Health Research Authority

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

May 2019

Present:

Name	Capacity	Items
Dr Tony Calland MBE	Chair	1.a., 1.b., 1.c.
Dr Murat Soncul	Alternate Vice-Chair	1.d., 1.e.
Dr William Bernal	CAG Member	1.a., 1.c.
Ms Sophie Brannan	CAG Lay Member	1.b., 1.c.
Professor Barry Evans	CAG Member	1.a., 1.b.
Mr David Evans	CAG Member	1.e.
Dr Katie Harron	CAG Member	1.d.
Me Andrew Melville	CAG Lay Member	1.e.

Also in attendance:

Name	Position (or reason for attending)
Miss Katy Cassidy	Confidentiality Advisor, HRA
Miss Kathryn Murray	Senior Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a. 19/CAG/0072 - Validation of a novel scoring system to predict inpatient mortality in exacerbations of Chronic Obstructive Pulmonary Disease requiring assisted ventilation with supplementary longitudinal assessment of quality of life and other patient-centred outcomes over one year.

Context

Purpose of application

This application from Northumbria Healthcare NHS Foundation Trust sets out the purpose of medical research which aims to assist decision-making in the treatment of exacerbations in Chronic Obstructive Pulmonary Disease (COPD).

Exacerbations of COPD account for 12% of UK hospital admissions. During an exacerbation, the lungs may be unable to adequately clear carbon dioxide ("waste gas") and the blood becomes more acidic as it accumulates (termed respiratory acidaemia). Respiratory acidaemia has a high mortality and non-invasive ventilation (NIV) can be lifesaving.

Clinicians currently lack a simple method to accurately predict outcome and often overestimate the risk of death, resulting in under-use of NIV. The applicants aim to assist decision making by developing a simple prognostic tool, used to inform discussions about treatment options with patients/families, resulting in increased use of NIV in those who will benefit, and enhanced palliative care provision in those who will not.

The applicants collected survival and readmission data for up to 12 months post-discharge. Consent was not required from patients as the direct care teams at each site collected the patient information and only anonymised data was shared with the host site. The applicants had not accounted for the possibility that patients would be readmitted to a hospital that was not participating in the research, or die within the community, and now required the disclosure of confidential patient information from participating trusts to the host site, Northumbria Healthcare NHS Foundation Trust, for collation. The collated confidential patient information was then disclosed to NHS Digital and NHSWIS for linkage to Hospital Episode Statistics (HES) and Patient Episode Database Wales (PEDW) respectively, so that data including emergency department attendance, hospital admission, including to intensive care admission, length of stay and cause of/reason for admission can be accessed. De-identified data was then returned to the host site.

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

Confidential patient information requested

Cohort:

Male and female patients aged 35 years and over, diagnosed with Chronic Obstructive Pulmonary Disease. with an exacerbation complicated by respiratory acidaemia and which is treated with assisted ventilation.

The following items of confidential patient information are requested for the purposes set out below:

- NIVO study-specific ID – linkage,

- NHS number – sample linkage and validation
- Date of birth - sample linkage and validation, and analysis
- Date of death - sample linkage and validation, and analysis, DD/MM/YYYY
- Postcode - sample linkage and validation, and analysis
- Admission Hospital - sample linkage and validation, and analysis
- Gender - sample linkage and validation, and analysis
- Ethnicity - sample linkage and validation, and analysis

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. The Group recognised the importance of collecting follow-up data from patients seen at other hospitals or who died in the community. Members raised no queries in this area.

Practicable alternatives

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

- Feasibility of consent

The applicant explained that it was important that all patients who received non-invasive ventilation were included in the study so that the predictive tool is appropriately validated.

The applicants had explained that eligible patients were likely to be very unwell and seeking individual consent was impractical. It was likely that a number of patients would have died in the year since their discharge. Patients were not required to undergo any additional tests and the data collected was observational only.

The CAG accepted the rationale that consenting patients was not feasible. Members were content to provide a recommendation of support under the Regulations.

