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

July 2017

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Ms Rachel Heron	Confidentiality Advisor

Application title: **National investigation into suicide in children and young people**

CAG reference: **15/CAG/0120**

IRAS project ID: **159134**

REC reference: **15/NW/0184**

Context

This application from University of Manchester set out the purpose of a multi-agency designed study combining available sources of information on cases of suicide and probable suicides in those aged 20 and under to provide a range of information at individual patient level that is currently not available. The study aims to identify the characteristics and antecedents of young person suicide and use these findings to help inform policy and safer practices with a view to reducing suicide rate in this age group.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover researcher access to confidential patient information from ONS, NHS Trusts Serious Untoward Incident reports and data held on the National Confidential Inquiry's database on individuals under the contract of mental health services prior to death. Scanned documents would be requested from participating organisations.

Amendment Request

The following amendments were requested:

1. An extension to the end date
2. Permission to reduce the remit of the study so that the applicant only collects and examines data on individuals aged 10-19 years who died by suicide or suspected suicide in England, Wales, Scotland or Northern Ireland.

Support is currently in place to obtain data on individuals aged under 25 years who died by suicide or suspected suicide in all UK countries. Delays to data collection have reduced the time available for collection and analysis of the full range of data, therefore the applicant wished to focus available resources on this narrower remit.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was of the opinion that the time extension was reasonable given the problems with data collection. The reduction in remit would not affect confidentiality or security. The Chair was of the opinion that the study remained in the public interest despite the restricted remit.

It was emphasised that the CAG advice applied only to England and Wales.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair 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. **v14 confirmed published, reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed.**

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **BPSU facilitated study on Rickets**

CAG reference: **14/CAG/1042**

IRAS Project ID: **144785**

REC number: **14/LO/2221**

Context

Purpose of Application

This application from Royal Free London NHS FT set out the purpose of completing a surveillance study to investigate nutritional rickets caused by vitamin D deficiency presenting to secondary care.

Rickets is unique to growing children and adolescents and occurs when growing bones do not develop adequately. As a result the child's bones soften which can lead to distressing short and long term consequences. These include pain, delayed walking, deformed limbs in need of surgical correction, or difficulty with child bearing. The disease can be recognised in children and adolescents by specific clinical signs and/or bone x-rays.

Rickets is the commonest childhood complication of vitamin D deficiency (VDD) and is caused by a lack of dietary calcium or problems with the supply or use of vitamin D inside the body. Rickets can also be caused by the lack of phosphate, from the loss of kidneys or from genetic problems.

Currently there is little data on the number of rickets cases and the last national UK survey of rickets was conducted in 1945. The limited data that is available to date shows that VDD in the UK is steadily increasing. The knowledge of population based data will allow us to follow trends of the disease in different populations over time. The data will also help to provide evidence for the supplementation of vitamin D.

As a disease that can be identified by specific clinical and radiological signs, the number of new cases (incidence) and treatment of rickets in the UK can be monitored and evaluated. In the recent Chief Medical Officer's (CMO) report 2012, Dame Sally Davies recommends investment to be made into universal and targeted vitamin schemes and whether the approaches are cost effective. This project aims to estimate the incidence of nutritional rickets presenting to secondary care and to identify and describe the presentation, management and known risk factors.

A recommendation for class 1, 2, 5 and 6 support was requested to allow an authorised user to extract and anonymise the information, to obtain and use information about past or present geographical location and for auditing, monitoring and analysing patient care and treatment.

Amendment Request

The amendment requested additional data linkage with HES data managed by NHS Digital in order to improve case ascertainment.

Confidentiality Advice Group Advice

The amendment request was considered by the Vice Chair who confirmed that it suggested a sensible way to improve case ascertainment in a project for which the number of cases in this country was small and it was noted that part of the purpose of the study was to calculate incidence of childhood rickets in order to understand if the number of cases was changing.

The Vice Chair acknowledged that whilst BPSU method was well established and generally successful, there was potential to miss some cases and the suggested amendment would bring the applicants closer to full ascertainment. It was acknowledged that the applicants would use HES to find cases that might have been missed, however, they would refer to the established BPSU method to seek details from the treating secondary care team. The cases would be found by the established process of asking HES to provide details based on ICD10 codes over the specified time period. HES would provide the minimum identifiers to allow the applicant to identify the cases and the treating secondary care team to facilitate the request for the details required for the study.

