Minutes of the meeting of the Confidentiality Advisory Group

17 September 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Malcolm Booth	Yes	CAG Member
Ms Sophie Brannan	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Dr Lorna Fraser	Yes	CAG Member
Mr. Myer Glickman	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair
Dr Murat Soncul	Yes	CAG Alternative Vice-Chair
Dr Harvey Marcovitch	Yes	CAG Member
Mr Marc Taylor	No	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Senior Confidentiality Advisor/Service Manager

1. Introduction, apologies and declarations of interest

Any declarations of interest are declared below for each application.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **20 August 2020** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority decision following the advice provided by the CAG in relation to the **20 August 2020** meeting applications is pending.

3. New Applications – Non-Research

a. 20/CAG/0111 - Under 16 Cancer Patient Experience Survey 2020-2023

Context

Purpose of application

This application from NHS England and NHS Improvement and Picker Institute Europe (Picker) set out the purpose of a patient survey to collect patient experience data for patients aged under 16 years of age with a diagnosis of cancer.

The National Cancer Patient Experience Survey (CPES), commissioned and managed by NHS England and NHS Improvement, is one of the ways that patient experience data for cancer patients in England is captured. The results of these surveys are used to help commissioners, providers and national policy makers to identify priority areas of improvement for services. However, as recognised in the Achieving World Class Cancer Outcomes: A Strategy for England 2015-2020, January 2015, NHS Independent Cancer Taskforce, the CPES is not appropriate for use with children with cancer. This Strategy recommended that NHS England and NHS Improvement "should develop a methodology to collect data on patient experience for under 16s". This commitment to improvement was recently restated in the NHS Long Term Plan, January 2019, NHS England. This application supports NHS England and NHS Improvement to fulfil the Cancer Strategy recommendation and Long-Term Plan objectives. NHS England and NHS Improvement has commissioned Picker Europe Ltd.to develop and carry out the Under 16 Cancer Patient Experience Survey over the period 2020-2023.

The applicants are seeking support to collect and use confidential patient information for patients under 16 years of age diagnosed with cancer and other tumours in order to conduct the Under 16 Cancer Patient Experience Survey between 2020 and 2023. Confidential patient information will be disclosed from NHS Principal Treatment Centres (PTCs), delivering children's cancer care and treatment in England, to Picker Europe Ltd. Picker will also liaise with PTCs so that patient questionnaires are sent to recipients on the letter-headed paper for the appropriate trust. The survey materials will be addressed to parents of children who have received care. The first wave of data collection is due to take place in the autumn of 2020 and repeated on an annual basis thereafter. Support is sought for the first three years of the survey.

Once Picker receives the patient information from the PTCs, most of the checking and mailing processes are automated (in-house) with access limited to approved individuals in accordance with their Information Security Management System.

Other details are needed to verify survey responses, check eligibility to take part or to provide data that patients could not be expected to supply. These details (e.g. age and coding of

cancer diagnosis ICD10 codes) will be used to check the accuracy of the sample data, and to compare different groups' experiences of acute cancer care at the reporting stage, where numbers allow.

As hospitals do not routinely collect email and/or mobile phone numbers for patients, for the first 1-2 survey waves, the applicants intend to approach patients by post using a paper-based survey, with the option for respondents to complete the survey online, should they prefer. However, in response to advances in digital communications, for future waves the applicants intend to explore a mixed-method approach in instances where email and/or mobile phone numbers are available, e.g. an initial approach by email, or survey reminders sent by SMS. Support is therefore requested for email and/or telephone number to be collected to further explore the digital potential for the survey. The patient name and address will be needed to send out postal surveys to recipients, and the email address and mobile phone number of the parent(s)/carer(s) (where available) will be needed to explore whether a mixed-mode approach could be used in future waves of data collection.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All children aged under 16 at the time of their care, with a confirmed primary diagnosis of cancer or a non-malignant brain, other central nervous system or intracranial tumour, who are aware of their diagnosis and have received NHS care and/or treatment for their cancer or tumour within a recent twelve-month period. This will include: • Admitted patients who did not stay overnight (e.g. emergency admissions and planned day cases) • Admitted patients who did stay overnight • An ICD-10 code of C00 – C97, D32 - D33, D35.2 - D35.4, D42 - D43, D44.3 - D44.5, D48, D76.1.

