Minutes of the meeting of the Confidentiality Advisory Group

02 July 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair
Dr Lorna Fraser	Yes	CAG member
Mr Andrew Melville	Yes	CAG member
Mr Anthony Kane	Yes	CAG member
Prof Jennifer Kurinczuk	Yes	CAG member
Mr Marc Taylor	Yes	CAG member
Prof Barry Evans	Yes	CAG member
Dr Martin Andrew	Yes	CAG member

Also in attendance:

Name	Position (or reason for attending)

Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Dr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Mr Ben Caswell	Observer

1. Introduction, apologies and declarations of interest

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 **04 June 2020** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **04 June 2020** meeting applications.

3. New Applications – Research

a. 20/CAG/0084 – PIONEER

Context

Purpose of application

This application from University Hospitals Birmingham NHS Foundation Trust set out the purpose of medical research which aims to create and manage the PIONEER database, which will be used to understand and inform acute healthcare processes

and long-term consequences for patients admitted to hospital which can inform current and future patient health care and health processes.

Acute care traditionally has not been the subject of research or innovation, despite its scale and the costs involved, and acute care records are traditionally siloed within individual NHS organisations. Linking records at a population level and allowing use of this data for research purposes could provide significant benefits. PIONEER will gather and link data from across acute care providers to become the first such research database to combine routine acute care provision. Using linked organisation level data, rather than national level data will provide a greater granularity of data and greater utility.

The PIONEER database will be managed within University Hospitals Birmingham NHS Foundation Trust. Initially, routinely collected acute care data from University Hospitals Birmingham NHS Foundation Trust data will be linked with routinely collected data from West Midlands Ambulance Service NHS Foundation Trust. It is expected that the database will expand the number of NHS organisations submitting routine clinical care data over time, although future unspecified organisations were not considered within this application.

Processing elements requiring support

The application indicated that, in most instances, the data to be transferred from participating organisations to University Hospitals Birmingham NHS Foundation Trust will be in a pseudonymised format. Upon receipt University Hospitals Birmingham NHS Foundation Trust will process this data through briefly reidentifying two identifiable fields (NHS number and date of birth) in order to link the data to that of other organisations. This element of processing for the purpose of linkage would require a lawful basis.

Where participating organisations do not have the capacity to pseudonymise the data prior to transfer, they would send the data in an identifiable format to University Hospitals Birmingham NHS Foundation Trust to undertake the pseudonymisation. A lawful basis would be required for this sub-set of organisations to disclose this identifiable information to University Hospitals Birmingham NHS Foundation Trust for this purpose.

Researchers can apply for data extracts for specific research projects, which will undergo a defined application process, including scrutiny by lay members, before released in an anonymised form (for example, only age will be provided, not date of birth). Support would be required to process and render relevant information fully anonymous prior to disclosure.

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	Patients who have undergone an acute care contact, within University Hospitals Birmingham NHS Foundation Trust or West Midlands Ambulance NHS Trust. Data will be collected retrospectively (from 01 January 2000 at the earliest) and prospectively.
Data sources	1. University Hospitals Birmingham NHS Foundation Trust 2. West Midlands Ambulance NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Postcode 2. Date of birth 3. Gender

	4. Ethnicity 5. Diagnosis information (including rare diseases)
Additional information	Postcode is not provided to researchers. Instead, a less specific geographical unit such as the Lower layer Super Output Area (LSOA), or the associated data of interest such as the Index of Multiple Deprivation score will be provided. Date of birth is not provided to researchers. It will be used to calculate the age of the patient at the time of interest to the researcher.

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 noted the considerable public interest for this application, with the outputs having the potential to produce substantial evidence for management of acute care, and resultant benefits to both the NHS and participants alike.

Scope

As is understood by the group, the applicants were requesting support for the following elements:

- Provision of pseudonymised routine clinical care data from participating organisations to University Hospitals Birmingham NHS Foundation Trust. This was expected to be the method used for most participating NHS organisations to provide data to University Hospitals Birmingham NHS Foundation Trust.

- Provision of identifiable routine clinical care data from participating organisations to University Hospitals Birmingham NHS Foundation Trust, which will be pseudonymised by University Hospitals Birmingham NHS Foundation Trust, for those organisations that do not have capacity themselves.

