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CRC COVID: Colorectal cancer services during COVID-19 pandemic. Study protocol for service evaluation

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ABSTRACT

Introduction: COVID-19 has had an impact on the provision of colorectal cancer care. The aim of the CRC COVID study is to describe the changes in colorectal cancer services in the UK and USA in response to the pandemic and to understand the long-term impact.

Methods and analysis: This study comprises 4 phases. Phase 1 is a survey of colorectal units that aims to evaluate adherences and deviations from the best practice guidelines during the COVID-19 pandemic. Phase 2 is a monthly prospective data collection of service provision that aims to determine the impact of the service modifications on the long-term cancer specific outcomes compared to the national standards. Phase 3 aims to predict costs attributable to the modifications of the CRC services and additional resources required to treat patients whose treatment has been affected by the pandemic. Phase 4 aims to compare the impact of COVID-19 on the NHS and USA model of healthcare in terms of service provision and cost, and to propose a standardised model of delivering colorectal cancer services for future outbreaks.

Ethics and dissemination: This study is a service evaluation and does not require HRA Approval or Ethical Approval in the UK. Local service evaluation registration is required for each participating centre. In the USA, Ethical Approval was granted by the Research and Development Committee. The results of this study will be disseminated to stakeholders, submitted for peer review publications, conference presentations and circulated via social media.

Registration details: Nil.

1. Introduction

The COVID-19 pandemic has had a significant impact on the provision of healthcare worldwide. As of the 29th June 2020, COVID-19 has resulted in 311,155 confirmed cases and 43,550 deaths in the UK [1]. At a local level, hospitals have been forced to make a number of work-force modifications and changes to service-provision to combat the crisis and maintain standards of care for our patients [2,3]. Face-to-face consultations have been dissolved or minimized in favour of telephone or virtual clinics. Provision of investigations (including CT scans and endoscopies) have been significantly reduced and all benign surgical procedures postponed [4,5]. Furthermore, the treatment algorithm for confirmed colorectal cancer cases has proved challenging.

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In the UK, over forty thousand patients are diagnosed with colorectal cancer each year [6]. Deviation from NICE colorectal cancer (CRC) guidelines may lead to significantly poorer outcomes. However, the current model of cancer services delivery cannot be maintained, because of both resource limitation and the potential risks to patients and staff during the pandemic. There is a lack of High Dependency Beds, which are being utilized for COVID-19 patients. There is the risk of exposing colorectal cancer patients (the majority of whom are elderly and have significant comorbidities) to the virus during their treatment within the hospital. Patients requiring neo-adjuvant or adjuvant therapy are at particular risk. Finally, staff safety must also be considered, particularly around aerosol-generating procedures such as endoscopy and laparoscopic surgery [4,7].

Intercollegiate General Surgery Guidance on COVID-19 outlined general principles on the provision of a safe surgical service during the pandemic [7]. However, there has been no specific guidance to date on how to best modify colorectal cancer (CRC) service provision during the pandemic. In the absence of a national consensus, the onus is on individual hospital trusts and multidisciplinary teams to make very challenging decisions about individual patient care. Lack of a unified approach may have important consequences at patient and healthcare institution levels.

Delay in cancer diagnosis, or treatment due to service modification is likely to create an increased demand in resources once the crisis has passed. Predicting the economic impact and planning for this is essential.

How hospitals approach the new constraints on CRC care and allocate resources may vary between the UK and USA. It is hoped that gaining insights from both perspectives will improve the problem solving.

2. Methods and analysis

2.1. Aims and objectives

The aim of the CRC COVID study is to describe the changes in colorectal cancer services in the UK and USA in response to the COVID-19 pandemic and to understand the long-term impact. Our primary and secondary objectives relevant to each phase of the study are listed in Table 1.

2.2. Study design

This is a multi-centre service evaluation conducted through a research collaborative with the support of the CRC COVID Steering Committee. All colorectal units continuing to provide cancer services in the UK, Ireland and the USA have been invited to participate. All study and recruitment information is available on the website crccovid.org. This service evaluation has been endorsed by the Royal College of Surgeons of England (RCS).

This service evaluation will be carried out in 4 phases (Fig. 1).

Phase 1 uses a questionnaire to assess the modifications adopted by each colorectal unit in order to continue provision of the colorectal cancer services during the COVID-19 pandemic. It has been developed using an iterative process after research of all relevant guidelines to construct the standard against which services would be evaluated.

