Health Research Authority

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

October 2021

1. New Applications

a. 21/CAG/0064 - How are assessment tools and chronologies used by health and social care professionals in England to identify child neglect? Short title: The Use of Child Neglect Assessment Tools

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Mr Dan Roulstone	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor

Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Context

Purpose of application

This application from Oxford Brookes University set out the purpose of medical research that seeks to establish how the assessment tools and chronologies undertaken by health visitors and social workers in England are used to identify child neglect.

Neglect is the most prevalent form of child maltreatment in England and its identification and assessment pose significant challenges to practitioners. Tools and standardised approaches have been found to aid professionals in conducting robust and systemic analyses in cases featuring neglect, however, they are not consistently used. The study will explore the factors that influence the use of child neglect assessment tools and chronologies by health visitors and social workers in England. The extent to which these tools may mediate the quality of analysis and planning, and outcomes for children who have suffered neglect, will also be examined.

The project is comprised of two phases. Phase 2 involves semi-structured consented interviews, and is outside the scope of support sought. The first phase will explore the extent to which use of the child neglect assessment tools and chronologies impact on the quality of social work analysis and planning. The applicants will undertake a retrospective case file review of 60 case files for children and the appraisal of their health visiting case records via data linkage. The data collection will take place in Oxfordshire County Council local authority. A list will be made of all the children who were made subject to child protection plans for neglect between April 2018 and March 2019 and whose ages were 0 to 11 years (inclusive) at the time the plan was implemented. The Performance and Information Manager at the Local Authority will produce a report (R1) containing identifiable data for children meeting the inclusion criteria. This consists of Liquidlogic Children's social care System (LCS) number, NHS number, LCS status, Name and Date of birth for the 60 children whose case files will be included in the study sample. This will be sent to the NHS direct care team at Oxford Health NHS Foundation Trust, who will undertake a check against the Carenotes system to establish which of the 60 children also have a Carenote record. A new data file is produced (R2), containing only the LCS and corresponding NHS numbers for the

study sample. If any of the children do not have a Carenote record, their NHS number will be removed from R2, and it will contain their LCS number only.

The NHS Direct care team will send the datafile containing only LCS and NHS number to the CI at the University. The CI will add a unique study reference number to each patient to create R3. Data linkage between R3 and Liquidlogic, the electronic Local Authority Children's social care database, will be undertaken by the CI at home using the LCS number, via an Oxford Brookes University laptop. She will only record pseudonymous information into a separate file for analysis. Data linkage between R3 and Carenotes, the electronic database for health visitor records, will be undertaken by the CI at the NHS Trust on a Trust PC, using the NHS number. She will only record pseudonymous information into a separate file for analysis.

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

Confidential patient information requested

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

Cohort	60 children aged 0 - 11 who were made subject to child protection plans for neglect between 01/04/2018 and 31/03/2019 24 health and social care professionals, who are outside the scope of support
Data sources	1. Children's Social Care (LA) case files (Liquidlogic electronic database for social work records- Oxfordshire County Council Local Authority Children's Services) 2. NHS health visiting care notes (Carenotes electronic database for health visitor records- Oxford Health NHS Foundation Trust).
Identifiers required for identification of the cohort	1. Liquidlogic Children's social care System (LCS) number 2. NHS number 3. LCS status 4. Name 5. Date of birth

Identifiers required for linkage purposes	To link to Children's Social Care (LA) case files; 1. Liquidlogic Children's social care System (LCS) number 2. unique study reference number To link to NHS health visiting care notes; 1. NHS number 2. unique study reference number
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age 4. Disability status
Additional information	The dataset for analysis can be considered pseudonymous, however the CI still retains the file containing the LCS, NHS and unique study reference numbers (R3), stored separately from the analysis file.

Confidentiality Advisory Group advice

The CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in a full CAG meeting.

1. **Please provide favourable opinion from the REC (this is a standard condition of support, see below).**

The applicant has provided this to the CAG on 9 September 2021.

2. **Please provide evidence of a DSPT review for Oxford Brookes University (this is a standard condition of support, see below).**

On 6 September 2021, NHS Digital provided confirmation that all DSPTs were satisfactorily reviewed.

3. **Please explain if the children are in the care of the local authority and if the local authority consenting on their behalf would be a possible practicable alternative.**

The applicant has responded that as they are using a random selection of case files, it is not possible to predict how many, or indeed if any, of the children included in the

sample would be in the care of the local authority. The CAG accepted the response of the applicant.

