Minutes of the meeting of the Confidentiality Advisory Group

15 October 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Patrick Coyle	Yes	CAG Vice-Chair
Dr Lorna Fraser	Yes	CAG Member
Dr Rachel Knowles	Yes	CAG Member
Professor Jennifer Kurinczuk	Yes	CAG Member
Dr Harvey Marcovitch	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Dr Murat Soncul	Yes	CAG Alternative Vice-Chair
Mr Marc Taylor	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

1. Introduction, apologies and declarations of interest

Any declarations of interest are detailed for each application below.

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 decision in relation to the **17 September 2020** meeting applications is pending.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **17 September 2020** meeting applications.

3. New Applications – Non-Research

a. 20/CAG/0130 - Yorkshire and Humber Care Record (YHCR) Population Health Management (PHM) for non-research purposes

Context

Purpose of application

This application from Humber Teaching NHS Foundation Trust set out the purpose of creating a Population Health Management Solution, which will allow organisations in the Yorkshire and Humber Region to request and receive data for non-research purposes, as part of the Local Health and Care Record Exemplar (LHCRE) Programme.

Population Health Management is a technique for local health and care partnerships to use data to design new models of proactive care and deliver improvements in direct care resulting in a positive impact upon health and wellbeing of patients. This will take advantage of digital technologies and data analytics that can be used to prevent avoidable delays in diagnosis, unnecessary repeat tests and reduce clinical uncertainty that can slow down the speed at which people are able to begin to receive the treatment and care they need. The main aims of this work are to

- Improving the physical and mental health outcomes and wellbeing of people, whilst reducing health inequalities within and across the Yorkshire and Humber region.
- The reduction of re-occurrence of ill-health, including addressing wider determinants of health, and requires working with communities and partner agencies.
- Addressing the wider determinants of health to early intervention, primary, secondary and tertiary disease prevention.

Support is requested for the transfer of confidential patient information from participating organisations in the Yorkshire and Humber region to Humber Teaching Hospitals NHS Foundation Trust. The NHS number of patients will then be collated and sent to the NHS Digital's National De Identify / Re-Identify service, who will return a pseudonym. This will be applied to the data to render it pseudonymous prior to the person requesting access to view the data for analysis on the Humber Teaching Hospitals NHS Foundation Trust system.

A recommendation for class 1 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 patients and service users irrespective of age or characteristics from organisations in the Yorkshire and Humber area who have not opted out via the national data opt-out.

	The applicants anticipate that 5.5 million service users will be included once fully deployed
Data sources	1. Humber Teaching Hospitals NHS Foundation Trust 2. Rotherham, Doncaster and South Humber NHS Foundation Trust 3. Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS number 2. Postcode
Identifiers required for analysis purposes	1. LSOA or postcode to be able to do geographical analysis and link to deprivation but will not identify individual households.
Additional information	No medical images nor free text information will be included in the clinical data provided.

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.

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.

Members understood that this was an application from the Yorkshire and Humber area as part of the Local Health and Care Record Exemplar (LHCRE) Programme. The group agreed that this application had a medical purpose, and that the public interest in this programme is substantial, given the potential benefits that it may bring to care.

It was noted that this is the first LHCRE programme to submit to the CAG and that further applications from other areas may follow in due course. As such, and despite the substantial public interest and considerable member support, the group provided the following comments to ensure that the scope of support is clear and that patients and the public have full information to make an informed choice about their data being used as part of this programme.

Scope

The group noted that this was a non-research application and, as such, the data may only be used for the management of health and social care, not for medical research. In the event that there is a desire to use this data architecture for the extraction of data for medical research purposes a separate research application will need to be made.

The group noted the long list of organisations that are planned to participate in this programme, although the only organisations to have agreements in place to begin are Humber Teaching Hospitals NHS Foundation Trust, Rotherham, Doncaster and South Humber NHS Foundation Trust, and Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust. Members confirmed that any initial support provided will be specific to these Trusts only and does not extend to other organisations listed in the application. Where further organisations are ready to participate, an amendment should be submitted to include these.

Data Flows

There were some uncertainties within the group around the precise flows of confidential patient information between which legal entities, and the extent of the data flows. Members generally understood that data, identified by NHS number, will be transferred from the host organisation to Humber Teaching Hospitals NHS Foundation Trust, where data from multiple organisations will be collated. The NHS number only will be sent to NHS digital who will convert this to a pseudonym and return to Humber Teaching Hospitals NHS Foundation Trust. The clinical information will then be identified by the pseudonym within the systems of Humber Teaching Hospitals NHS Foundation Trust, and where it will be accessed by those undertaking the project.

However, the main uncertainty lies with the extent of the data flows and whether all data of all patients from participating organisations wil be transferred to Humber Teaching Hospitals NHS Foundation Trust for pseudonymisation and subsequent interrogation as and when requested, or whether only relevant data of a specific patient group will be requested on a per project basis.

Members requested clarification so that the member understanding around data flows is correct, and the extent of the data transferred as per these data flows.

Exit Strategy

Members wished to confirm the exit strategy for using confidential patient information. It was understood that there is no overall exit strategy (other than new regulations being implemented) and that support will be required on an ongoing basis until any new regulations are implemented. However, on a per project specific basis the data will be pseudonymised with the end user not having access to the key (therefore it is effectively anonymised). Further, data will be deleted at the end of each project, or after 12 months of inactivity.

