Health Research Authority

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

February 2018

Reviewers:

Name	Capacity
Dr Tony Calland MBE	Chair
Dr Kambiz Boomla	Committee Member
Mr Anthony Kane	Committee Member
Miss Kathryn Murray	Senior Confidentiality Advisor

CAG reference: **14/CAG/1030**
REC reference: **14/SC/1219**
Study title: **Cluster randomised trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest - Airway Management in cardiac arrest patients (AIRWAYS2)**

Context

Purpose of application

This application from University Hospitals Bristol NHS Foundation Trust set out the purpose of reviewing patient confidential information regarding patients who have had an out of hospital cardiac arrest (OHCA) to establish the most effective method by ambulance staff to restore breathing: the placement of a breathing tube (intubation) or by the insertion of a supraglottic airway device (SAD).

The study will be a randomised controlled trial (RCT) in four English NHS ambulance services. It will recruit adult OHCA patients who have suffered a cardiac arrest that is not due to injury. Paramedics who agree to take part will be divided into two groups and given structured education on CPR and rescue breathing. One group will be required to use the i-gel and the other intubation as the first method of rescue breathing in all cases of OHCA that they attend during the study. Patients will be followed up hospital, and 3 and 6 months later, to find out the quality of life of survivors and the NHS resources used during their hospital stay and subsequently.

Patient confidential data will be obtained from the ambulance service regarding OHCA patients who are initially admitted to hospital alive. Personal identifiers of survivors will be used for verifying survival status with NHS Digital. NHS Digital use the collected identifiers to provide the NHS number so that all identifiers can be erased however, NHS number, date of birth and postcode will be retained to then seek consent.

A recommendation for class 3, 4 and 6 support was requested to select and contact patients to seek their consent, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of these purposes.

Confidential patient information requested

Access was requested to name, NHS number, hospital number, date of birth, date of death, postcode, ethnicity.

Clarification regarding the retention of patient identifiers

The Applicant advised in their email response dated 8 December 2014 that the potential indefinite retention of patient identifiers was only intended where patients had consented (options A and B). The Applicant recognised however that the consent process did not specifically reference the retention of identifiers.

The Applicant therefore decided that identifiers from all patients would only be retained until the data had been validated and locked.

Amendment Request

This amendment requested support to follow-up all patients enrolled in the AIRWAYS2 trial, through linkage with the HES dataset held by NHS Digital.

Support was requested to allow the disclosure of NHS number, Date of Birth, Surname, Forename, Gender and Postcode from the trial team at University Hospitals Bristol NHS Foundation Trust to NHS Digital, to be linked with the HES datasets (A&E, Inpatients, Critical care and Outpatients). HES data will be returned to the trial team by NHS Digital as a spreadsheet linked by patient identifiers. The trial team at University Hospitals Bristol NHS Foundation Trust will link the information to the study database. The trial team create a pseudonymised dataset and transfer this to the Nuffield Department of Population Health at the University of Oxford who will undertake analysis.

It was acknowledged that support was in place for the retention of confidential patient information until all study data had been validated and the trial database locked. The applicants confirmed that the HES linkage would be undertaken prior to the database lock, as confidential patient information was required to facilitate linkage. It was anticipated that this would be completed in early 2018.

Confidentiality Advisory Group Advice

The amendment was considered by a Sub-Committee in correspondence. It was noted that the justification for the amendment was that, by linking with HES data, the applicants would be able to estimate the difference in mortality between the two patient cohorts included in the project and estimate the cost-effectiveness of the i-gel in comparison with tracheal intubation. Members acknowledged that this additional health economics analysis, would complement the clinical effectiveness study. The Sub-Committee was assured that there was public interest in this additional data linkage, which had an established medical purpose through medical research. The CAG was content to recommend support to the amendment.

Confidentiality Advice Team Conclusion

In line with the considerations above, the Sub-Committee 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 – 02/02/2018)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – REC favourable opinion was issued on 19/01/2018).**

CAG reference: **17/CAG/0198**
IRAS project ID: **214795**
REC reference: **16/NE/0401**
Application title: **Long term outcomes of functional neurological symptoms in children**

Group Members:

Name	*Present*	*Notes*
Dr Patrick Coyle	Yes	Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of the establishment of a research database into neurological symptoms in children. The applicants state that children and young people with functional symptoms will be identified from a database operating in the Newcastle paediatric neurology department since 1997. The identified patients' Newcastle hospital medical records will be examined to see to what extent their problems have persisted into adulthood and to try to identify factors associated with successful (symptom free) long term outcomes. The applicants will also perform a record-linkage study to identify involvement of the local NHS Trust that provides psychological and mental health services, to see whether involvement of these services has been associated with better long term outcomes.

