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

Amendments March 2015

Reviewers:

Name	Capacity	Items
Mark Taylor	Chair	1a
Gillian Wells	Lay	1a
Kambiz Boomla		1a

1. AMENDMENT – NON-RESEARCH

a) Child In-patient Survey CAG 1-05(a)/2014

Context

Purpose of application

This application from the Care Quality Commission detailed the first iteration of a national children's survey conducted as part of the national NHS patient survey programme. The survey was developed to incorporate the views of children and young people into existing national patient surveys.

A recommendation for class 5 and 6 support was requested to cover access to contact details of patients (children aged 0-17) who had been admitted as an inpatient or received treatment as a day case patient in June 2014.

Confidential patient information requested

Access was requested to name and address of patient and the patient's parent/carer.

Amendment request

The amendment detailed a change in the Trust reporting threshold from 30 to either 20 or 25 and the applicant requested confirmation that this was included within the application.

Confidentiality Advisory Group advice

Members reviewed the request and agreed that they were supportive due to the reasons outlined within the paper. Members advised that the applicant should confirm final thresholds once known and that they should ensure that data was not published at Trust level or provided with any other data items which may increase identifiability.

Confidentiality Advisory Group conclusion

In line with the considerations above, the sub-committee 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. Data should not be published at Trust level or provided alongside any other identifiers.
2. Confirmation of final threshold, 20 or 25, should be confirmed once known.

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

Precedent Set March 2015

Reviewers:

Name	Capacity	Items
Mark Taylor	Chair	2b
Tony Calland	Chair	2a, 2b
Patrick Coyle	Chair	2c, 2d
Robert Carr	Member	2a
Jennifer Kurinczuk	Member	2a, 2d
Barry Evans	Member	2b, 2d
Murat Soncul	Member	2c
Hannah Chambers	Member (Lay)	2c

2. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) Surveillance of Type 2 Diabetes in children under the age of 17 years in the UK and Ireland - 15/CAG/0102

Context

Purpose of Application

This application from University Hospitals Bristol NHS Trust set out the purpose of utilising the British Paediatric Surveillance Unit (BPSU) surveillance methodology to ascertain a dataset to assess the epidemiology of Type 2 Diabetes in children under the age of 17 years. Clinicians participating within the BPSU reporting mechanism will be reporting cases of incidence to the BPSU office. The BPSU office will notify the lead investigator and the research team will send a proforma consisting of specified identifiers and associated clinical data to the clinicians to complete and return. The identifiers will be kept separately from the clinical data for case verification and to de-duplicate the dataset. Once the data has been collated, the research team will remove all identifiers from the dataset to enable further analysis.

A recommendation for class 1, 5 and 6 support was requested to cover access to an authorised user for the process of extracting and anonymising data and also for auditing, monitoring and analysing patient care and treatment.

Confidential Patient Information Requested

Access was requested to the NHS number, date of birth, gender and ethnicity.

Confidentiality Advisory Group Advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activities carried out provided a significant public interest due to the increase in childhood obesity and the emergence of type 2 diabetes in children.

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. Members noted the approved BPSU methodology for rare conditions will be implemented for this study. Members agreed that consent would not be feasible as it would be important for maximum ascertainment, and agreed that to pursue a consent based approach would lead to bias due to small numbers involved in a study of a rare condition.

Justification of identifiers

The members agreed that the identifiers specified are necessary for this BPSU study. It was noted that the study required access to ethnicity which deviated from the typical BPSU methodology; however, members noted that the ethnicity identifier would be required within the list of identifiers due to the recognised ethnic distribution of type 2 Diabetes in adults, which will need to be investigated for children.

Application Inconsistencies

The members noted inconsistencies and errors within the application form. Members noted that the applicant stated that the research study is to only take place within England and noted that BPSU studies cover UK in its entirety. For the purposes of this support, please note that approval only covers data generated In England and Wales.

The members added that the applicant stated that children will not be participants of this study; however, the overall study is reviewing Diabetes data of children.

Members also noted that the applicant failed to address the main ethical issue in relation to the use of identifiable information, even with an abbreviated list of identifiers, without consent.