- For University Hospitals Birmingham NHS Foundation Trust receive, retain and process information held within the PIONEER database (see information about pseudonymisation below)

Members understood routine clinical care data to encompass three different types of data:

1. Structured clinical care data
2. Unstructured data in the form of medical images
3. Unstructured data in the form of free text data

Definition of data transfer/processing

Whilst the applicants stated that the routine clinical care data will be transferred to, and held by, University Hospitals Birmingham NHS Foundation Trust in a pseudonymised format, the group were clear that this was not strictly the case. University Hospitals Birmingham NHS Foundation Trust will have the key to be able to reidentify identifiable information. Indeed, data (NHS number and date of birth) will be reidentified to be able to link the data from different organisations, which will be undertaken on a regular basis. As such, the group agreed that the use of the term pseudonymised, may be misleading in this context, due to the ability of University Hospitals Birmingham NHS Foundation Trust to reidentify the data at regular

intervals. In this instance, it appeared to members that the data would remain identifiable to the applicant. Comment on this aspect was requested.

Scope of support in University Hospitals Birmingham

Members noted that the applicants were not requesting support for the individual hospitals that make up University Hospitals Birmingham NHS Foundation Trust to submit data to the PIONEER database. The reason given was that the activity would not expose confidential data to staff who would not otherwise have access during routine clinical care. An email from the Data Protection Office was submitted who stated that "*Further to your email below, I can confirm that our Health Informatics Team would be accessing the same dataset as part of their support for routine clinical services (clinical audit/service evaluation).*" Members however pointed out that this access, as described, was for purposes of direct care, but this request covered non-direct care (research) purposes, and queried on what common law duty of confidentiality legal basis these staff would be accessing the data, and whether support should be extended to the transfer or routine clinical care data from the hospitals that make up University Hospitals Birmingham NHS Foundation Trust. To assist in this consideration, members queried the structure of the medical information systems within University Hospitals Birmingham NHS Foundation Trust, and whether there are separate systems for each hospital, or whether they are all linked.

Letter of support

It was noted that, initially, West Midlands Ambulance NHS Foundation Trust will provide data to University Hospitals Birmingham NHS Foundation Trust. However, no letter of support from West Midlands Ambulance NHS Foundation Trust was provided in the application as would be typically provided in support of an application for 'section 251 support'. It was advised that a letter of support from West Midlands Ambulance NHS Foundation Trust Caldicott Guardian or equivalent should be provided to CAG that confirms they require this legal support to transfer identifiable information to the PIONEER database to avoid a breach of the common law duty of confidentiality.

Geographical extension

The group were however unclear as to the future planned geographical extension of the PIONEER database, whether it will remain as a West Midlands area database or whether it will expand the database to a much wider geographical scope. Members noted that the project filter of the CAG application had ticked Northern Ireland, Scotland and Wales as countries who would be supplying data to the database. Members asked for clarity on the ultimate ambition of the database in terms of geographical scope.

As such, the group agreed that support will be limited, initially, to University Hospitals Birmingham NHS Foundation Trust processing of data for this purpose and the West Midlands Ambulance NHS Trust transfer of fully identifiable information. Prior to extending further, members would require evidence that the processes between the supported organisations are working as intended and details of any issues that have arisen in the initiation of the database, and how these have been resolved.

Free text information

The applicants clarified that support was initially requested to collect structured data, unstructured data in the form of medical images, and unstructured data in the form of free text data. Whilst the group were content to support the use of structured and medical image data, at this time support is not provided for the use of unstructured free text data. The reason for excluding this element from the current scope of support was that the CAG had concerns about the use of free text data and the mechanisms to be used to ensure that all direct and indirect identifiers would be removed during the pseudonymisation process at source, and for those unable to pseudonymise. In noting that the applicants had confirmed that they would be understanding of this approach as the need for free text data was not currently a critical part of the initial data extraction, the Group agreed they would consider this point further once the applicants consider the pseudonymisation methods of free text data at source and are able to demonstrate its effectiveness through submitting a paper at the appropriate time.

Medical purpose

Members were uncertain whether the resultant data collected in the PIONEER database under ‘section 251’ support had the potential to be used for non-medical purposes. The group wished to make clear that ‘section 251’ support is given for medical purposes only, and that this extends to the use of the resultant data by

researchers for medical research purposes only as requested. As such, the data should not be used for non-medical purposes.

Outputs of the PIONEER database

Whilst the group acknowledged the high potential for PIONEER to bring benefits to the NHS and patients, the group were uncertain on the initial planned uses of the research database. Members noted the example use cases on page 13 of the protocol but felt the application did not provide a firm description of what research questions the applicants are hoping to answer and requested concrete examples of the research questions that the database will initially be used to answer.