- Use of anonymised/pseudonymised data

NHS Digital and NHS Wales Informatics Service required confidential patient information in order to perform searches of the ONS mortality database and the relevant hospital episode statistics databases. The Group raised no concerns in this area.

Justification of identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the study aims, and no queries were raised in this area.

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 an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out.

The Group commented that, from the information provided, it appeared that views had only been provide from one patient representative around the use of confidential patient information without consent.

It was recognised that wider activity had been undertaken in this area with additional lay persons within the trial steering group meeting. Members asked that the specific issue of access to confidential patient information without consent was tested with these patients who had already been consulted. Feedback around this activity was required prior to any final recommendation of support coming into effect.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The applicants explained plans to display notices in the other supplying Trusts, these would only be visible to patients if they were attending these hospitals. The Group asked that notices were made available on the websites of the trusts involved. Copies of these notices would be requested together with confirmation of the website distribution prior to support coming into effect.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Further patient and public involvement and engagement activity should be carried out to test the acceptability of using confidential patient information without consent. Wider lay representatives who have previously been involved

in the study should be approached to provide views. An overview of the activity undertaken, and feedback provided is required.

2. Provide copies of the patient notices which will be displayed at Trust sites for information.

3. Wider communications should be made available via the websites of participating Trusts – provide confirmation to this point and copies of any documentation.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee **(Pending)**.
2. Confirmation of suitable security arrangements for organisations processing confidential patient information with support (**Pending):**
    a. NHS Digital has a "standards met" grade on the DSPT submission,
    b. NHS Wales Informatics Service has a satisfactory CPIP Assurance report,
    c. Northumbria Healthcare NHS Foundation Trust – Pending confirmation of NHS Digital's review of the Data Security and Protection Toolkit.

d. 19/CAG/0077 - Enhanced surveillance of neonatal herpes simplex disease in UK and Irish infants less than 90 days of age.

Context

Purpose of application

This application from the Royal Alexandra Children's Hospital, Brighton & Sussex University Hospitals NHS Trust set out the purpose of medical research, where the applicants are seeking to determine whether infants who receive prompt treatment for Herpes simplex virus (HSV) have a better outcome that those whose treatment is delayed.

Herpes simplex virus (HSV) is a virus. This is very common and usually causes benign cold sores in adults. However, it can cause dangerous illness and death in new-born infants. Neonatal HSV disease is when the virus makes a baby sick in their first few days or weeks of life. This usually occurs as disseminated disease (affecting the blood) or HSV meningoencephalitis (affecting the brain). Both have a high mortality and severe consequences. Infants who receive prompt treatment for HSV have a better outcome that those whose treatment is delayed.

The last HSV surveillance study was undertaken over 11 years ago.

The applicants aim to study all cases of neonatal HSV in infants under 90 days of age in the UK and Ireland over a 2-year period between 2019 - 2021. Paediatricians will be asked to notify the applicants of cases of neonatal HSV as they occur via a routine reporting source called the British Paediatric Surveillance Unit (BPSU). The usual BPSU methodology will be followed. The condition will be included on the

BPSU “Orange Card” sent to members monthly be e-mail. This card has a list of disorders currently being studied and the clinician ticks a box if they have seen a case or ticks "nothing to report" if not. The BPSU records only the number of cases ticked and does not receive details of any cases.

The investigator will then send the study questionnaire directly to the reporting clinician. The questionnaire asks for clinical details of the case and for minimal identifiers. The front page of the questionnaire contains information only for case verification and de-duplication and can be separated from the remaining pages that contain clinical research data. The questionnaire can be completed online, via the REDCap system, or sent by secure email. The clinician can also choose to request a paper questionnaire.

