Health Research Authority

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

**April 2020**

## 1. New applications

### a. 19/CAG/0230 - Advanced analytics in primary care: provision of actionable information for quality improvement for antibiotic reduction, care advice and medication safety (ACTION)

| Name | Notes |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

**Purpose of application**

This application from the University of Manchester set out the purpose of medical research that seeks to evaluate the impact of online feedback dashboards, used by health professional, on improvements in patient care, the rate of antibiotic prescriptions and the incidence of potentially hazardous prescribing and monitoring.

The applicants are seeking to make better use of the data available in Electronic Health Records (EHRs) and to present it in more user-friendly ways to health professionals. Three eLab dashboards will be created, the PINGR (Performance Improvement plaN GeneratoR), SMASH (Smart MedicAtion Safety dashboard) and Building Rapid Interventions to reduce antimicrobial resistance & over-prescribing of antibiotics (BRIT). GP practices and other NHS sites in Greater Manchester and the Wirral will be recruited to the study and sign up to the service. Each practice involved will receive the eLab dashboards. The effectiveness of using the intervention will be evaluated quantitatively using an interrupted time series study design, by comparing the numbers of patients who receive an appropriate antibiotic in each practice before and after implementation of the eLab dashboards. Log files of the eLab dashboards will be examined to investigate the frequency with which the dashboards are used and how this varies between practices and over time.

ResearchOne will generate pseudonyms for primary care data, using a SALT, and transfer this to NHS Digital, who will generate HES data with pseudonyms and the research team at the University of Manchester will receive de-identified primary and secondary care data. It would be technically possible for NHS Digital to identify patients in the ResearchOne cohort, therefore the applicants sought support under Section 251 for this data linkage.

A recommendation for class 1 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** | Male and female patients from birth upwards with an infection whose data was included in ResearchOne.<br><br>Greater Manchester and Wirral has a population of 3 million people, and the applicant noted that this was the |

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| | potential maximum number of patients whose data would be included. |
| **Data sources** | 1. ResearchOne<br>2. HES data held by NHS Digital |
| **Identifiers required for linkage purposes** | No items of confidential patient information are required for data linkage. Linkage will be performed using a SALT ID number. |
| **Identifiers required for analysis purposes** | No items of confidential patient information will be required for analysis. |

**Confidentiality Advisory Group advice**

The applicant's response to the provisionally supported outcome was considered by the CAG.

1. **Clarify that the lawful basis relied on for the processing of personal data is: Article 6(1)(e) Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.**

The applicant confirmed that this was correct. The CAG reviewed this response and was satisfied that the query had been addressed.

2. **Clarify that the lawful basis relied on for the processing of special category data is Article (9)(2)(j) Processing is necessary for scientific research purposes in accordance with Article 89(1).**

The applicant confirmed that this was correct. The CAG reviewed this response and was satisfied that the query had been addressed.

**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 standard conditions of support as set out below.

**Specific conditions of support**

1. Favourable opinion from a Research Ethics Committee. **Confirmed 09 March 2020.**

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. **It was confirmed that the relevant DSPT submission related only to NHS Digital.**

## b. 19/CAG/0208 - Aetiology, timing and risk factors for tuberculosis-associated deaths in London: a retrospective, case-control study

| Name | Notes |
|---|---|
| Dr Patrick Coyle | CAG Vice-Chair |
| Mr Marc Taylor | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

## Purpose of application

This application from the London North West University Healthcare NHS Trust set out the purpose of medical research that seeks to investigate the causes and timing of death for people with a diagnosis of tuberculosis who either die during tuberculosis treatment or in the six months following the end of treatment.

Tuberculosis is an infection, usually occurring in the lungs, that affects approximately 5,000 people within the UK each year. Patients are generally treated with a course of antibiotics over at least six months. This treatment will cure the majority of patients, but around 5% will die during the treatment. Some deaths will be related to the tuberculosis infection itself or the treatment.

