Health Research Authority

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

January 2019

Present:

Name	Capacity	Items
Dr Tony Calland MBE	Chair	1.a., 1.b. 1.c. 2.a.
Dr William Bernal	CAG Member	1.a. 2.a.
Ms Sophie Brannan	CAG Lay Member	1.b. 1.c.
Dr Barry Evans	CAG Member	1.b. 2.a.
Dr Lorna Fraser	CAG Member	1.d. 1.f.
Mr Myer Glickman	CAG Member	1.a. 1.c.
Mr Anthony Kane	CAG Lay Member	1.e.
Dr Rachel Knowles	CAG Member	1.e. 1.f.
Dr Murat Soncul	Chair	1.d. 1.e. 1.f.
Mr Marc Taylor	CAG Member	1.d.

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 19/CAG/0002 - Outcome of resuscitated term babies with no heart rate detected at 10 minutes of age

Context

Purpose of application

This application from NHS Lothian set out the purpose of medical research which aims to identify the incidence of babies born at term which received prolonged resuscitation after delivery and have no heart rate detected at 10 minutes. The study will collate information around the demographics, clinical features and initial management of this patient population. The study also aims to describe the mortality rate, timing and cause of death for those patients within this cohort which do not survive.

This study is run through the British Paediatric Surveillance Unit (BPSU) "Orange Card" notification scheme. The BPSU methodology has received support in principle from the CAG. All senior paediatricians in the UK are sent a monthly email asking if they have seen any cases that match the definition of currently running studies. The BPSU informs the research team of potential cases and the team will approach the notifying clinician for further details. The study will run a 24 month reporting period. An initial assessment questionnaire will be completed at birth. For those babies who survive, follow-up will be carried out at one and two years to assess the neurodevelopmental outcome.

Case ascertainment will be maximised by flagging the study with the MBRRACE-UK (Mothers and Babies: Reducing Risk through Audit and Confidential Enquiries across the UK) audit programme, to ensure that babies who die are also captured in the project. Any infant captured via the MBRRACE-UK audit would be reported to the study as standard via the orange card system.

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

Confidential patient information requested

Cohort

Term infants who are resuscitated at birth and have no detectable heart beat at 10 minutes. It is anticipated that around 300 babies would be reported across the 24 month reporting period.

The following items of confidential patient information will be released from participating Trusts and Health Boards in England and Wales to the applicants for the purposes set out below:

- NHS number – sample validation,
- Hospital Number – sample validation and follow-up,
- Date of birth – sample validation and analysis,
- Date of death – sample validation and analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the application defined an appropriate medical purpose, which was medical research. Members recognised the potential benefits in the proposal for both babies and their families, as it was intended to extend the knowledge base on the outlook for these babies which may help future decisions on resuscitation and ongoing intensive care. The Group agreed that the proposal was within 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 applicant had advised that consent was not feasible for the project on this basis that complete case ascertainment was required and it had the potential to introduce sample bias. The Group agreed this was valid justification when studying a rare condition and raised no issues in this area.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was required to validate the patient sample and prevent case duplication. Minimal patient identifiers would be retained to facilitate the longer term follow-up at one and two years, which was necessary to facilitate patient identification. The CAG was assured that processing confidential patient information was necessary and raised no issues in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the application aims. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was confirmed that for surviving patients, confidential patient information would be retained until the two year follow-up questionnaire had been returned. For deceased patients, confidential patient information would be destroyed at the point the research team received notification of the child's death and any relevant clinical information required for analysis. The CAG was assured by the planned exit from support under the Regulations and raised no issues 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. Members noted that representatives from SANDS (Still Birth and Neonatal Death Charity) and BLISS (For Babies born Premature or Sick) had reviewed the study protocol and patient information materials. It was further acknowledged that as part of the BPSU review process, the study was considered by the BPSU Scientific Committee, which included two lay members. The Group was assured by the engagement and support of the named charities for the study 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 copies of a study information leaflet and supplementary text which would be displayed on the BPSU website for consideration. Members agreed that the documentation provided a clear overview of the study and detailed the right to dissent. A study poster would also be displayed in outpatient waiting rooms and inpatient ward noticeboards. The CAG agreed that sight of this document was required prior to any final recommendation of support coming into effect.

Security Assurance

It is the policy position of the Department of Health in England that all approved applications seeking support under these Regulations must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the NHS Information Governance Toolkit (and its new format moving forwards).