The applicants had confirmed that they were supplementing public information to cover this amendment. Support was recommended for the amendment.

Confidentiality Advice Group Conclusion

In line with the considerations above, the Vice Chair 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 – 14/07/2017 – Royal College of Paediatrics & Child Health, V14 2016/17 reviewed as satisfactory – email confirmation provided by NHS Digital)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 11 July 2017).**

Reviewers:

Name	Capacity
Dr Tony Calland	Vice Chair
Dr Rachel Knowles	CAG Member
Dr Mark Taylor	Chair
Dr Murat Soncul	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Analysing Emergency and Urgent Care System Demand in Yorkshire and Humber: A data-linkage study of pre-hospital, emergency department and out of hours service data**

CAG reference: **17/CAG/0024**

IRAS project ID: **215818**

REC reference: **17/YH/0024**

Context

Purpose of Application

Addressing the long term rise in demand in EUC services is a key focus for the NHS. In the ambulance service the large proportion of urgent type calls that make up the service demand, point to the potential for an alternative response to the traditional ambulance transport to the ED. However there is currently a lack of detailed analysis of the demographic profile and characteristics of ambulance calls which would assist in deciding which calls and patients may be suitable for this alternative response.

This application from University of Sheffield set out the following purpose. This study aims to collect and analyse routine NHS data from a number of providers of emergency and urgent care (EUC) in the Yorkshire and Humber region and link the data to provide a coherent picture of EUC demand for a period of 60 months (2011 - 2015). It will map in detail the use of EUC services in order to identify patterns of service use and outcome by different patient and demographic groups over time; to identify groups of patients who currently utilise EUC services in different ways and who may benefit from an alternative, more appropriate approach to care.

It will achieve this through creating a database of routine health data to describe a detailed profile of patient demand across pre-hospital, hospital EUC settings and Out of Hours (OOH) services in Yorkshire and Humber over time, specifically to examine:

1. A detailed picture of the pathways of care users of pre-hospital ambulance and urgent care services, OOH services, ED and inpatient services utilise.
2. A detailed case mix analysis of these users of pre-hospital ambulance and urgent care services, OOH services, ED and inpatient services in order to understand patterns of service use by different patient groups or conditions (e.g. COPD, diabetes, mental health) and presentation based (e.g. frail elderly) in order to identify which patient groups present the greatest challenges to these services.

3. Identify explanatory factors affecting the use of these acute and emergency services including factors modifiable by services (such as availability of services e.g. Mental health pathways) and factors not modifiable by services such as population, geographical and health factors known to affect service use.

A recommendation for class 4, 5 and 6 support was requested to cover access to the following specific items:

Identifiers required for validation/linkage:

- Name
- NHS Number
- Data of birth
- Date of death
- Address
- Postcode (unit level)

Identifiers to be retained for analysis:

- Postcode (sector level – for deprivation scoring)
- Gender
- Ethnicity

Amendment Request

The amendment requested the following two revisions to the application:

1. Extension to the duration of support – it was acknowledged that existing approval was in place to enable the applicants to collate data for 2011-2015; however, the applicants are requesting an extension to the duration of the application scope to collect additional data for all of 2016 and part of 2017.
2. Inclusion of an additional data source – the applicants are requesting linkage with mental health records held by Sheffield Health and Social Care NHS Foundation Trust.

Confidentiality Advisory Group Advice

The amendment request was forwarded to a Sub-Committee for consideration.

Members were assured that the duration amendment was appropriate and would enable the applicants to undertake more meaningful analysis on a larger and more current dataset. Support was recommended for this amendment. The Sub-Committee acknowledged receipt of revised documentation which reflected the extended study duration.

The Sub-Committee considered the additional data source and it was commented that the information provided within the amendment form did not clearly articulate how the data provided from this proposed data source would differ from that which was received under the existing supported data sources. The applicants clarified that this amendment concerned an additional cohort of patients which were under the care of a different type of provider (Health and Social Care Trust) and confirmed to have a mental health complaint (such as a serious mental health illness). Further clarification was provided around the additional data which be supplied by this data source and it was acknowledged that there were no additional items of confidential patient information provided from this data source.