The applicants will carry out a retrospective review of case notes and other specified medical records for patients who have died of tuberculosis and a control group, age-matched to the patient group. Public Health England will generate a list of patients who died from tuberculosis independently of the London Tuberculosis Register. These data will be sent to the Chief Investigator, who will cross check it with a list of patients known to have died from TB generated from each of the local London Tuberculosis Registers, held at London North West University Healthcare NHS Trust and Bart's Health NHS Trust, to check for omissions. Age matched controls will be randomly selected from the local London Tuberculosis Registers as well. The Chief Investigator will then access electronic confidential patient records at the two Trusts involved. The records of patients at London North West University Healthcare NHS Trust will be accessed by the Chief Investigator for this project, who is also a member of the direct care team. The Chief Investigator will also access patient records held at Bart's Health NHS Trust, where they are not a member of the direct care team. Paper records may need to be requested, if the electronic record is incomplete, but the applicant anticipated that this would happen rarely.

A recommendation for class 1, 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** | 225 Male and female patients aged 16 years and over, diagnosed with tuberculosis and who died during treatment for tuberculosis, prior to the start of treatment or in the six months following the end of treatment<br><br>225 Age-matched controls who survived treatment for tuberculosis will also be included. |
| **Data sources** | 1. The London Tuberculosis Register, held at London North West University Healthcare NHS Trust and Bart's Health NHS Trust<br>2. Public Health England record of tuberculosis related deaths in London<br>3. Electronic and paper records held at London North West University Healthcare NHS Trust<br>4. Electronic and paper records held at Bart's Health NHS Trust |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Hospital ID number<br>4. Date of birth<br>5. Date of death |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Gender<br>3. Ethnicity |

**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 Group noted the public interest in the proposed activity.

## 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 advised that it was not practicable to seek consent as half of the cohort will be deceased. A number of the age-matched control group may also have died. The records may be up to ten years old, and up to date contact details may not be available.

The applicant also noted that the patient group included a significant number of migrants, who may have moved away from the catchment area. Restricting recruitment to patients who were contactable may introduce bias by excluding younger patients, who were more likely to be mobile, from the research. The Group accepted the rationale given as to why consent could not be sought.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data from the London Tuberculosis Register with a database held by Public Health England to ensure that the cohort is accurately identified. The Group accepted that this could not be undertaken in any other way.

## Data Access arrangements

The Group noted that the applicant would be accessing confidential patient information onsite at Bart's Health NHS Trust and London North West University Healthcare NHS Trust. The Caldicott Guardian at London North West University Healthcare NHS Trust had confirmed that they supported the study. Members asked if the Caldicott Guardian at Bart's Health NHS Trust was also satisfied with the access arrangements.

## '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 objection 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.

Posters and leaflets will be placed in the tuberculosis clinic waiting rooms. These will explain the planned activities and the patient group involved, and also invite the control group patients to request more information or dissent from inclusion. This approach had been decided upon because it was felt that attempting to directly contact possible

survivors by phone or post would risk disclosing medical information to other occupants of their address, surviving relatives or unrelated individuals if the intended recipient has moved.

The control cohort, who had TB and survived, were given the opportunity to dissent via the posters and leaflets made available in the tuberculosis clinic waiting rooms at both Bart's Health NHS Trust and London North West University Healthcare NHS Trust sites. The Group noted that not all patients would have English as a first language and queried whether the poster and leaflet would be provided in other languages.

The Group asked that the reference to the CAG in the leaflet was amended to read, "However, in exceptional cases where this isn't possible we apply for special permission from the Health Research Authority based on review by the Confidentiality Advisory Group."

The Group queried if the National Data Opt-Out applied by NHS Digital would be respected and if any checks would be undertaken to determine if historic dissent from inclusion in research had been recorded.

## 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 proposed methodology was discussed with the London North West University Healthcare NHS Trust TB Multi-Disciplinary Team, who had approved the methodology.

