# Minutes of the meeting of the Confidentiality Advisory Group

**15 June 2023 via Zoom**

## Present:

| Name | Role |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Ms Clare Sanderson | CAG Alternate Vice Chair |
| Dr Sandra Duggan | CAG Member |
| Dr Pauline Lyseight-Jones | CAG Member |
| Ms Diana Robbins | CAG Member |
| Mrs Sarah Palmer-Edwards | CAG Member |
| Professor James Teo | CAG Member |

## Also in attendance:

| Name | Position (or reason for attending) |
|---|---|
| Ms Katy Cassidy | HRA Confidentiality Advisor |
| Ms Emma Marshall | HRA Confidentiality Specialist |

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| Dr Paul Mills | HRA Confidentiality Advice Service Manager |
| Mr Dayheem Sedighi | HRA Approvals Administrator |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Fehzaan Maqbool | HRA Information Governance Support Assistant (Observer) (items 3a – 3d only) |
| Dr Pia Hardelid | Chief Investigator and Associate Professor of Epidemiology (item 3a only) |

## 1. Introduction, apologies and declarations of interest

CAG members Dr Martin Andrew, Mr Anthony Kane & Dr Stephen Mullin send their apologies.

The following conflicts of interest were declared;

- CAG member Mrs Sarah Palmer-Edwards declared a potential conflict of interest with item 3b, as she works at one of the participating Trusts. However she does not work at the submitting organisation and has had no involvement in this application. The Chairs consider this not to be a conflict and she did participate in the discussion and recommendation provided by CAG.

## 2. Support decisions

### Secretary of State for Health & Social Care Decisions

There were no non-research applications in the 11 May 2023 meeting.

### Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **11 May 2023** meeting applications.

### Minutes:

The minutes of the following meetings have been ratified and published on the website:

- 27 April & 11 May full meeting minutes
- 21 April, 05 May & 19 May Precedent Set

## 3. New Applications

### a. 23/CAG/0060 - Kid's Environment and Health Cohort (KITE)

**Context**

**Purpose of application**

This application from UCL Great Ormond Street Institute of Child Health set out the purpose of creating a research database, a data resource which researchers will use to study the links between school and home environments and children's health and education.

The health of children, as well as their cognitive development and associated school outcomes, are disproportionately affected by the physical environment in and around homes and schools. This includes their exposure to indoor and outdoor air pollution, busy roads and noise, and access to green and blue spaces. The social environment of the local area, including availability of local services, such as nurseries, and exposure to fast food, or gambling outlets may influence child health and development. The applicants seek to create a research database, containing data on all children born in England from 2006 onwards. Information for the children's mothers will also be collected from hospital patient records and Census records. Both live births and still births will be included in the cohort, but only live born children will be followed up via linkage to health and education data.

Regulation 5 support is sought for the disclosure of confidential patient information (NHS numbers, dates of birth, sex and full postcode) from ONS to NHS England for linkage to Birth Registrations and Mortality data. The linked dataset will then be held within the ONS Secure Research Service. The research team at University College London will only have access to anonymised data.

The applicants also seek support for ONS to store PDS derived UPRNs and postcodes separately to the KITE cohort. Researchers, other than the UCL team, will be able to

request linkage to external environmental data mapped to Unique Property Reference Numbers/postcodes to the cohort via UPRNs and/or postcodes from the PDS or birth registration. UPRNs & postcodes will be encrypted by ONS before placed in the SRS for linkage.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | The initial database will contain data from all infants born (both live and still births) in England between 01 January 2006 and 31 December 2023. The applicants estimate that 11 million children will be included in the database when created. Data for patients' mothers will also be required. The initial cohort will comprise approximately 22 million people.<br><br>The database will be updated annually. Around 585,000 live births occur in England each year. Including both patients and mothers will mean around 1 million patients will be included in the database each year. |
| **Data sources** | 1. Birth Registrations and Mortality data, Office of National Statistics (ONS)<br>2. Personal Demographics Service, NHS England |
| **Identifiers required for linkage purposes** | Infants:<br><br>1. Name<br>2. Date of birth<br>3. NHS number<br>4. Gender<br>5. Postcode<br>6. Unique Property Reference Number (UPRN)<br><br>Mothers: |

| | |
|---|---|
| | 1. NHS numbers<br>2. Date of Birth<br>3. Postcode |
| **Identifiers required for analysis purposes** | 1. Gender<br>2. Ethnicity<br>3. Age of mother at birth |
| **Additional information** | The applicants have clarified that patients' hospital number (i.e. the MRN number at individual trusts) is not needed for linkage. |

## 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. Following consideration the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

### Scope

The applicants intended to collect information for all live births in England and details of the infants' mothers. Members queried whether information would also be collected for the infants' siblings and fathers. Dr Pia Hardelid, Chief Investigator of the project, attended the meeting and clarified that siblings included in the data extract will be linked, but no linkages will be undertaken to identify siblings not included in the extract. Details on the fathers will not be collected, due to the difficulty in identifying the fathers.

The CAG noted that there was uncertainty over whether UPRNs are considered to be items of confidential patient information. Dr Hardelid advised that ONS had not yet confirmed that they considered UPRNs to be confidential patient information, but that the query had been discussed with Information Governance and Data Protection

experts who had advised that it probably is an identifier. The CAG agreed that UPRN should be considered an item of confidential patient information due to the specific cohort involved in the study, however ONS needed to confirm this.

Members advised Dr Hardelid that it needed to be made clear in the patient information when identifiable, anonymised and pseudonymised data was used.

Brock University, Canada, was referenced in the application and members queried whether any confidential patient information would be shared with the University. Dr Hardelid confirmed that no confidential patient information would be shared.