It was noted that relevant organisations in Scotland do not routinely complete the English Information Governance Toolkit; however, the application detail confirmed that processing of confidential patient information would take place at Scottish sites.

It was noted that separate to the CAG consideration, a process had been agreed that where the Scotland's Public Benefit and Privacy Panel had approved relevant processing in relation to Scottish sites, that this would be accepted as adequate for security assurance purposes. This application had acted as a 'test' case to ensure the process was suitable for all parties.

Once a final approval letter is provided from the PBPP, this will be accepted as providing adequate security assurances in relation to Scottish sites. It was also noted that at time of annual review, the most current and up to date letter from PBPP should be provided as evidence of continuing support.

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 (Summary)

1. A copy of the study poster should be provided.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and final 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, the HRA will confirm approval and support will come into effect following this confirmation.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 08 March 2017**).

2. Final approval letter from the Scottish Public Benefit and Privacy Panel (PBPP) in relation to this study. (**Pending**).

b) 19/CAG/0004 - Follow up of young people treated in CAEDS 2009-2014.Longitudinal Follow Up of Eating Disorder Treatment (L-FED)

Context

<u>Purpose of application</u>

This application from South London and Maudsley NHS Foundation Trust set out the purpose of medical research which aims to follow-up a cohort of people who were treated for an eating disorder when they were in their childhood or adolescence, to gain understanding of their health, wellbeing and use of other services since discharge. The study aims to bring the gap between the follow-up carried out as part of a randomised-controlled trial and population-based longitudinal studies. This will aid a greater understanding of the maintenance of treatment effects beyond initial trial follow-up and identification of factors predicting chronicity which will inform further treatment development.

A Research Associate/Assistant Psychologist will be appointed for the purposes of the study to the clinical care team; however, this individual will not be known to the former patients. Support has been

requested under the Regulations to legitimise this individual's access to confidential patient information in order to facilitate the invitation process for the follow-up study. Former patients will initially be contacted by postal invitation letter, which will be followed-up by telephone and email contact. A maximum of four attempts to contact the patient would be made across all four communication mechanisms.

A recommendation for class 2, 3 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

358 patients treated in the National and Specialist CAMHS Eating Disorder Service, South London and Maudsley NHS Foundation Trust (CAEDS) between 01/08/2009 and 31/01/2014. These patients would now be aged 16-27 years.

The following items of confidential patient information are requested for sample validation and to facilitate the invitation process:

- Name,
- Date of birth,
- Full address and postcode,
- Email address,
- Telephone number.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose which was medical research. Members recognised that the proposed activity had an established public interest in following up patients who had been treated for an eating disorder in childhood to gain an understanding of how their health and wellbeing had progressed once discharged from the services.

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 recognised that access to confidential patient information was being sought in order to facilitate an invitation and consent basis for the proposed research. The CAG was satisfied that seeking consent prior to the invitation process was not feasible, as eligible patients would need to be identified to be approached. No issues were raised in this area.

- Invitation by the Direct Care Team

The applicant had explained that due to the historic nature of the patient cohort to be included in the study, their previous clinicians may no longer be working within the Trust service. It was further noted that patient records would need to be accessed in order to determine the past clinicians, so the breach of

patient confidence would have already occurred at this point. The Group was satisfied that recruitment by the historic direct care team was not feasible.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was necessary to identify the eligible cohort and to facilitate the invitation process which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The CAG was satisfied that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Members recognised that patient consent was the intended exit strategy from support under the Regulations. The applicant anticipated that the study would take six months to complete.

For patients who declined consent to participate, confidential patient information would be destroyed at the point dissent was informed.

For those patients who do not respond to the invitation request, confidential patient information will be destroyed one month following the final attempt to contact. Onward retention of confidential patient information would only be for those patients who consent to participate in the study.

The Group was satisfied with the proposed exit strategy from support under the Regulations. It was recognised that a maximum of four attempts would be made to contact the patient cohort and Members were supportive of the limited retention period following last contact attempt for confidential patient information in relation to those patients who did not respond. No issues 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 CAG recognised that the applicants had engaged with both patients and parents of the Child and Adolescent Eating Disorder (CAEDs) involvement group around the project, the recruitment methodology and patient-facing materials.

