NHS
Health Research Authority

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

14 January 2016

Present:

Name	Capacity	Items
Patrick Coyle	Chair	1a 1b 1c
Mark Taylor	Chair	1d
Kambiz Boomla		1a
Robert Carr		1a
Hannah Chambers		1b 1c
Claire Sanderson		1b
Marc Taylor		1c
Professor Jennifer Kurinczuk		1d
Mr. Anthony Kane (Lay)		1d

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 2016 Community Mental Health Survey - 15/CAG/0200

This application from the Care Quality Commission (CQC) set out the purpose of carrying out the 2016 mental health survey, one of the surveys within the NHS national patient survey programme. The survey data would be used by NHS trusts and Clinical Commissioning Groups (CCG's) in local improvement activities. CQC would use data as part of its regulatory and surveillance activities and other relevant functions and data would also be shared with NHS England and the Department of Health.

A recommendation for class 5 and 6 support was requested to cover access to confidential patient data from mental health trusts providing mental health services to one of four 'approved' contractors, to enable contractors to send out questionnaires.

Please note that this study achieved most recent approval under the reference CAG 9 (PS1) 2014 – 2015 Mental health survey. Changes to the application since last year have been

highlighted within the application form. Substantive changes may be referred to a full review at a CAG meeting.

The fundamentals did not appear to deviate significantly from what had been approved previously other than the review of the "approved contractor status" which was currently underway. The applicant confirmed that the contractor for the Co-ordination Centre for 2015 will be confirmed in November 2015 and relevant updates will be sent to the committee at that time.

Confidential patient information requested

Access was requested to name, address, year of birth, gender, ethnicity, date of last contact, CPA status, GP practice code and mental health care cluster code from NHS trusts, 1 September 2015 to 30 November 2015.

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

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 27/08/2015**

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

b) Impact of bystander disease after primary PCI to the culprit vessel after STMI (prevalence of Ischemia and incidence of clinical events - 15/CAG/0202

This application from the University of Southampton Hospitals NHS foundation Trust sets out the purpose of this study to assess the local outcome of patients presenting to University Hospital Southampton with STEMI (ST elevation myocardial infarction – heart attack), and multi-vessel disease who have undergone emergency primary percutaneous coronary intervention (PPCI) for the heart attack artery alone and then progressed to further stent treatment on the basis of a positive stress MRI test.

A STEMI, is the result of a blocked coronary artery. Current treatment is to reopen the blocked artery as soon as possible to restore blood flow to the heart muscle and minimise long term damage. STEMI patients undergo PPCI, which usually means placement of a stent to the blocked artery. Some patients are found to have additional narrowings in other

coronary arteries and it has been unclear how best to treat this “bystander disease”. Two randomised trials have recently reported a significant benefit to heart attack patients when all coronary narrowings are treated prior to discharge. As a result, some international guidelines have been altered to reflect the benefit of complete treatment of all narrowings.

The study aims for a retrospective collection of data from patient notes by the patients' usual clinical care team. The clinical team will have access to personal identifiable data. This data will then be anonymised prior to collection by the host institution and subsequent analysis thereafter, so both for analysis and publication of the findings.

The applicant is seeking s251 support to allow other trusts or GP practises to be contacted for patient’s status at 12 months. GPs and infrequently other Trusts may be contacted by a single clinician, Cardiology Specialist Registrar, who will ensure data is handled with care and that confidentiality maintained. The clinician will identify patients from a clinical database to which they will have access as part of their clinical role. It will be necessary to provide GPs/Trusts with the name and date of birth of patients where we are requesting mortality status. GPs will only be contacted when survival data is not readily available from the hospital systems. GPs will be asked to provide patients' mortality status only and date of death if applicable. No additional medical information is required. As this application requires access to deceased person’s data it is acknowledged that the usual information about public engagement in relation to Precedent set applications do not apply.

Confidential patient information requested

Access was requested to mortality status and date of death

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a project 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.

- Use of anonymised/pseudonymised data

It was noted that the applicant had queried whether the data was available from the HSCIC on the grounds that next of kin would need to be contacted for consent. Members questioned whether this was correct and felt that there was potential for the applicant to explore the possibility further of being supplied with anonymous data or members of the care team providing this through other hospital systems

Additional points

It was noted that there was no public engagement and although members had some sympathy with the arguments provided the applicant was reminded of their

responsibilities to publicise the study in line with the Data Protection Act wherever possible.

Confidentiality Advisory Group advice conclusion

The CAG recommended that support under the Regulations did not appear to be required as the applicant has confirmed that no identifiable data will be disclosed outside the clinical care team. The applicant was advised that this should not be considered as an endorsement of the approach or as legal advice.

c) Understanding patient mortality in the month following contact with the out of hours service: a data-linkage study. - 15/CAG/0211

This application from the Oxford Health NHS foundation trust set out the purpose to establish the proportion of patients dying in Oxfordshire over a year who were assessed by the Oxfordshire out of hours service (run by Oxford Health NHS foundation trust) in the four weeks prior to their death and to evaluate whether there are clinical and demographic features which could help distinguish patient subgroups at higher risk of death within 4 weeks of contact with the out of hours service.