The following guidelines relevant to the management of colorectal cancer have been used as standards for this service evaluation:

1. NICE guidelines: Colorectal Cancer [NG151] [8];
2. NICE guideline: Suspected cancer: recognition and referral [NG12] [9];
3. Association of Coloproctology of Great Britain & Ireland (ACPGBI): Guidelines for the Management of Cancer of the Colon, Rectum and Anus (2017) [10–14];
4. British Society of Gastroenterology/Association of Coloproctology of Great Britain and Ireland/Public Health England post-polypectomy and post-colorectal cancer resection surveillance guidelines (2020) [15].

Informal consultations with consultants, nurse specialists and patients have been used to develop the tool and then it has been modified after clinician review for face validity, flow, and relevance. The final instrument comprises 21 questions.

Phase 2 investigates the provision of colorectal cancer services during the COVID-19 pandemic by evaluating the performance of each unit against the National Bowel Cancer Audit outcomes [16]. All centres participating in Phase 2 will be required to register this service evaluation as per local protocol prior to commencement of data collection on REDCap; this will be the responsibility of the local lead.

Phase 3 of the study will develop a prediction model of the economic burden of the modifications in cancer service delivery. This model will be designed jointly by two international business schools, based on previous publications and national statistics.

Phase 4 will evaluate and compare the impact of the COVID-19 pandemic on the NHS and the USA healthcare, using data collected during Phase 2 and the predictive mode utilized in Phase 3. Specific differences in modifications of CRC services will be examined.

2.3. Recruitment

Phase 1 survey has been distributed to all colorectal consultants in the UK and Ireland through personalised emails, social media and the RCS. The recruitment of colorectal cancer units in the

Table 1
Primary and secondary study objectives.

Phase	Primary objective	Secondary objectives
Phase 1	Evaluate adherences and deviations from best practice guidelines on colorectal cancer during COVID-19 pandemic	• Describe modifications to screening process for CRC • Describe modifications to pre-operative, intra-operative and post-operative CRC service delivery • Demonstrate global effect of COVID-19 pandemic on CRC service provision irrespective of the type of healthcare system • Outline consensus recommendations for sustainable modifications to CRC services
Phase 2	Determine the impact of CRC service provision following modifications on long-term cancer specific outcomes compared to national standards	• Predict the impact of modifications on the incidence and prevalence of different CRC stages in 12 months • Plan adjustments to CRC service provision after the end of pandemic
Phase 3	• Predict the costs attributable to modifications of CRC services during COVID-19 pandemic • Predict additional resources required to treat patients whose treatment has been affected by COVID-19	
Phase 4	• Compare the impact of COVID-19 on the NHS and USA model of healthcare in terms of service provision and cost • Propose a standardised model of delivering colorectal cancer services for future outbreaks	

