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

October 2016

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Rachel Heron	Confidentiality Advice Team

1. NEW AMENDMENTS:

a) 15/CAG/0143 National Prostate Cancer Audit

Context

Purpose of application

This application from Royal College of Surgeons, sponsored by the Healthcare Quality Improvement Partnership, set out the purpose of collecting Patient Reported Outcomes Measures (PROMS) and Patient Reported Experience Measures (PREMS) data in response to patients who underwent radical treatment between 1 April 2014 and 31 March 2015 and candidates for radical treatment between 1 April 2015 and 31 March 2016 for whom the National Prostate Cancer Audit (NPCA) has complete data.

A recommendation for class 4 and 6 support was requested to cover access by Quality Health (on behalf of the Royal College of Surgeons) to patient name and address from the National Cancer Registration Service (NCRS) in order to send out surveys, and NHS number and date of birth requested to ensure that patient sample and survey response data were accurately matched.

Quality Health would send out postal questionnaires to patients and carry out mortality checks using DBS.

Amendment request

The applicant proposed to extend the approach already approved by CAG to carry out the study in England, to Wales. They stated that this involved a change in data flows and data sources. They would collect PROMs and PREMs data via a third party.

Confidentiality Advisory Group advice

The amendment requested was reviewed by the Chair, who was convinced of the rationale for extending the survey to Wales. The Chair observed that the method of

processing data was already approved for England, and that the content of the covering letter was consistent with previous discussions between the applicant and the Confidentiality Advisory Group.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed via email from James Burleigh, HSCIC - 1 July 2016**

Reviewers:

Name	Capacity
Natasha Dunkley	Head of Confidentiality Advice Service
Rachel Heron	Confidentiality Advisor

b) NEW AMENDMENTS: 15/CAG/0120 National investigation into suicide in children and young people

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, in order to provide a range of information at individual patient level that was currently not available. The study aimed 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 request was to extend the data collection to Wales, Scotland and Northern Ireland (separate applications to be made to Scotland and N. Ireland) in order to allow a more comprehensive and detailed exploration of the characteristics of young people who die by suicide and the antecedents of suicide (e.g. role of frontline services and risk recognition). This proposed extension to the study was documented in the original, approved version of the study protocol (Version 1: 09/02/2015).

Confidentiality Advice Team advice

The amendment requested was forwarded to the Confidentiality Advice Team. Minor changes to the application, Protocol and information sheet were noted, reflecting the progress of the study including revision of estimated figures concerning suicide in young people, and the methodologies to be used for obtaining data in Wales, Scotland and Northern Ireland.

Information was requested from the applicant with regards to the sources of data in Wales. Several sources would be accessed, details of which were outlined by the applicant. In discussion with the Head of the Confidentiality Advice Service it was determined that confirmation of satisfactory Information Governance toolkit for the

University of Manchester would suffice for the purposes of the application, as they would be the recipients of the data.

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.

Support only applies to England and Wales.

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 5 September 2016**

Reviewers:

Name	Capacity
Rachel Heron	Confidentiality Advisor

c) NEW AMENDMENTS: ECC 6-06(b)/2009 Validation of Risk Assessment instruments for patients discharged from Medium Secure Services (VoRAMSS)

Context

This research application from the University of Manchester set out a prospective study that aimed to validate and assess the reliability and utility of recently developed risk assessment instruments in a group of 560 patients across 38 medium secure units in England and Wales with a diagnosis of Schizophrenia. A recommendation for class 1, 2, 4, 5 and 6 support was sought in order for the research group to access patient medical notes at 6 and 12 months to link with information on the Police National Computer. Identifiers requested were name and date of birth.