With regards to the recruitment methodology and access to confidential patient information without consent, the applicant explained that five families were directly consulted and were supportive on the basis that access was limited to contact details prior to the patient providing consent. Three parents and two young people assisted with the preparation of recruitment documentation.

It was further noted that three parents of former patients sit on the CAEDs research steering group which would be consulted during the management and dissemination of findings. The activity is proportionate to the proposed activity and the findings provided are supportive. Members were assured by the activity which had been carried out in this area, which sought the views of a relevant patient and public group around the proposed activity. The outcomes were supportive of the project and its design and the Group raises 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 confirmed that study-specific notification would be carried via social media. Tweets would be issued from Beat (the eating disorders charity), SLaM and Kings Eating Disorder Research accounts about the study. A draft of this text was provided for review.

Members were supportive of the proposed communications strategy for the study, which appeared appropriate for a young adult population which had been discharged from the services.

The Group commented that the invitation materials did not provide specific information around the patient's ability to dissent to their involvement in the study. It was recognised that these documents had been reviewed by both the patient and public representative and the Research Ethics Committee. As such, Members support would be recommended on a conditional basis, with confirmation required from the applicant within one month of this outcome, that the invitation letter had been revised to include detail around the patient's right to object.

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. Revise the patient invitation letter to include a sentence around the patient's right to object to their participation in the study. Confirmation should be provided within one month of the date of this outcome letter that this has been actioned, and a revised document provided for information.

2. Favourable opinion from a Research Ethics Committee (**Confirmed – 20 December 2018**).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – South London and Maudsley NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

c) 19/CAG/0013 - Cerebrovascular accident and Acute coronary syndrome and Peri-operative Outcomes Study

Context

<u>Purpose of application</u>

This application from the University of Nottingham sets out the purpose of medical research which aims to better understand the link between poor surgical outcomes for patients who have previously suffered a heart attack or stroke.

The study will link together information from the following four data sources:

- Sentinel Stroke National Audit Programme (SSNAP) – Healthcare Quality Improvement Partnership (HQIP – controller) carried out by King's College London,

- Myocardial Ischaemia National Audit Project (MINAP) Healthcare Quality Improvement Partnership (HQIP – controller) carried out by the NICOR (National Cardiovascular Outcomes Research) team at Bart's Health NHS Trust,
- Hospital Episodes Statistics (HES) – NHS Digital,
- ONS Mortality Data – NHS Digital.

Confidential patient information will be disclosed from SSNAP at King's College London and MINAP by NICOR at Bart's Health NHS Trust to NHS Digital, which will act as trusted third party and facilitate linkage with the wider datasets and disclose a pseuodnymised dataset to the University of Nottingham for analysis.

A recommendation for class 1, 2, 4 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All patients aged over 18 years listed with one or more surgical episode in the HES dataset between 01/01/2007 and 31/12/2017. It is estimated that this primary cohort would include 44 million patients in this initial primary cohort of which, around 400,000 patients would be expected to have undergone surgery having previously suffered a stroke or heart attack.

The following items of confidential patient information will be released from both the Sentinel Stroke National Audit Programme at King's College London and Myocardial Ischaemia National Audit Project from the National Cardiovascular Outcomes Research team at Bart's Health NHS Trust to NHS Digital to facilitate linkage and other purposes where specified:

- NHS Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage,
- Date of death – analysis,
- Hospital Trust – analysis,
- Sex – 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. The study is in the public interest as there is potential to benefit future patients by better informing decisions on risks and timing of surgery for those with a history of stroke or heart attack.

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 was assured that on the basis of the size of the primary and sub-cohorts for inclusion in the study, consent was not feasible for this proposal.

- Use of anonymised/pseudonymised data

Processing of confidential patient information is required to facilitate the linkage process between the specified datasets, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information specified were appropriate and proportionate to the proposed activity. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support under the Regulations had been requested on a time limited basis only to facilitate the data linkage between the various specified data sources. The applicant confirmed that NHS Digital would retain the patient identifiers for a period of three months following completion of the linkage in order to address any issues with the pseudonymised anlaysis dataset. Members were assured by the methodology put in place for the project and 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 applicants had sought views from the National Institute of Academic Anaesthesia Patient, Carer & Public Involvement & Engagement group around the project. Whilst this activity had been limited to five individuals, the feedback provided was supportive of the project. Members acknowledged that whilst the activity in this area was limited in terms of the number patients involved, the patient group involved was appropriate and the activity carried out proportionate to the level of intrusion within the study. No issues were raised 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 confirmed that a study-specific communications mechanism and project-specific dissenting mechanism was being progressed with both Barts Health NHS Trust and King's College London. Members acknowledged the precedent which had been established in previous applications for this notification mechanism, when utilising data collected under the national audit programmes. The CAG was content to recommend support conditionally on this basis. Confirmation of the communication strategy, project-specific dissenting mechanism and sight of the patient-facing materials to support this would be requested within three months of this outcome being issued.

