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

November 2018

1. APPLICATIONS

Group Members:

Name	*Present*	*Notes*
Dr. Liliane Field	Yes	
Ms Clare Sanderson	No	Alternate Vice-Chair
Ms Gillian Wells	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.**

CAG reference: **18/CAG/0153**

IRAS project ID: **238743**

REC reference: **18/WA/0291**

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research which aims to evaluate whether the use of birthing pools during labour and water births leads to an increased risk in poor maternal and infant outcomes. Data will be collected on all births in around 30 maternity units between January 2015 and November 2020 to find out how many women used birthing pools during labour, the number of water births and whether the women or infants come to any extra harm as a result of water birth. Routinely collected data will be used. For infants needing specialist care, data will be retrieved from the National Neonatal Research Database (NNRD). The NNRD operates with support under the Regulations via application reference ECC 8-05(f)/2010. There is a supplementary qualitative element to

the study which involves online discussion boards and site case study observations which does not require consideration by the CAG.

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

Confidential patient information requested

Cohort

All women giving birth at a participating NHS site in England or Wales between January 2015 and November 2020. It is anticipated that this will include 600,000 maternity records.

The following items of confidential patient information will be released by EuroKing to the National Neonatal Research Database, based at the Chelsea and Westminster Hospital NHS Foundation Trust, for the purposes of sample validation and linkage:

- Study-specific Linking Field,
- Surname,
- Infant's NHS Number,
- Infant Date of Birth,
- Postcode,
- Maternity Unit of Birth,
- Ethnicity – for analysis.

Confidentiality Advisory Group advice

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

1. **Clarify the retention period for confidential patient information by EuroKing Maternity Software Solutions and Chelsea and Westminster NHS Foundation Trust.**

It was confirmed that Chelsea and Westminster NHS Foundation Trust via the NNRD currently holds identifiable data for the purpose of linkage in perpetuity, as per the conditions of support under the Regulations (ECC 8-05(f)/2010). NNRD will destroy all confidential patient information provided for linkage after linkage or before the date of study completion 3 August 2021.

Euroking Maternity Software Solutions would remotely access each of the NHS site's servers, run the data extract script and download the extract onto the EuroKing secure server. The extracts will then be immediately transferred to both NNRD and Cardiff University and on confirmation of successful receipt of data transfer by Cardiff University and NNRD, the data extract held on EuroKing server will be deleted. A copy of the extract will be retained on the site server as a database reports to ensure an audit trail of data extracted is retained for the duration of the study.

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

2. **An alternative mechanism for raising an objection to the use of confidential patient information within the study should be offered as part of the patient notification strategy – provide confirmation of this alternative means and revise the supporting documentation accordingly.**

The applicant confirmed that a further mechanism in which women can opt-out from the POOL study by phoning or emailing the maternity unit and requesting their record be flagged as opted-out had now

been included. This would ensure any women uncomfortable requesting this directly with their midwife has a mechanism to opt out. The applicant confirmed that this has been discussed with the lay representatives on the study, who were happy with this additional method to opt-out. It was also confirmed that where the National Opt Out scheme had been put in place at study sites these opt-outs would also be upheld for this study. A revised copy of the information leaflet was provided for information purposes.

The Sub-Committee was content with the additional objection mechanism. The revised information leaflet was considered. Members agreed that the word retrospectively should be removed from the dissenting paragraph. As this revision was minor, this requirement would be added as a condition of support to be enacted prior to the study commencing; however, it could be reported back at the time of first annual review that this actioned.

3. Confirm that women who have a water birth will be proactively provided with a copy of the study information leaflet.

The applicant confirmed leaflets would be readily available for distribution in the birthing unit to women having a water birth. Midwives would be advised, as part of training, to provide a leaflet to each woman who uses a pool.

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

Recommendation:

The following point is added as a recommendation only and will not be considered as part of the final recommendation of support.

1. It would be beneficial if wider patient and public involvement and engagement activity was undertaken as the study progressed, in order to assist with a means of disseminating research findings as example.

The applicant confirmed that a PPI stakeholder event was planned at the end of the project, no formal decisions had been made as yet but this is scheduled for the dissemination phases of the project. The planning of the PPI event would be carried out between analysis of data and publication of results. This event is planned with the specific aim of PPI representatives being able to inform the interpretation of study results and assist in drafting in recommendations for practice. In addition, lay and PPI representation is in place on the study's monthly management group meetings and annual study steering committee meetings. These representatives have already and will continue to inform strategies for study publicity and dissemination.

The Sub-Committee received the supplementary information and raised no queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Revise the patient leaflet to remove the word 'retrospectively' from the dissenting paragraph. This should be actioned prior to the study start; however, confirmation should be provided at the time of first annual review that this was undertaken.

2. Favourable opinion from a Research Ethics Committee (**Confirmed – 09 October 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Chelsea and Westminster NHS Foundation Trust and EuroKing Maternity Software Solutions (Healthcare Software Solutions YGMAJ) have confirmed satisfactory reviewed grade on Version 14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Murat Soncul	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Understanding local Heart Failure Pathways of Care**

CAG reference: **17/CAG/0196**

Context

Purpose of Application

This application from Blackpool Teaching Hospitals NHS Foundation Trust set out the purpose of service evaluation to perform an in-depth diagnostic of Heart Failure care delivery by the provider and associated care settings across the Health Economy. This diagnostic will describe and quantify all aspects of the pathway and provide vital data to inform the transformational programme of delivering seamless systems of care for HF patients on the Fylde Coast.

The service evaluation has the following aims and objectives:

- To define current practice in triage of patients at the point of hospital discharge, to varying intensity and methods of condition surveillance. In order to support consistent delivery of care in the future.
- To characterise and cost the current provision of HF care and surveillance across the Fylde Coast Health Economy in order to inform new financial and contractual models.

This application will allow the applicants to collect vital baseline data from across primary, community and acute care setting that will inform the analytics aspects of the transformational project. It is necessary to integrate some patient-level data in order to understand the individual Heart Failure patient pathway accurately, delivery effective pathway redesign and confirm impact of the changes made.

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

Confidential Patient Information Requested

Cohort

The population of the Fylde Coast health economy (covering Blackpool CCG and Fylde & Wyre CCG) of patients who have been diagnosed with stage C or early stage D (NYHA class II – early IV) Heart Failure either with a primary or secondary Heart Failure diagnosis. This is estimated at 4,732 patients

The following items of confidential patient information will be released by Blackpool Teaching Hospitals Acute Informatics Team to the Community Informatics Team and the Midlands and Lancashire CSU for the purposes as described:

- NHS number – validation and linkage,
- Hospital number – validation and linkage,
- Date of birth – for analysis,
- Date of death – for analysis,
- Gender – for analysis,
- Postcode – translated to Lower Super Output Area (LSOA) for analysis.

Confidentiality Advisory Group Advice

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

1. **Practicable Alternatives – consider whether a pseudonymisation at source methodology could be established for the project as an alternative to seeking support under the Regulations. Provide response with supporting justification if this is not deemed feasible for the proposal.**

The applicant explained that discussions had taken place in March 2018 with both the community data team and primary care data team to explore whether a pseudonymisation at source could be established. Matthew Wright, Divisional Business Intelligence Manager, for the community data team felt that this would be possible at their side as the data held here is linked to a non-PID key generated by the data team at the hospital (e.g. RXL00016). However, Louise Ross, Data Quality Manager at Midlands and Lancashire CSU, explained that they could not receive the data in a pseudonymised format as NHS Numbers were required to undertake searches. The applicant confirmed that, due to this limitation in the CSU's ability to process pseudonymised data, it wasnot be feasible to use this alternate methodology for the project.

The Sub-Committee received the response and no queries were raised in this area. It was recognised that the applicant had explored the potential practicable alternative and evidenced that this was not feasible for this project. The Sub-Committee was content to provide a recommendation of support under the Regulations.

2. **Provide further information around the proposed data flows within the project and clarify where confidential patient information is being transferred. It was also unclear at what stage of the project the study data would be pseudonymised which should be clarified in the data flows.**

The applicant confirmed that the data flow chart depicted the accurate flow of data to support the project. It was clarified that the aim of the activity was to extract the data from the three sources above with the data lead at the Blackpool Teaching Hospitals NHS Foundation Trust extracting SUS PID data and then providing this data to the data leads at Midlands and Lancashire CSU Data Quality team and Blackpool Teaching Hospitals Community Informatics Team via a secure N3 connection. This will then be used to extract the data from the respective systems before the data is de-identified and the encrypted linker key enabled, allowing data to provide a complete picture of heart failure care for the local health economy. Confidential patient information will be deleted immediately in line with the relevant organisations governance procedures. The resulting dataset will not contain any confidential patient information and will be used to inform the future provision of heart failure care.

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

3. **Consider whether the proposed data linkage can be facilitated on NHS Number alone – confirm that this can be achieved, or advise any additional identifiers which would be required to facilitate linkage.**

The applicant confirmed that this was discussed in March 2018 with both the community data team and primary care data team to ensure that the data linkage could be done by NHS Number alone. Both organisations confirmed that the data linkage could be achieved on NHS number alone received from the Hospitals data team.

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

4. **Consider whether postcode could be translated into Lower Super Output Area (LSOA) for analysis – provide confirmation that this would be actioned or provide further justification to support why this is required in its complete format.**

The applicant confirmed that both the community data team and primary care data team confirmed that this was possible and would be put in place as part of the data extraction process.

The response was received by the Sub-Committee and no issues were raised.

5. **Patient Notification and Dissent – the poster which will be utilised to promote the proposed activity within the public domain and inform patients how their data would be used requires revision to address the following points:**
   a. **The language used within the document requires revision to make the content of the document more accessible to the general public,**
   b. **Abbreviations should not be used within the text,**
   c. **A system to enable patient objection to the use of their data needs to be established for the project – an overview of how this will be operated should be provided for consideration,**
   d. **Information around the right to object should be included within the poster, including contact details, e.g. email, telephone,**
   e. **Patients or the public should be involved in the revision of the documentation to assist with making this more accessible.**

The applicant provided a revised poster for consideration which addressed all points raised. It was confirmed that the poster had been reviewed by several members of the public in order to ensure it was understandable. The document provided contact details by telephone and email should anyone wish to object/opt out of the data collection process.

