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

June 2020

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1.a
Ms Sophie Brannan	CAG member	1.a
Dr Martin Andrew	CAG member	1.a
Mr Myer Glickman	CAG member	1.a

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 20/CAG/0072 - How effective and cost-effective is water fluoridation for adults? A 10-year retrospective cohort study

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to determine whether water fluoridation for adults is affects the invasive dental treatments received by adults attending NHS dental practices, and whether water fluoridation is cost-effective.

Tooth decay is common and is costly both to the NHS and patients. The NHS currently spends £3.4 billion on NHS dental services, and patients pay another £653 million in patient charges. The majority of these costs are spent on the treatment of tooth decay and its consequences. Fluoride has been added to some public water supplies since the 1940's and has been added to toothpastes since the 1970's. In America and Australia, fluoride is added to almost all public water supplies, while 10% of water supplies in England contain fluoride. It is the decision of Local Councils whether fluoride should be added to the water supply and currently little modern research has been carried out that supports the benefit of water fluoridation.

The applicants are seeking support to process confidential patient information collected in NHS dental practice records in order to understand the impact of water fluoridation on adults. The number and type of dental treatments provided to approximately 6 million people living in fluoridated or non- fluoridated areas over a ten-year period will be compared. Anonymised, patient-level dental data will be provided from the NHS Business Services Authority to the research team at the University of Manchester. Patients in fluoridated or non- fluoridated areas will be 'matched' so that patients can be compared to other patients who as similar as possible.

A recommendation for class 1 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	Six million patients who attended a dental practice within England at least twice between 2010 and 2020. Patients will have been aged 12 years and over at the start of the time period. The applicants anticipate that twenty million patient records will be included in the transfer to anonymised patient records from NHS BSA to the University of Manchester. The six million patients required will be selected from this, according to which individuals best meet the matching requirements. The applicants will request a full ten years of retrospective data. Specific dates could not be provided, as the extract would be ten years from the date that NHS BSA accessed the system and extracted the dataset.
Data sources	1. Information on dental care held by NHS Business Services Authority
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode 5. Composite ID used by NHS BSA, composed using patient surname, first initial, gender and date of birth
Identifiers required for analysis purposes	1. Postcode – sub-sector level 2. Lower Super Output Area of postcode 3. Gender 4. Ethnicity 5. NHS dental charges exemption category

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 applicants sought to determine the effect of fluoridation of the water supply on dental treatment received by adults. Substantial knowledge on this topic was available, but little of this information was recent. The Group agreed that the application was in the public interest.

Cohort

The applicants had advised that none of the patients would be children. However, the cohort will contain patients who were aged 12-16 at the time of treatment. The CAG requested further justification on why these patients needed to be included.

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.

- **Minimising flows of identifiable information**

The Group requested justification on why NHS BSA could not apply the study criteria and release 6 million rather than the full 20 million.

NHS BSA had offered to undertake propensity matching in order to provide aggregated data. Members queried why aggregated data was not sufficient. If NHS BSA were able to undertake propensity matching, members queried why this could not be applied to patient level data, which would considerably reduce the number of patients for whom data needed to be released.

- **Feasibility of consent**

The applicant advised that it was not possible to seek consent, as up to twenty million patients would be included in the anonymised extract from NHS BSA, from which six million patients will be selected for inclusion in the research.

The data collected by NHS BSA was for NHS management purposes and patients had not given consent to use of their data in research. Patients had originally consented to the storage of their data for 10 years. As the cohort would include patients treated from 2010 onwards, then there was a risk that patients' data would be retained for longer than 10 years. The Group requested clarification on whether any patient data would be retained for longer than the 10 years patients had consented to.

- **Use of anonymised/pseudonymised data**

NHS BSA need to process confidential patient information in order to produce an anonymised dataset for release to the applicants at the University of Manchester. The Group accepted that could not be done in any other way.

'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 applicants explained that a web page containing a Privacy Notice specifically for this study would be created and added to the University of Manchester's Dental Public Health and Primary Care Research group web page.

As noted above, there was a risk that patients' data would be retained for longer than the 10 years that patients had consented to. The CAG considered whether efforts should be made to contact individual patients to inform them that their data may be retained for a longer period and used in research. Members determined that this was not feasible, but that further efforts needed to be made to inform patients about the study. The applicants were asked to consider ways in which the study could be promoted, e.g. via appropriate websites.

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 explained that they intended to involve patients and the public throughout this study. 12 patients who attended an NHS dental practice in Salford were consulted in November 2018 to inform the development of the application to NIHR. Feedback from this engagement was positive. The use of confidential patient information as proposed in the application was discussed and no concerns were raised.

Two lay members had been recruited to the study team, one as part of the Operational Management Group and one to the Study Steering Committee, to provide lay input on all study decisions. Allowance has been made in the budget for training and to attend meetings. The Group noted the information provided and raised no queries.

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 clarification on whether any patient data would be retained for longer than the 10 years patients had consented to.

2. Further information on why it is necessary to release data on 20 million patients from NHS BSA to the research team;

    a. Clarify if NHS BSA can apply the study criteria or propensity matching, and release data on only the 6 million patients required.

    b. Advise why aggregated data from NHS BSA is not sufficient.

3. Provide further justification on why patients who were children when they received treatment need to be included.

4. Consider whether any further steps can be taken to promote the study and provide feedback on the further steps to be taken.

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 27 May 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 – NHS Business Services Authority has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 06 September 2019).**

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