The study will also investigate how each child has been in the year following their diagnosis, if they have residual problems or if they have had any relapse of the condition. Reporting clinicians will be sent a follow-up questionnaire after one year by the study team (this will be sent via a secure link to a REDCap questionnaire, or to secure nhs.net email if preferred). The case will have been assigned a unique study number by the BPSU: The reporting clinician will be given this number as a point of reference, in case they identify more than one case during the study period. This unique number and DOB only will be referred to when requesting follow-up information.

The applicants intend to collaborate with the RCOG UKOSS (UK Obstetric Surveillance System) to ensure that obstetric data are complete. The applicant confirmed that confidential patient information will not be shared with RCOG UKOSS. UKOSS has confirmed that, for all BPSU studies including this one, anonymous data (including names, hospital numbers, maternal DOB, etc.) is not collected / recorded. Their sole role is to facilitate contact with reporting clinicians in relevant local hospitals (there is one UKOSS reported for each hospital). The applicants will then liaise directly with the local team, using only infant and maternal DOB to link cases in order to request missing obstetric information.

HES/ONS data on cases of neonatal HSV will be requested to ensure the completeness of the data collected (i.e. to ensure that the number of cases reported via the BPSU system is equivalent to the number reported by these sources). This will provide reassurance that information on all cases of neonatal NHS during the study period have been captured; this is particularly important given the small number of cases expected. No confidential data will be disclosed to NHS Digital: cases will be linked using name of hospital, age & sex of baby only.

Local laboratories will be contacted by the study team in the uncommon event that there is incomplete information provided on the BPSU questionnaire (for example, HSV typing & CSF cell counts). The study team will contact the laboratory via telephone (to identify a senior lab member) and then an email will be sent by nhs.net mail to this team member, requesting missing data. Cases will be linked using the minimal patient identifiers, including DOB / date of sample.

A recommendation for class 2, 4 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort:

Infants of 90 days or younger diagnosed with Herpes Simplex Virus infection between 2019-2021. It is estimated that between 90 – 130 cases would be reported over the two-year period. This is anticipated to be June 2019-June 2021.

The following items of confidential patient information are required for the purposes specified:

- NHS number – sample validation and linkage,
- Hospital ID number – sample validation and linkage,
- Date of birth - sample validation, linkage and analysis,
- Date of death - sample validation, linkage and analysis,
- Hospital name and postcode - sample validation and linkage,
- Gender - sample validation, linkage and analysis,
- Postcode (district level) – analysis
- Ethnicity - analysis

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. HSV has severe consequences for babies and cases of neonatal herpes are on the increase, and the Group recognised the public interest in the study as the findings could be used to inform future practice on detection and treatment.

Practicable alternatives

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

- Feasibility of consent

Members considered whether consent should be sought and determined that this would alter BPSU methodology as the orange card system was conducted retrospectively. Patients may no longer be in contact with the clinical care team for consent to be sought. Seeking consent could lead to extra work for the study team or clinicians, and possibly cause distress to patients and families. Members noted that bias could be introduced through the loss of data subjects, due to the small number of patients. The Group raised no queries in this area.

- Use of anonymised/pseudonymised data

Confidential patient information is required in order to identify duplicate case notifications, as patients may be reported by more than one clinician. Counting these notifications as separate cases would lead to an erroneously high incidence of cases being recorded.

Minimal patient identifiers are required to accompany each case notification to allow for matching of duplicate records by the researcher. If questionnaires are incomplete or incorrect, then study investigators will need minimal identifiers to identify these patients in correspondence with the responsible clinician. The Group raised no queries in this area.

Justification of identifiers

The CAG was assured that the NHS numbers, Hospital ID number, date of birth and gender of patients were appropriate and proportionate to the study aims.

Patients' date of death was collected but it was unclear why. Members requested justification from the applicant for this data item.

It was also unclear whether postcode would be collected. Members requested that this was clarified.

Exit Strategy

Patient identifiers (NHS number, DOB, Sex, Hospital No. and ethnicity) will be collected along with clinical information about the patient via a questionnaire. On receipt of the questionnaire (electronic or paper), the study team will separate patient identifiers from the clinical information. They will be stored in separate locations, linked only by a unique study code.