It was explained that a spreadsheet had been created that will be used to log queries and a column to indicate if the person had specifically requested not to have their data used. This will be shared with the Blackpool Teaching Hospitals NHS Foundation Trust informatics team prior to the extraction so that these patients can be removed if necessary from the data collection process.

The Sub-Committee received the revised document and supplementary information. No queries were raised.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Blackpool Teaching Hospitals NHS Foundation Trust and Midlands and Lancashire CSU, satisfactory reviewed grade on Version 14.1, 2017/18, confirmed by email received 05/11/2018).**

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr Patrick Coyle	Yes	Vice-Chair
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **DEveloping a Complex Intervention for DEteriorating Patients using Theoretical Modelling (DECIDE study)**

CAG reference: **18/CAG/0178**

IRAS project ID: **247047**

REC reference: **18/NE/0118**

Context

Purpose of application

This application from City, University of London set out the purpose of medical research which aims to develop an intervention to change the behaviour of nurses when reacting to a patient's 'Early Warning Score' (EWS). EWS is a tool which is used in hospital to assist nurses in recognising deteriorating patients. These tools provide a record of clinical observations, including blood pressure, heart rate, breathing rate, temperature and oxygen levels, which also generating an early warning score every time observations are performed. The higher the score, the risk is greater that deterioration will continue. The tools also instruct staff on what action to take – for example, if a patient has a medium or high EWS, nurses should contact a doctor for assistance. There is however evidence that these instructions are not always followed, leaving unwell patients at risk.

The proposed study involves staff only and has been submitted to the CAG as an element of the project will involve researchers observing nurses undertaking clinical observations on hospital wards. The behaviours which are observed on the wards will be compared to the ideal behaviours set out in the published guidance. The research team do not require access to confidential patient information for the purposes of the study; however, it is recognised that in observing staff undertaking their daily tasks, it is likely that the researcher will be incidentally exposed to confidential patient information.

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

Confidential patient information requested

Cohort

Staff observations will be undertaken at two hospital wards providing general care for acutely unwell medical and/or surgical patients. Across 6-8 months period, 180 hours of staff observation will be undertaken across the two wards.

The applicant is not seeking support to access any confidential patient information during the observation of nursing on the hospitals wards; however, it has identified that this may incidentally be disclosed. It cannot be foreseen what items of confidential patient information would be disclosed. Some clinical details may be of interest to the study; however, it is confirmed that these would relate to the clinical observations that form part of the EWS and would not fall within the definition of confidential patient information.

Confidentiality Advisory Group advice

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

1. **Replace the text in the poster to provide a make clearer how a patient can object to the researcher's observation – provide a revised document for review.**

The applicant provided a revised poster for information.

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

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed 30/10/2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University College London Hospitals NHS Foundation Trust – has a published satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Mr. Myer Glickman	Yes	
Mrs Diana Robbins	Yes	Lay Member
Dr Murat Soncul	Yes	Alternate Vice-Chair
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Synergy between PCI with TAXUS and Cardiac Surgery: SYNTAX Extended Survival (SYNTAXES)**

CAG reference: **18/CAG/0145**

IRAS project ID: **237300**

REC reference: **18/EM/0258**

Context

Purpose of application

This application which has been submitted by University Hospital Southampton NHS Foundation Trust on behalf of the Erasmus Medical Center (based in Netherlands), set out the purpose of medical research which aims to undertaken a ten year follow-up of patients who participated in the SYNTAX trial. The SYNTAX trial was the first large-scale randomised controlled trial which investigated Coronary Artery Bypass Grafting (CABG) versus Percutaneous Coronary Intervention (PCI) with drug-eluting stents in patients with coronary artery disease. The study follow-up completed at five years follow-up; however, questions remain outstanding around which of the two treatments provided better outcomes for patients within the trial. This application proposes undertaking a non-interventional 10 year follow-up of patients who were enrolled in the trial via NHS administrative datasets.

The follow-up will be coordinated by University Hospital Southampton NHS Foundation Trust on behalf of all sites within England and Scotland. Confidential patient information in relation to the study participants will be disclosed from the seven English sites to the named applicant at University Hospital Southampton NHS Foundation Trust, who will coordinate the follow-up process via NHS Digital. Alternative arrangements will need to be made by the applicant in relation to the Scottish site.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All 245 patients who participated in the SYNTAX trial, in England.

The following items of confidential patient information are required for the purposes stated:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage
- Hospital ID – sample validation,
- Date of birth – sample validation and linkage,
- Date of death – analysis,
- Gender – analysis,
- Study ID – sample validation and linkage.

Confidentiality Advisory Group advice

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

1. **Provide further justification to explain why confidential patient information will be disclosed to the University Hospital Southampton NHS Foundation Trust site, prior to onward transmission to NHS Digital.**

The applicant explained that SYNTAXES was a multinational study based upon collecting 10 year mortality on the original SYNTAX population. This data was unique and would offer important outcomes to inform the decision-making and counselling for patients who have a choice between surgery or stenting for complex coronary disease. Given the multinational nature of this project, the applicant's believed that the most effective way to ensure robust data collection for the UK was to use a coordinating site to collate data and submit a single application on behalf of the English sites to NHS Digital for the 245 UK patients, rather than separate applications and data collection across participating Trusts.

It was stated that this was more likely to ensure accurate and secure transmission of data to establish survival status. The research team at Southampton would coordinate the UK data collection in a structured and safe manner, so that the patient data is handled appropriately.

The Sub-Committee was assured by the response provided and raised no further issues in this area.

2. **Confirm that information would be returned from NHS Digital in a pseudonymised format with Study-ID alone.**

The NHS digital application will request that mortality data was returned to the coordinating site in a pseudonymised format with Study-ID alone.

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

3. **Confirm at what stage confidential patient information retained with support under the Regulations would be deleted by NHS Digital and University Hospital Southampton NHS**

Foundation Trust, in order to clarify the duration of support which is required under the Regulations.

Confidential patient information will be destroyed by both NHS digital and the coordinating site once mortality data has been secured. The pseudoanonymised data will be retained for a period of 15 years.

The Sub-Committee considered the response and it was noted that the timeframe for the destruction of confidential patient information remained unclear. The applicant was reminded of their responsibility to assess the ongoing necessity to retain confidential patient information with support under the Regulations. A report would be required at the time of first annual review around the ongoing requirement for this data retention.

4. **Patient and public engagement activity should be undertaken to test the acceptability of using confidential patient information without consent for the application purpose. An overview of the activity undertaken and the feedback provided is required prior any recommendation of support coming into effect.**

The applicant confirmed that they had arranged for the application to be reviewed by the Chairman of the British Cardiac Patients Association, who has written a letter of support for this project which was provided for information.

The Sub-Committee recognised that the British Cardiac Patients Association was an appropriate organisation to engage with around the study; however, it was commented that the letter of support from the Association's Chairman did not address the request which had been made. Members did not wish to unnecessarily delay the project start date and agreed that support would be recommended on a conditional basis, with a requirement that the applicant undertakes some activity in this area with patients and the public in order to test the acceptability of using confidential patient information for the study purposes. An overview of the actual activity undertaken, together with details of the feedback provided would be required at the time of first annual review. If the responses given were negative, the CAG would take this into account when considering whether support can continue, or whether further action is required.

5. **Patient Notifications and Dissent – provide a copy of the text which will be displayed on the historic site website in order to raise the profile of this proposed follow-up study. This should also describe how patients can object to the use of their information for these purposes. Confirmation should also be provided that all historic sites have confirmed that they will display this information of their websites as part of the communications strategy to support the follow-up study.**

The applicant provided a copy of text which participating Trusts would be asked to display on their websites. This included details on an objection mechanism for patients who did not want their information to be included in the follow-up trial.

The Sub-Committee reviewed the draft of the proposed website text and raised no issues in this area.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Support extends to the English sites only.
2. Involvement and engagement activity should be undertaken with an appropriate group of patients and members of the public to test the acceptability of using confidential patient information without consent for the application purpose. An overview of the activity undertaken and the feedback provided would be required at the time of first annual review. If the responses given were negative, the CAG would take this into account when considering whether support can continue, or whether further action is required.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 06/11/2018**).
4. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - University Hospital Southampton NHS Foundation Trust and NHS Digital show a published satisfactory reviewed grade on V14.1, 2017/18**).

Application title:	**Comprehensive Patient Records (CPR) for Cancer Outcomes: A feasibility studyWorkstream 5: Patient Reported Outcome Measures (PROMs)**
CAG reference:	**18/CAG/0119**
IRAS project ID:	**233983**
REC reference:	**18/LO/1043**

Context

Purpose of application

This application from the University of Leeds set out the purpose of medical research which, through the overarching research programme, aims to investigate the long-term effects of cancer and cancer treatment. The specific work stream which is presented in this application (Work Stream 5) relates to the collection of PROMs (Patient Reported Outcome Measures) data from patients around their opinions on their health, treatment, quality of life and other issues. This information will be linked with the wider clinical information collected throughout the study to create a comprehensive patient record, showing the long-term effects of cancer of quality of life, health and wellbeing.

The recruitment process is directed by the direct care team of patients; however, the applicants have identified two points within the process were wider staff at Leeds Teaching Hospitals NHS Trust, who would not be considered part of the direct care team, would potentially have access to confidential patient information and are seeking support under the Regulations to legitimise this data access. Patients invited to participate in the study will provide consent to wider activities, including linkage of the PROMs information with their wider clinical care record, which is out of scope for the CAG. The study will include a cancer patient cohort and a matched control cohort for comparison.
A recommendation for class 3 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

- Cancer Patients – 2,000 Breast, ovarian and colorectal cancer survivors aged over 18, at around five years post-diagnosis.
- Control Patients – 4,000 patients referred to dermatology for suspected cancer, but no cancer diagnosis was made.
- Controls will be matched on age, gender and GP practice.

