Health Research Authority

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

April 2018

Present:

Name	Capacity	Items
Ms Clare Sanderson	Chair	1.a
Dr Lorna Fraser	Member	1.a.
Mr Andrew Melville	Lay Member	1.a.
Dr Tony Calland MBE	Chair	1.b.
Dr William Bernal	Member	1.b.
Mr Anthony Kane	Lay Member	1.b.

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 18/CAG/0067 - A cross-sectional study to justify and inform a future randomised controlled clinical trial of metformin versus placebo to improve overall survival in patients with inoperable pancreatic ductal adenocarcinoma (PDAC).

Context

Purpose of Application

This application from the University of East Anglia sets out the purpose of medical research which aims to assess whether Metaformin, a drug commonly used to treat diabetes, is beneficial in the treatment of patients with inoperable pancreatic ductal adenocarcinoma (PDAC). This is a clinical observational study reviewing the notes of patients diagnosed with PDAC, treated at Norwich and Great Yarmouth hospitals to obtain data to firstly justify and secondly inform a future trial of metformin versus placebo to improve overall survival in patients with PDAC, which cannot be removed surgically.

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

Confidential Patient Information Requested

Cohort

- Male and female patients treated between 1st January 2013 to 31st December 2016 at the hospitals in Norwich and Great Yarmouth,
- With inoperable PDAC,
- Diagnosis of PDAC confirmed by histology/cytology,
- In absence of histology/cytology, clinical symptoms and at least one radiological investigation suggestive of PDAC,
- Approximately 165 individual patient records will be surveyed, having been identified from the pancreatic multidisciplinary team (MDT) and oncology databases. It is anticipated that 150 patients will be included in the project.

Access will be required to the full patient records in order to extract the required clinical information for analysis. Records will be accessed at Norfolk and Norwich University Hospital and James Paget University Hospital. The following items of confidential patient information will be used for the purposes details below:

- Hospital number – to identify patients and obtain records,
- Date of birth – used to calculate patient's age at diagnosis,
- Date of death – used to calculate survival time,
- Gender – for analysis.

No confidential patient information will be retained – extracted data will be pseudonymised. Wider clinical information will also be extracted from the patient's records.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose of medical research. Members noted that this was a feasibility study which aimed to assess whether Metaformin, a drug commonly used to treat diabetes, is beneficial in the treatment of patients with inoperable pancreatic ductal adenocarcinoma (PDAC). The Group agreed that there was public interest in the activity proceeding.

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 CAG accepted the rationale presented by the applicants that it was not feasible to seek consent for this activity, due to the high proportion of deceased patients within the cohort and the potential distress of following up with either seriously ill patients or relatives of those deceased.

- Extraction by the Direct Care Team

The Group recognised that the direct care team would identify the cohort of patients who were eligible for inclusion in the study in order to limit access to confidential patient information by those outside the direct care team. Support was requested to enable the named student investigator access to patient

records to enable extraction of the pseudonymised dataset required for analysis. Members accepted that the complete data extraction could not be undertaken by members of the direct care team due to their extensive clinical commitments and were content to provide a recommendation of support to the proposed methodology.

- Use of anonymised/pseudonymised data

It was acknowledged that the study analysis would be undertaken on a pseudonymised dataset; however, access to confidential patient information was required in order to extract the relevant information.

Justification of Identifiers

Members acknowledged that access to the full patient record was requested in order to extract the data relevant to analysis.

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 applicants had confirmed that the patient identification list would be retained for three months to enable extraction of the pseudonymised dataset to be used for extraction.

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 had provided an overview of planned activity which would proceed with the 'Together against Cancer Norfolk' Group which represents patients and carers in the relevant locality in the delivery and standard of cancer care in the region. Members recognised that patient and public involvement and engagement was a positive step and was particular importance for a feasibility study which may inform future research.

The Group accepted the plan for work in this area and agreed that feedback would be required at the time of first annual review around the actual activity which has taken place. It was also recommended that the applicants look to widen the scope of involvement and engagement activities by linking national charities, as well as the locally referenced charity. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

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.

Members recognised that specific patient notification for the project is not possible as it was likely that the majority of the cohort would be deceased; however, it was agreed that there was an opportunity to raise the profile of the proposed research which should be undertaken. The Group agreed that this was particularly important for a feasibility study which may inform future research projects. It was agreed that an overview of the project should be displayed on the Trust websites in order to raise the profile of the

study; however, the CAG decided that this requirement should not delay the project. Confirmation was required at the time of first annual review around the activity which had been undertaken in this area to promote the project. It was also recommended that the 'Together against Cancer Norfolk' Group are approached around displaying information on their website.

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. Assurance is currently assessed against Version 14.1 (2017/18) of the toolkit; however, it appeared from the NHS Digital website that both Norfolk and Norwich University Hospitals NHS Foundation Trust and James Paget University Hospitals NHS Foundation Trust did not yet appear to have made submission of this recent version of the toolkit. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website.

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. Evidence of the favourable ethical opinion for the study would be required prior to any recommendation of support coming into effect.

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

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. Patient and Public Involvement and Engagement – planned activity should progress with the named local charity. An overview of the actual activity undertaken should be provided at the time of first annual review, together with any feedback provided by the group. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Patient Notification – information around the proposed study should be displayed on the websites of the relevant Trusts in order to raise the profile of the study. Confirmation is required at the time of first annual review that this was taken forward.
3. Favourable opinion from a Research Ethics Committee **(Pending).**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Pending).**

Recommendations

The following recommendations were also made by the CAG; however, these points are not mandated as a requirement to enable a final recommendation of support to be made under the Regulations.

