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

**11 September 2020**

## Present:

| Name | Capacity | Items |
|---|---|---|
| Dr Patrick Coyle | CAG Vice-Chair | 1a, 2a |
| Mr David Evans | CAG Member | 2a |
| Prof Jennifer Kurinczuk | CAG Member | 1a, 2a |
| Mr Andrew Melville | CAG Member | 1a |

## Also in attendance:

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

## 1. New Precedent Set Review Applications – Research

## a. 20/CAG/0110 - Understanding the epidemiology in the transition from neonatal to paediatric care: a data linkage study

### Context

### Purpose of application

This application from University of Leicester sets out the purpose of medical research that aims to describe and understand the epidemiology of children who receive neonatal and/or paediatric care by linking together information about the care they have received. The aim is to understand which children who receive neonatal care also go on to need paediatric care, how this affects service providers, and how patients and families can be best supported.

Following birth, around one in seven babies are admitted for specialist neonatal care in the UK. Admission rates to neonatal care have increased, partly due to improved survival of the most vulnerable babies, particularly those born very prematurely or those with serious health problems. More of these babies now survive, but the impact of their health and the care received immediately after birth can be lifelong. There has also been an increase in admissions to Paediatric Intensive Care Units (PICU) in the last ten to fifteen years. Many admissions relate to children who received neonatal care immediately after birth, although the exact number is not known. Very little is known about what happens between neonatal and paediatric care including which children are likely to experience both types of care, and how clinical services, parents and professionals manage the transition.

This study will use information from two established databases, both of which have a legal basis to collect confidential patient information under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002: the National Neonatal Research Database (NNRD) (CAG ref: ECC 8-05(f) / 2010) and the Paediatric Intensive Care Audit Network (PICANet) (CAG ref: PIAG 4-07(c)/2002). The NNRD captures information about all babies admitted for neonatal care after birth. PICANet captures information related to referrals, transports and admissions to PICU. Applicants will focus on care received in the first two years of life but for those children who were also subsequently admitted in later years, information relating to later admissions will also be received.

Each database will provide the identifiers from their datasets to NHS Digital, who will link the 2 data sets together as a trusted third party. NHS Digital will establish three datasets - those only in the NNRD, those only in PICANet, and those common to both datasets. NHS Digital will then link these data to Hospital Episodes Statistics (HES) and mortality data (ONS). The datasets from NNRD and PICANet will also be linked to Patient Episode Database for Wales (PEDW) by NHS Wales Informatics Service (NWIS), to collect information about admissions in Wales. The pseudonymised linked datasets will be transferred from NHS Digital and NWIS to the researchers at University of Leicester. Pseudonymised clinical datasets will also be transferred directly from the NNRD/PICANet to the research team at the University of Leicester, containing data related to demographics, care, treatment and outcomes. The researchers will then link the clinical datasets to the pseudonymised linked (to HES, ONS, and PEDW) NNRD/PICANet datasets, using a pseudonymised identifier.

All data provided to the team at the University of Leicester will be pseudonymised. The pseudonymised data can only be linked to personal data by NHS Digital or the teams at the NNRD or PICANet. The University of Leicester cannot link back to any personal data and will not hold any of the primary datasets.

A recommendation for class 4 & 6 support was requested to cover 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.

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|---|---|
| Cohort | All children admitted to neonatal care in England and Wales from 1 January 2013 to 31 December 2018 (~480,000 babies) and all children aged <2 years admitted to PICU from 1 January 2013 to 31 December 2020 (~ 80,000 admissions). |
| Data sources | 1. National Neonatal Research Database (NNRD): (Chelsea & Westminster Hospital NHS Foundation Trust)<br>• Information about all babies admitted for neonatal care.<br>2. Paediatric Intensive Care Audit Network (PICANet): (University of Leeds)<br>• Information about children aged <2 years admitted for paediatric intensive care, |

| | |
|---|---|
| | • and Information about children who were subsequently admitted after age two years for relevant children.<br>3. NHS Digital:<br>• Mortality data (Office for National Statistics - ONS)<br>• Hospital Episode Statistics (HES) data<br>4. NHS Wales Informatics Service (NWIS):<br>• Patient Episode Database for Wales (PEDW) data |
| Identifiers required for linkage purposes | 1. NHS Digital will complete linkage using:<br>• NHS number<br>• Date of birth<br>• Sex<br>• Postcode<br><br>2. The NHS Wales Informatics Service will complete the linkage using only NHS number |
| Identifiers required for analysis purposes | 1. Age<br>2. Sex<br>3. Ethnicity<br>4. Date of death (modified to age of child at time of death) |
| Additional information | All records transferred to NHS Digital will include a pseudo-anonymised identifier to allow linkage back to the clinical data by the team at the University of Leicester. No clinical data will be transferred from the NNRD or PICANet to NHS Digital. |

