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

February 2017

Reviewers:

Name	Capacity
Dr Murat Soncul	Chair
Ms Rachel Heron	Confidentiality Advisor

Study title: Analysing Emergency and Urgent Care System Demand in Yorkshire and Humber: A data linkage study of pre-hospital and emergency department data.
REC reference: 14/CAG/1015
IRAS project ID: 157633

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment is conditionally approved, subject to compliance with the standard and specific conditions of approval.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Purpose of application

This research application from the University of Sheffield described a study which aimed to utilise routine NHS data from a number of providers of emergency and urgent care in Yorkshire and Humber. The application described linking the data to provide a coherent picture of emergency and urgent care demand for a period of 12 months. The data would be used to map the use of emergency and urgent care services in order to identify pattern of service use and outcome by different patient and demographic groups to identify groups of patients who currently utilised emergency and urgent care services in different ways and who may benefit from an alternative approach to care.

A request for class 4 and 6 support was made to allow the disclosure of confidential patient information from Yorkshire Ambulance Service and Emergency Department and inpatient Patient Administration System data to researchers within the University of Sheffield.

Confidential patient information requested

Confidential patient information from the Yorkshire Ambulance Service and a number of NHS Trusts was requested in relation to patients using services over a 12 month period.

Name, postcode, NHS number, date of birth and date of death were requested in order to carry out linkages. It was confirmed that all identifiers were required in order to carry out

linkages across ambulance data as limited data is recorded at this stage. The study was likely to include data in relation to over 1 million patients.

Amendment request

The amendment request was to extend the scope of the project to include children. The data items and methodology would remain the same.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who advised that review by Sub-Committee was necessary.

The Sub-Committee agreed that it was reasonable and in the public interest to extend the analysis of emergency care to all patients using the service. The inclusion of data from children was agreed to be justified.

The patient notifications were currently aimed at adult patients and would therefore need to be amended to ensure they were clear and accessible to young people. This process should involve young people; therefore further public involvement work would be necessary.

It was agreed that this need not delay the implementation of the change but progress should be reported back to the CAG at annual review stage.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Patient notifications should be revised to ensure they are accessible to young patients. The updated patient notifications should be provided to the CAG at annual review along with details of any public involvement work that has been carried out.
2. Confirmation of suitable security arrangements via IG Toolkit submission. **Version 13 confirmed reviewed and published as satisfactory.**
3. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewed documents

Document	*Version*	*Date*
Amendment Request form		20 January 2017

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **HQIP NCA 099 National Clinical Audit & Quality Improvement Programme for Chronic Kidney Disease in Primary Care**

CAG reference: **CAG 6-07(c)/2013**

Secretary of State for Health Approval Decision

The Secretary of State for Health, having considered the advice from the Confidentiality Advice Team as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

This audit application from Informatica Systems Limited set out the purpose of a national primary care CKD audit covering all GP practices in England and Wales and the interfaces between primary and specialist secondary care. This activity aims to improve the diagnosis and recording of chronic kidney disease (CKD) in primary care, to audit primary care management against NICE quality standards and understand and map the variation of patient care in this setting. A recommendation for class 1, 4 and 5 support was requested to enable patient information regarding all patients with relevant Read codes to be extracted from participating GP practices using a tool developed by the applicant and linked to Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data.

Confidential Patient Information Requested

Access was requested to NHS number, date of birth and postcode.

Amendment Request

It was stated in the original application that the National CKD Audit was commissioned for three years with an option to extend a further two years. Due to delays with NHS Digital processing of the HES data applications the linked data was not made available in time to be reported in December 2016. This amendment requests an extension to the end date of the project, to cover up to 19 December 2017, in line with the extension that had been granted by HQIP.

Confidentiality Advice Team Advice

The Confidentiality Advice Team agreed the amendment request to be in line with the principles of the original approval. It was noted that the extension amendment was solely for the processing of data captured during the audit and no further data was to be extracted from the GP systems.

Confidentiality Advice Team Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
   (Confirmed – Version 13, 2015-16, reviewed grade of satisfactory at 66%).