Communications and Transparency

The Confidentiality Advice Team noted that the applicant has amended the details of the information sheet to make it clearer how a patient or their parents can object to being part of study and aligned with the BPSU PIL Wording. The Confidentiality Advice Team also noted that the applicant will add the information sheet to the applicant's public website and will also ask

Diabetes UK to add the patient notification to the Diabetes UK website. The Confidentiality Advice Team noted that the leaflet will be made into a small poster and will be forward to all 178 Paediatric Diabetes Units in England and Wales, for use within diabetes clinic waiting rooms.

Retention

The Confidentiality Advise Team noted that the applicant will remove the NHS/CHI number as soon as possible and will only be retained for the duration of the collection and analysis for case verification and de-duplication. The Confidentiality Advice Team noted that this process will not last longer than six months of the completion of the collection of the follow – up data. The Confidentiality Advice Team also noted that the date of birth would be converted into age in months and that the identifiers will be separated from the clinical data as soon after collection. The BPSU reference number will be used as the link key.

Confidentiality Advisory Team 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. Support only applies to data generated in England and Wales.
2. Favourable opinion from a Research Ethics Committee – Date received 9 December 2014.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) Behçet's syndrome in children and young people in the United Kingdom - 15/CAG/0103

Context

Purpose of application

This application from Alder Hey Children's NHS Foundation Trust set out the purpose of utilising the BPSU surveillance methodology and notifications to members of the British Society of Paediatric Dermatologists, to ascertain a dataset to assess the epidemiology of Behçet's syndrome in children and young people in the United Kingdom. Clinicians participating within the BPSU reporting mechanism will be informing cases of incidence to the BPSU office. The BPSU office notify the lead investigator and the research team will send a questionnaire consisting of specified identifiers and associated clinical data to the clinicians to complete and return. The identifiers will be kept separately from the clinical data for case verification and to de-duplicate the dataset. Once the data has been collated, the research team will remove all identifiers from the dataset to enable further analysis.
A recommendation for class 1, 2, 5, and 6 support was requested to cover access to an authorised user for the process of extracting and anonymising data, to obtain and use

information about past or present geographical area and also for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to NHS Number, date of birth, postcode at district level, gender and ethnicity.

Confidentiality Advisory Group advice

Public interest

Members agreed that the activities carried out provided a significant public interest due to the importance of improved understanding of incidence and burden of disease associated with Behçet's syndrome in children and young people. Members agreed that this study is for a medical purpose as defined within the s251 (12) NHS Act 2006.

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. Members noted the approved BPSU methodology for rare conditions will be implemented for this study. Members agreed that consent would not be feasible as it would be important for maximum ascertainment, and agreed that to pursue a consent based approach would lead to bias due to small numbers involved in a study of a rare condition.

Justification of identifiers

The members agreed that it is necessary for the reporting mechanism to require patient identifiers for the purposes of case verification and to de-duplicate the dataset. Once the data has been collated, the research team will remove all identifiers from the dataset to enable further analysis.

Retention

Members noted that there is a requirement to retain the identifiers and clinical data separately and should be deleted once the de-duplication activity. Members noted that the Research Ethics Committee had not approved the 1 year follow –up and therefore, a new application should be submitted in relation to the further processing of the identifiers and clinical data.

Additional points

Members noted that both initial letter to clinician and follow-up letter mention National Information Governance Board (NIGB) and should be changed to the Health Research Authority (upon advice from the Confidentiality Advisory Group)

Members noted the utilisation of the BPSU methodology and the need to ensure that there is correct patient confidential information for case verification. The members agreed that

confirmation was required to establish if secure email and security controls are in place to transfer the patient confidential information.

Members agreed that there was limited information provided regarding patient material which is to be made available to raise awareness of the data collection. Members agreed that further clarity is required.