## Confidentiality Advisory Group advice

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

## Public interest

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

The CAG agreed that the application was in the public interest and has a clear 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.

- **Feasibility of consent**

The applicants reason that consent is not practicable or appropriate for a number of reasons, including that opt-out options already exist with the NNRD and PICANet; the size of the cohort (up to 560,000), the emotional burden on parents to be contacted potentially years after the admission, and the inability for the research team to ensure correct contact information.

The CAG agreed with the rationale given for not seeking consent.

- **Use of anonymised/pseudonymised data**

The applicants require confidential patient information for linkage from NNRD to PICANet, and also for linkage from these 2 datasets to HES, ONS and PEDW data.

The Group noted that the applicants plan to use existing legal databases and their protocol follows a well established model of using NHS Digital as a trusted third party to perform the linkages, and release pseudonymised data back to the researchers. As such, the CAG were content that this could not be performed in any other way that would reduce the use of identifiers.

## 'Patient Notification' and mechanism for managing dissent

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

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

The applicants detailed that information letters outlining the study will be sent to Lead Clinicians in all neonatal units and paediatric intensive care units. The REC favourable opinion of the NNRD offers individual neonatal units the opportunity to opt-out of research projects. This is an established approach used by the team who manage the NNRD. Applicants also mention potentially creating a study poster, and have provided a study privacy notice will be placed on the University of Leicester website. The applicants commented that further Information about the project will also be made available online, on the PICANet and NNRD websites.

It was noted by the CAG that for this study patient notification will be difficult - as posters are unlikely to be seen by parents of babies included in the cohort and are discouraged at present because of Covid-19. The Group commented that the information letters to be sent to the clinical units involved are not a method of patient notification, as they would not be notifying the cohort of patients who are involved, and it was mentioned that the letters do not include any request to promote the study.

The CAG accepted that online notification is likely the only appropriate method in this case; However, the study privacy notice is not sufficient on its own. Although the content is appropriate, it is not likely to be seen by anyone involved. It is likely that NNRD and PICANet websites, alongside the University of Leicester website are the most appropriate way of informing those involved. Members noted that no project specific notification material has been provided with the application that details a study specific opt out (see below). However the Group are content to support the application on condition that the applicants provide the patient notification material, including a project specific opt out, within three months from the date of this outcome letter.

Applicants have not provided a study specific opt out mechanism and have mentioned that they plan to direct parents to NNRD and PICANet websites if they wish to withdraw their child's data. As mentioned above, all neonatal units will be written to with information about the study and offered the opportunity to opt-out. This is an established process. PICANet has approval to be used for research, and all PICUs will receive information about this study. Applicants have confirmed that the national data opt out will be applied.

The CAG considered that there should be a study specific opt out mechanism available on the NNRD and PICANet websites. Although they agreed it was unlikely that a parent would want to only opt out of the study rather than the particular database, the option still needs to be provided. The Group additionally commented that it is not appropriate for the applicant to

encourage opting out of the NNRD and PICANet entirely, when a parent may only object to this particular study. However, the CAG are content to support the application on condition that the study specific dissent mechanism is provided within three months from the date of this outcome letter.

## 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 parents with experience of a child having received neonatal care helped to develop this research project, that the idea for the study was triggered from a PPI meeting, and parents will continue to be involved throughout. A parent advisory group will be established for the purposes of this study. However, the CAG were not clear if applicants have tested the acceptability of using patient identifiable data in this specific project without patient consent, despite a response to a query regarding this.

