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

May 2020

Present:

Name	Capacity	Items
Dr William Bernal	CAG Alternative Vice-Chair	1.a, 1.b
Mr Anthony Kane	CAG member	1.a, 1.b
Dr Malcolm Booth	CAG member	1.a
Mr David Evans	CAG member	1.b

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 20/CAG/0055 - Can clinical and biochemical variables be used innovatively to improve risk modelling of mortality in patients undergoing emergency abdominal surgery?

Context

Purpose of application

This application from the Portsmouth Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to investigate and test innovative ways of using clinical data and blood tests to predict the risk of death for patients who undergo emergency abdominal surgery.

Emergency abdominal surgeries are performed to treat bowel emergencies, such as a bowel blockage or perforation. This is a high-risk surgery for many patients and has a mortality rate of 10%. Risk models are routinely used within the NHS to predict a patient's risk of death prior to carrying out the laparotomy. This information can then be used by clinicians to help discuss the risks of surgery with patients and plan their care before and after surgery. The applicants plan to investigate and test ways of using clinical data and blood tests to improve the accuracy of models used to predict the risk of death for patients who undergo emergency laparotomy. The applicants plan to use the results of this study to guide the development of a larger, multi-site study.

The applicants seek support to process confidential patient information for patients who underwent emergency laparotomy at Queen Alexandra Hospital from December 2013 onwards. Data for these patients was entered into the National Emergency Laparotomy Audit (NELA) database. The student researcher, who is not a member of the direct care team, will extract the confidential patient information from the NELA database. The NELA database for Queen Alexandra Hospital is stored on Portsmouth Hospital NHS Trust servers. The patient's NHS or Medical Records Number (MRN) will be used to extract clinical and biochemical data from electronic hospital records into datasets. Logistic regression analysis and other classification algorithms will be used to assess the predictive value of novel variables.

A recommendation for class 1, 4 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	Patients aged 16 years and over who have had an emergency laparotomy for an intestinal emergency at Queen Alexandra Hospital from December 2013 onwards. The applicants anticipate that 2000 patients will be included.
Data sources	1. The National Emergency Laparotomy Audit (NELA) database within Portsmouth Hospitals NHS Trust 2. Electronic patient records within Portsmouth Hospitals NHS Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode
Identifiers required for analysis purposes	1. Date of death

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.

Scope

The CAG requested further clarity over who would have access to confidential patient information. The application stated that only the applicant herself and the named Trust data manager would have access to confidential patient information prior to pseudonymisation. However, in the answer to Q9-2, the applicant has stated that 'Members of the research team accessing patient information will have appropriate contacts' and 'Access rights to the identifiable data will only be granted to those who need it.' Members requested clarification on whether any members of the research team, who were not members of the direct care team, other than the applicant and Trust data manager would access any confidential patient information.

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 explained that the patient cohort was historic and that up to 2000 patients may be involved. It was not feasible to seek consent from this retrospective cohort.

The applicant had advised that patients who received an emergency laparotomy for an intestinal emergency at Queen Alexandra Hospital from December 2013 onwards will be included, but no end date for inclusion was provided. The CAG asked that this was clarified. The Group accepted that it was not feasible to seek consent from patients recruited retrospectively and queried whether any patients would be recruited prospectively. If so, further justification would need to be provided as to why consent could not be sought from this group.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patient records from the NELA database to electronic patient records at Portsmouth Hospitals NHS Trust. The data will be pseudonymised once extracted.

Justification of identifiers

The applicant had explained that patients' date of death would be converted to age, however date of death was listed as an identifier that was retained for analysis purposes in answer to Q38 on the IRAS form. Members requested clarification on when the date of death was converted to age at death. The Group also queried whether it would be possible to convert date of death to days following laparotomy as a numeric value.

'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 objection 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 advised that the study would be advertised on the website for the research and innovation department of Portsmouth Hospitals NHS Trust. A patient and public involvement focus group with the Portsmouth Hospitals NHS Trust Patient Research Group will be held once the study has started in order to design a poster to be displayed in appropriate areas of the Trust.