Questionnaires and focused interviews were conducted to test the acceptability of this research plan with current tuberculosis clinic patients. The patients completing the questionnaires and interviews were from a range of age groups and ethnicities approximately representative of the TB clinic patient population as a whole.

The participants were provided with a written summary explaining the aims of the project, the scope of the data review, and the pathway of data access and use. The issues with obtaining consent were also explicitly explained. To ensure comprehension the participants were also given an oral summary of the information and the opportunity to clarify any points or ask for more information.

The Group noted that the approach described was proportionate to the scope of the study, given that a significant number of patients were deceased.

**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. Provide assurance that the Caldicott Guardian at Bart's Health NHS Trust is satisfied with the access arrangements to information within that Trust.

2. Further information on patient notification and dissent is required;

    a. Clarify if the National Data Opt-Out will be respected.

b. Clarify if any checks will be undertaken to determine if historic dissent from inclusion in research has been recorded.

3. The Group noted that not all patients would have English as a first language and queried whether the poster and leaflet would be provided in other languages.

4. The Group asked that the reference to the CAG in the leaflet was amended to read, “However, in exceptional cases where this isn’t possible we apply for special permission from the Health Research Authority based on review by the Confidentiality Advisory Group.”

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 (Provisional)

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. **Pending**

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.

    - **Confirmed: Bart’s Health NHS Trust (by NHS Digital email dated 18 September 2019) and Public Health England (by NHS Digital emailed**

**dated 02 September 2019) have a confirmed 'Standards Met' grade on DSPT submission 2018/19.**

- **Pending – confirmation that London North West University Healthcare NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 is required.**

## c. 19/CAG/0187 - Multifrequency Bioimpedance in the Early Detection of Lymphoedema after Axillary Surgery

| Name | Notes |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Dr Martin Andrew | CAG Member |
| Dr Malcolm Booth | CAG Member |
| Mr David Evans | CAG Member |
| Dr Harvey Marcovitch | CAG Member |
| Mr Andrew Melville | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to determine whether bioimpedance electrical analysis (BEA) or perometer assessment is the optimal technique to predict early development of lymphoedema and to determine the optimum cut-off value for either multi-frequency bioimpedance or perometer arm swelling.

The original trial was a clinical investigation of a medical device, set up to determine whether multi-frequency bioimpedance electrical analysis (multi-frequency BEA) could be used instead of a fixed perometer to detect early arm swelling and predict

lymphoedema development 2 years after axillary surgery. Lymphoedema (arm swelling greater than 10% volume increase) occurs in up to 35% of patients after removal of all axillary lymph nodes during treatment for breast cancer. Lymphoedema is difficult to treat and prevention would be a better and more cost-effective strategy. Current methods for measuring lymphoedema are based on tape measurement of arm circumference or perometer arm measurements, which involves 3D scanning of the arm, using non-invasive techniques, to measure the arm volume. Perometer measurement, to generate a 3D profile of the arm and look at changes over time from before surgery, has suggested that early increases in arm volume within 6 months of surgery predict the later development of lymphoedema by 18 months or 2 years. Multi-frequency BEA is a non-invasive technique developed to measure total water content, which involves passing an extremely small electrical current through the body and measuring the impedance (or resistance) of the flow of this current.

Patients in the trial were identified and approached by members of the direct care team and their participation proceeded on a consented basis. The original trial required a 60-month follow-up period to look for lymphoedema and recurrence. The applicants now plan to link the data collected during the original trial to the following NHS databases: Hospital Episodes Statistics (HES), Multiple Index Deprivation Domain (MIDD), the Office of National Statistics (ONS), National Radiotherapy Dataset (RTDS) and National Cancer Registration and Analysis Service (NCRAS). The linkage will be undertaken by Public Health England (PHE). The applicants had not always received notification that participants had died, experienced recurrence or been lost to follow-up and the data linkages via PHE would be undertaken in order to establish a fully saturated follow-up dataset for the study. PHE had determined that patients in the original trial had not been sufficiently informed of the scope of the follow-up involved and that the consent given did not cover the planned follow-up. The applicants are therefore seeking support under Section 251 and its Regulations to undertake the data linkages.

