2. Whilst an onboard 5G router maximises the chances of a good connection vital for the clinician/patient video interaction and offers the potential to perform in-transit data transfer of the images taken by the CCE device, 5G coverage was limited in the areas where testing took place.
3. Further testing/investigation is required to understand the appropriateness of a fully trackable solution for the IntelliGI Smart box. And if required, further work is needed to identify a suitable solution to align with NHS logistics and/or pathways.

5. Financial end of programme requirements

All claims are based upon collating & submitting the associated information/evidence to DCMS on a quarterly basis following the agreed financial principles between the respective parties i.e. DCMS and WM5G, only when the evidence is approved, grant payment is made. In the final quarter of delivery, all evidence associated with each program / project is shared with DCMS and further information is available upon request as supporting evidence."

6. Benefits Realisation:

Testbed monitoring demonstrated specific benefits in relation to connectivity and tracking. A total of 40 users testing either the MVP (phase 1) or the prototype (phase 2). 100% of users were able to successfully connect with the clinician. In most cases, a 5G connection was not achieved, this was due to the location of the user in their home (or other building) and/or 5G network coverage. Where a 5G signal was achieved the signal was good. Whilst in all cases a successful connection was achieved, there were a several occasions where the user had to move location e.g. within their home to achieve a better connection suitable for video communication.

In phase 1, 20 'dummy' patients tested the MVP including the patient-facing instructions, operating the onboard communication devices and CCE equipment and connecting to the nurse. 100% of dummy patients found the MBP usable and effective. Their feedback was captured and iterative improvements e.g. to the box construction were completed. In phase 2, 100% (n=20) of professional volunteers successful tested the prototype IntelliGI. 100% of test completers found it found it usable and effective. Their feedback helped to refine the SOPs, patient video and GP guidance delivered in Phase 2.

The IntelliGI Smartbox was successfully tracked with a total of 1,124 pings. The expected time between pings was 11-12 minutes. The average time between pings was 20m 20s (largest time 26h 34m). Of the 1,124 pings received from the IntelliGi Smartbox, the duration between pings that were greater than 1 hour only occurred 21 times (1.9% of pings). Therefore, 1,103 (98.1%) pings were received within 1 hour. The reasons for loss of location were due to transport via rail and the Smartbox being inside large and/or modern commercial buildings. The time it took to rectify loss of tracking was directly linked to the duration the Smartbox was on the train or in the buildings. The location of the Smartbox was known in that it had been tracked to / from the location but no active ping was received to confirm the location. The box arrived and was returned in agreed timescales on 100% of occasions.

State aid and spend compliance

From a state aid / subsidy control perspective, residual asset values are of significance primarily under Article 25 GBER, whereby residual asset values could have the potential to create incompatible state aid. This would be in a scenario where the grant recipient claimed the full costs of the equipment/materials/land/buildings (as opposed to just an amount relating to the depreciation value over the life of the project – where that item is likely to have a use life/residual value at the end of the project) and the equipment is retained by the grant recipient at the end of the project. Under Article 26 the same provisions in relation to calculation of eligible costs based on depreciation values are not set out in the GBER Article. Therefore, the following outlines WM5G's compliance with the state aid approach and there no outstanding legal challenges.

Workstream	Project Partner	State aid/subsidy exemption
Health	NHS Arden & Greater East Midlands CSU	Intra-state transfer
	Corporate Health Limited	Minimal financial assistance