The CAG queried whether this poster would be designed after the project had begun and the processing of confidential patient information was already underway. If so, it was not clear whether patients would be provided with sufficient time to consider whether the study and register their dissent. The CAG asked that the poster was created before the study began and was submitted to the CAG for review.

The applicants stated that the poster would contain information to patients on how to apply to the National Data Opt-Out scheme. No linkages to NHS Digital, who will apply the National Data Out-Out, were described in the application, therefore it was unclear how the researchers would be aware that patients had registered an Opt-Out with NHS Digital. The Group asked

that a local dissent process was created. The Group noted that Trusts need to have implemented the National Opt-Out at Trust level before September 2020.

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.

A Patient and Public Involvement representative had been recruited, following a presentation to the Portsmouth Hospitals NHS Trust Patient Research Association Group. The representative had provided advice on the project during development and will be involved in the dissemination of findings. The presentation to the Patient Research Association Group included discussion of access to confidential patient information without consent. The Group were supportive of the proposal.

The applicants also plan to hold patient and public involvement focus groups with the Portsmouth Hospitals NHS Trust Patient Research Association Group to design a patient information poster, to be displayed in relevant areas of the hospital. As noted above, the poster should be created and provided to the CAG for review, before the project begins.

Data Protection Compliance

Further information is required to demonstrate how Principles a, b and the Accountability Principle of the GDPR Principles will be met.

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. Clarify whether any researchers outside of the direct care team, other than the applicant and named Trust data manager, will process confidential patient information for this application. If other researchers will access confidential patient information, please provide a justification for this and clarify their employment status within the Trust.

2. The start and end dates for inclusion in the study need to be clarified.

3. Clarify whether any patients will be recruited prospectively. If so, justification needs to be given as to why consent cannot be sought from these patients.

4. Provide clarification on whether patients' date of death would be converted to age death or days following laparotomy as a numeric value, and when this would be done.

5. The poster, designed to promote the study, needs to be submitted to the CAG for review.

6. A local dissent mechanism needs to be created.

7. Further information is required to demonstrate how the following GDPR Principles will be met.

    a. Principle a: information processed lawfully, fairly and transparently with basis for processing special category data listed.
    b. Principle b: information collected for specified, explicit and legitimate purposes
    c. The controller shall be responsible for the handling of personal data in accordance with the principles ('accountability principle)

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 30 April 2020.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

   Confirmed – Portsmouth Hospitals NHS Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by a check of the NHS Digital tracker on 20 May 2020.

b. 20/CAG/0064 - Health, education and social outcomes of children with visual impairment and blindness (VI/SVIBL)

Context

Purpose of application

This application from the University College London set out the purpose of medical research that seeks to investigate the health, educational and social outcomes of children who are newly diagnosed with full spectrum visual impairment.

Severe visual impairment and blindness in childhood (SVIBL) is uncommon but has a significant impact on all aspects of life. Children diagnosed with SVIBL are likely to have worse health outcomes and therefore experience poorer health compared to children without a visual disability. The applicants aim to explore outcomes for children diagnosed with SVIBL and visual impairment within England.

Socio-demographic and clinical data collected in two previous national surveillance studies, BCVIS and BCVIS 2, will be linked to administrative hospital and school records by NHS Digital in order to obtain long-term follow up data for the cohorts involved in the two studies. BCVIS 2 had support under s251, under CAG reference 14/CAG/1028, to collect the confidential patient information required via the British Ophthalmological Surveillance Unit and the British Paediatric Surveillance Unit. BCVIS was started in 1998, prior to the creation of s251. The longitudinal linked data collected during these studies will be used to develop understanding of the health and educational trajectories of children with visual disability, from the point of diagnosis throughout their childhood. The applicants aim to identify factors associated with few hospital admissions and better school attendance and educational attainment. Two representative cross-sectional samples of the general child population will also be sought from NHS Digital as control groups for the BCVIS and BCVIS 2 cohorts. The control groups will be selected to mimic the cross-sectional design of the BCVIS studies and reflect the distribution across age groups.

The applicants also seek support to disclose items of confidential patient information, including patients' date of birth, full postcode, sex and ethnicity, and the study ID for participants in the British Childhood Visual Impairment and Blindness Study (BCVIS) to be sent via a secure transfer system to the ONS Secure Research Service. The ONS Secure Research Service will carry out the data linkage to the National Pupil Database (NPD) and return a pseudonymised extract from the NPD, alongside the study ID, to the research team at University College London.