A recommendation for class 3, 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** | 1232 participants in the Multifrequency Bioimpedance in the Early Detection of Lymphoedema. The study began in 23/07/2010 and closed to recruitment in February 2016. The study is currently in active follow-up. |
| **Data sources** | 1. Hospital Episodes Statistics (HES)<br>2. Multiple Index Deprivation Domain (MIDD)<br>3. Office of National Statistics (ONS) Mortality data<br>4. National Cancer Registration and Analysis Service (NCRAS)<br>5. National Radiotherapy Dataset (RTDS)<br>6. Cancer Waiting Times |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Date of birth<br>4. Date of death |
| **Identifiers required for analysis purposes** | 1. Date of death |

**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 Group noted the clear public interest in the research. A percentage of patients who had underwent removal of lymph nodes will develop lymphoedema and the applicants were seeking to understand the medical reason behind this.

## Cohort

The Group noted that it was unclear how many patients would be included. Page 8 of the application form referred to 11,000 patients across seven centres, however it was unclear whether this referred to the current application or what had been undertaken previously. Members requested clarification on the number of patients included in the scope of this application and that this application was to follow-up patients in the original study, and not undertaking research with new patients.

## 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**

1400 patients had been included in the original trial and a significant proportion could no longer be contacted for consent. The applicants explained that almost 10% of participants had been lost to follow-up and16% of patients were known to have died or experienced recurrence of their disease.

The issue of whether patients should be contacted and consented for the use of their data in follow-up had been discussed with a patient and public involvement and engagement group, who had recommended that participants were not re-consented. The Group accepted the rationale for not seeking consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required in order to link the data from the trial database to other, specified NHS databases, which cannot be undertaken 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 objection 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.

Participants were informed in the original consent form that they had the right to withdraw from the study at any time. A study specific privacy notice would also be included on the Manchester University NHS Foundation Trust, describing the planned linkage for the trial data with external NHS databases. This will be accessible by the public prior to the linkage process and will include contact details of the study team, should any participants wish to express dissent or concern regarding the linkage of their data. The Group reviewed the information provided and was satisfied with the dissent process and that sufficient patient notification would be carried 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 applicant advised that a group of 10 lymphoedema sufferers from the University Hospitals of South Manchester NHS Foundation Trust had been involved for 2 years in helping to develop better treatments for lymphoedema. The group had been involved in the design of the trial. Patients who developed lymphoedema following axillary node clearance surgery had also agreed to sit on the patient management group.

The University Hospitals of South Manchester NHS Foundation Trust had also involved the Patient and Public Involvement Forum to ensure patients and the public were informed of plans to carry out research. The University Hospitals of South Manchester NHS Foundation Trust ceased to exist in 2017, and the applicant confirmed that the advisory group remained in place at Manchester University NHS Foundation Trust. The team had also liaised with charities that had a role in patient support, including Breast Cancer Campaign and Breakthrough Breast Cancer to involve the public and patients in this research.

The applicants participated in a patient and public involvement and engagement focus group, which involved 3 cancer patients and a variety of staff members such as nurses, doctors and trial coordinators. Details of the questions asked and responses received were included in the application form, alongside changes made to the study design. Members of the focus group were supportive of the proposal. The Group noted the information provided and was satisfied by the patient and public engagement carried out.

**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. Provide clarification on the number of patients to be included under the scope of this application.

2. Clarify that this application is to follow-up patients enrolled in the original study and research will not be undertaken with new patients.

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 (Provisional)

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 14 June 2019.**

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.