CAG advice conclusion

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

Specific conditions of support

1. Amendments to be made to the initial letter to clinician and follow-up letter to reflect correct approval bodies
2. Confirmation of retention period for patient identifiers.
3. Favourable opinion from a Research Ethics Committee - received 22 January 2015
4. Confirmation of suitable security arrangements via Information Governance Toolkit (IGT) submission.

c) **Retrospective Cohort Study of standard dose versus low dose isotretinoin treatment for acne vulgaris - 15/CAG/0103**

Context

Purpose of application

This application from Betsi Cadwaladr University Health Board set out the purpose of conducting a retrospective comparison between the standard dose and the low dose of Isotretinoin for the treatment of acne in Glan Clwyd Hospital from 2009 to 2013. Isotretinoin is a hospital – only prescribed drug and the researcher is required to extract a list of prescribed patients between the specified time period from the hospital Pharmacy department's system. From this, it is intended that the Chief investigator will collect the identifiers for medical record staff to collect the selected patient notes.

A recommendation for class 1 and 6 support was requested to allow access to an authorised user for the purpose of extracting and anonymising the information.

Confidential patient information requested

Access was requested to Name, NHS Number, Hospital ID Number, Date of Birth and Postcode.

Confidentiality Advisory Group advice

Medical Purpose

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006.

Feasibility of consent

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.

Members advised that where it is possible for consent to be obtained as a practical alternative, this should be explored in full noting the requirements of the regulations. The applicant did not provide a response regarding the possibility of obtaining consent within the IRAS form and members concluded that as the cohort was small and within one NHS organisation, requesting consent may be feasible for the applicant. The applicant is therefore, required to demonstrate the reasons why consent is not feasible for this study.

Use of anonymised/pseudonymised data

The members agreed that the specified identifiers were necessary in order to trace the patient records for the researcher to record the data.

Data Flows

The members noted that the data flows were mapped to one NHS organisation. The members considered the legitimate relationship between the researcher and the cohort of patients and agreed that the researcher did not appear to form part of the patient clinical care team.

Communications and Transparency

The members noted that there had been no information provided in relation to notifying patients that their information was to be used for research and for these purposes, individuals outside of the care team will have access to their record. The members advised the applicant to consider their obligations under the Data Protection Act 1998.

Security Assurances

The members noted that the applicant should provide clarification surrounding the data extraction arrangements. This included confirming the organisation's compliance against the Wales Caldicott Principles into Practice.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Confirmation of reasons why consent is not feasible for this study
2. Provide patient notification material and consider Data Protection Act 1998 provisions.
3. Confirmation of data extraction arrangements

d) Surveillance of Childhood Acute Rheumatic Fever (SCARF) - 15/CAG/0111

Context

Purpose of application

This application from Birmingham Children's Hospital NHS Foundation Trust set out the purpose of utilising the BPSU surveillance methodology to ascertain a dataset to assess the epidemiology for the surveillance of childhood acute rheumatic fever (SCARF). Clinicians participating within the BPSU reporting mechanism will be reporting cases of incidence to the BPSU office. The BPSU office will notify the lead investigator and the research team will send a proforma consisting of specified identifiers and associated clinical data to the clinicians to complete and return. The identifiers will be kept separately from the clinical data for case verification and to de-duplicate the dataset. The applicant also requested support to utilise the specified identifiers for the purposes of linking with Hospital Episode Statistics (HES) data to ensure cases have not been missed.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to an authorised user for the process of extracting and anonymising data, to obtain and use information about past or present geographical location, to link patient identifiable information obtained from one or more sources and also for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to date of birth, NHS Number, Hospital identifying number, gender, ethnicity and partial postcode.

Confidentiality Advisory Group advice

Public interest and Medical Purpose

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activities carried out provided a public interest as there is need to assess the epidemiology and improve knowledge of a rare childhood condition, Acute Rheumatic Fever.

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. Members noted the approved BPSU methodology for rare conditions will be implemented for this study. Members agreed that consent would not be

feasible as it would be important for maximum ascertainment, and agreed that to pursue a consent based approach would lead to bias due to small numbers involved in a study of a rare condition.

Data Flows and Justification of identifiers

The members agreed that the data flows and identifiers specified within the application are necessary and standard practice for a BPSU study. The members noted that the use of the identifiers is necessary for the purposes of case verification, to de-duplicate the dataset and for linkage with HES data to ensure cases have not been missed.