	The applicants estimate that this will include between 1,000 and 10,000 patients per year.
Data sources	1. NHS Principal Treatment Centres (PTCs)
Identifiers required for linkage purposes	1. Patient name 2. Address 3. Sex 4. Ethnic group 5. Date of birth 6. ICD10 code 7. Discharge date 8. Specialty code 9. NHS number 10. Site code 11. Trust code 12. Patient classification 13. Parent email address and mobile phone number will be collected, where available.
Identifiers required for analysis purposes	No identifiers are required for analysis purposes

Confidentiality Advisory Group advice

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

Cohort

The CAG requested further details around the cohort, in order to clarify the scope of the support sought.

The applicants had indicated that between 1,000 and 10,000 patients would be included each year, which was a large range. Members asked if a more precise figure could be provided.

Patients treated within a recent 12-month period would be included. Members asked that further clarification on when this 12-month period would be was provided.

Members noted that the inclusion criteria should make it clear that patients and their parents/carers are aware that the patients have a diagnosis of cancer. The CAG asked how the applicants would ensure that patients, or their parents/carers, who may not be aware that their diagnosis was of cancer would not find out via this survey.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that it was not feasible to seek consent prior to sending the survey due to the number of patients involved. Patients, or their parents/carers will be sent a survey. Their participation will then proceed on a consented basis. Sending a letter to patients before sending the survey would involve the same disclosure of confidential patient information as required to send the surveys. The CAG agreed that it was not feasible to seek consent prior to sending the surveys.

- **Use of anonymised/pseudonymised data**

The applicant advised that patients' names and addresses were required in order to send out postal surveys and undertake data and quality checks. The CAG agreed that this could not be undertaken in any other way.

Justification of identifiers

The applicants sought support to collect the telephone number and email addresses of patients. The CAG understood that the applicants were intending to adopt a mixed-methodology approach for future surveys, however this was not planned for this round of surveys. The Group queried whether it was necessary to collect the telephone numbers and email addresses, or whether the applicants could create a flag to indicate whether the telephone number and/or email address was available.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to 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 Data Protection Act 2018.

The PTCs will display fair processing information about the survey and provide contact details for patients to opt out if they wish. These will be the PTC survey lead details. PTCs are required to remove these patients' details when they select the sample. These details will never reach Picker.

Information relating to individuals who have informed their PTC that they would like to opt-out of the survey ahead of the sample being drawn and sent to Picker will be excluded from the sample. The same approach has been used for all national NHS surveys since 1998 and is adopted as standard on the English NHS Patient Survey Programme, which is widely acknowledged to be a robust and methodologically rigorous programme.

Information relating to individuals who have informed their PTC that they would like to opt-out of the survey ahead of the sample being drawn and sent to Picker will be excluded from the sample. The same approach has been used for all national NHS surveys since 1998 and is adopted as standard on the English NHS Patient Survey Programme, which is widely acknowledged to be a robust and methodologically rigorous programme.

The CAG noted that if patients did not respond to the invitation or reminder then they were considered to have dissented from the inclusion. Patients could also contact the study team to dissent. Members also queried how many reminders the patients would be sent after the survey was initially sent.

A poster will be displayed in the PTCs. This poster would need to be displayed for a sufficient amount of time for patients to take note of the survey and register dissent. Members requested clarification on how long the poster will be displayed for. Members also advised that the poster needed to contain telephone, email and postal address contact details for patients to use, and asked for confirmation that each PTC would be asked to include these details.

The Group noted that the age group included in this survey were likely to engage with social media. Members suggested that the applicants explore additional ways of promoting the study.

The names and address of patients who dissented or did not respond would be stored for 12 months. The CAG requested clarification as to why these details would be retained, as it would be less disclosive to retain patients' NHS numbers and either their date of birth or age. The CAG noted that age would be preferable. It also needed to be explained in the patient notification that details on those who dissented would 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 the unconsented activity should go ahead.

The applicant advised that the survey and methodology have been developed with input from children with cancer, their parents and the survey's advisory group.

The advisory group includes patients, parents, commissioners, representatives from children's cancer charities, academics, hospital trust clinicians and NHS cancer programme representatives. This advisory group meets quarterly to advise on methodological decisions. The clinical members of the Advisory Group have also provided advice on the care pathways and treatment options to ensure the survey design is appropriate.