- **Confirmed – Public Health England has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 02 September 2019.**

- **Pending - Manchester University NHS Foundation Trust does not yet have a confirmed 'Standards Met' grade on DSPT submission 2018/19.**

## d. 19/CAG/0225 - Raised intracranial pressure following intracerebral haemorrhage: association with survival and physiological variables

| Name | Notes |
|---|---|
| Dr Patrick Coyle | CAG Vice-Chair |
| Dr Malcolm Booth | CAG Member |
| Ms Sophie Brannan | CAG Member |
| Mr Myer Glickman | CAG Member |
| Ms Diana Robbins | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from University of Manchester set out the purpose of medical research which aims to explore whether increase intracerebral pressure increases the risk of death. Spontaneous intracerebral haemorrhage (ICH) accounts for 1 in 5 of all strokes. Caused by bleeding into brain tissue, it carries a high risk of death or disability. The brain sits tightly inside the skull, so any increase in pressure on the brain structure, known as raised intracranial pressure (ICP), resulting from high blood pressure, the blood clot itself or swelling of brain tissue after the bleed, may cause a worsening of stroke-symptoms. Treatments, which aim to reduce pressure in the brain after ICH,

have been a target for stroke physicians but there is currently no evidence that these measures improve outcome for patients.

The study will use existing clinical data to compare measurements of blood pressure recording from time of admission and from the first 72 hours of presentation with measurements of ICH, to assess if lowering blood pressure has an impact on ICH and patient recovery. The project will analyse patients within an existing dataset of 1500 records of patient admitted to Salford Royal NHS Foundation Trust (SRFT) following ICH, some of whom will have been treated in intensive care for the first 72 hours of their stay and had ICP measured. A patient cohort is already established for inclusion in the study, having been identified through the provision of direct care.

In order to meet the aims and objectives of this project, it will be necessary to extract additional data on a sub-set of patients (approximately 400 patients), who were treated within the intensive care unit (ITU) during the first 72 hours after ICH. The applicants will also extract all blood pressure recording for the first 72 hours of care for patients admitted to the ward. This additional clinical data, specifically clinical observation data e.g. pulse and blood pressure readings along with other measurements of central venous pressure (CVP) and intracranial pressure monitoring recorded during the first 72 hours after admission; will be extracted from the electronic patient record (EPR) and added to the research dataset. The data extraction will be undertaken by a member of the research team who is not part of the direct clinical care 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** | 1500 patients aged over 18 years, who were treated onsite at Salford Royal NHS Foundation Trust between 01 June 2013 to 31 May 2019 for acute intracerebral |

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| | haemorrhage confirmed by brain imaging. The CAG remit extends to a sub-cohort of approximately 400 patients who were treated in the critical care area. |
| **Data sources** | 1. QI database of eligible patients, Salford Royal NHS Foundation Trust<br>2. Electronic patient records, Salford Royal NHS Foundation Trust |
| **Identifiers required for linkage purposes** | 1. Hospital ID |
| **Identifiers required for analysis purposes** | 1. Sex<br>2. Ethnicity<br>3. Age |

**Confidentiality Advisory Group advice**

The applicant's response to the provisionally supported outcome was considered by a sub-committee of the CAG.

1. **The poster document should be revised to provide a clearer explanation of the patient information which would be accessed and extracted for the study. This document should also include a clearer overview of the dissenting mechanism.**

Revised documents were provided. These were reviewed by the Sub-Committee, who was satisfied by the changes made.

2. **The information sheet should be revised to more clearly explain what is meant by the restricted access to records. This document should also include a clearer overview of the dissenting mechanism.**

The revised information sheet was provided. This was reviewed by the Sub-Committee, who was satisfied by the changes made.

3. **Feedback from the user involvement activity in relation to the patient-facing material should be provided to understand the views which were expressed and how these were acted upon in the revision of the documentation.**

A summary of the panel discussions from the meeting on 27th January. Following advice from the panel, an audio-visual version of the Dissenting Information Sheet was created. This was provided as a video. The Sub-Committee was satisfied with this additional information.