A recommendation for class 2, 4, 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	1074 patients whose data was collected during the BCVIS and BCVIS 2 studies. Control group for BCVIS cohort – all children 0-16 years of age with any outpatient hospital attendance between 01 January 2003 and 21 December 2003. The applicants anticipate that

	approximately 544,000 visits will have been made to ophthalmology departments. Control group for BCVIS 2 cohort – all children 0 – 18 years of age with any outpatient hospital attendance between 01 January 2003 and 31 December 2003. The applicants anticipate that approximately 814,448 visits will have been made to ophthalmology departments.
Data sources	1. Data collected for the BCVIS study, held at University College London Great Ormond Street Institute of Child Health. 2. Data collected for the BCVIS 2 study, held at University College London Great Ormond Street Institute of Child Health. 3. HES data held by NHS Digital 4. The National Pupil Database, held by the Department for Education
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID number 3. Date of birth 4. Postcode – unit level 5. Sex
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Name of hospital where treatment took place 5. Gender 6. Ethnicity

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 CAG agreed that the application was in the public interest.

Legal Basis

Whilst it was noted that support was requested in the original application for 'section 251' support for BCVIS 2, members were less clear on the legal basis for the applicants to retain the data for the BCVIS participants. The first study preceded section 60 and members thought this was likely to have been kept in good faith but, regardless, the group need clarity on the common law duty of confidentiality legal basis for holding of the identifiable data for BCVIS participants for so long.

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 applicants advised that this was not practicable to seek consent from patients in BCVIS, due to the historic nature of this dataset, as some patients may have died or not be contactable. The applicants also hoped to avoid bias, noting that the most socio-economically vulnerable families were less likely to take part and were also more likely to have adverse outcomes.

Members agreed that it was impracticable to seek consent due to the reasons described by the applicant.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to link data collected for the BCVIS and BCVIS 2 studies to data held by NHS Digital. This cannot be undertaken in any other way.

It was noted that the applicants wish to retain the identifiers until 2033. Members who voiced concerns about the length of time proposed. Members wished for further justification as to why these should be retained until 2033.

‘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 objection 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.

Privacy notices containing information on how patients can dissent will be linked to the information page about the study on the UCL GOS Institute of Child Health website. The privacy notice will also be shared on the websites of key national vision charities, including VISIONUK and the RNIB. The Great Ormond Street Hospital Young Persons Advisory Group (YPAG) will advise on the content of a ‘child-friendly’ privacy notice, which will also be available on the study website and above channels.

Those involved in the original BCVIS studies will be referred to the NHS Digital website, as per the information in the privacy notice. The National Data Opt-Out will also be applied by NHS Digital.

Members felt that the patient notification materials were appropriate, but they wished to emphasise that these should be in an appropriate format for the cohort. The group encouraged the applicants to take up the offer of VISION UK to support development of materials, as outlined in their letter of support.

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.

The applicants have consulted the GenerationR Alliance Young People’s Advisory Group for Moorfields Hospital. This Group is comprised of 25 children and young people with vision or eye disorders. Feedback from this group was supportive and was used to inform the development of public and patient facing study literature. The discussion with the Young People’s Advisory Group included consideration of the language used to explain use of ‘unconsented data’ and creating a dissemination strategy.

Members commended the applicants on their Patient and Public Involvement and Engagement activities and noted that the appropriate questions were put to the user groups.

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. Provide a clear explanation of the legal basis, under the common law duty of confidentiality, for which identifiable information of the BCVIS participants has been kept.

2. Consider providing the patient notification materials in an appropriate format for this cohort.
    a. Provide any updated materials as a result of this consideration.

3. Provide further justification for retaining the identifiers until 2033.

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 8 June 2020**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **The NHS Digital DSPT review was confirmed as 'Standards Met' for University College London Great Ormond Street Institute of Child Health (DSPT Tracker checked 22 May 2020), NHS Digital (confirmed by email 10 June 2019) and Department for Education (confirmed by email 26 June 2020).**

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date