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

28 May 2021

Present:

Name	Capacity	Items
Professor William Bernal	Chair	1a, 2a
Dr Liliane Field	CAG Member	1a
Dr Katie Harron	CAG Member	2a
Mr Andrew Melville	CAG Member	1a
Mr Marc Taylor	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/CAG0067 - Derivation and narrow validation of a clinical decision rule for paramedics to triage older adults with a traumatic brain injury. Short tile: Clinical Decision Rule for TBI in Older adults (CEREBRAL)

Context

Purpose of application

This application from South East Coast Ambulance Service NHS Foundation Trust set out the purpose of medical research that aims to develop and test a clinical decision rule (CDR) that paramedics could use to aid triage of patients aged 60 years or older who could be at risk of a traumatic brain injury (TBI), to a hospital with neurosurgical services onsite.

It is now considered that older adults are a large proportion of the TBI patient population, with the majority presenting to the emergency department (ED) via emergency services. Therefore the responsibility of the initial assessment, triage, and transportation of these patients falls to the paramedic. However clinical presentation following a TBI may not correlate with the severity of injury, and as a result, the triage of older adults suffering a TBI can be inaccurate, increasing the risk of poor patient outcomes. When older adults with traumatic injuries are transported to an appropriate hospital, they are more likely to have a good outcome. Understanding which older TBI patients should be transported to a hospital with onsite neurosurgery and the variables that may predict this could help paramedics in the acute triage and management of older adults with suspected TBI.

Currently, it is difficult to accurately identify patients with a TBI until they have had a scan of the head which can only occur in a hospital. Therefore, to identify patients presenting to the ambulance service with a clinically significant TBI, the applicants plan to work backwards from the hospital records. Retrospective patient records will be identified from two different hospital sources;

1. Hospital records of patients meeting the inclusion criteria referred to neurosurgeons will be screened via the online neurosurgical referral service. These records will be screened and extracted by the applicant, who is not a member of the direct care team. The direct care team do not have capacity to undertake this screening and extraction. He has explained that the access to the online Neurosurgical referral platform will be through Kings College London NHS Foundation Trust (KCL), as they are the central Trust in SELKaM Trauma Network, who operate a hub and spoke model, and all neurosurgical referrals go through KCL, and for Sussex trauma network data will be extracted from Brighton and Sussex University Hospital. He will extract CAD incident number if available, alongside date of transport, NHS number, date of birth, date and ED admission time, Gender, ethnicity, and other clinical information. He will securely send this dataset to the Business Intelligence department at South East Coast Ambulance Service NHS Foundation Trust (SECAmb).

2. Hospital records of patients meeting the inclusion criteria who attended the ED but were not referred to neurosurgeons will be screened via the ED hospital registry. Intelligent information specialists at hospitals within East Kent Foundation Hospitals Trust for SELKaM Trauma Network, and University Hospitals Sussex NHS Foundation Trust for Sussex Trama network+ will identify and extract a dataset regarding eligible patients. Support is requested for this, as the Trusts may not consider these staff to be the direct care team. They will and extract CAD incident number if available, alongside date of transport, NHS number, date of birth, date and ED admission time, Gender, ethnicity, and other clinical information. They will securely send this dataset to the Business Intelligence department at South East Coast Ambulance Service NHS Foundation Trust (SECAmb).

The patient's hospital records regarding neurosurgical referrals and ED data will be linked together by SECAmb Business Intelligence (BI) department, and also linked to SECAmb ambulance patient record using CAD numbers, NHS numbers and dates of birth. Once linkage is complete, The BI team will assign a pseudonymous study ID, and the CAD number, NHS number and date of birth are removed and destroyed. No key between the pseudonymous ID and identifiable information is retained. The dataset is sent to the study team at University of Surrey. and it can be considered anonymous to the research team, as they will be unable to re-identify the patients. The study team will not have access to patient identifiable information.

The final dataset will also include SECAmb patients who were not transported to the hospital over the same period, however this element does not require CAG support.

A recommendation for class 1, 2, 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	Older adults (60+) who have a TBI or suspected TBI or head injury, and present to South East Coast Ambulance Service (SECAmb) between the 1st of January 2020 and the 31st of December 2020 and transported to hospitals within the trauma networks of South East London, Medway, and Kent (SELKaM) Trauma Network or Sussex Trauma Network. Approximately 1080 patients expected.

