Health Research Authority

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

August 2017

Present:

Name	Capacity	Items
Dr Rachel Knowles		1b
Dr Murat Soncul	Chair	1a, 1b
Ms Gillian Wells		1a, 1b
Dr Kambiz Boomla		1a

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0145 Outcomes of Drug Coated Balloon Angioplasty, A UK Real Life Experience from 2009 to 2015

Purpose of application

This research application from Norfolk and Norwich University Hospital NHS Foundation Trust set out the purpose of investigating long terms outcomes of Drug Coated Balloon Angioplasty Treatment, a novel therapy as opposed to standard Drug Eluting Stent insertion. This could provide an important source of information for health professionals and patients to guide future clinical practice and research.

It is currently standard practice for drug eluting stents to be used, which lead to challenging long-term complications. Early studies with the alternative method of Angioplasty with Drug Coated had shown encouraging results in terms of overcoming these complications and leaving less of a permanent impact. This study would investigate outcomes of this method for all types of coronary artery disease from 01/01/209 to 31/12/2015 at this NHS centre, with an estimated cohort size of over 1000 patients.

Data from the Trust database would be linked with NICOR (National Institute for Cardiovascular Outcomes Research) data to enable recording of any follow-up events for at least 12 months following the procedure.

Identifiers would be disclosed to NICOR for this purpose – the data returned from NICOR would be pseudonymised.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activity as described in the application.

Confidential Patient Information Requested

Cohort

Data from Norfolk and Norwich University Hospital NHS Foundation Trust in relation to patients who have received Drug Coated Balloon Angioplasty.

NHS Number, gender and date of birth would be disclosed to NICOR to obtain follow-up data.

NHS Number, gender and date of birth would also be disclosed to the direct care team at other hospitals, should a patient have had a repeat procedure at a different site.

Confidentiality Advisory Group advice

Public Interest

The Sub-Committee commented that the application had a strong medical purpose which held a clear 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

The Sub-Committee was assured that consent was not feasible for the proposal, due to the large numbers involved and it was acknowledged that as mortality data was a key outcome for the project, an attempt to consent could potentially being bias into the results as the mortality data would be lost.

- Use of anonymised/pseudonymised data

Members acknowledged that use of identifiable data was required to enable linkage with the NICOR data set.

Justification of identifiers

The Sub-Committee was satisfied that the identifiers specified were required to undertake the data linkage proposed.

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.

Members acknowledged the exit strategy proposed within the application, which stated that confidential patient information would be required for 2-3 months to enable data linkage, after which time identifiers would be destroyed.

Additional points

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.

Members considered the information provided around an engagement activity which the applicant had held with a group of 25 patients around the proposal and it was agreed that this proportionate and appropriate to the activity proposed.

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 Sub-Committee reviewed the patient notification document which had been included within the application. It was commented that the document included a reference to 'approval from the CAG' which would need to be revised to accurately reflect a recommendation of support from the CAG. A minor typographical error was also identified within the document which would need to be corrected.

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. 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. This would need to be addressed by the applicant.

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.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Patient Notifications – the applicant was asked to submit a revised notification document to address the following points:

a. Correct the reference to the 'CAG Approval' within the document – the CAG provides a recommendation to the Health Research Authority (HRA) as appointed decision-maker for research applications. The HRA takes the final decision to support an application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent,
b. Correct the reference to the 'Caldicott Guardian' (typographical error).

The revised patient notifications were supplied by email on 7 September 2017 and deemed appropriate.

Specific Conditions of Support

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 04 May 2017).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending)**

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0115 ECG Diabetic Foot Ulcer Pilot

Purpose of Application

This service evaluation from NHS England set out the purpose of establishing whether routine ECG for patients with diabetic foot ulcer reduced 1-5 year mortality rates in these patients.

The 5-year mortality rate for the 60,000 diabetic patients who presented every year with foot ulceration was around 50%. To address this, a pilot had been set up by NHS Improving Quality (now part of NHS England), embedding an ECG for all new diabetic foot ulcer (DFU) patients into routine care. This would enable clinical action to be taken should any issues be discovered.

To assess the effectiveness of the pilot, the applicant would cross reference National Diabetic Food Audit data with ONS mortality data to identify whether patients who received an ECG as part of routine care at the pilot sites had significantly differing 1-5 year mortality rates when compared to patients within the NDFA who received care at other sites. If the use of routine ECG for this cohort was found to significantly reduce 1-5 year mortality rates then this would have the potential to bring about a change in clinical practice across England, ultimately reducing the numbers of people who die within 5 years of developing a DFU.

Linkage would be carried out by NHS Digital, who would receive identifiers from NHS Trusts along with the ECG and NDFA status of the patient. NHS Digital would link this information with mortality status and return the data set to the applicant.

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

Confidential Patient Information Requested

Cohort

All diabetic patients presenting with foot ulceration at participating Trusts.

Access was requested to the following data items:

Data from participating trusts in relation to diabetic patients presenting with foot ulceration.

- The NHS number
- The ECG status of the patient
- The NDFA status

Data from NHS Digital (via CARMS, Clinical Audit and Registries Management Service) to the applicant:

- NHS Number
- NDFA status
- ECG status
- ONS Mortality status

Confidentiality Advisory Group Advice

Public Interest

Members agreed that the activity was in the public interest and defined a medical purpose.

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 acknowledged that the National Diabetic Food Audit audit takes place under consent; however, to gain consent for this proposed linkage would be impracticable as many of the cohort may be deceased.

- Use of anonymised/pseudonymised data

It was acknowledged that use of patient identifiers was required in order to undertake the data linkage between the National Diabetic Food Audit and HES.

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 application referred to involvement via Diabetes UK, stating that the patients considered the consent given for the National Diabetic Food Audit adequate for the linkage with ONS data.

Patient Notifications 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 acknowledged the patient notification mechanism would be managed via the NHS Digital website. A link was provided to the information, and it was noted that information in relation to this pilot activity was included alongside the more comprehensive information in relation to National Diabetes Footcare Audit and its associated information materials. It was acknowledged that opt-out was managed directly via NHS Digital and an email address and contact number had been provided. The Sub-Committee was assured that the notification and dissent mechanisms were appropriate to the activity proposed.

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 NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**NHS Digital v14 confirmed published and reviewed as satisfactory).**