4. **Please develop a notification method that provides an opt out option.**

As advised by CAG, the applicant has undertaken consultation with the public regarding notification and opt out, and the messages conveyed by patients do not support the development and implementation of a notification document providing an opt out. This is described further in the section below. The Members considered this response carefully, as 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. However the Committee felt that exceptionally in this case, there was an overwhelming public interest in this activity being undertaken, and therefore the CAG accepted the response regarding not having any notification or opt out. The Members felt that every possible effort to try to ensure a better system for managing neglected children should be supported, and although comments on principles of notification and transparency in the provisional letter provided on 2 June 2021 still stand, the CAG were content to make exceptions for this application due to the overwhelming public interest in the activity.

5. **Please undertake patient and public involvement in a representative group of adults with relevant experience <u>and</u> children, potentially using links provided by charities as described in this letter. The Members wish to see a patient and public involvement opinion regarding the acceptability of this use of confidential patient information without consent, and regarding implement of a notification and opt out strategy.**

The applicant approached the organisations suggested by CAG but they were unable to provide the required feedback. The applicant therefore approached 8 people, of whom 4 adoptive parents of children aged 11, 12 and 13 years who have suffered childhood neglect and 1 adult survivor who has experienced childhood maltreatment and has been in local authority care for most of their childhood, responded. The applicant has presented the participants with an overview of the application, and this included specific discussions regarding confidential patient information without consent, which was supported. The participants also confirmed they did not consider notification to be appropriate. There are further details in the response document to CAG.

The Members accepted this response and commented that the applicant should be commended for managing to put together this Patient and public involvement group. They did however note that the majority of this group were adoptive parents, and the CAG were unsure if these people could be entirely representative of those who experienced childhood neglect. This being the case, the CAG requested that ongoing patient and public involvement should be undertaken as the study progresses, in order

to re-assure the CAG that this use of confidential patient information without consent continues to be supported by a representative cohort. The Members strongly recommend that this should include further opinions from people who have experienced neglect as children. As a further suggestion, the CAG noted that the local Authority have a group called the Children in Care Council (CiCC), (https://oxme.info/life/children-care-council), who seem an appropriate group to approach for opinions.

6. **Please provide justification for the CI to retain the decoding document (R3) after the pseudonymous dataset has been extracted, or consider if the decoding document (R3) could be retained by the local authority and NHS Trust.**

The Applicant has provided further justification in their response to provisional, including the local authority and NHS Trust representatives advising the applicant that their electronic case recording platforms do not offer the facility to store this type of document. Additionally for accountability and auditing purposes, the usual practice for this type of research is for the decoding key to be kept by the lead organisation until the study ends. The CAG accepted these justifications.

7. **Please confirm that the home working set up is secure, so CAG can be reassured the appropriate safeguards are in place.**

The applicant confirmed that the CI's home environment is secure, and the work laptop will be stored in a locked cabinet when not in use. The CI is familiar with and adhering to the University's Mobile Computing and Remote Access Policy, which has been provided for review. The Committee accepted these responses.

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

The following sets out the specific conditions of support.

1. Please undertake continued patient and public involvement, and present feedback to CAG at annual review. The CAG strongly recommend that this should include further opinions from children who have experienced neglect.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 05 July 2021**

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

   The NHS Digital **20/21** DSPT reviews for **Oxford Health NHS Foundation Trust** (RNU) and **Oxfordshire County Council, Local Authority Children's Services** (608) and **The Faculty of Health and Life Sciences, Oxford Brookes University** (EE133864-FHLS) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 30 September 2021)

b. 21/CAG/0120 – NHS England Hepatitis C Virus Case Finding in Primary Care Pilot (HepCAPP)

Name	**Capacity**
Dr Patrick Coyle	CAG vice-chair
Ms Sophie Brannan	CAG member
Mr. Myer Glickman	CAG member
Professor Jennifer Kurinczuk	CAG member
Ms Rose Payne	CAG member

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research that seeks to establish the acceptability of wide-scale HCV screening of general public through primary care.

Approximately 100,000 people in England have chronic Hepatitis C Virus (HCV) infection. Over 85% of these infections were acquired via intravenous drug use. Due to the recent development of Direct Acting Antivirals (DAA), chronic HCV can now be cured in over 95% of patients. Targeted case-find using risk markers for HCV has recently shown to be effective. However, people infected with HCV but who have no history of intravenous drug use recorded on their history, may have been missed. The applicants will test the acceptability of wide-scale HCV screening of the general public, conducted via primary care services, to inform whether the intervention should be rolled-out nationwide. The applicants will invite patients aged 40-64 years of age who are registered at participating GP practices to have a HCV test using an Oral Fluid swab home testing kit. Patients will be informed of their result and will be followed up accordingly if they have a positive result.

