Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group 08 June 2016

Reviewers:

Name	*Capacity*
Dr Patrick Coyle	Vice-chair

CAG 8-03(PR11)/2013; Hip Fracture Audit, amendment

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.

Amendment request

This amendment is to add ‘commissioning support’ to the list of approved purposes for secondary use of the data (in an anonymised format).

Confidentiality Advisory Group advice

The vice chair was content that CAG should advise approval of this amendment, noting that it is only for an additional purpose and does not involve any change in use of identifiers, with only anonymised data being used for the extra purpose which is commissioning. This will be in the public interest as it will allow quality of outcome to be included in decisions about commissioning.

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.

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
6 June 2016

Reviewers:

Name	*Profession*	*Present*	*Notes*
Dr Mark Taylor		Yes	
Ms Gillian Wells		Yes	
Dr Tony Calland		Yes	
Dr Patrick Coyle		Yes	

Amendment

15/CAG/0120 – National investigation into suicide in children and young people

Context

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

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

Amendment request

The amendment request is for;

1. The first amendment seeks permission to extend the remit of the study to allow collection and examination of data on individuals aged under 25 years who died by suicide or suspected suicide (open verdict). Currently approval is in place to investigate suicide by children and young people aged under 20 years. This proposed change in the study sample was documented in the original, approved version of the study protocol.

2. Permission is also sought to add an additional staff member to the research team: Ms Nicola Worthington, Administrative Assistant.

3. The final amendment is regarding minor modifications made to supporting documents. These changes are due to extending the study to include individuals aged under 25 years and the

addition of a new member to the research team. The revised documents are the study protocol, the participant information sheet, and the letters which will be sent to chief constables, medical directors and coroners to request data. Please find the amended documents attached for review.

Confidentiality Advisory Group

The amendment requested was forwarded to the Chair team who were in agreement that the amendment request fitted with the protocol and original application.

Members noted that the amendment request had been advised in a previous amendment request submitted on 11 November 2015 which had not been processed when this request was submitted, therefore the applicant had duplicated some of the detail.

The previous amendment had subsequently been approved.

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.

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
30 April 2016

Reviewers:

Name	*Profession*	*Present*	*Notes*
Dr Mark Taylor		Yes	
Ms Gillian Wells		Yes	
Dr Tony Calland		Yes	
Dr Patrick Coyle		Yes	

Amendment

15/CAG/0120 – National investigation into suicide in children and young people

Context

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

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

Amendment request

The amendment request is for;

1. Since ethical approval for the study was granted, two members of the research team - Dr David While (Research Fellow) and Dr Kirsten Windfuhr (Project Manager) have left their posts. Dr Saied Ibrahim (Research Associate / Statistician) and Dr Pauline Turnbull (Project Manager) have joined the study team.

2. Following receipt of ethical approval for this study, an additional source of relevant data (Form B from the Child Death Overview Panel [CDOP]) has been recommended which was not known prior to data collection beginning. The original ethics application only permits the research team to request Form C. Therefore, another change to this study is to request approval for the research team to ask for the Form B from the CDOP process to be provided for analysis.

3. The third change is regarding minor modifications made to supporting documentation – specifically, (i) the letters to coroners requesting inquest proceedings and (ii) the letter to Local Safeguarding Children's Board Chairs to request CDOP Forms B and C. This is to ensure that as much data as possible is captured for cases included in the study. Please see the attached protocol and letters for further details regarding specific changes.

4. The final amendment is regarding the data extraction proforma. Examination of data received from our sources as well as feedback from the study's external reference group (members are from external organisations related to the field of work) has highlighted areas warranting exploration. Questions which probe these areas were not included in the original version of the proforma. Therefore, the proforma has been revised to ensure that such data is extracted for analysis, which is attached.

Confidentiality Advisory Group

The amendment requested was forwarded to the Chair team who reviewed the amendments outlined in the request.

