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

MAY 2019

1. NEW APPLICATIONS

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Dr Barry Evans	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Using Health Informatics to Improve Neurological Services**

CAG reference: **19/CAG/0056**

IRAS project ID: **255676**

REC reference: **19/NW/0178**

Context

Purpose of application

This application from Lancashire Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to assess neurological services in the Trust area. Areas which will be explored include an analysis of diagnosis by geographical area and GP, an investigation of appointment types and patient pathways and an exploration of appointment attendance, non-attendance and cancellation. This will provide evidence for future service redesign and the provision of more efficient care.

The applicant will collate routinely collected information from outpatient neurology appointments linked with data extracted from the wider business intelligence data at Lancashire Teaching Hospitals NHS Foundation Trust to create a pseudonymised dataset to be used for analysis. The clinical data would also be linked to publicly available Census information using Lower Super Output Areas (LSOA) for population-based analysis.

Attention was brought to the state of neurological services in 2011 by a National Audit Office (NAO) report entitled ‘Services for people with neurological conditions’. The issues highlighted by this report include delays in diagnoses, incorrect GP referrals, geographical

inequalities in access to consultant neurological care, and the lack of good quality data on neurological conditions. Previous studies in other areas such as cardiology have demonstrated that routinely collected patient data can be used to investigate issues like these. Research has been conducted into areas including re-visit patterns in outpatient clinics, and the effect that diagnosis has on appointment attendance.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover the disclosure of specified confidential patient information from Lancashire Teaching Hospitals NHS Foundation Trust to the student investigator in order to facilitate linkage with wider hospital data sources in order to create a pseudonymised data set for analysis.

Confidential patient information requested

Cohort

All patients who were offered an appointment with neurological services in Lancashire Teaching Hospitals NHS Foundation Trust between the 18 September 2015 and 15 January 2019. There were 5,800 appointments offered within this study period.

The following items of confidential patient information are requested for the purposes set out below:

- NHS number – sample validation and linkage,
- Hospital Number – sample validation and linkage,
- GP registration – analysis,
- Date of birth – accessed to calculate age for analysis,
- Postcode – accessed to calculate Lower Super Output Area (LSOA) for analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

The Sub-Committee considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide further justification to support the requirement to retain GP practice name for analysis. If this is required in its current format, explain why this would be required, or alternatively, clarify how this would be coded within the analysis dataset.**

The applicant explained that GP practice information was necessary for the purposes of analysis to identify whether it is a significant factor in referral rates. This would also enable recommendations for targeted interventions to be made in certain locations (if the statistical analysis supports this). It was recognised that retaining the actual GP practice name could represent a risk for identification, especially in small populations. As such the applicant confirmed that GP Practice name would be replaced in the analysis information with a linked code (the key to which the researcher will not have access to).

The Sub-Committee received the response and raised no further issues in this area.

2. **Provide details of the communications strategy which will raise the profile of the proposed activity within the public arena and offer a mechanism by which patients can object to the use of their data within the study. Copies of any documentation which would be used to facilitate this strategy should be provided for review.**

A poster document was provided which would be displayed in the neurology outpatient clinics at the Royal Preston Hospital (RPH). The document provided details of how objection could be raised. Further details were also provided around the wider patient and public involvement and engagement activity which was planned.

The Sub-Committee received the documentation and supplementary information and raised no further queries in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Lancashire Teaching Hospitals NHS Foundation Trust has a satisfactory grade on V14.1, 2017/18).**

Name	*Notes*
Dr Tony Calland MBE	Chair
Ms Sophie Brannan	CAG Lay Member
Dr Liliane Field	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Ms Clare Sanderson	Alternate Vice-Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Deciphering AMD by deep phenotyping and machine learning - PINNACLE retrospective study**

CAG reference: **19/CAG/0046**

REC Reference: **19/WA/0079**

IRAS Project ID: **259360**

Context

Purpose of application

This application from the University of Southampton set out the purpose of medical research which aims to use retrospective medical imaging and clinical data understand whether machine learning computer algorithms can be used to discover imaging markers of retinal aging and to predict individual progression and conversion to late Age-Related Macular Degeneration. This is a collaborative project which involves sites in Vienna and Switzerland combining anonymised patient images and information to test computer software.