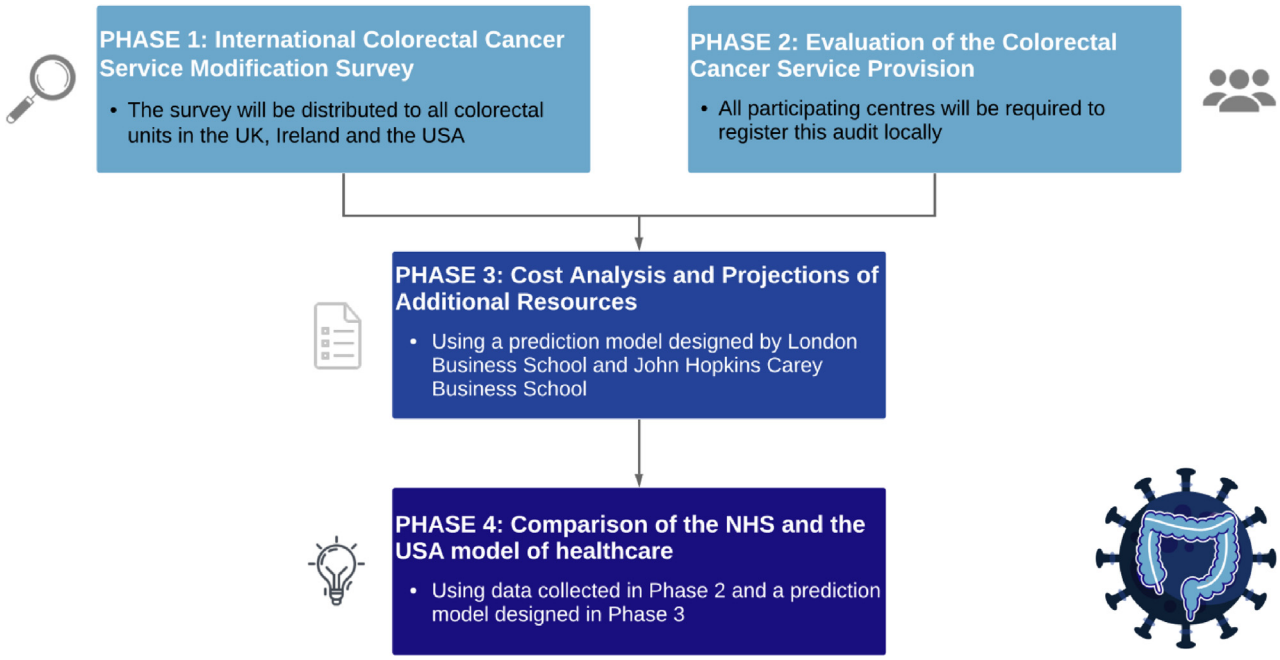

Fig. 1. Phases of CRC COVID.

USA will use similar approach. All units recruited into Phase 1 are recruited into Phase 2. Participation in Phase 1 is not mandatory in order to participate in Phase 2.

2.4. Data collection

All surveys and data collection follow the GDPR requirements and comply with Caldicott principles. Individual patient identifiable data is not collected in this study. Study data is collected and managed using REDCap electronic data capture tool hosted at The Kennedy Institute of Rheumatology at the University of Oxford [17,18]. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources [17,18].

After the close of the Phase 2 data collection period, all data sets will be checked for missing data. Where possible, centres will be given an opportunity to rectify missing data. Centres where >5% of data is missing will be excluded from data analysis and local leads will be notified. A nominated data validator will need to ensure data accuracy prior to submission. If during this process major discrepancy is identified within the data set, the centre's data will be excluded completely from the analysis.

For details of the data collected in Phase 1 and Phase 2, please refer to Supplement 1.

2.5. Data analysis

Phase 1: Responses to the survey pertaining to deviations from diagnostic and treatment protocols during the COVID-19 pandemic (see Supplement 1) will be converted to a numerical scale, where 0 will denote no deviation and 1 will denote complete cessation of service provision. The scores will be summarized using appropriate summary statistics and analyzed using unsupervised learning (k-means and hierarchical clustering) to identify clusters of homogeneous response to the pandemic.

Phase 2: Every month participating centres will report their diagnostic and treatment activity (see Supplement 1). To determine the impact of COVID-19 on colorectal cancer activity we will use time-series methods and data on historical activity and patient outcomes [19,20] to estimate a baseline of expected monthly activity that would have taken place in the absence of the pandemic. The baseline and a 95% confidence interval will be estimated at the national, regional, and individual NHS trust level. The baseline estimate will then be compared to the actual activity as reported by publicly available data [19] and data collected by this study. The difference between expected and actual activity will provide an estimate of the reduction in activity.

To quantify the impact on patient outcomes associated with the estimated reduction in activity and deviation from standardized care protocols we will use estimates of disease progression available in peer-reviewed literature [21–28]. A similar methodology will be used to predict the impact of the pandemic on the incidence and prevalence of different colorectal cancer stages in the following 12 months under different scenarios. Predictions will be made at the regional and national level, and depending on data granularity, at the trust level.

Phase 3 will estimate the financial costs of modifications to the CRC service provision due to the COVID-19 pandemic. This will allow prediction of the expenditure and the additional resources required to resume routine services. We will base this on the literature regarding the price of treatment at different disease stages [21] and the information about the cost of resource utilization (consultations, diagnostic tests, operating theatre time and hospital stay). Phase 4 will compare the results from phases 1–3 in the UK with those in the US.

3. Discussion

Cancer care and maintaining high standards of diagnosis and treatment has long been a priority of the NHS and international health care systems. The pandemic has shifted this focus away from the cancer services. Colorectal cancer patients are particularly

vulnerable to the disruption of their care as diagnosis through endoscopy was stopped due to concerns about virus aerosolysation [4]. This study is important because it is the first study to ask how individual units had to modify their services and adapt to the new constraints.

In addition to describing the changes and understanding whether different units had different approaches, we wish to go further by understanding the effects of diagnostic and treatment delay by prospective data collection of cancer cases, referrals diagnosis, staging and treatment and comparing them to nationally collected audit data [16].

These data will allow us to model the economic impact of the delay and what resources are required to restore cancer services to pre-COVID-19 standards.

The strengths of this study are in the multi-modal approach to the issues, international collaboration and support from the Royal College of Surgeons. Our diverse team of management and business academics, colorectal surgeons, nurse specialists and patient advisors enable us to have a range of approaches to collect and analyse the data.

