Health Research Authority

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

11 June 2021

Present:

Name	Capacity	Items
Dr Patrick Coyle	Vice-Chair	1a, 2a
Dr Martin Andrew	CAG Member	1a
Professor Barry Evans	CAG Member	2a
Professor Lorna Fraser	CAG Member	1a
Mr Myer Glickman OBE	CAG Member	2a

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 21/CAG/0093 – Facilitating access to online NHS primary care services - current experience and future potential (Di-Facto)

Context

Purpose of application

This application from The university of Exeter sets out the purpose of medical research that aims to explore patient access to digital services provided by primary care.

The COVID-19 pandemic has led to an increase in digital routes of contact offered by general practices (for example online triage platforms) and therefore an increased need for patients to be capable of using digital routes to access care. During the early stages of the COVID-19 pandemic, NHS England encouraged all general practices to move to a 'total triage' model which requires all patients to make an initial contact with their general practice via an online platform (those patients who cannot use online services must use the telephone) so that the information can be used to decide which type of appointment a patient requires. However, recently published data has shown that even during the pandemic, telephone was the most commonly used alternative to a face-to-face consultation, shown to comprise around 90% of all consultations, indicating that digital routes of contact are still far from routinely used by patients even though they are more available.

It is therefore important to understand how barriers to uptake might be overcome and patients best supported in the move to online services of all kinds. One way to address this is with digital facilitation; supporting NHS patients and carers in their use of online services. 'Digital facilitation' is defined as 'that range of processes, procedures, and personnel which seeks to support NHS patients in their uptake and use of online services.' There is, however, no existing evidence as to the nature and scope of applying digital facilitation. This is compounded by the fact that the nature and extent of innovative approaches offered by practices are unknown. It is important to understand the extent to which digital facilitators or other approaches to digital facilitation are being used, how they are used, how they may be impacting patient health and access to healthcare information and services, GP practices, and the wider NHS.

This study is one which primarily operates using consent as the legal basis (and therefore outside the scope of support). However, as part of the study researchers, not part of the direct care team, will be observing 8 GP practices (to be identified). These observations are interested in the interactions between patients and staff, and between staff, and are not interested in patient information. However, during the observations, confidential patient information may be incidentally disclosed (e.g. overhearing staff talk about a patient). No audio recordings are made and no notes are take relating to confidential patient information.

A recommendation for class 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.

Cohort	Patients at 8 GP practices whose confidential patient information may be incidentally disclosed during observations
Data sources	1. 8 GP practices to be identified
Identifiers required for linkage purposes	1. No items of confidential patient information will be collected for analysis purposes
Identifiers required for analysis purposes	1. No items of confidential patient information will be collected for analysis purposes

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 medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members agreed that this application had a clear medical purpose and a strong public interest.

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**

Consent is taken as part of the study for those elements which are out of scope. The researchers will be observing staff/patient interaction, as well as staff/staff interaction. Patient information is not the focus of this study. It is not possible to consent for the incidental disclosure of confidential patient information as it is not possible to accurately predict what the exposure might be. The Sub-Committee were content with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is not required for the purpose of the study, but researchers may be exposed to confidential patient information incidentally while observing staff/patient and staff/staff interactions at practices. No items of confidential patient information will be collected or recorded by the researchers, without written consent. For observations, researchers will be making field notes. They state they have no interest in patient information and will not be recording any of this (no audio recordings to be made). The Group accepted that it is not possible to anonymise or pseudonymise all data that could be disclosed incidentally, and that is the purpose of this application.

'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 poster is provided that will be displayed at GP practices where observations are taking place. In response to the REC the applicants have simplified this poster, and as a response to CAT queries they have stated they could amend the poster to state patients can request a researcher leaves the area where a patient is present, but this has not yet been provided. It is not possible to apply the national data opt out to incidental observations.

The Sub-Committee considered the poster to be broadly satisfactory, and were impressed with the fact a photo of the researcher was included. However, they did feel that the applicant should fulfil their offer to add opt-out to their poster, and this should be updated and provided to the members for review. The CAG also thought it would be appropriate for practice websites to also display the notification, as so few patients currently enter the surgery premises due to COVID.

The Members wished for reassurance that the researcher will wear an identity badge, and when appropriate be introduced to the patient. The Sub-Committee also required evidence that researchers undertaking observations have an equivalent duty of confidentiality to that of a health professional, e.g. confidentiality policy, clauses in employment contract.

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 have a patient advisory group of six patients, with a diverse background of collaborators. This group has met mainly remotely during the project as well as being involved and updated by email. The project also has a co-applicant who is a patient, carer, and member of the Peninsula patient and public involvement group and is an integral member of the research team. The application states that these patient representatives have been involved in the case study set up, being involved in the design of patient facing documents seeking to ensure these are engaging and understandable for patients.