4. **Final drafts of the patient-facing materials should be provided for review prior to any final recommendation of support coming into effect.**

The applicant confirmed that the final versions of the documents had been provided and would be displayed appropriately once support had been granted. The Sub-Committee was satisfied by this confirmation.

**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 standard conditions of support as set out below.

## Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 19 November 2019**

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. **Confirmed – Salford Royal NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 19 November 2019.**

## e. 20/CAG/0049

| Name | Notes |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Sophie Brannan | CAG Member |
| Dr Katie Harron | CAG Member |
| Dr Harvey Marcovitch | CAG Member |
| Dr Paul Mills | Senior Confidentiality Advisor |

**Context**

### Purpose of application

This application from King's College Hospital set out the purpose of medical research which aims to create a new dataset to aid in developing a predictive tool to estimate the degree of pregnancy-associated progression and adverse pregnancy outcomes in women with CKD, including those with rare renal disease.

Moderate-severe chronic kidney disease (CKD) affects approximately 0.9 – 3.1% of women of childbearing age and is associated with higher rates of adverse pregnancy outcomes compared to healthy women. Approximately one in three women with moderate-severe kidney disease will require dialysis or lose at least 25% of kidney

function within six months of delivery. It is estimated that over 1000 pregnancies per year in the UK are affected by moderate-severe CKD. This number is set to rise due to maternal factors associated with CKD, such as obesity and advancing maternal age, and the accessibility of assisted conception. Current risk estimates for pregnancy-associated pregnancies are based on a small, single centre study examining pregnancies between 1971 and 1997, which does not reflect contemporaneous practice or enable accurate individual risk prediction. There is also no up to date information for patients with rare renal disease, including those already receiving renal replacement therapy and kidney transplants.

Two renal datasets, the National Registry of Rare Kidney Diseases (RaDaR) and the UK Renal Register (UKRR), will be linked with two pregnancy data sets, Hospital Episodes Statistics and Maternity Services Data Set, by NHS Digital. The linked data will form a new dataset, to be used to create a prediction tool to improve the accuracy of information and the communication of risk between pregnant women with CKD and their clinicians. The datasets will be linked using NHS number and date of birth and pseudonymised linked data reported to the UK Renal Registry who will further link the data with UK Renal Registry records for renal outcomes. The UK Renal Registry will then transfer an anonymised dataset to the King's College Hospital 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** | An estimated 750 pregnant women with Chronic Kidney Disease in England |
| **Data sources** | 1. National Registry of Rare Kidney Diseases, held by the Renal Association and the UK Renal Registry, held by the Renal Association |

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|---|---|
| | 2. HES and Maternity Services Dataset at NHS Digital |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Date of birth |
| **Identifiers required for analysis purposes** | 1. Ethnicity |

**Confidentiality Advisory Group advice**

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Provide details of the patient notification methods to be used, including where the notification will be placed.**

The applicant clarified in the protocol (V2.0, 11/04/20) that patients who have consented to participate in the RaDaR renal registry will be notified about the PREDICT: RaDaR and UKRR Data study on the Rare Renal Disease Registry Website https://rarerenal.org/. The sub-committee of the CAG were satisfied with this explanation.

2. **Provide the patient notification materials to be used, which should include detail on how patients can opt out (including email address, postal address and telephone details).**

The applicant, in the protocol (V2.0, 11/04/20), provided the text to be used in the patient notification text on the Rare Renal Disease Registry Website. The sub-committee of the CAG were content with the provided text.

3. **Clarify what Patient and Public Involvement and Engagement has been undertaken in preparation for this research, addressing the inconsistencies in the information.**

The applicant provided further detail on what Patient and Public Involvement and Engagement has been undertaken in the protocol (V2.0, 11/04/20). This included review by two patient groups (Kidney Care UK Patient Advisory Group and UK Renal Registry Patient Council) of the linkage of patient identifiable data without consent. The protocol also provided detail on the views of the attendees. The sub-committee of the CAG were happy with the clarification.