Members noted that Dr Saied Ibrahim was employed as a Research Associate/Statistician and that as such would be expected to have the same contractual confidentiality obligations as all other employees.

Members were in agreement that the amendments, 2- 4, requested were in line with the objectives of the application.

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.

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
17 May 2016

Reviewers:

Name	*Profession*	*Present*	*Notes*
Dr Tony Calland		Yes	

Amendment

16/CAG/0008 – The management and risk of patients with personality disorder prior to suicide and homicide

Purpose of application

This application from The University of Manchester set out the purpose of this study which was to inform clinical policy and practice by recommending safety improvements which may reduce patient suicide and homicide by people with personality disorder.

Recommendations were to be highlighted in a report and were to form part of the NCISH toolkit for use throughout the service.

The study aims were to:

Describe the characteristics of patients with PD who died by suicide or committed homicide.

Examine the care pathway for patients with PD who died by suicide or committed homicide.

Examine the extent to which care received adhered to NICE guidelines for personality disorder.

Evaluate the quality of risk management intervention (assessment, planning and implementation of risk plans) in the 3 months prior to death or homicide.

A mixed methodology was to be used to examine the care and risk management of patients with personality disorder (PD) who had died by suicide in 2012/13 or were convicted of homicide in 2010-2013 in the UK. Cases were to be identified from the existing National Confidential Inquiry into Suicide and Homicide by People with Mental Illness [NCISH] database. (PIAG 4-08(d)/2003))

Additional information was to be obtained through a number of data sources, such as a web based survey, medical records, focus groups with clinical teams across the UK, and interviews with support and representatives groups for patients with PD.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to allow the study's participating organisations to correctly locate the medical records held on the participants, and for access to their medical records in order to extract information.

Specifically; The study was to receive data from the following sources:

1) Service providers: Medical records of the individuals in cases included in the study.

2) Data from the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness cases of people in contact with mental health services in the 12 months prior to their death

Other aspects of the project listed in the application did not require support as consent was to be obtained and were therefore not part of this request:

3) Responses from the Web based survey

4) Transcripts of the focus groups with clinicians

5) Transcripts of the telephone interviews with patient group representatives

Confidential patient information requested

Access was requested to Date of birth, Date of death, gender, last name, first name and address – required for validation purposes

Date of birth, date of death, post code, gender and ethnicity is to be retained for analysis.

Amendment request

The amendment is to data sources being requesting from mental health trusts/providers, specifically to request Serious and Untoward Incident reports relating the death by suicide or homicide of the people whose care will be reviewed in the study. The change will affect the following below:

1.Change to the study protocol to include request for serious untoward incident reports (SUI) in addition to medical records

2. change to the wording of the medical director letter to incorporate request for SUI

3. substantial revision to the proforma to extract clinical data from medical records and SUI

Confidentiality Advisory Group/ Confidentiality Advice Team advice

The amendment requested was forwarded to the Vice Chair who considered that this application was of considerable public interest, and the additional items will render the research much more accurate and relevant.

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.

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

20th May 2016

Present:

Name	Capacity	Items
Dr Mark Taylor		1a
Ms Clare Sanderson		1a
Dr Kambiz Boomla		1a

Also in attendance:

Name	Position (or reason for attending)
Ben Redclift	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) TargetCOPD: A randomised controlled trial of targeted case finding for COPD versus routine practice in primary care 16/CAG/0072

This application from the University of Birmingham set out the purpose of a project to compare the benefits and cost-effectiveness of two alternative case-finding approaches to identify undiagnosed COPD in general practice. There is significant under-diagnosis of COPD patients and this represents a group of people who could benefit from management by their GP. There is increasing interest in finding these patients but no evidence as to which approach to case-finding would be most effective or cost-effective in the short or longer term.