This is a single purpose study and the assembled dataset will be destroyed after use. The topic of study is functional neurological symptoms - problems with abnormal movement, sensation, inability to move etc. with no conventional medical cause resulting from psychological factors. The project's aim is to identify long term outcomes after children present with functional neurological symptoms: whether their problems persist into adulthood.

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

Confidential Patient Information Requested

Access was requested to the following items of data for the project:

- NHS Number – data linkage,
- Hospital ID no – data linkage,
- Name – data linkage,
- Last known address – data linkage,
- Date of birth – data linkage,
- Date of death – data linkage,
- Postcode (clarified this is required at unit level) – data linkage,
- Gender – data linkage,
- Health service district– data linkage.

Cohort

The cohort will be established from an existing database containing 11,000 records and it was anticipated there will be approximately 120 individuals who would meet the inclusion criteria for the project.

Confidentiality Advisory Group Advice

The Chair considered the applicant's response to the request for further information included within the provisional outcome in correspondence.

1. **Provide clarification around the data linkage and extraction process which would be undertaken at the NTW Trust. An overview of this process is required before support for the application activity can come into effect.**

The applicant provided an overview of the linkage an extraction process, which had been agreed with the appropriate individuals at the NTW Trust.

The response was received and no further issues were raised.

2. **Provide clarification that the dataset which will be used for analysis will be stripped of confidential patient information, including translation of dates (i.e. date of birth) into month and year format or age, where applicable, to reduce the identifiability.**

The applicant confirmed that once NTW involvement with a patient was clarified, the study dataset would be stripped of all patient-identifying data by NUTH. All dates including dates of birth, dates of presentation and diagnosis and of NTW involvement would be stripped of day data (i.e. rounded to month, year format).

The response was received and no further issues were raised.

3. **Confirm the study 'census dates' to clarify up to what point access to patient records will cease.**

It was confirmed that the study census date will be 31/12/17. No clinical records subsequent to that date would be accessed.

The response was received and no further issues were raised.

4. **Provide further detail around the promotion campaign which will be undertaken via FND Action social media channels to provide further clarity on the communications strategy for the proposal.**

The applicant confirmed that the text of the proposed "teaser" alerting message (to be shared via social media) and the substantive "further information" sheet had now been approved by the REC as Substantial Amendment 1 (letter dated 11th January 2018). A copy of this outcome letter was received.

It was clarified that the teaser message would be promoted via FND Action's Facebook channel once the final outcome from CAG is obtained, and at approximately fortnightly intervals for a period of eight weeks (four notifications in total). NTW would also share information about the study via its Twitter and Facebook accounts.

The applicant explained that once the period of eight weeks had passed any requests for individuals' data to be excluded would be honoured and the study would commence. If any late requests for exclusion were received prior to finalisation of analysis for publication to academic journals, these could also be honoured and relevant records would be deleted from the study dataset and from any published reports. It should be noted however that some examination of these individuals' medical records may have occurred by then. In the interests of scientific rigour, the number of requests for exclusion and any evidence of important biases in the subset of individuals requesting exclusion in terms of age, gender, year and mode of presentation will be reported.

The response was received and no further issues were raised.

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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed – 11 January 2018).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – NTW Trust shows a 76% satisfactory rating on Version 14, 2016/17).**

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Ms Hannah Chambers	Yes	Lay
Dr Patrick Coyle	Yes	Vice Chair
Dr Harvey Marcovitch	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

CAG reference: **17/CAG/0193**
Application title: **UKRETS (United Kingdom Registry of Endocrine and Thyroid Surgery)**

Context

Purpose of Application

This application from the British Association of Endocrine and Thyroid Surgeons sets out the purpose of a clinical audit into endocrine and thyroid surgery. The United Kingdom Registry of Endocrine and Thyroid Surgery audit was set up in 2004 to measure the quality of endocrine and thyroid surgery and to use that information to improve the quality of the surgery across the NHS for patients, commissioners and regulators of healthcare professionals. The audit outcomes also provide reassure to patients that the quality of clinical care is being actively monitored and improved. It audit has collected over 80,000 cases since its establishment in 2004.

Members of the British Association of Endocrine and Thyroid Surgeons record a number of outcome measures (as well as pre-operative and operative details) for each endocrine surgical operation performed including length of stay, mortality, voice change, hypocalcaemia (for thyroid and parathyroid surgery) and persistent disease (for parathyroid surgery). This data is transferred at the point of entry into a database which is maintained by Dendrite Ltd.

