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

23 June 2016

Reviewers:

Name	Capacity
Gillian Wells	Vice Chair

1. NEW AMENDMENTS: ECC 8-05(f)/2010; A National Neonatal Research Database

Context

This application proposed to set up a national neonatal research database to be used as a research resource. Support under the Health Service (Control of Patient Information) Regulations 2002 was sought to enable routinely collected patient identifiable data to be populated on this research database. In addition to routinely collected clinical data, the application also included requested use of NHS Number, hospital ID, date of birth, date of death, postcode, gender, ethnicity, maternal NHS number and ethnicity, and postcode of infant at two years old.

Amendment request

The applicant wished to extend their support to link to other databases, for which REC approval would be sought – including but not limited to, birth notification data (Patient Demographic Service), National Infant Physical Examination programme (NIPE), and Clinical Practice Research Database (CPRD).

In addition, they sought support for an additional purpose, allowing them to select and contact patients to seek their consent for participation in future studies. The proposed contact of individuals would be through the clinician responsible for the individual's care. Individuals would not be contacted directly.

Finally the applicant sought support to retain identifiers in perpetuity in order to facilitate long term research.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who noted that the amendment form listed a change in purpose, approaching participants for consent, the retention of identifiers in perpetuity, and linkage to all databases. This was considered a significant change and a new application is required. Cases for linking to all databases and keeping identifiers in perpetuity will need to be particularly strong in any application, and CAG

would need to have robust and factual information on the view of patients regarding this (some of which was included in the amendment form considered).

8 July 2016

Reviewers:

Name	Capacity
Tony Calland	Vice chair

1. NEW AMENDMENTS: 15/CAG/0119; MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)

Context

This application from University of Oxford set out the purpose of the Maternal, Newborn and Infant Review Programme (MNI-CORP) which is a national programme which aims to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events.

A recommendation for class 2, 4 and 6 support was requested to cover access to confidential patient information from ONS and NHS Trusts. Patients treated between 1 Jan 2009 and 31 March 2017 would be included.

On 22 June 2015, an amendment was supported for access to confidential patient information from the National Confidential Enquiry into Suicide and Homicide (NCISH) at the University of Manchester, rather than directly from Mental Health Trusts, due a number of difficulties accessing the required information from Trusts.

Amendment request

The amendment request was to limit the extent of the redaction which is carried out for the perinatal confidential enquiries. Redaction will be solely limited to the complete removal of the mother and baby identifiers, and project team will not redact the hospital and clinician details.

There are two reasons for this proposal. The first reason is that the redaction of the details of the clinician and hospital results in the loss of important information about who is delivering care and what level of care is available in that Unit to be provided. Redaction of the clinician details in particular leads to loss of information about the seniority of the clinicians providing care and importantly making key clinical decisions and redaction of the hospital details leads to loss of information about the level of services which are provided. This has important implications in terms of assessing the quality of care in terms of deciding what services are available and what can care can thus reasonably be expected to be delivered, who is making critical decisions, whether any inappropriate decisions were inappropriate simply because the staff member was too junior to be making critical decisions, that a more senior member of

staff should have been called or whether decisions were inappropriate despite senior staff being on hand.

The second reason is that going forward the MBRRACE-UK budget will be cut by 15% and it is therefore necessary to find practical ways of making savings whilst still being able to deliver the whole national Maternal, Newborn and Infant Clinical Outcome Review Programme. This proposal will reduce by more than half the time taken to redact each set of case notes.

Confidentiality Advisory Group advice

This application was forwarded to the Vice-Chair who noted that there was a very strong public interest and that there were no practicable alternatives in view of reduced resourcing.

11 July 2016

Reviewers:

Name	Capacity
Tony Calland	Vice chair
Katie Harron	Member
Murat Soncul	Member

1. NEW AMENDMENTS: 1-06(c)/2011; National Oesophago-gastric Cancer Audit

Context

This application from the Health and Social Care Information Centre provided details of a follow-on audit of the National Oesophago-gastric (OG) cancer audit, due to commence in April 2011. The Audit would examine the quality of care received by patients with oesophago-gastric cancer in England and Wales. Linking with the first Oesophago-gastric Cancer Audit would allow for results to be published on a longitudinal basis and so highlight areas where care had improved and where improvement was still needed.

A recommendation for class 3, 4, 5 and 6 support was sought to collect data on all patients aged 18 and over who had been diagnosed with oesophago-gastric cancer between 1 April 2011 and March 2014 in England and Wales. Support was also sought to permit linkage with the first National OG audit in order to carry out longitudinal analyses, and to extend the cohort in April 2012 to include patients in England and Wales diagnosed with High-Grade Dysplagia. In particular, the audit requested access to NHS Number, postcode, sex, and date of birth. Linkages would be carried out with mortality data, HES, PEDW and the Casemix Programme within the ICNARC datasets.

Amendment request

This amendment proposes to link the records of patients submitted to the Audit by English hospitals to the records of these patients contained in the Clinical Practice Research Datalink (CPRD) primary care dataset. By linking patient records from the Audit with records in the CPRD database, the audit team will be able to examine the care pathway from first presentation to treatment and thereby investigate what factors are related to delays in the diagnosis of patients (whether, for example, it was

because the diagnosis in primary care had been missed or masked by proton pump medication, or because the late presentation had occurred due to delay elsewhere).

It is anticipated that the results will provide information for NHS services on how they might be able to expedite diagnosis. Improving the rates of early diagnosis will also lead to patients having an improved prognosis because their cancer will be diagnosed at a less advanced stage.