**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 and standard conditions of support as set out below.

## Specific conditions of support

1. Favourable opinion from REC **15 Received April 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as 'Standards Met' for the duration of support, and at time of each annual review. **King's College Hospital NHS Foundation Trust, NHS Digital and The Renal Association have been confirmed as 'Standards Met' by NHS Digital. Confirmed via DSPT tracker, checked 23 March 2020.**

# 2. NEW AMENDMENTS

## a. PIAG 2-10(f) / 2005 – Case Mix Programme

| Name | Notes |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

**Amendment request**

The applicants seek support to collect additional treatment data on critically ill patients with confirmed or suspected COVID-19 infection. This data will be used to provide data analyses on the patients to the Strategic Incident Director at NHS England, for the purpose of informing incident planning within the NHS. The applicant confirmed that no items of confidential patient information would be disclosed to NHS England.

Information on antiviral, antimicrobial and corticosteroid drugs will be collected data from hospitals already participating in the Case Mix Programme.

The current list of data items to be collected daily during critical care unit stay are, as follows:

- COVID-19 status (suspected or confirmed) – Yes/No
- Antivirals (Oseltamivir, Lopinavir, Ritonavir, Other) – Yes/No to each
- Other interventions (corticosteroids, intravenous immunoglobulin, interferon alpha) – Yes/No to each

The applicant noted that further information may be required as the pandemic progresses, and that further amendments would be submitted as appropriate.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the amendment was in the public interest and recommended support.

**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 Secretary of State for Health and Social Care.

**Specific conditions of support**

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed – ICNARC has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 29 May 2019.**

## b. CAG 2-05(b) / 2013 – Pandemic Influenza Triage in the Emergency

| Name | Notes |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

**Amendment request**

Support was initially given in 2013 for the applicants to conduct a prospective observational cohort study of patients attending emergency departments with suspected pandemic influenza so as to evaluate existing triage methods, identify clinical predictors of adverse outcomes and develop new triage methods. The applicants are now ready to activate this application in order to study patients with COVID-19. This amendment has been submitted to bring the study up to date prior to activation and to seek support to study respiratory infection pandemics, rather than influenza alone. The applicants are also amending the application name from

PAINTED (Pandemic Influenza Triage in the Emergency) to PRIEST (Pandemic Respiratory Infection Emergency System Triage). The study protocol has been revised to reflect the change in the aims of the application.

As no data controller was named when the application was first given support, the applicants have also amended the application to name the University of Sheffield as the data controller.

The applicants are also changing the data sources, in order to collect patient on data outcomes from NHS Digital, rather than from ONS and ICNARC. Data from NHS Digital will also be used in identifying outcome data for any ambulance services and trusts joining the study.

NHS Digital may also help with the study's new aim of identifying patient characteristics and discriminant value of alternative triage methods for predicting severe illness in patients, however NHS Digital have yet to confirm that they can undertake this work.

During a pandemic, ambulance Trusts involved in the study will be ask to collect predictor triage data for 111 and 999 calls, in addition to data collection from patients being transported to hospital, in order to reflect the change in triage role that ambulance services play during pandemics.

The applicants also seek support to collect additional data items, in order to reflect the changes in the type of infection that may be included in the study and a greater use of ambulance services in a triage role during a pandemic. The ambulance service will be asked to record:

- The ambulance service incident number
- Whether the patient was conveyed to an emergency department
- The name of the hospital of destination

The central research team in Sheffield will not require the ambulance service incident number, however local researchers at NHS sites will require this to identify patient's NHS number, for the purposes outlined in the original application.