University Hospital Southampton Foundation Trust and Moorfields Eye Hospital will be providing patient images and data in England. Optical Coherent imaging tomograms (OCT) images will be extracted from clinical databases on site the company which created the imaging software. The images will include confidential patient information which cannot be removed prior to extraction. The research team will use the confidential patient information present on the OCT images to wider clinical information within the patient's hospital record. Once linked, all items of confidential patient information will be removed from the dataset which will be used in the study analysis. A linkage file will be created and held onsite by a member of the clinical care team.

The study will also request supplementary information and samples from the UK Biobank; however, this information will be released to the applicant in an anonymised format and is out of scope of the CAG application.

Support is requested to allow the extraction of confidential patient information from patient records at University Hospital Southampton Foundation Trust and Moorfields Eye Hospital by the software company which designed the OCT imaging software. Support is also required to enable the research team to use specified items of confidential patient information to facilitate the linkage of OCT images and wider clinical data held within patient's medical records.

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

Confidential patient information requested

Cohort

Patients aged over 50 years who underwent OCT imaging at University Hospital Southampton Foundation Trust and Moorfields Eye Hospital. It is estimated that 72,000 scans will be included from these sites. The time frame for patient inclusion is 01/01/08-31/12/18.

The following items of confidential patient information are requested for the purposes described:

- Name – present on extracted OCT images,
- Hospital ID – to facilitate linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. Confirm the start and end date of the patient inclusion timeframe.

The time frame for patient inclusion was confirmed as 01/01/08-31/12/18.

The response was received, and no further issues were raised in this area.

2. Provide further information around the cohort size to explain how many patients would be included in the overarching sample of 13,000 scans.

The applicant responded to explained that when checking through the practicalities of extracting the data, it had been discovered that the initial estimations provide in this area were extremely conservative. From Moorfields the number of patients will equate to about 25,000. From Southampton this figure is around 47,000.

The Sub-Committee acknowledged that the scope of support had been extended considerably from the initial estimation. Members recognised the identified public interest in the proposal and were content to provide a recommendation of support.

3. **Clarify discrepancies between the items of confidential patient information cited as required for linkage between the CAG application form, the protocol and the data sharing plan. Confirmation is required of the specific data items which would be used to facilitate linkage within the English sites.**

The applicant confirmed that patient ID would be used. This will be changed to a study ID as the point of linkage of image data (OCT scans) and electronic medical information.

The Sub-Committee received the response and raised no further issues in this area.

4. **Confirm who would facilitate the linkage between OCT scans and wider clinical information which would be used for analysis.**

It was clarified that this would be facilitated by the local NHS IT department who will provide access to the OCT scans and wider clinical information. The data manager from Vienna would link the records, using their software, while being overseen by a member of the local research team.

The response was received and no further issues were raised in this area.

5. **Provide finalised drafts of website text which would be displayed on the Southampton University and Hospitals Trust websites for consideration. It is noted a telephone number and postal address should be provided to facilitate dissent.**

The applicant provided a draft of the website text for review.

The Sub-Committee considered the document which was provided. Members commented, from the detail presented, a member of the public may struggle to understand that confidential patient information would be processed to enable the creation of the dataset to be used in analysis. It was also noted that the document did not explain that a legal basis had been established, via seeking support under Section 251 of the NHS Act 2006 and its Regulations to legitimise the processing which would be undertaken without consent.

It was also noted that the text made reference to the Information Commissioner's Office but did not provide explanation of what the entity was. It was also noted that the ordering of the text could be changed to provide the project specific objection mechanism prior to informing patients that future research would be carried out on an anonymised dataset.

The Group agreed that further work was required on the drafted website text to make this more accessible to a lay audience. It was agreed that support under the Regulations would be recommended on the basis that this revised text was provided within two months of this outcome letter.

6. **Confirm that patient notification information would also be displayed on the Moorfields Eye Hospital website.**

This was confirmed.

