NHS
Health Research Authority

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

13 January 2017

Present:

Name	Capacity	Items
Ms Sophie Brannan	Reviewer	1a
Dr Mark Taylor (Chair)	Reviewer	1a and 1b
Mr Andrew Melville	Reviewer	1a
Ms Hannah Chambers	Reviewer	1b
Dr Murat Soncul	Reviewer	1b

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0013 Do Patients with Social Deprivation present late with Dementia?

Purpose of application

The research study set out the purpose of establishing whether there was a relationship between the area of Liverpool patients were from, and the stage of the illness at which the patient presented to services. There was anecdotal evidence from clinical practice that patients with dementia presented later in the course of the illness and that opportunities to treat these patients earlier were being missed. The findings could influence the allocation of resources, for example to increase awareness of dementia symptoms in these areas.

The research team would collect data from assessments of new patients who presented to Mossley Hill Hospital Old Age psychiatry services with dementia. The data analyst department would extract all EPEX numbers that corresponded with patients within the Trust who received a dementia diagnosis between January 2016 and December 2016, and the particular Trust locations at which their case notes were stored. This list would be provided to three researchers who would access the case notes at each

of these locations. The data would be recorded in pseudonymised form on a Mersey Care PC before leaving each location.

A recommendation for class 1, 4, 5 and 6 support was requested for the process of extracting and anonymising the information, to link patient identifiable information obtained for more than one source, for auditing, monitoring and analysing patient care or treatment and to allow access to authorised users for the above purpose.

Confidential patient information requested

Access was requested to: age, ethnicity, gender (recorded in binary fashion), MMSE (mini mental state examination) on 1st presentation, duration of symptoms, diagnosis, postcode, smoking status, alcohol use, illicit drug use and other comorbid medical conditions.

Confidentiality Advisory Group advice

Public interest

It was agreed that the application had a clear medical purpose and was in the public interest.

Practicable alternatives

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

- Feasibility of consent

It was accepted by the CAG that consent would not be practicable given the retrospective nature of a case note review and the numbers of patients involved (a cohort of 400), and the resources available to the research team.

The argument that patients might not be able to consent due to a lack of capacity was not accepted by the CAG. The researchers would not have contact with patients during the retrospective case note review and therefore could not make assumptions about capacity. If in contact with patients who lacked capacity, the researchers would be obliged to comply with the Mental Capacity Act which lay outside the remit of CAG. For both these reasons, the issue of capacity was not relevant in this case.

- Use of anonymised/pseudonymised data

The CAG observed that efforts had been made to reduce the identifiability of the data by recording gender in binary form and age range rather than exact date/age. The postcode would be converted to IMD score, however this would not take place until after the data had been taken offsite.

Justification of identifiers

It was agreed that the inclusion of postcode in the dataset to be extracted increased the risk that a patient could be identified from the information taken off-site. Members agreed that this risk would be removed by converting the postcode into IMD code at the hospital site.

Additional points

An inconsistency in the form had been noted with regards to HES data. Although in later correspondence it had been stated that HES data would not be accessed, the CAG requested confirmation of this point and stressed that support was not given for access to HES data.

Patient notification and opt out

The application was not compliant with the CAG principle that patients should have the opportunity to opt out of the use of their data. Although it was agreed that consent could not be sought, the research team bore the responsibility for making patients aware of the study, and enabling them to opt out if they so wished. The application had not included copies of any patient notifications or an explanation of how opt outs would be respected.

Patient/Public Involvement

Members welcomed the reference to future work to be carried out with patient and carers' groups, and agreed to request further detail to clarify how and when it would be carried out.