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

1. Confirmation of the project's communication strategy, established with Barts Health NHS Trust and King's College London should be provided within three months of this outcome letter. This should include details of the project-specific dissenting mechanism together with copies of any patient-facing documentation for review.

2. Favourable opinion from a Research Ethics Committee (**Confirmed – 19 December 2018**).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University of Nottingham (controller) and NHS Digital (processor) have published satisfactory reviewed grades on V14.1, 2017/18**).

d) 19/CAG/0011 - British Ophthalmic Surveillance Unit: National Surveillance of the Incidence of Fungal Keratitis in the United Kingdom

Context

Purpose of application

This application from the London School of Hygiene & Tropical Medicine set out the purpose of medical research which aims to evaluate the incidence of Fungal Keratitis in the UK. The study will use the established British Ophthalmological Surveillance Unit (BOSU) methodology to support data collection for the study.

The BOSU reporting card system, a methodology approved in principle by the CAG, would be used: this is a compulsory reporting system for ophthalmologists who are obliged to report an incidence of any of the rare conditions currently under surveillance. For this proposal, when a case of Fungal Keratitis is encountered, the clinician would record this on a monthly reporting card which is returned to BOSU. BOSU then notify the research team, who would send a questionnaire to every clinician for each reported case of this condition. The clinician enters clinical data in relation to the patient on the questionnaire and returns it to the research team. A follow-up questionnaire is sent after six months. Fungal Keratitis will be included on the BOSU card for a 13 month reporting period. The study will involve all UK nations; however, the remit of the CAG extends to England and Wales only.

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

Confidential patient information requested

Cohort

All patients diagnosed with acute fungal keratitis in England and Wales across the 13 month reporting period. It is estimated that around 300 cases would reported within this time period.

The following items of confidential patient information will be disclosed by the treating ophthalmologists to the applicants at the London School of Hygiene & Tropical Medicine for the purposes specified:

- Hospital ID – sample validation and linkage,
- Month and year of birth – analysis,
- Postcode (Sector Level) – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members agreed that there was a clear public interest in gaining a wider understanding of the prevalence and effect of Fungal Keratitis.

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 recognised that the project would follow the established BOSU methodology and it was agreed that the importance of complete case ascertainment for this project was sufficient justification to support that consent was not feasible. No further issues were raised in this area.

- Use of anonymised/pseudonymised data

Members were assured that the limited patient identifiers requested were required to facilitate sample validation and patient follow-up. It was recognised that the information items requested were limited and had been reduced to a less identifiable format; however, as the study focussed on a rare condition, the risk of identifiability was increased in this instance. The Group acknowledged that the collation of limited data items was in line with the agreed BOSU methodology and it did not appear possible to fully anonymise the dataset. No issues were raised in this area.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity and raised no issues in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Confidential patient information would be retained for the data collection period only, to enable sample validation and to facilitate the six month follow-up. An anonymised dataset would then be created for analysis and all items of confidential patient information would be destroyed. No issues 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 application was considered by the Lay Advisory Group at the Royal College of Ophthalmologists, in line with the standard BOSU review processes. It was also noted that the scope of data collection was informed by lay input. The activity in this area was appropriate and proportionate to the proposed activity and no issues were raised by the Sub-Committee.

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. A patient information leaflet had been drafted which would be made available across participating Trusts and Health Boards.

The Group noted that the document made reference to patients being anonymously included in the study. It was commented that this did not accurately explain that items of confidential patient information would be disclosed by the treating ophthalmologist to the research team. It was agreed that the document would require revision to explain that limited patient identifiers would be disclosed for the purposes of the study. Members agreed that support under the Regulations would be recommendation on a conditional basis, with a request that the revised patient information leaflet was submitted within two months of support coming into effect. This should be supported by appropriate evidence that the revised document has been accepted by the reviewing Research Ethics Committee.

