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

18 November 2022

Present:

Name	Role	Items
Dr Murat Soncul	CAG Alternate-Vice Chair	2a
Dr Malcolm Booth	CAG Member	2a
Dr Pauline Lyseight-Jones	CAG Member	2a

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Expressions of interest

No expressions of interest were declared.

2.New Precedent Set Review Applications – Research

a. 22/CAG/0160 - National Prospective Cohort Study and Surveillance of Sympathetic Ophthalmia in the United Kingdom

Context

Purpose of application

This application from Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research which aims to describe the incidence of patients newly presenting with sympathetic ophthalmia (SO) in the UK, over a one year surveillance programme operating via the British Opthalmological Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists.

SO is a condition where the eye becomes inflamed and can result in loss of vision. It is a very rare, but potentially blinding complication of surgery and ocular trauma, with no uniform consensus regarding its optimal management. In a previous BOSU study completed in 1998, 17 cases were reported for a 59 million UK population. The SO incidence following primary and revisional vitrectomy surgery needs to re-evaluated, as the decision to proceed with complex and repeated vitreoretinal procedures can be decided by the risk of SO, and perhaps a contemporary SO risk may not be directly associated with vitrectomy interventions. Therefore it is in the public interest to re-evaluate SO incidence so that clinicians and patients can better evaluate the risks and benefits of certain procedures.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will anonymously indicate that they have seen a new patient who has sympathetic ophthalmia through the BOSU reporting system via University of Dundee. The University of Dundee system will generate the initial questionnaire for the reporting ophthalmologist to fill in via the University of Dundee data safe haven online platform. This will contain confidential patient information. Follow-up will be conducted at six-months following initial reporting, and the University of Dundee system will generate this questionnaire for the reporting ophthalmologist in the same manner as the initial questionnaire.

Each case will be given a unique study number by the BOSU study centre. Hospital number, month and year of birth, gender, and postcode will be recorded alongside

clinical data on the questionnaires. All identifies will be deleted once the follow-up is completed, postcode is converted to deprivation score, and duplicates identified.

A recommendation for class 1, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Approximately 20 patients who have experienced sympathetic ophthalmia All patients with new onset bilateral, non-necrotising, diffuse granulomatous panuveitis affecting the fellow, sympathising eye following ocular surgery, trauma or laser therapy to the inciting eye (This patient would have a diagnosis associated with a newly-diagnosed sympathetic ophthalmia) who report to a treating ophthalmologist across the 12 months reporting period, expected to be between 01 February 2023 and 01 February 2024.
Data sources	1. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for linkage purposes	1. Hospital number (identify duplicates and identify same patient for follow up) 2. unique study number
Identifiers required for analysis purposes	1. Month and Year of birth 2. Gender 3. Postcode – converted to social deprivation score

Additional information	1 year of baseline collection 01 February 2023 and 01 February 2024, and then additional 6 month follow up until 01 August 2024.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Members agreed that this was in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicant has reasoned that due to the rarity of the condition, complete case ascertainment is required to inform true prevalence. A previous study carried out on the basis of consent demonstrated the introduction of basis and loss of complete sample. The CAG Members were content with this reasoning, but wished to ensure that all opt out options are therefore available and publicised as best as possible, as consent will not be sought.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for Identifying duplications, identification of correct patient and linkage with follow-up records. The Sub-Committee agreed that it was not feasible for this to be undertaken with anonymised information.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant provided a leaflet, which will be available on the BOSU section of the RCOphth website, and the same leaflets will be distributed to all eye units who will be asked to display them in the appropriate areas. This has a study specific opt out option on the leaflet - patients can inform their doctor they wish to opt out, and this is explained to them on the leaflet. The National Data Opt Out will also apply.

The Members commented that although content with the notification methodology, the content will need to be revised. The leaflet provided is describing the old BOSU methodology, rather than the methodology that this application is using, via Dundee. The leaflet also mentions anonymous information will be passed form their clinician to researcher, and that is not correct. The Sub-Committee also considered that some of the documents which are on the website are presented in more accessible language and are more visually appealing than the provided information sheet, and therefore the applicant is advised to view other studies notification documentation for good examples. The members considered that the dissent information is not immediately obvious to the lay person.

The notification material should therefore be improved in terms of clarity, plain English descriptions (including how to opt out), and will need to reflect the updated BOSU methodology for this study involving Dundee. The notification will need to be clear that personal data will be passed from the clinician as stated in this application, and that this is not anonymous.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

There is lay representation as part of the BOSU review process and the applicant confirms that the study has been reviewed by the lay advisory committee of the Royal College of Ophthalmologists.

The CAG felt that further details about the Patient and Public Involvement undertaken should be provided, as the Members required evidence of the acceptability of this use of confidential patient information without consent.

Exit strategy

Confidential patient information is erased once data collection is complete and prior to analysis. This will be shortly after 01 August 2024. The Sub-Committee were content with the exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide to CAG updated patient notification material in line with advice in this letter, which reflects the updated BOSU methodology for this study involving Dundee.

2. Please provide further details about the Patient and Public Involvement undertaken, to evidence the acceptability of the use of confidential patient information without consent in this application.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed (with conditions) 25 April 2019. Evidence of conditions met 15 August 2019.**

2. Security assurance requirements **Confirmed:**

   Health Information Centre - University of Dundee – Data safe haven – security is assured via NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (PBPP) Approval 9th April 2020, and amendment regarding new BOSU methodology 01 November 2022.

   Due to the number of participating reporting ophthalmologists involved it is the responsibility of Moorfields Eye Hospital NHS Foundation Trust, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Murat Soncul, CAG Alternate Vice-Chair		*29 November 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*28 November 2022*