Data sources	• Hospital online Neurosurgical referral platform: For SELKaM Trauma Network, accessed only at **King's College Hospital,** and for Sussex trauma network this is accessed at **Brighton and Sussex University Hospital** • Participating Emergency Department hospital records, in SELKaM Trauma Network; 1. King's College Hospital 2. William Harvey Hospital 3. Queen Elizabeth Queen Mary Hospital 4. Canterbury Hospital and Sussex trauma network; 1. Brighton and Sussex University Hospital 2. Worthing Hospital 3. St Richards Hospital 4. Princess Royal Hospital 5. Conquest Hospital 6. Eastbourne Hospital • SECAmb ePCR database (South East Coast Ambulance patient electronic records)
Identifiers required for linkage purposes	1. CAD number 2. NHS number 3. Date of birth 4. Date and time of ED admission 5. Pseudonymous ID
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Pseudonymous ID 4. Age (Effectively anonymous 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 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.

The Sub-Committee were satisfied that the application has a clear medical purpose and is in the 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**

The applicant reasoned that it is impractical to contact all patients (or their consultees) for consent to use their data, as this would take a significant investment of time and resourcing. The CAG Sub-Committee agreed with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to undertake linkage, and the data will be anonymised at the earliest opportunity. The Members agreed with the justifications for the use of confidential patient information.

'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 notification poster has been developed in response to queries (and also as a response to queries from the REC), which each participating site will be asked to publish to advertise the study. A study specific opt out mechanism has been developed in response to queries, via the notification poster, and the national data opt out will apply.

The Members were broadly content with the content of the notification provided, however they commented that there appeared to be some confusion over the retrospective calendar year for the study. The poster refers to 2019 but the application 2020. The notification poster will therefore need to be updated to ensure this also states 2020. It was also stated that the poster should also have a postal address for opt out. The applicant has responded to queries stating that each participating site would 'publish' the poster, but the members felt that it was not clear

if publish meant displayed in clinical areas, put on trust websites, or both. This should be clarified, and the Sub-Committee also felt the patient notification materials should be put on the SECamb website additionally.

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.

SECAmb actively involves public and patient (PPI) representatives in research. Through collaborative processes with PPI members and supervisors, the research design evolved to include the development of a clinical decision rule (CDR). During the study, PPI members will work alongside the study team members to guide and monitor its development, and will be involved in disseminating this study's results. The study was proposed to the National Institute of Health Research as part of a package of workstreams for the Clinical Doctoral Research Fellowship Award. The expert panel with PPI representation returned a favourable opinion.

The revised research proposal was presented to a wider public audience at SECAmb's annual PPI engagement event, attended by 70 individuals reflecting various backgrounds, ages, and gender to involve service-users and patients. During a roundtable workshop, the study was discussed in-depth. There were initially some concerns raised about consent and how patient data would be handled, however the applicant then altered the study design according to PPI feedback. The patients and public group members involved in the review understood that data would be extracted from the neurosurgery platforms by a person who was not part of the direct care team, without consent, and they were content with this being undertaken.

The Members considered the patient and public involvement work undertaken to be satisfactory to recommend support, and felt it was positive that the applicant had listened to feedback and made changes accordingly.

Exit strategy

After linkage, confidential patient information will be removed from the dataset and destroyed. Data will be effectively anonymous to the applicant for analysis. Linkage is expected to be completed by December 2021, and support therefore required until then.

The Sub-Committee were content with the exit strategy, however commented that this was an ambitious timeline to undertake these linkages.

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 update the notification poster to confirm the retrospective calendar year as 2020 rather than 2019, and provide an updated document for review.

2. Please update the notification poster to include a postal address for opting out, and provide an updated document for review.

3. Please confirm if the patient notification will be displayed in clinical areas at participating sites, on websites, or both, and confirm if the notification can additionally be displayed on the SECamb website.

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 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 10 June 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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**

- **South East Coast Ambulance Service NHS Foundation Trust**
- **King's College Hospital**
- **East Kent Foundation Hospitals Trust**
- **University Hospitals Sussex NHS Foundation Trust (new merged Trust, should currently be covered by the below;**
- **Brighton & Sussex university Hospital NHS Trust and**
- **Western Sussex Hospitals NHS Trust**

2. New Precedent Set Review Applications – Non-Research

a. 21/CAG/0084 - National Cancer Patient experience survey 2021 (NCPES)

Context

Purpose of application

This application from Picker Institute Europe on behalf of NHS England and NHS Improvement set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2021. This will enable comparisons between Trusts, for commissioners, providers and patients (all of whom can access the published results), allow for monitoring of improvements in services, drive further improvements, and provide NHS England with an up to date overview of cancer patient experience across England.

The Cancer Patient Experience Survey (CPES) 2021 fieldwork period will begin at the end of October 2021 and is due to close in January 2022. Survey findings will be published in March 2022.

The 2021 survey will replicate the methodology used in previous iterations of the survey. Picker Institute Europe works with Greens Limited to mail initial questionnaires and then reminders (as required) to eligible participants following the above checks using name and address. The survey will be conducted by post, with two reminders (to non-responders only) as is the case with other national patient surveys. A standard questionnaire, covering letter and up to two reminder letters will be used. Patients will also be sent a link to complete the survey online should they prefer to do so.