No issues were raised by the Sub-Committee.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

3. The website notification text should be revised to address the following points. A copy of the final draft should be provided within two months of the date of this letter for review.
    a. Provide a clearer explanation that confidential patient information would be processed in order to create the analysis dataset,
    b. Explain that a legal basis in relation to the common law duty of confidentiality had been established to legitimise this processing without seeking direct consent from patients,
    c. Information around the patient's right to object to the inclusion of their data in this study should be relocated to an earlier point in the text,
    d. It is recommended that the reference to the Information Commissioner's Office is explained.
4. Favourable opinion from a Research Ethics Committee **(Confirmed 20 March 2019)**
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: University Hospital Southampton Foundation Trust and Moorfields Eye Hospital both have published satisfactory reviewed grades on V14.1, 2018/18.)**

Name	*Notes*
Dr Murat Soncul	Alternate Vice-Chair
Ms Diana Robbins	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Triage-HF Plus: Cardiac Implantable Electronic Device Remote Monitoring Combined with Telephone Triage to Identify and Manage Worsening Heart Failure**

CAG reference: **19/CAG/0055**

Context

Purpose of application

This application from Manchester University NHS Foundation Trust set out the purpose service evaluation which aims to follow-up patients who registered for remote care monitoring via the Medtronic CareLink platform to assess the current care monitoring pathway operated by the Trust and assist in the development of future state care models.

Medtronic CareLink transmissions from the ambulatory Cardiac Implantable Electronic Device (CIED) population are routinely reviewed as part of standard clinical practice. Advances in heart failure diagnostics mean that it is possible to identify patients at risk of worsening heart failure using information from their implanted device. The Medtronic 'Heart Failure Risk Score' (HFRS) uses input from integrated device diagnostics to detect changes in the patient's key physiological parameters, stratifying patients as low, medium or high-risk of a heart failure event in the next 30 days. Since 2016, the Trust has used HFRS-based alerts for the remote identification of worsening heart failure in CIED patients who are enrolled in the CareLink platform. High-risk HFRS alerts prompt a telephone consultation with the patient, using the information provided by the remote transmission and patient reported symptoms appropriate clinical actions in line with clinical guidelines are instigated. The Trust refers to this as the 'Triage-HF Plus pathway'.

The purpose of the application is to link confidential patient information in relation to the patient cohort enrolled on the care link platform with Hospital Episodes Statistics (HES) and ONS Mortality information held by NHS Digital in order collect 30 and 90 day and 12 month outcome data (elective and non-elective hospital attendance and mortality information) to facilitate evaluation of the Triage-HF Plus Pathway.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All patients fitted with a Cardiac Implantable Electronic Device under the care of the Manchester University NHS Foundation Trust, who have consented to remote monitoring via the CareLink platform. It is estimated that there are 1,010 patients eligible for inclusion.

The following items of confidential patient information will be disclosed from Manchester University NHS Foundation Trust to NHS Digital to facilitate linkage with HES and ONS:

- NHS number,
- Date of birth,
- Sex,
- Postcode.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's below response to the request for further information requested in the provisionally supported outcome in correspondence.

1. **Clarify the expected timeframe for the data linkage process and confirm when NHS Digital will be deleting confidential patient information in relation to the cohort to establish the exit strategy from support.**

The applicant explained that once support under the Regulations was in place for the application activity, an application would be made to NHS Digital to undertake data-linkage. Once the linked data has been returned to the IAO, statistical analysis will be undertaken. Upon completion and verification of the analysis, the source (linked) data received from NHS Digital can be destroyed upon expiry of the Data Sharing Agreement. Similarly, the corresponding confidential patient information held by NHS Digital can be destroyed at the expiry of the Data Sharing Agreement. The specific date is yet to be confirmed, but the applicant envisaged this to be after data analysis and verification has been completed, and within 12-months of receipt of the data from NHS Digital.

The Sub-Committee received the response and raised no further issues in this area.

2. **Patient views around the use of confidential patient information without consent to achieve the project aims should be tested. Provide an overview of any activity which was undertaken to test the acceptability of the processing together with feedback provided. If the responses given are negative, the CAG would take this into account when considering whether support can be recommended, or whether further information is required.**

The applicant provided a letter from the panel administrator for the Manchester Academic Health Sciences Centre (MAHSC) Patient-Public Involvement panel, following attendance on 14 March 2019. This provided an overview of the activity and evidenced that the panel was in support of the application.

The Sub-Committee received the document and raised no further queries in this area.

3. **Patient information materials should be updated to include a contact email address to enable queries and objections to the study to be raised by patients. Provide revised documentation, including updated version control information.**

The applicant made the requested revisions and provided revised documentation for review.

The Sub-Committee received the revised documentation and raised no further issues in this area.