Anonymised clinical information will be stored for 20 years, in accordance with MRC guidance. Patient identifiers will be used for the purpose of de-duplication only will be removed from the clinical information on a monthly basis.

The CAG accepted the rationale for retention of the clinical data for 20 years. Members noted that it was unclear what would happen to the identifiers, which were held in a separate server, and asked that the identifiers were destroyed as soon as possible. This would be clarified with the applicant. If not, justification for storing the identifiers for the full 20 years needed to be provided.

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 an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out.

The Group noted the patient and public involvement carried out and raised no queries in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The applicant had provided a standard BPSU patient-facing leaflet to support the study. The document provided an overview of the proposed activity and provided a means of objection via the treating team. The CAG recognised that this was in line with the standard communications mechanism for BPSU activities and raised no queries in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Further information on the identifiers collected needs to be provided;
   a. Explain why patients' date of death is required,
   b. Confirm whether postcode will be collected. If so, confirm in what format this is required and why.

2. Clarify how long confidential patient information will be retained. If this information is to be held for 20 years, then a strong justification to support this is required.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee **(Confirmed).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (IGT) submission **(Brighton And Sussex University Hospitals NHS Trust – Pending confirmation of NHS Digital's review of the Data Security and Protection Toolkit).**

b. 19/CAG/0080 - Parents' and children's informed and voluntary consent to heart surgery

Context

Purpose of application

This application from University College London set out the purpose of medical research to explore the views and experience of children referred for heart surgery. Children and their parents will be observed before and after surgery, and they will be interviewed post-surgery. Forty clinical staff will also be interviewed and selected discussions between staff and families will be recorded. Interviews will also be audio-recorded and transcribed. Wards, out-patient clinics and multi-disciplinary team (MDT) meetings, where the care of the patient will be discussed, will also be observed. Patients recruited into the study, their families/carers and staff will be consented for the above aspects.

The applicant explained that, due to the nature of multi-disciplinary meetings, it is possible that researchers will be present when doctors talk about patients who are not in the study. The researchers will not make any written notes of confidential information of patients who are not enrolled in the study. Medical meetings will not be audio-recorded.

Regarding the observation of daily activities in the wards and outpatient clinics, those present will be informed that they are being observed and of their right to opt out. Some families and children might find it difficult to opt out from being observed by directly saying this to the researcher or to a member of the staff. Red-stop cards will be provided, which they can display as an alternative to opt out. The researchers will wear a 'Researcher' badge, and display posters and give handouts to inform them about the research.

A recommendation for class 1, 2 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort:

60 patients between 6 and 15 years of age, who have undergone heart surgery at Great Ormond Street Hospital NHS for Children and Evelina Children's NHS Hospital. The age limit is for child participants is 15 years at the time of recruitment. The reason for not setting an upper age limit is that parents and healthcare staff are also participants.

The applicants do not require access to confidential patient information without consent for the purposes of the study analysis. Support is being sought in case of incidental disclosures during multi-disciplinary team meeting observations.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members observed that seeking the views of children and parents would aid clinicians in the future when undertaking the consent process for heart surgery in children, and therefore was in the public interest. The Group raised no queries in this area.

Practicable alternatives

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

- Feasibility of consent

The applicant explained that only the confidential patient information of patients who, or their parents/carers, had consented into the study would be processed. There was a possibility that the researchers would be exposed to incidental disclosures of confidential patient information relating to wider patients who were not consented whilst observing multi-disciplinary team meetings. In this case, no information about these patients would be recorded by any means.

The applicant explained that they could not predict which cases might be discussed during the observation of the multi-disciplinary team meetings, and it was impracticable to seek consent from all patients who may be discussed.

Members noted that multi-disciplinary team meetings were usually administrated by a co-ordinator and queried whether it was possible for the co-ordinator to arrange to have the patients who had consented to the study discussed in a block so that the researcher could be present only for these discussions. The researcher could then leave the meeting prior to discussion of further cases.