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

- Name – invitation,
- NHS number – invitation and sample validation,
- Full address and postcode – invitation.

Confidentiality Advisory Group advice conclusion

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

recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 10/09/2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Leeds Teaching Hospitals NHS Trust – Version 14.1, 2017/18 – reviewed grade satisfactory**).

Group Members:

Name	*Present*	*Notes*
Dr. Liliane Field	Yes	
Ms Clare Sanderson	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **2018 Children and Young People's Patient Experience Survey**

CAG reference: **18/CAG/0150**

Context

Purpose of application

This application submitted by Picker Institute Europe and commissioned by the Care Quality Commission, set out the non-research purpose of facilitation of the 2018 Children and Young People's Patient Experience Survey. The survey, which will be third carried out to date, forms part of the NHS National Patient Surveys Programme and was last ran in 2016 when it was called Children and Young People's Inpatient and Day Case Survey (15/CAG/0209).

Trusts will be asked to conduct the survey with preparations expected to begin in January 2019 and fieldwork expected to start from February 2019. All Trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey. There are some proposed changes to the methodology for the 2018 Children and Young People's Patient Experience Survey. These changes are in line with applications within the wider NHS National Patient Surveys Programme, which had recently been considered by the CAG in relation to other submissions. The changes are as follows:

1. The inclusion of relevant Trust email and postal address information, if available, on dissent posters alongside a contact telephone number for patients to contact should they wish not to participate
2. Dissent posters being available in the ten most commonly spoken languages in England. Trusts can display these optional posters alongside the mandatory English poster to maximise reach for their patient population.
3. An earlier first reminder letter, sent five working days after the first mailing has been sent.

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

Confidential patient information requested

Cohort

Patients aged between 14 days and 15 years who were admitted as inpatients, day cases, and emergencies to an acute hospital between 01 November 2018 and 31 December 2018. Trusts will be required to draw a minimum sample of 400 patients, up to a maximum of 1,250. If this is not possible across the sample period, Trusts will be instructed to sample back to 01 October 2018 to achieve the required 400 patients.

The following two datasets will be shared by the participating Trusts in order to achieve the purposes sets out:

Mailing File – is used to facilitate the circulation of the survey and ensure this is addressed to the appropriate patient:

- Standardised survey identifier,
- Child's first name and surname,
- Address Fields,
- Postcode.

The sample file is being used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. This will contain:

- Trust code,
- Standardised survey identifier (as above),
- Year of birth,
- Sex,
- Ethnicity,
- Date of admission,
- Date of discharge,
- Length of stay,
- Main speciality on discharge,
- Treatment function code,
- CCG code,
- Treatment centre admission,
- Admission method,
- NHS Site code of admission,
- NHS Site code of discharge.

Confidentiality Advisory Group advice

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

1. Confirm the sampling timeframe of patient eligibility for inclusion in the survey.

The applicant confirmed that all eligible admitted patients, discharged from the Trust between 1st November 2018 and 31st December 2018, who were aged between 15 days and 15 years (inclusive) at the time of their discharge.

The maximum sample size for this survey is 1,250 and the minimum total sample size is 400. If a Trust is not able to draw a sample of at least 400 eligible patients within the established inclusion timeframe, they will be given the option to include eligible patients discharged between within October 2018.

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

2. Provide confirmation that confidential patient information submitted in relation to patients in a larger sample size than 400 would be destroyed and confirm the timeframe for undertaking this destruction.

The applicant confirmed that the maximum sample size for this survey is 1,250, with the aim being that all Trusts will be able to achieve as close to this target as possible using the agreed stratified sampling method. The 1,250 sample size is unchanged from the 2016 Children's Survey (CAG reference: 15/CAG/0209), consisting of: 450 patients aged 14 days to 7 years, 400 patients aged 8-11 and 400 patients aged 12-15. These target sub-sample sizes have been carefully designed to boost representation from the 8-11 and 12-15 age groups, as they account for a small proportion of admitted patients (compared to those aged 14 days to 7 years). The reason for setting the subsample size for those aged 14 days to 7 years slightly higher is to account for the lower response rate achieved for this group previously. By setting the sample sizes in this way, the applicants should be able to provide Trusts with results broken down by the 0-7, 8-11 and 12-15 age groups separately, allowing more targeted improvement initiatives to be implemented (compared to Trusts only having results combined for all patients aged 0-15)

It was explained that the rationale for setting a minimum sample size of 400 patients per Trust, was also driven by the value of reporting. If a Trust were to submit a sample below this limit, there are concerns they would receive too few responses to allow statistically robust analysis to be conducted, reducing the confidence Trusts and CQC have in their results.

This means no patients in a sample greater than 400 but less than or equal to 1,250 would need to be destroyed. However, if a Trust were to exceed the 1,250 maximum sample size, the applicant confirmed that they would consider this a breach of Section 251 approval and immediately destroy the information, requesting approved contractors and Trusts to do this also, where appropriate. Any incidences of this would also be reported to the Confidentiality Advisory Group.

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

3. Clarify in what format free text information provided in the questionnaire would be shared with Trusts, the CQC and researchers. If information will be disclosed in an identifiable format, clarify what the lawful basis would be for this onward disclosure in relation to current data protection legislation.

The applicant confirmed that all free-text comments are required to be submitted, in excel spreadsheet format, to the Survey Coordination Centre. Free-text comments would be analysed to check for safeguarding concerns that CQC needs to be aware of. In order to enable CQC to make the most effective use of the comments for regulatory activities these comments are not anonymised before being shared with the Survey Coordination Centre.

It was confirmed that the legal basis for the onward disclosure of information is consent. A disclaimer is present on each questionnaire to make it clear to participants that by writing any free-text comments they are providing consent for that information to be shared in full with the hospital, CQC and researchers in the Survey Coordination Centre. As participants are aware of how their comments will be used they have control over what they feel comfortable disclosing, are able to make a choice about opting in to volunteering this optional information (no question on the survey is mandatory) and have a free choice to opt out by not providing any comments.

All comments would be anonymised by CQC, approved contractors and Trusts prior to publication if there is a possibility the individual could be identified from their comments in isolation or by being combined with other response data. Additionally, prior to sharing comments as part of final data, where comments name a member of staff member, Trusts can exercise discretion and redact this information.

The Sub-Committee received this response and raised no issues with the clarification provided. It was noted that parents/carers would also be completing parts of the questionnaire and would be able to review their child's response. Members commented whether there had been any consideration of the potential impact this may have on the child's freedom to respond. It was agreed that no formal action was required from this point; however, it would be noted for information purposes for the applicant's consideration.

4. **Clarify why contractors would retain confidential patient information for a period of up to 12 months, acknowledging that survey reminders would be circulated within five days of the initial correspondence. If this extended retention is not required, confirm a shorter duration.**

It was clarified that confidential patient data, including free-text comments, is retained by approved contractors for both safeguarding and to support data quality assurance. Free-text comments are analysed to check for any safeguarding concerns that CQC may need to be made aware of. In the case of serious safeguarding issues, CQC may request patient information from the contractor. Information is held for a period of up to 10 months, the duration of the survey from sampling to publication, to ensure data remains available should issues arise following safeguarding analysis. It should be noted that all information held by contractors is held in compliance with GDPR guidelines.

Additionally, it was confirmed that confidential patient data and survey data is kept to ensure that investigations can be carried out where any data quality issues arise. The time from sampling to publication is typically ten months on a national survey and so data is kept for this period to ensure it is available for the reasons identified.

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

5. **Clarify whether the five recommendations which came out of the stakeholder consultations were incorporated into the questionnaire.**

The applicant provided a detailed over of the five recommendations from the stakeholder consultations, how these were assessed and acted on for consideration.

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

6. **Provide copies of the survey questionnaire documentation for information purposes.**

Copies of the questionnaires, information flyers and dissenting posters were provided for information.

Documentation was received by the Sub-Committee and no issues were raised in this area.

7. **Confirm the final contractor which will facilitate the survey distribution, together with the NHS IG Toolkit organisation code to enable security assurances to be checked.**

The applicant confirmed that there would no longer be a fourth contractor involved in the survey.

The Sub-Committee received the clarification and no issues were raised.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Picker Institute Europe, Quality Health and Patient Perspective all have a published satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Tony Calland MBE	Yes	Chair
Mr Anthony Kane	Yes	Lay Member
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Housing, family and environmental risk factors for hospital admissions in children**

CAG reference: **18/CAG/0159**

IRAS project ID: **235275**

REC reference: **18/LO/1514**

Context

Purpose of application

This application from University College London set out the purpose of medical research which aims to investigate the impact of environment and socio-economic factors on hospital admissions in children. The project will use an established birth cohort of infants born in England between 2005 and 2014. This will be linked by the Office of National Statistics (ONS) to 2011 Census Data and small area level data on air pollution and building characteristics in order to create a dataset to facilitate analysis.

The birth cohort was established with support under the Regulations via application PIAG 2-10(g)/2005, which was subsequently amended under application reference CAG 9-08(b)/2014. The amended application linked the birth cohort data with HES data at NHS Digital to collate information on mothers and babies admitted/readmitted to hospitals in the first year of birth. An amendment was subsequently supported in May 2016 which linked the dataset with ONS mortality data to collate additional information around deaths in infants aged over one year and maternal deaths within one year of delivery of the child. City, University of London is the controller for the birth cohort information which is retained by ONS.

The application has been submitted for consideration by the CAG to seek support to use the data held within the established dataset for the wider research purposes described within the application. Support is also sought for the processing of confidential patient information which will be undertaken by ONS to link this dataset with Census, air pollution and building characteristic information. These supplementary datasets do not fall within the legal definition of confidential patient information, as set out at section 251(11) of the NS Act 2006, and processing of this information would not fall within the remit of the CAG to support. The dataset with which the birth cohort will be linked are as follows:

- 2011 Census information (for births between March 2010 and March 2012 – one year before/after Census) – data collected will include information on overcrowding, house type and tenure, type of heating, mother and fathers length of stay in the UK and knowledge of English,
- Department for Environment, Food and Rural Affairs information on full postcode level data on annual levels of eight specified pollutants modelled using atmospheric transport models,
- Information around distance to A roads and motorways using maternal postcode at delivery,
- Ministry of Housing, Communities and Local Government information around Energy Performance Certificates (EPC) for building characteristics.