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. Revise the patient information leaflet to clearly explain that limited items of confidential patient information would be disclosed by the treating clinician to the research team for the purposes of the study. A copy of the revised document should be provided within two months of the date of this letter together with evidence that this document has been accepted by the reviewing Research Ethics Committee.
2. Support extends to England and Wales only.
3. Favourable opinion from a Research Ethics Committee (**Confirmed**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - London School of Hygiene & Tropical Medicine has a published satisfactory reviewed grade on V14.1 2017/18**).

e) 19/CAG/0023 - Naevoid Melanoma: Prognosis between two subtypes

Context

<u>Purpose of application</u>

This application from the Royal Surrey County Hospital set out the purpose of medical research which aims to investigate whether there is a prognostic difference between two sub-types of naevoid melanoma. These comprise of papillomatous and maturing naevoid melanomas, both with distinct clinical, histopathological and immune-histochemical features that may also be prognostically significant.

The eligible patient cohort will be identified from records and sample slide review by the Chief Investigator at the Royal Surrey County Hospital. Once the patient cohort has been identified, wider patient records will be accessed by the named study coordinator in order to extract wider clinical

information for analysis and to enable patient outcomes to be followed up with their referring clinician. Support is requested under the Regulations to extend to the study coordinator's access to confidential patient information, as this individual is not deemed to be part of the direct care team.

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

Confidential patient information requested

Cohort

Patients aged 16 and over who have been diagnosed with naevoid melanoma, following treatment at the Royal Surrey County Hospital. 151 patients would be included in the study, identified retrospectively between 01/04/2004 and 30/06/2017.

The following items of confidential patient information will be extracted from the Royal Surrey County Hospital pathology records and will be utilised for the following purposes:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID – sample validation and linkage,
- GP Registration (Name and Address) – sample validation and linkage,
- Date of birth – sample validation, linkage and analysis,
- Date and cause of death (calculated to age) – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised that there was a public interest in the proposed study, which aimed to identify whether there was a prognostic difference between two sub-types of naevoid melanoma.

Cohort

Members agreed that further clarity around the patient cohort to be included in the study was required. It was noted that both the application form and protocol stated that only patients with naevoid melanomas were eligible for inclusion in the study; however, the detailed secondary outcomes referenced non-naevoid melanomas. It was unclear whether a comparison control cohort was being included. Clarification was required from the applicant around the scope of the patient cohort prior to any recommendation of support coming into effect.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data 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 had explained that a proportion of the patient population to the included in the study would be deceased, so consent would not be possible for this sub-cohort. It was further commented that there was potential for an approach for consent to cause distress amongst living patients. Members were

assured by the rationale provided and agreed that operating a consented model for the proposed activity was not practicable.

- Use of anonymised/pseudonymised data

It was confirmed that the direct care team did not have capacity to carry out the data extraction on behalf of the research team. The Group recognised that access to confidential patient information within patient records and facilitation of the patient follow-up process could not be otherwise achieved and raised no issues in this area.

- Processing by the Direct Care Team

The applicant confirmed that the direct care team did not have capacity to carry out the data extraction on behalf of the research team. Members accepted the justification and raised no issues in this area.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The CAG was not assured that all items of confidential patient information which had been requested were necessary for the purposes of the study. Whilst it was recognised that the study coordinator would have access to the patient's full medical record, Members were not assured that the items of confidential patient information which would be extracted had been sufficiently justified. As an example, it was queried why patient name, NHS Number and Hospital ID were all required.

The Group agreed that the applicant would be asked to reassess the items of confidential patient information requested for the study. Clarification would be required around the data items which had been determined to be necessary, together with a clear justification to support these items measured against the potential risk of identifiability.

The Group further noted that the follow-up correspondence would include patient name and NHS Number. It was commented that there was risks in disclosing such identifiable data items. Members queried whether it would be possible to reduce the data items shared in this correspondence by including a study specific-ID. The applicant would be asked to consider this point with a view to reducing the items of confidential patient information disclosed in the correspondence.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Members acknowledged that the exit strategy from support under the Regulations which had been proposed in the application was anonymisation prior to analysis. However, it was unclear over what timeframe this would be carried out as the application suggested that information may be retained for up to five years.