The CAG queried whether the proposed method for data collection would mean that children who were home-schooled or attended fee-paying schools, and children who moved to England after birth, were missed. Dr Hardelid noted that collecting data for all children in England was challenging. She also advised that 93% of children attended state school, therefore most children would be included.

## 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 explained that all children born in England from 2006 onwards will be included in the database. It would not be feasible to seek consent from the 11 million patients who will be included in the cohort.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to ONS and NHS England to undertake linkages, for the purpose of identifying patients for inclusion in the initial cohort, annual updates of the original cohort and the addition of new births.

## ‘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 object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants advised that the database will be promoted by information provided on the data controller's website, information in the local press, via charities and support groups and by social media.

Feedback from the patient and public involvement conducted had recommended that information provided online and via social media was preferred over the use of leaflets. A website will be made available after CAG and REC Support are in place. Information will also be made available on the ADR-UK website.

The National Data Opt-Out will be applied.

The Privacy Notice provided advised patients/parents to contact the Chief Investigator if they did not want their/their child's data included, but also noted that the research team at UCL could not withdraw information for individual patients. The applicants advised that they had discussed with the ONS whether a project specific opt-out mechanism could be put in place. Patients/parents would advise the UCL team that they wished to opt-out. The UCL team would ask patients for their NHS number, date of birth, sex and postcode. These details will then be shared with ONS to locate and remove patients' details. The applicants noted that it would not be possible to remove patients once the data linkages have taken place and the data is in ONS SRS. For those opting out after initial linkage has taken place, it may be possible to exclude their records from being updated from the point at which they have opted out.

Members noted that ONS would be able to identify patients in order to collect the annual follow-up information, therefore it was unclear why patients who had dissented could not be identified. The CAG asked that the dissent process was discussed further with ONS.

The applicants noted that information about the study specific opt-out on the website, both in the patient notification information and in the Q&A section on the website.

The CAG noted that the Privacy Notice and Patient Notification needed to be separate documents. Members also advised that a layered approach to notification was recommended, such as providing brief information with linked to more details. Dr Hardelid noted that they had experienced delays in creating the website but that the text information to be included could be provided for CAG review. The applicants also planned that information about the study would be made available in the press but were waiting for ethics approval before starting this process.

The CAG determined that the communications plan for disseminating information about the study, including all patient notification materials, draft website text and an outline of how the study will be publicised in the national press, needed to be provided.

## Patient and Public Involvement and Engagement

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

The applicants noted that all children in England are included in the cohort. A programme of public involvement with children, young people and parents will be undertaken. The public involvement and engagement plan was included in Appendix D of the Protocol. The applicants advised that they have held a series of meetings with groups of parents and young people to test the acceptability of processing identifiable patient data without specific consent. The applicants will continue meeting with parents and young people to discuss the project.

Following feedback from the UseMYData group, who suggested the applicants should meet more groups outside London, the applicants are meeting the Liverpool YPAG to discuss the project in May 2023. Dr Hardelid advised that feedback from this was positive.

Members agreed that it was not clear whether any changes had been made to the application following feedback given during patient and public involvement. The CAG asked that details were provided.

## Applications to use the KITE database

Members requested that details were provided on the process that third-party applicants would follow to request data from the KITE database. Dr Hardelid explained that applications would need to have been reviewed by a REC, however this could be an NHS REC, university REC or a National Statistics REC. The CAG advised that applications to use the data must have a medical purpose and suggested that a small group was created to review applications to ensure that they had a medical purpose.

### 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. Confirmation needs to be provided from ONS that the UPRN an item of confidential patient information.

2. The ONS need to clarify why patients cannot be identified to remove those who have registered dissent.

3. A communications plan and patient notification materials need to be provided.

4. The patient notification materials need to be clear on when the data processed is identifiable, pseudonymised and anonymised.

5. Details of any further patient and public involvement undertaken need to be provided.

6. Details of the changes made as a result of feedback given during patient and public involvement need to be provided.

## 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**

2. Confirmation provided from the DSPT Team at NHS England 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**:

   The NHS England 2021/22 DSPT reviews for **UCL Great Ormond Street Institute of Child Health, the Office for National Statistics, and NHS**

**England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023)

## b. 23/CAG/0066- Urgent and Emergency Care (UEC) – Data Integration: London Ambulance Service and NHS Trusts without Foundry

**Context**

### Purpose of application

This non-research application from London Ambulance Service (LAS) sets out the purpose of providing data and analytics led insights that will inform emergency pathway interventions, by understanding the outcome of patients treated by LAS, once transferred to Emergency Care at a Trust. Applicants plan to link Trust outcome data with LAS data to create a pseudonymised extract in order to conduct analysis and support collaborative working to improve emergency pathways and interventions to the benefit of the patient population.

An initial pilot has already been implemented with Lewisham and Greenwich NHS Trust (LGT) but it is now planned for this pilot to expanded across London with other NHS Trusts. For the pilot, both LGT and LAS used the Foundry platform, which enabled data to be pseudonymised at source within the LGT instance of Foundry and then transferred to the LAS Foundry, however, the applicants plan to roll this out across London, and not all NHS Trust's have Foundry. Therefore this application is to seek 's251' support to cover the transfer of Confidential Patient Information from NHS Trusts, who do not have Foundry, to the LAS Foundry for the purposes of linking and applying an automated process of pseudonymisation within the LAS Foundry.