A recommendation for class 2, 4 and 6 support was requested to cover activities as described in the application form.

Confidential patient information requested

Cohort

All children born alive in England to English resident mothers between 01 January 2005 and 31 December 2014. There are 7 million children recorded in the existing sample. A sub-cohort of patients within this will be established for linkage with the 2011 Census which will include all births between March 2010 and March 2012.

The following items of confidential patient information held within the established birth cohort dataset will be used for the purposes described:

- Name (Mother) – linkage to 2011 Census information,
- NHS Number (Infant) – linkage to fully identifiable ONS birth registration data as part of linkage to Census,
- NHS Number (Mother) – within the birth cohort data set,
- Date of birth (Mother and Infant) – linkage,
- Date of death (Infant) – analysis,
- Date of death (Mother) – within the birth cohort data set,
- Postcode (birth) – linkage and analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

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

1. **Consider whether provision of a single direct email contact with the patient notification material is appropriate, accounting for the size of the cohort to be included in the study. Provide a revised document if deemed appropriate detailing wider means of communication.**

The applicant confirmed that a project-specific email address had been set-up, to manage queries around this project. This email address will be monitored by the principle investigator and the data manager of the study. A revised patient notification document was provided for review, which detailed the new email address and also provided a link to contact details of the UCL Great Ormond Street Institute of Child Health, to enable direct contact with the main applicant is necessary.

The Sub-Committee received the response and supporting document and no issues were raised in this area.

2. **Clarify how the objection mechanism would be operated for the study, explaining how any dissent raised would be respected.**

The applicant confirmed that in accordance with the GDPR, they would respect individuals' right to object if objections would not seriously impair the research. Serious impairment of the research would only occur if a substantial proportion of the 6.7 million children and/or their mothers object. If an individual contacts the study team to object to processing, using any of the methods provided, they would be asked to provide a form of identification (and, if they are objecting for their children) proof of parent or legal guardian status. NHS number, date of birth and postcode would be required to enact the dissent request. Contact would be made with the ONS to ask them for the study number of the individual objecting, as the applicant would not have access to the identifiers. The individual would then be excluded from the analyses. If linkage to Census, air pollution and building characteristics data has not yet occurred when the objection is raised, the individual would be excluded before the cohort is linked to these data sources.

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

3. **Provide an overview of how a wider communications strategy can be implemented in order to raise the profile of the study more widely in the public arena. It is recommended that established links referenced within the application, with Shelter and the British Lung Foundation, could be drawn upon to promote the study more widely.**

The applicant clarified that, as outlined within the application, the British Lung Foundation, through the Clean Air Parents' Network (CAPN, https://www.clientearth.org/clean-air-parents-network/) had agreed to post information about the study on their website and Facebook page. CAPN also sends out newsletters to parents who have indicated their interest, where the study could also be promoted. The applicant confirmed that they would also work with the CAPN and Shelter to hold meetings with parents concerned about air pollution or have been affected by poor housing. At these meetings, parents would be asked for their ideas of how the public profile of the research work could be raised. The applicant explained that whilst they had discussed the potential of promoting the study via Shelter's social media presence; however, whilst Shelter is highly supportive of the aims of the study their policy is to only post about their own reports and research.

The study itself and any results from the study would also be promoted via UCL social media (Twitter and/or Instagram) and information about the study could be placed on the main UCL website (https://www.ucl.ac.uk/). It was also confirmed that infographics would be developed which explained the cohort and the results (when these are available) which will be promoted via UCL social media and website. Further information about the study and any outputs will be available on dedicated websites hosted by UCL.

The Sub-Committee received the response and no issues were raised.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee (**Confirmed 05 October 2018**).
2. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Office for National Statistics has a published satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Tony Calland MBE	Yes	Chair
Mr Anthony Kane	Yes	Lay Member
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI) – Transfer of Controllership Arrangements**

CAG reference: **18/CAG/0166**

Context

Purpose of application

This application has been submitted by the Trauma Audit and Research Network (TARN) for non-research purposes. The application seeks support under the Regulations for the change of controller of the confidential patient information which was collated under the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) its physical transfer to TARN.

The National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) was commissioned by the Healthcare Quality Improvement Programme (HQIP) on behalf of NHS England to examine current provision of services for patients who have suffered severe injuries. The UK Specialist Rehabilitation Outcomes Colloborative (UKROC) submitted the application on behalf of HQIP. The NCASRI audit application was initially considered by the CAG in September 2016 under application reference 16/CAG/0108. The audit received a final recommendation in January 2017. The audit was completed on 30 June 2018 when its three year National Clinical Audit and Patient Outcomes Programme (NCAPOP) contract ended.

The Trauma Audit and Research Network (TARN) is the national clinical audit of trauma care. It is not part of the NCAPOP suite of audits commissioned by HQIP on behalf of NHS England. TARN currently operates with support under the Regulations via application ECC 7-05(g)/2011.

UKROC is a national clinical database which routinely collects key information about every patient admitted to a specialist rehabilitation unit in England. It is not commissioned by HQIP and processes confidential patient information under direction from NHS England.

A key component to the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) was to undertake record level linkages from the TARN and UKROC datasets in order to be able to track individual patients discharged from major trauma centres to identify those that subsequently received specialist rehabilitation.

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

Confidential patient information requested

Cohort

All patients who were included in the National Clinical Audit of Specialist Rehabilitation following Major Injury, which operated from 01 July 2016 to 30 June 2018.

The following items of confidential patient information would be transferred within the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) dataset from UK Specialist Rehabilitation Outcomes Colloborative (UKROC) to Trauma Audit and Research Network (TARN). Information will be retained in an identifiable format to facilitate future linkage:

- NHS number,
- Date of birth,
- Postcode (District Level),
- Date of treatment,
- Date of death.

Confidentiality Advisory Group advice

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

1. Confirm the number of patients included within the NCASRI dataset.

The applicant confirmed that 4,021 episodes were recorded in the NCASRI dataset.

The Sub-Committee received the clarification and raised no issues.

2. Clarify how the requirement for ongoing retention of the data would be assessed on an annual basis.

The applicant explained that NCASRI feasibility audit demonstrated that patients discharged from the major trauma centres (MTCs) may take 12 months or more to appear within the UK-ROC database. The existing dataset contains TARN patients that remain unlinked (due to the time period between discharge and appearing on UK-ROC). With separate permissions, further linkage would provide a more robust evaluation of service provision and also assist in determining why certain patients with specialist rehabilitation needs did not receive these services.

It was confirmed that the requirement for ongoing retention would be reviewed by the TARN Executive committee every six months and any recommendations documented and included in the report to CAG.

This data could be used for service evaluation and non-research purposes, once future permissions are granted or in place and will be stored in a University of Manchester Data Safe Haven, which is in line with NHS Digital's data storage requirements.

The Sub- Committee noted that the ongoing retention requirement would be reviewed by the applicant every six months. The initial review at six months would inform the report requested by CAG as a condition of the recommended support. The applicant had asked for further clarity to understand the rationale for this condition of support. As the application did not set out any specific purposes for which the retained data would be used, it was unclear what the ongoing public interest in retaining the NCASRI dataset in an identifiable format would serve. Provision of feedback at the six month period is required to confirm a specific purpose for which the data would be used and justify the retention of confidential patient information by assuring that these identified purposes could not be achieved if the data was retained in an anonymised format only. On receipt of the initial report at six months, the CAG would consider whether further interim reports would be required to supplement the mandatory annual review submission.

3. **Patient notification and dissenting documentation should be drafted which describes the ongoing retention of the NCASRI audit dataset and provides a mechanism for dissent to be raised. An overview of where information will be displayed is required together with details of how any dissent would be respected.**

The applicant confirmed that information about how data is used, stored and collected and available within the public section of the TARN website. If support to retain this historically linked dataset was recommended, the applicant advised that details of this would be clearly documented on the website including purposes for retaining this dataset. The same methods for patient dissent applied to TARN would also apply to this dataset. It was confirmed that the TARN website also provides guidance on how patients can opt out, which would be applicable to the linked dataset.

With regards to the NCASRI dataset, it was explained that during the data collection period, local teams put up posters in all of the centres offering the option of 'opt out' from the NCASRI for patients (or their families) who did not wish to participate. As this is a historical dataset, the applicants advised that they did not expect that patients would still be in the units in which they were treated. As such, any patients wishing to opt out can so through the TARN website, as previously described. It was also confirmed that any queries linked to the UKROC elements of the data would be directed to the UKROC team.

The Sub-Committee received the response and raised issues in this area.

4. **Provide further information to show how the proposed activity is compliant with Article 5(1) – principles (a)-(f) of the GDPR.**

The applicant provided a detailed overview explaining how the activities complied with the requirements of the GDPR. It was confirmed that processing was necessary for the performance of a task carried out in the public interest and was necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance.

The Sub-Committee received the clarifications and raised no issues.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Support is extended for a six month period only from the date of the final recommendation. Within this time, an assessment should be undertaken to establish the future purposes of the only going data retention. A report should be provided to the CAG in order to establish an ongoing public interest in the retention of the dataset. This would need to be supported by a duration extension amendment as appropriate.
2. Support extends to non-research purposes only.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Trauma Audit and Research Network, published satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Ms Sophie Brannan	Yes	Lay Member
Dr Patrick Coyle	Yes	Vice Chair
Mr. David Evans	Yes	
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Epidemiological studies of the Porton Down veterans: a ten-year update of mortality and cancer incidence**

CAG reference: **18/CAG/0171**

IRAS project ID: **192792**

REC reference: **18/LO/1760**

Context

Purpose of application

This application from King's College London, University of Oxford and University of Lancaster set out the purpose of medical research which aimed to undertake a 10 year update of mortality and cancer incidence of the patient cohort included in the 2002-07 Porton Down Veterans study. The previous study investigated whether military veterans who were exposed to chemical agents as part of the 'human volunteer programme' at the UK government's research establishment at Porton Down, had unusual rates of cancer incidence or mortality compared to veterans who did not attend Porton Down, and the general population.