The application also stated that data will be requested from the HES dataset via NHS Digital around the number of surgical procedures undertaken; however, this would be requested in anonymised format only and would not involve the processing of confidential patient information to facilitate the data release.

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

Confidential Patient Information Requested

Cohort

All patients within England and Wales undergoing thyroid, parathyroid, adrenal or endocrine pancreatic surgery. This is approximately 8-9,000 patients per year.

The following items of confidential patient information will be entered by the direct care team into the web-based registry, maintained by Dendrite:

- NHS number (in England and Wales) – validation and follow-up of patients,
- Date of birth – validation (only available to the clinical care team) and analysis (age at procedure),
- Gender – analysis,
- Date of death (if applicable) – calculate length of stay for analysis
- Date of operation – validation and analysis.

Confidentiality Advisory Group advice

The Sub-Committee considered the applicant's response to the request for further information included within the provisionally supported outcome in correspondence.

1. **Historic Practice of the Audit Programme – further clarification is required around the history of the activity as follows:**

a. **Confirm under what legal basis in relation the common law duty of confidentiality confidential patient information has been processed to facilitate the audit programme,**

b. **Provide a copy of the historic correspondence with the Information Commissioner's Office (ICO) around the audit programme in which they clarified that the data processing which had been undertaken did not involve a breach of the Data Protection Act 1998,**

c. **Clarify whether confidential patient information (date of birth, date of death and gender) has been retained by Dendrite Ltd. in relation to the patients (circa. 80,000) which had already been entered into the audit programme database. If this is the case, it is recommended that this data retention is discussed with the ICO in the interests of transparency and to ensure compliance against the DPA.**

The applicants provided a comprehensive response to the above points. It was acknowledged that the historic interaction with the ICO had been undertaken verbally so there was no formal documentation to reference the previous guidance. Contact had been made with the ICO more recently and the applicants provided clarification that the historic data disclosure was within the public interest, which satisfied the common law requirements.

The Sub-Committee received the response. It was noted that support could not be retrospectively applied to the data processing which had previously undertaken. Members were content to recommend support for the application activity under the Regulations moving forward.

2. **Further rationale is required to support to the public interest in the audit activity. The following points should be considered in the response:**

a. **Specific reference should be made to the current ascertainment rate of the audit and what steps will be put in place to improve this in order to produce an effective national programme.**

The applicants confirmed that the audit programme had previously achieved a 54% case ascertainment, noting that for the 2016-17 financial year, the audit had recorded parathyroid and parathyroid data in 10,465 cases and 19,395 cases had been reported in HES data. The applicants confirmed that, by receiving support to link to NHS Digital HES data, work could be undertaken to better understand the ascertainment rates and identify which Trusts were not submitting the compulsory audit data.

The Sub-Committee received the response and it was recommended that the applicants continue work to improve the ascertainment rate of the audit programme as the project progressed. An update would be required at the time of annual review around the improvements which had been achieved.

3. **Clarification is required around the role of Health Quality Improvement Programme (HQIP) in the audit activity. Response is required to the following issues:**

a. **Confirm whether the audit programme is commissioned and funded by HQIP,**

b. **If so, clarify who is acting as data controller for the application activity.**

The applicants confirmed that HQIP managed the Clinical Outcomes Publication (COP) programme on behalf of NHS England, which the audit forms a part of. Funding was provided to the audit by HQIP purely to support its operational participation in the programme (HQIP is not a commissioner of the audit as a whole). HQIP was not a data controller or data publisher of the audits data. NHS Choices publish the aggregate data provided by the audit as part of COP. It was confirmed that BAETS was data controller for the programme and Dendrite Ltd was acting as data processor.

The Sub-Committee received the response and no further issues were raised in this area.

4. **Scope of Support – clarify whether the request for support under the Regulations is intended to extend to the retention of the audit database to date.**

The applicants confirmed that support was requested to extend to the ongoing retention of the previously collected audit data.

The Sub-Committee received the response and it was acknowledged that whilst support could not be extended retrospectively to the collection of this data, it could be recommended for the ongoing retention.