The Group queried what would happen in practical terms once a patient opted-out and whether the multi-disciplinary team would be informed in advance about an opt-out, so that the researcher could leave the room before the patient who had opted-out was discussed.

The Group did not agree that the researcher leaving and re-entering the room during the meeting would be detrimental to patients and clinical staff. Members noted that it was unclear whether the protocol required that clinical staff were blinded to which patients were in the study, in which case there was a rationale for the researchers remaining in the room for the duration of the meeting.

Members were not assured by the rationale provided in this area. Practicable alternatives appeared to be available which would prevent the researchers being exposed to wider patient information. It was agreed that further information would be required from the applicants to support the requirement for support under the Regulations for this activity.

- Use of anonymised/pseudonymised data

The applicant explained that no confidential patient information would be held without consent. The Group raised no queries in this area.

Justification of identifiers

The Group noted that no confidential patient information would be held by the applicants without consent. The Group raised no queries in this area.

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 an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out.

The Group noted that members of the Children's Heart Foundation had reviewed the research proposal and expressed no concerns about the observation of multi-disciplinary team meetings. Members asked if the acceptability of possible disclosures of confidential patient information relating to patients who had not consented had been discussed. It was agreed that further information was required in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The CAG observed that the study poster advised patients to inform the researcher or a nurse if they wished to opt-out of the researcher being present during discussions. The study leaflet did not contain information about the incidental disclosures and how to opt-out. Members agreed that the leaflet would need to be amended to contain this information, if the project was to support with support under the Regulations.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, whilst supportive of the proposal in principle, due to the clear medical purpose and public interest in the proposed activity, it was unable to provide a recommendation of support where it appeared a practicable alternative was available.

The applicant is asked to consider the below guidance around a potential practicable alternative to enable the project to proceed without the requirement to seek support under the Regulations in the first instance.

1. Consider if it is possible for the multi-disciplinary team co-ordinator to arrange discussion of consented patients in a block so that the researcher can be present for these discussions only.

2. If this can be implemented, there would be no requirement for support under the Regulations as steps had been implemented to prevent incidental disclosures of confidential patient information. The project could proceed without the requirement to resubmit the application for CAG review.

3. If this cannot be implemented, or is deemed unfeasible, a further application could be made to the CAG to seek support under the Regulations. This would need to provide a clear and detailed argument to justify why this alternative methodology cannot be implemented.

Request for further information

If progressing with the CAG application, the following additional points would need to be addressed:

Clarify whether the protocol requires that clinical staff are blinded to which patients were in the study.

1. Confirmation that the acceptability of possible disclosures of confidential patient information relating to patients who had not consented to the study had been specifically discussed with the patient and public involvement group is required. Provide details of the activity undertaken in this area and the feedback provided.

2. Revise the study leaflet to contain information about the possibility of incidental disclosures at MDT meeting and provide details of how to opt-out.

3. Clarification needs to be given regarding what will happen in practical terms once a patient opts-out and whether the multi-disciplinary team will be informed in advance about an opt-out, so that the researcher can leave the room before the patients who opt-out are discussed.

c. 19/CAG/0086 - Pre-operative CPEX and 90-day mortality after oeosphagectomy

Context

<u>Purpose of application</u>

This application from the Norfolk and Norwich University Hospitals NHS Foundation Trust set out the purpose of medical research to determine whether a fitness test prior to surgery to treat oesophageal cancer can identify patients most at risk of dying.

In the UK, 25 people are diagnosed with oesophageal cancer every day, but only three will be still be alive within five years. Surgery can cure oesophageal cancer. However, out of 100 people who undergo surgery, four die within the first three months. Fitter patients may have a better chance of surviving their operation. The applicants seek to determine if a single exercise bike test before surgery can identify the patients most at risk of dying and if improving the fitness level of patients can help them to survive after surgery.