The original study was considered by the Patient Information Advisory Group (PIAG) in December 2002 and support was recommended for the project (at that time, under Section 60 of the Health and Social Care Act 2001). Within this study, the University of Oxford assembled a cohort of patients who were flagged in the NHS Central Register which comprised of c20,000 Porton Down veterans who took part in the 'human volunteer programme' between 1941 and 1989. The patient records were linked to routine data held by the Office for National Statistics to compare their pattern of deaths and cancer registrations up to 2004, with that of a comparison cohort of c20,000 non-Porton Down military veterans. The study established that, although there was a small (6%) excess of all-cause mortality, this could not be attributed to any specific exposure at Porton Down and might have been related to unmeasured factors such as smoking. There was no excess of cancers.

This study will update mortality and cancer registration data by at least 10 years. This new data will enable the analyses carried out previously to be repeated, but with increased statistical power so a more full examination of the impact of rare exposures and outcomes at a level of detail not possible in the original study. The remit of the CAG extends to data linkage to be undertaken via NHS Digital. The application references linkages via NHS Scotland and the North Ireland Statistics and Research Agency; however, an alternate legal basis would need to be established in relation these patient groups.

A recommendation for class 2, 4 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

The proposed study involves the same patient cohort which was established during the original 2002-07 study. This included a cohort of Porton Down veterans' who attended the facility as part of the 'human volunteer programme' between 1941 and 1989, comprising of 18,276 individuals. A control comparison cohort was also included which comprised of individuals with a military service number adjacent to a Porton Down veteran, but did not attend the facility themselves, comprising 17,600 individuals.

The following items of confidential patient information have been identified by the applicant as being required for the study purposes:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage (where available),
- Date of birth – sample validation, linkage and analysis,
- Date of death – sample validation and linkage,
- Address – (text of address at discharge from military service) – linkage,
- Postcode (District Level) – sample validation and linkage,
- Gender – analysis.

Confidentiality Advisory Group advice

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

1. Justify the requirement for patient address to be included within the study dataset.

The applicant explained that in the original study, the UK Ministry of Defence made the military personnel records for the cohort members available to the research team. These were mainly military service records dating from the Second World War and the immediate post-war period and were much less comprehensive than a Service person's record might be today. From these original military service records, the research team abstracted information to assist NHSCR in the original flagging. A high proportion of the addresses abstracted had no postcode because they were recorded by the military in the pre-postcode era.

For the updated study, the applicants confirmed that they intended to again supply NHS Digital with what information is held on the cohort members last known address, i.e. 'address at discharge', to assist with re-flagging and linkage. Recent correspondence with NHS Digital had confirmed that additional identifiers, such as address, can be useful to help confirm a trace where there is some doubt, and when tracing has failed at auto-match and operators have been requested to perform a manual trace. The applicant confirmed that address would not be requested as part of the disclosed data set from NHS Digital following linkage.

The Sub-Committee received the response and no issues were raised.

2. **Confirm the roles of the three joint controllers, King's College London, University of Oxford and University of Lancaster, within the proposed application activity.**

It was explained that the applicant had used the term 'data controller' within the application as defined by the Information Commissioner's Office ('a controller determines the purposes and means of processing personal data'). The research programme is a collaborative project between King's College London, Oxford and Lancaster universities; all three institutions have jointly defined objectives and methodology, will jointly oversee the analysis, and be responsible for the findings of the research.

When 'data controller' is used in the sense of 'the organisation in whose premises the data are housed', the data is currently housed in Oxford (where the original research was carried out); however, all data will be transferred to King's Centre for Military Health Research (King's College London) once necessary approvals has been obtained.

The Sub-Committee received the response and no issues were raised.

3. **Clarify whether the University of Oxford will continue to have access to confidential patient information in relation to the cohort following the initial disclosure.**

The applicant confirmed that once all necessary approvals had been obtained, all study data would be transferred from Oxford to King's Centre for Military Health Research, King's College London; therefore, Oxford would no longer have access to confidential data.

The Sub-Committee received the response and no issues were raised.

4. **Clarify the overall duration of the confidential patient information in order to define the exit strategy for the project.**

The applicant confirmed that, for the study update, personal identifiers and confidential information on mortality and cancer would be held for at least the duration of the project, estimated to end November 2021. Personal identifiers will be separated from information on mortality and cancers, and all analyses will be conducted using pseudonymised datasets.

The long-term intention is to make full use of this globally unique cohort data. Subject to relevant approvals, the applicants planned to link the cohort with HES data to explore additional health outcomes (e.g. psychiatric outcomes, as outlined in our study protocol), and to complete a second follow-up, up to 2024.

To complete these future objectives, the applicants clarified that further approval would be sought to retain personal identifiers until 2024, which would be needed to assist with data linkage, and individual opt-out requests. If no further study update is forthcoming, it was confirmed that the applicant would electronically and physically destroy all confidential data.

The Sub-Committee received the response and no issues were raised.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Patient and public involvement and engagement activity should be progressed as per the plans which were detailed in the initial application. An overview of the actual activity undertaken should be provided at the time of first annual review, together with any feedback which was provided, for consideration. If the responses given were negative, the CAG will take this into account when considering whether support can continue, or whether further action is required.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 26 October 2018**).
3. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – King's College London – King's Centre for Military Health Research and NHS Digital have published satisfactory reviewed grades on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Dr Lorna Fraser	Yes	
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Understanding the mental health needs of mothers involved in family court cases: A research study exploring linkage between family court and mental health data**

CAG reference: **18/CAG/0112**

IRAS project ID: **245343**

REC reference: **18/SC/0363**

Context

Purpose of Application

This application from South London and Maudsley NHS Foundation Trust and King's College London Institute of Psychiatry set out the purpose of medical research through the establishment of a research database which intends to generate evidence about the health needs of mothers who are involved in care proceedings (including recurrent care proceedings). Care proceedings are family court cases where the local authority applies to the court to have a child removed from parental supervision because they believe a child is risk of significant harm.

The application proposes to link information from Children and Family Court Advisory and Support Service (Cafcass) around care proceedings to patient records held in the Clinical Research Interactive Search (CRIS) database, which holds information on mental health service users at the South London and Maudsley (SLaM) NHS Foundation Trust. Health data for women who link to mental health records within the CRIS database will be compared against the records of women who do not.

The three objectives which have been cited for the research database are as follows:

1. Evaluate linkage success between Cafcass and mental health service data held by CRIS,
2. Describe the frequency, type and timing of mental health service use among mothers involved in care proceedings,
3. Evaluate risk factors (such as live birth interval) for involvement in care proceedings for women using mental health services.

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

Confidential Patient Information Requested

Cohort

- Cohort One: Women involved in care proceedings who were resident in one of the Local Authorities between 01/04/2007 and 31/03/2017 as identified from the Children and Family Court Advisory and Support Service (Cafcass) dataset. This consists of 3,396 mothers who will be included within the cohort regardless of whether successful linkage is achieved with mental health records within the South London and Maudsley NHS Trust CRIS database. This cohort will be used to answer the questions set out in objectives one and two.
- Cohort Two: The CRIS database will provide information in relation to women accessing mental health treatments within the four Local Authority Areas which SLAM Covers (Lambeth, Southwark, Lewisham and Croydon) and information in relation to women accessing supplementary addiction services for an additional three local authorities (Wandsworth, Greenwich and Bexley). Women will be aged 16 – 55 years accessing mental health services from 01/04/2007 – 31/03/2017. The sample size for this cohort has not yet been established; however, the applicants have estimated, based on previously published information, that the CRIS cohort will include 399,630 women aged 20-59 years, so it is expected that the target cohort will contain similar numbers, based on a slightly different age range. This cohort would be used to answer the questions posed in objective three.

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

- Name – linkage,
- Date of birth – linkage,
- Postcode – linkage and analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

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

1. Confirm which organisation is acting as controller for the purposes of the project.

It was confirmed that South London & Maudsley Trust (SLaM) is the controller for CRIS data; CAFCASS is the controller for the CAFCASS data. SLaM and CAFCASS will work in partnership in order to obtain the linkage. SLaM and CAFCASS will act as joint data controllers for the application activity and will be data controllers in common with regards to the resulting linked data set.

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

2. Provide an overview of further planned patient and public involvement and engagement activity with a cohort which has been involved in care proceedings. Detail should be provided how and when activity will be undertaken, together with an overview of what will be explored as part of these sessions.

The applicant explained that engagement activity was planned with groups of women who may have direct experience of family court proceedings. Via Addiction services at SLAM, the applicant would work with the clinical team to identify two service users to discuss the project. The applicant had also approached the coordinator for the Pause project based in Hackney, London, to identify a service user meeting or forum when the project could be discussed. The patient and public involvement convenor for the Children's Policy Research Unit, based at University College London had also been approached, to facilitate a group session with vulnerable parents when the Cafcass-CRIS project can be discussed. It was confirmed that these arrangements were in progress, and meetings were expected to be held within the next six months. The applicant confirmed feedback would be provided at the first annual review in line with the specific condition detailed.

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

3. Provide a copy of website text which would be displayed on the SLaM-CRIS website around the project for review. This should provide specific details about the project and enable an opt-out facility.

The applicant provided a copy of the lay summary for the project, which would be listed on both the CRIS project page, and on the CRIS Data Linkages page.

The Sub-Committee considered the website text provided. Whilst Members agreed that the text did provide a clear overview of the focus of the study, it did not make clear that confidential patient information would be used within the study or provide a means for patients to object to the use of the data. The Group agreed that the website text would require further revision to address these points; however, it was agreed that support would be conditionally recommended on this basis. The revised text should be provided within three months of support coming into effect.