The following point in raised for information purposes, as it was recognised that amending consent process for direct care activities was not likely to be within the applicant's remit to progress directly:

4. **Consideration should be given to making improvements to the patient consent process, to include data sharing for service evaluation purposes, to prevent the need for future applications of this kind.**

The applicant thanked the CAG for the recommendation and agreed that changes could be made to improve the existing patient consent process. The applicant explained that they had begun to make arrangements to broaden the consent model of future patients so that, at the time of their enrolment onto the remote monitoring platform. It was also confirmed that specific consent would be obtained to include data sharing for service evaluation purposes.
The Sub-Committee received the response and raised no further issues.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submis**sion (Confirmed - NHS Digital has a Standards Met grade on the Data Security and Protection Toolkit submission for 2018/19).**

Name	*Notes*
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Piloting a new questionnaire to understand patient experiences of liver transplant services**

CAG reference: **19/CAG/0051**

Context

Purpose of application

This application from the Picker Institute Europe set out the purpose of undertaking a pilot assessment of patient experiences of Liver Transplant Services in England. The aim of the study is to conduct a pilot survey of adults who have received a liver transplant within the last three years, but more than three months ago, to:

1. Increase understanding of the views, preferences and experiences of people who have received liver transplants in England and Scotland.
2. Develop and pilot a national Patient Reported Experience Measure (PREM) as a tool for future assessment of patient experience of liver transplant services in England and Scotland
3. Gather comparative evidence of patient experience of liver transplant as a basis for improving transplant services across England.

The patient cohort will be identified from seven specialist NHS Transplant centres within England as follows: Royal Free Hospital, King's College Hospital, University Hospitals Birmingham, Cambridge University Hospitals, Leeds Teaching Hospitals and Newcastle Hospitals. A further site will be located in Edinburgh; however, this is out of scope for the CAG application. Participants will be sent a paper questionnaire surveying their experiences of pre-transplant, transplant, and post-transplant care.

Picker runs and coordinates the NHS Patient Survey Programme (NPSP) under the title of the Survey Coordination Centre. In addition, Picker is an approved NHS contractor. The patient experience of Liver transplant services in England survey, will adopt a similar methodology to the NHS Patient Survey Programme (NPSP) – alterations to this methodology will be described below, mainly:

- Picker will be addressing and mailing out the survey packs to avoid patient identifiable information being shared with sub-contractors.
- Picker will have access to the mailing data in order to circulate the survey packs,
- Data files will be password protected and saved on a non-network drive with restricted access to necessary staff,

- The mailing file will be kept separate to the response file, linked by a unique reference, to ensure that survey responses are pseudonymised and there is no risk of linkage between the two files.

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

Confidential patient information requested

Cohort

Liver transplant patients aged over 18 years who have had a liver transplant between three months and three years prior to extraction of the patient sample at one of the following sites: Royal Free Hospital, King's College Hospital, University Hospitals Birmingham, Cambridge University Hospitals, Leeds Teaching Hospitals and Newcastle Hospitals. It is estimated that 3,000 patients would be included in the study.

The following items of confidential patient information are requested in order to facilitate the distribution of the survey and no analysis purposes:

- Full name and title,
- Full address and postcode,
- Date of transplant,
- Treatment centre code,
- Study specific ID,
- Month and year of birth,
- Sex.

Confidentiality Advisory Group advice

The applicant's response to the request for further information detailed in the provisionally supported outcome was considered by Chair's Action in correspondence.

1. **Confirm that month and year of patient birth would be requested to ensure that patient's eligibility could be assessed prior to invitation.**

The applicant confirmed that both the month and year of patient birth would be requested to ensure patient's eligibility prior to invitation. The sampling instructions will be amended to reflect this.

The response was received, and no further issues were raised in this area.

2. **A nominated individual within the liver transplant care team at each site should be appointed to manage the patient objection mechanism. Provide confirmation to this point.**

The applicant confirmed that they had understood the points raised by the Group with regards to patient dissent and the potential issue of patient's disclosing personal details and health status to the PALS service.

It was explained that this dissenting mechanism had been selected due to the fact that it is followed in the National Patient Survey Programme. It was also felt to be the most comfortable option for patients, in terms of feeling able to opt-out from the process. Some of the transplant centres have low throughputs and are relatively small so in these instances, the chance of a patient being known to members of staff on these liver transplant teams could be quite high. Therefore, it would not always be possible to ensure that there is someone distant from the person's care available to fulfil this role.