The Members agreed that the Patient and Public Involvement undertaken was good. It involved fairly small numbers of participants, but those who did take part seemed to have in depth involvement into the study design. It was noted that the issue of confidentiality was addressed in a 90 minute online meeting with four patient representatives.

Exit strategy

The observations are expected to be completed March 2022. The CAG were content with this exit strategy.

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 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, the applicant was required to respond back to all of the requests for further information within one month.

Request for further information

1. Please amend the poster to state patients can request a researcher leaves the area where a patient is present, and provide an updated version for review.

2. Please confirm that GP practice websites can also display the notification.

3. Please confirm that the researcher will wear an identity badge, and will be introduced to the patient if appropriate.

4. Please provide evidence that researchers undertaking observations have an equivalent duty of confidentiality to that of a health professional, e.g. confidentiality policy, clauses in employment contract

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 a final support outcome will be issued.

Specific conditions of support

The following sets out the specific conditions of support.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 27 April 2021**

2. 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: Security assurances are required for the sites where the observations take place. Support will be based on confirmation that the DSPT at the site will be complied with and that no identifiable information will be kept onsite or removed from the site. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.**

2. New Precedent Set Review Applications – Non-Research

a. 21/CAG/0094 - Time limited access for NHS Digital to undertake record linkage of East Anglian Air Ambulance patients to HES and ECDS

Context

Purpose of application

This non-research application from East Anglian Air Ambulance (EAAA) sets out the medical purpose which aims to link routinely collected clinical data regarding patients treated by East Anglian Air Ambulance to hospital held NHS data to audit and evaluate the care provided by the air ambulance in relation to the complete patient pathway and patient outcomes. This application is for support to link information regarding the 2020 cohort of patients, and an amendment will be submitted should the applicant wish to undertake linkages of further cohorts.

East Anglian Air Ambulance are a key provider of pre-hospital emergency care within East Anglia, attending the most critically ill patients within the region. Alongside regular audit that is undertaken using in house data, this application requests to link this with centrally held NHS

data to audit and evaluate the care provided by the air ambulance in relation to the complete patient pathway and patient outcomes. This gives opportunity for improved clinical excellence, gives learning opportunity for clinical staff and, ultimately, can lead to improved care for future patients (members of the public) of the air ambulance. The intention is to also share outcomes with other air ambulances and NHS partners, so that this project can potentially be of wider regional and national benefit in terms of using data to maximise patient benefit.

Some examples of expected outcomes:

- Accuracy of Dispatch and of Diagnosis: To identify the proportion of patients whose condition is correctly categorised: 1) At tasking 2) At scene based on working diagnosis.
- Survival: Proportion of people who survive to discharge.
- Decision making: To consider accuracy of conveyance (e.g. where patients are soon transferred onwards to another hospital) or unnecessary conveyance (patients who had no additional investigations or treatments at hospital which need to be provided in a hospital setting)
- Special cases or rarer conditions - analysis of patient record to look at the whole patient pathway and consider any learning opportunities.
- Impact of pre-existing comorbidities on pre-hospital care. These are recorded as associated diagnoses on the hospital record, but are often not well known about or not recorded during emergency care.

EAAA will provide NHS Digital with identifiers of eligible patients. Whilst these may be more than usual these are the minimum necessary to ensure linkage given the EAAA do not record NHS numbers as standard practice. This has been discussed and agreed with NHS Digital. NHS Digital will link to the requested datasets and return the data in pseudonymised form, where it will be linked to currently held clinical data for the purposes described.

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.

Cohort	All patients treated by East Anglian Air Ambulance, (excluding those who die before admission to hospital) in 2020. These patients are either taken by air ambulance to hospital, 'ground escorted' by EAAA to hospital, whereby EAAA crew accompanies the patient in a road ambulance, or treated by EAAA at scene and then taken to hospital by road ambulance with the normal ambulance crew. This initial phase will test linkage on the 2020 cohort (1384 patients) to test feasibility and usage of date before expanding

	to further years of data collection, however amendments will be submitted to CAG for support for further cohorts.
Data sources	NHS Digital datasets 1. Hospital Episode Statistics (HES): Admitted patient care 2. Hospital Episode Statistics (HES): Critical care 3. Emergency care data set (ECDS)
Identifiers required for linkage purposes	2. Full name (first name and surname) 3. Date of birth 4. Age 5. Home address, including postcode 6. Gender 7. Date of admission 8. Hospital of admission
Identifiers required for analysis purposes	1. None
Additional information	Note that the data will be linked to EAAA data through a code, but EAAA will not attempt to reidentify patients through this.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

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.