To measure this association, the applicants will use a national audit dataset, the National Oeosphago-gastric Cancer Audit (NOGCA) held by NHS Digital, which has information on all oesophagectomies undertaken in the UK. NHS Digital will be asked to provide NHS numbers of patients to be included in the dataset. All other variables will relate to their clinical care e.g. date of operation and histology of their oesophageal cancer.

This dataset will allow the applicants to identify all oesophagectomies undertaken in the UK between 2012 to 2018 by hospital site. NOGCA does not measure CPEX scores. Therefore, the only way to link oeosphagectomy patients with their CPEX data is to use their NHS number as an identifier. The NHS number will be given to the care team of the patient at each hospital, so the care team can link the dataset with CPEX values. Each participating site will receive a login for REDCap, which will have a list of NHS numbers requiring CPEX data to be linked. Once the applicants receive this data from each site, the NHS number will be removed and the dataset will be anonymised for subsequent data analyses. If 90-day mortality data is missing from NOGCA, the local participating NHS site may be asked to supply this.

By analysing the subsequently anonymised data, the applicants will determine whether CPEX scores (fitness) are associated with 90-day risk of death.

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

<u>Confidential patient information requested</u>

Cohort:

Male and female patients between the ages of 18 and 100 who underwent an oesophagectomy between 1 April 2012 to 31 March 2018. Cohort size is 3278 patients.

The following items of confidential patient information are requested the purposes set out below:

- NHS Number – sample validation and linkage
- Hospital in which the operation was performed – sample validation, linkage and analysis
- Date of death – analysis
- Gender – analysis

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. The applicants are seeking information on how to improve the survival rates of patients who have undergone oesophagectomies. The Group accepted that the application was in the public interest and raised no queries in this area.

Cohort

The application did not provide any information around the number of eligible patients include in the audit dataset within the specified timeframe. However, the total sample size given in the application was 3278 patients.

The Group considered this information and agreed that some further reassurances were required in this area. The applicant would be asked to provide assurance that data was being requested for the minimum number of patients required to conduct the study. Assurance was also required that the patient numbers were enough to make the study analysis scientifically sound.

Practicable alternatives

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

- Feasibility of consent

The applicants explained that a majority of patients will be deceased, as even after curative resection, the survival rate is low.

More than 3000 patients, or their families, would need to be contacted in order to request consent. The applicant advised that the research team did not have the resources available to contact this number of patients. The Group raised no queries in this area.

- Use of anonymised/pseudonymised data

The applicants explained that confidential patient information was needed for data linkage as the NHS Number was the only item of data that could be used within Trusts to link data on oesophageal operations with CPEX and mortality data.

The Group considered whether it was necessary for the applicants to identify the patient cohort from the audit database. At Q14 of the application form, it was noted that some centres participating in the research study may not participate in the national audit. The applicant had stated that these centres would be able to provide an anonymised dataset of the linked data required for the study analysis.

Members queried why this same methodology could not be applied to the wider centres which were participating in the audit and the proposed study. The Group agreed that further clarity was required from the applicant on why it was not practicable for all participating sites to provide data in this format. This would be followed up with the applicant to provide assurance that this did not provide a practicable alternative to seeking support under the Regulations.

Justification of identifiers

In the application form, it was stated that information on 90-day mortality may be requested. It was suggested that date of death would be required. However, the protocol stated that the outcome of 90-day mortality would be provided in binary form. The Group requested clarification on where this information would be obtained from and whether the full date of death was required.

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 an unconsented activity should go ahead.

The applicant advised that they had interacted with the Oesophageal Patients Association (OPA), an independent national charity which provided high quality information for patients, their carers and family. The local representative for the charity provided comments on the application and indicated support for the proposal.

The Group received this information but agreed that further work could be undertaken to engage with the patients, carers and families which the charity supported. It was agreed that a plan of further patient and public involvement engagement activity would be required from the applicant prior to support coming into effect. The applicant would be asked to provide a report against this planned activity at the time of annual review.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The applicant explained that the information available on the NOGCA website covered the activity to be undertaken for this application. On review, it was noted that the information on the website referred to anonymised data being made available to researchers, which did not cover the activities undertaken in this application.