Given that the cohort could include patients who lacked capacity, it was recommended that family members and carers' views be included in the consultation.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. It was agreed that the information extracted from the patient's record could not be considered anonymous as it contained postcode. Confirmation should be provided that the postcode would be converted to IMD code onsite, and if this was not possible a justification for the extraction of this data should be provided.
2. Copies of patient notifications should be provided to the CAG for review, along with a description of where they would be placed and how patient objections would be respected. The notification should explain the purpose of the study, the specific use of patient data and contact details to enable patients to opt out.
3. A fuller description of the plans for public and patient involvement work, including carers and family members, and the timescale for the work, to be provided.
4. Confirmation to be provided that access to HES data is **not** requested.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 9 January 2017.**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0014 Hospital readmission and myocardial infarction after aortic surgery: A service evaluation

Context

Purpose of application

This application from Guys and St Thomas' NHS Foundation Trust set out the aim of understanding what happened to patients following major aortic surgery at St Thomas'. More information on the long –term risks of this surgery could help both patients and clinicians to make an informed choice about whether this operation should be undertaken, assist with cost-benefit analysis and inform the direction of future research.

Current survival data suggested that a large proportion of patients did not survive to two years after their operation. Diseases of the aorta were common, especially in older men. Endovascular repairs were increasingly offered to older and more unwell patients. Evidence from the United States suggested that patients who had endovascular repairs often had short life expectancy due to disease other than their aneurysm.

St Thomas' was a national leader in treating aortic disease and providing complex endovascular repairs. The site held details of 1800 patients who had been treated by the vascular surgical team. The service evaluation aimed to describe:

- The rate of hospital admission in the five years following surgery and the reasons for these admissions
- The rate of myocardial infarction in the five years following surgery

As St Thomas' was a tertiary referral centre, these patients were treated from across the country therefore in order to obtain this information there was a need to link to national datasets.

A recommendation for Class V Support was requested for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to name, date of birth, NHS number, and date of surgery, which would be provided to NHS Digital for linkage.

HES data would be requested from NHS Digital to determine the rates and reasons for hospital admissions.

Similar data would be requested from the myocardial infarction national audit project (MINAP) database, which collected data nationally on patients who have suffered myocardial infarctions.

(A full list of the data items to be returned was provided in the application).

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the application had a clear medical purpose and that there was public interest in the work.

Practicable alternatives

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

- Feasibility of consent

Members agreed that consent was not feasible given the age of the database (10 years) and the wide geographical spread of patients which meant that most were not in contact with the care team and some would be deceased.

- Use of anonymised/pseudonymised data

The application requested support for the applicant to provide data to NHS Digital and NICOR for linkage, in order to return a pseudonymised dataset for analysis.

Justification of identifiers

Members raised no issues with the identifiers to be provided for linkage and were satisfied that the data returned was the minimum required.

Additional points

Members agreed that the patient notification materials could be improved by shortening and simplifying the language. They would benefit from review by patients or the public to ensure that they could be easily understood. Members also commented that further clarification on the role of NHS Digital was necessary, as it was not strictly a 'healthcare body' as patients would understand it.

It was noted that the applicant had completed some public engagement work.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

3. Revised patient notification materials to be provided for review. These should be shorter and easier to understand. It is recommended that the materials are reviewed by patients or members of the public.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission Published on website, review grade Satisfactory – **confirmed 13 January 2017**.

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

27 January 2017

Present:

Name	Capacity	Items
Ms Clare Sanderson	Chair	1a
Dr Lorna Fraser	Reviewer	1a
Mr Anthony Kane	Reviewer	1a

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0016 Patient Reported Outcome Measures for Neurological Conditions

Context

Purpose of application

This application from Aneurin Bevan University Health Board set out the purpose of validating and assessing a Patient Reported Outcome Measure (PROMIS Plus questionnaire) for a range of neurological conditions across Wales. The questionnaire would ask for patients' views on their own health and their quality of life. It would be validated in those diagnosed with the following neurological conditions: Multiple Sclerosis, Acquired Brain Injury and Parkinson's Disease, with the aim of creating a PROM which could be used for all neurological conditions. At present there were PROMs tailored to each individual neurological condition, and one generic PROM which measured health-related quality of life but did not capture the impact of common impairments and limitations in function shared by people with neurological conditions.

The use of one PROM for a range of neurological conditions would standardise the data collected for different conditions identifying inequalities in health and social care provision across Wales and support the evaluation of service development.

Questionnaires would be sent to patients from specialist clinics across Wales. Lead clinicians at neurological clinics would screen their clinic lists for eligible patients and provide this to researchers to enable them to send questionnaires.