Picker have also consulted two focus groups, each comprised of six parents of children with cancer. Picker have also conducted nine in-depth interviews with children with cancer, in order to develop understanding of their cancer pathways, experiences and care priorities. Feedback was used to inform the survey questions and design. The themes arising from this initial qualitative research were presented to the advisory group to review, comment on and add to, before being used to draft the survey questions. The draft survey questions were shared with the advisory group for review and comment ahead of being cognitively tested. Written feedback from the patient and public involvement and engagement was provided to the CAG.

Members asked if the specific question of sending confidential patient information to Picker and the number of contact attempts that would be made had been raised during patient and public involvement. If so, details of the feedback received needed to be provided.

Checks of deceased patients

The CAG noted that there are often delays in death registrations and asked if checking via the Patient Demographic Service could be done instead using the NHS notification of death which would be available prior to the official registration.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Further clarification on the cohort is required:

    a. Provide a more precise number of anticipated patients.

b. Provide further clarification on when the 12-month period will be.

c. The inclusion criteria need to include a criterion that patients and their parents/carers are aware that the patients have a diagnosis of cancer.

2. Advise whether the email addresses and telephone numbers of patients needs to be collected, or whether a flag could be created to indicate whether the telephone number and/or email address was available. If the telephone numbers and email addresses will be collected, then justification for this needs to be provided.

3. Advise how it will be ensured that patients, or their parents/carers, who may not be aware that their diagnosis was of cancer would not find out their diagnosis via this survey.

4. Clarify how many reminders the patients will be sent after the survey was initially sent.

5. Further details on the patient notification and dissent process are required:

   a. Clarify how long the poster will be displayed for.

   b. Confirm that all PTCs will provide a telephone number, email and postal address on the poster, for patients to use to register dissent.

   c. Provide clarification as to why the names and addresses of patients who dissent will be retained to ensure patients are not re-contacted, or whether it is possible to retain patients' NHS numbers and either their date of birth or age. It also needs to be explained in the patient notification that details on those who dissented will be retained.

   d. Additional ways of promoting the survey, including via social media, are to be considered and fed back to the CAG.

6. Clarify if the specific question of sending confidential patient information to Picker and the number of contact attempts that would be made had been raised during patient and public involvement. If so, details of the feedback received need to be provided.

7. Can the check that patients are still living be done via the Patient Demographic Service using the NHS notification of death which would be available prior to the official registration.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed – Picker Institute Europe has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital email dated 17 July 2019)**

Declarations of Interest

There were no declarations of interest.

4. New Applications – Research

a. 20/CAG/0101 - FFRCT In Stable Heart disease & CTA Helps Improve Patient care and Societal costs

Context

Purpose of application

This application from Liverpool Heart and Chest Hospital NHS Foundation Trust sets out the medical purpose to undertake medical research to determine which of two diagnostic pathways are superior in the chest pain pathway.

Chest pain may be a symptom that is related to a narrowing of the heart blood vessels (coronary artery disease [CAD]). This chest pain, known as angina, can result in a reduced

quality of life and, if not diagnosed and managed appropriately, could result in a heart attack. Guidelines recommend the use of tests to help diagnose and manage chest pain 'angina' patients. Coronary computed tomography angiography (CCTA) is a test that takes images of the heart blood vessels. It is the main test for patients presenting with angina. A new technology, CT-derived fractional flow reserve (FFRCT) uses the CCTA images to make a 3D model of the heart blood vessels that shows whether there is a limitation in the blood flow to the heart which is causing the symptoms. The National Institute for Health and Care Excellence (NICE) recommends the use of FFRCT in a chest pain pathway. However, use of this new technology remains limited due to funding restrictions and uncertainty as to its benefit in the NHS.

This study will collate the data of approximately 120,000 patients from participating NHS Trusts. Confidential patient information from participating Trusts will be linked with data from the Hospital Episode Statistics (HES) database, diagnostic imaging data (DID) set and the emergency care dataset (ECDS).. In addition, Trusts will also provide patient referral to treatment time (RTT) data, including NHS number. Further, a commercial entity, Heartflow (who receive patient data for clinical purposes related to FFRCT) will provide FFRCT data. The exact data flows were unclear, and the CAG requested that further clarifications, detailed below, were provided.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All individuals at participating NHS Trusts that received a CTCA during the 2-year period of the national FFRCT programme (2018-2020) and a year prior to the programme (2017-2018)
Data sources	1. Participating NHS Trusts 2. Heartflow

Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. Gender 2. Postcode 3. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the study was in the public interest and had a clear medical purpose.

