# Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

**02 July 2021**

## Present:

| Name | Capacity | Items |
|---|---|---|
| Dr Tony Calland MBE | Chair | 1a, 1b |
| Ms Sophie Brannan | CAG Member | 1a |
| Mr David Evans | CAG Member | 1a |
| Professor Jennifer Kurinczuk | CAG Member | 1b |
| Dr Harvey Marcovitch | CAG Member | 1b |

## Also in attendance:

| Name | Position (or reason for attending) |
|---|---|
| Ms Caroline Watchurst | Confidentiality Advisor |
| Ms Kathleen Cassidy | Confidentiality Advisor |

# 1. New Precedent Set Review Applications – Research

## a. 21/CAG/0066 – Improving outcomes in Advanced Colorectal Tumours: The IMPACT I Project. Assessing multidisciplinary team management and referral patterns of patients with locally advanced and recurrent rectal cancer in the UK. Short title:(IMPACT I)

**Context**

### Purpose of application

This application from Newcastle University set out the purpose of medical research that aims to identify and assess multidisciplinary team (MDT) referral and management patterns, decision-making and treatment strategies in all patients with locally advanced rectal cancer (LARC) and locally recurrent rectal cancer (LRCC) in the UK.

In the United Kingdom (UK), around 14,000 new cases of rectal cancer are diagnosed every year. It is estimated between 5% and 10% of rectal cancer will be locally advanced at presentation (LARC), and approximately 10% of patients will develop a local recurrence following previous curative resection of rectal cancer (LRRC). There is significant disparity in the management of patients with LARC and LRRC, with inconsistent referral practices and variable access to specialist centres. There are also differences in clinical decision making with regards to patient selection and treatment strategies at an MDT level. The Association of Coloproctologists of Great Britain and Ireland (ACPGBI) has identified the mapping out of clinical pathways in LARC and LRRC as a key area for improvement. This project should identify whether local units are complying with current guidance on the management of patients with LARC and LRRC, and identify regional and national patterns of decision-making. The results will help build standardised regional and national referral strategies for patients with LARC and LRRC, to increase the number of patients referred to specialist centres and provided with appropriate treatment, with an end aim to improve patient-reported, clinical and oncological outcomes.

Applicants plan to link to routinely collected clinical datasets to measure short and long term clinical and oncological outcomes. This study is planned in three phases. Phase one does not require CAG support. Phase two will assess the current MDT decision-making for patients with LARC and LRRC across all colorectal cancer MDTS. Phase three will assess clinical decision-making within specialist MDTs for the management of patients with LARC and LRRC.

Consecutive patients will be identified prospectively by members of the direct care team, through records of MDT meetings across the UK, across a 6-month time period for each phase. This will include approximately 1000 patients from all colorectal cancer MDTs for phase two, and for phase three only specialist MDTs for the management of patients with LARC and LRRC will participate, and around 100 patients are expected to be recruited. Clinical data from patients who are eligible will be disclosed to the University of Newcastle, via uploaded to the IMPACT I database by the direct care team. All items of confidential patient information are removed,

apart from the NHS number and patients date of death (if applicable) which is required for linkage, both between different MDTs, and to outcome data. REDCap will generate a unique patient identification number. Local MDTs will send information sheets to patients, however this is not designed as a consent document. The research team at University of Newcastle will receive opt out requests, and feed back to the local MDTs to ensure removal. The flow of identifiable information regarding opt out does not require CAG support, as the patient is providing this information for the purposes of opt out.

A 12 month follow up is undertaken at local participating sites. At two years and five years, linkage with COLoRECTal Repository (CORECT-R), a research database containing linked national clinical datasets held at University of Oxford is undertaken. CORECT-R links the English National Cancer Registration Dataset (COSD), Hospital Episodes Statistics (HES), Cancer Waiting Times (CWT), National Radiotherapy (RTDS), National Bowel Cancer Screening Programme (BCSP) records and Systemic Anti-cancer Therapy (SACT) data. Data from IMPACT will be linked with CORECT-R using NHS numbers only. CORECT-R will retain a flag for IMPACT I patients between two and five years, meaning applicants will not have to disclose NHS number again. Following data linkage the NHS number will be deleted, and date of death will be modified to overall survival from date of diagnosis and/or date of MDT; the dataset will therefore be effectively anonymous for analysis.