Reviewed Documents

Document	*Version*	*Date*
Amendment Request Form		12 January 2017

Reviewers:

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

Study title: **Study of Heart and Renal Protection (SHARP)**

CAG reference: **MR1113** **(ECC 5-02(FT4)/2009)**

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

2. The amendment is approved, subject to compliance with the standard conditions of support.

Context

This application was for further follow-up of participants in the Study of Heart and Renal Protection - (SHARP) Registry – following the end of the study in 2009, support had been given to continue to collect follow-up data on the participants.

NIGB approval for the Study of Heart and Renal Protection (SHARP) was initially granted in April 2009, with data processing approved for event notifications for ONS mortality, cancer and exit data from the NHS in England and Wales. Continued support was granted by the NIGB in July 2012 for access to follow-up data for this same cohort and again on both 03 September 2015 and 02 September 2016.

Amendment request

This amendment was submitted to add Hospital Episode Statistics (HES) to the existing section 251 support for use of registry data for the SHARP trial. Linkage to HES data was not routinely available when the original application (2009-2010) for registry data was submitted.

The aim was to obtain all relevant registry associated outcomes from healthcare data sources, including NHS Digital and other disease-specific registries, for all UK-based SHARP trial participants from the time of randomization. This would improve knowledge associated with chronic kidney disease (an area lacking funding for research) and could lay the foundation for future randomised controlled trials of treatments.

The applicant also wished to add data from the UK Renal Registry and this request had been agreed by the UKRR.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was of the opinion that the original consent showed the intent to seek as complete outcome data as possible. The provision of HES data was within the spirit of the original consent, and confidentiality would not be further compromised by the addition of HES data to the original support.

It was also agreed that data from the UK Renal Registry lay within these parameters and could be added to the terms of the Section 251 Support.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed on website – published reviewed grade 97%**
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewed documents

Document	*Version*	*Date*
Amendment Request form		20 January 2017

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Dr Patrick Coyle	Vice Chair
Dr Tony Calland	Vice Chair
Ms Clare Sanderson	Alternate Vice Chair

PIAG/ECC/CAG reference number: 1-07(e)/2004

Application title: The British Women's Heart & Health Study

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment is conditionally approved, subject to compliance with the standard and specific conditions of support.

Context

The British Women's Heart and Health Study was a long-running study which aimed to support the prevention and treatment of heart disease.

Amendment request

Professor JP Casas, the Director the British Women's Heart & Health Study (BWHHS) obtained a new job as Chair in Clinical Epidemiology and Informatics at the Institute of Health Informatics within the Faculty of Population Health Science at University College London (UCL). As funding was awarded to, Professor JP Casas as an individual, support was requested for the transfer of data controllership from the London School of Hygiene and Tropical Medicine (where the research was previously carried out) to UCL.

Confidentiality Advisory Group advice

The amendment requested was forwarded to a Sub-Committee of members who agreed that the change of data controller was justified and could be supported.

However it was noted that the change in data controller occurred in December 2015.

Section 251 Support under the Control of Patient Information Regulations had been given for LHSTM as data controller. As support could not be given by the CAG retrospectively, the study had been operating at UCL without Section 251 support since December 2015.

The CAG noted that patients had been informed of the change, however to avoid future breaches of the terms of support the applicant was advised to submit amendment requests in advance of any changes.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewed documents

Document	*Version*	*Date*
Amendment request form		10 September 2015
Patient newsletter 2015		December 2015

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title:	**Impact and Evaluation of a Burns Risk Assessment of Neglect and Maltreatment in Children Tool.BuRN-Tool A multi centre study**
CAG reference:	**15/CAG/0203**
IRAS project ID:	**169420**
REC reference:	**15/WA/0259**

Health Research Authority Approval Decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This research application from Cardiff University set out the purpose of the application to develop and test a Clinical Prediction Tool for use in the Emergency Departments (ED)/MIU'S (Minor Injury Units) and Burns Units to help identify features that may be significant when considering if a burn or scald is due to neglect or maltreatment. A further aim was to conduct a before and after study to evaluate the acceptability, efficacy and accuracy of the BuRNtool to identify maltreatment when implemented into clinical practice in Emergency Departments, Minor injury Units and Burns Units. Finally, a further aim was to identify if a version of the tool can be developed for use by child protection professionals.