Data flows

The applicants provided two potential options for the flow of data. It was noted by members that neither data flow outlined the RTT data flows. The description of the data flows in the applicant's response to the CAT referred to the first option, where NHS Digital would receive confidential patient information from Heartflow and undertake the data linkage to data provided by participating trusts. In the second option, the applicants would receive confidential patient information from Heartflow undertake the linkage to trust data. The data flow diagrams provided contradict this description and did not show how the Referral to Treatment (RTT) data would flow.

The CAG agreed that it was not clear which option would be used. Members asked that the applicant determine which methodology would be followed and inform the CAG of their decision. A clear data flow diagram will need to be provided.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The CAG noted that both NHS number and Hospital ID would be provided to NHS Digital for the data linkage. NHS Digital would be able to perform the linkage on NHS number only. Members asked if the Hospital ID number would be provided to NHS Digital in the event that the linkage to Heartflow data was undertaken by NHS Digital, as Heartflow used Hospital ID.

- **Feasibility of consent**

The applicants state that, due to the retrospective nature of the study and the size of the cohort, it is not possible to seek consent from patients. The CAG agreed that seeking consent was not practicable.

- **Use of anonymised/pseudonymised data**

NHS Trust patient level data and Heartflow data needs to be linked to data held by NHS Digital held data, which could not be undertaken using pseudonymised/anonymised data flows.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to 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 Data Protection Act 2018.

The applicants provide a patient information sheet, which is provided to Trusts for eligible patients. A poster was also referred to in the application, but this had not been provided. The

CAG asked that this was provided for review. Further details on how the study could be promoted online, due to the Covid-19 pandemic, were requested.

The poster asked patients to contact the study team if they wanted to dissent from inclusion. The CAG asked that further details were provided on any study-specific dissent mechanism in place. Details on how patients could dissent also needs to be included on the poster and website notifications.

The Group noted that revisions to the patient leaflet were required. The leaflet needed to explain that patients may have undergone FFRCT. The involvement of Heartflow, a private company, also needed to be explained. The CAG recommended that the leaflet was reviewed by a patient group.

The applicants had advised that the National Data Opt-Out will apply.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

Patient and public involvement was undertaken with 15 patients. The CAG was satisfied with the patient and public involvement and engagement carried out.

Exit strategy

The study was expected to run for 24 months. The pseudonymised data collected would be retained for 15 years. The application referred to potential further data requests if funding was granted in the future. The CAG requested further clarification on any planned or potential follow-up.

The application also referred to the use of anonymised data for machine learning. The CAG requested assurance that this usage was outside the scope of the s251 support sought.

REC Opinion

The CAG noted that a REC application had not been submitted at the time of the CAG meeting. Members agreed that they would like to see the comments made by the REC when determining whether support should be recommended.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Provide a data flow diagram which clearly sets out the flow of confidential patient information and anonymised/pseudonymised data. This also needs to clearly explain how the data linkages will be performed and which organisation they will be undertaken by, including the Referral to Treatment data.

2. Further details on the patient notification and dissent mechanism needs to be provided, as follows:

    a. A study-specific dissent mechanism needs to be created and details given to the CAG.

    b. A revised patient information sheet is to be created. The leaflet needs to explain that patients may have undergone FFRCT, the involvement of Heartflow and a study-specific dissent mechanism.

    c. The study poster needs to be submitted for review. Details on the study-specific dissent mechanism need to be provided on the poster.

d. Details on how the study will be promoted online, including the text of any website notifications, needs to be provided. The online information also needs to contain details on the study-specific dissent mechanism.

3. Details on any planned or potential follow-up or further usages of the data collected in this application need to be provided.

4. Provide assurance that the data used for machine learning will be anonymised and that this usage of data is outside the scope of the s251 support sought.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: Liverpool Heart and Chest Hospital NHS Foundation Trust - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.**

   As a result, the following specific condition of support has been added: all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0107 - Childhood outcomes after perinatal brain injury: a population-based linkage study

Context

Purpose of application

This application from University College London Great Ormond Street Institute of Child Health (UCL GOS ICH) set out the purpose of medical research that aims to conduct a population-based matched cohort study of children born in England 2008-2020, to investigate differences in long-term health, mortality and educational outcomes in children with perinatal brain injury compared to those without brain injury. The primary outcome for the study is neurodisability at 2, 5 and 12 years, and secondary outcomes include all-cause mortality, mental health and behavioural conditions, chronic conditions, academic attainment, and special-educational needs.