The CAG agreed that clarification would be sought from the applicant around the expected timeframe for the exit from support under the Regulations.

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. It was unclear from the information provided within the

application, or in response to queries raised by the Confidentiality Advice Team ahead of the application review, whether any activity had been carried out in this area.

Members agreed that further information was required from the applicant in this area to ensure that engagement with an appropriate patient group had been undertaken to test the acceptability of using confidential patient information without consent to achieve the study aims. Activity should be arranged with an appropriate patient and relative group, or alternatively, if activity had previously been carried out, an overview of this would be required together with any feedback provided from the session. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

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 confirmed that posters would be displayed within the Royal Surrey County Hospital and local GP practices to inform patients about the study. Supplementary information would also be made available via the Royal Surrey County Hospital website. Copies of these documents had not been provided for review.

The CAG agreed that sight of the patient-facing materials was required prior to any final recommendation of support under the Regulations coming into effect. It was suggested that this documentation could be reviewed by patients as part of the engagement activity to ensure this was deemed acceptable and provided a clear overview of the study and any dissenting mechanism.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for the Royal Surrey County Hospital NHS Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Other Points

Whilst the CAG recognised that a proportion of the patient cohort to be included in the study would be deceased, it queried whether a mechanism had been incorporated into the study design to feedback any clinically relevant results from review of the pathology slides to living patients or their clinicians. Members recognised that this query would fall within the remit of the REC to explore with the applicant. However, it agreed that a note would be included within the outcome letter as a query only and would not require formal response to progress the recommendation of support under the Regulations.

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 (Summary)

1. Confirm the scope of the patient cohort to be included in the study. If a control cohort will also be included, a clear overview of this sub-group should also be provided.

2. Reassess the items of confidential patient information which have been requested to ensure this is the minimum necessary to achieve the study aims. A definitive list of the data items required should be provided, together with a clear justification around why each item is necessary.

3. Review the patient follow-up process and associated documentation to assess whether this could be achieved by disclosing a smaller set of patient identifiers within the documentation. Provide a response and revised documentation.

4. Clarify the exit strategy from support under the Regulations, including the timeframe for the destruction of confidential patient information.

5. Patient and public involvement and engagement activity should be undertaken to test the acceptability of using confidential patient information without consent to achieve the study aims. If activity has previously been undertaken, provide an overview of the format of this and the feedback provided. If not, activity should be arranged with an appropriate patient group and feedback provided. If the responses provided are negative, the CAG would take this into account when considering whether support can be recommended or if further action is required.

6. Provide copies of any patient-facing materials used to facilitate the communications strategy (posters/website text) to promote the study and patient's right to dissent. It is recommended that this documentation is reviewed as part of the patient engagement activity.

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, the HRA will confirm approval.

Other Points

The following point is raised as a query only and does not require a formal response in order to progress the application for support under the Regulations.

1. Consider whether it is necessary to incorporate a feedback mechanism to clinicians/patients within the study design, should a clinically relevant result present from review of the pathology slides.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending**).

f) 19/CAG/0027 - A diagnostic evaluation of malaria detection in patients presenting to the emergency department - a large teaching hospital retrospective cohort study

Context

Purpose of application

This application from Manchester University NHS Foundation Trust set out the purpose of medical research which aims to assess the necessity of the three routinely repeated blood tests carried out on patients who have presented to the emergency department with suspected malaria.

The applicants will identify patients from the laboratory database at Manchester University NHS Foundation Trust who have presented in the emergency department in the previous five years with suspected malaria. Confidential patient information, together with a study-specific ID number, will then be transferred to Public Health England, in order to facilitate linkage with the National Malaria Registry. Applicants will be working on site at Public Health England to carry out the data linkage directly; however, confidential patient information would be temporarily stored on Public Health England networks during this process. The applicants will have access to the National Malaria Registry whilst on site at Public Health England – the database is outside of the scope of information for which they would ordinarily have legitimate access. Linked information will be returned to the applicant in a pseudonymised format by study-ID only for analysis.

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

Confidential patient information requested

Cohort

Patients who presented to Manchester Royal Infirmary's Emergency Department or Manchester Children's Hospital Emergency Department (within Manchester University NHS Foundation Trust) in the last five years, and underwent investigation for suspected malaria. It is estimated that approximately 1,200 patients would be included in the study.