Patient and Public Involvement

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 CAG noted the extensive patient and public involvement that has been undertaken as part of the setup of the LHCRE programme and commended the applicants for this. However, it was not clear from the provided information as to whether patient and public involvement has been undertaken to discuss the specific point of sharing of confidential patient information (i.e clinical data identified by NHS number) without consent, and members requested further information about this specific aspect. Where this has not been undertaken members requested that this is done prior to a final outcome being issues.

Given the large scale nature of this project, the group requested further information about the plans for ongoing patient and public involvement throughout the lifetime of the project.

‘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.

As it was understood by the group, the applicants initially were not developing any patient materials until support under Regulation 5 was given. Following initial enquiries, the applicants subsequently confirmed that each participating organisation will be responsible for their own patient notification, and then provided a template poster that organisations will localise. The group also noted plans to use pull up banners and TV screen promotions in waiting areas.

Given the updated responses the group were unclear about the patient notification strategy to be used in this large-scale project and requested further clarification on the patient notification materials to be used. The group also wished for confirmation whether local patient notification approaches will still be adopted and, if so, asked for the template materials to be used in current participating organisations if so.

Members felt that the supplied poster should be revised to make clearer to patients what is happening with their data, including the flows of identifiable data. The group suggested that, in revising the poster, patient and public views on this should be requested to ensure that it is clear to service users.

The applicants stated in the application that they planned to only use the national data opt out because they would be in "*danger of developing new information silos that are unable to support care when an individual moves between different localities, or when they are a member of a cohort of patients whose needs are best served at a wider geographical level*". Members did not accept this argument and believed that using only a national opt out mechanism for a specific project could present wider issues where it would restrict processing of data of those patients for all projects when they may just wish to opt out of this project. A such, members requested that a local opt out mechanism is adopted for this project and this should be included on patient notification materials.

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**

Members agreed with the applicant that consent is not feasible for this project, given the potentially large scale nature of the data collection.

- **Use of anonymised/pseudonymised data**

The group noted that the applicants have taken great care to restrict the use of identifiable information as much as possible so that data is pseudonymised rapidly and, for the end user, is effectively anonymised.

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, 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 absolute clarity on the identifiable data flows within this application, and between which legal entities these flows will be.

2. Confirm that participating organisations are not transferring all data within their systems at once, only data required for each specific project will be transferred.

3. Confirm that there is no exit strategy for the project as a whole (support will be ongoing) but that there is a clear exit strategy for each project as data will be deleted once the project has finished (or after 12 months of inactivity).

4. Confirm whether the patient and public involvement events discussed the flow of confidential patient information (i.e. clinical data identified by NHS number) without

consent. If this was not discussed further patient and public involvement will be required to ensure discussion about this central specific issue, before support can be given.

5. Provide further information on the plans for ongoing patient and public involvement throughout the lifetime of this project.

6. Ensure that a project specific opt out is provided as part of this application and describe the mechanism that will be used to achieve this requirement.

7. Update the patient notification materials to make these more understandable for the general public. It is suggested that this is considered by a patient and public involvement group to aid with this. The updated patient notification materials should include information on how to opt out (using both the local and national opt out mechanism).

8. If there are any further organisations specific patient notification materials being used, please provide these to the group for consideration.

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. Support is provided for the medical purpose of the non-research activity of the management of health and social care only and does not extend to medical research.

2. This support applies only to Humber Teaching Hospitals NHS Foundation Trust, Rotherham, Doncaster and South Humber NHS Foundation Trust and Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust in the first instance. Where further organisations are in a position to undertake this work an amendment should be submitted to extend this support to these organisations.

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 submission for Humber Teaching NHS Foundation Trust (18/19), Rotherham, Doncaster and South Humber NHS Foundation Trust (19/20) and Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (18/19) was confirmed as ‘Standards Met’ by NHS Digital (by check of DSPT tracker on 18 October 2020).**

Declarations of Interest

Lorna Fraser declared a potential interest and did not participate in the development of the recommendation provided by the CAG.

Murat Soncul declared an interest and left the meeting when this item was considered

4. Resubmitted Applications - Research

a. 20/CAG/0133 - Yorkshire Specialist Register of Cancer in Children and Young People

Context

Purpose of application

This application, from the University of Leeds, sets out the purpose of establishing a database for medical research purpose, which aims to undertake research on the area of cancer.

Cancer is a rare disease in children and young people and one that places a considerable burden not only upon the patients themselves but also on their families and the health care system. Little is known about the causes in this young age group. The Yorkshire Specialist Register of Cancer in Children and Young People is an established population-based register of tumours diagnosed in the childhood, adolescent and young adult age ranges. The Register currently contains information on 10,500 young people diagnosed with cancer while living within the former Yorkshire Regional Health Authority.

The primary aim of the Register is to investigate the causes of cancer through the application of epidemiological analyses. This includes monitoring time trends and investigating geographical patterns of disease across the region. Secondly, our aim is to investigate the delivery of care to young people with cancer in Yorkshire to ensure the best treatment is available and to minimise long-term health and social effects; for example by looking at pathways of care, factors that influence survival and minimise long-term complications.