Approximately 30 practices across Bristol, South-West London and Leeds will be invited to take part in the study. The participating GP practices will run a search on their Electronic Medical Records to create a list of eligible patients. This list will be sent to Public Health England Laboratories. PHE will then send potential participants a study invitation letter via post. If patients would like to participate, they are directed to a web link and a QR code. This will take them to the study participant information leaflet and e-consent form. One reminder letter will be sent. 2-3 weeks after completing the study E-consent form, participants will receive the Oral Swab home testing kit via post.

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

Confidential patient information requested

Cohort	Patients aged between 40 and 64 years of age who are registered at one of the participating GP practices. 100,000 patients will be contacted. The applicants anticipate that 1 in 10 will consent and that 10,000 patients will be included in the final cohort.
Data sources	1. Electronic medical records at participating GP surgeries

Identifiers required for linkage purposes	3. Name 4. NHS Number 5. GP registration 6. Date of birth 7. Unit level postcode and full postal address
Identifiers required for analysis purposes	5. Name 6. Date of birth 7. Postcode – unit level

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Clarify whether patients' gender and ethnicity will be obtained by the researchers after patients consent.**

The applicant confirmed that patients' gender will be obtained, but not their ethnicity. The gender will be recorded after patients have given consent. The CAG raised no further queries.

2. **A project-specific opt-out mechanism needs to be created and information on this provided to the CAG.**

Details had been included on the poster, advising how patients can opt-out of being invited to take part in the study. Patients are advised to contact their GP practice if they do not wish to be sent an invite letter. GP practice staff will then ensure that the patients name and contact details are deleted from the spreadsheet before it is sent to PHE.

The CAG considered whether other methods of dissent should be used, such as asking patients to contact the researchers, who then provide an exclusion list to PHE before the mailing. Members determined that opt-out via GPs was acceptable.

3. **The poster needs to be revised as follows:**

a. **A brief explanation of the purpose of the study and why it is being conducted needs to be included.**

b. **An explanation of the methods by which patients can opt-out of being contacted needs to be included.**

The poster had been revised to include a section headed: 'Why are we doing this study?' and details the purpose of the study and its main aims. The CAG raised no further queries.

4. **The invitation letter needs to contain a clearer explanation of the purpose of the study and how many reminder letters will be sent.**

The invitation letter had been amended to include a paragraph which provides further details of the purpose of the study and how many reminder letters will be sent. The CAG raised no further queries.

5. **The reminder letter should state that it is the final reminder.**

The reminder letter had been amended to state that is the final reminder letter and that the patient will not be contacted again. The CAG raised no further queries.

6. **All patient notification materials need to explain the information that will be provided from GP practices.**

The invitation letter and the reminder invitation letter had been revised to include details on the information that GP practices will be supplying to the research team. The patient information sheet already included this information under the heading 'Will the information I provide be kept confidential?'. The CAG raised no further queries.

7. **Clarify why confidential patient information for patients who do not consent will be retained for six months.**

The applicants advised that, if after 3 months, the researchers had not been contacted from the patient following them being sent two invitation letters, PHE will destroy the patient information. The CAG raised no further queries.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 20 September 2021.**

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

   The NHS Digital **2020/21** DSPT review for **the University of Bristol and Public Health England were confirmed** (tracker checked 08 October 2021).

c. 21/CAG/0126 - A retrospective cohort study to investigate body composition and survival in metastatic breast cancer

Name	**Capacity**
Professor William Bernal	CAG alternative vice-chair
Professor Lorna Fraser	CAG member
Mr. Myer Glickman	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Southampton set out the purpose of medical research that aims to use computerised tomography (CT) scans from deceased patients with metastatic breast cancer from University Hospital Southampton NHS Foundation Trust to describe how body composition (fat and muscle distribution) changes over the course of disease and investigate the value of body composition measurements as prognostic factors for survival and response to chemotherapy.