Members were assured by the additional clarifications provided and it was agreed that support was recommended for the complete amendment proposal.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair together with a Sub-Committee of the main 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 – Version 14, 2016-17, reviewed grade 88% satisfactory on 07 August 2017)**.
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Favourable Opinion issued on 27 June 2016).**

Reviewers:

Name	Capacity
Dr Murat Soncul	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The fracture liaison service database**

CAG reference: **15/CAG/0158**

Context

Purpose of Application

This application describes a database, commissioned by the Health Care Quality Improvement Partnership (HQIP), to support the implementation of the Department of Health's Prevention Package for Older People by collecting high quality data to raise the standard of care and improve the patient pathway consistently with the Quality Outcomes Framework in primary care.

A recommendation for class 1,4 & 6 support was requested to cover access to data from The Fracture Liaison Service (FLS) and Office of National Statistics (ONS) and Hospital Episodes Statistics (HES) data from the Health and Social Care Information Centre in relation to men and women aged 50 years and over with a fragility fracture.

Amendment Request

The amendment requests a change to the approved data flows within the application. Details of the amended data flows are as follows:

- Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) has been contracted as statistical provider for the national Falls and Fragility Fracture Audit Programme (FFFAP) which covers the Fracture Liaison Service Database (FLS-DB) beginning 1st April 2017.
- Contracting with the Royal College of Surgeons (RCS-CEU) clinical effectiveness unit will cease on 31st March 2017.
- Data flow arrangements will be amended such that de-identified patient level data plus date of death will flow to NDORMS where previously it would flow to RCS-CEU.

The applicants provided confirmation that no data had been transferred to NDORMS, pending confirmation that a recommendation of support was in place for the proposed change to the data flow.

Confidentiality Advisory Group Advice

The amendment was forwarded to the Alternate Vice-Chair for consideration. It was acknowledged that the amendment requested a change to the statistical provider only and changes were proposed to the data flows accordingly. Support was recommended for the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Alternate Vice-Chair 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.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Royal College of Physicians, 97%, Crown Informatics, 97%, reviewed satisfactory grade on Version 14, 2015/16, University of Oxford, 100%, reviewed satisfactory grade on Version 14, 2016/17).**

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Getting It Right First Time Programme**

CAG reference: **15/CAG/0144**

Context

Purpose of application

This application from Royal National Orthopaedic Hospital NHS Trust set out the purpose of a service evaluation project to determine the specific causes of medical negligence claims as surgical specialities through detailed case analysis from law firm data from the NHS Litigation Authority (NHSLA) panel firms. The project aims to improve the provision of patient care and the management of health services in the surgical specialities. The project aims to identify poor practice and influence national guidelines to address this poor practice.

A recommendation for classes 5 and 6 support was requested to cover access to data from NHSLA panel law firms in relation to patients who have made a claim against an NHS Trust in relation to surgical care since 2003.

Amendment Request

The scope of the programme has been broadened to include determination of all clinical negligence claims against all medical and surgical specialities as well all areas in which NHS Litigation Authority receives claims. The original application focussed on surgical specialities only. The updated programme will be looking at all the data held by the NHS Litigation Authority on its claims system as well as the information held by its panel law firms and not just the law firm summary data previously used. This reflects the Secretary of State for the Health extending the remit of GIRF I from 11 to over 29 specialties both medical and surgical and the role GIRFT plays to help NI-IS LA learn from claims.

The applicants specified that all claims reported to the NHS Litigation Authority need to be included within the scope of this amendment as there is expected to be further expansion of the programme to include all litigation claims handled by the NHS Litigation Authority. The applicants confirmed that there was no change to the Data Controller for the GIRFT work stream which remains Royal National Orthopaedic Hospital.

The applicant confirmed that the extension to the programme was for a further three and a half years from April 2017 through to 01 November 2020.

