

## **Minutes of the meeting of the Confidentiality Advisory Group**

**06 April 2023 via Zoom**

**Present:**

| <b>Name</b>               | <b>Role</b> |
|---------------------------|-------------|
| Dr Tony Calland, MBE      | CAG Chair   |
| Ms Diana Robbins          | CAG Member  |
| Dr Ben Gibbison           | CAG Member  |
| Professor James Teo       | CAG Member  |
| Dr Malcolm Booth          | CAG Member  |
| Dr Sandra Duggan          | CAG Member  |
| Dr Pauline Lyseight-Jones | CAG Member  |
| Dr Harvey Marcovitch      | CAG Member  |

Also, in attendance:

| Name                | Position (or reason for attending)         |
|---------------------|--|
| Ms Kathleen Cassidy | HRA Confidentiality Advisor                |
| Mr William Lyse     | HRA Approvals Administrator                |
| Dr Paul Mills       | HRA Confidentiality Advice Service Manager |
| Dr Joanne Bailey    | CAG Member (observing)                     |

## 1. Introduction, apologies, and declarations of interest

CAG Alternate Vice Chair Professor William Bernal, and Dr Stephen Mullin sent their apologies.

## 2. Support decisions

### Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **09 March 2023** meeting applications.

### Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **09 March 2023** meeting applications.

### Minutes:

The 09 March full CAG, and the 17 March 2023 Precedent set minutes have been ratified and published.

## 3. New Application

**a. 23/CAG/0040— Access to outcome data for patients treated by East Anglian Air Ambulance who are conveyed to the regional major trauma centre (Cambridge University Hospitals NHS Foundation Trust)**

**Context**

**Purpose of application**

This non-research application from the East Anglian Air Ambulance set out the purpose of an audit and evaluation of the outcomes of the outcomes of patients treated by the service.

The East Anglian Air Ambulance (EAAA) provides pre-hospital critical care to patients across the East of England, in collaboration with the East of England Ambulance Service and attends around 1,600 critically ill and injured patients per year. EAAA do not routinely receive information about their patients after discharge from their care. Obtaining outcome data will allow EAAA to audit and evaluate the pre-hospital care they provide, with the aim of improving care for future patients of the air ambulance.

The most seriously injured patients in the East of England are conveyed to the single major trauma centre in Cambridge. The applicants seek support to allow the disclosure of confidential patient information from EAAA to Cambridge University Hospitals NHS Foundation Trust (CUHNFT). CUHNFT will then link patients treated by the Trust and EAAA between 2015 and 2022, and on a continuous monthly basis for two years from support being given. Confidential patient information will be disclosed from East Anglian Air Ambulance (EAAA) to CUHNFT. This will include patients NHS number and (if available) CUHNFT medical record number (MRN), in addition to a unique identifier. CUHNFT will match these patient identifiers to their electronic medical records. The second data flow from CUHNFT back to EAAA will contain anonymised outcome data that is uploaded directly to the EAAA patient record using the pseudonymised unique identifier.

A recommendation for class 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

**Confidential patient information requested**

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

|   |   |
|---|---|
| <b>Cohort</b>                                     | <p>All patients treated by East Anglian Air Ambulance and conveyed to the regional major trauma centre (CUHNFT) between 01/01/2015 - 31/12/2022., and on a continuous monthly basis for two years from the date support was given.</p> <p>The applicants estimate that 2983 patients will be included from 2015-2022.</p> <p>Based on historical trend data, the applicants anticipate the prospective monthly cohort would be approximately 35 patients per month.</p> |
| <b>Data sources</b>                               | <ol style="list-style-type: none"> <li>1. Electronic patient records at: <ol style="list-style-type: none"> <li>a. East Anglian Air Ambulance</li> <li>b. Cambridge University Hospitals NHS Foundation Trust</li> </ol> </li> </ol>  |
| <b>Identifiers required for linkage purposes</b>  | <ol style="list-style-type: none"> <li>1. NHS Number</li> <li>2. CUHNFT Medical Record Number (pseudonymised)</li> <li>3. EAAA Unique Identifier (pseudonymised)</li> </ol>   |
| <b>Identifiers required for analysis purposes</b> | No identifiers are required for analysis  |

### **Confidentiality Advisory Group advice**

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

### **Public interest**

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application was strongly in the public interest.

### **Scope**

The applicants provided dates for the retrospective collection, but also planned to collect data on an ongoing basis from the date support was given. The retrospective data collection would end of 31 December 2022 and the CAG noted that there may be several months between the end of the retrospective data collection and the

granting of s251 support. Members requested clarification on when the prospective data collection would begin.

The CAG requested clarification on the type of work that would be undertaken with the collected data. The CAG took note of the potential future sharing of data with other air ambulance trusts and stated that, should this occur, the applicants must return to CAG with a refreshed application or amendment. A revised application would also be needed should the data collected be used for research purposes.