In women diagnosed with early breast cancer, those who are obese are more likely to die earlier and have more side-effects from their cancer treatment than those who are not obese. However obesity is determined by raised body mass index (BMI) which does not take body composition, meaning the proportions of muscle, fat and bone in the body, into account. Studies in other countries have suggested that poor muscle quality is linked to shorter survival and lower muscle quantity is related to the amount of severe chemotherapy side-effects women experienced. This suggests that it may be possible to use body composition measurements to help predict how long women with metastatic breast cancer will live and how likely they are to suffer from severe treatment side effects. Few studies have looked at how body composition changes during the course of metastatic breast cancer disease. This research may help design prospective studies in metastatic breast cancer patients, including interventional studies to optimise nutritional support and chemotherapy dosing to improve oncological outcome.

Identification of potential cases for inclusion in this study will be undertaken by researchers, using University Hospital Southampton NHS Foundation Trust electronic clinical records, including the Southampton Breast Cancer Database. This database allows filtering of patients by diagnosis and disease/alive. Therefore only the filtered deceased patients' clinical data will be screened by researchers using hospital electronic records to clarify if patients meet the study inclusion and exclusion criteria. A pseudonymous identifier will be applied to each individual, and a key linking the pseudo ID to hospital number and initials will be retained by the direct care team at the Trust. A researcher will have access to the key until it is deleted after 2 years. Routine CT images will be viewed in anonymised format at an NHS radiology workstation within University Hospital Southampton and the images will be analysed using "SliceOMatic" software. All patient identifiable data will remain within the University Hospital Southampton electronic systems and server and only pseudonymous data will be transferred to the University of Southampton

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

Confidential patient information requested

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

Cohort	300 women diagnosed with metastatic breast cancer at Southampton University Hospital between 2012 and 2021 who have subsequently died 1st September 2021.
Data sources	1. University Hospital Southampton NHS Foundation Trust clinical records including; • Southampton Breast Cancer Database • E-docs (clinic letters) • Electronic medical records • PACS (electronic radiology system) CT scans • ARIA chemotherapy prescribing system records of chemotherapy prescriptions
Identifiers required for patient identification and to extract a pseudonymous dataset	8. Hospital ID 9. Date of death Medical records will be viewed in order to extract a pseudonymous dataset
Identifiers required for analysis purposes	N/A
Additional information	Key retained by direct care team within the Trust, however a researcher who is not part of the direct care team will have access to the key until it is deleted. The key will be deleted as soon as the data extraction has been completed. Date of death is modified to month and year of death for analysis prior to transferring to University of Southampton.

Confidentiality Advisory Group advice
A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide clarification regarding the duration and rationale for the retention of the pseudonymisation key, or confirm the key can be deleted after pseudonymisation is complete.**

The applicant provided a response to clarify that it is anticipated that all data extraction and pseudonymisation will be completed within the first 24 months of the project. The data key will be deleted immediately after pseudonymisation has been completed and no later than 24 months after the project commences. The CAG were content with this response.

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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 12 July 2021**

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

   The NHS Digital **20/21** DSPT review for **University Hospitals Southampton NHS Foundation Trust** was confirmed as '**Standards Not Fully Met, Plan Agreed'** on the NHS Digital DSPT Tracker (checked 28 September 2021). Please note the updated specific condition of support below.

   University Hospitals Southampton 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.

d. 21/CAG/0127 - The Oxford Vascular Study: a population-based study of the incidence and outcome of stroke, transient ischaemic attack, acute coronary syndromes and peripheral vascular events: OxVasc

Name	Capacity
Professor William Bernal	CAG alternative vice-chair
Mr. Myer Glickman	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Oxford sets out the purpose of medical research that seeks to determine the incidence and case-fatality of stroke, transient ischaemic attack (TIA), acute coronary syndromes (ACS) and acute peripheral vascular events (PVE) in the same population at the same time. The Oxford Vascular Study (OxVasc) is a single centre, population based consented study which has been recruiting since 2002.

The applicants had been receiving long term health outcome data from HSCIC for some of the cohort, however they have not received any since 2016. In 2020, NHS Digital determined that the consent materials used by the study were not valid for the requested processing, and therefore the legal basis to supply the relevant information is no longer clear, under common law. NHS Digital recommended that ‘s251’ support be obtained to process data for participants that are either deceased, no longer in regular contact with the study, lacking capacity to understand new information about the study, or otherwise unable to consent. However, as the applicants are not planning to re-consent every participant from prior to June 2020, ‘s251 support is required to provide a legal basis for linkage under common law, for the entire cohort, with the exception of those who are fully re-consented. Since June 2020, all OxVasc participants

now receive the study Privacy Notice, and the linkage is undertaken with consent as the legal basis for processing.