Confidentiality Advisory Group Advice

The amendment was forwarded to the Vice Chair for consideration and it was acknowledged that the proposal extended a straightforward and justified linkage using minimal identifiers to allow lessons to be learned from cases in which patients undertake legal action against the NHS through the NHS Litigation Authority. This work was being undertaken by the 'Getting It

Right First Time initiative which is a partnership between the NHS Royal National Orthopaedic Hospital Trust (RNOH), which first hosted the pilot programme, and the NHS Improvement Programme's Operational Productivity Directorate. It was identified that the only change was in the increase to the range of specialties that will be subject to this analysis. The Vice Chair confirmed that the activity was in the public interest and support was recommended.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair 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.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Royal National Orthopaedic Hospital NHS Trust, Version 14, 2016-17, reviewed grade of satisfactory at 71%).**

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **National Maternity and Perinatal Audit**

CAG reference: **16/CAG/0058**

Context

Purpose of application

This application from the Royal College of Obstetricians and Gynaecologists set out the purpose of delivering a new Healthcare Quality Improvement Partnership (HQIP)-commissioned national, prospective, clinical audit of maternity services in England, Scotland and Wales, in order to improve the quality of services and the outcomes achieved for mothers and newborns.

The commissioned audit programme consists of three phases of work:

1. An 'organisational survey' to collect provider-level information on service delivery and the organisation of maternity care, which will contribute to a better understanding of the care provided to pregnant women.
2. A continuous prospective clinical audit that produces information for maternity units to monitor patterns of care and maternal and perinatal outcomes.
3. A series of in-depth topic-specific, time-limited audits ('sprint audits'), predominantly focusing on specific types of maternal and neonatal outcomes.

Most maternity units in the UK already use electronic maternity information systems (MIS) to capture demographic and clinical information related to each pregnancy and delivery under their care. These databases cover antenatal booking through to postnatal care. Although each MIS collects slightly different information, there is sufficient similarity between MISs to allow a minimum dataset to be developed.

In order to collect data covering a four-year period, for the first extract the applicants will request delivery data for the two previous financial years. Data on deliveries occurring between April 2014 and March 2016 will be requested in 2016, with refreshed data extract for the 2016-17 and 2017-18 periods requested in 2017 and 2018 respectively.

The data collected from English MIS systems will be linked to Hospital Episode Statistics (HES) maternity data from 2017, pending approval from the Health and Social Care Information Centre (HSCIC) Data Linkage and Extract Service. The HES data will in turn be linked to the Office for National Statistics (ONS) birth and death register. These linkages will be repeated annually and will enable the applicants to calculate case ascertainment for English births, and to examine additional processes and outcomes of maternity and perinatal care, including maternal and neonatal hospital readmission. A similar linkage exercise is

planned for the data collected from Welsh MIS systems using the Patient Episode Database for Wales (PEDW), pending approval from the Welsh Information Services Division.

Additional data linkages are planned as part of a series of topic specific 'sprint audits'. The linked MIS-HES/PEDW-ONS data will be further linked with data from the Intensive Care National Audit and Research Centre (ICNARC), the RCPCH's National Neonatal Audit Programme (NNAP) and Public Health England's surveillance systems (SCSS and LabBase2) to investigate maternal and neonatal intensive care admissions and blood-stream infections, respectively. This information will be released in a link anonymised format.

A recommendation for class 1, 4, 5, and 6 support was requested to cover disclosure of confidential patient information from English & Welsh NHS trusts to the Royal College of Obstetricians and Gynaecologists, in order to link this data with data contained in other national databases.

Amendment Request

This amendment was submitted to provide two clarifications of the specific details of support requested within the original application, together with an amendment.

1. **Clarification: Maternity records for individuals in the NMPA cohort will be linked to their past and future hospital episode records.**

The applicants sought to clarify the data requested from HES and PEDW in relation to the mothers who form the NMPA cohort. The applicants advised that the linkage will be between the maternity record of each mother and baby within the NMPA cohort and any hospital episodes they had attended, either before the index birth (which would include any of the mother's previous hospital admissions that resulted in the delivery of a baby) or after the birth. The applicants explained that hospital episode data will be drawn from HES in England and PEDW in Wales. The records being linked will include all hospital episodes pertaining to mothers and babies within the NMPA cohort (births from 1 April 2014 to 31 March 2018), dating back to 1 April 2000 and up until the end of the audit contract (currently 30 June 2019, with a possible extension of 2 years in the first instance). All hospital episodes will be included in the linkage i.e. Accident & Emergency, critical care, admitted patient care and outpatient episodes.