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**

Whilst the amount of data collected by PIONEER will be considerable, it was noted by members that the flows of identifiable information, in most cases would be minimised by use of pseudonymisation at source. The Group also understood that University Hospitals Birmingham NHS Foundation Trust would have the ability to re-identify a maximum of two data fields (usually NHS number and date of birth) to enable linkage of datasets. Members were generally content with this, but queried why, if a common pseudonymisation process was used, the linkage could not be undertaken on pseudonyms. Specific feedback on this element was requested.

Members also noted that participating healthcare organisations would also have the opportunity to transfer fully identifiable information to University Hospitals Birmingham NHS Foundation Trust for pseudonymisation, where there was not capacity for the participating healthcare organisation to do this themselves. As detailed by the applicants, it was expected that this would only be used for a small minority of organisations, with most undertaking this themselves and members reviewed the data flow diagrams. The group had concerns over this process and the

safeguards in place to minimise the use of identifiable information. As such, general support for this process was not currently provided. Where the applicants identify an organisation that is unable to pseudonymise themselves, the applicants should submit an amendment to add the new organisation, detailing the processes that will be used in further detail to pseudonymise the dataset, as well as how the use of identifiable information will be minimised in this process.

- **Feasibility of consent**

Given the scale of data collection, the need for a complete dataset and issues around bias and deceased patients, the Group agreed that consent would not be feasible.

- **Use of anonymised/pseudonymised data**

As detailed above, members were generally content that this study could not be undertaken without the use of identifiable information in order to enable linkages.

Access to Database Information

The group noted the processes in place to approve researcher access to anonymised information from the database. Members queried whether this would be via providing data extracts, or through enabling a 'safe haven' access approach. The group are aware that NHS Digital are pursuing researcher access to data though a safe haven, which provides additional security ad control of access to the data. The group queried whether this was an option that PIONEER are considering for researcher access to data.

'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 provided a privacy notice that was intended to be used to communicate with the relevant population. Members noted that privacy notices are a general organisational requirement that are typically focused on the handling of personal data under data protection legislation, are often legalistic in tone and typically only reviewed by the interested reader. Members noted that privacy notices are not typically the primary vehicle used to communicate with patients of the uses of their data under the common law duty of confidentiality.

The Group noted there were relatively limited other patient notification materials provided and a lack of detail on an overall patient notification strategy. In line with the above principle of support for patient notification, members wished for further patient notification materials, separate to the privacy notice, to be provided in plain English, with details on how and where these would be disseminated.

Further, given the potential scale and importance of the research database, members wished to be reassured that the applicants have working practices in place to ensure continued patient notification throughout the lifetime of this project, as well as how to handle media enquires in order to maintain public confidence of the database. As a condition of support, the group requested for the applicants to provide a comprehensive media and communications strategy to the CAG within three months of the final outcome letter. This should include details on how the applicants will maintain patient information to the wider public throughout the lifetime of this project and how the applicants will handle media enquiries.

The group noted how the applicants will use the national data opt out for managing patient objections, and that University Hospitals Birmingham NHS Foundation Trust has ensured compliance with this so that any patients who have registered an objection will not have their data transferred. The applicants also stated that there will be also be a local opt-out process for this application, with patients completing an opt-out form. The group agreed that the patient notification materials should clearly detail the opt out mechanisms for patients, including contact details for those who cannot complete an online form.

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 group commended the applicants on their thorough Patient and Public Involvement and Engagement work to date, as well as the plans for continuing engagement throughout the lifetime of this project. It was noted that Patient and Public Involvement and Engagement has been at the heart of the development of the database to date which is applauded, and members wished for this to continue throughout its lifetime.

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, please 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 letter from West Midlands Ambulance NHS Foundation Trust, as data controller, to confirm their support for this application and to confirm that ‘section 251’ support is required to enable this transfer for this purpose.

2. Provide firm examples of the research questions that the database will initially be used to answer.

3. Provide considerations as to why, if a common pseudonymisation process was used, the linkage could not be undertaken on pseudonyms.

4. Clarify the understanding of pseudonymisation within the application in terms of what is transferred to Birmingham and the Pioneer database.

5. Specify, in absolute clarity, the exact relationship between the four hospitals of University Hospitals Birmingham NHS Foundation Trust and the PIONEER database team who may access confidential patient information of these hospitals, providing confirmation where 'section 251' support is or is not required.

    a. On what common law duty of confidentiality basis are the PIONEER team accessing this data, for research purposes, considering the processing relates to a different purpose.

    b. Detail the medical system infrastructure within University Hospitals Birmingham NHS Foundation Trust. Are the systems of each hospital linked, or separate?