An Urgent and Emergency Care (UEC) analytics management tool accesses the pseudonymised dataset within Foundry (which is effectively anonymous to this data processor), in order to create management dashboards and support LAS and partner NHS Trusts with the following specific purposes: Paramedic learning, strategic visibility throughout the emergency pathway, utilisation of alternative pathways, population Health Management, and streamlining of ED operations. Overall this application aims to significantly improve the effectiveness of urgent and emergency care for patients, and improve patient outcomes. LAS estimates that outputs from this application could reduce conveyances (the transfer of a patient from one healthcare facility to another) by 3-5% (saving LAS £3-5m per year), and reduce ED attendance in London by 1-5%

(saving London Trusts £12-60m per year). If this programme were extended in future and rolled out across England's ambulance services and acute Trusts, LAS estimates it might save the NHS £200-500m per year.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | All individuals who received care from both LAS and the partner NHS Trust from 1st January 2019 onwards<br><br>Including:<br>· Patients who received care in A&E/ED (and would therefore be included in ECDS),<br>· Impatient Non-Elective admissions (and would therefore be included in APC),<br>· All outpatients referred from the emergency departments (and would therefore be included in OPA)<br><br>Approximate prospective numbers below:<br>~50k ECDS patients per week<br>~4k APC patients per week.<br>~2k OPA patients per week<br><br>Retrospectively from 2019 (234) until now, this would be approximately:<br>~11,700,000 ECDS patients<br>~936,000 APC patients<br>~468,000 OPA patients |
| **Data sources** | 1. Participating (Non-Foundry) Trusts – medical records<br>2. LAS – medical records |
| **Identifiers required for linkage purposes** | 1. NHS number<br>2. Forename<br>3. Surname<br>4. DOB<br>5. Postcode |
| **Identifiers required for analysis purposes** | 4. N/A this will be effectively anonymised for analysis |

| | |
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| **Additional information** | Applicant envisages multi-daily feeds of data to be uploaded from LAS and partner Trusts in an ongoing fashion<br><br>Applicant has confirmed the multi daily updates are for data collected on that same day, or the day prior, or though noted this will vary from hospital to hospital. |

**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. Following consideration the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

## Scope

The CAG accepted that 'section 251 support' is required for the flow of data from Trusts to LAS. However, the CAG was unclear if the applicant was requesting 'section 251 support' for the linkage of this data to LAS records, within the Foundry system. It was noted that the applicant has stated that this process is undertaken completely automatically, and there are no humans involved. Therefore, the CAG requested clarification on whether the applicant was requesting 'section 251 support' for the linkage of hospital data to LAS records, within the Foundry system.

## 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 applicant considers that consent would not be practicable or valid to obtain during ambulance conveyance or emergency acute setting, due to the fact that these patients are utilising the NHS in unplanned scenarios/circumstances, namely contact with London Ambulance Service and/or Emergency Departments. By their very nature, these disciplines of care will deliver care and provide support to individuals in differing levels of distress or harm, where the explanation and request for consent regarding linking of their identifiable information in order to create de-identified information for specific use cases would either not be practicable or appropriate.

The CAG was content that it is too difficult and time consuming for the direct care team to consent, whilst simultaneously trying to deliver emergency care, and that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage. The CAG was content that using anonymous information was not a practicable alternative.

- **Previous Ambulance Data Set application**

The CAG was content that this current application is sufficiently different to 22/CAG/0171 (Ambulance Data Set application from NHS England), and therefore agreed that 22/CAG/0171 is not a practicable alternative to 's251' support.

- **Foundry**

The Members noted that ‘section 251 support’ cannot be provided if there is an appropriate practicable alternative, therefore it is very important that this data is not flowed under ‘section 251 support’ once the participating Trusts have the Foundry system in place, and are able to flow pseudonymised data only rather than confidential patient information. The CAG therefore requested clarification on how the applicant will make sure each of the participating Trusts are close to completing their set up with the Foundry system, so that ‘section 251 support’ can be expired for those organisations, at the appropriate time, to avoid unnecessary breaches of confidentiality.

## ‘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 object 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 states that LAS and participating Trusts have already detailed within their privacy notices about the sharing and linking of datasets to improve the management of healthcare services.

The CAG noted that privacy notices were inadequate for the purposes of a patient notification mechanism for this application. The CAG requested a layered approach to patient notification, which entailed a newly developed patient notification document which is specific to this project, which could lead on to further detailed information in a privacy notice or another more detailed document. The CAG also suggested posters to be developed for A&E and LAS vehicles. is the patient notification documents should be understood easily by lay individuals. The notifications should also state that 'section 251 support' was recommended by the Secretary of State for Health and Social Care, on advice from the Confidentiality Advisory Group (CAG). The patient notification documents should have an application specific opt out described. The notification documents should be reviewed by a group of patients and the public for accessibility.

The CAG noted that the National Data Opt-Out would be respected. However the CAG considered that an application specific opt-out mechanism is also required for both the retrospective cohort and the prospective cohort. Members noted that these 2 cohorts were extremely different, and required separate considerations regarding how opt outs might be applied.

The CAG recognised that because the applicant had described a potential daily upload of data withing 24 hours of arriving at a Trust, operating a working opt-out mechanism in this environment would be extremely difficult. Therefore the CAG requested whether it was possible to delay the extract of daily data from Trusts in order to allow a working opt-out mechanism for prospective patients.

The CAG requested an opt-out mechanism that works for retrospective group, noting that this group is estimated to be over 11 million. The applicant should carefully consider where to place the notifications so that the cohort might see it, and the CAG recommended the applicant ask a group of patients and the public for advice as to where an appropriate place would be, or if any other methodology such as social media might be appropriate.

## Patient and Public Involvement and Engagement

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

The applicant states that LAS have comprehensive patient involvement in the form of their London Ambulance Service Public and Patients Council to communicate with data subjects regarding programmes they are involved in. However there is no indication of which patients reviewed this application, specifically the use of confidential patient information without consent.