2. **Clarification: How maternal intensive care records will be linked with the NMPA cohort.**

The applicants advised that the second point which required clarification was around how maternal intensive care records would be linked to the NMPA cohort. The applicants clarified that to avoid the unnecessary transmission of patient medical information, the NMPA Data Manager would pass to the Intensive Care National Audit and Research Centre (ICNARC) only demographic identifiers (date of birth, NHS number, postcode) of women in the NMPA cohort. ICNARC will then provide the NMPA Data Manager with the ICNARC records of any woman in the NMPA cohort who is also within this dataset, including a unique study ID. ICNARC will send a separate file containing the identifiers and the unique study ID, to enable linkage of the two datasets by the NMPA Data Manager. To allow for the possibility that the ICNARC dataset has captured some pregnant or recently pregnant women that had not been identified by the NMPA, ICNARC would also send the records of any other women who are flagged as being pregnant or recently pregnant at the time of admission.

3. **Amendment: Change of source of neonatal care data to be linked with the NMPA cohort.**

The applicants requested a change to source of neonatal care data to be linked with the NMPA cohort. The original recommendation of support covered data linkage with the National Neonatal Audit Programme (NNAP) dataset. However, the applicants had subsequently discovered that this database held only aggregated unit-level data, which was drawn from the BadgerNet neonatal database. As record-level linkage was required for the purposes of the audit, this amendment requested data linkage with the BadgerNet neonatal database.

Confidentiality Advisory Group Advice

The amendment was considered by the Alternate Vice-Chair who acknowledged that the initial two requests had been submitted to clarify points of the original application of the support for which a recommendation of support was made. The Alternate Vice-Chair agreed that the amendment request to change the source of neonatal care data was appropriate and would enable the applicants to receive the record-level data required to undertake the audit, for which support was recommended.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair 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.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed - Royal College of Obstetricians and Gynaecologists, Version 14, reviewed grade satisfactory at 100%)**.

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Application title: **A Study of the Natural History of Renal Disease in TSC2/PKD1 Contiguous Gene Deletion Syndrome.**

CAG reference: **16/CAG/0118**

IRAS project ID: **10073**

REC reference: **10/MRE09/2**

Context

Purpose of application

This application from the University of Cardiff set out the following detail. Tuberous sclerosis (TSC) is a rare, genetic condition that causes benign growths to occur in various body organs, particularly the brain, skin, kidney and heart. Other features of tuberous sclerosis include kidney (renal) cysts, seizures and intellectual impairment. Two causative genes have been identified, TSC1 and TSC2. Adjacent to TSC2 on chromosome 16, lies the gene PKD1. This gene is responsible for 85% of Autosomal Dominant Polycystic Kidney Disease, a genetic condition that causes multiple renal cysts to occur, usually in adulthood. Renal cysts are a well-recognised feature of tuberous sclerosis. There is a small subgroup of patients with tuberous sclerosis who have a more severe form of renal cystic disease, often with early or congenital onset. A gene deletion involving both TSC2 and PKD1 was described in 1994, known as the TSC2/PKD1 contiguous gene deletion syndrome.

The applicant aimed to determine the natural history of renal disease by a follow up study of these patients. This would provide important prognostic information for patients at diagnosis and help guide their management.

A recommendation for class 4 and 6 support was requested to cover the relevant activities specified in the application, in relation to deceased patients.

Amendment request

The amendment request an extension of the study end date to 31 August 2018, due to delays in recruitment.

The delay in obtaining CAG approval had caused a delay in recruitment and the applicant did not anticipate that they would be able to meet the recruitment target of 255 by 30 June 2017. They currently had 209 participants recruited, and were optimistic that they would be able to recruit 46 further participants by 31 August 2018, and to complete data processing within this period. Although living participants would be consented into the study, some referred cases within this period may relate to deceased participants.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team (CAT) who noted that the extension was to cover delays in recruitment and to extend the CAG support to access data on deceased patients within this time period. It was noted that there had been a delay in obtaining confirmation of CAG support which meant that the start of recruitment had been later than expected.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT 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. **V14 confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed in place for the study, and not required for this amendment.**

Reviewers:

Name	Capacity
Dr Murat Soncul	Alternate Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Evaluation of the NHS Breast Cancer Screening Programme - an Individual-Based Cohort Study of Mortality**

CAG reference: **PIAG 3-07(g)/2002**

Protocol number: **21 May 2002**

REC number: **MREC 02/1/064**

Context

The NHS Breast Screening Programme (NHSBSP) was introduced in England and Wales in 1988 and its operation has been monitored using performance indicators such as uptake, referral and cancer detection rates. However, this does not directly address whether the programme has been effective in its primary objective – the reduction of breast cancer mortality, and the question remains whether the level of reduction in breast cancer mortality observed in randomised controlled trials can be achieved by a population programme, such as the NHSBSP. In addition, mortality from breast cancer is falling in the United Kingdom and there is debate as to how much of the reduction is due to screening or improvements in treatment. The difficulty of producing quantitative estimates of the effect of a national screening programme on mortality is well recognised. Ecological studies using population level data and studies using surrogate outcome measures have been undertaken, but to assess the programme rigorously the Applicant requires the use of individual-level data and mortality from breast cancer as the outcome.

A retrospective cohort study of 700,000 women in England and Wales has been established with the primary aim of evaluating the impact of the NHS Breast Screening Programme on mortality from breast cancer. Individual-level data will be used to compare risks of breast cancer mortality over an eleven-year period in those invited for screening with a contemporaneous group of the same age who were not invited until a later date. The study will also assess mortality from breast cancer in relation to attendance for screening, and mortality from all causes, all cancers and vascular disease in relation to invitation to and attendance for screening.

Amendment Request

This amendment requested support for an additional one-off linkage via ONS to collect further follow-up data on the women within the established cohort. This additional flagging linkage would determine the current status of women within the cohort, any cancer registrations and death from any cause. This additional activity would provide an additional 10 years of follow-up data up 31 December 2015, with an overall 25 years of follow-up date.

Support was requested for the one off further linkage and retention of the information for analysis up to August 2020.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Alternate Vice-Chair who acknowledged that with the additional linkage, studies of more recent screening protocols and changes in protocol across the duration could be undertaken. It was also acknowledged that an evaluation of the screening programme over an extended duration could be undertaken, which had not previously been investigated.

It was identified that the amendment form referenced patient follow-up for an additional 12 years, taking the total follow-up to 27 years; however, this was not reflected within the protocol document. The applicants clarified that the request was for an additional 10 years of follow-up data in line with the information included within the protocol, which was approved by the REC.

The Alternate Vice-Chair recommended support for the amendment on the basis that the Data Access Agreement between the applicants and NHS Digital was renewed for the project.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Alternate Vice-Chair 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. Data Access Agreement with NHS Digital to be renewed for ongoing activity.
2. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – 08/05/2017 – Barts Cancer Centre, V14 2016/17, published reviewed grade of satisfactory at 100%).**
3. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmation-Favourable Opinion issued 18 December 2013).**

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **1) UK Transcatheter Aortic Valve Implantation (TAVI)**

2) UK Renal Denervation Registry (UKRDNR)

3) National Neuromodulation Registry (NNR)

CAG reference: **CAG 5-07(c)/2013**

Context

Purpose of application

This audit application from University College London described three national audit datasets:

1) The UK Transcatheter Aortic Valve Implantation (TAVI) registry – a record of all TAVI procedures performed in the UK since the introduction of the technique in 2007. The dataset included demographic data, indications, procedural details and outcomes up to hospital discharge. Follow up data would be collected at 1 and 3 years.
2) The UK Renal Denervation Registry (UKRDNR) – a UK registry of patients undergoing renal denervation for hypertension.
3) The National Neuromodulation Registry (NNR) – a database including all patients undergoing neuromodulation.

The datasets would be analysed with the aim to drive improvements in the quality of care. Findings would be shared with participating Trusts and aggregate analysis reports published.

A recommendation for class 4, 5 and 6 support was requested to cover access by NICOR to identifiable data on patients undergoing the relevant procedures, to track patients across NHS organisations and to link to national datasets such as Hospital Episode Statistics (HES) and ONS mortality data.