Amendment Request

The amendment seeks approval for the applicants to receive the full postcode to allow accurate calculation of deprivation scoring. The initial application was approved to allow access to postcode at sector level to enable deprivation scoring; however, the applicants have subsequently identified that the postcode should have been requested at unit level to ensure accuracy of this calculation. The applicants advised that this would involve entering the full postcode into an excel spreadsheet to enable the deprivation score to be calculated; however, it was clarified that only the deprivation score (not the postcode) would be entered into the research database. The applicants advised that if they were unable to calculate an accurate deprivation score, this would prevent the opportunities that a targeted burn/scald prevention scheme could offer.

Confidentiality Advisory Group Advice

The amendment request was forwarded an Officer of the CAG who agreed that the request for full postcode was justified and could be supported.

It was noted from the amendment form that the applicants had stated that patient notification was not applicable to this application. It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998. It was noted from historic correspondence that the applicants had identified some patient engagement plans. It was agreed that the applicants would be recommended to consider what patient engagement could be undertaken in relation to the project and how patient notification and a system of objection could be managed.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed - Version 13, 2015/16 showing a self-assessed score of 97% which has been reviewed and published as satisfactory).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Substantial Amendment 1 – Approved 28/10/2016).**

Recommendation

1. Patient Engagement, Notification and Objection – consider how this could be improved in terms of the project and provide an update to the CAG at the next annual review.

Reviewed documents

Document	*Version*	*Date*
Amendment Request Form		10 January 2017
REC Favourable Opinion		28 October 2016

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title:	**Improving the management of drug resistant tuberculosis in the UK.**
CAG reference:	**16/CAG/0092**
REC reference:	**16/LO/1269**

Health Research Authority Approval Decision

The Health Research Authority, having considered the advice from the Confidentiality Advice Team as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This application from University College London (UCL) set out the following aims. The increase in antimicrobial resistance is a source of concern. In the UK, for example, 6.8% of the 8,500 tuberculosis patients seen in 2012 were resistant to the first-line drug isoniazid. It is of great importance to prevent the loss of current anti-tuberculosis drugs. This project aims to inform clinical knowledge and policies surrounding drug resistant patients, thus improving management and reducing transmission by a) determining the best treatments for patients with isoniazid resistant tuberculosis disease and b) exploring the relationship between treatment outcomes and the causes of drug resistance.

A recommendation for class 1, 2 5 and 6 support was requested to achieve the purposes set out in the application.

Amendment Request

The amendment requested support for the collection of more detailed microbiological information in relation to the already approved project. The applicants clarified that this did not include any additional confidential patient identifiable information and the risk of identifiability was not increased through the collection of the more detailed clinical dataset.

The request for more detailed microbiology information (which contained no additional identifiable information) was as follows:

- Data on drug resistance are recorded in Public Health England's surveillance systems; the applicant currently has access to these data. A patient's bacteria are classed as 'resistant' or 'sensitive' (binary format) in these systems. In the original proposal, this was the level of detail that access was requested to for phenotypic drug resistance.
- Drug resistance can also be determined by sequencing the DNA of the bacteria (genotypic resistance). Many different mutations can cause resistance to a single drug. This sequencing to get data on genotypic resistance was approved in the original application. Both genotypic and phenotypic resistance results are critical for this project; one cannot substitute for the other in my analysis, as their correlation is complex and imperfect.
- A binary phenotypic resistance result does not represent the full picture. The laboratory would have generated continuous numeric results, meaning the applicants can class bacteria as 'very resistant', 'medium resistance', 'weakly resistant', etc. The original application only asked to access the binary format data from the laboratory, rather than the numeric results. The latter, however, have now been shown to be substantially more useful for the project and, in ethical terms, only represent more clinical detail versus what was requested before.
- Public Health England's laboratory database is the first port of call to get the phenotypic data with continuous numeric results. If the relevant data, particularly for older samples, have not been retained then the phenotypic testing will be repeated at the same time as the bacterial cultures are accessed for sequencing, thus requiring minimal extra manipulation of the bacterial cultures.
- The need to collect phenotypic data *per se* was not documented in the original application because Public Health England's surveillance team only gave data on isoniazid resistant patients (as per the scope of the study) and thus the applicants could easily infer the binary variable (all patients 'resistant', none 'sensitive'). The study inclusion and exclusion criteria thus capture this point. However, the proposed active data collection process to collect phenotype as a continuous variable will only start with this amendment and goes beyond that inclusion/exclusion criteria, thus the revision has been made.

