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

28 January 2022

Present:

Name	Capacity	Items
Dr Murat Soncul	CAG Alternate-Vice Chair	1a
Mr Myer Glickman, OBE	CAG Member	1a
Mr Andrew Melville	CAG Member	1a

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 22/CAG/0022– Patterns of Multiple Long-Term Vascular Conditions: A pilot study

Context

Purpose of application

This application from King's College London set out the purpose of medical research of linking data of patients with vascular (stroke and heart attack) episodes from national and local registries with their hospital and GP records to better understand patients health care journey and clinical outcomes, both mental and physical. This is part 2 of the project. There is a consented element, part 1, which does not require 's251' support.

Multimorbidity represents a significant health and societal burden, and commonly includes vascular risk factors and diseases. 32.4 million people annually suffer a stroke or heart attack worldwide, both being associated with significant mortality, morbidity and disabling conditions. Understanding the interrelationships between socio-demographics, vascular diseases, physical and mental outcomes, and early prevention and control of the development or progression of multimorbidity are all key to reducing the cumulative burden of these multiple long-term vascular conditions (MLTVCs) and their consequences. Gaps exist in effective prevention strategies in primary care; a recent analysis of 29,000 patients found that of 17,700 patients for whom a specific preventive treatment was clinically indicated before their first stroke, very few received the suitable treatments. linking of multiple health data sources has the potential to improve health outcomes among people with MLTVCs, as vascular events are largely preventable, and this linkage will help to identify which factors (social, biological, interventions) are associated with missed prevention opportunities and the data will aid in developing effective strategies for patients, their families, and clinical teams to reduce the likelihood of further vascular conditions.

Patients who have had a heart attack will be identified from the MINAP dataset by NICOR, who will disclose NHS number to NHS Digital in order to be linked with HES and ONS data. NHS Digital send the linked dataset back to NICOR, who will send this dataset, including NHS numbers, to the Clinical Data Linkage Service (CDLS) (hosted by SLaM). Clinical Record Interactive Search (CRIS) data including NHS numbers will also be disclosed to the CDLS. South London Stroke Register (SLSR), and Lambeth Data Network (LDN), will disclose only pseudonymised NHS number to CDLS, as they will use the same software which will change the NHS number into the same pseudonymised format, 's251' support is therefore not required for this disclosure. This will provide a complete picture of South London stroke patients.

CDLS will then use the same algorithm used by SLSR and LDN to pseudonymise the NHS numbers in the received datasets, and will then link together the MINAP, HES, ONS, CRIS, SLSR and LDN datasets using the pseudonymised NHS number. CDLS will then fully anonymise the data and retain the final dataset for analysis within SLaM, and the researchers from KCL will then be given permission to access the dataset.

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	Patient event between - 1st January 2003 to 31st March 2021 • All adults aged 18 and over admitted to hospital with a heart attack (MINAP data) • All adults aged 18 and over on South London Stroke Register • All adults aged 18 and over on Lambeth DataNet database • All adults aged 18 and over on The Clinical Record Interactive Search (CRIS) Applicants estimate this to be approximately 1.5 million individuals.
Data sources	1. Myocardial Ischaemia National Audit (MINAP) dataset, from National Institute for Cardiovascular Outcomes Research (NICOR), hosted at Barts Health NHS Trust, and controlled by HQIP. 2. NHS Digital – a. Hospital episode statistics (HES) b. Office for National Statistics (ONS) mortality data 3. Clinical Record Interactive Search (CRIS) data (at South London and Maudsley (SLaM) 4. Lambeth DataNet (LDN) – retained at South East London Clinical Commissioning Group 5. the South London Stroke Register (SLSR) -retained at Kings College London (KCL)

Identifiers required for linkage purposes	1. NHS number only between MINAP, HES and ONS 2. Pseudonymised NHS number between MINAP/HES/ONS, CRIS, SLSR, LDN 3. GP registration required regarding LDN data, to ensure catchment area, however this will not be linked to any direct identifier.
Identifiers required for analysis purposes	1. Gender 2. Occupation 3. Ethnicity The data is anonymous for analysis

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 agreed that this application was for an appropriate medical purpose which 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 reasoned that the process to be able to find, track and request consent from all individuals on the MINAP register, is very difficult, costly and time consuming due to age and number of records. The logistics and costs involved are impractical for research and would require years and funding beyond the scope available. The Members agreed with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage. It is not possible to undertake linkage with any less identifiable information than the applicant is already planning to use, and part of the described processes already describe linkage with pseudonymised NHS numbers where possible. The members were content with the justifications provided.

'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 has provided a participant information sheet, (PIS), however this is not relevant for the 's251' support part of the study. This PIS is for part 1, which is a consented interview, of a different cohort to part 2.

No notification materials have been provided regarding part 2 of the study, which requires 'ss251' support, however the applicant has explained that there will be a notification on the NICOR website, and the KCL website. The content of the notification has not yet been provided.

There is no current study specific method for dissenting, however the applicant is open to setting one up for NICOR to apply prior to the linkage being undertaken. After this time point it will not be possible to apply, as the data will be anonymised. The national Data Opt Out will be applied by NHS Digital. All other data sources also have their own opt out mechanisms, which will be respected.

The Members noted concerns regarding notification being available only on websites when so many patients are involved, as very few are likely to see it. The Sub-Committee wondered if, given that a subset of patients come from a particular area, perhaps a bit more could be done, for example via GPs, other local community/charity networks? This is a suggestion, rather than a request for further information.

Before recommending support, the Members wish to see the content of the patient notifications for the website, to try to inform the cohort about part2, including contact details regarding the study, and if possible a study specific opt out should be developed with NICOR and included in the content of the notification.

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 King's College London Stroke Research Patients and Family Group (SRPFG), established in 2005, has a core membership of 32 stroke survivors and carers from diverse backgrounds, up to 20 people attend 6-weekly meetings to discuss research findings, advise researchers and generate ideas for research. To monitor the progress of the project and research priority,

applicants plan to organise regular meetings (3 over 18 months) with study collaborators and this Patient and Public Involvement and Engagement (PPIE) group.

The applicants state they have undertaken PPI through King's College London SRPFG as described above. The SRPFG is led by Professor Chris McKevitt who is a stroke survivor and a co-applicant of this study. The applicants state that the Patient and public involvement undertaken provided supportive views about the study, and provided updated documentation to try to evidence this.

The further patient and public involvement provided does not appear to be relevant to this specific project, and therefore the Members were not clear regarding the evidence that patients and the public were supportive of this linkage study, specifically the use of confidential patient information without consent. The applicant is required to provide evidence of Patient and public involvement discussions regarding this specific application.

Exit Strategy

The exit strategy is anonymisation. The length of time support is required will be until linkage is complete. An estimate regarding how long this will take is approximately 20 months. The CAG 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 the content of the patient notification which will be available on NICOR and KCL websites, which clearly sets out ways to raise objections, and includes contact details.

2. Please provide an updated report on patient and public involvement activity reflecting recent views of participants on this specific use of confidential patient information without consent.

3. Please provide evidence of REC Favourable Opinion, as per standard condition of support.

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 **20/21** DSPT reviews for **Barts Health NHS Trust (NICOR), NHS Digital, and South London and Maudsley NHS Foundation Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 February 2022)

Minutes signed off as accurate by correspondence from Dr Murat Soncul, CAG Alternate-Vice Chair		*17 February 2022*
Signed – Officers of CAG		Date
Caroline Watchurst		*16 February 2022*
Signed – Confidentiality Advice Team		Date