NHS
Health Research Authority

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

10 March 2017

Present:

Name	Capacity	Items
Mr Malcolm Booth	Reviewer	1a, 2a
Mr Murat Soncul	Reviewer	1a, 2a
Mr David Smallacombe	Reviewer	2a
Dr Kambiz Boomla	Reviewer	1a

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0040 - Incidence Study of Birdshot Retinochoroidopathy in the UK V1

Context

Purpose of application

This application from Moorfields Eye Hospital set out the purpose of establishing the incidence of Birdshort chorioretinopathy (BRC) which was a relatively new diagnosis. This was the first incidence study, and would set a baseline rate for comparison with future studies.

BCR was an autoimmune inflammatory disease which caused slowly progressive visual dysfunction. It could be difficult to diagnose as early symptoms were not severe. Treatment often involved systemic immunosuppression, which carried a risk of significant side effects. The disease and treatment carried a high morbidity rate as well as psychological effects. The study would investigate risk factors using demographic and geographical data, and results of laboratory investigations.

The study would use the BOSU (British Opthalmological Surveillance Unit) reporting system, which has been developed in conjunction with the CAG and is approved in principle.

Opthalmologists would be asked to report any cases of BCR diagnosed within the last month to the research team, who would then send a questionnaire to the clinician for each case they had reported. The clinician would return the questionnaire, containing pseudonymised data including

demographic data and clinical data, to the research team for analysis. This questionnaire would be sent out again a year later.

A recommendation for class 2 and class 5 support was requested to obtain and use information about past or present geographical location and for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to month and year of birth, sex, ethnicity and 1st half of postcode of the patient (returned from the clinician to the applicant on the questionnaire). The applicant would calculate the age of the patient and enter this onto their database in months, rather than month and year of birth, to reduce identifiability of the dataset.

The other details would be retained.

Patients would be assigned a hospital ID number which would be kept to facilitate linkage for follow-up of patients after 1 year, when their clinician would be asked to return a second questionnaire.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the study had a medical purpose, the public interest was well described and the study was an important one.

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 in studying this rare disease it would be necessary to ensure that the full cohort, or as close as possible to the full cohort, was included in order to meet the aims of the research.

The CAG also considered the BOSU methodology which was developed with these ocular conditions in mind, taking into account that clinicians did not have the resources to seek individual consent.

Members agreed that consent was not practicable in this situation.

- Use of anonymised/pseudonymised data

It was noted that data returned from the clinician would be pseudonymised, and the applicant would undertake to further reduce the risk of identifiability by calculating the patient's age rather than storing it in months and years.

Justification of identifiers

Members accepted the justification provided for each of the pseudonymised data items, which were necessary in order to fulfil the aims of the study.

Additional points

Public involvement

Members noted that the applicant had the support of the Birdshot Society patient support group for the research, and that this group had also approved the patient notifications for the study.

Patient Notification and Opt-out

Members discussed the method of patient notification.

The applicant had confirmed that individual consent would not be sought, but that the clinician would hand out a patient notification leaflet to patients during a consultation.

It was observed this leaflet would be held alongside other patient information leaflets for BOSU studies, and that the reporting postcard was only sent to the research team every month. Given the busy workload of clinicians, members queried whether this information leaflet would in fact be handed out and whether a poster in the clinic would provide a better method of patient notification.

Members queried whether clinics would also have a poster giving a general explanation of the BOSU system and providing information on how to opt out, as this could be preferable to a leaflet system which was not always used.

Members acknowledged the benefits of the leaflet in cases of visual dysfunction where it would be useful for members of this cohort to be able to take the leaflet to be read by a carer, and where the patient might not notice the poster in the clinic.

It was acknowledged that discretion could be used by the applicant with regards to the method of patient notification, and that both posters and leaflets would be acceptable.

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. Favourable opinion from a Research Ethics Committee. **Favourable opinion letter provided by applicant.**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmation provided via Exeter helpdesk, email forwarded from NHS Digital on 13 March 2017.**
3. **Application was advised that approval only applies to England and Wales and the appropriate applications should be made for data processing in Scotland and Northern Ireland.**

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0045 - Hospice-led innovations for end of life care

Context

<u>Purpose of application</u>

This application from McKinsey and Company on behalf of Hospice UK and NHS England set out the purpose of evaluating the effectiveness of innovations in end of life care.

Research had shown that 80% of patients preferred to die at home, and only 5% in hospital, however the reality was that end of life care was more likely to take place in a hospital setting, which was costly as well as unwelcome for patients. Care models had been introduced at 24 hospices, aimed at reducing hospital-based end-of-life care. These models of care would be evaluated using both quantitative and qualitative methodology; the end result would be a report and set of recommendations for NHS England and end of life care commissioners, and advice for hospices on how to implement the most effective new models.

This application specifically related to the use of identifiable information to link patient datasets for quantitative analysis, in order to examine whether rates of hospital-based end-of-life care decreased where the new care models were used.

The Hospices involved would transfer identifiable information to NHS Digital, who would link these to the HES database, and provide PHE with the pseudonymous HES IDs. Support under Section 251 was requested to cover this activity only.

Further linkage would take place at PHE under an alternative legal basis. The applicant would be provided with aggregated, de-personalised data for analysis.

A recommendation for class 1, 3, 5 and 6 was requested for the process of extracting and anonymising the information, to link patient identifiable information obtained from more than one source, 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 number, date of birth, gender, postcode.

Confidentiality Advisory Group advice

Public interest

Members agreed that the public interest for the study was clearly outlined within the study.

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

Members agreed that consent was obviously not feasible from the retrospective cohort, as patients would be deceased.

- Use of anonymised/pseudonymised data

The CAG observed that applicants would only receive pseudonymous data.

Justification of identifiers

Confirmation had been received from NHS Digital that the data being collected was the minimum required for linkage.

Public involvement

Public support had been demonstrated via surveys investigating patient preference around end of life care; however the acceptability to patients of accessing identifiable data without consent for this purpose had not been tested. The applicant had confirmed that they could carry out public involvement with a hospice users group, or similar, to test its acceptability. The CAG agreed that this should be a condition of support.

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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

4. Public involvement work to be carried out with a hospice user group, or similar, to test the acceptability of accessing identifiable patient data without consent (outside the direct care team) for this purpose. This should be reported back at annual review.
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **IG toolkit confirmed published and reviewed as satisfactory.**