Over 3400 babies born in England suffer a brain injury every year. Neonatal brain injuries around the time of birth can have devastating lifelong consequences for children, parents and society as a whole. There have been major advances in healthcare that mean more babies with brain injuries survive, but the long-term effects of these injuries are not well-known. Currently, it is not known which infants suffering perinatal brain injury should be followed up, how long they should be followed up for, what conditions they are likely to develop or what additional support they may need from the NHS, social care, or schools in terms of their health, development and education. This study has been created with the aim of gathering information on the prognosis and quality of life after a neonatal brain injury in order to assist staff in conducting family-centred discussions about what the future may hold and help shape health and educational services.

Three cohorts will be included in the study. Cohort 1 will include all newborns with a perinatal brain injury who were born in England between 2008 and 2020. Cohort 2 will be a per-term control group and will contain a 1:1 propensity score matched comparator group for babies born before 34 weeks gestation. NHS Digital will match the cohort using Office of National Statistics (ONS) data in order to create Cohort 3, a full-term control group.

The National Neonatal Research Data (NNRD) captures data items, including date of birth, postcode, and infant NHS number, but does not reliably hold children's' registered names. Additionally, the NNRD contains the infants' postcodes at birth, but does not capture postcode changes throughout childhood. Therefore, the NNRD cohorts 1&2 will be linked to the NHS Digital Personal Demographics Service (PDS), using NHS number, date of birth, gender and postcode at birth: to identify registered forename and surname, and postcodes changes.

NHS Digital will then link all 3 cohorts to 3 datasets held at NHS Digital; Hospital Episode Statistics (HES), ONS mortality data, Mental Health Services Dataset (MHSD). NHS Digital will send identifiers to the Department for Education (DfE) for linkage with the National Pupil Database (NPD). The Neonatal Data Analysis Unit will create a pseudonymous file containing the neonatal care data for cohort 1 & 2. Cohort 3 will be identified by NHS Digital. Cohorts 1, 2 & 3 will be linked at NHS Digital and the Department for Education, and a pseudonymous file will be created for each linked dataset. The 5 pseudonymised datasets will then be securely transferred to ONS Secure Research Service (SRS), where they will be cleaned and merged. Data within the SRS will retain only an anonymous unique identifier - they key to which will only be held at the Department for Education and NHS Digital for their respective linkages. The data generated by the study will be analysed in the ONS secure research service. It will either be accessed through one of the ONS safe rooms of via a UCL SRS remote connectivity site.

A recommendation for class 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	• Cohort 1: All newborns with perinatal brain injury, born in England between 1 January 2008 to 31 December 2020 (approximately 43,582) • Cohort 2: Pre-term control group: Propensity score matched comparator group for those born <34 weeks gestation (1:1) to control infants using propensity score matching to account for confounders, born in England between 2008-2020 (approximately 16, 175) • Cohort 3: term control group: matched term population for the infants ≥34 weeks gestation in cohort 1, identified by NHS Digital using the covariates below, born in England between 2008-2020 (using a 1:3 algorithm; approximately 82, 221).

Data sources	1. National Neonatal Research Database controlled by the Neonatal Data Analysis Unit (NDAU) 2. ONS, PDS, HES and MHSD datasets, held by NHS Digital 3. National Pupil Database, held by the Department for Education
Identifiers required for linkage purposes	For linkage of cohort 1&2 with NHS Digital (PDS) data: 1. NHS number 2. Date of birth 3. Postcode at birth 4. Gender From these provided identifiers NHS Digital PDS will identify infant forename, surname and postcodes over time, which will validate linkages and be sent to DfE. For linkage of cohort 1,2 & 3 with NHS Digital: HES, ONS, MHSD data: 1. NHS number 2. Infant Forename 3. Infant Surname 4. Date of birth 5. Gender For linkage of cohort 1, 2 & 3 with National Pupil Database NHS Digital will send the following identifiers to the DfE: 1. Infant Forename 2. Infant Surname 3. Date of birth 4. Gender 5. Postcode at birth, 6. Most recent postcode Any additional childhood postcodes
Identifiers required for analysis purposes	No identifiers will be retained for analysis