Support is requested to enable sharing of confidential patient information between University of Leeds and Local NHS Trusts, EMIS, TPP, NHS Digital, Public Health England, Department of Education and Department of Work and Pensions in order to establish and maintain a research database. The database contains around 10,500 young people and linkages continue to be sought for these people. Linkages occur at monthly/quarterly intervals and each includes transfer of identifiers from the register to the organisation, with pseudonymised data returned (identified by study ID). For PHE, names are also returned to trace individuals' records in medical record departments in order to fill in any missing clinical information. For Trusts, the register receives a regular feed from the electronic health record systems.

In addition, prospective patients continue to be included in the registry. New childhood cases are notified by the 2 Principal Treatment Centres in Yorkshire: Leeds Teaching Hospitals NHS Trust and Sheffield Children's Hospital through nhs.net secure email and through NCRAS data from PHE for Teenage and Young Adult cases. Once these new cases are added, linkages with the above databases will continue.

The database is used for research purposes to which research teams can apply access to. Following approval by the advisory committee the researchers will be provided with an anonymised data extract. Note the protocol states that where the applicant requests identifiers (e.g. to contact the patient) this will require a separate application for support.

Confidential patient information requested

Cohort	All individuals between 0-29 diagnosed with a malignant (or benign central nervous system) tumour whilst resident in the area contiguous with the former Yorkshire and the Humber SHA region. Retrospectively data has been included in the registry since 1974. The data will also include prospective patients
Data sources	1. Local NHS Trusts 2. EMIS 3. TPP 4. NHS Digital (HES inpatient, outpatient, A&E and Mental Health datasets) 5. Public Health England (National Cancer Registration Service, Radiotherapy Dataset, Chemotherapy treatment, Systemic Anti-Cancer therapy dataset). 6. Department of Education 7. Department of Work and Pensions

Identifiers required for linkage purposes	1. NHS number 2. Date of Birth 3. Date of Death 4. Postcode
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode 4. Gender 5. 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 noted that this was a revised application of a research database which is currently operating under Regulation 5 support. The members noted the extremely important outputs that the database has already achieved in the field of children and young people with cancer, and that the activity is justified as being in the public interest.

This is a research application and members wished to reinforce that the data is only used for medical research purposes. Any use for non-research purposes, in the management of health and social care, will require a separate application.

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 stated that consent is not feasible given the large retrospective cohort involved, that contacting patients may cause unnecessary stress at a difficult time, and the need for a complete dataset to produce accurate outputs.

The CAG considered these points and agreed that the consent is not feasible.

- **Use of anonymised/pseudonymised data**

Members agreed that it is not possible to undertake these activities without the use of confidential patient information, and that the applicants are minimising the use of confidential patient information as far as possible.

'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.

Members noted the strides that the applicant has undertaken to improve the patient notification materials since a previous amendment was supported in October 2019.This was particularly relevant for the information sheets for children and young people.

The group did notice that the poster provided did not include information on how patients can opt out of their data being used and requested this is updated. Further, the opt out process document did not state that opting out will not affect the care provided and requested that this is also updated. Updates made on these points should be provided at the next annual review.

Lastly, members felt that the website remained hard to navigate (a comment noted on the supported amendment letter of 18 October 2020), and requested that the applicant reviews this and adds a menu item to make it easier for patients to navigate to the information about

data held, security arrangements and the process for opting out; and reports back at the next annual review. Further, the PDF documents in that area should have clear titles that point to the relevant content for people considering whether to dissent, rather than just filenames.

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 understood the further work that the applicant has undertaken in patient and public involvement, with plans to continue this with the development of a Young Persons Advisory Group and commended this work. Members requested, at the time of the next annual review, to be provided with details on the make up of the Young Persons Advisory Group.

It was also noted that the Advisory group that considers requests for data does not currently have any lay representation. Members requested that the applicants look to include lay members in this group, reporting back at the next annual review. The group also suggested that there is a link between the Young Persons Advisory Group and the Advisory group that considers requests for data.

System Architecture

The group understood that there are plans to update the system architecture which holds the confidential patient information. Members requested further details of this change to be provided at the next annual review.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. At the next annual review provide confirmation that the study website has been revised to make it easier for patients to access full information.

2. At the next annual review, provide an updated poster which details the mechanism for opting out of use of data.

3. At the next annual review, provide details on the make up of the Young Persons Advisory Group.

4. At the next annual review, provide confirmation that at least one lay person has been appointed to the Advisory Group that reviews requests for data. It is also suggested that there are formal links between the Young Persons Advisory Group and the Advisory Group that reviews requests for data.

5. At the next annual review, provide an update on the change of system architecture at the University of Leeds.

6. At the next annual review confirm that the opt out information provided to patients has been updated to clarify that opting out will not affect the care of the patient.

7. Support for this application has been provided for medical research purposes only. Where the data is to be used for non-research purposes in the management of health and social care a separate application for support should be submitted.

8. Support is provided on the understanding that data provided to researchers is effectively anonymised. Where a researcher requests identifiable data, a separate, project specific application should be submitted for support.