The Confidentiality Advice Team (CAT) query responses mention that in 2020, OneLondon, a collaboration between London's five ICBs and LAS held the worlds largest public deliberation on the use of health and care data, a key takeaway of which was '*Participants were surprised to hear that data is not more joined-up, although for some this confirmed their concerns that the system is too fragmented*'.

The CAG noted that the Patient and public Involvement cited was inadequate, as the applicant has given information about the OneLondon event, but gives no indication of the make-up of the group, for example how many people were there, or whether they represented the cohort. No indication has been provided regarding whether there was discussion about the use of confidential patient information without consent, for the purposes of this specific application. The Members noted that the patient and public involvement cited appears to be intended for a much wider purpose than the proposed data flows in this specific application.

CAG therefore requested that specific patient and public involvement was undertaken with representative groups, to discuss the acceptability of this use of confidential patient information without consent, with regards to this specific application. The patient and public involvement undertaken should be proportionate to the application, which is requesting data for a very large amount of people.

## Exit strategy

All confidential patient information will be removed once the process of pseudonymisation has been concluded. This is an automated process via the LAS Foundry platform. For the individual patient, this happens immediately after linkage.

The applicant envisages multi-daily feeds of data in an ongoing fashion, with no perceived end date, as there is currently not a technical solution in place which would negate the need for confidential patient information to be used for linkage. Once that

the appropriate technology regarding the use of Foundry is in place at local NHS Trusts, the process will be changed to one where no transfer of confidential patient information is necessary, as it can be pseudonymised at source.

The CAG noted that the exit strategy is when the last participating Trust manages to set up the Foundry system. However, as the applicant is unclear when this would take place, 'section 251 support' will be required in an ongoing fashion for the continuing daily uploads. Therefore a condition of 'section 251 support' for a five-year duration has been applied.

**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 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, within one month.

**Request for further information**

1. Please provide clarification on whether 'section 251 support' is requested for the linkage of hospital data to LAS records, within the Foundry system.

2. Please confirm to CAG how you will ensure that you are aware of when each participating Trust is set up with the Foundry system to ensure they can be expired from 'section 251 support' at the appropriate time.

3. Please create patient notification materials specific to this project as per advice in this letter. These should include an opt out mechanism, and be reviewed by a group of patients and the public to ensure a lay reader would understand the content.

4. Please explain whether it is possible to delay the daily uploads from Trusts in order to allow working opt-out mechanism for prospective patients. If this is not possible, please justify why it is not possible to delay the daily uploads.

5. Please provide an opt-out mechanism that works for retrospective group, considering where to put the notification so the cohort might see.

6. Specific patient and public involvement needs to be undertaken with a representative group, to discuss the use of confidential patient information, without consent, for the purpose of this application. Feedback from the discussion is to be provided to the CAG.

7. Confirmation should be provided from the DSPT Team at NHS England to the CAG that the 22/23 Data Security and Protection Toolkit (DSPT) submission for Palantir has achieved the 'Standards Met' threshold, as per standard condition of support (see below).

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, 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. 'Section 251 support' is provided for five years. A duration amendment will be expected at that time, should the applicant wish to extend the duration of 'section 251 support'.

2. Confirmation provided from the DSPT Team at NHS England 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:**

   The NHS England **22/23** DSPT review for **Amazon Web Services** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 19 June 2023)

   The NHS England **22/23** DSPT review for **Palantir** was pending

   Due to the number of participating organisations involved, it is the responsibility of LAS as controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

## c. 23/CAG/0067- An evaluation of the clinical efficacy and risk profile of routine spinal operations performed in the National Health Service

**Context**

### Purpose of application

This application from Queen Mary University of London set out the purpose of medical research that seeks to assess the clinical outcomes of common spinal surgery procedures for low back pain.

Back pain is a common disorder, affecting over three quarters of people at some point. Although more common in the elderly, younger people who suffer with bulging spinal discs also often suffer. Back pain drastically affects an individual's quality of life, preventing them from performing key daily activities such as walking, using the bathroom, exercise and sleeping. Back pain also costs the economy over £12 billion per year through lost work hours, painkiller consumption and disability benefits. Around one in ten of those affected go on to develop chronic back pain, which is linked to several mental health conditions. Spinal research undertaken so far have been limited in numbers and in follow-up, and there is little understanding in how effective spinal surgery is and the risk of complications.

Confidential patient information from the British Spine Registry (BSR) will be disclosed to NHS England for linkage to HES data. BSR will also disclose a dataset containing the study identifier, but otherwise de-identified, to Queen Mary University of London. The study identifier will be used to link the two datasets. The final dataset, anonymised other than patient date of death, will be used for analysis.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Patients who underwent any of the following spinal surgical procedures; Discectomy, Fusion, Laminectomy, Cauda equina decompression surgery, Kyphoplasty, Intervertebral disc replacement, Deformity surgery (scoliosis, kyphosis).<br><br>The applicants will obtain data from HES for patients who underwent spinal surgery between 01 January 2000 – 01 January 2023.<br><br>As the BSR was not set up until 2012, data from BSR will be collected between 01 January 2012 – 01 January 2023. |

| | |
|---|---|
| | The applicants estimate that 1,000,000 patients will be included. |
| **Data sources** | 1. British Spine Registry, held by British Association for Spine Surgeons<br>2. HES-APC, HES-PROMS and ONS data, held by NHS England |
| **Identifiers required for linkage purposes** | 1. NHS Number<br>2. Date of birth<br>3. Postcode – unit level |
| **Identifiers required for analysis purposes** | 1. Date of death<br>2. Gender<br>3. Ethnicity |

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

### Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. Following consideration the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

### Practicable alternatives

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

- **Feasibility of consent**

Patients have consented to the inclusion of their data in the British Spine Registry.

