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

26 February 2021

Present:

Name	Capacity	Items
Ms Clare Sanderson	CAG Alternative Vice Chair	1a
Dr Katie Harron	CAG Member	1a
Mr Andrew Melville	CAG Member	1a

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 21/CAG/0036 - Identification of Specific Low-Uptake Population Segments in Breast Cancer Screening

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research that aims to confirm the extent to which socio-demographic and co-morbidity factors predict breast screening adherence. It also aims to establish whether combinations of these factors are more strongly associated than single demographics. The applicant therefore aims to characterise a non-compliant phenotype, and this will later inform targeted measures to increase breast cancer screening adherence. This is a retrospective analysis of two linked datasets; the NHS Breast Screening Programme (NHSBSP) and Hospital Episode Statistics (HES). Linkage will be performed by NHS Digital as a trusted third party, and applicants will only have access to a dataset which is effectively anonymised.

Breast cancer is the most common cancer amongst women in the UK, and incidence rates are increasing. The NHSBSP was introduced in 1988, and it has been estimated that breast screening saves 1300 lives annually. Despite this, the number of people taking up the invitation to screen is falling, and uptake has dramatically declined over the past 5 years in some regions. Such trends can be a public health concern, and as such significant work has been undertaken to counteract this decline. Demographic and cognitive factors have been associated with poorer uptake of screening, however much of this previous research does not acknowledge geographical variability. Understanding the common and disparate characteristics of the non-compliant populations in differing regions where uptake is poor, would potentially allow for the development of more effective interventions. The applicants aim to more accurately characterise which patients do not undertake screening, and better inform a tailored intervention to increase screening compliance amongst low uptake subgroups.

Public Health England (PHE) will identify, from the NHSBSP database, a dataset containing all people who were invited to attend breast screening in England between 31st March 2012 to 1st April 2020. The dataset will contain NHS number, date of birth, postcode alongside type of invitation and whether or not the person attended. PHE will then securely transfer the dataset to NHS Digital, who will be responsible for linking with socio-demographic and medical information from the Hospital Episode Statistics (HES) database. NHS Digital will modify date of birth to age, modify postcode to LSOA, and then remove NHS number, date of birth and postcode. No other identifiers remain in the dataset. A pseudonym in the form of encrypted HESID is added for transfer to the applicant, however this flow of data can be considered anonymous and does not require support. NHS Digital transfer the data to the applicant at the Imperial College London Big Data and Analytical Unit (BDAU). NHS Digital will retain the key

that links the encrypted HESID to identifiers for 3-6 months after the linkage is performed, and then this will be deleted.

A recommendation for class 1, 2, 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	Females aged between 49y and 8months to 70 years and 11 months who were invited for breast screening in England between 31st March 2012 to 1st April 2020 The cohort includes both people who did not attend and people who did attend, and the applicants estimate this to be approximately 5.6million people.
Data sources	1. PHE; National Breast Screening Programme (NHSBSP) 2. NHS Digital; Hospital Episode Statistics (HES)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age 4. LSOA 5. Comorbidities (can be considered anonymous to the researchers)
Additional information	NHS number, date of birth, and postcode are removed by NHS Digital before sending to researchers at Imperial college London, and a pseudonym in the form of encrypted HESID is added.

	The key between the HESID and identifiers are retained by NHS Digital for a short time period and then deleted.

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 Sub-Committee commented there was a clear medical purpose and public interest in this research.

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**

This project aims to utilise retrospective data for 6 million women across a seven-year period. Seeking consent is thus not likely to be feasible; with such large numbers of patients, it is impractical to seek individual consent.

The Sub-Committee were content with justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage from NHSBSP dataset to HES data, and data is pseudonymised at the earliest opportunity and provided to the applicants in a format which is effectively anonymised. The CAG was content that there were no practicable alternatives which would be less disclosive.

'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.

A privacy notice for the institution website has been provided - The link will be placed upon the IGHI website https://wwwf.imperial.ac.uk/blog/ighi/2020/10/14/breaking-down-barriers-raising-breast-screening-attendance-in-north-west-london//

The privacy notice will also appear on the data release register provided by Public Health England to inform service users of how their data is being used https://www.gov.uk/government/collections/public-health-england-data-release-register. This has been the standard for PHE, regarding the use of screening data for research.