The Group requested that a project-specific communication was made available via the NOGCA website, which provided patients with contact information and a means of dissent. Copies of these documents would be required prior to a final recommendation of support coming into effect.

Confidentiality Advisory Group advice conclusion

The CAG agreed that, whilst supportive in principle of the proposal due to the clear medical purpose and public interest, further information would be required prior to confirming that the minimum criteria under the Regulations had been met. The CAG therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Provide further clarity around why it is not practicable for all Trusts participating in the study, regardless of their participation in the national audit, to provide an anonymised linked dataset of information required for analysis.

2. Confirm the overall patient cohort which is needed for the purposes of study analysis.

3. Provide assurance that this patient cohort was of a sufficient size to make the study scientifically sound. If the proposal has undergone statistical review, evidence of this can be provided as support to this point.

4. Clarify the source of the 90-day mortality information and confirm that date of death would be provided in binary format as detailed in the protocol.

5. A project-specific communication strategy is required to promote the study via the NOGCA website and provide patients with an objection mechanism. Copies of any supporting documentation are required for review.

6. Further patient and public involvement and engagement activity should be planned. An overview around how this will proceed should be provided for review.

Specific conditions of support (Provisional)

1. A report will be required at the time of first annual review around the wider patient and public involvement and engagement activities which have been undertaken against the plan. If the feedback provided is negative, the CAG would take this

into account when considering whether support can continue or whether further information is required.

2. Favourable opinion from a Research Ethics Committee **(Confirmed).**

3. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission. **(Pending - DSPTs required for Norfolk and Norwich University Hospitals NHS Foundation Trust).**

d. 19/CAG/0111 - Cambridge Blood and Stem Cell Biobank

Context

Purpose of application

This application from the University of Cambridge set out the purpose of creating a research tissue bank, which aims to provide tissue for use in research into blood or stem cell related disorders, or the study of normal developmental processes.

There will be four broad groups of samples in this biobank. The first group are samples collected prospectively from healthy bone marrow, lymph node biopsy, stem cell harvest and normal cord donors. The second group is comprised of samples collected from patients with haematological malignancies, immunological disease and related disorders. These samples will be obtained from diagnostic/surgical routes, or as an additional peripheral blood sample or buccal swab. Group 3 are samples obtained from staff, unaffected relatives and other individuals recruited to donate normal blood and buccal swabs only. The fourth group are existing materials imported from other ethically approved studies and clinical trials.

The CAG application concerns eligible patients in Groups 1 and 2. These patients will be identified by research staff, who will review clinic lists and hospital medical records only for patient identifying data by screening potential participants beforehand and may also note anyone deemed not appropriate for research. In line with hospital policy, potential participants will then be approached by members of the clinical care team in the first instance. The research team will be involved both in identification of patient participants with the relevant condition and taking informed consent.

Some cases will be more sensitive, and the clinical care team will direct the whole consent process as they will have a far better understanding of which donors might be appropriate for the research. The relatives of existing patient donors will be identified by a member of the clinical care team caring for the donor, and appropriate information will be given to them. Also, prospective stem cell harvest donors will be identified by a member of the clinical care team on the wards or in the out-patient clinic where the donor is being assessed for stem cell harvest. The research team will only look at these records after consent has been given.

All data will be link-anonymised using a unique code so that researchers do not receive identifying information. Identifying information held will be name, MRN and date of birth for NHS patients, and name only for staff donors. Samples transferred from other studies and outside the UK are anonymised on arrival if not already anonymised at source. Identifying data will be held in NHS systems only.

A recommendation for class 1, 3 and 6 support was requested to the activities as described in the application.