Using a cluster randomised controlled trial (RCT) design in 54 West-Midlands general practices; the TargetCOPD study assessed two approaches (targeted case finding vs usual care). Using an individual patient RCT nested in the targeted arm, the effectiveness and cost-effectiveness of active case finding using a postal questionnaire, and opportunistic case finding at usual surgery consultations were also compared. Patients who reported positive respiratory symptoms were invited for further spirometric assessment to ascertain whether they had COPD or not. All data was anonymised to the investigators until patients voluntarily provided their information. The most effective and cost-effective method in identifying new patients had therefore been compared, this study aims to carry out longer term follow-up to evaluate whether the different approaches are also effective in improving long-term health of patients.

Previously, within the targeted arm of the trial, participants were randomly allocated (on a per household basis) to receive either the active case finding intervention or the opportunistic case finding intervention. As part of the previous study participants were eligible if they were aged 40-79, current or ex-smokers, and not diagnosed with COPD. Potential participants were identified

through GP practice registers and anyone potentially eligible screened by the GP before being invited to take part. GPs assessed their suitability for the study; i.e. if they had conditions such as terminal illness or dementia or other reason their GP considered them unsuitable they were excluded at this stage. GPs also ensured that anyone who had died was removed from the list. In the active targeted arm, participants were offered a short questionnaire (either at the surgery during a routine visit or by post) with patient information sheet [attached] which they returned to the investigators or ignored if they so wished. They were informed of the purpose of the study which was to identify new cases of COPD. People returning the questionnaire and reporting any of the required respiratory symptoms were invited for spirometry assessment and consent was provided. GPs were informed of any patients that met the criteria for diagnosing COPD. Patients in the opportunistic targeted arm also had their records flagged to prompt the healthcare practitioner to deliver the questionnaire as above, however, they did not receive a postal questionnaire.

In the routine arm of the trial, eligible participants did not have any individual contact with researchers. GP practices continued with their usual care and new cases of COPD were identified according to usual practice. Practices provided investigators with anonymised information on the eligible patients with basic demographic/medical characteristics at the start of the study period. Practices then notified the investigators of the new cases at the end of the one-year period with some other information including consultation rates, deaths and those who had left the practice.

In order to gather information on longer-term hospital and mortality data, the researchers now need to link GP records of all eligible patients via the HSCIC. This requires temporary access to the PID of all eligible patients whether consented or not by the researchers. As there are nearly 75,000 patients, it is proposed to seek consent for this on an opt-out basis, whereby information about the proposed linkage and associated processes will be displayed in posters in the relevant participating GP practices. These posters will link to further information on the study website and also provide contact details so that patients can opt-out.

S251 support is request cover access to patient identifiable information from GP records in relation to the NHS number, Sex, Date of Birth, Postcode. This will be transferred to the HSCIC for linkage. Hospital use data, including A&E admissions information, outpatient and inpatient data as well as mortality data, including date and cause of death will be sent back to the researchers

PID for all eligible patients whether consented or not will be accessed and stored for a maximum period of about 6 months while the information is collated and send to the HSCIC for linkage. Once linkage is successful, The PID information will be destroyed.

A recommendation for class 1, 2, 4, 5 and 6 support was requested for the process of extracting and anonymising the information, to obtain and use information about past or present geographical location, to link patient identifiable information obtained from more than one source, for auditing, monitoring and analysing patient care and treatment and for one or more of the above purposes.

Confidential patient information requested

Access was requested to NHS number, Sex, Date of Birth, Postcode from GP records

Confidentiality Advisory Group advice

Public interest

Members agreed this was an important medical purpose in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

It was agreed that there were too many patients for consent and they might not all be contactable. Members noted that had the issue of consent been identified at the initial phase it would have been possible for the applicant to gain consent for the linkage from at least some of the study participants.