Confidentiality Advice Team Advice

The amendment requested was considered by the CAT and it was agreed that as the additional information requested was specifically clinical and had no impact on the potential for identifiability, support was recommended. The additional information was in line with the original approval but at more detailed level. Support was recommended.

Confidentiality Advice Team Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed via website – Version 13, 2015-16, reported a satisfactory reviewed grade at 71%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Reviewed documents

Document	*Version*	*Date*
Amendment Form		24 November 2016
Protocol (Clean/Tracked)	2	24 November 2016

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Application title:	**Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England (PEARL)**
CAG reference:	**16/CAG/0053**
IRAS project ID:	**177855**
REC reference:	**16/SC/0222**

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advice Team as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of support.

Context

This application from University of Oxford set out the purpose of this project to create a linked dataset between HFEA infertility data and health data from the Clinical Practice Research Database (CPRD) mother-baby track and to use the linked dataset to assess the effect of ART on the health of women and their children after successful fertility treatment.

The study would include about 270,000 mothers and their children, around 4000 of who would have had fertility treatment.

The information would be obtained from the following sources: details of fertility treatments held by the Human Fertilisation and Embryology Authority; Health records from GP practices in England held by the Clinical Practice Research Datalink, and records of hospital care, from Hospital Episode Statistics already linked to CPRD data and held by NHS Digital.

Amendment request

Following a recommendation from the primary care data holders (CPRD's Independent Scientific Advisory Committee), a minor change to the data flow was proposed. The original data flow had fertility data, stripped of identifiers and given a unique study ID, being sent by HFEA to the study team at the University of Oxford. The new data flow would have the same data being sent by HFEA to CPRD, where it would be stripped of the study ID and given the CPRD's ID. The CPRD would then send the fertility data to the study team at University of Oxford, where they would merge it with the primary care and HES data, using the CPRD ID number. The study team will now only receive pseudonymised data with the CPRD ID number.

Confidentiality Advisory Advice Team advice

The amendment requested was considered by the CAT, who noted that the amendment further reduced the risk of identification of participants at Oxford University.

Confidentiality Advice Team conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed v13 reviewed, Satisfactory grade published.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 1 February 2017.**

Reviewed documents

Document	*Version*	*Date*
Amendment request form		5 January 2017
PEARL Protocol	1.2	
Describing the restructuring of the PEARL protocol		5 January 2017
REC favourable opinion letter		1 February 2017
Revised Study flow chart		

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title: **National investigation into suicide in children and young people**
CAG reference: **15/CAG/0120**
IRAS project ID: **159134**
REC reference: **15/NW/0184**

Health Research Authority Approval Decision

The Health Research Authority, having considered the advice from the Confidentiality Advice Team as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

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

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

Amendment Request

The amendment requested permission to extend the study end date from the current date of 31st March 2017 to 30th June 2017. This additional time would be used to write up the study findings.

The amendment also requested an administrative change to the lead R&D contact.

Confidentiality Advice Team advice

The Confidentiality Advice Team agreed that the amendment request was aligned with the principles of the original approval. It was acknowledged that the extension to the study end date did not involve any additional data processing and was only requested to enable additional time to write-up the study findings.

Confidentiality Advice Team conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **IG toolkit version 13 published as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed – Minor Amendment Categorisation Received.**

Reviewed Documents

Document	*Version*	*Date*
Amendment Request form		08 February 2017
Amendment Categorisation Email		02 February 2017