It is an important part of the OxVasc study design to receive comprehensive follow-up of long term health outcomes and all-cause mortality, and therefore data linkage with NHS central health records (NHS Digital) is essential. By developing a high-quality epidemiological evidence-base the applicants hope to better target preventive treatment.

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	Previously consented OxVasc patients, prior to June 2020: Any adult over 18 years of age diagnosed with stroke, transient ischaemic attack, acute coronary symptoms or a peripheral vascular event registered with a collaborating GP within the catchment of the John Radcliffe Hospital, at the time of their first acute vascular event April 1st 2002 – 2016 (cohort already flagged with NHS Digital) – 9000 patients 2016 – June 2020 (cohort not yet flagged with NHS Digital) around 400 patients annually CAG support would not extend to those who have been fully reconsented.
Data sources	2. University of Oxford OxVasc database 3. NHS Digital – • Hospital Episode Statistics (HES) • ONS Mortality data • Cancer registration data

Identifiers required for linkage purposes	1. First and last name, 2. Date of birth, 3. NHS number 4. Unique Oxvasc participant number
Identifiers required for analysis purposes	8. Date of death 9. Unique Oxvasc participant number Other data items are retained for analysis with consent as the legal basis

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **The applicant should develop new notification material, (a poster for GP practices and a website text for the OxVasc website). This notification should explain that as the consent forms pre June 2020 did not specifically allow linkage with NHS Digital datasets, that the linkage with NHS Digital datasets is now being undertaken with 's251' support as the legal basis under common law, unless re-consented on a new form. The notification should provide an option to opt out of the linkage specifically. The Applicant should specify that they will not be seeking to individually re-consent patients, and if the individual does not do anything, then linkage will be undertaken with 's251'.**

The applicant provided a new notification document to be displayed in GP practices. This same text will be used on the website. The CAG were content to now recommend support, although they strongly recommended that the applicant rephrase the language of the notification in order to ensure plain English is used. For example, *'re-consent'* could be altered to state '*ask for your permission again'*. However the CAG did not wish to see an updated version of the document before recommending support.

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

The following sets out the specific conditions of support.

1. Support is provided for five year in the first instance, and this should be extended with a duration amendment when required.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: Favourable Opinion of substantial amendment relating to the CAG application (IRAS ID 292632) 02 September 2021**.

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

   The NHS Digital **20/21** DSPT reviews for **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health** and **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 05 October 2021)

e. 21/CAG/0058 - Evaluation of Homeless Health Peer Advocacy: an analysis of secondary data. Short title: HHPA evaluation: Secondary analyses of Hospital Episodes Statistics

Name	Capacity
Ms Sophie Brannan	CAG member
Dr Simon Kolstoe	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the London School of Hygiene & Tropical Medicine & University College London (as joint data controllers) sets out the purpose of medical research that seeks to explore how the homeless health peer advocacy (HHPA) intervention affects homeless peoples' use of health services. The applicants are proposing using a retrospective cohort of homeless adults who used an NHS hospital in London, and comparing the frequency of hospital use over 12 months between HHPA clients and controls. The research team has an ongoing mixed-methods consented research project (IRAS 271312) to evaluate the effect of HHPA, however Covid-19 related restrictions have caused the consented study to be halted. Applicants therefore propose this alternative design in order to meet the evaluations objectives.

People experiencing homelessness suffer extreme health inequalities. The health care costs of people who are homeless are estimated to be 8 times higher than the general population. Groundswell, a third sector organisation, have pioneered HHPA among homeless populations in London, a model that is being adapted by others. Peer advocates who themselves have experience of homelessness provide one-to-one support to attend health care appointments, which could be an acceptable, effective and cost-efficient intervention. However there is limited evidence showing the impact of HHPA on health service utilisation and other health and social outcomes. Further evidence would facilitate development and scale-up of the intervention among homeless and other vulnerable populations in London and elsewhere.

Groundswell's HHPA data manager will identify the last 150 new clients who received support from a peer advocate to attend an outpatient appointment prior to 1st March 2019 as intervention participants. Their confidential patient information will be collected (Name, NHS number, hospital ID, Date of birth, postcode (district level), sex, Nationality and ethnicity), alongside their HHPA start date. A Unique ID number is assigned by Groundswell's HHPA data manager, and the identifiable dataset is disclosed to NHS Digital in order for NHS Digital to link the details with the Personal Demographic Service (PDS) to locate any outstanding NHS numbers. NHS Digital will then undertake linkage of the intervention cohort to Hospital Episode Statistics (HES) records for the 12 months prior to and after their HHPA start date. NHS Digital then removes identifiers and discloses the linked dataset alongside the Unique ID back to applicants at UCL Data Safe Haven (DSH). Groundswell will also disclose a pseudonymised dataset linked to Unique ID to the UCL DSH in order for the applicants to be able to link this to the pseudonymised HES-linked dataset that is returned by NHS Digital, using the Unique ID.