By linking mortality data from the Health and Social Care Information Centre with OOH records for Oxfordshire all people who have died in Oxfordshire in a 12 month period can be identified. The researchers can then establish whether these people had made contact with the OOH service in the four weeks before their death and the proportion of people who contacted the service. Using the OOH electronic record will allow demographic and clinical information to be recorded on this group, such as age, social deprivation, and the outcome of the contact with the OOH service. Researchers will also look specifically at those patients who did not contact the service due to end of life issues.

There is currently no integrated feedback system regarding patient deaths between local GP practices, the out of hours service and hospitals in the Oxfordshire region. One potential repercussion of this is that the proportion of patients who make contact with the out of hours service and who die within four weeks of that contact remains unknown. It is also unclear why these patients die, and whether it is possible to identify any particularly high risk subgroups of patients making contact with the out of hours service.

S251 support is requested to allow the disclosure of NHS numbers, dates of birth and dates and cause of death for all patients dying within Oxfordshire on a 12 month basis, expected to be around 7,000 patients. Data from the HSCIC will be cross-referenced with the Oxfordshire out of hours electronic medical record to identify patients seen by the Oxfordshire out of hours service within four weeks of their death. Sub sector level postcode will enable an evaluation with indices of deprivation. NHS numbers will be replaced with study identification numbers and all information relating to patients who

had not seen the OOH service within 4 weeks of their death will be securely deleted as soon as linkage is complete.

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover access to an authorised user for the process of extracting and anonymising the information, to obtain and use information about past or present geographical location, for linking patient identifiable information obtained from more than one source, and for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to NHS numbers, dates of birth and dates and cause of death.

Confidentiality Advisory Group advice

Public interest

Members noted that this was a valuable study in the public interest.

User involvement

It was noted that there had been limited evidence of public involvement in the planning and design stages of the project. It was suggested that the applicant consult with GP Patient Participation Groups to inform them of the study if possible.

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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries.

Please provide confirmation that the above conditions have been accepted and/or met. Once provided, the response will be reviewed and if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

d) PEPS Data Linkage Study - 15/CAG/0208

This application from University of Nottingham sets out the purpose of the study is to clarify safety and service use among participants in the PEPS trial by examining data obtained from the Health and Social Care Information Centre (HSCIC). The number and type of hospital admission, emergency department attendance and deaths which will be looked at to find out whether participants who were allocated to receive PEPS therapy experienced more of these events than participants who were allocated to receive usual treatment only.

Support is requested to allow the disclosure of NHS number and date of birth from the sites who participated in the original PEPS trial to the HSCIC for linkage purposes.

These participating sites will submit participant identifiable information (NHS number and date of birth) to the Health and Social Care Information Centre (HSCIC) for data linkage purposes.

HSCIC will search for the data for the relevant participants and provide this data to the University of Nottingham for analysis. Data received from HSCIC will have the NHS number removed and will be identified by the trial ID number and date of birth only.

HSCIC data will be linked with the existing PEPS trial dataset so that the data on hospital admissions, emergency department attendances and deaths received from HSCIC can be analysed by treatment group (i.e. by whether participants were allocated to receive PEPS therapy or usual treatment).

A recommendation for class 1, 4 and 6 support was requested.

Confidential patient information requested

Access was requested to NHS number for linkage purposes and Date of Birth and Date of Death are to be used for analysis purposes. Date of Birth is to be removed once validation of linkage has been done, Date of Death is to be retained for a period of 7 years.

Confidentiality Advisory Group advice

Public interest

Members were in agreement that this study is in the public interest because it aims to clarify issues of safety and service use among the PEPS trial sample.

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 were in agreement that consent was not practicable but wished to ask the applicants opinion about the consent which had been given for the original PEPS study.

Patient notifications

Patient information and opt out – members thought that there was limited information to participants about how their data is to be used and how they can opt out. It is a requirement of the DPA under fair processing that data subjects are made aware of how their data is used and for what purpose. Similarly, but separate to the DPA, the CAG consider how patients are notified about the use of their data and how patients can opt out should they wish to.

Additional points

Precedent set criteria

Members noted that the applicant selected the precedent set review criteria 4, this criteria states; the activity should be limited to 6 months. This limit applies to one-off data linkage and the total data extraction process. As it is intended to hold date of death for a period of 7 years it was felt this criteria is not valid. However, members were contend that precedent set criteria 2 applies, the criteria is; Access to a deceased person's data.

Data linkage

Members noted that it is proposed to link to HES and ONS data only, but one of the collaborating hospitals is in Wales and so while the mortality data would come from ONS, Welsh data for inpatient admissions comes from the Patient Episode Database Wales (PEDW) and not HES. This doesn't seems to have been mentioned so the group would like to check with the applicant, as if the application is approved as it stands the applicant would not have the relevant cover for the Welsh in-patient data.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Members would like your views on your understanding of the relevance of any previous/ re consent in relation to this application.
2. Can you advise how fair processing and patient notifications, including the process for opt out, will be made available to data subjects/patients?
3. Confirmation whether the PEDW data is requested in this application?

Once received the information will be reviewed by the members of the original precedent set sub-committee. Members may request that the application is reviewed at a full CAG meeting. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

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