6. Detail the ultimate ambition, in terms of geographical scope, of the PIONEER database.

7. Provide, separate to the privacy notice, further patient notification materials. This should include:

    a. Information, in Plain English, for service users to understand the work of PIONEER

    b. Details of how service users may use the local opt out for PIONEER, including contact details.

    c. Supplementary information on where the provided patient notification materials will be used.

Once received, the information will be reviewed at the next available CAG meeting and a recommendation and decision issued as soon as possible. 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. Support is limited to the involvement of West Midland Ambulance Trust initially. Prior to the addition of subsequent external organisations, a report should be sent to the CAG for consideration on the success of the processes with this Trust, detailing any issues that have arisen in the initiation of the database, and how these have been resolved.

2. Support is limited to the use of structured data and unstructured medical image data only.

3. Support is not provided for the use of unstructured free text data. Where the applicants wish to use this form of data in the future, a detailed amendment/paper should be submitted to the CAG, providing information on how the applicants have considered the pseudonymisation methods of free text data at source, and how they demonstrate its effectiveness in deidentification.

4. Support is not currently provided for participating organisations, other than to transfer identifiable information to University Hospitals Birmingham NHS Foundation Trust to undertake the pseudonymisation process. Where this situation is expected to occur, an amendment should be submitted to the CAG, providing assurances on the minimisation of identifiable information and the further detail on the processes that will be used.

5. Within three months of the final outcome letter date, provide the CAG with a comprehensive media and communications strategy. This should include details on how the applicants will maintain patient notification to the wider public throughout the lifetime of this project, and how the applicants will handle media enquiries.

6. Support is given for the use of data for medical purposes only. This extends to the use of resultant datasets by researchers. As such, the data must not be used for non-medical purposes

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

8. 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 throughout the duration of support. See section below titled 'security assurance requirements' for further information. **The NHS Digital DSPT review for West Midlands Ambulance Service NHS Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 29 June 2020).**

The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS DSPT Tracker (checked 29 June 2020). Support is conditional upon organisation meeting the action plan, as agreed with NHS Digital, and maintaining the agreed standard for the duration of support. All University Hospitals Birmingham staff handling information under this support must act in accordance with all details specified in the application.

b. 20/CAG/0081 – Use of artificial intelligence to predict vascular complications in diabetes

Context

Purpose of application

This application from Barts Health NHS set out the purpose of medical research to determine whether artificial intelligence (AI) can identify and predict the progression of diabetes foot disease.

Diabetes is an important public health problem. It currently affects almost 3.7 million people in the UK, with 12.3 million at increased risk of type 2 diabetes. Vascular complications include diabetic foot disease, which, in the three-year period 2013-2016 was responsible for 121,067 hospital admissions and 1,688,699 days spent in hospital in England by 73,388 patients, 31% of whom had more than one admission. Over the same time period, 7119 major amputation procedures were performed, an age and ethnicity standardised rate of 8.1 major amputations per 10,000 population-years. This project has been created to contribute towards improving the health of the public by using natural language processing (NLP) and machine learning methods, applied to text rich hospital records and to develop predictive tools with which to identify those at high risk of an active diabetic foot problem and/or amputation at an earlier stage than currently possible. The applicants aim to enable newer interventions to prevent or delay disease progression to be tested and management of diabetes to be optimised.

The research team will extract the structured and free text records from case patients (diabetics who developed foot disease) and controls (diabetics who did not develop foot disease) at Barts Health NHS Trust into a study database, held within Barts Health NHS Trust. The free text data will be run through a natural language processing program to turn the free text into structured codes (Snomed codes). The research team will then compare the codes extracted from free text data against the structured data within the patient medical records to determine the effectiveness of the program in predicting onset of diabetic foot disease.

A recommendation for class 1, 2, 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	Matched groups of equal size of patients at Bart's Health NHS Trust that have either diabetes foot disease or diabetes that have not developed diabetes foot disease.

	Patients are over 18 years old and must have had at least one encounter with Bart's Health NHS Trust since 2014 which produced free-text data. The applicants anticipate that approximately 5000 patients will be included.
Data sources	1. Bart's Health NHS Trust
Identifiers required for linkage purposes	1. Hospital ID
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Occupation 4. Ethnicity 5. Postcode
Additional information	All free text information from patient records would be temporarily processed for this research. Once retrieved the free text data will be run through natural language processing to turn it into structured data codes. Free text data will be deleted following this process.

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 proposed activity had a medical purpose and was in the public interest.

Scope

The application contained references to the collection of data from GP practices as well as from within Barts Health NHS Trust. Members requested clarification on whether any data would be obtained from GP practices.