For comparison participants, applicants will request NHS Digital to identify from the HES database 1000 adults aged 25 or more who had hospital-based care in London between March 2018 and March 2019 and who are likely to be homeless. People who have opted out or those who are HPPA clients are excluded, and other exclusions are listed in the application. The comparison participants HES records are requested for the 12 months prior to their first hospital visit in this time span, and for 12 months after. Identifiers are removed from this dataset by NHS Digital, and disclosed to the applicants at UCL.

A recommendation for class 1, 4 & 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 participants will be: • aged 25 years or older, and • Homeless, per UK government definition • Had hospital-based health care in London between March 2018 to March 2019. 150 intervention participants; The last 150 newly-enrolled HHPA clients who received support from a peer advocate to attend an outpatient appointment prior to 1st March 2019. (HES records linked 12 months prior and 12 months after start of HHPA enrolment) 1000 control participants identified by NHS Digital (HES records linked 12 months prior and 12 months after first hospital visit)
Data sources	4. Groundswells HHPA database 5. Personal Demographics Service (PDS) (to find any missing NHS numbers) - NHS Digital 6. Hospital Episode Statistics (HES) - NHS Digital
Identifiers required for linkage purposes	Data items sent by Groundswell to facilitate linkage with PDS: 1. Name (first name, surname, aliases) 2. NHS number

	3. Hospital admission date 4. Hospital of admission 5. Date of birth, 6. postcode (district level), current and previous 7. Nationality, 8. Ethnicity 9. Sex 10. Unique ID number (HHPA start date additionally sent) NHS Digital will then use the NHS number to link with the HES database.
Identifiers required for analysis purposes	1. Ethnicity 2. Nationality (converted to WHO region of birth) 3. Gender 4. Postcode (district level) 5. Age This dataset can be considered anonymous to the applicant

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide further justification regarding which identifiers are definitely required for identifying the NHS number from the PDS service, and if it is the proposed amount, justification for why the higher amount of data items is required. Please also provide clarity on which items of confidential patient information NHS Digital will then use to link to HES, as detailed above.**

The applicant confirmed the data items required for linkage with NHS Digital datasets, and after further queries from CAG, provided a clear justification for why more identifying information than usual was required. As the population is transient, there is likely to be substantial missing data, so further indicators are requested in order to ensure the highest quality linkage. The Sub-Committee were content with this response.

2. **Please provide supportive communications from NHS Digital to confirm they can undertake the processing activities as described in the application.**

The applicant supplied a supportive email from NHS Digital. The Sub-Committee were content with this response.

3. **Please provide an updated dissent information sheet that is clear and precise about the data flows, including making it clear that Groundswell already retain items of confidential patient information. It should be clear surrounding what will be linked, and be consistent concerning sex/gender.**

The applicant supplied an updated dissent information sheet. The Sub-Committee were content with this response.

4. **Please provide a notification poster which can be displayed on the locations listed in the application.**

The applicant supplied a notification poster. The sub-committee requested that this be updated with further contact details for the research team, and make it clearer that you could opt out rather than merely asking for further information. The applicant updated the poster, and the sub-Committee were content with the final response.

5. **Please provide an NHS Digital reviewed DSPT for Groundswell when available, this is a condition of support as set out below.**

This was provided to the CAG inbox on 25 October 2021.

6. **Please provide a favourable opinion from the REC when available, this is a condition of support as set out below.**

The applicant has provided this as per standard condition of support.

7. **Please provide the final version (not DRAFT) of the signed CAG form, before final support is provided.**

The applicant has provided this as per standard requirement for applying to CAG.

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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 3 June 2021.**

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

   The NHS Digital **20/21** DSPT equivalent review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 October 2021)

   The NHS Digital **20/21** DSPT review for **Groundswell (8J114**) was confirmed as 'Standards Met' (by email to the CAG inbox 25 October 2021)

f. 20/CAG/0112 - Ethnic Density and Psychosis in a British Pakistani Population: an investigation using data from the East Lancashire Early Intervention Service

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Liverpool set out the purpose of medical research that seeks to determine whether living in areas with a higher proportion of one's own ethnic group protects against the risk of developing psychosis in British Pakistani groups in a region of Northern England.

