NHS
Health Research Authority

Minutes of the Precedent Set reviews of the Confidentiality Advisory Group

01 July 2016

Present:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a
Mr Anthony Kane	Member	1a
Mr David Smallacombe	Member	1a

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA
Mr Ben Redclift	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 16/CAG/0093 British Paediatric Surveillance Unit (BPSU) study of deaths in children with epilepsy aged under 16 years in the UK and the Republic of Ireland.

Context

Purpose of application

This application from the Institute of Child Health at University College London set out the purpose of providing important information regarding the number of deaths in children under 16 years of age with epilepsy in the UK. There is very little information regarding the extent of the problem and a prospective pilot study is much needed, to determine the size of the problem of death in children affected by epilepsy, to compare the differences between sudden unexplained death in epilepsy (SUDEP) and other causes of epilepsy deaths, and to allow future studies in this field.

Epilepsy is a common condition, affecting more than 500,000 people in the UK. This means that almost one in every 100 people has the condition. It mainly affects the brain and causes repeated 'fits' or seizures. Epilepsy can start at any age, but it most often begins during childhood. It is very rare for a child to die from a seizure. However, studies have shown that people with epilepsy, including children and young people, have a higher risk of death than people without epilepsy. Death in a child with epilepsy may be due to a number of causes, including sudden unexplained death in epilepsy (SUDEP). SUDEP is defined as death for no obvious reason in a person with epilepsy, and it is hard to predict.

Using the BPSU 'orange card' reporting system, all Consultant Paediatricians in the UK and Republic of Ireland will be asked on a monthly basis to report all cases of deaths they have seen in children with epilepsy aged 16 years and under that meet the surveillance case definition (see section A17-1 and A17-2). The BPSU will subsequently inform the research team of the details of all clinicians who report a case. The research team will request the reporting clinician to complete a brief questionnaire using routinely collected information from the child's medical record. The questionnaire will seek clinical data relevant to the study objectives (see sections A10 and A11) and limited patient identifiable data will be required to inform the analysis and identify duplicate cases. Patient identifiable information collected for the purposes of case verification and prevention of duplication only will be destroyed once this process has been completed. Questionnaire paper records will be stored in such a manner that the front sheet containing patient identifiers will be stored separately from clinical data sheets, in two separate locked cabinets and linked only by unique BPSU study case code.

A recommendation for class 1, 2, 5 and 6 support was requested to cover access for the process of extracting and anonymising the information, to obtain and use information about past and present geographical location, for auditing monitoring and analysing patient care and treatment and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to NHS/CHI number, date of birth, date of death, local hospital number, partial post code (first 4 digits only) for the purpose of identifying duplicate reporting cases. Age at presentation and age at death, ethnicity, sex and partial postcode will be retained for analysis.

Confidentiality Advisory Group advice

Public interest

The Committee commented that although there was a clear medical purpose in determining the incidence of deaths of children with epilepsy, the scientific method was not clearly outlined. It was not clear what the researchers expected to find from the data, which weakened the argument for a public interest in this study. However it was agreed that the potential benefits of this study were sufficient to support the application.

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.

The Committee noted that the BPSU reporting methodology was a long established method requiring approval from the BPSU approval panel. The Committee agreed that this study met the requirements for this method, with the stipulation that details on 'How to Opt Out' should be included in the Participant Information Sheets.

- Feasibility of consent

The Committee accepted the rationale that bias would be introduced if the small number of eligible participants were to be consented. It was also noted that the consent process could

cause distress to relatives of deceased children. Therefore it was agreed that consent would not be feasible.

- Use of anonymised/pseudonymised data

It was noted that identifiers would be removed once linkage was complete and duplicate cases excluded from the dataset.

Justification of identifiers

The Committee accepted the justification that identifiers were needed to complete linkage with clinical data, and to ensure that duplicate cases were not included in the dataset.

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. Participant Information Sheets to include information on how to opt out of this use of data.
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 24 June 2016**