9. Favourable opinion from REC **Received 15 May 2000 (updated through amendments since)**

10. 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 submission for University of Leeds (18/19), NHS Digital (19/20), EMIS (19/20, and TPP (19/20) were confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker on 18 October 2020).**

    The NHS digital review for Department for Education (19/20) and Department for Work and Pensions (19/20) confirmed that equivalent standards have been met (by check of DSPT tracker on 18 October 2020).

The NHS Digital DSPT submission for Public Health England (18/19) was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS Digital DSPT Tracker (checked 18 October 2020). Please note the updated specific condition of support below.

Public Health England should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

Declarations of Interest

Lorna Fraser declared an interest and left the meeting.

5. New Applications – Research

a. 20/CAG/0117 – Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health

Context

Purpose of application

This application from University College London (UCL) sets out the purpose of medical research that aims to research what roles resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational parents and their neonates, as compared to their cis-heterosexual peers, during their antenatal care.

There is an assumption that those using pregnancy-related health services are cisgender and heterosexual. The patient population also includes those of different genders and sexual orientations. Structural cis-genderism and hetero-sexism in reproductive healthcare may cause stressors of stigma and discrimination, including social and medical exclusion, during critical windows of foetal development. Stress and discrimination are linked to higher rates of miscarriage, preterm birth, macrosomia, and other undesirable birth outcomes. These stressors affect more than 525,000 lesbian, gay, bisexual, queer, and/or transgender (LGBTQ+) potential gestational parents in the UK, resulting in preventable higher risk for

prenatal complications. The applicants intend to assess the impact of vulnerability as a measure of minority stress and systemic exclusion, alongside multi-level resilience factors.

Patients will be recruited from three inner London maternity wards and one ward in Brighton. Currently, King's College Hospital NHS Foundation Trust (KCL) and University College London Hospitals NHS Foundation Trust (UCLH) have agreed to take part. Two other trusts will be added at a later date. Recruitment will focus on 275 LGBTQ+ gestational parents, defined as those who have disclosed themselves to be lesbian/gay, bisexual, transgender, gender non-conforming, and/or non-binary (LGBT+) within their electronic health records. A 3:1 case-matched sample of 825 cis-heterosexual respondents will also be recruited. Support is sought to allow the applicant to access confidential patient information at UCLH in order to identify suitable patients and extract their name, email address and recorded due date. Due to coronavirus restrictions, the applicant will be given remote access to the electronic patient records at UCLH. At KCL, patients will be identified by a member of the direct care team, who will extract their name, email address and recorded due date. Support is also required for the disclosure of patient identifiers from KCL the UCL Data Safe Haven. The identifiers from both trusts will be transferred to the UCL Data Safe Haven and an electronic invitation, including a screener survey, will be sent via email to patients currently pregnant and receiving antenatal care at the study sites, inviting them to consider participating in the study. Patients will be surveyed once during pregnancy and once after birth. The survey responses will be linked to patients' electronic health records. 30 patients will also be invited to complete an at-home journal activity to examine their experiences of antenatal and postpartum care. Data will also be collected about their infants and this will be collected at the time of birth and at their first follow-up. Consent, along with the surveys, will be gathered electronically through Research Electronic Data Capture (REDCap), a survey platform that is integrated into secure systems, hosted on the UCL Data Safe Haven.

A recommendation for class 2, 3 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 16 and 49 years who are receiving active antenatal care at the 4 participating trusts. Patients will either identify as lesbian, gay, bisexual, queer, and/or

	transgender or, for patients in the case-matched sample, will identify as cisgender and heterosexual. The control cohort sample will be case-matched to the study cohort by age. 1100 patients will be included. The infants born to patients in each cohort will also be included, but the applicants are unable to give a number of expected neonates due to live births of singletons and multiples, miscarriages, still births, and other complications. The applicants estimate that the records of 48,098 patients will need to be accessed to identify the required number of patients.
Data sources	1. Electronic patient records from King's College Hospital NHS Foundation Trust 2. Electronic patient records from University College London Hospitals NHS Foundation Trust
Identifiers required for screening prior to recruitment	1. Name 2. E-mail address 3. Recorded due date
Identifiers required for analysis purposes (patients are consenting to these being used)	1. Date of Birth 2. Date of Death 3. Postcode District level 4. Borough of place of work 5. Borough of home address 6. Gender 7. Ethnicity 8. Sexual orientation
Additional information	Patient data that will be extracted from the electronic health records includes, but may not be limited to: • Gestational Parent: Blood Pressure • Gestational Parent: Urinalysis • Gestational Parent: Height • Gestational Parent: Weight • Gestational Parent: BMI • Gestational Parent: Additional measures as relevant • Infant: APGAR Score • Infant: Gestation length

	• Infant: Birth Weight • Infant: Height/length • Infant: Head circumference • Infant: Additional measures as relevant (at first postnatal check-up) Information about neonates will be collected including but not limited to: birth date, Hospital ID (linkage-follow-up), weight, length/height, APGAR scores

Confidentiality Advisory Group informal advice

The following sets out the informal 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 but the clear public interest was not clear due to the issues outlined below.

Study design

Members noted that it was unclear whether the sexual orientation and gender identity of patients would be clearly recorded in the patient records and how reliably patients email addresses were recorded. If the records did not contain this information, then the applicant may need to access a large number of records unnecessarily, leading to a greater breach in the common law duty of confidence than is required. This may also result in misclassification of participants.