Although the methodology is the same as previous surveys, the questionnaire is slightly altered, to allow for the pandemic, and to allow further inclusivity. Information on gender identity alongside sex will be collected, however this is self reported in the questionnaire rather than disclosed to Picker from Trusts. ICD 11 code will also be collected alongside ICD 10 code.

A recommendation for class 1, 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	approximately 125,000 patients All adult patients (aged 16 and over), with a **confirmed diagnosis of cancer**, who have been admitted to hospital as inpatients for **cancer related treatment**, or who were seen as day case patients for **cancer related treatment**, and have been discharged between 1st April 2021 and 30th June 2021 will be included in the survey
Data sources	1. Acute and specialist NHS Trusts in England that provide adult cancer services.
Identifiers required to be disclosed to Picker	Identifiers disclosed by the Trusts: 1. Trust Code 2. Anonymised reference number for each record (applied by Trust) 3. Name 4. NHS number 5. Full address 6. Sex 7. Ethnic group 8. Date of birth 9. ICD10 code 10. ICD11 code 11. Admission and discharge dates 12. Speciality code 13. Referring CCG 14. Admission type 15. Site treated at
Identifiers required for analysis purposes	16. Postcode – (modified for analysis) 17. Anonymised reference number for each record (applied by Trust)

	18. ICD10 code 19. ICD11 code 20. Speciality code 21. Ethnic group 22. Age 23. Self reported sex (from questionnaire response) 24. Self reported gender (from questionnaire response)

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 agreed that this activity has a clear medical purpose and is in the 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**

The applicant has put forward a number of justifications regarding not using consent, including the burden on clinicians that consenting this amount of patients would cause, and the potential for bias to be introduced into the patient sample. These justifications are in keeping with rationale previously accepted for survey activities, and the Sub-Committee accepted that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to validate the patient sample and circulate questionnaires, and the members agreed that this could not be undertaken without using identifiable information. It was noted by the members that confidential patient information may also required for Picker to undertake "deceased checks", and queried whether this would involve further disclosure of identifiers. It appears this is conducted through the DBS (demographics batch service), and is secure, however it was not clear if support is required for the disclosure of identifiable information from Picker to NHS Digital.

'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 applicants advised that the Trusts were sent dissent posters, and leaflets to advertise the 2021 survey during the sampling frame of April, May and June. The design of the poster and leaflet was made suitable for display on digital screens, and Trusts have been able to request them in alternative languages to English. This could additionally have been displayed on websites, but no specific website wording was provided. This material provided space to add details of a nominated person within each local trust that patients could contact, should they wish to opt out of the survey, which is in line with previously supported applications.

The survey is exempt from the National data opt out, but local Trust contacts will be provided to manage any patient dissent regarding an invitation. The covering letter also provides details on how to opt out at the point of receipt.

The Members were content that the patient information provided is clear and appropriate, and the opt out options are in line with previously supported surveys.

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 survey is overseen by an advisory group which consists of patients, professionals, voluntary sector representatives, academics and patient survey experts. For 2021, the questionnaire has been redeveloped to bring it up to date with service provision. The Cancer Patient Experience Advisory Group (CPEAG) were involved in the development process advising on the themes the questionnaire should cover and how specific questions should be worded. In addition to this, the questionnaire has gone through cognitive testing with 30 patients and 8 members of staff to ensure that questions are being understood as intended.

As a response to queries regarding the acceptability of the use of confidential patient information without consent for the purposes of the survey, the applicant provided further supportive information; During the cognitive testing phase with 30 patients, patients were also asked about how they would feel about receiving a survey in the post without providing previous

consent. All patients were happy with their data being shared as long as this organisation was approved by the NHS and as long as it was clear that they had the option of not completing the survey and opting-out if they wanted to.

The Sub-Committee were content with the patient and public involvement undertaken.

Exit strategy

The exit strategy is the deletion of confidential patient information by Picker and Greens Ltd. For those patients who do not confirm that their data can be retained, confidential patient information will be destroyed 12 months after publication, by 31 March 2023. Those patients who consent to the inclusion and retention of their data will be out of scope of support once this has been confirmed in their survey response.

The CAG Sub-Committee were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Please confirm if support is required for confidential patient information to be disclosed from Picker to NHS Digital in order to undertake 'deceased checks', within one month from the date of this letter.

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:**

   The NHS Digital **19/20** DSPT reviews for **Picker Institute Europe and Greens Ltd** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 June 2021)

Minutes signed off as accurate by correspondence from Professor William Bernal, CAG Alternate Vice-Chair		*01 October 2021*
Signed – Officers of CAG		Date
Caroline Watchurst		20 July 2021
Signed – Confidentiality Advice Team		Date