1. It is recommended that the scope of the patient and public involvement and engagement activity in the project is widened to include interaction with relevant national charities.
2. The named local charity, 'Together against Cancer Norfolk' Group, should be approached around the inclusion of study information on their website in order to widen the communications strategy for the study.

b) 18/CAG/0080 - Development and Validation of Barts Heart Centre Surgical Infection Risk (B-SIR) Tool to Predict Surgical Site Infection After Cardiac Surgery

Context

Purpose of Application

This application from Barts Health NHS Trust set out the purpose of medical research which aims to develop an assessment tool that will help identify patients at risk of developing surgical site infections after cardiac surgery. The study also aims to compare the new tool with the other risk assessment tools. Surgical site infections are serious complications following surgery which can lengthen a patient's stay in hospital and increase the risk of morbidity and mortality.

The applicants will be undertaking a retrospective case note review of patients who underwent a coronary artery bypass graft (CABG) and/or valvular surgery at the Barts Heart Centre between January 2016 and December 2017, who meet the study inclusion criteria. Wider clinical information will be collated from locally held records of data which were prospectively collected for submission to the following audits/surveillance activities: Intensive Care National Audit and Research Centre (ICNARC), National Institute of cardiovascular Outcomes Research (NICOR) and Public Health of England (PHE) SSI Surveillance.

A recommendation for class 1, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

Patients underwent a coronary artery bypass graft (CABG) and/or valvular surgery at the Barts Heart Centre between January 2016 – December 2017. This will be established from a search of the locally held SSI Surveillance register at Bart's Heart Centre. It is estimated that 2,000 patient records will be included.

The following items of confidential patient information are requested for the purposes of linkage between the three datasets:

- Medical Record Number/Hospital Number,
- Date of birth,
- Date of surgery.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the project defined an appropriate medical purpose, which was medical research. Members were in agreement that there was public interest in the project proceeding, as the development of a tool which can predict patients at increased risk of developing surgical site infections had the potential to improve patient outcomes.

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 considered the applicant's rationale that consent was not feasible for the project, due to the retrospective nature of the patient cohort, who may now be lost to follow-up or deceased. Members were assured that consent was not feasible for this project.

- Use of anonymised/pseudonymised data

It was acknowledged that access to confidential patient information was required in order to facilitate the linkage between the three datasets of focus to the study. Members recognised that the analysis dataset would be anonymised at the earliest point, following the completion of the data linkage. No further issues were raised in this area.

Justification of Identifiers

The CAG agreed that the items of confidential patient information requested were appropriate and proportionate to facilitate the proposed data linkage.

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 had confirmed that they had not undertaken any work in this area to date; however, it was noted that the work into wound infections was a high priority area of research identified by patients at a recent cardiac surgery PPI event at St Bartholomew's Hospital. Members agreed that further work was required in this area in order to test the acceptability of using confidential patient information without consent for the purposes of the research. It was suggested that the applicants may be able to interact with an established patient group at the Trust site in order to progress this work. It was agreed that feedback in this area would be required prior to the research commencing, to ensure patients are supportive of the research proceeding by the agreed methodology. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

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 CAG recognised that the applicants had been prompted in this area ahead of the application review; however, an adequate response was not provided. Members were in agreement that a communications strategy would need to be developed for the study in the interests of transparency in order to promote how confidential patient information would be used to achieve the study aims. It was suggested that posters within the relevant outpatient department and a notice on the Trust website would be required as a minimum.

Members were not assured by the applicant's argument that enabling an opt-out facility for the project would introduce a bias into the study results. It was commented that patients who had died were more likely to have encountered the complications of interest to the research, so it was unclear how enabling a dissenting mechanism to living patients could cause any significant detriment to the study findings. The Group agreed that a study specific objection mechanism would need to be built into the project.

Notification materials would need to be drafted for the study which should provide a description of the project, listing the purpose and who is undertaking the study. It should also explain how patients can opt out or dissent to the use of their information for this purpose, providing relevant contact details (email/phone etc.). Documentation would need to be submitted to the CAG for consideration, together with an overview of how any objections would be respected.

The Group were minded to accept the rationale that the manual checking of all patient records for evidence of dissent was not feasible, due to the size of the cohort and minimal capacity within the research team. It was unclear from the information which had been provided whether the Trust would have access to any electronic records which would confirm any historic dissent from secondary use of data. The applicants would be required to investigate this further and provide further clarification in this area.

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. It was noted that Bart's Health NHS Trust had submitted an unsatisfactory self-assessed score on Version 14.1, 2017/18 of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field as satisfactory on the IGT website. This would need to be addressed by the applicant.

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. Confirmation of the REC favourable opinion would be required prior to any recommendation of support coming into effect.

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. Patient and public involvement and engagement activity should be undertaken to test the acceptability of using confidential patient information without consent for the study purposes. Feedback should be provided around what activity was carried out and the feedback provided as part of this. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Patient Notifications and Dissent – further work is required in this area to address the following points:
   a. A communications strategy for the study should be designed, to include outpatient posters and a website notification as a minimum. The information materials should include an opt-out mechanism. Copies of the documentation should be provided for review by the CAG,
   b. An overview of how the objection mechanism would be operated is required,
   c. Seek clarification from the Trust around whether there is any scope to check for evidence of historic dissent recorded by patients on an electronic system and provide to confirm whether this would be possible.

Once received, the information will be reviewed by a sub-committee of members 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. **(Pending).**