A recommendation for class 3 and 6 support was requested for the purpose of selecting and contacting patients to seek their consent, and to allow access to an authorised user for that purpose.

Confidential patient information requested

Access was requested to patient's age, health status (ie are they pregnant), and rough geographical location to enable researchers to establish eligibility.

Date of birth is listed as an identifier used for comparison with the national dataset.

Name and full address including postcode was requested in order to send out questionnaires.

Confidentiality Advisory Group advice

Public interest

It was accepted by the members of the CAG that the application had a clear medical purpose.

Although it was also accepted that the validation of the questionnaire was in the public interest, members were not convinced that it was necessary for the research team to access patient identifiable data in order to achieve this aim.

Practicable alternatives

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

- Feasibility of consent

The applicants intended to use a consented approach – the application concerned the recruitment of patients only.

- Use of anonymised/pseudonymised data

The CAG queried why the clinician could not contact the patient and ask them to contact the researcher, rather than passing the patient identifiable information to the researcher.

The applicant had stated that clinicians in neurological clinics would not have time to consent patients before providing their data to the research team; however members were unconvinced by this argument given that the cohort size was relatively small. Clinicians were already committing some time to the study in sharing details from their clinic lists, and it was observed that other PROMS approaches had worked by gaining consent from the patient in hospital.

Justification of identifiers

Concerns were raised about the numbers of patients whose identifiable data would be shared with the researcher.

Section 14 of the application stated that a patient list would be provided by the clinicians, and patients selected from each clinic to participate in the study if they met the inclusion criteria.

This implied that all patients from the clinic could be screened by the researcher. Although not included in the inclusion/exclusion criteria for the study, it was stated that participants who lacked capacity to consent would not be approached. It was unclear who would make the decision about whether to approach patients.

It was agreed that these points would need to be clarified in order to determine the scale of access to patient data, and whether this was justified in relation to the aims of the study.

The Sub-Committee also requested further details with regards to how long data would be retained without consent, specifically if no response was received following the second letter.

Additional points

Members discussed patient notification and opt out.

Copies of patient notifications had not been provided, although it was stated that these would be placed in clinics to enable patients to register any objections.

Patient information provided appeared to rely on the lay summary from the Study protocol, which was not in lay friendly language. It was agreed that this was an issue to be addressed during the REC review of the application.

Although it was mentioned that PPI groups had been involved with reviewing patient materials for the study, there was no mention that these groups were consulted on the methodology for the study or the need to share identifiable data with the researcher.

Members agreed that PPI work should be carried out to gauge public opinion on the use of data, and suggested involving PPI groups at the hospital or approaching patient groups for the neurological conditions being studied.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Given the small sample size, the applicant was asked to provide further justification as to why the clinician could not send out questionnaires to potential participants, or gain their consent prior to the sending of the questionnaires.
2. The applicant was asked to clarify who would be responsible for selecting patients to be included in the study, and if this would be done by the researcher to clarify how many patient's details they would anticipate receiving before reaching a cohort of 300? They were also asked to clarify how participants who lacked capacity to consent would be identified in this process?
3. The applicant was asked to provide a copy of the posters to be placed in clinics to notify patients and allow for opt out from the study and please provide assurance that these will be displayed at least a month in advance of the study to allow patients to register an objection.
4. The applicant was asked to confirm where the research team were based and where paper files would be stored.
5. The applicant was asked to confirm how long personal identifiers will be retained if there was no response to the second letter.
6. The applicant was asked to provide a programme of the PPI work to be carried out, in order to gauge the acceptability of sharing identifiable data without consent, for this study.

3. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0026 Evaluating outcomes and complications of knee arthroscopy

This application was submitted to obtain support for linkage via NHS Digital. Following receipt of the advice form, and after discussion with NHS Digital, the applicant withdrew the application for the following reason:

'*NHS Digital have advised me they already have the data and do not require CAG approval as they are providing me with pseudonymised data only - therefore, the reason (for withdrawal) is there is no breach of patient confidence'*.