4. Provide a copy of the website text which would be displayed on the Cafcass website around the project for review. This should provide specific details about the project and provide a link to the SLaM-CRIS website in order to inform patients about the opt-out facility.

The applicant confirmed that the project would be listed on the 'External research supported by Cafcass' page as an ongoing project. The project title will be listed as well as the names of the lead investigator. It was confirmed that the title would link directly to the SLaM-CRIS website with the lay summary provided in response to question three. The applicant also provided the text of a privacy notice which would also be displayed at that this webpage.

Members considered the response and drafted text provided. It was recognised that the purpose of the privacy notice was to satisfy the requirements of current data protection legislation. However, as this information had been provided directly in response to the queries raised by the CAG, it was understood that this was also intended to fulfil the patient notification requirements in relation to the common law duty of confidentiality. The Sub-Committee noted that the text did not clearly describe that confidential patient information would be processed in order to create the dataset required for the research analysis. It was agreed that the text would require revision to make clear that confidential patient information would be processed during the course of the project. Members agreed that support would be recommended conditionally on this basis, with feedback required from within three months of support coming into effect.

5. Explain how the project specific opt-out mechanism would be operated. Confirmation is also required around the lead-in duration that information would be displayed ahead of the data linkage being undertaken, in order to allow a specific time period for meaningful opt-out.

It was explained that patients have the right to opt out from having their records in CRIS. Records would be automatically excluded from the CRIS repositories if they appeared on an exclusion list of source system IDs. This means that SLaM patients who had previously opted out of sharing their data for research purposes, would be removed from the linked dataset provided to the applicant. It was confirmed that once all regulatory approvals were in place, information about the study would be made available via the websites, allowing a three month window for patient objections to be made.

The Sub-Committee received the response and raised no queries. It was noted that the revised website text requested at points three and four above would need to be provided, prior to this being made available via the study websites.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. The project summary on the SLaM-CRIS website should be revised to clearly state that confidential patient information would be processed in the creation of the analysis dataset to be used in the study and provide clear objection methods. A copy of the revised text should be provided for review within three months of the date of this outcome letter and prior to any detail being posted on the study websites.
2. Support is extended to processing of confidential patient information by South London and Maudsley NHS Trust to facilitate linkage with the information disclosed by the Children and Family Court Advisory and Support Service only.
3. Support only extends to the creation of the dataset for cohort one, required to address objectives one and two, at this time. Feedback is required on the findings of these elements of the study before support would be considered in relation to objective three of the overall project.
4. Feedback would be required at the time of first annual review around the outcomes of the planned patient and public involvement and engagement activity. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
5. Favourable opinion from a Research Ethics Committee (**Confirmed – 05 September 2018**).
6. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – South London and Maudsley show a satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Professor Barry Evans	Yes	
Mr. David Evans	Yes	
Ms Clare Sanderson	Yes	Alternate Vice-Chair
Ms Gillian Wells	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Prevalence of hip femoroacetabular impingement (FAI) syndrome in the general population**

CAG reference: **18/CAG/0151**

IRAS project ID: **241544**

REC reference: **18/IEC08/0020**

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to use existing data which was collected under the Somerset and Avon Health Survey (SASH), which was conducted between 1993-5 and 2002-3, to understand how common hip impingement syndrome (Femoroacetabular Impingement – FAI) is in the general population. The purpose of the original Somerset and Avon Health Survey was to determine population requirements for elective surgery, including hip replacement.

Hip impingement syndrome was first described in 2003 and is a condition of the hips which causes pain in young adults. The symptoms are hip pain or clicking, catching or stiffness, restricted range of hip movement, lack of hip osteoarthritis and presence of certain types of hip shapes seen on x-ray.

Data and x-rays collected under the previously consented Somerset and Avon Health Survey will be used for this additional research purpose. As the condition was first described after this initial research was carried out, the existing consent which was in place would no longer be considered valid for these additional research purposes. Guidance was sought from the Confidentiality Advice Team as part of the review undertaken by the NHS Research Ethics Committee around this point. The application has been submitted to the CAG to seek support under the Regulations to use this existing historical data for the

additional research purposes which were not described within the initial study. No additional linkage is proposed in the study.

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

Confidential patient information requested

Cohort

22,978 patients who had originally provided consent to participate in the Somerset and Avon Health Survey.

Access the following items of confidential patient information will be required, to facilitate the creation of the pseudonymised dataset required for analysis purposes in the newly proposed research study:

- Name/Initials – to be deleted from analysis dataset,
- GP Registration – will be replaced with a number variable in the analysis dataset,
- Date of birth – will be used to calculate age at the time of examination for analysis,
- Date of death – will be used to calculate age at death for analysis,
- Postcode – will be replaced with broad geographical areas for analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

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

1. **Confirm the expected duration that access to the confidential patient information held in the original SASH dataset would be required to create the pseudonymised dataset for analysis. Clarify whether the referenced 12 month duration was the anticipated timeframe to undertake the required study analysis on the pseudonymised dataset.**

The applicant explained that access to confidential patient information held in the original SASH dataset was expected to last one to two months, in order to create the pseudonymised dataset for analysis. It is anticipated that the FAI hips study analysis using the pseudonymised dataset will take the remaining 10-11 months of the overall project.

The Sub-Committee received the response and raised no issues.

2. **Provide a revised copy of the website text which provides clear information around how a patient can raise a dissent to the use of their data in this specific project – a named contact should be provided, together with contact telephone number, email and post addresses.**

The applicant provided a revised copy of the website text for CAG consideration.

Members considered the revised text and it was commented that the document quite complex and may not be accessible to all patients. It was agreed that the text should be revised; however, the CAG was content to provide support to the application, on the basis that the revised text was provided with three months. It was recommended that the revised text be reviewed by a patient group prior to submission to ensure that this is deemed acceptable.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. The website text should be revised to make this more accessible to a wider public audience. This should be reviewed by a patient group prior to resubmission. This should be provided for review within three months of the date of this outcome letter.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 18 June 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements (**Confirmed – University of Bristol SSCM - The Hip Study (EE133799-SSCM-THS), has submitted a Data Security and Protection Toolkit. NHS Digital email confirmed standard met – V14.1 2017/18 IG Toolkit equivalent on 15/11/2018**).

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Tony Calland MBE	Yes	Chair
Mr. David Evans	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **National Ophthalmology Database (NOD) Audit**

CAG reference: **18/CAG/0149**

Context

Purpose of Application

This application from the Royal College of Ophthalmologists, on behalf of the Healthcare Quality Improvement Partnership (HQIP) set out the medical purpose of clinical audit which consists of consists of a national cataract audit in England and Wales, as well as a feasibility study for the collection of cataract patient reported outcome measures (PROMs).

The audit was initially funded for three years from 01/09/2014 to 31/08/2017, during which pseudonymised data only was collected. The audit programme has now been extended for a further two years from 01/09/2017 through to 31/08/2019, during which a change to the methodology is proposed to enable confidential patient information to be collected as part of the audit programme. It is explained that by collecting confidential patient information, the applicants will be able to:

- Check the completeness of extracted data from providers by cross checking patient ID against NHS Digital data for individual cataract operations done by each centre,
- Link patients' data if collected at different centres and track patients moving between providers for second eyes (R/L) or operations by another provider to deal with complications,
- Match the patient's postcode to the English and Welsh indices of social deprivation.

The Royal College of Ophthalmologists has been commissioned by HQIP to provide the audit. Data processing for the audit has been sub-contracted to Gloucester Hospitals NHS Foundation Trust (GHNHSFT).

There is a feasibility element to the project around the collection of PROMs data from patients which will be operated at 5-10 sites who are providing data to the audit.

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

Confidential Patient Information Requested

Cohort

- All adult patients in England and Wales undergoing cataract surgery, between 01/09/2017 to 31/08/2019.
- Sample size is not known; however, 420,000 cataract operations were undertaken across England and Wales in the last audit reporting period (2016/17).

The following patient identifiable data will be extracted from the EMR systems and databases of participating centres in England and Wales and transferred to Gloucester Hospitals NHS Foundation Trust (GHNHSFT). This information would also be disclosed to NHS Digital and NHS Wales Informative Service in order to facilitate linkage with wider administrative datasets.

- NHS Number,
- Date of birth,
- Person Gender Current (Sex),
- Ethnic category (where available),
- Post Code of Usual Address – to calculate IMD.

Confidentiality Advisory Group advice

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

1. **Provide a clear justification for the collection of NHS Number, date of birth and patient sex within the audit dataset.**

The applicant provided the following justification for the specified items of confidential patient information:

- **NHS number** is needed to identify the patients receiving cataract surgery, to identify gaps in the reporting of individual patients to the audit (e.g. those with poor outcomes not being reported), and to track patients that may present at different providers for dealing with consequences of possible complications or second eye surgery.
- **Date of birth** is needed to calculate age at surgery and as a secondary linkage key to assist with accurate matching of data from different sources.
- **Gender** is needed to report on basic demographics of patients undergoing cataract surgery and for risk adjustment of outcomes.

All three data items would also be used to the link the audit data with the NHS Digital and NHS Wales Informatics Service (NWIS) databases. The data linkage would enable the audit to perform a detailed assessment of care received by cataract patients and also allow accurate assessment of case ascertainment. It is known that both age and gender are relevant to the risk of surgical complications these data items are needed to risk adjust the results of centres and surgeons. Risk adjustment is a fundamental part of the audit and can assist with case allocation and surgeon training. The applicant had also considered reducing the postcode to sector level following the completion of the IMD matching, and it was confirmed that the second half of the patient postcode would be excluded from the analysis set once the IMD score calculation has been completed.

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

2. **Further consideration should be given to the proposed data flows between Gloucester Hospitals NHS Foundation Trust, the processor for the audit, and NHS Digital and NWIS in**

order to limit the flow of and prevent duplicated flow of confidential patient information. A revised methodology should be described and confirmed. If it is decided that no changes will be made to the data flows with NHS Digital and NWIS, a strong rationale would be required to support this decision.