5. **Patient Notifications and Dissent – further information is required around how the audit programme will be promoted to patients and within the public domain together with the materials used to achieve this communications. Further response is required as follows:**

a. **Provide further information around how information for the audit is provided to patients.**

i. **This should include clarification around whether every patient who undergoes thyroid or other endocrine surgery will receive a copy of the information leaflet,**

ii. **How the website is promoted – though it was referenced that electronic materials alone were not a sufficient notification system.**

The applicants confirmed that all patients undergoing thyroid or endocrine surgery by a BAETS member would receive a copy of the patient information leaflet. It was explained the applicants could recommend to those Trusts, identified by cross checking UKRETS with HES data that were not contributing their data that their surgeons become BAETS members, to enable contribution to this national audit; however, this cannot be enforced.

It was explained that the website was promoted in a number of ways: through the national meeting, via national thyroid / endocrine charities such BTA, Butterfly, AMEND, HypoparaUK etc, during clinical consultations between patients and BAETS members, with the patient information leaflet and via publication of COP data on surgeons' outcomes which are available on the BAETS website.

The Sub-Committee received the response and no further issues were raised in this area.

b. **The patient information leaflet requires further revision as follows:**

i. **The information around the patient's right to opt-out should be made more prominent and brought forward to an earlier place within the information sheet,**

ii. **Date of death does not need to be directly referenced in the document; however, patients should be informed that wider clinical outcomes from the surgical procedure would also be collated as part of the audit,**

iii. **The document should advice that NHS Number will be collected,**
iv. **It was agreed that the document required revision to make the text more accessible to the wider patient audience. It was recommended that patients were approached to assist with this revision,**
v. **The revised document should be submitted for consideration by the CAG.**

The Sub-Committee considered the revised patient information leaflet provided by the applicants. Members agreed that the document was still quite complex in places and would benefit from further review with input from patients, to ensure that this was appropriate to the intended audience. It was agreed that support would be recommended for the project with the information sheet in its current format; however, a condition would be attached the recommendation that the applicants undertake further work to improve the information leaflet. A report on activity undertaken in this area, together with a revised information sheet would be required at the time of first annual review.

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 for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. Support is recommended for the ongoing retention of the audit which had been historically collected.
2. Support under the Regulations would be extended on a time-limited basis whilst work is undertaken to progress to a fully-consented model for inclusion within the audit programme. An update would be required at the time of annual review around the activity which has been undertaken to progress with the consenting model.
3. An update is required at the time of first annual review around the activity which has been undertaken to improve the case ascertainment which is reported to the audit.
4. Patient and Public Engagement and Involvement – ongoing work should be undertaken with the relevant charities and patient groups which were referenced with the application as the audit programme continues. A report would be required at the time of first annual review around the activity which had been undertaken here, together with any relevant feedback. If the responses provided from the patient and public involvement and engagement activity were negative, the CAG would take this into account when considering whether support for the activity could continue or whether any additional actions are required.
5. Patient Notifications – further work should be undertaken to improve the patient information leaflet which supports the audit programme. It is recommended that engagement with a patient group is undertaken to assist this process. An update would be required at the time of first annual review around the activity which has been undertaken in this area, together with a copy of the revised information leaflet for consideration.

Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Dendrite Ltd. shows a reviewed satisfactory grade on Version 14, 2016/17)**.

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay
Mr Anthony Kane	Yes	Lay
Mr Andrew Melville	Yes	Lay
Dr Murat Soncul	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

CAG reference: **18/CAG/0005**
Application title: **Using Guthrie cards for a serosurveillance study of maternally-derived antibody against pertussis**
IRAS project ID: **234583**

Context

Purpose of Application

This application from Public Health England sets out the purpose of medical research which aims to identify the amount of antibody which is required to be administered to pregnant women to protect infants from pertussis (whooping cough) in order to inform the maternal vaccination programme. The applicants will use dried blood spots from newborn baby dried bloodspot screening cards for the study. The study will be undertaken comparing antibody from DBS from 150 infants with pertussis that occurred during 2012 with DBS from 300 healthy controls. The project will be facilitated by using the PHE national surveillance activity that identified babies with pertussis disease and requesting laboratories storing the cards to take up to two of the dried blood spots that remain on the card for analysis. The laboratories will also be asked to provide two other cards taken at the same time to act as the healthy controls. The antibody test which was developed at Public Health England will be used to measure antibody concentrations to work out how much antibody is needed to protect babies from pertussis.

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

Confidential Patient Information Requested

Cohort

- 150 infants under the age of three months identified by national active surveillance between 1st September 2011 and 1st September 2012, infected with pertussis.
- 300 healthy controls – gestational age and sex matched.