The applicants advised that it would be impractical to individually contact all patients (over 100,000) who have data recorded in the BSR to ask whether they have consented for their data to be used by HES and ONS.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

NHS England require confidential patient information in order to link data from the BRS to HES and ONS data.

The CAG was content that using anonymous information was not a practicable alternative.

### Justification of Identifiers

The CAG noted that the applicant stated that the final dataset, anonymised other than patient date of death, will be used for analysis and that the date of death is required for accuracy. The CAG queried why date of death was required for accuracy and whether this could be converted to age at death.

### '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 object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants advised that the study will be registered on a publicly available website. An outline of the study in lay terms and the process of linking and analysing the data will be included. Contact details for the study administrator will be included for patients to request opt-out.

No patient notification materials were provided with the application.

Members noted that the confidential patient information in the British Spine Registry (BSR) is held with patient consent.

The National Data Opt-Out will be applied.

The CAG agreed that it was unclear how the study would be promoted. Members advised that the applicant undertake further patient and public involvement to discuss the best way of notifying patients. The patient notification materials and a communication plan, created following these discussions, needed to be provided to the CAG for review.

The CAG also asked that a study specific opt out mechanism was created. The patient notification materials needed to contain an explanation on how patients can opt-out.

## 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 patient and public involvement has been undertaken and the issue of linking confidential information without consent discussed.

Eight patients attended a face-to-face session where the research proposal was discussed. The activity was an open discussion over our proposed research proposal presented in lay terms and all patients agreed that linking the datasets without consent was actually a responsibility of doctors to help improve standards of care as long as the data was de-identified. All were in support of the linkage without consent. Patients were from various demographics including British, Indian, Pakistani and European ethnicities and an even distribution of sexes.

The applicants explained that they would carry out further discussions every six months. Funding from NIHR has been obtained to run further patient and public involvement discussions after they reviewed our plans and project proposal.

The CAG noted considering that there were only 8 people involved in the PPI group, they were impressed by the diversity of the group. However, members were unclear whether those 8 patients were from the BSR group and requested clarification. Members agreed that the number of patients included in the PPI group needed to be increased.

The CAG agreed that further patient and public involvement needed to be undertaken including patients registered in the BSR where the specific issue of undertaking data linkages despite the consent form they originally signed stating that no linkages would be undertaken.

Members also noted that patient and public involvement should be undertaken throughout the project.

## Exit strategy

The applicants will have access to pseudonymised information only.

The CAG is content with the exit strategy.

**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. The CAG asked that patient date of death was converted to age at death. If this could not be done, justification as to why not needed to be provided.

2. Further patient and public involvement needs to be undertaken. This needs to cover the following:

    a. The number of people involved in the PPI group needs to be increased.
    b. Provide clarification on whether the 8 patients in the face-to-face session are from the British Spine Registry (BSR).
    c. Patient and public involvement needs to be undertaken around the issue of use of confidential patient information for data linkages despite the consent form they originally signed stating that no linkages would be undertaken.
    d. A commitment to ongoing patient and public involvement needs to be given.

3. A patient notification strategy and dissent mechanism need to be created:
    a. Patient and public involvement needs to be undertaken to discuss the best way of notifying patients. The patient notification materials and a communication plan, created following these discussions, need to be provided to the CAG for review.

    b. A study specific opt-out needs to be created and an explanation on how patients can opt-out included in the patient notification materials.

**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 19 June 2023**

2. Confirmation provided from the DSPT Team at NHS England 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:**

   The NHS England **21/22** DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 June 2023)

   The NHS England **21/22** DSPT review for British Association for Spine Surgeon was **pending**

## d.23/CAG/0068- Maximising the value of the Caerphilly Prospective Study (CaPS)

**Context**

### Purpose of application

This application from the University of Bristol set out the purpose of continued holding of confidential patent information collected for the Caerphilly Prospective Study.

The Caerphilly Prospective Study (CaPS) recruited patients between 1979 and 1988. 2512 men aged 45-59 years were recruited from the town of Caerphilly and adjoining villages between 1979 and 1983, with an additional 447 recruited between 1984 and 1988. Men were initially seen at an evening clinic, where they completed a questionnaire, had anthropometric measures (measurements of the proportions, size, and weight of the human body) and an electrocardiogram (ECG) taken to check the heart's rhythm and electrical activity. They also completed a food frequency questionnaire at home. They subsequently re-attended an early morning clinic to have fasting blood samples for a wide variety of tests.

Patients were initially recruited under consent. Most of the participants have died and the remaining survivors are likely to be frail and/or cognitively impaired. After 35 years of follow-up, it was decided to no longer collect any new data directly from the cohort, but to update any new clinical events through routine linkage with NHS England. The applicants seek support to continue to hold confidential patient information for the cohort and disclosure of a unique patient ID and patients dates of birth to NHS England for linkage to ONS and cancer registry data.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | Patients recruited into the Caerphilly Prospective Study |
| **Data sources** | 1. Caerphilly Prospective Study records, at University of Bristol<br>2. ONS and cancer registry data, held by NHS England |
| **Identifiers required for linkage purposes** | 1. Unique ID<br>2. Date of birth |
| **Identifiers held in database** | 1. Full Name<br>2. NHS number<br>3. Date of birth<br>4. Year of birth<br>5. Date of death<br>6. Postcode – unit level<br>7. Gender<br>8. Occupation<br>9. 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. Following consideration the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

## Scope

The CAG noted that the patients had lived in Wales when recruited, however the applicants sought support to link to data held by NHS England. Members queries whether support also needed to be given for access to any databases held in Wales.

## 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 state in the answer to Q29-3 that consent has been sought on multiple occasions. However, the applicants also note that, while patients initially consented to participate, consent was not sought for disclosure of their confidential patient information to NHS England for linkage to ONS datasets.