A recommendation for class 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

## Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

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| **Cohort** | Phase two:<br><br>Approximately 1000 Patients with a new diagnosis of locally advanced rectal cancer (LARC) or locally recurrent rectal cancer (LRRC) discussed within a colorectal surgery MDT meeting during the study period<br><br>6-month prospective recruitment period:<br><br>Phase 2 Data Collection Period: September 2021 – Feb 2022. (6 Months).<br><br>Phase three:<br><br>Patients with a new diagnosis of locally advanced rectal cancer (LARC) or locally recurrent rectal cancer (LRRC) discussed within a specialist MDT for the management of |

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| | patients with LARC and LRRC during the study period. The applicants anticipate that approximately 20 specialist centres will participate. The sample size for this phase will be approximately 250 patients.<br><br>6-month prospective recruitment period:<br><br>Phase 3 Data Collection Period: Sep-2021 to Feb-2022 (6 Months) |
| **Data sources** | 1. Participating Colorectal units with a dedicated colorectal cancer MDT, 65 sites in England and 7 in Wales for phase two. (Phase three will have approximately 20 or 30 participating centres)<br><br>2. COLoRECTal Repository (CORECT-R) research database (REC 18/SW/0134) at the University of Oxford. The CORECT-R dataset consists of data linked across the following datasets:<br>- English National Cancer Registration Dataset (COSD)<br>- Hospital Episodes Statistics (HES)<br>- Cancer Waiting Times (CWT)<br>- National Radiotherapy (RTDS)<br>- National Bowel Cancer Screening Programme (BCSP)<br>- Systemic Anti-cancer Therapy (SACT) |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Unique Patient identification number<br>3. Date of death |
| **Identifiers required for analysis purposes** | 1. Age<br>2. Gender<br>3. Date of death – will be modified to overall survival from date of diagnosis/date of MDT for analysis. |
| **Additional information** | A 12 month follow up is undertaken with participating sites<br><br>A 2 year and 5 year linkage is undertaken with CORECT-R. |

## Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

## Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Members agreed that there was very strong public interest in this application, as the work may reduce disparity in referral patterns and access to specialist cancer services.

## Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicant has provided feedback from a Patient and Public Involvement group, who felt that a traditional consent strategy for patients across multiple MDTs would be burdensome during what is perceived to be an incredibly stressful time. The patients felt that the applicants proposed strategy was the least burdensome and patient friendly in determining referral patterns across MDTs and ensuring appropriate recruitment. The CAG were content to accept the views of the Patient and Public Involvement group, and also noted that it would not be practicable to seek consent from more than 1000 patients.

- **Use of anonymised/pseudonymised data**

NHS number is required to link the same patient across different MDTs, and also to link to outcomes in the CORECT-R database. Date of death is required for the applicant to identify overall survival from date of diagnosis/date of MDT, for analysis. The Members were content that linkage could not be undertaken in any less disclosive manner.

## 'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

All enrolled patients will receive a patient information leaflet from their local MDT. The patient information leaflet contains details about the research, including data linkage and the collection of their NHS number. It is the responsibility of the local MDTs to send out the Patient Information Leaflets to all enrolled patients. There will be an option of REDCap to confirm that this has been performed and the date the leaflet was sent will need to be recorded onto REDCap. All local centres will keep a local copy of their own data and will have a record of whether patients have

died prior to sending out any study related information. The information leaflet, updates, news and result summaries will be posted on the IMPACT research website hosted by Newcastle University; http://research.ncl.ac.uk/impactstudy. Contact details for the study team will also be provided, as well as a privacy notice informing participants of their rights as per GDPR.

As part of the patient information leaflet, patients will be informed that they do not need to 'actively' participate as the study involves the collection of routine clinical data. However, if patients wish for their data not to be collected for the research, they can opt out via email, or via the website. Patients are required to provide the applicants with their partial surname, post code, DOB and gender and the name of their local rectal surgery. The local MDT will be informed of the patient's decision to not have their data collected and no further research data will be collected. The National Data Opt-Out will be applied.

The CAG were broadly content with the patient notification materials and opt out provided, however a few points require amending. Members commented that the diagram on the leaflet looks quite confusing, and suggested patient input into making it more patient friendly.

The Committee also noted that the national datasets are described as 'anonymised', however this cannot be true as CORECT-R contains at least NHS Number in order for the applicant to be able to undertake linkage. The sentence stating this is anonymised information should be updated to an accurate description.

As part of the Confidentiality Advice Team (CAT) query responses, the applicant stated that a telephone number and postal contact was added to the leaflet in order to opt out, however this does not appear to have been updated in the version CAT received. The CAG agreed that a phone number and postal address in addition to an email address is required in order for patients to opt out.

## Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have a dedicated IMPACT Patient and Public Involvement Group, a diverse group of patients from a variety of backgrounds, but who all have a diagnosis of advanced colorectal cancer. The Patient and Public Involvement Group were involved in the conceptualisation and design of this project, and approved the study protocol. They will have ongoing input into case report form development and the dissemination of results. They are also responsible for the patient information leaflets.

The acceptability of using confidential patient information as proposed in the application was discussed by the Patient and Public Involvement Group. The overall feeling was that it was acceptable to use demographic, clinical and treatment related data without patient consent, as the aims of the study were to improve referral patterns for patients with locally advanced and recurrent rectal cancer. The Patient and Public Involvement Group felt that it was acceptable to collect patient name address and NHS number with a view to contact them to inform them of their enrolment into IMPACT I during Phase II and III. The Patient and Public Involvement group were in favour of the opt out strategy, noting that this was an appropriate and respectful way of informing patients of their enrolment into the study. They also stated that it would

reassure patients that their data was handled appropriately and confidentially. The PPI group felt that it was reasonable to use confidential patient information from the national dataset link to local data.

The CAG were content with the Patient and Public Involvement undertaken, noting the applicant described a dedicated Patient and Public Involvement group, which is representative of the cohort, and the use of confidential patient information without consent was discussed.

## Exit strategy

At 5 years CORECT-R will provide the applicants with the final data from the patient cohort, based on previously pseudo anonymised data linkage at year 2. They will provide overall survival data, but not full date of death. Following on from this no more data will be collected or analysed from this cohort of patients. It is noted that the NHS number will have been deleted after the year 2 linkage with CORECT-R, as a flag will be placed for IMPACT I on the CORECT-R database. It is also noted that CORECT-R will not be disclosing full date of death back to the applicants at either 2 or 5 years. Full date of death will only be received at baseline and at 12 months from participating sites, and this is required in order to calculate overall survival from date of diagnosis/date of MDT. The Members were not clear why the full date of death was planned to be retained for 5 years, and suggested it could be retained after the 12 month follow up in modified format (i.e. month and year of death), after overall survival times had been calculated.

### Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

## Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide an updated patient notification leaflet, which has a more patient friendly diagram, does not state that CORECT-R is anonymised, and contains a telephone number and postal address in order to opt out, to the CAT, within three months form the date of this letter.

2. Please truncate the full date of death after survival times have been calculated, or provide a justification why this is not feasible, and provide a response to the CAT, within three months form the date of this letter.

3. Support provided for English and Welsh data only.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 23 April 2021**

5. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

The NHS Digital **19/20** DSPT reviews for **University of Newcastle - Health and Social Care Data** (EE133852-HSCD) and **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health (**EE133863-MSD-NDOPH-NDPH) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 July 2021)

## b. 21/CAG/0096 - Development of Image Analysis and Artificial Intelligence Tools using eye Images and Data

### Context

#### Purpose of application

This application from Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research that seeks to determine whether Algorithms and Tools can be developed using standard patient images and data, to be used to enhance patient care in the future.

Many causes of loss of vision are due to diseases that affect the inside of the eye and the retina, such as diabetes and age-related macular degeneration. The number of people with eye disease that causes sight loss is expected to increase significantly over the next 10 years. It is important that effective detection, classification and monitoring of these and other eye conditions can be done in order to reduce the risk of sight loss. Many patients with a sight threatening disease may be unaware of a problem with their eyes in early stages of the disease, for example, those with diabetic retinopathy, patients may be unaware that they have the most severe form of retinopathy (blood vessels growing in the back of their eyes - proliferative diabetic retinopathy "PDR" or "New Vessels"), until they lose vision suddenly when these vessels bleed. The applicants seek to discover whether computer learning using photographs of the inside of the eye and data can be used to detect eye conditions accurately.

The study will be divided into 2 sets. In Set 1, retrospective collection of images and data collected during routine clinical care will take place. Participants in Set 1 will not be consented as their images and data will be anonymised after linkage. The anonymised images and data will then be used to develop tools and algorithms in order to identify, assess and monitor eye disease. Algorithm training, validation and testing will be undertaken. In Set 2, participants will consent to the sharing of their routinely taken images and data. The images and data will be collected at initiation and over the course of the study. These images and data will be coded (pseudonymised) with a unique participant study ID number so that future images and data can be collected during the study. The coded images and data (with no patient identifiable data) that will be used to develop Tools and train and develop Algorithms to compare time points e.g. year 1 and year 4 in order to try to identify predictive features e.g. which eyes will progress in disease severity. This will also include tools and algorithm development, and algorithm training, validation and testing.