Members asked whether the applicant had considered using a staged process, accessing records for smaller numbers of patients and moving to another selection of records until the required number of patients had been recruited. This would reduce the amount of confidential patient information disclosed.

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**

Patient records will be screened in order to identify suitable patients, who will then be approached for consent. The applicant advised that it was not possible to seek consent prior to accessing the patient records, as access to the records was required to identify suitable patients. The applicant had consulted with clinical staff, who had recommended contacting eligible patients via email and, potentially, promoting the study via social media. Discussions with clinical staff had determined that staff are often reluctant to ask questions about patients' gender identity and sexual orientation, therefore it was not feasible for staff to seek consent from patients.

The Group noted that no patient and public involvement had been undertaken, which meant that the views had not been sought on the design of the study, including whether consent was feasible and whether patients would be supportive of the use of confidential patient information as intended in order to identify and recruit patients. The CAG advised that patient and public involvement would need to be undertaken around the issue, in order to satisfy the CAG that the proposed approach was the most suitable.

- **Use of anonymised/pseudonymised data**

It is not possible to contact patients to seek consent to participate the study without using identifiable data. The CAG was not certain that the proposed design was the most appropriate method of identifying patients. As noted above, patient and public involvement needed to be undertaken around the design of the study, including whether a sufficient number of patients could be recruited proactively, using advertising of the study.

'Patient Notification' and mechanism for managing dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018.

Although often confused with a requirement to seek consent, patient notification is not the same as seeking consent from individual patients. Patient data is still accessed without consent, however information is provided to patients so they have the option to find out about this use of their data and to express an objection if they so wish. The method for respecting any such objections should be described in the application and a copy of the information must be provided as well.

The notification should provide a description of the activity, listing the purpose of the study and who is carrying out the study. It should explain how service users can opt out or dissent, where appropriate, to the use of their information for this purpose.

Patients will receive an email inviting them to take part in the study. This will include the Participant Information Sheet. The applicant advised that they had not yet determined how many times patients would be re-contacted, should they not respond to the initial contact email. Contact attempts would cease once the recorded due date had passed.

The applicants noted that patients may see information about the study on the study website and proactively contact the research team. Ward staff may also provide patients with a contact slip. Details about the study, including the patient information sheet, will be made available online in order to support the participants.

The applicant provided patient notification materials to be displayed on social media (Twitter, Facebook and Instagram), as well as the patient information sheet, contact slip and web information.

Patients will be approached for consent. The applicant confirmed that patient records will be checked for any evidence that they have signed up to the National Data Opt-Out or whether dissent to inclusion in research has been recorded locally. The CAG queried whether the records would be checked for evidence of dissent to inclusion in research before the researcher was given access.

The Group noted that patients would be contacted for consent, however a notification strategy and dissent mechanism needed to be created so that patients could opt-out prior to being contacted and, ideally, before their records were accessed.

The participant information leaflet had been provided with the application, but the accompanying email had not. The study had been sensitively described in the leaflet, but the email would also need to be provided.

Patient and Public Involvement and Engagement

The applicant advised that they had undertaken a similar project within the USA, also involving LBGTQ+ patients. Feedback from that project had influenced the topic and design. The applicant also intends to seek feedback from peers in LGBTQ+ parenting support groups on the survey measures, however these reviewers have not yet been confirmed. The applicant noted that it was likely that these reviewers would not be UK residents or NHS patients. The applicant had sought advice from clinical staff in the relevant settings, who had advised that that the asking of these questions is not mandatory, so are also sometimes avoided by clinical staff because they feel uncomfortable asking about a patient's gender identity and/or sexual orientation

No patient and public involvement has been undertaken around the use of confidential patient information without consent. The CAG noted that a large number of patient records would potentially be accessed in order to identify a relatively small number of patients. Members agreed that patient and public involvement needed to be undertaken around the design of the study, including the access to confidential patient information for the purpose of identifying and contacting suitable patients. The potential number of patients whose records may be accessed and that the records will be accessed remotely needs to be made clear to those taking part in the patient and public involvement. It was unclear how many times patients would be re-contacted, if they did not respond to the first attempt. How many times that it would be appropriate to contact patients would need to be explored. The patient involvement needed to include cis-heterosexual patients as well as those identifying as LGBTQ+, as records from both groups would be accessed.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided and the issue of a REC unfavourable opinion, they did not have sufficient information to undertake a full review and to provide a recommendation under the Regulations. The CAG agreed that the area of research had significant public interest and was very supportive of the aims of the study.

Informal advice for a future application

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised applications submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Patient and public involvement needs to be undertaken to inform the design of the study and whether it would be feasible to recruit patients proactively via advertising and promotion of the study, rather than the use of confidential patient information to identify and contact patients.

If, following the patient and public involvement, it is determined that obtaining confidential patient information from records for the researcher to make contact with patients with an invitation to take part is the most feasible way of conducting the study, then the following will also need to be addressed.

1. Patient and public involvement will also need to be undertaken to explore the following issues:

    a. Access to confidential patient information in order to identify and recruit patients will need to be discussed, including making the scale of the potential disclosure clear.

    b. The number of times that it would be appropriate to contact patients will need to be explored.

    c. The patient involvement needs to include cis-heterosexual patients as well as those identifying as LGBTQ+, as records from both groups would be accessed.