The applicants advised that recontacting patients to seek consent was not feasible as most the cohort are now deceased.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information needs to be disclosed to NHS England for linkage to ONS and cancer registry data, to allow collection of follow-up data.

The CAG was content that using anonymous information was not a practicable alternative.

## '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 object 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.

Newsletters have been sent previously, but this was stopped around a decade ago.

Information about CaPS will be made available on the University of Bristol website.

The applicants advised that they had not intended to undertake formal patient notification. The applicants noted that most patients in the cohort will now be deceased.

NHS England will apply the National Data Opt-Out.

Patients can dissent by emailing the study team. Contact details are available on / the University of Bristol website but this link only contained a postal address and no email or telephone details.

The applicants noted that, when the MRC Unit at Llandough was shut down by the MRC in the late 1990's, the applicants contacted all patients who they held current addresses for to advise that their questionnaires, biosamples and electronic data would be transferred to University of Bristol for future research. Patients were given the opportunity to opt-out of the transfer and, consequently, the ongoing use of their data. No patients opted-out.

The CAG noted that no patient notification has been provided for review. The CAG requested that the applicants create patient notification materials and a mechanism for patients to dissent to use of their data. Members noted that notification is still possible even if it's only a public notification, as there might be people who are still alive and well or interested in their family.

## 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 noted that the project was set up in 1979/1980 and it was not usual practice at that time to set up a patient and public involvement group. Participants were kept aware of the results of the research and future activities by the sending of regular newsletters. Around 600 participants attended a 25th birthday party for CaPS.

The applicants intend to set up a data access committee, which will review requests for data use and which will include lay members, who can advise on the suitability of future research. This would be ideally one of the original participants but given the very few survivors and their current health status this is unlikely to be feasible.

The CAG requested the further patient and public involvement was undertaken with local people and that these discussions included the use of confidential patient information without consent as proposed in the application.

The CAG was requested further details on the Data Access Committee and how requests to access the data were handled.

## Exit strategy

The applicants plan to continue to hold confidential patient information in the Caerphilly Prospective Study database.

The CAG is content with the exit strategy.

### 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. Appropriate patient notification materials need to be created.

2. Further patient and public involvement need to be undertaken with local groups and the discussions need to include the use of confidential patient information without consent as proposed in the application.

3. Provide further details on the Data Access Committee and how requests to access the data are handled.

4. Clarify whether any linkages will be conducted to data held within Wales and whether support is needed for this.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 11 May 2023**

6. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. **Confirmed:**

   The NHS England **21/22** DSPT review for **University of Bristol (Bristol Medical School) and NHS England** was confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (21 June 2023)

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

## e. 23/CAG/0070- NCL ICS application for secondary use of data

**Context**

### Purpose of application

This non-research application from North Central London Integrated Care Board (NCL ICB), sets out the purpose of creating a dataset using data from the NCL ICB direct care data platform (HealtheIntent), linked to NHS England national datasets. The NCL ICB shared care record does not include care delivered elsewhere in the country, and therefore this can lead to a gap in full understanding of a patient. This can be especially problematic in London where there can be a large transient population of students and workers. This dataset will be used for non-research secondary purposes, such as population health management (PHM), risk stratification, and planning and analysis, regarding the North Central London population.

Since 2020, GPs, Trusts and Local Authorities in NCL have submitted identifiable data to an integrated patient record system managed by NCL ICB for direct care purposes. Social care data is in the process of being included This activity does not require 'section 251 support' as is for the purposes of direct care.

Separately, NHS England datasets are acquired, under s261(4) of Health and Social Care Act 2012 Act, and CAG 7-07 (a-c) 2013 (regarding invoice validation), via the North of England Commissioning Support Unit Data Services for Commissioners Regional Office (NECS-DSCRO), and flow into NHS Northeast London ICB, who disclose the data to NCL ICB, hosted by Cerner. This activity does not require 'section 251 support' as is for the purposes of commissioning and invoice validation.

NHS England datasets will be linked to the direct care data within the NCL ICB. 'section 251 support' is sought to undertake this processing and enable use of the data for secondary purposes as described in the application. This data will be transferred to a separate segregated environment within the platform. Access to this environment would be strictly controlled via Role-based Access Control (RBAC), and only made available for the purposes of supporting the use cases described. Direct access to this data would only be permitted to create datasets for analysis, and would be limited to a small team of developers and NCL ICB/ICS analysts. Anonymised and aggregated data outputs will be provided to end users who have need to understand the populations and

services within NCL, for example clinical, analytical, commissioning or planning users. Patient-level identifiable data outputs will be provided to clinical users who have a direct clinical responsibility to those cohorts, with regards to risk stratification.

A recommendation for class 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 registered and receiving care within North Central London from health and social care organisations in the London Boroughs of Barnet, Camden, Enfield, Haringey and Islington<br><br>Approximately 1.8 million individuals<br>this will include deceased patients. |
| **Data sources** | 1. NCL ICB direct care data platform (HealtheIntent), already linked together for purposes of clinical care, created from 198 organisations including Primary Care, Secondary Care, Mental Health Trusts, Local Authorities, Social Care<br><br>2. NHS England datasets, via NECS DSCRO, which are already flowed to NCL ICB.<br>• Secondary Uses Service Dataset (SUS)<br>• Emergency Care Dataset (ECDS)<br>• Community Services Dataset (CSDS)<br>• Mental Health Services Dataset (MHSDS)<br>• Patient Demographics Service (PDS)<br>• National Waiting List Data (Minimum Data Set)<br>• Diagnostic Imaging Dataset (DIDS) |
| **Identifiers required for linkage purposes** | 1. Full Name<br>2. NHS Number<br>3. Address and Postcode<br>4. Date of Birth<br>5. Gender |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. Phone number – appears to be being presented back to direct care organisations regarding risk stratification purposes.<br>2. Postcode – modified to LSOA.<br>3. Date of Birth – modified to month and year<br>4. Gender<br>5. Ethnicity<br><br>For the purposes of the CAG application, the applicant has stated that data is pseudonymised for analysis, with the exception of the provision of phone number back to direct care team, for risk stratification purposes. |

**Confidentiality Advisory Group advice**

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

## 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. Following consideration the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

## Scope

Incoming data flows

NHS England datasets regarding the NCL population are acquired under s261(4) of Health and Social Care Act 2012 Act, in pseudonymised format, to support commissioning activities. There is also a flow in place for the purposes of invoice validation (supported under CAG reference CAG 7-07 (a-c) 2013).