An opt out option is mentioned on the notice, linking to PHE and NHS Digital opt outs, but no specific study specific opt out has been developed because the applicants have no way to identify people to remove them from the dataset. Despite there being a pseudo-ID attached to the dataset, they key is deleted by NHS Digital 3-6 months after linkage. PHE and NHS Digital national data opt outs are applied to the received dataset, however there is no study specific opt out option.

The Sub-Committee were in agreement that although the content of the patient notification documentation is sufficient, it would need to be disseminated further than the ICHI and PHE websites. They wondered whether a social media strategy could be devised for this study, which would be likely to reach more women. Members noted that the IGHI has an active Twitter account that it uses to show the work they are doing, and require as a request for further

information, that the research study is mentioned on the IGHI twitter account. The members also suggested that the applicant consider additional notification approaches which might reach more of the cohort, for example could the applicant involve CRUK?

Member commented they would expect a study specific opt out to be provided, despite the applicants receiving an effectively anonymised dataset. If the applicant displays patient notification documents immediately and ask for those that wish to contact them to do so by the date of data sharing, then that would provide sufficient time for people to opt out if they wish. It is possible for studies requesting anonymous datasets from NHS Digital to develop study specific opt outs whereby the patient can contact NHS Digital to opt out of this specific linkage prior to the event, rather than having to register a national data opt out. Members would like the applicant to implement a study specific opt out, or provide a justification as to why this cannot be implemented.

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 stated that they have not formally tested the acceptability of identifiable data without consent. However, they have discussed the research plans with 20 diverse members of the public at a People's Research Cafe at a community venue in Shepherds Bush. The applicants state everybody was supportive and that there was no objection to the use of retrospectively collected demographic data, provided confidentiality was maintained throughout the process – the researchers assert that this describes their study process as they will not have access to any identifiable data.

Applicants also discussed the study with a CRUK cancer research group of 15 participants representing those with screening experience held virtually. The discussion included using routinely collected data analytics (without explicit consent) such as ethnicity, date of birth and postcode. The applicant states there was support for this approach providing measures were in place that only essential parties had access to data. This study has subsequently gained support through the CRUK Imperial Data Science Award. They also plan further Patient and Public Involvement and Engagement events including upcoming virtual focus groups, although the CAG has not been provided any further detail on these plans.

The members commented that despite not asking the specific questions surrounding the acceptability of using confidential patient information without consent, some Patient and Public

Involvement has taken place with different groups and in different ways, which is encouraging. It was noted that the study is low risk, and there could be a reasonable expectation that data on screening could be used in this way. It was also commented that where further Patient and Public Involvement is planned, applicants are often asked to provide feedback at annual review - but because the support required is for less than a year, it would not be possible to receive any feedback by this means.

The sub-committee were content that the Patient and Public Involvement undertaken is sufficient, and the members were prepared to accept what has been done so far with no requests for further information or conditions of support. However, the applicant is encouraged to continue with the planned events.

Exit strategy

Support is requested to cover the time period taken for the linkage performed by NHS Digital, which is estimated to take approximately 6 weeks from the date requested (after support is in place). NHS Digital delete the key between the encrypted HESID and the identifiers approximately 3 to 6 months after linkage has taken place, however applicant has stated support is not required for this element.

The members considered this to be an appropriate 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 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 favourable opinion from the REC when available, see below as part of the standard conditions of support.

2. Please confirm within one month from the date of this letter, that the research study will be mentioned on the IGHI twitter account and consider developing a social media strategy for patient notification for this study.

3. Please develop a study specific opt out, or provide a justification as to why this cannot be developed, within one month from the date of this letter.

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. **Pending**

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:**

   The NHS Digital **2019/20** DSPT review for **Public Health England (PHE) and the equivalent for NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 March 2021).

   A DSPT for Imperial College London (Big Data Analytical Unit (BDAU) is not required as no confidential patient information is processed at this organisation for the purposes of this study.

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