Additional information	For NHS Digital to identify cohort 3 the following non identifiable data from the infants ≥34 weeks gestation in cohort 1 is required: 1. Birthweight 2. Year of birth 3. Multiplicity 4. Gender 5. Lower layer Super Output Areas (LSOA) The ONS SRS will receive 5 pseudonymised files: file 1 from the NNRD containing neonatal care data for cohorts 1 and 2; files 2-4 containing survival, health and mental health data for cohorts 1-3; and file 5 containing educational outcomes data for cohorts 1-3. None of these will contain personal identifiers. The data generated by the study will be analysed in the ONS secure research service. It will either be access through one of the ONS safe rooms of via a UCL SRS remote connectivity site

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Group agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that obtaining contact details for patients in order to seek consent would also involve the processing of confidential patient information outside the direct care team. Contacting the families of children who had suffered a perinatal brain injury, who may have severe disabilities or have died, would be potentially distressing. The applicants also noted that over 80,000 patients would potentially be included. The CAG accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to link patients across datasets held by NHS Digital, the NDAU and the Department for Education. The CAG accepted that this could not be done in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to 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 Data Protection Act 2018.

A patient notification leaflet was provided, which would be displayed on website for University College London Great Ormond Street Institute of Child Health (UCL GOS ICH). The CAG asked that further efforts were made to promote the study, for example by making the leaflet, or other form of notification, available on the websites for BLISS and the Meningitis Research Foundation, and other appropriate websites. The CAG asked that patient notification was undertaken 6-8 weeks before the data extraction and linkage began, to give patients sufficient time to register dissent.

The Group asked that the patient information leaflet was reviewed by a patient group and revised in line with any suggestions made.

The applicant confirmed that the National Data Opt-Out will be applied by NHS Digital. A project specific dissent mechanism had not been created. Members noted that the NDUA had a mechanism for patients to dissent to inclusion in the NNRD and asked that the applicants

discuss a project-specific dissent mechanism with the NDUA. Details on this dissent mechanism are to be provided in the patient notification.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants had circulated a questionnaire, seeking feedback on the proposed study aims and objectives, to affected patients and families from the Great Ormond Street Parent Advisory Committee, the BLISS charity insight and involvement group and the Meningitis Research Foundation. Feedback was provided from over 30 affected children and families. Feedback was supportive, including the use of confidential patient information without consent. Letters of support from BLISS and the Meningitis Research Foundation were provided.

The applicants advised that project advisory meetings will be held to discuss the study with representatives from public health organisations, BLISS, health care providers and parent representatives. A parent representative is being sought to sit on the project advisory committee. Two focus groups, to be held with affected parents, are also planned. The issue of how the study information should be communicated to families on the neonatal unit will be explored with these focus groups.

The CAG noted the patient and public involvement and engagement undertaken. Members asked that feedback from the planned continuing engagement was provided when submitting annual reviews to the CAG.

Exit strategy

The Group noted that the data linkage would not be completed until August 2022. Members queried why the project would take this long to complete.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The applicants are to collaborate with the NDAU to design and implement a study-specific dissent mechanism. Details of the dissent mechanism are to be provided in the patient notification leaflet.

2. The patient notification leaflet is to be made available on the websites for BLISS and the Meningitis Research Foundation, and other appropriate websites. The leaflet needs to be displayed for 6-8 weeks before the data extraction and linkage begins, to give patients sufficient time to register dissent.

3. The patient notification leaflet is to be reviewed by a patient group and revised in line with any suggestions made.

4. Clarify why the data linkage will not be completed until August 2022.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Feedback from the planned continuing engagement is to be provided when submitting annual reviews to the CAG.

2. Favourable opinion from a Research Ethics Committee. **Pending**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **The NHS Digital DSPT review for the following organisations were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 18 September 2020)**

    - **University College London – School of Life and Medical Sciences (standards met for DSPT 2018/19)**
    - **Office for National Statistics (standards met for DSPT 2019/20)**
    - **Department for Education (standards met for DSPT 2019/20)**
    - **NHS Digital (standards met for DSPT 2018/19)**
    - **Chelsea & Westminster Hospital NHS Foundation Trust (standards met for DSPT 2018/19)**

Declarations of Interest

There were no declarations of interest.

c. 20/CAG/0112 - Ethnic Density and Psychosis in a British Pakistani Population: an investigation using data from the East Lancashire Early Intervention Service

Context

Purpose of application

This application from the University of Liverpool set out the purpose of medical research that seeks to determine whether living in areas with a higher proportion of one's own ethnic group protects against the risk of developing psychosis in British Pakistani groups in a region of Northern England.