Amendment request

An amendment request was received on 15 November 2013 seeking an extension of support under the Regulations until September 2016, on the grounds that the original study had identified a higher number of discharged patients returning to prison than had been expected. There was therefore an interest in finding out why this might be through evaluating the factors influencing the decision to return to prison rather than choosing a health or social care pathway and identifying what healthcare those discharged to prison received while in prison and following release. This would involve a more detailed follow-up of those already discharged to prison and identification of new discharges from medium secure psychiatric facilities, including consideration of additional discharges in order to generate an accurate picture of why more people than expected were transferred back to prison and what happened to them. A refreshed version of the study protocol was supplied to support the amendment.

This amendment was approved in January 2016. The current request was for an extension of the approval until September 2017, on the grounds that significant delays had been experienced when attempting to gain follow-up data for the cohort described above. A fragmented system of mental health services was described, where services had been outsourced to alternative providers who had different procedures for research approvals. New applications had to be made, which caused difficulties and delays in data collection.

Confidentiality Advice Team advice

The Confidentiality Advice Team noted that this amendment request involved no changes to the Protocol other than an extension to the time allowed for data collection. There was no change to the exit strategy.

Data collection was now retrospective rather than prospective, as participants had moved on to community settings or to other prison settings. It was noted that this would make it difficult to contact patients to give them information about the study, and would involve accessing further confidential information to ascertain their whereabouts. Therefore this would not be practicable.

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. **Version 13 published as satisfactory**
2. Confirmation of a favourable opinion from a Research Ethics Committee**. Amendment not required by REC for extension to end date.**

Reviewers:

Name	Capacity
Mark Taylor	Chair
Rachel Heron	Confidentiality Advisor

d) NEW AMENDMENTS: CAG 8-03(PR11)/2013

Context

This audit application was originally submitted by the Health and Social Care Information Centre and received approval by the Secretary of State for Health on 11 April 2011. The application set out aims to use case-mix, process and outcome data together with quality standards to improve the quality of care. A recommendation for class 1, 3, 4, 5 and 6 was requested to cover linkage with Hospital Episode Statistics (HES) data. Access was requested to NHS number, date of birth, date of death and postcode.

An amendment request to the original application ECC 3-04(s)/2011 was received on 30 August 2013, following prior discussions with the Confidentiality Advice Team, to change the data processor for this application to the Royal College of Physicians of London. The Healthcare Quality Improvement Partnership (HQIP) would remain data controller. An amended application and details of resultant changes to data flows were provided.

A further amendment request was submitted for the purpose of converting the date of death identifier to life status at thirty days and the return of the data to the submitting hospitals to perform root cause analysis of all deaths within thirty days. The amendment request also included to extend the user base to clinical teams within trusts for direct care purposes and also for secondary use of anonymised data for the purposed of audit, service evaluation and research. The applicant would only share anonymised data with credible third party applicants however; the amendment request was to allow the flow of confidential patient information to the HSCIC for the purposes of data linkage of HES data with subsequent flow of a linked (anonymised) dataset to the third party applicant organisation. A further additional amendment was submitted in order to seek support for the purpose of submitting confidential patient information to the NHS Wales Informatics Service (NWIS) for linkage with PEDW and forwarding anonymised data to the relevant third party applicants.

In 2016, an amendment request was submitted and approved to add ‘commissioning support’ to the list of approved purposes for secondary use of the data (in an anonymised format).

Amendment request

The current amendment was submitted in response to a request from NHS Digital to clarify the specific datasets for which support has been given.

The applicant clarified that the linkages would be performed by HSCIC/NHS Digital to NHS Digital held datasets (including, but not limited to HES, SUS, ONS and PEDW for Wales) for general commissioning purposes and potential onward flagging to commissioning organisations, as opposed to specific linkage with HES data only.

Confidentiality Advisory Group advice

The amendment was reviewed by the Chair, who agreed that support could be given for the named datasets.

