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

**19 November 2021**

## Present:

| Name | Capacity | Items |
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| Dr Tony Calland MBE | CAG Chair | 1a |
| Dr Sophie Brannan | CAG Member | 1a |
| Dr Martin Andrew | CAG Member | 1a |
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## Also in attendance:

| Name | Position (or reason for attending) |
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| Mr Michael Pate | HRA Confidentiality Advisor |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

# 1. New Precedent Set Review Applications – Research

## a. 21/CAG/0159 – UK-REACH: United Kingdom Research Study into Ethnicity And COVID-19 outcomes in Healthcare workers

### Context

### Purpose of application

This application from the University of Leicester (with the controller for the activity confirmed to be the University of Leicester) sets out the purpose of the medical research which aims to examine if, how and why, ethnicity affects COVID-19 outcomes and the impact of COVID-19 on healthcare workers (HCWs). It is made up of five work packages (WP) which are briefly detailed below:

1. Work package 1: Linkage and analysis of anonymised healthcare worker regulator and human resource data to electronic healthcare records

2. Work package 2: Longitudinal consented cohort of healthcare workers

3. Work package 3: Policy analysis of the legal and ethical issues of linking HCW data to health outcomes

4. Work package 4: Qualitative study of HCWs' experiences of working during the pandemic

5. Work package 5: Stakeholder and public engagement

Only work package 1 is covered by this application. Within WP1, the primary aim is to determine whether COVID-19 diagnosis, hospitalisation and mortality rates differ between ethnic and occupational groups in HCWs. The study team will conduct both a broad analysis, encompassing all those registered as healthcare workers (HCWs) on 1 February 2020 in the UK, and a detailed sub-study analysis in those actively working during the COVID-19 pandemic, incorporating more granular ethnicity, occupation and exposure information.

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.

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| **Cohort** | <u>Main study</u><br><br>All healthcare workers aged 16 yrs and over with an electronic staff record, or are registered at least one of<br><br>the regulators (General Medical Council, Nursing and Midwifery Council, General Dental Council, General Pharmaceutical Council, General Optical Council, or Health and Care Professions Council) as of 1st February 2020. This equates to 1.5 million people.<br><br><u>HR Sub-Study</u><br><br>All healthcare workers aged 16 yrs and over with an electronic staff record, or are registered at least one of<br><br>the regulators (General Medical Council, Nursing and Midwifery Council, General Dental Council, General Pharmaceutical Council, General Optical Council, or Health and Care Professions Council) as of 1st February 2020, that have worked at least one day over the course of the study period. |
| **Data sources** | <u>UK Healthcare Workers Cohort</u><br><br>1. The Department of Health and Social Care;<br>ESR (Electronic staff records) for England and<br><br>ESR (Electronic staff records) for Wales.<br><br>2. Professional registration databases i.e. General Medical Council, Nursing and Midwifery Council, General Dental Council, General Pharmaceutical Council, General Optical Council, or Health and Care Professions Council.<br>**(This data has already been disclosed and linked, however it is still retained in identifiable format by DHCW in order for ESR data to be linked to the registrant data)**<br><br><u>Health Outcome Data from NHS Digital</u><br><br>1. GPES Data for Pandemic Planning and Research (COVID-19)<br><br>2. Covid-19 Second Generation Surveillance System (Pillar 1)<br><br>3. Covid-19 UK Non-hospital Antigen Testing Results (Pillar 2) |

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| | 4. COVID-19 Hospitalization in England Surveillance System (CHESS)<br><br>5. Hospital Episode Statistics (HES) including all patient episodes, including elective but excluding maternity, from 1st February 2018 (24 months prior to study start date) to the most recent data available. This will enable assessment and adjustment of confounding comorbidities in the analyses.<br><br>6. Emergency Care Data Set (ECDS)<br><br>7. Civil Registration (Deaths) data.<br><br>8. ICNARC – applicant to confirm.<br><br>9. Personal Demographics Service<br><br><u>Health Outcome Data from SAIL</u> **(the below has already been linked under the COPI notice, and does not require support under Regulation 5)**<br><br>1. Outpatient referrals from primary care (OPRD)<br><br>2. GP primary care (WLGP)<br><br>3. Critical care dataset (CCDS)<br><br>4. Patient Episode Database for Wales (PEDW)<br><br>5. Welsh Demographic Service (WDSD)<br><br>6. Annual District Death Extract (WDDE)<br><br>7. Intensive Care National Audit (ICNC)<br><br>8. COVID-19 Pathology Test results (PATD)<br><br>9. COVID-19 symptom tracker dataset (CVST) |
| **Identifiers required for linkage purposes** | For linkage between the regulator data:<br><br>1. Family Name<br>2. Given Name<br>3. Other Names<br>4. Gender<br>5. Date of Birth<br>6. Postcode<br>7. Address lines 1-5 |

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| | For linkage to the health outcome data:<br><br>1. Unique Reference (SYSTEM_ID)<br>2. Family Name<br>3. Given Name<br>4. Other Names<br>5. Gender<br>6. Date of Birth<br>7. Postcode<br>8. Address lines 1-5 |
| **Identifiers required for analysis purposes** | Main study<br><br>1. Ethnicity<br>2. Occupation<br>3. Age<br>4. Sex<br>5. Modified postcode to measure socioeconomic deprivation<br><br>HR Sub-Study<br><br>1. Ethnicity via religious belief, country of birth, immigration status and nationality. |

## 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 accepted that the study was of benefit to the cohort of staff and patients under study.