Members noted correspondence prior to the meeting as to whether these flows need an additional common law legal basis, specifically to enable the data to be used for the purposes described in this application. CAG considered this and agreed that a flow of confidential patient information can only have one common law legal basis, and that the NHS England datasets already had this in place, either via s261(4) of Health and Social Care Act 2012 Act or Regulation 5 support for invoice validation.

As such, CAG agreed that it was not the flows of data that need 'Section 251 support', but the use of confidential patient information to link the datasets together for other, secondary purposes as described in the application. Members noted that this position aligns with that stated by the National Data Guardian in November 2022.

Confidential patient information is also already flowing from health organisations to NCL ICB for the purposes of the shared care record for direct care purposes, since 2020, and therefore 'section 251 support' is also not required for these flows.

Therefore, the CAG requested that the applicant revise the data flow diagram to align with the descriptions in this letter, with regards to the common law legal bases of the flows of data into the NCL ICB.

Risk Stratification

The applicant states there might be occasions where confidential patient information would flow back to the direct care team, for the purposes of risk stratification and case-finding, and these flows would be within scope for this 'section 251 supported' application.

CAG was unclear with regards to the difference between direct care purposes and risk stratification purposes as described in the application, and were therefore unclear if 'section 251 support' was required to cover the flow of confidential patient information back to the direct care team. The CAG therefore requested the applicant further describe the risk stratification purposes that would be under 'section 251 support', (as compared to direct care purposes where support would not be required), so the CAG is clear where ''section 251 support' is requested.

With regards to the main NHS England risk stratification application, 'section 251 support' is not required for the flow of identifiable data back to the direct care team, as this is for direct care purposes at this time point. However, it was unclear to Members if data regarding risk stratification was disclosed back to direct care team or people outside the direct care team, because the CAG noted that in the application form it was stated "*These users don't have an immediate direct care responsibility but are working to obtain such".* The CAG would like to note that there are either individuals who are part of the direct care team, or individuals who are not part of the direct care team, and there is no in between.

The GMC defines the direct care team as: '*made up of those health and social care professionals who provide direct care to the patient, and others, such as administrative staff, who directly support that care.*' The Information Governance Review in 2013 by the National Data Guardian stated that '*direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers...Care teams may*

*also contain members of staff, who are not registered with a regulatory authority, but who may need access to a proportion of someone's personal data to provide care safely'*.

The CAG requested clarification that the applicant is clear with regards to direct care team vs individuals who are not part of the care team, and that there is no in between in regards to the comment around 'immediate direct care'.

## 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 applicant reasons that it is not practicable to ask the 1.8 million currently registered patients for consent.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage between datasets. It is not possible to undertake linkage without identifiers.

The CAG was content that using anonymised information was not a practicable alternative.

## Justification of Identifiers

The application form states that telephone number is required for analysis, however it appears to CAG that telephone number would only be required to be disclosed to the direct care team in order for them to contact the patients with regards to risk stratification purposes of the application. The CAG requested clarification whether this was the case and for confirmation that phone number was not required for analysis.

The CAG noted that in the application, the applicant had stated that they may wish to use other identifiers in future for both linkage and analysis. The Committee stated that if any additional items of confidential patient information are planned for linkage or analysis, this should be specified via amendment to CAG.

## ‘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 object 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 NCL webpage: Opting out of the joined-up health and care record - North Central London Integrated Care System (nclhealthandcare.org.uk) and NCL privacy notice were provided for review. This is being displayed by the participating organisations within the NCL area, and on the NCL Integrated Care System (ICS) website transparency page.

Individuals indicating that they wish to opt-out of data sharing (for the purposes of direct care) will be omitted from the Local Data flows cohort. This is and will continue to be managed by the locally implemented NCL opt-out form advertised on the NCL and local provider websites.

The applicant has stated that the National Data opt out will be respected, but has not yet described the timepoint at which this will be applied. The CAG noted that the patient notification and opt out provided appears to be specific to only direct care purposes (shared care record). The Committee felt that currently there was no appropriate patient notification or opt out, for the purposes described in this application. The CAG noted that privacy notices alone are not enough notification to inform patients of these secondary purposes.

Therefore the applicant is requested to develop new patient notifications, using a layered approach, which can lead on to a privacy notice if required. The notifications should describe the use of confidential patient information for the secondary purposes described in this application. This notification should make it very clear that these purposes are separate to direct care. These should be written in lay language.

The new notification should contain an application specific opt out option, which is separate from the opt out offered for direct care purposes. The Committee also observed the current process of opting out of the shared care record was not very accessible, as it appears the patient has to download a document, print it out, and fill it in, and send back by post. Therefore the CAG wanted to make clear that any opt out developed for the purpose of this application should be easily accessible, with no download or printing of documents required, and have a phone number, email and postal address for the purpose of opting out.

The CAG also requested clarity around when the National Data opt out will be applied.

The CAG requested an updated communication plans including any actual notification materials that the applicant is planning to use.