It was confirmed that the Confidentiality Advisory Group could not give open-ended approval for access to any datasets held by NHS Digital. If any further data sources were to be accessed, the required source should be named in a future amendment request.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Version 13 published; reviewed grade confirmed as 'satisfactory'**

Reviewers:

Name	Capacity
Tony Calland	Chair
Murat Soncul	Sub-Committee member
Hannah Chambers	Sub-Committee member
Rachel Heron	Confidentiality Advisor

e) NEW AMENDMENTS: PIAG 4-09(k)/2003, PIAG 1-05(f)/2006 Effectiveness of prostate cancer screening study

Context

This research application from the University of Bristol set out the purpose of an ongoing DH/CRUK-funded cluster randomised controlled trial in which GP practices in 8 centres in England and Wales were randomly allocated to either population based PSA testing, akin to screening (the ProtecT study) or standard (unscreened) practice. In the intervention (ProtecT) practices, men aged 50-69 years were invited between 2001-2008 to undergo PSA testing. In the comparison arm practices, men aged 50-69 years undergo standard NHS management (provision of an informed choice to any man over the age of 50 who requests a PSA test). All men were being followed-up for vital status, incident and fatal prostate cancer via the Health and Social Care Information Centre (HSCIC) in accordance with their protocols for the transfer and use of NHS classified data. The primary outcome was prostate cancer mortality after a median 10 years follow-up (reached in 2016), analysed by intention-to-screen. Secondary outcomes included all-cause mortality, cost-effectiveness and disease status and stage (after 10, 15, and 20 years). A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to data from the HSCIC.

<u>Confidential patient information requested</u>

Access was requested to name, date of birth, NHS number, hospital number, postcode, GP practice and cause of death.

Amendment request

Three amendment requests were received by the CAG detailing changes to data flows for the application.

1) Summary data on prostate cancer mortality and prostate cancer diagnosis in groups not in routine follow-up; proposal of analysis at HSCIC (amendment to obtain aggregate data on groups not in routine follow up): Of the men attending the ProtecT intervention arm PSA testing 4,706 declined to participate in the subsequent ProtecT trial. These men had not been included in the flagging requests at the HSCIC for status and cancer incidence at an individual level. However as there was a possibility that

these men could have a greater likelihood of dying with prostate cancer or dying within the 10 year follow up, excluding these men would introduce bias into the CAP trial.

2) Request for an extension of approved methodology for routine data extract for CAP (amendment to send data to SAIL for linkage with Patient Episode Dataset for Wales PEDW)
The application to HSCIC had stated that approx. 10% of the data from Welsh Clinical Centre would not have HES data and would therefore require linkage to PEDW, however the steps for linkage were not explicitly stated. This amendment requested CAG approval for explicit linkage to HES requiring the surname and forename of individuals from the School of Social and Community Medicine (SSCM) to be transferred to SAIL for linkage with PEDW

3) Data extraction for stage and grade of prostate cancer (Amendment to the process for obtaining stage and grade data)
Current S251 support gave approval to get stage and grade of prostate cancer tumours from cancer registry data. This amendment seeks approval to access the electronic records at the hospital for participants where stage and grade of tumour is not available.

Confidentiality Advisory Group advice

The amendment requests were forwarded to a sub-committee who agreed support for these amendments.

In terms of the first and second amendments the Committee recommended support but felt that information materials should be updated to reflect this change of scope with benefits highlighted.

In terms of the third amendment, relating to stage and grade data being obtained directly from hospitals to complete missing stage/grade data coming from the cancer registries. The committee recommended support for this amendment but confirmed that the applicant should test the acceptability of the amendment with a small group of patients. Progress should be reported at next annual review

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 these amendments, and therefore advised recommending support to the Secretary of State for Health.

Specific conditions of support

- Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed 29 July 2016.**
- Information materials are updated to reflect change in scope with benefits highlighted.**Updated information materials were submitted on 29 July 2016.** The Sub-Committee reviewed these and agreed that the changes had been made as

requested, although it was commented that they would benefit from being further simplified. The information materials were approved, but the Sub-Committee recommended testing them with the Patient and Public Involvement group to ensure that they were in accessible language.