Ethnic minority groups have an elevated risk of developing psychosis. However, it has been found that living in areas with a higher proportion of one's own ethnic minority group (ethnic density) protects against this risk, described as the ethnic density effect. Contrary to other ethnic groups, survey studies have indicated an absence, or potentially a reversed effect, of increased ethnic density on risk of psychosis for Pakistani groups in the UK. These findings are currently preliminary, and past studies have been limited by unreliable, self-report questionnaire measures of clinical diagnosis. The applicants aim to test the ethnic density effect in British Pakistani populations, using more clinically reliable data collected by the East Lancashire Early Intervention Service (ELEIS). The service accepts referrals for those experiencing psychosis for the first time (or are within their first three years of treatment).

Secondary data, collected by the NHS trust as part of routine practice, will be used. Full postcodes for patients are required in order to accurately estimate geographical variables consisting of area ethnic density and neighbourhood social deprivation. These variables will be generated by matching postcodes to both Census Area Statistic (CAS) Wards and also the more detailed Lower Super Output Area (LSOA), using 2001 and 2011 UK census data.

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

Confidential patient information requested

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

Cohort	Patients aged between 14 and 65 years of age, referred to ELEIS with psychosis, or at high risk of psychosis, residing or registered with a GP in the selected districts,

	presenting with psychotic symptoms for the first time (or are in their first three years of treatment). Data for referrals between 2005 and 2020 will be analysed. The applicants anticipate that 1500 patients will be involved.
Data sources	7. East Lancashire Early Intervention Service (ELEIS) at Lancashire & South Cumbria NHS Foundation Trust
Identifiers required for linkage purposes	10. Postcode – unit level
Identifiers required for analysis purposes	10. Postcode – unit level 11. Gender 12. Ethnicity 13. Age at time of referral

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Please provide confirmation that the direct care team cannot undertake the process of converting the postcodes into Lower Super Output Area, thereby removing the need for support under s251.**

The applicant advised that the direct care team had confirmed they did not have the capacity to convert the postcodes to LSOAs. A a letter from Dr Masood Qureshi, consultant psychiatrist at the service, confirming this was provided. Though the process is not overly complicated, converting potentially over a thousand postcodes may still require a substantial amount of time. The CAG noted this information and raised no further queries.

If the direct care team cannot undertake the conversion and support under s251 is required, the following will need to be addressed:

2. **Clarify the age range of patients included.**

The applicant advised that the data will only involve those between 18-65 years of age. The IRAS form had been amended to make this clear. The CAG noted this information and raised no further queries.

3. **A clear patient notification strategy, including any patient-facing materials, needs to be created and provided to the CAG for review.**

The applicant explained that a patient notification strategy had been devised with the service. A poster had been provided, which would be displayed in the areas of the services buildings which can be seen by any service users. The CAG noted this information and raised no further queries.

4. **Patient and public involvement and engagement needs to be undertaken with those from the Pakistani community, particularly around the issue of how to promote the study, and feedback provided to the CAG.**

The applicants advised that they were preparing a PPI meeting with community leaders from the Pakistani community in East Lancashire focusing on promoting the study.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 07 January 2021.**

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

- **Confirmed:**

- **University of Liverpool has a confirmed 'Standards Met' grade on DSPT submission 2020/21 by NHS Digital.**

- **East Lancashire Early Intervention Service (ELEIS) at Lancashire & South Cumbria NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2020/21 by NHS Digital.**

g. 19/CAG/0177 – The Child Death Review Programme

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from Public Health Wales NHS Trust set out the non-research medical purpose of the ongoing operation of the Child Death Review Programme (CDRP) for Wales. The programme was started as a pilot project in 2009 and became established and an integrated part of core activity within Public Health Wales NHS Trust (PHW) in April 2014. The aim of the programme is to learn from common factors contributing to child deaths in order to reduce preventable child deaths in Wales.

The objectives of the programme are to:

- ascertain and collate data on child deaths in Wales and deaths of children who are normally resident in Wales,
- undertake surveillance of child deaths including the identification of and description of patterns and causes of child death, including any trends,
- identify modifiable factors that may be contributing to child deaths in Wales,
- identify opportunities for prevention of future child deaths,

- share the findings to inform action.