The main limitation to the study is non-responder or sampling bias as we require voluntary participation from colorectal teams. We will ensure that we adjust statistical analysis for any under-representation. We expect that even with minimal participation, useful models can be generated to understand future resource requirements at an individual hospital level. The methodology employed by other units will demonstrate the utility of the model.

In summary this is a novel and important multi-phase study that is vital to understand how to best care for cancer patients and ensure that the effects of the pandemic are mitigated.

4. Ethics and dissemination

This study is a service evaluation and does not require HRA Approval or Ethical Approval in the UK. Departmental approval has been granted by the university. Each participating centre must seek local permission from their local audit department prior to commencement of data collection. In the USA, Ethical Approval was granted by the Research and Development Committee.

Data for Phase 1 will be submitted for publication as soon as the results become available. Interim data analysis will be presented to the Royal College of Surgeons COVID-19 research collaborative. Data for other phases will be submitted for publication once the data collection has been completed, which is anticipated to be after the routine service provision resumes. All data will be presented at national and international conferences, circumstances permitting.

5. Guarantor

None.

6. Research registration number

None.

Ethical approval

None.

Author contributions

AC designed the study, wrote the initial proposal, drafted the manuscript based on the study proposal, and is part of the audit advisory group.

AMH, NS, ND, OW, SM, SR, GM, NT, MG, TD, BS, JEE, AD, PT advised on the study design and the protocol and is part of the steering committee.

CK is a project PI

All authors read, commented on and approved the study design, the protocol and the final manuscript.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] World Health Organization, The United Kingdom: WHO Coronovirus Disease (COVID-19) Dashboard, 2020. https://covid19.who.int/region/euro/country/gb. (Accessed 29 June 2020.
[2] COVIDSurg Collaborative, Global guidance for surgical care during the COVID-19 pandemic, Br J Surg (2020).
[3] A. Spinelli, G. Pellino, COVID-19 pandemic: perspectives on an unfolding crisis, Br. J. Surg. 107 (7) (2020) 785–787.
[4] British Society of Gastroenterology, Endoscopy activity and COVID-19: BSG and JAG guidance., 02 Apr 2020. https://www.bsg.org.uk/covid-19-advice/endoscopy-activity-and-covid-19-bsg-and-jag-guidance/. (Accessed 29 May 2020).
[5] NHS England, NHS Improvement, Letter to chief executives of all NHS trusts and foundation trusts, CCG accountable officers, GP practices and primary care networks, and providers of community health services., 17 Mar 2020. https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/urgent-next-steps-on-nhs-response-to-covid-19-letter-simon-stevens.pdf. (Accessed 29 May 2020).
[6] Cancer Research UK, Bowel cancer incidence statistics. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/incidence#heading-Zero. (Accessed 30 May 2020).
[7] Royal College of Surgeons of England, Updated Intercollegiate General Surgery Guidance on COVID-19., 07 Apr 2020. https://www.rcseng.ac.uk/coronavirus/joint-guidance-for-surgeons-v2/. (Accessed 29 May 2020).
[8] National Institute for Health and Care Excellence (NICE), Colorectal Cancer (NICE Guideline NG151), 2020. https://www.nice.org.uk/guidance/ng151. (Accessed Accessed 29 March 2020).
[9] National Institute for Health and Care Excellence (NICE), Suspected cancer: recognition and referral (NICE Guideline NG12), 2020. https://www.nice.org.uk/guidance/ng12. (Accessed Accessed 29 March 2020).
[10] C. Cunningham, K. Leong, S. Clark, A. Plumb, S. Taylor, I. Geh, S. Karandikar, B. Moran, Association of Coloproctology of Great Britain & Ireland (ACPGBI): guidelines for the Management of Cancer of the Colon, Rectum and Anus (2017) - diagnosis investigations and screening, Colorectal Dis. 19 (Suppl 1) (2017) 9–17.
[11] S. Gollins, B. Moran, R. Adams, C. Cunningham, S. Bach, A.S. Myint, A. Renehan, S. Karandikar, V. Goh, D. Prezzi, G. Langman, S. Ahmedzai, I. Geh, Association of Coloproctology of Great Britain & Ireland (ACPGBI): guidelines for the management of cancer of the colon, rectum and anus (2017) - multidisciplinary management, Colorectal Dis. 19 (Suppl 1) (2017) 37–66.
[12] G. Langman, M. Loughrey, N. Shepherd, P. Quirke, Association of Coloproctology of Great Britain & Ireland (ACPGBI): guidelines for the management of cancer of the colon, rectum and anus (2017) - pathology standards and datasets, Colorectal Dis. 19 (Suppl 1) (2017) 74–81.
[13] K. Leong, J. Hartley, S. Karandikar, Association of Coloproctology of Great Britain & Ireland (ACPGBI): guidelines for the management of cancer of the colon, rectum and anus (2017) - follow up, lifestyle and survivorship, Colorectal Dis. 19 (Suppl 1) (2017) 67–70.
[14] B. Moran, C. Cunningham, T. Singh, P. Sagar, J. Bradbury, I. Geh, S. Karandikar, Association of Coloproctology of Great Britain & Ireland (ACPGBI): guidelines for the management of cancer of the colon, rectum and anus (2017) - surgical management, Colorectal Dis. 19 (Suppl 1) (2017) 18–36.
[15] M.D. Rutter, J. East, C.J. Rees, N. Cripps, J. Docherty, S. Dolwani, P.V. Kaye, K.J. Monahan, M.R. Novelli, A. Plumb, B.P. Saunders, S. Thomas-Gibson, D.J.M. Tolan, S. Whyte, S. Bonnington, A. Scope, R. Wong, B. Hibbert, J. Marsh, B. Moores, A. Cross, L. Sharp, British Society of Gastroenterology/Association of Coloproctology of Great Britain and Ireland/Public Health England post-polypectomy and post-colorectal cancer resection surveillance guidelines, Gut 69 (2) (2020) 201–223.