Data in relation to the patient cohort will be taken from the PHE national surveillance records, which were gathered during a 2012 outbreak. The information by laboratory staff to identify a control cohort blood spot for inclusion in the study:

- NHS number – used to match records to sample

- Date of birth – used to match records to sample and identify matched control cohort,
- Gestational Age at birth – identify matched control and analysis,
- Sex – used to match records to sample and identify matched control cohort,
- Ethnicity – used to match records to sample and identify matched control cohort.

Confidentiality Advisory Group Advice

A Sub-Committee of the CAG considered the applicant's written response to the request for further information included within the provisionally supported outcome in correspondence.

1. **Clarify whether date of birth will be included within the research database and if so, in what format will this be retained.**

The applicant explained that the laboratories required two complete identifiers in order to identify the case cards: date of birth and NHS number. Date of birth would also enable the laboratories to select the next two eligible controls matched for gestation, sex and ethnicity. It was confirmed that neither date of birth, nor NHS number would be retained on the research database. It was confirmed that the applicants required gestation, sex and ethnicity within the research database as all three factors were likely to affect the amount of antibody recovered and therefore need to be accounted for in the study analysis. The applicants stated that they had kept identifiers to an absolute minimum in order to respect confidentiality.

The Sub-Committee received the response and no further issues were raised in this area.

2. **Clarify the retention period for the confidential patient information items requested. If it is intended to retain these for the two year period, provide further rationale to support this requirement.**

The applicants reiterated that they would not retain the confidential patient identifiers once the dried blood spot cards had been selected. It was clarified that the remaining data will be anonymised using the unique patient identifiers which would not be linked in any way to identifiable information. The applicants clarified that this anonymised data would be the only data retained during the two years of the project.

The Sub-Committee received the response and it was acknowledged that once the required samples had been identified and an anonymised dataset created from the confidential patient information, the requirement for support under the Regulations would fall away.

3. **Patient notifications and dissent – further work is required in this area to address the following points:**
    a. **Work should be undertaken to find a more appropriate channel for patient notifications for this study. If a specific support group for pertussis cannot be located, explore more generic support networks for new parents to find a suitable alternative,**
    b. **Revise the text of the patient notification materials to make this study-specific and make it clearer that the information is around a research study.**

Following review of the previous application (17/CAG/0166 - Using Guthrie cards for a serosurveillance study of maternally-derived antibody against Group B Streptococcus), the applicants explained that they had developed the site which will be situated for free on the GBSS website. The applicants explained that GBSS was currently the only charity supporting families following neonatal infection. It was also clarified that the two studies were being run in tandem, by the same team.

It was clarified that the webpage has its own web address distinct from GBSS website which would be used on all advertising material. The text of notification material was developed together with the supporting patient involvement group. The applicants confirmed that the text would make it explicit that this is research. The applicants confirmed that they would continue to seek out other organisations with an express interest in pertussis; however, they had not yet been able to identify any relevant organisations that are willing to site a webpage for the project free of charge no cost. A revised copy of the website text was provided for information.

The Sub-Committee received the response and it was acknowledged that due to the time pressure on the project, due to impending destruction of the Guthrie card samples, further work to improve the scope of the patient notification mechanism could be added as a condition of support, with feedback required at the time of annual review on progress in this matter. The revised text was received and no further issues were raised.

4. **Provide further information around the intended destruction of the Guthrie cards, as it was acknowledged from detail within the application that this should already have been actioned.**

The applicants confirmed that the moratorium on Guthrie card research was lifted on the 4th January 2018 and cards are due for destruction from 28th February 2018.

The response was received and no further issues were raised.

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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following points:
    a. Undertake further activity with a wider audience to include parents, both mothers and fathers, who have an appropriate interest in the research,
    b. Specific engagement about the proposed study, rather than general discussion around the use of Guthrie cards for research purposes, should be undertaken,
    c. A report would be required at the time of first annual review around the activity which has been undertaken, together with nay feedback,
    d. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Patient notifications and dissent – further work is required in this area to address the following points:
    a. Work should be undertaken to find a more appropriate channel for patient notifications for this study. If a specific support group for pertussis cannot be located, explore more generic support networks for new parents to find a suitable alternative,
    b. A report should be provided at the time of first annual review around the activity which has been undertaken in this area, together with the confirmation of any wider communications that have been published around the project.
3. Favourable opinion from a Research Ethics Committee. (**Confirmed – North East – York REC (17/YH/0323) – favourable opinion issued 12/10/2017**).

4. Confirmation from the IGT Team NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed - Public Health England shows a reviewed reported grade of 72% satisfactory on version 14, 2016/17**).