- The acceptability of receiving stage and grade data directly from hospitals to complete missing stage/grade data coming from the cancer registries should be tested with a small group of patients and outcome reported at next annual review. **To be reported at annual review.**

Reviewers:

Name	Capacity
Dr Patrick Coyle	Chair
Rachel Heron	Confidentiality Advisor

f) NEW AMENDMENTS ECC 7-04 (j)/2010 Long term risks of paediatric fluoroscopic cardiology and PIAG 4-06(c)/2006 Long-term sequelae of radiation exposure to computed tomography in childhood.

Context

The proposal was to establish a registry, for long-term follow up, of children and young adults who underwent fluoroscopic cardiology procedures and to assess their cancer risk in relation to the estimated radiation doses they received. Support was sought to enable flagging with the Central Register; patients would also be matched with congenital anomaly registers to identify the heart defects involved and infants with Down's syndrome. Exposed individuals would be identified primarily from records of radiology and paediatric cardiology departments in Great Britain where interventional cardiology was performed in paediatric patients.

The application requested access to name, date of birth, hospital ID, and NHS number, date of death, full postcode, address and sex for linkage purposes. For analysis purposes, the following would be retained: date of birth, date of death, postcode for deprivation scoring and gender.

Amendment request

The request was to send details of the cohort (NHS numbers only) to the NHS Transplant Registry for matching in order to determine which cohort members had received a transplanted organ.

The results of a pilot study had suggested transplantation could have a large confounding effect on the apparent relationship between radiation and cancer. This could result in an upward bias of the risk per unit dose of radiation, potentially leading to medical radiation exposures being unnecessarily withheld.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was of the opinion that the amendment request was justified in terms of medical purpose and public interest. Accuracy in knowing the long term outcomes of the use of diagnostic radiation was important in assessing the long term risks of its use, and transplantation was clearly a serious confounding factor.

The Chair noted that patient notification materials had not been provided. A general principle of activities taking place under support was that there are suitable patient notification materials provided to the potential cohort and a mechanism for registering patient objection, therefore this was something which would need to be addressed.

Given the size and long term retrospective nature of the cohort it was acknowledged that it would be difficult to reach participants, however the Confidentiality Advisory Group required assurance that efforts had been made.

The applicant was also advised to consider that their application should be consistent with the provisions of the Data Protection Act, and drew the attention of the applicant to the Fair Processing principle.

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. An explanation to be provided with regards to how any objections to this processing of data could be respected, and confirmation that patient notification materials had been produced and made available to the cohort.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation of a favourable opinion from a Research Ethics Committee.

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

October 2016

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Rachel Heron	Confidentiality Advice Team

2. NEW AMENDMENTS:

Study title: **Prescription Of analgesia in Emergency Medicine (POEM)**
CAG reference: **CAG 3-02(c)/2014**

Context

Purpose of application

This application from Royal Berkshire NHS Foundation Trust set out the purpose of a study to determine the factors that lead to failure to assess pain and provide timely pain relief and to assess the adequacy of pain management in consecutive patients presenting to emergency departments within the Thames Valley with confirmed breaks or dislocations to either the arms or legs. The data may highlight factors associated with failure to provide timely pain relief in the population.

A recommendation for class 1, 2 and 3 support was requested to cover access to data in relation to patients from emergency departments within 4 hospitals over 26 consecutive weeks who had a radiograph of a long bone (approximately 6000 patients).

Data including postcode would be transferred to the University of Reading in order to carry out deprivation scoring. This process required access to postcode for a total of 48 hours.

Confidential patient information requested

Access was requested to hospital ID and postcode.

Amendment request

New sites were to be added for data collection – since the study was adopted onto the NIHR Portfolio, other sites had expressed an interest in providing information for the study, and a larger sample size was required due to the development of new outcome measures (reflecting new information from the pilot study) Procedures for data processing remained the same.