2. Clarify with the participating trusts whether the patient records will reliably contain information on patients' gender identity and sexual orientation, as well as their email addresses.

3. Advise whether a staged process could be used, accessing records for smaller numbers of patients and moving to another selection of records until the required number of patients had been recruited.

4. A patient notification strategy and dissent mechanism needs to be created.

5. The text of the email that would be sent to patients needs to be provided.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0127 - Admissions far away from home or to adult wards - understanding the impact of current practices for accessing inpatient care for adolescents with mental health difficulties: a surveillance study

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that seeks to determine the extent that young people aged between 13 and 17 are admitted to units far away from their home, defined as over 50 miles from their postcode or to a different NHS region, or to an adult ward.

Young people with mental health disorders of a severity that requires inpatient admission are at risk of poor long-term outcomes, including persistent mental health problems, poor physical health and academic under-achievement. These long-term outcomes are often associated with long-term health and societal costs. National policy specifies that young people who require inpatient admission should be cared for in units appropriate to their age-group. Unfortunately there are few units that serve children with poor mental health and places are limited, and many young people are admitted to adult units or units far away from their home. This means that inpatients may be separated from family or friends, or receive care not specifically tailored for their age. This may worsen the distress experienced by the young people and their families, and impact on the care they receive after discharge. Limited information is available at a national level regarding the number of admissions of young people to units away from home or to adult units and the applicants are seeking to collect information on this, in order to inform clinical practice, guidelines and service organisation and commissioning.

Data collection will be undertaken via questionnaires completed by reporting consultant psychiatrists, utilising the Child Adolescent Psychiatry Surveillance System (CAPSS). CAPSS uses an active surveillance approach to facilitate epidemiological studies which are looking at either rare mental health disorders or events amongst children and adolescents in the United Kingdom and Ireland. CAPSS maintains a database of consultant child and adolescent psychiatrists in the United Kingdom and Ireland. Using these contact details, administrative staff from CAPSS send out a CAPSS report card or a weblink on a monthly basis to this

centrally held mailing list of child and adolescent psychiatrists. This will contain a list of conditions being surveyed, together with reporting instructions. Reporting psychiatrists will be asked to check boxes against the reportable conditions they have seen during the preceding month or indicate that they have seen no eligible cases, and then return the card/weblink to CAPSS. This report will not contain any patient identifiable data.

CAPSS then contact the research team with the contact details of the reporting consultant. The research team will send an email or letter to the consultant with the questionnaire for them to complete with the patient details, including confidential patient information, and return to the research team. Data will also be extracted from patient medical records by the same clinician. A follow-up questionnaire will also be sent to the reporting clinician after 6 months. Data will be entered into a computerised database and patient identifiable data will be stored on a separate database to the rest of the questionnaire data. These will only be linked by a unique study ID number for each case.

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	Patients aged 13-17 years who require admission to an inpatient psychiatric unit and who were admitted to a unit over 50 miles from home, out of commissioning area or to an adult ward, during the 12-month data collection period. The aim of the application is to establish how often this occurs, therefore a total sample size could not be provided.
Data sources	1. Questionnaires completed by reporting consultant psychiatrists

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level 4. Gender
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Gender 4. 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 Group agreed that the application had a clear 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**

CAPSS standard methodology will be used, it is usual in these studies that reporting clinicians do not seek consent from patients. The CAG noted that seeking consent from patients would potentially skew the results, due to the small number of patients involved. Members agreed that seeking consent was not feasible.

- **Use of anonymised/pseudonymised data**

The confidential patient information collected will be used to identify and remove duplicate reports. Patients' date of birth, unit level postcode, gender and ethnicity will be retained for use in analysis. The applicant advised that the full postcodes were required in order to accurately calculate the distance from patients' homes to the inpatient unit. The applicant explained that converting postcodes to Lower Super Output Area would risk using one point to falsely represent a dispersed population. This can create large errors especially in rural areas - for example, the centre of a large rural LSOA is unlikely to contain any population centre, with distances to outlying villages considerably underestimated.

The CAG queried whether the applicants could convert the full postcode to Lower Super Output Area (LSOA) or xy coordinates, in order to reduce the potential identifiability of the retained data. Members noted that the Confidentiality Advice Team had queried whether LSOA could be used and that the applicants had advised that full postcodes were needed to accurately calculate distances from home to hospital. The CAG noted that LSOA often calculated distances to within half a mile, which should be sufficient accuracy for the purpose of the study.

'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.

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 provided a Public Information Leaflet, which would be made available on the CAPSS website. The postal address, email and telephone number for the study team were provided, should patients have queries. Patients were asked to let the study team know if they wished to opt-out. The Public Information Leaflet will be sent out by CAPSS to all reporting consultants who will be requested to display this in suitable areas of their clinic/unit.

Reporting clinicians will check patient records for any evidence that the patient had dissented to the use of their records in research, including registration with the National Data Opt-out. Their parents or carers will also be able to dissent to the use of the patients records in research.

The Group agreed that it was unclear when the National Data Opt-Out will be applied, as the patient may no longer be under the care of the reporting clinician when the researcher sends the questionnaire. Members asked that this was clarified.