Support is therefore required for Set 1 of the study. Participants will be identified from the Electronic Patient Record at Moorfields Eye Hospital, including the imaging database and the Zeiss imaging software. The images will then be linked to the patient date from the Electronic Patient Record (EPR) via participant identifiers. The images and data will then be anonymised for the study and all participant identifiers removed. Identification of these images and data will be carried out by a delegated member of the research team.

A recommendation for class 1, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

## Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

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| **Cohort** | Patients aged 16 years and over who have undergone Zeiss imaging at Moorfields Eye Hospital.<br><br>Set 1: 50-100000 anonymised patient image sets at initiation and then 50-75000 annually (collected very 4-6 months) for the project duration.<br><br>Set 2: 3-5000 pseudonymised image sets per year.<br><br>The applicants estimate at 500,000 patients will be included. |
| **Data sources** | 1. Electronic patient records and scans held at Moorfields Eye Hospital NHS Foundation Trust |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Hospital ID Number<br>4. Ethnicity |
| **Identifiers required for analysis purposes** | 4. Gender<br>5. Ethnicity |

## Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

## Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application activity was in the public interest..

## Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants explained that 50-100,000 images and data will be extracted initially and then 50-75,000 at 4-6 monthly intervals over a 5-year period, and it would not be feasible to consent this number of patients. The CAG agreed with the reasoning for not seeking consent.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information in order to identify suitable patients and link the images to their information. Once the linkage has taken place, the dataset will be anonymised. The CAG agreed that this could not be done in any other way.

## 'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Study specific notices will be displayed to notify patients that the study is being conducted. These will advise patients that they can dissent from the use of the images and data in the research. A privacy notice, to be used as a poster, was provided. This only provided an email address to register dissent. The Posters will be displayed in all medical retina clinic departments where imaging will take place and by the imaging machines.

The Poster and information will be placed on the Moorfields Eye Hospital website. The EPC project team will discuss the suggestion of "social media" notices with Moorfields Communications department to see if this can be organised.

The applicants noted that data that was already included in the study would remain if a patient changed their mind about sharing data, but no further data would be collected. The applicants advised that this was because Set 1 refers to anonymised data. Once anonymised it will not be possible to re-identify patients and therefore not be possible to remove the anonymised data.

If a patient has dissented to use of their data in research, this will be records on the Electronic Patient Record at Moorfields Eye Hospital. If a patient has indicated dissent, their images and data will not be collected.

The CAG noted the information given. Members agreed that a poster should be created, aimed at patients in Set 1, which describes what will happen to their data. A telephone number for opt-out also needs to be provided, alongside the email address.

## Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The protocol and the HRA and CAG applications have been fully discussed with Moorfields Research and development and information governance teams, who agreed that the project would be of value to enhance patient care in the future.

The applicants had carried out a patient satisfaction survey of patients who attended the Medical Retina Clinics at Moorfields Eye Hospital over a four-week period. The response to this survey was positive and patients reported that they were pleased to see the inside of their own eye to aid in visualising the importance of appropriate management of their systemic conditions, and felt they were more involved in their management plan. There was a very positive response to the introduction of new imaging technology and patients were open to possible new ways of working, such as virtual clinics and remote

The study documents were discussed with and reviewed by patients who attend Moorfields and other Hospital Eye clinics prior to submission. Feedback was favourable and some patient information forms were simplified in response to feedback. The documents were also reviewed by patients recommended by the Diabetes UK charity and by a research co-ordinator from the Macular Society.

### Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

## Request for further information

1. A poster is to be created, aimed at patients in Set 1, which describes what will happen to their data. A telephone number for opt-out also needs to be provided, alongside the email address.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may

be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

## Specific conditions of support

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 13 July 2021.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending:**

   Confirmation that the NHS Digital 2020/21 DSPT review for Moorfields Eye Hospital NHS Foundation Trust is 'Standards Met' on the NHS Digital DSPT Tracker is pending.

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| *Minutes signed off as accurate by correspondence from Dr Tony Calland MBE, CAG Chair* | | *12 October 2021* |
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| Signed – Officers of CAG | | Date |
| | | |
| Caroline Watchurst | | 01 October 2021 |
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| Signed – Confidentiality Advice Team | | Date |
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