Amendment Request

From 1st July 2017, the data controller and data processor responsibilities for the TAVI Registry will transfer from University College London to Barts Health NHS Trust (Barts Health). This amendment includes the transferring of the existing data from UCL to Barts Health relating to this programme and the ongoing collection of data at Barts Health.

The applicants clarified that there was no actual transfer of data as the IT and data storage systems remain the same (remote external storage). It was clarified that the only aspect that would change was that the sub-contract will be changed from UCL to Barts Health. It was confirmed that NICOR staff will be TUPED to Barts Health from July 1st 2017 to ensure business continuity and maintenance of IG standard.

The applicants explained that the transfer related to the TAVI Registry only as this is the only one of the original three audits which remains active. It was explained that:

- The ***UK Renal Denervation Registry (UKRDNR)*** had never been established due to a lack of clinical effectiveness evidence for the procedure. A decision was made to wait for the results of clinical trial evidence for the USA before proceeding with the registry. This evidence is not yet available.
- The ***National Neuromodulation Registry (NNR)*** pilot was set up and was now being discontinued for lack for funding.

Confidentiality Advisory Group Advice

The amendment was forwarded to the Chair who acknowledged that aside from the transfer of data controller and processor arrangements to Barts Health, all other aspects of the application remained the same.

The Confidentiality Advice Team advised that revised application submissions had been received as part of the wider programme of applications affected by this change. To ensure consistency of process, the applicants were advised that support for this amendment would be recommended on an interim basis only, pending the submission of a revised application form. A timescale for submission was agreed with the applicants. Interim support would be recommended to 30 September 2017.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair 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.

Specific conditions of support

1. Support was recommended for the transfer of data controller and processor responsibilities from University College London to Barts Health NHS Trust with effect from 01 July 2017.
2. Support extends on an interim basis up to 30 September 2017 only.
3. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed - Barts Health reports an assessed satisfactory score at 77% (version 14 (2016-2017).**

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **NICOR registries/audits**

CAG reference: **CAG 10-07(b)/2014**

Context

Purpose of Application

This application set out the purpose of undertaking three audits for the NHS England Commissioning through Evaluation (CtE) programme. The CtE programme comprises the following registries:

1. Percutaneous Mitral Valve Repair: a catheter-based device which is used to repair heart valves, providing an alternative to open heart for those patients who are clinically appropriate
2. Left Atrial Appendage Occlusion: a device used to prevent stroke in patients with atrial fibrillation (irregular and rapid heartbeat)
3. Patent Foramen Ovale Closure in Adults: a procedure to close a hole, or potential hole, between the upper chambers of the heart, to prevent stroke

A recommendation for class 4, 5 and 6 support was requested to allow access to patients undergoing the procedures. Data would be collected from NHS organisations undertaking procedures, the Health and Social Care Information Centre (Hospital Episode Statistics) and the Office of National Statistics.

Amendment Request

From 1st July 2017, the data controller and data processor responsibilities for the CtE programme will transfer from University College London to Barts Health NHS Trust (Barts Health). This amendment includes the transferring of the existing data from UCL to Barts Health relating to this programme and the ongoing collection of data at Barts Health.

The applicants clarified that there was no actual transfer of data as the IT and data storage systems remain the same (remote external storage). It was clarified that the only aspect that would change was that the sub-contract will be changed from UCL to Barts Health. It was confirmed that NICOR staff will be TUPED to Barts Health from July 1st 2017 to ensure business continuity and maintenance of IG standard.

Confidentiality Advisory Group advice

The amendment was forwarded to the Chair who acknowledged that aside from the transfer of data controller and processor arrangements to Barts Health, all other aspects of the application remained the same.

The Confidentiality Advice Team advised that revised application submissions had been received as part of the wider programme of applications affected by this change. To ensure consistency of process, the applicants were advised that support for this amendment would

be recommended on an interim basis only, pending the submission of a revised application form. Interim support would be recommended to 30 September 2017.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair 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.

Specific conditions of support

1. Support was recommended for the transfer of data controller and processor responsibilities from University College London to Barts Health NHS Trust with effect from 01 July 2017.
2. Support extends on an interim basis up to 30 September 2017 only.
3. Confirmation of suitable security arrangements via IG Toolkit submission. (**Confirmed - Barts Health reports an assessed satisfactory score at 77% Version 14 2016-2017**).