The patient leaflet and the letter sent to clinicians did not explicitly explain that patients were able to dissent, although details to make contact with the study team with any questions were given. The CAG asked that these were revised to explain that patients could dissent and the process. Other patient notification documents did state that parents and/or carers were able to dissent. The patients involved would be between 13 and 17 years of age and may be considered competent to register dissent. The CAG asked that the documents were revised to state that patients could also dissent and provide the detail for opting out.

The CAG also noted that the leaflet stated that anonymised data only was used. Patients' NHS number, date of birth, postcode, gender, ethnicity were disclosed, which were potentially identifiable. Members asked that the leaflet was revised to explicitly state the items of data that would be collected and to remove the statement that anonymised data only will be used.

Members requested clarification on whether the clinician letter was sent to the reporting unit or to the receiving unit, or whether different letters would be sent to the units.

Patient and Public Involvement and Engagement

The applicants explained that they would set up two separate Parent and Young Person Lived Experience Advisory Panels, through ARC East Midlands. They would recruit 4-6 people to each Panel. Participants would have personal experience of the admissions being research and be able to provide valuable insights into key issues.

The application had been discussed with NHS England, YoungMinds (a user-led organisation), the Care Quality Commission (CQC) and the Royal College of Psychiatrists. CAMHS clinicians and commissioners of community CAMHS and commissioners from NHS England have also been consulted. Early drafts of the study lay summary were reviewed by the New Youth advisory group (to the Nottingham Youth Mental Health and Well-being network) and the Participation Lead at the Lancaster adolescent unit.

A specific question was asked around the use of confidential patient information without consent. Feedback from this was, as long as the information shared contained the postcode only and not names and addresses, that this would not be an issue.

The applicants also consulted with and secured support for the study from the NIHR CLAHRC East Midlands Public Involvement Programme Lead, who offered additional support via the Patient and Public Partners' Council (PPPC) of the NIHR CLAHRC East Midlands.

Feedback from the patients consulted was that they were content with the information shared as long as it was not identifiable. As noted above, patients' NHS number, date of birth, postcode, gender, ethnicity were disclosed. It was unclear whether the level of disclosure and the retention of confidential patient information had been discussed during patient and public involvement. Members asked that this issue was discussed during the ongoing patient and public involvement and feedback provided to the CAG t the first annual review.

Exit strategy

The applicants anticipated that the data collection period would start before December 2020 and would last for 12 months. The confidential patient information would be retained for a further 12 months after the end of data collection to identify and remove duplicate cases. Confidential patient information would be retained for a maximum of 24 months before the NHS number was redacted. All other Clinical data will be held securely for a period of 7 years in accordance with University of Nottingham policy.

The CAG was unclear on the data that would be retained and how it would be stored. Questionnaires could be returned in a number of ways, including by return of an online questionnaire or a paper questionnaire returned by post. The application explained that the front sheets of the online questionnaires would be printed out and the front sheet of the postal questionnaires would be retained in a locked filing cabinet. The CAG requested further details on how the hard copies would be retained, including how long they would be retained for.

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 whether the full postcode can be converted to Lower Super Output Area or xy co-ordinates. If not, please provide a justification as to why the full postcode is needed.

2. Provide an explanation on how and when the National Data Opt-Out will be applied, including whether this is applied by the reporting unit or the receiving unit.

3. The patient notification materials and clinician letter need to be revised as follows:

    a. The potentially identifiable information that would be processed needs to be clearly explained.

    b. It needs to be made clear that patients are able to dissent, including that patients deemed competent are able to dissent, as well as their parents/carers.

4. Provide clarification on whether the clinician letter will be sent to the reporting unit or to the receiving unit.

5. Provide further details on how the hard copies will be retained, including how long they will be retained for.

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. Report at the first annual review about the further patient and public involvement that have been undertaken, particularly around the level of potentially identifiable data that will be processed.

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 University of Nottingham organisation was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 15 October 2020)**

Declarations of Interest

There were no declarations of interest.

c. 20/CAG/0131 - Optimising value-based, preventive care delivery in NHS General Dental Services

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research that seeks to develop a computerised model of skill-mix use in NHS General Dental Services to optimise the delivery of value-based, preventative-led care.

Tooth decay, gum disease and mouth cancer are preventable conditions and dental teams have a considerable role to play in supporting patients to change their lifestyle or by providing preventative treatments. Many of these treatments could be provided by dental hygienists, nurses or therapists. Using the skills of other members of the dental team is known as 'skill mix'. The applicants seek to develop a computerised tool, to be used to show service planners and dental practices the potential benefits of changing their practice to increase the use of 'skill mix'.

This application is formed of three parts:

Part 1: Data will be collected on the treatments received by adult and child patients from NHS dentists in Wales. Clinical guidelines will be examined in order to establish the preventative care patients should be receiving. Dental professionals and patients will also be consulted to reach a consensus on what the ideal care-pathway would be.

Part 2: The applicants will work out the time requirements of providing the additional preventative advice and care by observing dental procedures in 8 Welsh NHS Practices. Dental professionals will be asked to comment on the timings collected. The applicants confirmed that no patient care will be observed by the researchers, a self-administered on-line questionnaire survey that will be used to collect dental professionals' estimation of the mean and range of time taken to undertaken 55 common clinical dental tasks.