The patient cohort will be identified by the research team within Barts Health NHS Trust using third party clinical natural language processing (NLP) software. Patients with foot complications were identified via search of free text. The Group asked for assurance that patients with diabetes will be identified from coded data only and not via free text.

The Group queried whether the free text extracted would contain any sensitive data items, i.e. data relating to sexual or mental health. If any sensitive data items would be retained, members requested that justification for retaining these items was provided.

The CAG observed that, should the applicants intend to develop the dataset for use in future research, then amendments may need to be submitted to the CAG to reflect this. Details on governance arrangements for the database and how requests to access the data would be managed would 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.

- **Feasibility of consent**

The applicants had advised that consent was not feasible due to the size of the cohort and that a number of patients may have died. The Group agreed that seeking consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants explained that analysis of the free text data, which may contain patient identifiers, could not be completed with only the use of anonymised or pseudonymised data. The applicants would take steps to minimise the use of identifiable data wherever possible.

Justification of identifiers

The applicants had advised that patients' date of death, gender, occupation, ethnicity postcode and Lower Layer Super Output Area (LSOA) would be retained for analysis. Members queried why it was necessary to retain both postcode and LSOA.

'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 had not provided a patient notification and dissent mechanism with the application. This had been queried by the Confidentiality Advice Team in advance of the meeting and the applicants had advised that they were developing a strategy. Members asked that the patient notification strategy and dissent mechanism were provided.

The CAG asked that patient notification strategy was implemented at least six weeks prior to the beginning of the data extraction, to allow patients sufficient time to dissent.

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 have worked with Barts Health NHS Trust Diabetes Research Group and Diabetes Clinical Research Network at the QM William Harvey Institute to organise patient and public involvement activities to test the acceptability of using patient identifiable data in their local diabetes population. The applicants have also attempted to engage with a wider patient population via Twitter. The project proposal was explained, and three specific questions asked. The applicants also planned to make a video, to be distributed via social media and the Barts Life Sciences website. The applicants have also contacted two other patient and public involvement groups for consideration of the project but had not yet received feedback.

The Group noted that patient and public involvement carried out so far. Members agreed that it was unclear whether the specific issue of processing confidential patient information without consent had been discussed and asked that further involvement was undertaken and feedback provided.

Start date of project

The CAG noted that the application stated that the data extraction would begin in February 2020. Members asked that the revised start date was provided.

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, please 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 clarification on whether data from GP practices will be obtained.

2. Confirm that patients in the diabetes cohort will be identified from coded data only and not via access to free text.

3. Clarify whether any sensitive data items would be contained in the extracts from free text and, if so, whether these details would be removed from the free text extract. If any sensitive data items would be retained, provide justification for the retention of these details.

4. Clarify whether both patients' postcode and Lower Layer Super Output Area needed to be retained for analysis.

5. Patient and public involvement and engagement needs to be carried out around the specific issue of access to confidential patient information without consent, and feedback from this provided to the CAG.

6. A patient notification strategy and dissent mechanism needs to be created and provided to the CAG for review. The patient notification strategy needs to be implemented at least six weeks prior to the beginning of the data extraction, to allow patients sufficient time to dissent.

7. The start date needs to be clarified.

8. Confirm that amendments will be submitted if the database were to be made available for other research in future.

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. **Confirmed 13 April 2020.**

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: Barts Health NHS 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.

c. 20/CAG/0080 – CADENCE: Crp probAble DEpression iNflammation Cfs/mE

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to evaluate whether raised C-reactive protein (CRP) is associated with probable depression, as measured on the Revised Childhood Anxiety and Depression Scale.

Paediatric chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) is relatively common (prevalence 0.1–2%), with significant morbidity for children and their families. Co-morbid mental health disorders are common in children and young people with CFS/ME. Up to approximately 30% of children diagnosed with CFS/ME have co-morbid depression. In these children, depression is not thought to be the primary cause of the fatigue or disability. Whilst we assume the depression is secondary to the disability, loss of function and subsequent loss of social life/school and friendships, it is possible that the depression describes a phenotype of CFS/ME. Several pro-inflammatory markers have been associated with depression, most notably CRP. Adult population-based studies have demonstrated an association between elevated CRP and both increased risk of depression and increased severity of depression. This study aims to understand more about the association of high CRP and probable depression; it thereby addresses an unmet need by attempting to better understand, diagnose and treat co-morbid depression in children and adolescents with CFS/ME. Establishing whether neuroinflammation could contribute to the manifestation of depression in young people with CFS/ME may help us to both phenotype the different forms of CFS/ME and also give insights into the aetiology of depression in this population.