The CAG agree that the parent advisory group sounds supportive, but feel they require some more information regarding who was involved in this, how many members there are, whether it was ongoing and how it had assisted the project thinking. The CAG especially wish to hear feedback surrounding whether they have specifically considered the use of confidential data without consent. However members are content to support the application on condition that the applicants provide a report detailing that the use of confidential patient information without consent was discussed with the patient group, their response to this and how many patients were involved in this discussion is provided within three months from the date of this outcome letter. The CAG also wish, at the first annual review, to see a report on the ongoing activities of the parent advisory group.

## Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to all of the actions required to meet the specific conditions of support where indicated.

### Specific conditions of support

1. The patient notification text, to be displayed on the University of Leicester, NNRD and PICANet websites, to be provided to CAG within three months from the date of this letter. This notification should include clear details for a study specific dissenting mechanism.

2. Provide a report, within three months from the date of this letter, detailing the Patient and Public Involvement and Engagement undertaken that describes the acceptability of using identifiable data without consent, including the number of participants.

3. Provide a report, at the first annual review, of the ongoing activities of the parent advisory group.

4. Favourable opinion from a Research Ethics Committee (**Confirmed 28 September 2020**).

5. 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 Leicester - College of Life Sciences (EE133832-CMBSP**),
    - **Chelsea & Westminster Hospital NHS Foundation Trust (RQM)**,
    - **University of Leeds -SEED (8E218-SEED)** and
    - **NHS Digital (X26) –**Equivalent to DSPT) **have a confirmed 'Standards Met' grade on DSPT submission 2018/19 (Confirmed by check of DSPT tracker 22 September 2020)**
    - Security assurances for **NHS Wales Informatics Service (NWIS)** have also been provided in the form of a CPiP out-turn report dated 15th June 2020.

### Declarations of Interest

There were no declarations of interest.

## 2. New Precedent Set Review Applications – Non-Research

### a. 20/CAG/0108 - HES anterior cruciate ligament data request. DARS-NIC-339727-Y2H8M-v0.4

**Context**

## Purpose of application

This application from University College London Hospital NHS Foundation Trust (UCLH) sets out the medical purpose of the management of health and social care services which aims to establish revision rates of anterior cruciate ligament (ACL) surgery.

ACL reconstruction surgery is a very common procedure in the UK, however data is lacking regarding revision rates and specific complications associated with this procedure. Revision rates for ACL surgery in the UK have not been examined in large numbers. Linking the NLR with HES data would allow the applicants to undertake in-depth analysis of risk factors for infection and revision surgery examining surgical technique and implant performance, and also look into complications such as stroke, venous thromboembolism, heart attack and death following ACL surgery. The applicants also intend to examine revision rates and complications associated with poorly performing implants which may influence the development of arthritis.

Whilst the NLR is a fully consented registry, launched in 2011, support under the Regulations was requested following discussions with NHS Digital to enable this linkage. The applicants will transfer confidential patient information (including the NLR ID) of patients undergoing primary and revision ACL reconstruction from the NLR to NHS Digital. NHS Digital will link the data with HES data regarding complications and revision rates of ACL reconstruction surgery. NHS Digital will send a pseudonymised linked dataset back to UCLH using the NLR ID.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | All Patients undergoing primary and revision ACL reconstruction recorded in the NLR, with no exclusion criteria.<br><br>This will include approximately 12,000 patients. |
| **Data sources** | 1. National Ligament Registry (data processed by Amplitude Clinical Services Limited) |

| | |
|---|---|
| | 2. HES data held by NHS Digital |
| **Identifiers required for linkage purposes** | 1. Surname<br>2. Forename<br>3. Date of Birth<br>4. Home address including postcode<br>5. NHS Number or national identifier<br>6. Gender<br>7. Date of death |
| **Identifiers required for analysis purposes** | 1. Age<br>2. Gender<br>3. NLR processing Key |
| **Additional information** | The applicant has confirmed date of birth is modified to age by NHS Digital, and the applicants do not receive Date of Birth. |

## 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 medical purpose 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 agreed that there is a clear public interest in determining revision rates of anterior cruciate ligament (ACL) surgery.