## 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 held a Citizens' Summit, to explore the use of confidential patient information without consent, and outside the direct care team. Materials used in the event are published on this website - https://onelondon.online/citizenssummit/

The event was over 4 days, and involved 100 Londoners of varying backgrounds that were representative of the cohort. Overall, as participants became increasingly informed about current and potential use of confidential patient information, they became increasingly supportive of using health and care data for purposes beyond individual care, (ie. the purposes of this application). However, there was also consistent support for an opt out to be available. A set of recommendations were developed by participants, which were explored with representatives from marginalised and vulnerable communities during a one-day workshop convened shortly after the Citizens' Summit.

CAG requested clarity on the outcomes of the recommendations that were discussed by representatives from marginalised and vulnerable communities, as this was not described as part of the document provided. The CAG noted references to appendix E, but this was not provided as a separate document.

The CAG noted that the application relied heavily on the OneLondon event which was three years ago. The patient and public involvement does not appear specific for the purpose of linking the exact datasets listed in this CAG application. The Committee commented that this campaign, although very good, is therefore not specific to this application. The CAG requested further patient and public involvement to be undertaken, with regards to this specific application, which involves more participants. The CAG also requested an ongoing plan of relevant continuous patient and public involvement. The newly developed patient notification materials should be reviewed by a patient and public involvement group.

## Data Access Committee

The application was unclear how access to the pseduonymised dataset would be audited and monitored. Terms of Reference have been provided two groups. The first for North Central London ICS Population Health Management (PHM) Group. The make up appears to be 36 experts and 2 patients, not yet appointed. The group will meet every 6 weeks. The second for The North London Partners (NLP) Information Governance (IG) Working group. Two Community Representatives are invited as Members. The group will meet on a monthly basis. It is unclear how these groups interact with each other, nor whether either or both groups will review applications for data uses under this CAG application. As part of the query responses the applicant has stated that; 'A new management process will the established to manage new use cases and is dependent on an ongoing ICS governance review'

Members considered the process for reviewing requests for data and felt these were ambiguous. The CAG asked for a clear description on the processes/groups used to consider request to access data. Members agreed any group that is considering these requests should include lay representation.

### Exit strategy

The applicant is asking for 'section 251 support' for a period of 3 years in the first instance for the ongoing data linkage.

Regarding the exit strategy for the individual patient, the application states ''*Five years but this may vary by contributing controller. This retention period is needed so that analysis can be carried out on long term data sets. Population health management is a way of supporting frontline teams to understand local cohorts and to predict what would help improve health/wellbeing based on historic and current data'.*

On querying whether data planned to be deleted 5 years after health event for each individual, the applicant has stated they will not be deleting data – '*we will put data beyond use where we accept a patient / subject / citizen request that objects to processing. We would maintain data in-line with NHSE/ DSCRO retention periods.'*

The CAG noted that exit strategy for individual patients is therefore unclear. It appears that the identifiable data will not be deleted. The CAG requested clarification whether the data will be retained.

### 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. Please revise the data flow diagram to align with the descriptions in this letter.

2. Provide further description of the risk stratification purposes, as compared to direct care purposes, so the CAG is clear where support is required, specifically regarding the flow of confidential patient information back to the direct care team.

3. Confirm that, at the point of access, an individual is either part of the direct care team, or not.

4. Please confirm that telephone numbers are disclosed exclusively to enable contact with patients for the purpose of risk stratification, and therefore also confirm that phone number is not required for analysis purposes.

5. Please update the patient notification materials as follows, in line with advice in this letter, and provide to CAG for review.
    a. Produce a new patient notification which clearly describes the purpose and content of this application, distinct from any notification relating to direct care purposes
    b. This should be separate from privacy notices, and a layered approach is advised.
    c. Patient notifications should be written in language suitable for a lay reader.
    d. Create a study specific opt-out which is clearly separated from the opt out used for the shared care record, which is easily accessible, by including a phone number, email and postal address.

6. Please clarify at exactly what stage the National Data opt out will be applied.

7. Provide an updated communication plan, including any materials that are to be used.

8. Further patient and public involvement should be carried out in line with advice in this letter;
    a. Further patient and public involvement should be undertaken, with more people, which is specific to the linkages and purposes described in this application.
    b. An ongoing patient and public involvement plan is to be provided.
    c. All newly developed patient notification materials should be reviewed by a patient and public involvement group.

9. Please provide detailed feedback on the outcomes of the recommendations that were discussed by representatives from marginalised and vulnerable communities, as this was not described as part of the document provided.

10. Please provide a clear account of your plans for reviewing data access requests and for lay involvement in the process.

11. The CAG noted that the exit strategy for individual patients is unclear. Please clarify whether confidential patient information will be retained after 5 years, or if you plan to delete it at any point.

12. Please provide evidence of the NHS England DSPT review for North Central London Integrated Care Board, as per standard condition of support.

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. 'Section 251 support' is provided for three years from the date that final support is provided. An amendment will be required at that time to extend the duration of 'section 251 support'.

2. If any additional items of confidential patient information are planned for linkage or analysis in future, this should be specified via amendment to CAG.

3. Confirmation provided from the DSPT Team at NHS England 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**:

   The NHS England **21/22** DSPT review for **ORACLE CORPORATION UK LTD and Amazon Web Services** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (confirmed 19 June 2023)

   The NHS England **21/22** DSPT review for **North Central London Integrated Care Board** was pending.

## 4. Any other business

No other business was raised.

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

| Signed – Chair | Date |
| --- | --- |
| Dr Patrick Coyle, Vice Chair | *28 June 2023* |

| Signed – Confidentiality Advice Team | Date |
| --- | --- |
| *Ms Caroline Watchurst, HRA Confidentiality Advisor* | *22 June 2023* |