### Practicable alternatives

- **Feasibility of consent**

The applicant explained that there are over 1 million healthcare workers in the healthcare system; a consent-based approach is therefore not appropriate or proportionate in the context of this work. The scale of the data being combined and linked in work package 1 means that applicants will have the power to assess both ethnic and occupational group differences in terms of COVID outcomes and also address the interaction between ethnicity and occupation.

Using a consented cohort would give:

(i) a biased sample of those willing to take part, and

(ii) would be unlikely to reach the numbers required for our analysis to provide the answers required by the government.

- **Use of anonymised/pseudonymised data**

The data is pseudonymised as early as possible, and it is not possible to link without some items of identifiable information.

## 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 study has a dedicated website which contains descriptions of the study (https://www.uk-reach.org/main/faq/) and a privacy notice pertaining to work package 1

As part of CAG advice, the applicants were asked to use the websites of the healthcare regulators as part of the notification process. The applicants responded to say that they will work with the healthcare regulators to ensure that alongside study details are available on websites, including a link to the associated privacy notice and contact details for the study team.

The CAG requested that the notification mechanism be strengthened by utilizing GMC and NMC newsletters, particularly, in order to notify the cohort about the study and provide a mechanism of opt-out.

The National Data Opt-Out will apply to datasets requested through NHS Digital.

The applicants reason they are not able to apply a study specific opt out to the activity, as it would mean de-encrypting data – as the regulators have already provided the relevant information to DHCW, so it is not possible for the regulators to apply an opt out prior to disclosure.

The CAG requested that a study-specific opt out be created, or further justification provided as to why a study-specific opt out is not possible.

## 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.

A Professional Expert Panel was set up, consisting of doctors, nurses and ancillary staff of various ethnicities and genders. The Panel meets bi-monthly to provide guidance and advice.

Work package 3 specifically looks at the acceptability of the legal and ethical aspects of the project. Applicants provided a full PPI response in the query responses, in addition to a document surrounding the uses of confidential patient information without consent.

WP1 has been discussed with numerous stakeholder groups and no particular concerns were identified regarding the process of undertaking the linkages described.

## Exit Strategy

Once regulator registration datasets, ESR data and health outcomes data are linked, identifiable data will no longer be processed. The data will reside in SAIL databank and will exist as a pseudonymised dataset with strict access controls in place.

This will take until approximately 30th September 2022, but support is required until the linkage is completed.

It was noted that all the data disclosed to NHS Digital will be about every healthcare professional employed. Not all of these will have relevant health records from the datasets held at NHS Digital. NHS Digital will disclose a list back to DHCW containing the Unique Reference (SYSTEM_ID) and linked health outcome data. There will be some Unique Reference (SYSTEM_ID) numbers that will not have any associated health information.

The CAG would like to know if DHCW merely delete these individuals, and they are not retaining any confidential data regarding healthcare workers who do not have a relevant health record?

## Letter from Caldicott Guardian or equivalent

It is usual for an application to contain a letter of support from the Caldicott Guardian of the data controller. The application appeared to be missing this.

The CAG request that a letter of support from the Caldicott Guardian of the data controller should be provided in any response

## Data Sources

The application was not clear on the legal entities that were responsible for the data sources in question. The application makes reference to ICNARC data being collected, but then in response, the applicant has said that ICNARC data would not be collected “from NHS Digital”. There is also reference to the Personal Demographics Service, which was not listed as a data source in the original application.

The CAG would like confirmation as to whether data will be collected from the Personal Demographics Service whose legal entity is NHS Digital.

The CAG would like confirmation as to whether data is collected from ICNARC, that is its own legal entity. If this is the case, please explain how this data is linked, as it will need to be included in the scope of support.

## Identifiers Kept for Analysis

The application states that postcode is kept for analysis of deprivation score. It is usual for the postcode to be modified prior to analysis, so that identifiable data is minimized.

The CAG would like to know if the postcode will be modified prior to analysis of deprivation score.

## 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 applicant is asked to provide specific justification as to why "public interest" is an appropriate common law legal basis to transfer English and Welsh ESR data to DHCW.

2. Within one month, the applicant is asked to devise a specific notification mechanism which involves GMC and NMC newsletters and which allows the applicant to opt-out.

3. Within one month, the applicant is asked to create a study-specific opt-out mechanism, or if this is not possible, to provide a stronger justification as to why this cannot be done.

4. The applicant is asked to confirm that DHCW do not retain any confidential data of individuals whose health outcome data cannot be linked.

5. The applicant is asked to provide a letter of support from the Caldicott Guardian of the data controller, or equivalent from within the information governance function.

6. The CAG would like confirmation as to whether data will be collected from the Personal Demographics Service whose legal entity is NHS Digital.

7. The CAG would like confirmation as to whether data is collected from ICNARC, that is its own legal entity. If this is the case, please explain how this data is linked, as it will need to be included in the scope of support.

8. The CAG would like to know if the postcode will be modified prior to analysis of deprivation score.

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

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 21 October 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information (Department of Health and Social Care, Digital Health and Care Wales, NHS Digital and the SAIL Databank i.e. Swansea University) is in place once support under Regulation 5 is active.**

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| Dr Tony Calland MBE | 21 December 2021 |
| Signed – Officers of CAG | Date |
| Mr Michael Pate | 21 December 2021 |
| Signed – Confidentiality Advice Team | Date |