Furthermore, it was explained that some patients may feel some anxiety about telling the team that had provided direct care to them that they wish to opt out. The applicants explained that the believed that the PALS would be viewed as a more 'impartial' dissent option for such patients. It was further noted that the applicant did not wish to burden the transplant teams further, who are very busy clinically and already assisting with the survey administration process by facilitating the display of posters and sampling of patients.

The response was considered by an Officer of the CAG who accepted the rationale provided by the applicant to support the proposed dissenting mechanism, acknowledging the potential difficulties for patients and the additional burden for clinicians. The dissenting mechanism was accepted and no further issues were raised.

3. **Revise the poster to include a statement advising that patient's care would not be affected by a decision to opt-out of participation in the survey.**

The applicant provided a revised document which addressed this point.

The document was received, and no further issues were raised in this area.

4. **Provide copies of the covering letter and questionnaire which would be used for the project.**

The applicant provided copies of the requested documentation.

The documents were received and noted. No further issues were raised in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: Picker Institute Europe has a satisfactory reviewed grade on V14.1, 2018/18)**

Name	*Notes*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Lancashire ANCA Vasculitis and Glomerulonephritis Study**

CAG reference: **19/CAG/0060**

IRAS project ID: **257174**

REC reference: **19/NS/0054**

Context

Purpose of application

This application from Lancashire Teaching Hospitals NHS Foundation Trust aims to review the epidemiology and outcomes of patients with small vessel vasculitis from a single centre by undertaking a retrospective observational study to help address current knowledge gaps. Pauci-immune small vessel vasculitis is a rare disease with a peak incidence of between 65-74 years.

Patients will be identified from Department of Renal Medicine at Lancashire Teaching Hospitals NHS Foundation Trust as part of a single centre study. A participant list will be identified from a kidney biopsy registry dated from 1994 - 2017 and at a local registry of patients with vasculitis, which is held by the Renal Department at the participating Trust. Information will be extracted from patient records to create a pseudonymised data set for analysis.

A recommendation for class 1, 4, 5 and 6 support was requested to allow activities as described in the application.

Confidential patient information requested

Cohort

All patients with biopsy proven ANCA-associated small vessel vasculitis treated at Lancashire Teaching Hospitals NHS Foundation Trust between 01 January 1994 and 31 December 2017. The definition of ANCA-associated small vessel vasculitis as outlined by the 2012 Chapel Hill Consensus Conference will be used. There are 287 eligible patients to be included.

The following items of confidential patient information are required for the purposes as set out below:

- Name – sample validation and linkage,
- NHS number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Date of death – anonymised for analysis,

- Sex – analysis.

Confidentiality Advisory Group advice

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome on behalf of the CAG.

1. **Confirm what format date of death would be retained in for analysis.**

The applicant confirmed that date of death with be delinked from identifiable participant information and be recorded in an anonymised format against the participants corresponding study number. Date of death will then be evaluated against other information gathered to determine outcomes of patient and renal survival according to therapy.

The response was received, and no further issues were raised in this area.

2. **Provide details of the communications strategy which will raise the profile of the proposed activity within the public arena and offer a mechanism by which patients can object to the use of their data within the study. Copies of any documentation which would be used to facilitate this strategy should be provided for review.**

A poster outlining the study activity will be placed in relevant out-patient clinical areas in order to raise the profile of the proposed study and offer access to further information as well as a means by which patients can object to the use of their information if wished. This will also be listed on the research and innovations webpage on the Lancashire NHS Foundation Trust website. The document was provided review.

The response was received and no further issues were raised.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed)**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Lancashire Teaching Hospitals NHS Foundation Trust has a satisfactory reviewed grade on V14.1, 2017/18).**

Name	*Notes*
Ms Clare Sanderson	Alternate Vice-Chair
Dr Lilianne Field	CAG Member
Professor Jennifer Kurinczuk	CAG Member
Mr Marc Taylor	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Does surgery for asymptomatic carotid stenosis reduce the long term risk of dementia, stroke, death and other important health outcomes? Extended UK post-trial follow-up of the Asymptomatic Carotid Surgery Trial (ACST-1). Phase 2**

CAG reference: **18/CAG/0195**

IRAS project ID: **249685**

REC reference: **18/LO/1866**

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertake a follow-up of patients who were previously consented participants in the ACST-1 trial, to evaluate the prevalence of dementia in this patient cohort. The ACST-1 trial randomly allocated participants with tight narrowing of the carotid artery to either immediate carotid surgery (endarterectomy) or to avoid surgery unless they had symptoms. The trial recruited patients between 1993 and 2003 and reported findings, for patients who underwent endarterectomy, that the risk of stroke was reduced by five years and for at least 10 years after the operation. There is suggestion that the narrowing of the carotid artery carries a higher risk of developing dementia.