The research team have previously undertaken two studies (FITNET-NHS and DDS/Wellbeing) in a cohort of children with CFS/ME. The Wellbeing study was completed about a year ago, whilst FITNET-NHS is still ongoing. Whilst a consented activity, the research team now wish to link the data from these studies with CRP data, held by Royal United Hospital Bath NHS Trust. The research team have discussed this with their sponsor (and data controller for the data), who believe that the original consent take was not adequate (specific enough) to provide a legal basis for the proposed activities in this retrospective part of the present study.

From the original study datasets, the applicants will create two new databases (one for each previous study) which will hold name, date of birth, respective study identifier (Participant Id/Research Id) and this study's Participant Code. Each will then be populated with questionnaire data from the original study and then pseudonymised (removing names, dates of birth and study identifiers leaving just the clinical data and the participant codes in each database). These two pseudonymised databases will then be merged into one pseudonymised dataset (minus the questionnaire data) that is then transferred to Royal United Hospital Bath NHS Trust. The Trust is then able to reidentify participants from the study keys that they already hold and populate the database with the CRP data. The returned pseudonymised CRP data is then merged with the questionnaire data to create the final dataset for the study for analysis.

A recommendation for class 1, 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	Participants in the Wellbeing study who have completed RCADS questionnaires (approximately 90). Participants in the FITNET-NHS study that have CRP blood results available in the Royal United Hospital Bath NHS Trust medical records at the RUH site and will be included in the current study (approximately 170).
Data sources	1. University of Bristol 2. Royal United Hospital Bath NHS Trust
Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. Study ID
Identifiers required for analysis purposes	1. None

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 within 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 had advised that the research sponsor and the Royal United Hospitals Bath had determined that the original consent was insufficient for the further linkages proposed in this application. Written confirmation from both organisations had been provided, as well as the participant information sheets and consent forms for both previous studies. These did not specifically refer to use of data for future research, nor to obtaining information from Royal United Hospitals Bath.

The applicants explained that consent was not feasible for this study as they had received low return rates to previous attempts to re-contact.

The CAG noted that 260 children in total had been involved in the two previous studies and that the applicants had up to date contact details for patients, and that it should be relatively easy to contact patients in order to seek consent. The Group noted that the two previous studies had not yet concluded and queried whether recruitment to the previous studies could be extended in order to recruit the required participants on

a consented basis. If the recruitment to these two studies could not be extended, then justification as to why not needed to be provided.

Previous attempts to recontact patients were referred to and the CAG requested confirmation that previous attempts had not been made to contact patients to seek consent for the specific activity proposed in this application. ICO guidance was that non-response was considered to be dissent and it would not be appropriate to use support under s251 to process confidential patient information for patients who had not responded to the applicants attempts to re-contact.

Members noted that the participants in the Wellbeing study had been informed that their information would be anonymised and kept confidential. The Group requested clarification on how the data linkages required for the CADENCE study would be undertaken for patients in Wellbeing if the data for these patients was anonymised.

If the data collected for patients in the Wellbeing cohort have not been anonymised, then the legal basis for continuing to hold the confidential patient information of participants in the Wellbeing cohort needs to be clarified. Members observed that s251 support cannot be granted retrospectively, if a legal basis was not in place for the retention of confidential patient information for this cohort. The Group suggested that the applicant seek legal advice from the data controller regarding the lawful basis, under the Common Law Duty of Confidentiality, for the current holding of this data, in collaboration with the Trust Caldicott Guardian and Data Protection Officer. Any lessons learnt and actions arising from this discussion that would support a response should be provided. Members asked that the advice requested focus specifically on meeting the Common Law Duty of Confidentiality in this context, and confirm that current holding of the information is compliant with data protection legislation, with the appropriate amount of granular detail.

- **Use of anonymised/pseudonymised data**

The applicants explained that the data would be pseudonymised as far as possible. The Royal United Hospital Bath NHS Trust would be provided with the study ID to enable the Trust to use the original study key code to reidentify the participants and enable CRP data to be collected. This will then be returned to the University of Bristol in a pseudonymised format. The CAG noted this information and raised no queries regarding this aspect of the application.

‘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 application refers to using posters and leaflets, but these had not been provided with the application.

The applicants advised that, if a participant in the FITNET-NHS and Wellbeing studies had expressed dissent, then a record of this was kept in the relevant original study and the CADENCE study and that participants’ data would not be used.