The applicants had advised that the disclosure of outcome data from CUHNFT to EAAA did not require support as the outcome data is anonymised. However, a pseudonymised unique identifier will be used and EAAA will be able to re-identify patients. This had been queried with the applicant, as the application form originally stated that CUHNFT will link the data on-site and upload pseudonymised outcome data to the secure EAAA electronic patient record, limiting the transfer of patient identifiable data. The applicants revised the information in section (n) of the application form to say that the information disclosed from CUHNFT to EAAA is anonymised, however the unique identifier will still be attached, allowing re-identification. Members agreed that it was likely that support was needed for the return of the dataset from CUHNFT to EAAA. If the applicants did not agree, further justification on why support was not required needed to be given.

The CAG queried whether other methods of undertaking the audit, such as using data from the Trauma Audit and Research Network (TARN) database, had been explored. Using TARN data could potentially reduce the confidential patient information to be processed or remove the need for processing of confidential patient information entirely. TARN could also provide data for all patients transported by EAAA, rather than limiting the project to patients treated at CUHNFT. If this alternative had been considered and determined not to be practicable, the rationale for this decision needed to be provided.

## **Practicable alternatives**

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants explained that consent was not practicable as patients treated by EAAA would be critically ill and it would not be possible to seek consent at the point

of treatment. EAAA also do not hold contact details for all patients to seek consent later. A number of patients may also have died following transfer to hospital.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Items of confidential patient information are needed so Cambridge University Hospitals NHS Foundation Trust can link data for the relevant patients.

### **Justification of Identifiers**

NHS numbers were used for linkage. Members queried whether the NHS number, and EAAA and CUHNFT patient numbers, would be sufficient for linkage purposes, or whether additional identifiers, such as date of birth and postcodes, would be needed.

### **‘Patient Notification’ and mechanism for managing dissent**

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A privacy notice will be placed on the EAAA website. This informs patients that their personal data may be shared for additional purposes such as audit, research and planning. This notice includes informing patients that they have a right to withhold their information from research and planning purposes and not be included in such activity.

The patient notification does not refer to this application specifically, although linkage to diagnosis and outcome data provided by NHS organisations is referenced.

The CAG asked that a study specific patient notification and a specific dissent mechanism are created and displayed on the websites for EAAA and CUHNFT.

## 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 the unconsented activity should go ahead.

The applicants met with the EAAA Patient Forum Group in February 2022. This forum included a broad range of former patients, their relatives and dedicated aftercare nurses. Patients were asked how they would feel about the sharing of their confidential information between EAAA and the hospital to understand the patient progress. Patients were also specifically asked how they would feel about their personal data, including their NHS number, being used to link to the NHS to find out their outcome for audit projects to help the service improve. There were no objections from the panel.

The minutes of this meeting were provided with the application.

The CAG noted that the patient and public involvement had been carried out in February 2022, over a year before the application to CAG was submitted. There was no indication of how many members of the public were involved or their diversity. The description of the proposed activity given to the PPI participants did not correlate with the activity described in the CAG application, which meant it was unclear whether the use of confidential patient information without consent, as proposed in the application, had been discussed and feedback sought. The CAG agreed that further patient and public involvement needed to be carried out, and this needed to include numbers involved, diversity and discussion of the use of confidential patient information as proposed in the application, and feedback provided.

## Exit strategy

The CAG requested clarity on the exit strategy. The CAG queried the state in which the identifiers will be held, including whether the data would be anonymised or pseudonymised and who would hold the pseudonymisation key.

The CAG also requested clarity on when the identifiers collected would be deleted.

## Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

### **Request for further information**

1. Advise whether other methods of undertaking the audit, such as using data from the Trauma Audit and Research Network (TARN) database, had been explored. If this alternative had been determined not to be practicable, provide the rationale for this decision.
2. Confirm whether support is needed for the return of the dataset from CUHNFT to EAAA. If support is not needed, further justification on why support is not required needs to be given.
3. Provide clarity on when the team will begin the prospective data collection.
4. Provide details on the type of work to be undertaken with the collected data.
5. Clarify whether patient NHS numbers, and EAAA and CUHNFT patient numbers, will be sufficient for linkage purposes, or whether additional identifiers, such as date of birth and postcodes, will be needed.
6. Please ensure that a study specific patient notification and a specific dissent mechanism are created and displayed on the websites for EAAA and CUHNFT.
7. Further patient and public involvement needed to be carried out, and this needed to include discussion of the use of confidential patient information as proposed in the application, and feedback provided.
8. Clarification on the exit strategy needs to be provided, including when the data will be anonymised, when the items of confidential patient information collected will be deleted, and where the pseudonymised key will be held and who will be able to access it.

### **Specific conditions of support (provisional)**

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Any future sharing of data outside the scope of section 251, such as, with other air ambulance trusts, must be returned to CAG for consideration, either via a new application or amendment.



2. A new application will be needed should the data collected be used for research purposes.
3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

The NHS Digital **21/22** DSPT reviews for **East Anglian Air Ambulance & Cambridge University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 April 2023)

#### 4. Any other business

Members were advised that the Community Insight Group would be changed to the HRA Community Committee in the near future. Further details would be circulated via email.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair

Date

Tony Calland

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21/04/2023

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Signed – Confidentiality Advice Team

Date

William Lyse

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27/04/2023

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