[16] Healthcare Quality Improvement Partnership (HQIP), National Bowel Cancer Audit. Annual Report 2019. An audit of the care received by people with Bowel Cancer in England and Wales v2.0, 2020. https://www.nboca.org.uk/content/uploads/2020/01/NBOCA-2019-V2.0.pdf. (Accessed 8 June 2020).
[17] P.A. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, J.G. Conde, Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support, J. Biomed. Inform. 42 (2) (2009) 377–381.
[18] P.A. Harris, R. Taylor, B.L. Minor, V. Elliott, M. Fernandez, L. O'Neal, L. McLeod, G. Delacqua, F. Delacqua, J. Kirby, S.N. Duda, R.E. Consortium, The REDCap consortium: building an international community of software platform partners, J. Biomed. Inform. 95 (2019) 103208.
[19] NHS England and NHS Improvement, Cancer Waiting Times, 2020. https://www.england.nhs.uk/statistics/statistical-work-areas/cancer-waiting-times/. (Accessed 29 June 2020).
[20] National Bowel Cancer Audit, NBOCA Data.gov Weblink, 2020. https://www.nboca.org.uk/resources/nboca-data-gov-weblink/. (Accessed 29 June 2020).
[21] Cancer Research UK, Incisive Health, Saving lives, averting costs. An analysis of the financial implications of achieving earlier diagnosis of colorectal, lung and ovarian cancer, 2014. https://www.cancerresearchuk.org/sites/default/files/saving_lives_averting_costs.pdf. (Accessed 29 May 2020).
[22] S. Sun, F. Klebaner, T. Tian, A new model of time scheme for progression of colorectal cancer, BMC Syst. Biol. 8 (Suppl 3) (2014) S2.
[23] J. Emery, P. Vedsted, New NICE guidance on diagnosing cancer in general practice, Br. J. Gen. Pract. 65 (638) (2015) 446–447.
[24] H.B. Keshava, J.E. Rosen, M.R. DeLuzio, A.W. Kim, F.C. Detterbeck, D.J. Boffa, What if I do nothing? The natural history of operable cancer of the alimentary tract, Eur. J. Surg. Oncol. 43 (4) (2017) 788–795.
[25] Y.H. Lee, P.T. Kung, Y.H. Wang, W.Y. Kuo, S.L. Kao, W.C. Tsai, Effect of length of time from diagnosis to treatment on colorectal cancer survival: a population-based study, PLoS One 14 (1) (2019) e0210465.
[26] D. Roder, C.S. Karapetis, I. Olver, D. Keefe, R. Padbury, J. Moore, R. Joshi, D. Wattchow, D.L. Worthley, C.L. Miller, C. Holden, E. Buckley, K. Powell, D. Buranyi-Trevarton, K. Fusco, T. Price, Time from diagnosis to treatment of colorectal cancer in a South Australian clinical registry cohort: how it varies and relates to survival, BMJ Open 9 (9) (2019) e031421.
[27] Cancer Research UK, Bowel cancer survival statistics, 2020. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/survival. (Accessed 29 June 2020).
[28] K.K. Turaga, S. Girotra, Are we harming cancer patients by delaying their cancer surgery during the COVID-19 pandemic?, Ann. Surg. (2020).