The Group asked that the patient notification materials were submitted for review. These materials needed to provide patients with a mechanism to dissent from the inclusion of their data in the CADENCE study.

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 have discussed the both work packages with the Bristol Young Person's Advisory Group and the young person's CFS/ME Patient Advisory Group, who were both supportive of the work.

Evidence of the Bristol Young Person's Advisory Group work was provided. However, the introduction implied that the processing was covered under the terms of the consent of the original study and the text referred to early anonymisation. While the applicants would take steps to minimise the use of identifiable information, it would not be anonymised. The CAG agreed that further patient and public involvement needed to be undertaken around the specific issue of the processing of confidential patient information without consent required in order to complete the required linkages.

Data Protection Compliance

The CAG agreed that information on how the GDPR principles would be met was required.

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, please 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. Clarify how the further data linkages required for the CADENCE study will be carried out for patients in the Wellbeing cohort, if the data for these patients has already been anonymised. If the data for patients in the Wellbeing cohort has not yet been anonymised, the legal basis for continuing to hold the confidential patient information needs to be clarified.

2. Confirm that the previous attempts made to contact patients had not been to seek consent for the specific activity proposed in this application.

3. Clarify if recruitment to the Wellbeing and FITNES-NHS studies could be extended so that the required number of patients can be recruited prospectively. If recruitment cannot be extended, please provide justification for this.

4. The patient notification materials need to be submitted for review. These materials need to provide patients with a mechanism to dissent from the inclusion of their data in the CADENCE study.

5. Further patient and public involvement needs to be undertaken around the specific issue of the processing of confidential patient information without consent required in order to complete the required linkages. Feedback from this needs to be provided to the CAG for review.

6. Demonstrate how the specific activity is operating in compliance with each principle of the GDPR and Data Protection Act 2018, as follows:

    a. Lawfulness, fairness and transparency - Information is processed lawfully, fairly and in a transparent manner in relation to individuals;
    b. Specific and legitimate purposes - Information is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes;
    c. Data minimisation - Information is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
    d. Accuracy - Information is accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;
    e. Storage limitation - Information is kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed;
    f. Security - Information is processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures;
    g. The accountability principle – Demonstrate how the controller shall be responsible for, and be able to demonstrate compliance with the accountability principle.

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. **Pending for Royal United Hospital Bath NHS Trust and the University of Bristol.**

4. Consideration Items

a. CAG 2-05(b)2013 – Amendment

Amendment request

Support was initially given in 2013 for the applicants to conduct a prospective observational cohort study of patients attending emergency departments with suspected pandemic influenza so as to evaluate existing triage methods, identify clinical predictors of adverse outcomes and develop new triage methods. The applicants submitted in amendment in February 2020 to activate this application in order to study patients with COVID-19. This further amendment has been submitted to make additional changes.

The protocol has been updated to include the following aims:

1. To link NHS 111 calls, identified as potentially relating to COVID19, to participating hospital and NHS Digital data, to determine whether patients calling NHS 111 were appropriately advised or provided with an ambulance response, in terms of whether they were admitted to hospital or suffered an adverse outcome.

2. To link ambulance ePR data to hospital and NHS Digital data, to determine whether patients attended by ambulance were appropriately advised to self-care at home or transported to hospital, in terms of whether they were admitted to hospital or suffered an adverse outcome.

3. To use ambulance ePR data recording patient characteristics to determine which patient characteristics, when recorded prehospital, are useful in predicting adverse outcome and determine the discriminant value of early warning scores, such as NEWS2, for predicting adverse outcome.

4. To explore the potential for data mining to provide new insights into the prediction of adverse outcome among patients contacting NHS 111 or ambulance services with suspected COVID-19.

The applicants also confirmed that NHS Digital and Yorkshire Ambulance Service (YAS) NHS Trust will act as data processors for the purpose of this study. An updated data flow diagram had been included to reflect this.

The following additional items of confidential patient information will be required to enable linkage between the core-PRIEST dataset, data supplied by NHS Digital and data supplied by Yorkshire Ambulance Service NHS Trust.