Communication and Transparency

Members agreed that there was not sufficient patient information for this study. Members noted that it is an important principle for activities taking place with support to provide a clear mechanism to manage the right of patient objection. Members had advised that patient information and notifications should clearly state that this can be done, either by informing the hospital clinical team, or by contacting the BPSU admin direct, with contact details supplied, and should state that this will not affect ongoing medical care. Members requested feedback on how this greater clarity can be enabled.

Retention

Members asked for clarification regarding whether the data which was to be retained for the requested twenty years included personal confidential information.

Additional Point - Application Inconsistencies

The members noted inconsistencies and errors within the application form. Members noted that the applicant stated that the research study is to only take place within England and noted that BPSU studies cover UK in its entirety. For the purposes of this support, please note that approval only covers data generated In England and Wales.

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. Support only applies to data generated in England and Wales.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Appendix 1. Confidentiality Advisory Group Sub Committee Minutes and Chair's Action Report

Chair's Action Report

March 2015

Reviewers

Name	Capacity	Items
Patrick Coyle	Chair	1a
Mark Taylor	Chair	1b
Tony Calland	Char	1c

1. AMENDMENTS – RESEARCH

a) Improving Outcomes from Out of Hospital Cardiac Arrest: The Cardiac Arrest Individual Registry and Outcomes (CAIRO) Programme (Work Package A) - 14/CAG/1003

Context

This application from University Hospitals Bristol NHS Trust detailed a research programme designed to monitor and improve patient care from initial ambulance response to cardiac arrest through to hospital discharge and beyond. A comprehensive patient registry, the CAIRO database, would be established to allow linkages to be made from different data sources and to track each cardiac arrest patient from initial collapse through to hospital discharge.
The aim of this specific application was to evaluate the feasibility of setting up the CAIRO database.

Confidential patient information requested

Support under class 1, 4 and 6 was requested to access name, NHS number, hospital ID, date of birth and date of death. NHS number, date of birth and postcode would be retained if a patient died prior to consent being sought to carry out data linkage. Patients would be identified through South Western Ambulance Service NHS Foundation Trust, consent would be sought from surviving patients whilst still in hospital where possible and mortality data obtained from the HSCIC prior to writing to patients to seek consent once discharged from hospital.
Confidentiality Advisory Group advice

The Confidentiality Advice Team forwarded pre-amendment review queries and applicant response to the Chair for consideration. The amendments which were requested were also forward to the Chair for review following the substantial changes from the original application:

a) **To include the patient screening in-hospital research nurses.**

The Chair agreed that it was necessary for the use of in-hospital research nurses in order to identify patients whose data is delayed from the ambulance service. The Chair noted that this would enable the completeness of the recruitment for the study.

b) **The applicant would like to enrol patients who had experienced an OHCA anytime from the date when both the original REC and CAG approvals were obtained. This included retrospective as well as prospective enrolment of patients.**

The Chair agreed that collecting confidential patient information from the ambulance service regarding all eligible OHCA patients, including those who have not survived, would be appropriate in order to obtain pre-OHCA data on these patients. The Chair noted that obtaining retrospective patients' name and address to approach patients for postal consent when this has not been previously obtained at point of access as an inpatient, was appropriate for this study.

c) **The applicant would like to use the patient's full postcode which is necessary for data linkage.**

The Chair noted that the Health and Social Care Information Centre (HSCIC) required full postcode for linkage and therefore, the Chair noted that support could be advised.

d) **The applicant would like to extend the collection of data beyond one year, with no specified duration, for a limited number of fields, should the registry prove feasible and be extended.**

The applicant confirmed that if collection of data was to be extended beyond one year, they would submit a further application for support. Therefore, this is out of scope of the current amendment request.

e) **The applicant would like to include mRS collection at discharge for patients who will choose consent to option 3**

The Confidentiality Advice Team advised that the patients who had consented were outside of the Health Services (Control of Patient Information) Regulations 2002 scope and therefore, support would not be required for this specific amendment.