Confidential patient information requested

Cohort:

Patients with haematological malignancies, immunological disease and related disorders, and healthy volunteers who have donated umbilical cord blood, bone marrow, lymph node biopsy and stem cell harvest donors.

The following items of confidential patient information are requested for the purposes set out below:

- Name – sample linkage and validation
- NHS Number – sample linkage and validation
- Hospital Number – sample linkage, validation and analysis
- Date of birth – sample linkage, validation and analysis

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. The applicants were seeking to establish a tissue bank to provide tissue for use in research into blood and stem cell related disorders, which was in the public interest.

Practicable alternatives

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

- Feasibility of consent

The Group noted that the application for support under the Regulations related to two of the four groups which would be included in the tissue bank. The two groups which were excluded from the CAG application related to healthy controls, made up of staff and unaffected relatives and the importing of existing samples from wider

studies or tissue banks which had the appropriate regulatory approvals. These two groups did not fall within the legal remit of the CAG to consider.

The application was seeking support for research staff, including research nurses or the study coordinator, to access confidential patient information within medical records to enable eligible patients to be identified and approached for consent by the direct care team. The applicant had explained that there was no capacity within the clinical care team to undertake this screening. However, it was also stated that the eligibility process would be directed by the clinical care team. The Group agreed that a stronger rationale was required from the applicant to explain why medical record screening could not be undertaken by the direct care team, to prevent the need for support under the Regulations.

- Use of anonymised/pseudonymised data

Access to confidential patient information is required so that the applicants can identify patients suitable for inclusion in the tissue bank. This could not be done using anonymised or pseudonymised data. The Group acknowledged the eligibility screening could not be achieved without access to confidential patient information and raised no queries in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested to identify eligible patients were appropriate and proportionate to the study aims. No issues were raised in this area.

Exit Strategy

Members noted that the date of birth and hospital ID numbers of patients who dissented or were deemed ineligible were retained by the study team. The applicants had explained that this was so patients were not re-approached. The Group agreed that the applicants would be asked to consider if there was another way of flagging these patients, so that confidential patient information did not need to be retained.

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 an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out.

The Group commented that the patient and public involvement activity was not extensive but agreed that as support was required for limited aspects of the study, this was adequate and raised no queries in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The Group observed that the poster and postcard submitted with the application did not include information on how patients could dissent from inclusion. Members asked that a paragraph was included, explaining how eligible patients were identified and to provide a means of dissent. Revised materials should be provided for consideration.

It was noted within the protocol document that information sheets and cards about the study would be provided to eligible cord donors within the maternity care pack, which was also known as 'Bounty Pack'. The Group understood that the Bounty packs were provided by a commercial organisation, Bounty, and requested reassurance that this company was not provided with any confidential patient information pertaining to the patients. It was further queried whether, as the clinical care team would be approaching patients directly for consent, there was an opportunity for the study information materials to be provided separately to this wider standard care maternity information.

Confidentiality Advisory Group advice conclusion

The CAG agreed they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Provide further information to explain why it is not feasible for the direct care team to carry out the initial identification of eligible patients prior to approaching for consent.

2. The poster and postcard provided should be amended to address the following points:
    a. Include an explanation about how eligible patients would be identified, explaining access to medical records by research staff,
    b. Provide a means for patients to dissent from being approached about the study.

3. Consider whether there is an alternative method to flag patients who had dissented or were deemed ineligible within the hospital record to prevent the need for confidential patient information needing to be retained in the database.

An alternative mechanism should be described, or a stronger justification provided to support the ongoing retention.

4. Confirm that confidential patient information relating to patients would not be disclosed to the commercial organisation which supplies the Bounty packs.

5. Consider whether information and consenting materials around the study could be provided to potentially eligible patients separately from the wider standard of care maternity information materials. Provide details of a revised distribution method, or a stronger justification to support why inclusion in the Bounty pack is necessary.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee **(Pending).**
2. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (IGT) submission (**Pending – DSPTs required for Cambridge University and Cambridge University Hospitals NHS Foundation Trust).**