The following items of confidential patient information will be disclosed from Manchester University NHS Foundation Trust to Public Health England for the purposes set out:

- NHS number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode – sample validation and linkage,
- Sex – 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. Members recognised that investigating the relevance and necessity of the three blood tests in diagnosing suspected malaria was within the public interest.

Scope of Support

The applicant had confirmed that access to the National Malaria Registry at Public Health England would be granted on a visiting worker contract. The CAG was unclear whether support under the Regulations was required to legitimise the applicant's access to confidential patient information held within the Registry at Public Health England.

The Group agreed that Public Health England, as controller for the National Malaria Registry, would be required to provide written confirmation around whether any recommendation of support which was provided under the Regulations for this proposal was required to extend to the applicant's access to the

Registry. This would be followed up with the applicant to ensure that the scope of any recommendation provided covered all necessary elements of the overarching application activity.

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 had stated that, due to the financial and time resources required, it would not be possible to operate a consented model for the proposed study as it was unfunded. A requirement to seek patient consent would prevent the study from proceeding. Members recognised that the intrusion for patients was limited as data would largely be handled by members of the past clinical care team and were content to accept the applicants justification on this basis.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage with the National Malaria Registry which could not be otherwise achieved. No issues were raised in this area.

Justification of Identifiers

The CAG was assured that the items of confidential patient information specified were appropriate and proportionate to achieve the proposed aims. No queries were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The CAG recognised that support was requested for a time limited period to facilitate linkage with the National Malaria Registry only, following which, confidential patient information would be deleted from the Public Health England servers. No issues 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 had conducted eight semi-structured interviews with patients and parents of paediatric patients in the Manchester University NHS Foundation Trust's Ambulatory Care Units to explore views about the project. The feedback provided supported the project proceeding without consent, on the basis that the information was secure and safeguarded. Members acknowledged that the activity carried out in this area was appropriate and proportionate to the proposed activity. No queries were raised 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 provided posters which would be displayed on the Manchester University NHS Foundation Trust’s website and via the Trust and research group’s Twitter accounts to

promote the project. Members were content with the documentation provided to support the communications strategy.

The Group agreed that as the data linkage at Public Health England would be carried out on a one-off basis, notification materials should be displayed with a lead-in time of no less than four weeks, to enable a meaningful period for patient objections to be raised. The applicant would be asked to confirm that this lead in time would be operated.

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 (Summary)

1. Public Health England, as controller of the National Malaria Registry, should provide confirmation around whether support under the Regulations is required to extend to the applicant's access to the Registry. Provide written confirmation from Public Health England around this point, to ensure any recommendation of support under the Regulations extends to the appropriate study scope.

2. Provide confirmation that the study notifications materials will be displayed as per the communications strategy, with no less than four weeks lead in time to the disclosure to Public Health England, to provide a meaningful period for patient dissent.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Manchester University NHS Foundation Trust and Public Health England have published satisfactory reviewed grades on V14.1, 2017/18**).

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 19/CAG/0005 - Outcomes of patients undergoing lower limb vascular procedures in the National Vascular Registry

Context

Purpose of application

This application from the North Bristol NHS Trust set out the purpose of undertaking a service evaluation in order to describe the longer term patient outcomes after lower limb vascular surgery in England. Clinical and demographics risk factors for poor outcomes will also be investigated. It is intended the findings of the service evaluation would enable clinicians and patients to be better informed and to facilitate future research.

Patients who have undergone lower limb vascular surgery will be identified within the National Vascular Registry (NVR), which is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). Patients undergoing elective surgery are included in the NVR via consent. For patients undergoing emergency surgery, support under the Regulations is in place via application CAG 5-07(f)/2013 to include these individuals in the registry. The NVR will disclose confidential patient information, together with a study-specific ID, to NHS Digital to facilitate linkage with HES and ONS. Wider clinical information from the NVR will be released to the applicant with the same study-specific ID attached. NHS Digital will undertake the wider linkage and release information to the applicant with the study-specific ID attached. The applicant will link the two pseudonymised datasets for analysis.

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

Confidential patient information requested

Cohort

All patients recorded in the National Vascular Registry who underwent lower limb vascular surgery from 01/01/2014 to 31/12/2016. The inclusion criteria cover 40,890 procedures; however, the number of patients may be lower if they have undergone multiple procedures during the inclusion timeframe.