NHS 111 telephone service patient identifiable items (from YAS)

- NHS Number
- Postcode of residence
- Date of birth

Emergency ambulance service patient identifiable items (from YAS)

- NHS Number
- Patient name (first name and surname)

- Postcode of residence
- Postcode of incident
- Date of birth

Demographic patient identifiable items (from NHS Digital)

- NHS Number
- Postcode of residence
- Date of birth

Death registration patient identifiable items (from NHS Digital, ONS)

- Date of death

Emergency department patient identifiable items (from participating English acute hospital Trusts)

- NHS Number
- Date of birth

The applicant also clarified that they would access records relating to activity occurring within the following periods:

- NHS 111 telephone service - 01/02/2020 to 30/09/2020 (inclusive)

- Emergency ambulance service - 26/03/2020 to 30/09/2020 (inclusive)

- NHS Digital supplied data (Emergency Care Dataset / HES Admitted Patient Care / HES Critical Care / Death registrations / Demographics) - 01/02/2020 to 30/09/2020 (inclusive)

The patient identifiers would be retained for up to 18 months after all data necessary for the planned analysis are obtained, subject to data sharing agreements with data providers, to ensure that the data linkage processes can be audited. Direct identifier data items (NHS Number, name, date of birth, postcodes, date of death) will not be present in analysis datasets.

The applicants advised that data would be processed on a virtual machine, hosted on University of Sheffield servers with access limited to specific users with nominated static IP addresses. Due to home working restrictions, it is no longer possible to limit

access from specific static IP addresses. However, access will be limited to specified users only and these users will require two distinct sets of credentials (username and password combinations) in order to access any identifiable data. Fully pseudonymised data may be stored on University of Sheffield (UoS) servers and accessed from UoS managed devices via a single set of (authorised) user credentials.

The applicant also provided an update on the patient and public engagement that had been carried out with two representatives from the Study Steering Committee and Yorkshire Ambulance Service patient research ambassadors. Feedback from these had been positive. The applicants are also working to establish an additional independent patient and public involvement group to advice on methods, data collection, results, and dissemination of all aspects of the PRIEST study. They were seeking members who have had COVID-19 while using emergency department and/or prehospital services.

Confidentiality Advisory Group advice

The Group agreed that there was a strong public interest in looking at the NHS 111 system and the appropriateness of the advice given. Members reminded the applicants that the database created can only be used for the purposes described in the application, quality control of the NHS 111 and ambulance crew decision-making and to develop an algorithm to assist them.

Members noted main concern regarding this amendment was the processing of free text data. The Group noted that processing of free text data was generally not supported by the CAG but recognised the need for this specific application. The Group noted that processing of free text data would be supported due to the particular circumstances and requirements of this application. An effective mechanism to pseudonymise the free text needed to be created and fed back to the CAG within 3 months of the amendment being given support. If an effective mechanism could not be created, then the free text data would need to be anonymised after use. Any identifiable information extracted from the free text needed to be destroyed.

The Yorkshire Ambulance Service was mentioned, but the application also referred to 40 participating hospitals, including some in Scotland. The Group queried the scope of support required and asked that a list of participating Trusts was provided.

The CAG noted the patient and public involvement that had been carried out and agreed that further activity needed to be carried out. The Group recognised the difficulty in conducting patient and public involvement during the Covid-19 pandemic but agreed that this needed to be carried out. Members suggested that a questionnaire was created and disseminated via engagement with appropriate patient groups and charities.

The Group noted that it would be difficult to conduct effective patient notification within the patient group, who may be severely affected by coronavirus. Given the breadth of information that would be collected, members agreed that a patient notification strategy needed to be created. This needed to contain an explanation on why the amount of information collected was required.

The Group noted that patient outcomes were divided into ‘adverse outcome’ and ‘no adverse outcome’. Members queried whether the need for hide-dose anticoagulation, incidences of stroke and increase in blood viscosity were included as adverse outcomes.

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 conditional 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.

In order to complete the processing of this application, please respond back to the following request for further information within three months. A detailed covering letter should be provided, together with any supplementary documentation for review.

Request for further information (Summary)

1. Confirmation needs to be given that further amendments, or a new application, will be submitted if the database is to be used for any purposes in addition to those described in the application.

2. An effective mechanism to pseudonymise the free text needs to be created and fed back to the CAG. If an effective mechanism cannot not be created, then the free text data will need to be anonymised after use. Confirmation needs to be given that any identifiable information extracted from the free text will be destroyed.

3. A patient notification strategy needs to be devised and fed back to the CAG. This needs to contain an explanation on why the amount of information collected is required.

4. Further patient and public involvement is to be carried out. Members suggested that a questionnaire is created and disseminated via engagement with appropriate patient groups and charities.

5. A list of participating Trusts is to 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 HRA will confirm support.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission.
   Confirmed – University of Sheffield – School of Health and Related Research (by NHS Digital email dated 06 August 2019), Yorkshire Ambulance Service NHS Trust (by check of the NHS Digital DSPT tracker on 25 June 2020) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT submission 2018/19.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Pending

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