Part 3: A computer programme will be created, showing how preventative care can best be delivered using currently available resources and give an indication of how much dental practices will need to be paid in order to increase the amount of preventative care they provide.

Support is sought for Part 1, the collection of data from NHS Business Services Authority (BSA) on the treatments provided to adult and child patients by NHS dentists in Wales. The other aspects of the study will be consented.

The applicants will request that NHS BSA provide detailed data on every course of treatment provided under an NHS GDS or Personal Dental Services (PDS) contract. These data, and data on oral health risk and need assessments, to the NHS Business Services Authority on an annual basis. The only item of confidential patient information required are the patients' postcodes and age at treatment.

NHS BSA confirmed that support under s251 needed to be in place before they would release the information to the applicant. E-mail correspondence from NHS BSA is provided.

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	All patients, both adults and children, who received treatment between 01 July 2018 and 30 September 2019 from NHS dentists in Wales. 55 dental practices are participating and the applicants estimate that 1,500 patient records per practice will be included, and 37,500 patients in total will be included.
Data sources	1. NHS Business Services Authority (BSA)
Identifiers required for linkage purposes	1. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level
Additional information	NHS BSA will also provide the following information for each patient: • Provider Information • Patient Information (anonymised patient identifier, city/town, postcode, age at date of treatment) • Incomplete Treatment and Treatment Dates • Treatment Category • Clinical Data Set • ACORN oral health risk and need • Other Services (Treatment on referral, Free repair/replacement, Further treatment within 2 months, Domiciliary services, Sedation services)

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

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 the only item of confidential patient information that would be transferred from NHS BSA to the University of Cardiff was the patients' postcodes. Members asked if NHS BSA could convert the postcodes to Lower Super Output Area (LSOA) prior to transfer to the University of Cardiff, which would remove the need for support under Regulation 5.

Alternatively, the CAG suggested that only the first part of the postcode was used, which would also remove the need for support.

If it was not possible for NHS BSA to undertake the conversion or to use the partial postcode only, the University of Cardiff will convert the postcodes to LSOA. The CAG asked the applicant to advise when this conversion would be done, so that the duration of support required can be clarified.

- **Feasibility of consent**

Confidential patient information will be provided for all patients who received dental treatment in Wales between July 2018 and September 2019. The applicants anticipate that this will involve several thousand patients and it will not be possible to seek consent.

- **Use of anonymised/pseudonymised data**

Patients' postcodes and age at treatment are needed to generate the required demand profile.

'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 applicant advised that no patient notification will be undertaken, as the data used is routinely collected data used for the reimbursement of dental practitioners. NHS BSA also do not offer a dissent mechanism.

The Group agreed that it would be difficult to carry out patient notification. Clarification was requested on when the patient postcodes could be converted to LSOA by the University of Cardiff. If this could be done immediately on receipt, then the CAG accepted that patient notification would not be feasible. If there would be delay in the conversion, then a patient notification strategy and dissent mechanism would need to be created and sufficient time allowed for patients to register dissent. The CAG usually expected notification to be carried out 6-8 weeks before any data extraction.

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 two patient representatives are named investigators on the application. They have attended research development meetings and have offered insight into patients' attitudes towards prevention-led care and the use of the skills of the wider dental team. They also highlighted areas they thought should be considered in the reorientation of pathways, such as: frequency and length of appointment; cost; and the need to communicate why other members of the dental team may be used to deliver care. Views have been sought from the patient representatives around the use of confidential patient information without consent. The potentially identifiable data will be kept to a minimum, however there was a risk that patients could be identified.

The project was presented to the "SUPER – Group" – hosted by PRIME Centre Wales. This is a patient and public involvement forum which offers advice to researchers on the development and implementation of research projects and members have received training and had experience in providing patient and public involvement input into primary care research. The meeting, which was attended by approximately 20-30 individuals, many of whom were NHS dental patients, received a presentation on the study methods, followed by an opportunity to ask questions. The opinion of this group was that the data used in the study was justifiable in line with the research questions.

The study is being funded by the Research for Patient Benefit Scheme, Health and Care Research Wales, as part of the funding process the study protocol was reviewed and agreed by the HCRW funding panel which includes lay and public representatives.

The CAG noted that patient and public involvement carried out and was satisfied that it was proportionate to the scale of 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, 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

The CAG noted that there were two potential practicable alternatives to the use of support under Regulation 5:

1. Advise if NHS BSA can convert the postcodes to Lower Super Output Area (LSOA) prior to transfer to the University of Cardiff.

2. Advise if only the first part of the postcode can be used.

If either of the above alternatives are possible, support under Regulation 5 will not be required. If the above are not possible, then following points will need to be addressed:

1. Advise when the conversion from full postcode to LSOA would be done, so that the duration of support required can be clarified.

2. If the conversion to LSOA cannot be carried out immediately on receipt by the University of Cardiff, a patient notification strategy and dissent mechanism will need to be created and sufficient time allowed for patients to register dissent. The strategy and accompanying materials will need to be provided to the CAG for review.

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 24 July 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. **Confirmed – University of Cardiff and the NHS Business**

Services Authority have confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT tracker on 16 October 2020.

Declarations of Interest

There were no declarations of interest.

6. 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