The applicant expects to be able to have the two data sources linked and the resulting dataset analysed within a one year period. They will combine primary care and audit data for patients diagnosed between 1 April 2011 to 31 March 2015.

Confidentiality Advisory Group advice

The group were satisfied that the amendment was within the spirit of the conditions which were previously supported, and that the linkage of the National Oesophago-gastric Cancer Audit to the CPRD primary care database to follow the 2,000 plus patients identified in the audit to try and establish where the delay in their diagnosis had occurred was in the public interest.

20 July 2016

Reviewers:

Name	Capacity
Tony Calland	Vice chair
Hannah Chambers	Member
Murat Soncul	Member

1. **NEW AMENDMENTS: PIAG 4-09(k)/2003, PIAG 1-05(f)/2006; Effectiveness of prostate cancer screening study**

Context

Purpose of application

This research application from the University of Bristol set out the purpose of an ongoing DH/CRUK-funded cluster randomised controlled trial in which GP practices in 8 centres in England and Wales were randomly allocated to either population based PSA testing, akin to screening (the ProtecT study) or standard (unscreened) practice. In the intervention (ProtecT) practices, men aged 50-69 years were invited between 2001-2008 to undergo PSA testing. In the comparison arm practices, men aged 50-69 years undergo standard NHS management (provision of an informed choice to any man over the age of 50 who requests a PSA test). All men were being followed-up for vital status, incident and fatal prostate cancer via the Health and Social Care Information Centre (HSCIC) in accordance with their protocols for the transfer and use of NHS classified data. The primary outcome was prostate cancer mortality after a median 10 years follow-up (reached in 2016), analysed by intention-to-screen. Secondary outcomes included all-cause mortality, cost-effectiveness and disease status and stage (after 10, 15, and 20 years). A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to data from the HSCIC.

Confidential patient information requested

Access was requested to name, date of birth, NHS number, hospital number, postcode, GP practice and cause of death.

Amendment request

Three amendment requests were received by the CAG detailing changes to data flows for the application.

1) Summary data on prostate cancer mortality and prostate cancer diagnosis in groups not in routine follow-up; proposal of analysis at HSCIC (amendment to obtain aggregate data on groups not in routine follow up)
   Of the men attending the ProtecT intervention arm PSA testing 4,706 declined to participate in the subsequent ProtecT trial. These men have not been included in the flagging requests at the HSCIC for status and cancer incidence at an individual level. However as there is a possibility that these men may have a greater likelihood of dying with prostate cancer or dying within the 10 year follow up excluding these men would introduce bias into the CAP trial.

2) Request for an extension of approved methodology for routine data extract for CAP (amendment to send data to SAIL for linkage with Patient Episode Dataset for Wales PEDW)
   The application to HSCIC had stated that approx. 10% of the data from Welsh Clinical Centre would not have HES data and would therefore require linkage to PEDW, however the steps for linkage were not explicitly stated. This amendment requests CAG approval for explicit linkage to HES requiring the surname and forename of individuals from the School of Social and Community Medicine (SSCM) to be transferred to SAIL for linkage with PEDW

3) Data extraction for stage and grade of prostate cancer (Amendment to the process for obtaining stage and grade data)
   Current S251 support gives approval to get stage and grade of prostate cancer tumours from cancer registry data. This amendment seeks approval to access the electronic records at the hospital for participants where stage and grade of tumour is not available.

Confidentiality Advisory Group advice

The amendment requests were forwarded to a sub-committee who agreed support for these amendments.

In terms of the first and second amendments the Committee recommended support but felt that information materials should be updated to reflect this change of scope with benefits highlighted.

In terms of the third amendment, relating to stage and grade data being obtained directly from hospitals to complete missing stage/grade data coming from the cancer registries. The committee recommended support for this amendment but confirmed that the applicant should test the acceptability of the amendment with a small group of patients. Progress should be reported at next annual review

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for these amendments, and therefore advised recommending support to the Secretary of State for Health.

21 July 2016

Reviewers:

Name	Capacity
Tony Calland	Vice chair
Harvey Markovich	Member
Miranda Wolpert	Member

1. NEW AMENDMENTS: ECC 4-03(h)/2012; IBIS-I (International Breast Cancer Intervention Study)

Context

Purpose of application

IBIS-1 was the largest European breast cancer prevention trial starting its recruitment in the early 1990s. It was a double blind, randomised placebo-controlled trial investigating whether tamoxifen can prevent breast cancer in women at high risk of developing the disease. 7,154 pre and post-menopausal women, aged 35-70 years, with an increased risk of developing breast cancer participated in the ISIB-1 trial.

The study was set up to investigate the use of tamoxifen as a preventative agent for healthy women with a moderate to increased risk of developing breast cancer.

The original application to the National Information Governance Board, Ethics and Confidentiality Committee, the predecessor organisation to the CAG, was submitted from the Paterson Institute for Cancer Research in order to seek confirmation as to whether the consent previously obtained was considered valid to enable flagging of the cohort. It was noted that this had previously been a clinical trial but had converted in 2008 to a cohort study to continue long-term follow-up; support was also sought for those patients who were not re-consented a second time in April 2013.

Amendment request

The applicant requested an amendment to the study for the addition of Diagnostic Imaging (DIDs) to be added to the data they were receiving. This would allow an increased chance of identifying cancers that can be missed by HES alone.

Confidentiality Advisory Group advice

Members agreed that the data requested are clinically important, in the public interest and loss of these data would seriously impact on the validity of the study.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.