The proposed follow-up study will measure cognitive impairment in living patients within the original ACST-1 patient cohort, via a single postal assessment requesting completion of a validated questionnaire 'Informant Questionnaire on Cognitive Decline in the Elderly'. The application has been submitted to the CAG to enable the survival status to be checked for the historic participant cohort and contact information held with consent to be updated via the NHS Spine by NHS Digital, to enable postal invitations and questionnaires to be distributed. Longer term follow-up of the ACST-1 cohort was carried out in 2016, via linkage with administrative datasets held by NHS Digital. This linkage confirmed that a proportion of the original cohort was now deceased – these individuals would not be included in the proposed application activity.

A recommendation for class 2, 3 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

The historic patient cohort of the ACST-1 trial. 195 patients from the original cohort of 230 were known to be alive at last follow-up. This sub-cohort would be followed up via NHS Digital, prior to invitation to the proposed study.

Confidential patient information will be disclosed from the University of Oxford to NHS Digital to facilitate linkage with NHS Spine and ONS information to perform survival checking. The following items of confidential patient information are required for the purposes stated:

- Name – linkage,
- NHS Number – linkage,
- Date of birth – linkage,
- Full postal address – to facilitate postal invitation,
- Date of death – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

A sub-committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide further information around the relationship between the proposed application activity and that which received a recommendation of support under the Regulations via application 16/CAG/0122.**

The applicant provided a detailed overview between the current submission and previously considered CAG application. It was also clarified that University of Oxford had been involved with the initial ACST-1 trial as administrative support and had always retained the confidential patient information in relation to the cohort.

The Sub-Committee received the response and raised no further queries in this area.

2. **Copies of the original information and consent materials used in the ACST-1 trial should be provided for consideration.**

The documents were provided for review.

The Sub-Committee considered these alongside the response to point one above and raised no further queries.

3. **Further consideration should be given to the management of patients who do not respond to or actively decline the invitation to participate in this follow-up study,**

and the ongoing retention of any confidential patient information held with support under the Regulations and, if appropriate, historic consent. Provide details of an exit strategy in relation to this sub-cohort of patients, together with any revised recruitment materials as necessary.

The applicant confirmed a mechanism of patient dissent had been introduced into the study, It was also noted that following the initial approach for consent, one further final reminder would be sent three weeks later. All confidential patient information will be destroyed in relation to those patients who did not respond to this final reminder request.

The Sub-Committee received the response and raised no further queries.

4. **Provide a copy of the text which would be displayed on the Alzheimer's Society website.**

The text was provided for review.

The Sub-Committee received the document and raised no further issues in this area.

5. **Confirm that the link between the Alzheimer's Society website and the study website has been activated.**

The applicant confirmed that this had been activated.

The Sub-Committee received the confirmation and raised no further issues.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University of Oxford-Medical Sciences Division-Nuffield Dept. of Population Health-Clinical Trials Service Unit and NHS Digital both have a published satisfactory reviewed grade on version 14.1, 2017/18**).

Name	*Notes*
Ms Clare Sanderson	Alternate Vice-Chair
Dr Martin Andrew	CAG Member
Dr Barry Evans	CAG Member
Dr Rachel Knowles	CAG Member
Mr Anthony Kane	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **International Surgical Outcomes Study: Long-term survival**

CAG reference: **18/CAG/0205**

IRAS project ID: **241147**

REC reference: **18/YH/0310**

Context

Purpose of application

This application from Queen Mary University of London on behalf of Bart's Health NHS Trust set out the purpose of medical research to follow-up patients who were enrolled in the International Surgical Outcomes Study (ISOS). ISOS was an international seven-day cohort study of adults undergoing in-patient elective surgery that provided detailed data describing post-operative complications and associated mortality.