The applicant explained that the proposed methodology for the study had been considered and had been revised accordingly to reduce the flow of confidential patient information. A revised data flow was provided to show the changed methodology. It was explained that Gloucester Hospitals NHS Foundation Trust would provide NHS Digital and NWIS with the details (NHS number, date of birth and postcode) of patients reported into the audit to enable linkage with the HES and PEDW databases. A list of patients who have had cataract surgery but had not been reported to the audit by the contributing centres would then be returned to Gloucester Hospitals NHS Foundation Trust for assessment of case ascertainment. The applicant confirmed that this revised methodology has been discussed with NHS Digital and NWIS, and provided correspondence to support agreement in principle to the linkage.

The Sub-Committee received the explanation of the revised methodology and supporting data flow diagram. Members were content to provide a recommendation of support to the audit programme on this revised methodology as the risk of duplication of data flows had been significantly reduced.

3. **Revised patient information materials should be provided to describe amended data flows with NHS Digital and NWIS, in light of any changes made at point two above.**

The applicant provided revised patient-facing materials which described the revised methodology and data sharing which would be undertaken during the audit programme.

Members received the revised documentation and no queries were raised in this area.

4. **Provide further information around the patient and public involvement and engagement activity which had been undertaken to date, explaining how this activity was carried, which charities were involved and how patients and the public were consulted with around the proposed change to the audit methodology.**

The applicant confirmed that the Royal College of Ophthalmologists Steering Group included representatives from the Patients Association, the Royal National Institute of Blind People (RNIB) and the Royal College of Ophthalmologists Lay Advisory Group (LAG) which includes memberd who are or have been eye patients and members who have a link to eye or health related organisations. These representatives maintain links with patients and their concerns. The applicant explained that, via this engagement, the views of patients and the public were fully accounted for in the development of the Royal College of Ophthalmologists' audit activities. It was further explained that the Steering Group included key stakeholders from England, Wales and Scotland (e.g. Clinicians, Independent Statistician, Commissioners and the College of Optometrists). The Group met twice a year and was responsible for the oversight and high level management of the NOD Audit.

The Sub-Committee received the clarification and no queries were raised in this area.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Gloucester Hospitals NHS Foundation Trust and Medisoft Limited both have a published satisfactory reviewed grade on Version 14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Mr. David Evans	Yes	
Professor Barry Evans	Yes	
Dr. Liliane Field	Yes	
Ms Clare Sanderson	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Evaluation of patient access to medical test result services in general practice.**

CAG reference: **18/CAG/0152**

IRAS project ID: **249637**

REC reference: **18/WA/0268**

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to gain a better understanding of the services currently offered to provide electronic medical test results of GP practice patients in England. The study involves a number of components involving patients and practice staff, on a consented basis in order to gain understanding in this area and to seek the views of patients and clinicians in relation to different text results services.

The CAG was being asked to consider one element of the overarching research programme relating to GP practice cases studies (section 3.4.3 of the research protocol). This element of the project involved the research team undertaking observations of GP practice staff. The aim was to observe how the test result services function, identify staff and staff roles, clarify electronic test result dissemination routes and collect documentation such as standard operating procedures. All GP practice staff who deal with medical test result services will be observed, which may include reception and back-office staff. There will be six GP practices involved in this element of the study, which will be observed at two time points: baseline in May 2019 and at the end of the fieldwork (January 2020). The researcher undertaking the GP practice observations is not considered part of the direct care team and may be incidentally exposed

to confidential patient information during the course of the observation, though this information itself does not form the focus of the observation. It was noted that support could not be provided to healthcare professionals/staff, but that support was requested only for the incidental disclosure of relevant patient information.

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

Confidential patient information requested

Cohort

All GP staff involved in the handling of medical test results will be observed, which may include reception and back-office staff. Patients registered with six GP practices which are participating in the observational element of the study, who have undergone a medical test for which results are received during the observation period, could potentially have their confidential patient information incidentally disclosed to the researcher during the course of the observation.

The applicant is not seeking support to access any confidential patient information during the GP practice staff observations; however, it has identified that this may incidentally be disclosed. It cannot be foreseen what items of confidential patient information would be disclosed.

Confidentiality Advisory Group advice

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

1. **Further information is required to explain the public interest in the staff observation element of the research programme. This should address the value of the staff observations to the overarching project, providing assurance that that the scheduled time to undertake the observations would provide sufficient exposure to test result handling to provide meaningful data for analysis and confirmation that this was the only methodology which could achieve these requirements.**

The applicant explained that the study was using a realist evaluation approach, which seeks to answer the question of "what works, for whom and in which circumstances?". Since so little is known about how electronic test result services are managed in general practice, observing different practices will help the applicant determine what is being done in practice.

It is possible that each participating general practice will use different systems or approaches for managing patients' electronic tests results, the applicants are interested in finding out what works well, or what does not, in each practice. The observational work will provide vital contextual information and will also help inform the quantitative and qualitative elements of the study by identifying the staff that need to be involved and the data that needs to be collected.

The applicant explained that as it was not anticipated that there would be much variation within each practice taking part in the observations, it is expected to be possible to observe the key process within the planned timeframe. Furthermore, since a maximum diversity approach is being used to select the participating practices for the observations, a good range of variation should be captured between practices. Direct observation is the best method for collecting data on non-standard processes, as interviews or surveys can result in reports of 'ideal' processes that are not actually followed in practice. For all of these aforementioned reasons, the applicant confirmed that the proposed direct observation was the only suitable methodology to achieve these requirements.

From a practical perspective, the applicant confirmed that they would liaise with each participating general practice to find out the best time to conduct the observational work. It was recognised that it was possible that some practices only manage patient test results at certain times of the day and if this was the case, it would be ensured that the researchers were present at these times in order to observe how practice staff manage patients' electronic test results.

The response was received by the Sub-Committee and no issues were raised.

2. Clarify what safeguards would be put in place during the staff observations to ensure that the risk of exposure to confidential patient information is minimised.

The applicant reiterated that researchers would not be collecting confidential patient information during the observational work, but appreciated that they may be accidentally exposed to such data during their observational work. The applicant explained that as it was envisaged that electronic test services would be provided differently in each practice, it was difficult to provide a definitive list of safeguards that would be put in place to minimise the risk of exposure in every situation. The applicant explained that the safeguards could include, but were not limited to the following:

- asking practice staff at the start of observations to limit their discussions to non-confidential information (whenever possible);
- ensuring that the researchers were not able to view any computer screens with confidential patient information on (for example, by positioning the researcher or re-positioning/covering computer screens as appropriate);
- ensuring that paper patient records were not visible to researchers;

- when looking at screens to observe the upload of patient test results, the part of the screen that shows confidential patient information may be covered with a post-it or similar device.

The applicant also confirmed that advice would be sought from practice staff about the best safeguards to use in their practice, as they were keen to ensure that the methods used still allow researchers to capture a true representation of the processes used in general practice to manage patients' electronic test result services.

In addition to these physical suggestions, the applicant confirmed that they had already taken proactive steps to ensure that all the researchers working on this project were aware of their responsibilities for safeguarding confidential patient information throughout the proposed study, by checking contracts of employment and ensuring GCP training was up to date. All researchers would have a current research passport and also be required to sign confidentiality agreements. The applicant also advised that observations of the wider practice would be kept at a minimum, to ensure observations were restricted to electronic test results services.

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

3. Confirm how researcher Dictaphone recordings would be managed to ensure there was no inadvertent recording of confidential patient information.

The applicant explained that, due to concerns raised around the use of digital audio recording devices during the observational work, it had been decided to limit the recording of observational work to written notes only.

The response was received by the Sub-Committee and no further issues were raised.

4. Revise the GP practice poster to provide clear explanation that researchers would be present within the practice undertaking observations of the practice staff.

The applicant provided a revised copy of the GP practice poster which addressed the point raised.

Members received the revised document and raised no queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 03 August 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Six Participating GP practices which have not yet been identified. Not requested for each site; support is based on the assumption that the applicant will ensure that satisfactory security assurances are in place for each site**).

2. NEW AMENDMENTS

Application title: **Renal Replacement Anticoagulant Management**

CAG reference: **18/CAG/0070**

IRAS project ID: **236515**

REC reference: **18/SC/0204**

Context

Purpose of Application

This application from the Intensive Care National Audit & Research Centre (ICNARC) set out the purpose of medical research which aims to study the effects of two anticoagulants, heparin and citrate, on patients who are undergoing continuous renal replacement therapy (CRRT). CRRT is often used in intensive care units when a patient is suffering from an acute kidney injury which prevents their kidneys working properly. CRRT is a machine which takes over the kidney functions until the patient's own kidneys recover. Traditionally heparin is added to the patient's blood as it enters the CRRT machine to prevent it from clotting. Recently, citrate anticoagulation is being used as it may be more controllable and cheaper. Both heparin and citrate anticoagulation therapies are associated with different risks for the patients and it is currently unknown whether either form of anticoagulation is more effective.

Detailed electronic health records are available for all patients admitted to UK ICUs. The applicants will use these records to identify adult patients treated in 184 non-specialist adult ICUs in England that needed at least one day of CRRT between 01/04/2009 and 31/03/2017. By surveying these ICUs to see which have swapped to citrate anticoagulation and when this changeover occurred, the applicants will examine the effects of changing from heparin to citrate on patients' well-being.

Confidential patient information will be released by ICNARC and the UK Renal Registry to NHS Digital to facilitate linkage with HES and ONS datasets. Linked records will be returned to the applicants in a pseudonymised format by study ID for analysis.

The applicants will look at patients' survival, degree of sickness and how fast they recover. Analysis will also be undertaken to measure the cost of the two types of anticoagulation so we can assess the cost/benefit trade-off for both types of anticoagulation.

The ICNARC Case Mix Programme operates with support under the Regulations under reference: PIAG 2-10(f)/2005.

