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

February 2015

Reviewers:

Name	Capacity	Items
Dr Patrick Coyle (Vice Chair)	Chair	1a and 1b
Mr Anthony Kane	Lay	1a and 1b
Ms Clare Sanderson		1a
Dr Robert Carr		1b

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) SOCCER (Symptoms of Colorectal Cancer Evaluation Research) 14/CAG/1043

Purpose of application

This application from Imperial College London set out the purpose of utilising data regarding non consented patients ("registered only") to determine whether a whole colon investigation, either via a colonoscopy, CT colonography or barium enema is necessary for all patients with symptoms suggestive of colorectal cancer (CRC) and for which patients flexible sigmoidoscopy might suffice. This study seeks therefore to confirm whether or not the presence of a specific combination of symptom(s) can reliably be used to inform if a cancer is located in the upper or lower part of the bowel and therefore whether patients with particular symptoms can be safely investigated by flexible sigmoidoscopy rather than examination of the whole bowel.

A recommendation for class 1, 4 and 6 support was requested to cover the process of extracting and anonymising the information, link patient identifiable information obtained from more than one source and to allow access to an authorised user for the above purposes.

Confidential patient information requested

Access was requested to name, NHS number, date of birth, address and postcode.

Confidentiality Advisory Group advice

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.

Members agreed that attempting to seek consent for these individuals would be disproportionately difficult in terms of the resource required and the risk of bias this would introduce.

It was noted that identifiers would be required to flag registered but non-randomised patients on the HSCIC cancer and mortality database so that the researchers would be informed of deaths and cancer diagnoses. It was noted that the HSCIC would only provide this information in a pseudonymised form.

Justification of identifiers

Members felt that the identifiers being sought were appropriate for the flagging of deaths and cancer diagnoses however it was unclear whether the HSCIC required patient names if NHS numbers are provided. It was suggested that the Applicant may wish to discuss this further with the HSCIC.

Scope of support

It was noted that this application for support only related to those non-consented patients who had registered for the study and for various reasons were no randomised.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research 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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 18 April 2013.**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) Predicting Response to Antipsychotic medication (STRATA) 14/CAG/1044

Purpose of application

This application from King's College London set out the purpose of seeking up to date contact details of participants who participated in previous studies to seek their consent for a new study to develop predictors of treatment response in psychosis.

Psychosis is a serious mental illness which has a highly variable outcome. Some patients recover while others suffer a chronic course that severely compromises their capacity to meet the demands of everyday life (Milev, Ho, Arndt, & Andreasen, 2005).

The term 'Outcome' refers to the long term trajectory of illness. For example, a classic definition of outcome is symptom severity in response to antipsychotic treatment. Accordingly, up to 30% of patients diagnosed with schizophrenia fail to respond to two antipsychotics after adequate trials – such patients are defined as having treatment resistant schizophrenia. Schizophrenia is estimated to cost £11.8 billion per year in England; some of this cost includes non-responsive treatment, which consumes 25-50% of the total NHS mental health budget and can lead to very high social care costs and lost productivity.

The aim of this project is to establish the extent to which genes influence clinical outcome in psychosis. Clinical outcome will be assessed in ~1,000 patients up to 8 years after their first presentation with psychosis. Participants of past psychosis studies will be recontacted to avoid a selection bias towards chronic samples if recruited prospectively and long term response outcome is known. A summary approach to genetic information capture will rely on polygenic scoring methodologies and pathway analysis.

A recommendation for class 2, 3 and 5 support was requested to cover access to obtain and use information about use information about part or present geographical location, to select and contact patients to seek their consent and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to name, NHS number, hospital number, GP registration, date of birth and date of death, current and past addresses and post code.

Confidentiality Advisory Group advice

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 noted that this application was to identify up-to-date contact details of participants from five previous studies to invite these individuals into the new treatment outcomes study and therefore to seek their consent.

Justification of identifiers

The identifiers sought were deemed adequate for the purposes of tracing the patients. It was noted that date of birth, gender and ethnicity would be retained, once consent had been given.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in research 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

3. Favourable opinion from a Research Ethics Committee.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Chair's Action Report

Reviewers

Name	Capacity	Items
Dr Tony Calland		1a
Dr Patrick Coyle		1b

1. AMENDMENTS – NON-RESEARCH

a) National Diabetes Audit (Adults) ECC 3-04(r)/2011

This application from the Health and Social Care Information Centre (HSCIC) set out the purpose of a three-year audit on all patients diagnosed with diabetes. A recommendation for class 3, 4, 5 and 6 support was sought in order to provide a legitimate basis for access to NHS Number, postcode, date of birth, GP practice code and date of death for linkage purposes. For analysis purposes, postcode, date of birth and date of death were required.

Amendment request

This amendment request detailed that the National Diabetes Audit had identified approximately 24,000 excess deaths in people with diabetes. It had also identified high rates of heart disease, stroke and kidney failure that contribute to this excess mortality but some international epidemiological studies suggest that there may be a number of other important causes such as acute diabetes complications, severe infections and high rates of cancer. In order to understand how best to reduce the excess mortality in diabetes it would be important to know which potentially preventable conditions are most responsible.

Cause of death data was requested to calculate mortality rates by cause for people with diabetes included in the audit.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the vice Chair who noted that this amendment was in line with other audit approvals, was justified appropriately and agreed that the stated outcomes would be in the public interest.

b) NCEPOD PIAG 4-08(b)/2003

This audit application from the National Confidential Enquiry into Patient Outcome and Death set out the purpose of a study to review clinical practice and identify potentially remediable factors in the practice of anaesthesia, surgery and other invasive medical procedures including primary care. A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to patient data.

Amendment request

An amendment was received for a new acute pancreatitis study based on the same methodology as the NCEPOD application.

The study would seek to identify the remediable factors in the quality of care provided to patients treated for acute pancreatitis.

Confidentiality Advisory Group advice

This amendment was reviewed by the Vice Chair, who was content that this study would use the NCEPOD methodology, which included the adequate safeguards for this activity.

Confidentiality Advisory Group conclusion

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