Health Research Authority

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

December 2017

Present:

Name	Capacity	Items
Dr Mark Taylor	Chair	1.a., 1.b.
Dr William Bernal	Member	1.a.
Ms Hannah Chambers	Member	1.b.
Professor Jennifer Kurinczuk	Member	1.b.

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA
Miss Kathryn Murray	Senior Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/00205 MAPPING Study

Context

Purpose of Application

This multi-site research study, sponsored by Barts Health NHS Trust and coordinated by Imperial Healthcare NHS Trust set out the overall purpose of evaluating three new imaging techniques which could be used to detect tumour in adjacent lymph glands in womb cancer without surgical intervention. This was important for optimal treatment planning, and would benefit future patients in that they would be able to avoid having nodes surgically removed for examination. The study would evaluate the diagnostic performance of the new tests.

Patients had been recruited to the study and given consent – however, new scenarios had arisen which had not been described to patients:

1. In some cases a 'false positive' had been identified, when an imaging scan showed a positive lymph node. After removing the node, it was found to be negative. However, further imaging then showed the lymph to have grown – in these cases, this might mean that the scan had not shown a 'false positive', but that the positive node had not been removed in surgery.
2. The research team asked for access to the post-surgical surveillance scans in order to correctly ascertain whether the 'false positive' node was in fact removed during surgery. This information was critical in order to achieve the study aims.

3. In some cases, patients did not undergo surgery or did not have any nodal tissue removed. In these cases the research team wished to access the post-surgical scans to enable them to ascertain whether the nodes shown on the scans were benign or malignant. Again, this was vital in order to evaluate the effectiveness of the scans.

Support was therefore requested for an additional nine-month follow up past the consented period in order to review and evaluate these scans.

A recommendation for class 5 and 6 support was requested for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for the above purpose.

Confidential Patient Information Requested

Access was requested to data from scans in relation to patients who consented to the MAPPING study.

Only study number will be used to identify the scans; however during review of the scans the patients may be identifiable to the study team.

Confidentiality Advisory Group Advice

Public Interest

Members agreed that the study demonstrated a clear medical purpose for which informed consent was taken. The proposed extension to the study, to access and review follow-up imaging to address some issues that had only become apparent through the 'real-world' experience of undertaking the study, was within the spirit of the originally proposed study. The extension would maximise the findings from the study, which members agreed 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

Members were not entirely convinced by the argument that to contact patients would cause distress, as the study appeared to have been relatively recent. In response to queries from the Confidentiality Advice Team, the applicant was planning to write to each participant to inform them of the extension to the study and enable them to express dissent.

Members were supportive of this approach, providing a mortality check was carried out prior to this mail-out, to avoid sending letters to the home of any deceased patient.

- Use of anonymised/pseudonymised data

It was observed that the study number would be used to identify the patient; support was requested due to the fact that the research team would view identifiers for a time-limited period while analysing the scan.

Justification of Identifiers

Members considered that the access to additional scan data was justified. Identifiers were already held under existing consent for the study.

Additional points

Patient notification

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The applicant had advised that they were preparing patient notifications to send out to each patient, allowing them to express dissent to this additional access to their data.

Provided that a mortality check was carried out prior to sending these notifications, members agreed that they would be content to recommend support once an appropriate opt-out mechanism was in place.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required 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. Please provide copies of patient notifications and describe the method that will be used to respect dissent.
2. Please confirm that a mortality check will be completed prior to contacting patients.

Once received, the information will be reviewed by the Chair 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, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Not checked for individual sites for multi-site studies – support is recommended on the understanding that the applicant will ensure that suitable security assurances are in place at each site, in the form of an up-to-date IG Toolkit which has been reviewed as satisfactory by NHS Digital.**
   Please see information governance section of the HRA website: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/ and contact Exeter.helpdesk@nhs.net with any queries.

b) 17/CAG/0206 The relationship between body composition, tumour activity, functional activity and survival in patients with advanced cancer

Context

Purpose of Application

This research study from Glasgow University, undertaken as part of a PhD qualification, set out the purpose of examining the relationship between the systemic inflammatory response, tumour activity,

body composition, functional activity and survival in patients with advanced cancer. This would enable a better understanding of the basis of the loss of muscle mass and functional activity in patients with advanced cancer. The study could ultimately improve clinician's ability to produce accurate prognoses for patients with advanced cancer.

The data to be used was already held as part of a previous, multi-centre study of over 300 patients examining the relationship between biomarkers and prognosis in patients with advanced cancer (the IPAC study). All of the participants in this study were now deceased.

The dataset was held in de-identified form with 'anonymisation codes' held by the CI of the IPAC study (who would also be the CI for the current study). Identifiable data would be required by the researcher in order to access patient CT scans. The applicant proposed to travel to sites in England and Wales with the anonymisation code for each individual patient. Local leads would then provide the NHS number for the patient at that site. The applicant would access the scans onsite and remove all identifiers before saving them to an encrypted USB stick. This would be marked with their unique study code (or 'anonymisation' code) before being uploaded to the IPAC database. De-identified data would then be provided to the researcher to complete their analysis.

A recommendation for class 1 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

Patients who had previously consented to their inclusion in the IPAC study.

Data will be accessed at individual NHS sites in England and Wales in relation to this cohort. NHS number and any identifiers which may be viewable on the CT scan will be accessed; however, patient identifiers will be removed from the copy of the scan which will be used or analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application presented a clear medical purpose and public interest to further explore data that had already been collected as part of a previous randomised controlled trial, to which the patients consented.

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 Group recognised that all patients who were involved in the historic IPAC trial were now deceased so seeking consent was not feasible.

- Use of anonymised/pseudonymised data

It was acknowledged that confidential patient information was required in order to access the patient's scans at the treating sites.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. It was acknowledged that use of identifiable information had been restricted to the minimum required to undertake the proposal.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicant had advised that two days were required at each participating site in order to collect the required anonymised scan data for analysis, which would be a maximum of 40 days. It was agreed that further clarification was required in this area to confirm the duration of support required under the Regulations, as it was noted that the data collection would take place over a longer time period.

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 an unconsented activity should go ahead. The applicants explained that engagement activity with the patient population to be included in the study was not possible, as the original IPAC study was carried out in patients with advanced palliative disease. This CAG acknowledged that this group of patients, pre-mortem, demonstrated their willingness to be involved in research into the condition from which they suffered and Members were assured that engagement with further different group of patients would not add anything further of significance.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. It was acknowledged that evidence of the favourable ethical opinion would be required prior to any recommendation of support coming into effect.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. As the proposed trial involved the applicant visiting 40 sites around England and Wales, in order to extract the required information, under the IG assurance at each site, assurance at each individual site was not checked, as is the practice for multi-site proposals. The applicants undertaking data extraction should be assured that the sites are compliant with the relevant IG Toolkit requirements.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required 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 acknowledged that the data collection would be undertaken over a 40 day period; however, clarification was required around the duration of support which is required under the Regulations, as it was acknowledged that the data collection would be undertaken over a longer duration.

Once received, the information will be reviewed by the Confidentiality Advice Team 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, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Pending)**.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Not assessed as multiple sites included in the project – it was advised that all sites are required to have a reviewed IG Toolkit rating of satisfactory on Version 14, 2016/17, which had been confirmed by NHS Digital).**