Members were agreed that this application describes an appropriate non-research medical purpose which is in the public interest.

Scope

Members were initially unclear on the scope of support requested regarding the cohort, as it was unclear if the applicant was planning to link information about patients from only 2020, or from other years as well. Support was originally requested until the 2025 cohort. However, during the course of the review, the applicant clarified that support was requested for the 2020 cohort only, and that a CAG amendment would be submitted should any further years be required. The members were content with this clarification.

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 cohort are critically ill patients and it would not be practical/appropriate to obtain consent at point of treatment. The EAAA do not have sufficient contact information to attempt consent at a later stage, nor do they have follow up contact. Further, many patients will not survive. As such, it is impractical to gain consent, and the Members agreed that consent is not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to enable NHS Digital to link to the requested datasets. The CAG agreed there was not a practicable alternative to undertake linkage that was less disclosive.

'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.

The applicant provided the EAAA privacy notice for review, however this is not specific to this application and is not patient notification as expected by CAG. Patient notification material was provided as a response to queries, which will be placed on the EAAA website, however there is no mention of CAG or which data items are disclosed to undertake the linkage. Applicants will draw people's attention to the website using 'calling cards' which are handed out to patients/families at the scene. The aftercare team send out a patient feedback form to all patients where a home address was recorded and where it is appropriate. A statement will be included on this form including a link to the materials on the website, including the statement about this project.

Regarding study specific opt out, the applicant has stated that If a patient informs the EAAA that they wish their information to be excluded this patient is flagged on the EAAA electronic patient record. Their details would not be provided to NHS Digital. However, there does not seem to be any indication of this opt out option on the notification provided in response to queries, instead they point people to the national data opt out, which is applied by NHS Digital. Contact details for EAAA are provided on the patient notification, but not specifically in relation to a study specific opt out.

The Sub-Committee considered that the draft website text does not explain clearly what the study is, and does not describe the study methods or proposed linkages. It also does not provide the option of a study specific opt-out or provide a means for opting out (e.g. contact details by web, email, phone, mail for research team), other than the national data opt-out page, and details provided for EAAA regarding queries. It is requested that this website text should be improved by including sufficient details of the study methods, linkage, and local opt-out details, and provided back to CAG for review.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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.

In response to queries, applicants state they have recently started a patient and public involvement Facebook group (with so far 45 members – ex patients and relatives) and will use this group to ask about attitudes to data sharing for this specific project. This will be completed within the next 3 months but has not yet been undertaken. East of England Ambulance NHS Trust have an established patient and public involvement group which applicants state they can use, however applicants have not undertaken any patient and public involvement activities as yet with this group.

The CAG Sub-Committee considered that there was no obvious urgency to justify the project going ahead without some patient and public involvement. Therefore, the applicant is required to carry out patient and public involvement activities surrounding the acceptability of confidential patient information without consent for the purposes of the application and provide feedback to the CAG before support is provided.

Exit strategy

The return of the data will be pseudonymised using a local ID which will be linked back to the EAAA clinical data only, but not the identifiers. The applicant indicates the key will not be destroyed; but it is retained by the direct care team only. The CAG Members were not clear on

the reasons that the applicant cannot fully anonymise the final linked dataset by removing the local pseudonymous ID. The applicant is requested to either commit to anonymising the dataset by removing the pseudonymous ID or provide sufficient explanation of why that would not be possible and provide an alternative exit strategy.

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 Secretary of State for Health and Social Care 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, the applicant was required to respond back to the all of the requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The website text should be improved by including sufficient details of the study methods, linkage, and local opt-out details, and provided back to CAG for review

2. Please carry out patient and public involvement activities surrounding the acceptability of confidential patient information without consent for the purposes of the application and provide feedback to the CAG.

3. Please anonymise the dataset by removing the pseudonymous ID or provide sufficient explanation of why that would not be possible and provide an alternative exit strategy.

4. Please provide evidence of NHS Digital review of the DSPT for East Anglian Air Ambulance (as per standard conditions of support below).

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 and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support

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. 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. **Pending:**

   The NHS Digital **19/20** DSPT equivalent review for **NHS Digital** is confirmed as 'standards met' on the NHS Digital DSPT Tracker (Checked 25 June 2021).

   The NHS Digital **19/20** DSPT review for **East Anglian Air Ambulance** is pending on the NHS Digital DSPT Tracker.

Minutes signed off as accurate by correspondence from Dr Patrick Coyle, CAG Vice-Chair		*21 July 2021*
Signed – Officers of CAG		Date
Caroline Watchurst		21 July 2021
Signed – Confidentiality Advice Team		Date