Ethnic minority groups have an elevated risk of developing psychosis. However, it has been found that living in areas with a higher proportion of one's own ethnic minority group (ethnic density) protects against this risk, described as the ethnic density effect. Contrary to other ethnic groups, survey studies have indicated an absence, or potentially a reversed effect, of

increased ethnic density on risk of psychosis for Pakistani groups in the UK. These findings are currently preliminary, and past studies have been limited by unreliable, self-report questionnaire measures of clinical diagnosis. The applicants aim to test the ethnic density effect in British Pakistani populations, using more clinically reliable data collected by the East Lancashire Early Intervention Service (ELEIS). The service accepts referrals for those experiencing psychosis for the first time (or are within their first three years of treatment).

Secondary data, collected by the NHS trust as part of routine practice, will be used. Full postcodes for patients are required in order to accurately estimate geographical variables consisting of area ethnic density and neighbourhood social deprivation. These variables will be generated by matching postcodes to both Census Area Statistic (CAS) Wards and also the more detailed Lower Super Output Area (LSOA), using 2001 and 2011 UK census data.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged between 14 and 65 years of age, referred to ELEIS with psychosis, or at high risk of psychosis, residing or registered with a GP in the selected districts, presenting with psychotic symptoms for the first time (or are in their first three years of treatment). Data for referrals between 2005 and 2020 will be analysed. The applicants anticipate that 1500 patients will be involved.
Data sources	1. East Lancashire Early Intervention Service (ELEIS) at Lancashire & South Cumbria NHS Foundation Trust

Identifiers required for linkage purposes	1. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Ethnicity 4. Age at time of referral

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that data would be collected from up to 15 years earlier. It was also not feasible to contact the number of patients involved, due to the limitations of the PhD project. The CAG accepted that it was not feasible to seek consent.

- **Use of anonymised/pseudonymised data**

The applicant advised that the full postcode was required in order to match postcodes to both Census Area Statistic (CAS) Wards and also the more detailed Lower Super Output Area (LSOA), using 2001 and 2011 UK census data. LSOAs represent more socio-economically homogenous populations within each unit, with electoral wards typically consisting of around 8 or 9 LSOAs. They also have greater continuity in comparison to other administrative boundaries, which can change frequently. Past research investigating ethnic density has shown that using less detailed geographical areas can obscure detection of ethnic density effects.

The CAG noted that the process of converting postcodes into LSOA was a very brief and simple process, and queried why the conversion could not be undertaken by the direct care team. This would remove the need for support under s251.

Cohort

The Group asked that the age range included in the study was specified, noting that the applicants had indicated that no children would be included, but the age range began at 14 years of age.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to 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 Data Protection Act 2018.

The applicants advised that no patient notification strategy had been created. They are investigating how a suitable strategy can be devised and implemented. The Group agreed that a patient notification and dissent strategy was important, due to the potential sensitivity of the research topic. A clear patient notification strategy, including any patient-facing materials, needed to be created and provided to the CAG for review.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants advised that a service user meeting was held on 27 July 2020 in order to discuss the processing of confidential patient information without consent. A summary of this discussion was provided to the CAG.

The CAG noted the patient and public involvement and engagement conducted. It was not clear if the patient group consulted contained representatives from the ethnic group that would be studied. The Group asked that patient and public involvement was carried out representatives from the Pakistani community, and advised that community leaders were engaged with, particularly around the issue of how to promote the study.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, the applicant was required to respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide confirmation that the direct care team cannot undertake the process of converting the postcodes into Lower Super Output Area, thereby removing the need for support under s251.

If the direct care team cannot undertake the conversion and support under s251 is required, the following will need to be address:

2. Clarify the age range of patients included.

3. A clear patient notification strategy, including any patient-facing materials, needs to be created and provided to the CAG for review.

4. Patient and public involvement and engagement needs to be undertaken with those from the Pakistani community, particularly around the issue of how to promote the study, and feedback provided to the CAG.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

    - **Confirmed - University of Liverpool has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 30 August 2019.**

    - **Pending – confirmation of a 'Standards Met' grade on DSPT submission for East Lancashire Early Intervention Service (ELEIS) at Lancashire & South Cumbria NHS Foundation Trust is required**

Declarations of Interest

There were no declarations of interest.

5. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date