f) **Clarifications regarding personal identifiable data collected and retained, and personnel who have access to these**

The Chair noted that obtaining retrospective patients' name and address in order to approach patients for postal consent when this had not been obtained at point of access as an inpatient, was appropriate. The Chair noted that the retention of identifiable data indefinitely appeared to be for consented patients only and would not require s251 support. However, the Chair advised that if the applicant would like to retain identifiers for unconsented patients indefinitely, it would be necessary to provide CAG with further justification and would require consideration from a full CAG committee.

g) To amend the approach to data linkage as it would be different for external sites

The Confidentiality Advisory Team noted that the applicant would be collecting the same data, although, utilising an alternative methodology to collect the data, which would include requesting and receiving data from external sites. This specific amendment request would therefore not have an impact on the s251 support for this study.

h) To amend the set of questionnaires being used and those who would administer them

The Chair noted that providing access to members who would be directly responsible for the questionnaire follow-up to the identifiable data was necessary, as the members would be required to complete this activity for the study. The approval to amend the set of questionnaires is an issue for the Research Ethics Committee.

i) With regard to access to personal identifiers prior to consent, it should be noted that on the rare occasion where a patient without capacity is discharged from hospital (either to another facility or their usual place of residence) before the opinion of a personal consultee can be sought, a personal consultee would be identified through communication with the clinical staff who were responsible for that patient's clinical care whilst in hospital. The modified PIL and two copies of the response form would be posted to the potential personal consultee with a covering letter, as stated in section 5.6 of the protocol. This would require the study team to have access to personal details (e.g. name and address) for the consultee, as well as the patient, prior to consent.

The Confidentiality Advise Team advised that third party information not relating to the patient falls outside of scope of the Health Services (Control of Patient Information) Regulations 2002. The Confidentiality Advice Team noted that the Research Ethics Committee would be required to approve the access to third party (consultee) information.

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. Retention of identifiers from consented patients only.

b) 'Heart Watch' Cardiac Rehabilitation: Mortality/Morbidity Audit – CAG 5 – 03(PR6)/2013

Context

This research application from the University of Hull set out a study to determine patient outcomes following participation in the Heart Watch cardiac rehabilitation programme, and the impact of exercise on cardiorespiratory fitness, through linking the programme's existing dataset to mortality and morbidity data. All participants gave consent for the cardiac rehabilitation programme and to have their clinical exercise and supervised training data routinely collected and used for research purposes.

Amendment request

The applicant had submitted an amendment request to permit the specified identifiers such as name, date of birth, and NHS Number, to be submitted to the Health and Social Care Information Centre for data linkage. This was to ensure that the data accurately reflects the underlying cause of death and admission.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who agreed that the additional disclosure to the HSCIC was required in order to appropriately resolve data accuracy issues of the data collected from Leeds Teaching Hospital Trust data sources.

c) Long-term risks associated with radiation doses from fluoroscopic cardiology procedures in children and young people - ECC 7-04(j)/2010

The original application was to establish a registry, for long-term follow up, of children and young adults who had underwent fluoroscopic cardiology procedures and assess cancer risk in relation to the estimated radiation doses that they had received. A limited number of studies have assessed cancer risks among children who underwent cardiac catheterization, with inconsistent results. The majority of these studies have been small, with a maximum of around 4000 patients. Standardised incidence ratios to relate risks associated with catheterization were used rather than obtaining estimates of organ specific radiation doses to allow dose response associations to be investigated and it is thought that it would only be through establishing cohorts in a number of populations that risks associated with interventional cardiology procedures in children can be addressed.

Amendment request

A request was received from the applicant to obtain approval for the following amendments to the original application:

(1) Data to be sought from the National Institute for Cardiovascular Outcomes Research (NICOR).

(2) To continue collating information on the patients within the original cohort who had undergone subsequent catheterizations after they had reached the age of 22 years.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who agreed that the project was in the public interest and it is necessary for the applicant to retain the identifiers for the purpose of conducting analysis every five years for the next fifteen years.