The following items of confidential patient information will be disclosed from the National Vascular Registry to NHS Digital to facilitate linkage:

- NHS Number,
- Date of Birth,
- NVR patient ID.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the proposed activity was within the public interest as it would help describe the longer term patient outcomes after lower limb vascular surgery in England.

Members considered the purpose of the application activity, which had been submitted as a non-research service evaluation. The applicant had confirmed in response to the queries which had been raised in advance of the application review that the project classification had been confirmed by the North Bristol NHS Trust Patient Safety, Assurance and Audit Service (part of the Clinical Governance Directorate). However, it was unclear from the information provided whether any guidance had been sought from the Trust's Research and Development office around the study classification.

There are separate established application processes and differing nominated decision-makers for activities seeking support under the Regulations for research and non-research purposes. The Secretary of State for Health and Social Care is responsible for the review of CAG advice in relation to non-research activities and cannot approve an application with a research purpose. On this basis, the Group raise concerns that the proposed activity may not receive the appropriate support under the Regulations, if it had not been accurately categorised. Members suggested that the applicant seek written confirmation from the Trust R&D department that the project has been appropriately categorised and should proceed on a non-research basis. A copy of this letter of support would be required prior to any final recommendation of support coming into effect, to support the application activity proceeding on this basis.

Members further commented that as the project had been submitted as non-research, the project would not undergo REC's assessment around the suitability of the project team to undertake the proposal. It was commented that as the main applicant was a junior clinician, confirmation was required that appropriate project supervision and support was in place from a more senior clinician. Assurance would be requested from the applicant.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data 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 CAG recognised that the patient cohort to be included in the project would be identified from the National Vascular Registry, which did not hold contact details for patients. The applicant had explained that operating a consented model for the project would require a more significant breach of patient confidence to facilitate this process. Patients undergoing elective surgery had consented to their inclusion on the NVR. This consent did extend to linkage with national datasets and disclosure of anonymised information to researchers. This specific application analysis required linkage to a wider dataset than was currently available via the NVR, which had brought about the specific application. Members were assured that consent was not a feasible option for the proposed activity and raised no issues in this area.

- Use of anonymised/pseudonymised data

Confidential information is required to facilitate the linkage between the data sources described which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The items of confidential patient information requested were deemed to be appropriate and proportionate to achieve the proposed activity. No issues were raised in this area.

Data Flows

Members were unclear from the information within the application and supporting data flow chart where the resulting linked pseudonymised dataset would be retained for analysis. Whilst it was presumed that this would be retained at North Bristol NHS Trust, it was agreed to seek written clarification from the applicant around this point, to ensure there was appropriate security in place.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support is requested on a time limited basis in order to facilitate the linkage process to be undertaken by NHS Digital. The applicant will not directly access any confidential patient information as a pseudonymised dataset would be released by NHS Digital. Members recognised that the processing of confidential patient information had been limited within the proposed methodology and raised no concerns around the described exit strategy from support under the Regulations.0020

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 applicants had approached a public and patient involvement group for Vascular Surgery at North Bristol NHS Trust and who were supportive of additional analyses using the data already contained within the NVR and NHS Digital datasets. Further work was planned as the project progressed. The Group agreed that the activity which had bene undertaken was appropriate and proportionate to the proposed activity and raised no concerns 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 confirmed that a communication strategy was being designed with the National Vascular Registry in order to promote the proposal and offer a project-specific dissenting mechanism. Members agreed that confirmation of the proposed methodology and sight of the documentation to support it would be required prior to any final recommendation of 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 and therefore advised recommending provisional support to the Secretary of State for Health and Social Care, 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 a letter of confirmation from the North Bristol NHS Trust that is has confirmed the project's categorisation as a non-research service evaluation and supports the activity proceeding on this basis.

2. Provide assurance that appropriate project support and supervision was in place for the project from a more senior clinician.

3. Confirm where the resulting linked pseudonymised dataset would be retained for analysis.

4. Provide details of the study-specific communications strategy established together with the National Vascular Registry, together with an overview of the project specific dissenting mechanism. Copies of any documentation to support this should be provided.

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, the SofS will confirm approval.

Specific conditions of support (Provisional)

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital (processor) has a published satisfactory reviewed grade on V14.1, 2017/18**).

Appendix 1. CAG Sub Group Minutes