- Use of anonymised/pseudonymised data

It was noted that HSCIC cannot yet fully apply pseudonymisation at source, but members saw this as precisely the sort of study where pseudonymisation at source should be applied. In theory the practices could pseudonymise their output, the salt key could be sent to HSCIC and HSCIC could link on the pseudonymised key. This may be a practical alternative in future but it was understood that for the time being HSCIC cannot routinely apply this. So members accepted that there were no currently practical alternatives.

Justification of identifiers

Patient identifiable data was needed on a temporary basis to establish the linkage at HSCIC between GP data of those in their trial, and their outcomes held at HSCIC in the form of HES and ONS data.

Fair Processing

Fair processing in the practices was seen to be sufficient, including the method for dissent, as well as patient involvement. Members were supportive of the dissent mechanism, as patients can simply phone a number, and don't have to ask their GPs to opt them out.

Additional points

Data retention was set at 6 months. The data flows were agreed as secure and satisfactory.

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. A letter of support from the Caldicott Guardian (or equivalent) at applicants organisation.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 16/05/2017**
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-

advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries.

Please provide confirmation that the above conditions have been accepted and/or met. Once provided, the response will be reviewed and if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group 30 April 2016

Reviewers:

Name	*Profession*	*Present*	*Notes*
Dr Mark Taylor		Yes	
Ms Gillian Wells		Yes	
Dr Tony Calland		Yes	
Dr Patrick Coyle		Yes	

Amendment

CAG 2-079c)/ 2013 - The Pesticide Users' Health Study: Nervous system, eye, respiratory and skin disease among certified pesticide users

Context

Purpose of application

This application from the Health and Safety Laboratory (HSL) detailed a large cohort study of pesticide users comprising of more than 60,000 individuals with the aim to determine whether exposure to pesticides can be associated with an increased risk of neurological disease.

Confidential patient information requested

Access was requested to patient level HES data in relation to inpatient episodes from the Health and Social Care Information Centre (HSCIC), this would then be linked to study data retained by the HSL using a unique reference number. In addition, support was requested to access mortality and cancer registration data in relation to the cohort from the HSCIC. This data had previously been accessed under the NHS Central Register (ECC 2-04(c)/2010) application.

Amendment request

The original request to HRA CAG from the applicant was for Hospital Episode Statistics (HES) for the years 1997/98 to 2011/12, and set out precisely which fields would be requested. Since then the HSCIC has recommended adding three new fields to the data request; Episode Status (EPISTAT), patient classification (CLASSPAT) and finished admission code (FAE). Therefore, the applicant requested an amendment to their s251 support to include these fields.

Confidentiality Advisory Group

The amendment requested was forwarded to the Chair team who agreed that the HSCIC have made this request in order to ensure their and the applicant's method of measuring disease counts was consistent and can therefore be analysed in a uniform way. This amendment has received REC approval.

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.

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
8 June 2016

Reviewers:

Name	*Profession*	*Present*	*Notes*
CAT		Yes	

Amendment

ECC 8-04(b) 2013 - Road Accident In-Depth Studies (RAIDS)

Context

This application from the Department for Transport detailed the establishment of a research database with the aim to be used in studies to reduce the risk of injury or death in road traffic accidents.

Confidential patient information (name, address and date of birth) would be provided by the police to hospitals in order to request information from hospitals in relation to patient injuries. Support was requested to allow the transfer of information from hospitals which would then be included within a research database including 'weak identifiers'.

Amendment request

This amendment requested an extension to the data collection timescale by a further four years and to include additional hospitals.

The additional four years requested was to cover the final two weeks of the first phase of data collection and to allow a second phase of data collection to be undertaken.

A number of additional hospitals have been added during the first phase of data collection, and these have been reported in Annual Reviews to CAG and the REC. It was noted that some hospital sites have requested a list of sites to be included in the IRAS application form.

Confidentiality Advice Team advice

The CAT confirmed with REC that a substantial amendment was not required to cover the changes detailed in this amendment as this is the responsibility of the R& D office (s), and were referred to the REC Standard Operating Procedures.

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.