For 111 and 999 triage calls, ambulance services may be asked to provide the University of Sheffield with the routinely collected, non-identifiable, triage question of patients with suspected respiratory infection pandemic. This routine data would not match data collected from participating hospitals, however it would more closely reflect the data that ambulances are collecting with patients and lessen the workload placed on front line staff. The applicants will work with participating Ambulance trusts to choose a data collection approach that best fits their capacity. The applicants will not collect additional direct identifiers beyond those already specified the existing application and this amendment.

All research sites will be asked to record a patient's recent travel history, which will be added to the triage data collection form. Sites will also be asked to record a patient's lactate level at triage, as higher lactate levels may indicate a greater severity of a patient's condition and therefore may be an indicator of a respiratory infection having adverse effects. Sites will also be asked to collect additional non-identifiable data, not included on the triage form, for patients with an adverse outcome. This information will include information on long-term conditions, ethnicity, lifestyle (smoking, alcohol, drug use), recent travel history, patient history, and medications. This additional information will allow for a greater understanding of which patients may require prioritisation during a pandemic.

The applicant advised that the NHS numbers of patients will be removed from the study data base no longer than six months after the end of a UK epidemic or pandemic of a respiratory infection.

Study sites will be given the option of transferring data electronically to the central research team. This option is being included to reflect the change to electronic collection of routine data by NHS services, including EDs and Ambulance services. Also to reduce the load on NHS services and trusts participating in this study and reduce the possibility of affecting patient care during a pandemic, and to facilitate rapid data collection and analysis, allowing reporting of findings during a pandemic.

The study documents have been updated from the previous application to be in line with changes from the PAINTED to PRIEST study. A link has also been added to the documents to a privacy notice, placed on the study website, to better describe patient's rights, including the right to withhold their information. Information leaflets will also be made available at the point of triage and data collection in participating hospitals and study posters displayed in prominent places during a pandemic.

For patients identified through 999 and 111 calls, the call handlers, where possible, will read out a short script describing the study and sending them to the study website for further information. The applicants recognised that during a pandemic there will be significant pressure on 111 and 999 services and if this approach is not possible, then a joint approach of conducting a local media campaign, such as through newspaper advertisements to inform the public of the intended use of their data and right to withdraw. Participating ambulance trusts, where possible, will be asked to inform patients and the public of their right to withdraw from the study through their services website and, if appropriate via social media. Opt-out at sites will be managed by research paramedics at sites, to prevent additional personal information being sent to the University of Sheffield. Additionally, NHS Digital will be asked to screen patients against the national opt out service where possible, providing an additional check.

**Confidentiality Advisory Group**

The amendment requested was considered by the Confidentiality Advisory Group. The Group asked that changes were made to the patient notification information documents. The poster needed revisions to be clearer that NHS numbers were identifiers and that pseudonymised data, rather than anonymised data, was processed. It also needed to be clear that the data will not be used to identify patients, but that the NHS number is required for linkage to other information to build a wider picture of the illness, management and treatment.

The information sheet needed to include information on how patients can opt-out, and a digital or telephone mechanism for patients to use to opt-out.

Revised documents were provided, which were reviewed. The CAG agreed that further changes were required to the documents, but was satisfied that support could be granted, conditional on the changes being made.

**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. The Adolescent Information Leaflet needs to be revised as follows;

    a. In the middle column, the word "directly" is to be inserted before "identified."

    b. In the section “What do you want from me?” is to be revised to add "an indirect identifier" after NHS Number.

    c. It also needs to be explained that the NHS Number will be used for linkage to other datasets or National registers.

2. The Child Information Leaflet needs to be revised so that the use of “pseudonymised” in the first column is changed to “anonymised.”

3. The poster for children needs to explain that the NHS Number will be used for data linkage.

4. On the Adult Information Leaflet, the last bullet point in the box titled “What will we do with your information?” needs to be amended from “anonymised” to “pseudonymised.”

5. The poster for adults needs to state that the NHS Number will be used for data linkage.

6. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed – University of Sheffield – School of Health and Related Research has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19 by NHS Digital email dated 06 August 2019.**

7. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 11 March 2020.**