A recommendation for class 2, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All patients aged 16 and over, admitted to an adult or general ICU in England and Wales, which participates in the ICNARC case mix programme, between 01/04/2009 and 31/03/2017. Patients would have been in receipt of CRRT for at least one calendar day during the ICU stay. It is estimated that 85,000 patients would be included within the project.

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

- NHS number – linkage,
- Date of birth – linkage and analysis,
- Date of death – linkage and analysis,
- Postcode – linkage and converted to LSOA for analysis,
- Gender – analysis,
- Ethnicity – analysis.

Amendment request

The amendment seeks support to extend data linkage to the Patient Episode Database for Wales (PEDW) via NHS Wales Informatics Service (NWIS) in order to obtain healthcare usage data for Welsh patients. NWIS had confirmed that the linkage would be facilitated on NHS Number alone.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAG, who recognised that this amendment had been anticipated following the initial application review. It was recognised that data flows and linkage would mirror the activity which was currently supported England, but would be facilitated on NHS Number alone. NHS Wales Informatics Service had provided written confirmation that the linkage could be achieved. The Vice-Chair was content to provide a recommendation of support for the amendment.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements (**Confirmed – Caldicott Principles Into Practice (CPiP) Assessment for NWIS received 25/10/2018**)
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – Non-Substantial amendment confirmed 24/08/2018**).

Application title:	**Critically ill children and young people: do national Differences in access to Emergency Paediatric Intensive Care and care during Transport affect clinical outcomes and patient experience? The DEPICT study**
CAG reference:	**17/CAG/0129**
IRAS project ID:	**218569**
REC reference:	**17/LO/1267**

Context

Purpose of application

This NIHR funded study set out the purpose of looking at how differences in access to paediatric intensive care (due to distance from the intensive care unit), and care provided during transport to intensive care, affect clinical outcomes and patient experience. The primary outcome would be 30 day mortality rate. Patient experience would be investigated via questionnaires (for which support was not required as they would take place under consent).

There are currently fewer than 30 paediatric intensive care units (PICUs) in the UK. This means that a critically ill child taken to their nearest hospital will need to be transferred to a PICU. Such transports are usually done by PICU retrieval teams (PICRTs), mobile teams who take specialist expertise to the child and safely transport them to a PICU. There are national variations in how PICRTs are organised and deliver clinical care.

The study would combine data from PICANet (an international audit of paediatric intensive care which collects data on all children admitted to paediatric intensive care units (PICUs) in the UK and Ireland) and the CMP (an audit of patient outcomes from adult, general critical care units (intensive care and combined intensive care/high dependency units managed by ICNARC) covering England, Wales and Northern Ireland. Various outcome measures would be extracted, including: how long it takes a PICRT to reach the patient, how long it takes the child to reach the PICU, the seniority of clinicians performing the transport, medical procedures performed by the PICRT and any critical incidents during transport, and investigate whether any of these factors influence how likely a child is to survive. This would provide a basis to complete cost/benefit analysis and to study if and how alternative models of service delivery could improve clinical outcomes.

Identifiers would be sent from PICANet and ICNARC to NHS Digital, who would look for any records from the CMP database that were also in the PICANet database. The resulting dataset would be linked with ONS/HES data and transferred in pseudonymised form back to PICANet.

CMP would also receive the pseudonymised list of those patients in both CMP and PICANet database, marked with the unique CMP identifier and the DEPICT study number before removing the CMP identifier and transferring this dataset to PICANet in Leicester, where the data would be analysed.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from PICANet and ICNARC in relation to critically ill children and young people under the age of 16 requiring emergency transport to a paediatric intensive care unit in England and Wales between 2014 and 2016 (IRAS form refers to participants identified from clinical notes – this is for the consented questionnaire aspect of the study):

NHS number, date of birth, name, postcode and unique local identifier and study number from PICANet, University of Leeds to NHS Digital.

NHS number, date of birth, postcode from ICNARC to NHS Digital (name is not available in the ICNARC dataset).

Amendment request

The amendment request seeks support to undertake the same follow-up as currently supported in England, for Welsh patients via NHS Wales Informatics Service (NWIS). Identifiers would be sent from ICNARC (Intensive Care National Audit and Research Centre) and PICANet (Paediatric Intensive Care Audit Network for the UK – based at the University of Leeds) to allow follow-up via the Patient Episodes Database Wales. This had been cited as a requirement in the initial application; however, the data flows required to support this have only now been finalised.

It was confirmed that NHS Number alone would be disclosed from PICANet and ICNARC to NHS Wales Informatics Service to facilitate linkage. The same data flows as currently supported for the English patients would then follow, with applicants only receiving pseudonymised linked by study ID for analysis.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair who agreed that this was a sensible extension to the application as this would enable similar follow-up of patients treated in Wales from the welsh secondary care database (PEDW) through NWIS. This would be achieved using NHS Number alone. Support was recommended for the amendment.

Confidentiality Advisory Group advice

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. Data linkage via NHS Wales Informatics Service would be undertaken on NHS Number alone – the protocol document should be updated to reflect this agreed process.
2. Confirmation of suitable security arrangements (**Confirmed – Caldicott Principles into Practice (CPiP) Assessment for NWIS received 25/10/2018**).
3. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 07/11/2018**).

Study title: **Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest**

REC reference: **14/CAG/1009**

IRAS project ID: **147538**

REC Reference: **14/SC/0157**

Context

Purpose of Application

This application from the University of Warwick set out the purpose of a trial to work out how safe and effective adrenaline is as a treatment for patients who suffer out of hospital cardiac arrest. Data in relation to 8,000 patients who have been treated for cardiac arrest was requested. All surviving patients would be invited to take part in the follow up and consent obtained to access data.

A recommendation for class 1, 2, 4 and 6 support was requested to cover access to confidential patient information in order to identify patients to seek consent from and to access mortality, HES, ICNARC and NICOR data in relation to deceased patients.

Confidential Patient Information Requested

Access was requested to Name, Address, Post Code, Date of Birth, NHS Number, gender in order to carry out linkages and seek consent. Date of death, Date of birth and gender would be retained for analysis purposes.

Amendment Request

The amendment seeks support to link the PARAMEDIC 2 cohort with the UK Transplant Registry. The following items of confidential patient information will be disclosed from the study dataset held at the University of Warwick, to the NHS Blood and Transplant Registry to facilitate linkage:

- First name, surname,
- DOB (or approx. age if DOB not available),
- Sex,
- NHS number,
- Address,
- Postcode.

The following data from the NHS Blood and Transplant Registry:

Standard National Organ Transplant dataset for all Paramedic 2 trial participants in the organ transplant database:

1. All organ transplants covering the period from date trial started recruitment 23.12.2014 to the recruitment end date 31.03.2018 (kidney, liver, pancreas (inc SPK), intestine, heart, lung, multi-organ),
2. Donor characteristics – type (living, DBD, DCD), age group, sex, cause of death,
3. Recipient characteristics – age group, sex, primary diagnosis,
4. Transplant information – year, organ(s) transplanted, transplant number, cold ischaemia time, HLA mismatch (where appropriate) & urgency status of recipient (where appropriate),

5. Graft and patient survival times and censoring indicators (as appropriate for each organ).

From the other datasets (i.e. Standard National Liver Transplant dataset, Standard National Pancreas Transplant dataset, Standard National Kidney Transplant dataset and Standard National Cornea Transplant dataset):

6. Follow up information - including complications, number of readmissions, immunosuppression, liver function tests

Confidentiality Advisory Group Advice

The amendment was shared with the CAG for consideration who recognised that there was a clear public interest in understanding the effect of using adrenaline on the success of organ donation following a death from cardiac arrest. The data flows to support the additional data linkage were clearly set out and the items of confidential patient information requested to facilitate this were appropriate and mirrored those in use in the wider application. The Chair was content to provide a recommendation of support for the amendment.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via relevant submission. **(Confirmed - University of Warwick Clinical Trials Unit and**
2. **NHS Blood and Transplant have a published satisfactory reviewed grade on v14.1, 2017/18).**
3. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed – issued 03 April 2018)**.

Study title: **National Gastro Intestinal Cancer Audit Programme (Bowel Cancer)**

CAG reference: **ECC 1-03(d)/2012**

Context

The National Gastro Intestinal Cancer Audit Programme (Bowel Cancer) is commissioned by HQIP as part of the programme of national clinical audits.

The National Gastro Intestinal Cancer Audit Programme (Bowel Cancer) is undertaken with the intention of informing patients and the public about the prevention, diagnosis, treatment and care of this disease and the outcomes. Every Trust in England and Wales fully participates in the audit and due to the high standard of data quality, it is possible to focus on trying to understand the variation seen by using case-mix adjustment and to work with organisations to improve the standard of care offered. The audit has demonstrated that many more patients are now receiving appropriate care and the amount of variation seen between trusts has reduced.

Amendment request

The amendment seeks support to link the audit database with the following NHS administrative datasets:

- Hospital Episode Statistics (NHS Digital) and Patient Episode Database for Wales (NHS Wales Informatics Service) – to enable access to outpatient and A&E data from 2011 onwards,
- Patient reported Experience Measures Surveys (PREMS), held by Quality Health on behalf of NHS Digital – for the period 2013-2015 only as support is already in place for 2015 onwards.

The audit uses the following items of confidential patient information, which will be used to facilitate linkage with the wider sources: NHS number, date of birth, date of death and postcode.

Confidentiality Advisory Group advice

The amendment request was shared with the CAG for consideration who recognised the public interest in the proposed linkages, which would further extend the available information around the coordination of services for patients so that outcomes could be aligned with timescales for treatment and different treatment outcomes. It was recognised that the audit had existing support to link to HES and PEDW datasets for admitted care records, and the PREMS dataset from 2016 onwards – the proposed amendment requested an extension to the existing scope of support. The Chair was content to provide a recommendation of support to the amendment.

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 – **Confirmed: NHS Digital and Quality Health have a published satisfactory reviewed grade on V14.1, 2017/18 of the IG Toolkit. NHS Wales Informatics has a current CPiP Assurance Report 2017/18.**