### Validity of consent

In considering whether the consent already obtained was sufficient to enable the proposed data flow, members reviewed the correspondence with NHS Digital in order to identify the

rationale behind the referral for support. Members noted there was no specific explanation from NHS Digital in the documentation as to why the original consent obtained was not considered sufficient to allow the proposed processing. The correspondence provided informed the applicant they needed to obtain 'section 251 support' but no further detail was available. Members noted that they would normally be provided with either a rationale from the DARS team or an extract from IGARD minutes that set out why the consent was not considered sufficient. Members also noted that the application documentation did not set out a case by the applicant why re-consent would not be feasible. In this absence, and noting learning for future similar applications, members reviewed the consent wording for inclusion in the NLR that included the following statement:

"My anonymised health data may be linked to other health databases relevant to the purposes of the registry.

Members noted that the consent originally obtained from 2011 onwards was relatively generic, and of its time, and compared the purpose of the activity against what may have been the general expectations of the patient when providing this consent. While agreeing that the consent wording of the time did not make explicit reference to the processing of HES data by NHS Digital, members agreed that based upon the activity that this activity would not likely to be a surprise to the participants. Members indicated that the original consent did cover the issues of linkages, albeit in a relatively vague fashion.

In order to prevent delays, members agreed that in this specific instance they would recommend support despite the controller's rationale for referral to CAG not being available. It was agreed that this approach would be on a one-off basis.

## Scope

The CAG discussed whether this is a retrospective linkage only or if further linkages would be requested for patients who had not yet been recruited to the NLR. Members noted that support would only apply retrospectively for patients who have already been consented to NLR on the provided consent form.

If there is to be further linkage with HES in the future prospectively, then the applicant is advised to amend the consent form to the NLR to include this specific linkage, liaising with NHS Digital to ensure the wording is satisfactory to provide a legal basis for NHS Digital to release data to the applicant without the need for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002.

## 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 CAG understood that this was a retrospective data collection of approximately 12,000 patients in the NLR database, and therefore agreed that due to these large numbers that re-consent was not likely to be practicable. It was noted that the application did not provide a clear justification why re-consent would not be feasible.

- **Use of anonymised/pseudonymised data**

The applicants require confidential patient information for linkage of the NLR cohort to HES data. The CAG were content that this project could not be performed in any other way that would reduce the use of identifiers, and commented that the identifiers appeared appropriate for the accurate linkage required.

## '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 advised that the patient notification and dissent materials provided by the applicant appeared to be limited to information about the NLR rather than the specific proposed linkage detailed in this application. This was acknowledged by the applicant who stated they will put a patient notification statement on the NLR website that will explain the proposed data flow. The applicants also advised that a project specific dissent will be available via individual patient NLR logon or email.

The CAG agreed that, prior to advising to moving to final support that the applicant should provide a copy of the project specific patient notification that should include details of the mechanism for patients to dissent.

## 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 application did not provide any details of the Patient and Public Involvement activity undertaken for this project.

The Group requested that the applicant undertakes project specific Patient and Public Involvement on the use of confidential patient information for the purposes of linking with HES outcomes, without their consent for this specific linkage. Members advised that as support is only required for a period of three months, and there are additional requests for information, relevant PPI should be undertaken before the project commences. CAG requested to be provided with a report on project specific Patient and Public Involvement and Engagement activity undertaken, within one month from the date of this letter.

- **Exit Strategy**

It is understood that this is a time limited application with the anticipation of completion within three months, with anonymisation being the exit strategy.

Members felt that the exit strategy was suitable and raised no issues.

## 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. Provide the project specific patient notification text that will be displayed on the NLR website, within one month from the date of this letter. This should include explicit details on how patients are able to dissent from the use of their data for this linkage.

2. Provide a report on project specific Patient and Public Involvement and Engagement activity undertaken, within one month from the date of this letter.

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. Support applies only to retrospective patients who were originally consented to the NLR database. The information related to prospective patients should be obtained with valid consent.

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

    - The NHS Digital **2018/19** DSPT equivalent review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 September 2020)

- The NHS Digital **2018/19** DSPT review for **University College London NHS Foundation Trust** was confirmed as **'Standards Not Fully Met (Plan Agreed)'** on the NHS Digital DSPT Tracker (checked 24 September 2020). Please note the updated specific condition of support below.

  a. **University College London NHS Foundation Trust** 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.

- **Amplitude Clinical Services Limited** on behalf of UK national ligament registry - Pending – **2019/20 DSPT** published, and is currently being reviewed by NHS Digital.

## Declarations of Interest

There were no declarations of interest.

Signed – Officers of CAG

Date

Signed – Confidentiality Advice Team

Date