Part of the planned analysis of ISOS was to follow up patients by linking to national datasets via confidential patient information to determine the long-term survival. ISOS completed patient recruitment, and closed, in 2014 and patient consent for linkage to national datasets to enable long term follow-up of those recruited within England was obtained. NHS Digital has subsequently advised the applicant that the historic consent is no longer deemed to be valid for the purposes of linkage, which brought about the application to the CAG.

A recommendation for class 1and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

Patients who consented to participate in the International Surgical Outcomes Study. The original study inclusion criteria was any patient aged over 18 undergoing elective surgery.

Confidential patient information will be released from Barts Health NHS Trust to NHS Digital to facilitate linkage with HES and ONS information. The following items of confidential patient information are required for the purposes specified:

- ISOS Study ID – sample validation and linkage,
- Name – sample validation and linkage,
- Sex – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage,
- Date of death – analysis.

Confidentiality Advisory Group advice

The applicant provided a written response to the CAG's request for further information, as detailed within the previously issued provisionally supported outcome. This was considered by the Confidentiality Advice Team.

1. **Revise the website text to provide a clear explanation that the extended follow-up is being carried out with support under the Regulations. The items of confidential patient information referenced in the text should be checked against those cited in the CAG application, to ensure these are fully referenced.**

The applicant provided a document which contained the revised information to be displayed on the website. The revised text included an explanation that the extended follow-up was undertaken with support under the Regulations. The items of confidential patient information to be disclosed were also listed.

The documentation was received and no further queries were raised.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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

1. Support will extend to the provision of follow-up data for years two and three only.
2. Support does not extend to the provision of the first 12 months follow-up data as a practicable alternative of valid consent under the common law already exists for this activity. Note that support cannot be provided where an alternative lawful basis is already in place. The activity in relation to the initial 12-month follow-up can proceed on the basis of the informed consent provided by participants.
3. Favourable opinion from a Research Ethics Committee (**Confirmed**).

4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - NHS Digital and Barts Health NHS Foundation Trust have published satisfactory reviewed grade on V14.1. 2017/18**).

2. NEW AMENDMENTS

Name	*Notes*
Dr Tony Calland MBE	Chair
Miss Katy Cassidy	Confidentiality Advisor

Application title: Epidemiology of Cancer after solid Organ Transplantation (EpCOT)
CAG reference: 16/CAG/0121
IRAS reference: 183974
REC reference: 15/YH/0320

Amendment request

This amendment has been submitted to request support to increase the items of confidential patient information disclosed to NHS Digital to facilitate the required linkage and to change the data processor.

Support currently extended to the disclosure of information from UK Transplant Registry, the UK Renal Registry and National Cancer Intelligence Network to NHS Digital to facilitate linkage with HES, ONS and the General Practice Extraction Service datasets by NHS Number alone. This amendment is seeking support to include date of birth, gender and postcode within this disclosure for linkage purposes.

The applicant explained that NHS Digital had advised that linking by NHS number alone may lead to instances of missed linkages, as there was no mechanism to check the linkages made against other identifiers. NHS Digital advised that the specified additional identifiers are included to maximise accuracy of the linkage process. Access to confidential patient information would continue to be limited to NHS Digital, acting as processor for the linkage.

The amendment also sought support for a change the data processor for study analysis from the University Hospitals Birmingham to the University of Birmingham, which was more appropriately placed to undertake the analysis. It was confirmed that University Hospitals Birmingham would remain as controller for the application purposes.

The timeframe and the rest of the study processes and flow remain the same.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair recognised that the additional items of confidential patient information requested to facilitate linkage were standard when seeking linkage via NHS Digital. It was acknowledged that these additional patient identifiers would increase linkage accuracy.

The change to the processor undertaking the study analysis was noted. The Chair was assured with the rationale provided to support this change, to ensure that the analysis would be carried out by the most appropriately qualified members of the overarching research team.

No issues were raised with the amendment and support was recommended.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed: The University of Birmingham has a satisfactory reviewed score for IGT v14.1 2017/18. NHS Digital has a satisfactory reviewed score for IGT v14.1 2017/18. University Hospitals Birmingham NHS Foundation Trust has a satisfactory reviewed score for IGT v14.1 2017/18)**
2. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed)**.