

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group
April 2018

1. NEW AMENDMENTS
Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice-Chair
Miss Kathryn Murray	

Application title: Investigation of Aneurysm Repair Decision Aid (ARDA) for Management of Abdominal Aortic Aneurysms: Safety Validation and Impact Assessment.

CAG reference: 17/CAG/0155

IRAS project ID: 213647

Context
Purpose of application

This application from the Royal Liverpool and Broadgreen University Hospitals NHS Trust set out the purpose of developing a binary clinical decision tool to help patients and surgeons decide on the best treatment strategy for abdominal aortic aneurysm (AAA), based on the Aneurysm Repair Decision Aid (ARDA), which the study also sought to validate.

AAA is a ballooning of the main artery supplying the body; if this grows and ruptures, 80% of patients will die. However, there are risks associated with repair of the artery. ARDA, a custom-designed computer programme, provides information on the expected AAA growth rate and risk of rupture, the chance a patient will need AAA repair, the chance of the patient surviving the repair and the length of time of survival (5 or 10 years). The development of a binary clinical decision tool based on this programme could potentially maximise patient survival and facilitate cost-effective use of resources.

In order to validate ARDA and develop the clinical decision tool, support was required for access to retrospective data from the National Vascular Registry (NVR). The data would be transferred to NHS Digital who would link it with ONS mortality data before transferring a de-identified dataset to the research team at Royal Liverpool and Broadgreen University Hospitals for analysis.

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

Confidential patient information requested

Access was requested to data in relation to all patients included on NVR having undergone an elective AAA repair between 01/01/2012 and 31/12/2015, who were over 18 and have not undergone previous aortic surgery.

The following data items will be transferred from the National Vascular Registry to NHS Digital:

- NHS number – to validate and link with mortality data,
- Date of birth – to validate. This will then be truncated for analysis to MM/YY format.

Amendment Request

The amendment requested support to change the flow of data within the project. The proposed flow of data is as follows:

- The National Vascular Registry (NVR) would send the specified identifiers and study ID only to NHS Digital, which would be utilised by NHS Digital to link the cohort to ONS Mortality data.
- The linked dataset would be returned to the Royal Liverpool University Hospital by Study ID only.
- In addition, NVR would also create a pseudonymised dataset, including wider clinical information, using the same study ID and transfer this direct to the Royal Liverpool University Hospital.
- Royal Liverpool University Hospital would link both datasets via the study ID.

Confidentiality Advisory Group Advice

The amendment documentation was shared with the Alternate Vice-Chair for consideration. It was recognised that the proposed changes to the data flows would not involve wider access to confidential patient information as patient identifiers would continue to be disclosed to NHS Digital for the purposes of linkage only. It was acknowledged that the proposed change to the flow of pseudonymised information required for analysis from the National Vascular Registry directly to the applicants would strengthen the privacy safeguards for the process. Confirmation had been provided by the applicants that NHS Digital and the National Vascular Registry were supportive of the proposed data flows. The CAG was content to recommend support for the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Alternate 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 Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – Royal Liverpool and Broadgreen University Hospitals NHS Trust and NHS Digital, Version 14, 2016/17, satisfactory**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**REC do not require the submission of an amendment in relation to this change as the ethical opinion extends to the access to pseudonymised data**).