Following on from the addition of new sites, an extra step was proposed to the data flow, to enable the sponsor site to query incomplete or inaccurate data. Different sites would now be finishing data collection at different times, and the data checking was more effective the

sooner it was completed following data collection. Therefore, sites that had already completed data collection would send their database to the Royal Berkshire Hospital for review. Incomplete or anomalous data would be recorded and a list of data queries returned to the sites for review. After receiving from each site the final 'completed database' within 8 weeks of data queries being sent, identifiable information would be removed.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was content to approve the addition of new sites.

In relation to the additional stage in the data flow, the Chair asked how much longer the test and final submissions would add to the time take to strip the datasets of their identifiers. If the whole process including the data checking and resubmission would take no longer than 8 weeks the Chair stated that he would be content to approve it.

The following response was received via email from the application on 28 September:

'*We feel that the test submissions for data quality checks will add approximately 6 weeks in total (2 weeks for generation of data queries and transfer of databases and 4 weeks for sites to complete the data checks). We would obviously like to factor in some degree of flexible time for teams to return data checks and so we anticipate that the whole process of test and final submissions will occur within 8 weeks for each site involved in the study'.*

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

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

Reviewers:

Name	Capacity
Dr Mark Taylor	Chair
Rachel Heron	Confidentiality Advice Team

Application title: **Investigation into predictors of diagnosis in PAH patients**
CAG reference: **16/CAG/0091**

Context

This application from Sheffield Teaching Hospitals NHS Foundation Trust (STHFT) set out the purpose of investigating Pulmonary Arterial Hypertension (PAH). PAH is a disease primarily of small arteries in the lung which results in a progressive rise in lung blood pressure and heart failure. There are several types of PAH including Idiopathic PAH and Associated PAH related to a range of disease processes, including cirrhosis, connective tissue disease, congenital heart disease, HIV infection and sickle-cell disease. Literature documents the difficulties with Pulmonary Arterial Hypertension (PAH) diagnosis which involves many different types of clinical tests, and the lengthy time it can take to diagnose the condition from the advent of a patient's first symptoms. This study aims to build a data environment for analysis in order to describe the PAH patient population in England, understand the natural history of disease and look for opportunities for improving predictive analytical methods to flag patients for diagnosis earlier.

The study design is a non-interventional retrospective database analysis of a PAH patient cohort based on data from the Pulmonary Vascular Disease Unit at Sheffield Teaching Hospitals NHS Foundation Trust (STHFT) and Hospital Episodes and Statistics (HES) data from the Health and Social Care Information Centre (HSCIC). It attempts to identify any predictive signals or markers which would allow earlier diagnosis of Pulmonary Arterial Hypertension patients and thus enable earlier right heart catheterization intervention, by analysing patient's usage pattern of hospital services ahead of a confirmed PAH diagnosis. In order to link the STHFT datasets to the Hospital Episode Statistics (HES) data, identifiable information is required to be passed from STHFT to the Health and Social Care Information Centre (HSCIC) in the form of the patient NHS number. The methodology and data flows are set out in the application.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to achieve the purposes specified in the application.

Amendment request

The amendment request was for an increase in the cohort size. The figure stated on the original application and approval letter was based on the number of patients in the Sheffield databases who had received a final confirmed diagnosis of PAH.

This calculation had not taken into account the number of patients referred with a suspicion of severe pulmonary hypotension which may have been suspected PAH which turned out to have other causes. In order to evaluate the diagnostic pathway and meet a secondary objective of the research, this additional data was required. In addition to this, there had been an increase in patient numbers at the unit and the inclusion of these additional patients would make the analyses more robust.

Confidentiality Advice Team advice

The amendment requested was considered by the CAT, who noted that there would be no change to data flows or data items. The purpose and scope of the application remained the same.

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. **Confirmation of a satisfactory published submission was noted (version 13, 74%)**
2. Confirmation of a favourable opinion from a Research Ethics Committee.

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date