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	• Death of any a live born child that occurs after 1 October 2009 and before the child's 18th birthday and where the child is either normally resident in Wales or dies within Wales. • It also includes where an incident which led to the child's death in Wales irrespective of place of normal residence; and children who are under local authority care and placed outside of Wales; or those who may temporarily reside outside of Wales for healthcare or education purposes. • Stillbirths and terminations of pregnancy are excluded.
Data sources	1. Patient Episodes Database (PEDW), NHS Wales Informatics Service 2. Welsh Cancer Surveillance Unit (WCISU), Public Health Wales, 3. Congenital Anomaly Register and Information Service (CARIS), Public Health Wales 4. Mothers & Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK), University of Oxford 5. All Wales Perinatal Survey, Public Health Wales 6. Office for National Statistics (ONS) via NHS Wales Informatics Service (NWIS) 7. Welsh Demographic Service (WDS), NHS Wales Informatics Service (NWIS)

Identifiers required for linkage purposes	1. Child's forename and surname, 2. Date of birth, 3. Date of death, 4. Full address and postcode, 5. NHS number.
Identifiers required for analysis purposes	**Deceased child's details** 14. Sex 15. Date of birth 16. Time of birth 17. Treating hospital 18. Treating clinician(s) 19. Date and time of death 20. Place of event that led to death (home, hospital or other) 21. Address of event if hospital or other

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Provide further information to explain in what circumstances disclosures from the police force or local authorities would fall within the remit of the CAG to legitimise. Please make reference to the definitions of 'patient information' and 'confidential patient information' set out in section 251(10) and (11) respectively in the response. Also, provide assurance there where disclosures from these entities do not fall within the remit of the CAG to legitimise, that an alternative legal basis is in place.**

The applicant explained that the disclosures from the police force may fall under the remit of CAG, as the police are responsible for completing a child death notification form following the PRUDiC (Procedural Response to Unexpected Death in Childhood) meetings. These meetings are multiagency and include health therefore health (i.e. patient) information may be included in the notification form.

Similar to the police, local authorities may send the programme information on a child death from a multiagency meeting (e.g. MAPF – Multiagency professional forum) which may include health information.

Where disclosures from these entities do not fall within the remit of the CAG to legitimise, the legal basis for the activities of the programme were stated in section 1(l) of the application form. The applicants also cited Article 6 (1) (e) of GDPR. The applicants also noted that the activity of the CDRP is in the public interest. .

2. **Provide assurance that an alternative legal basis has been established to legitimise any onwards disclosure from the child death review programme database to wider third parties.**

The applicant advised that the alternative legal basis are paragraphs 3(b) and 3(c) of the Public Health Wales NHS Trust (Establishment) Order 2009. The applicants also cited Articles 6 (1) (e) and (h) of the GDPR.

Onward disclosure from the child death review database to wider third parties will be restricted to the following:

- Transfers of data to other health databases within Public Health Wales (WCISU, CARIS) so that their records can be updated e.g. with date of death/cause of death of a child on the WCISU or CARIS databases for children who had cancer or congenital anomalies/rare diseases respectively,
- Releases of data to health and social care professionals who may have access to information about patients for whom they had responsibility,
- Releases of data to health and social care professionals who have responsibilities to take action as per the PRUDiC (Procedural response to unexpected deaths in childhood) guidance and who may not be aware of the child's death e.g. if the child died in England, CDRP may be notified but the Head of Safeguarding in the health board in which the child resided may not be aware.
- Releases of data to Regional Safeguarding Children Boards (RSCB) or Welsh Police Forces if they request information on deaths of children in their own area (e.g. names and date of birth/death of children who died from a particular cause in a given area may be required for RSCB / Police to carry out a local review).
- Releases of data to Welsh Government where a public health concern has arisen (e.g. higher number of deaths than expected from a certain cause in a certain timeframe).
- Releases of data (name, date of birth, date of death, local authority area of residence) as part of requesting further information for thematic review purposes to Regional Safeguarding Children Boards, Police, Coroners, health boards and primary care.

- Releases of data to the National Crime Agency's Operation Marshall database (a database which collates information on intra-familial suspicious child deaths and homicides).

3. **Clarify whether it is the intention to retain confidential patient information indefinitely within the programme database. If so, a strong justification was required to support this requirement as it was recognised that some data items could be reduced to a less identifiable format once data linkage had been completed.**

The applicants explained that it was necessary to retain information indefinitely, as one of the purposes of the Child Death Review Programme is surveillance. This requires linkage of data from multiple sources over long periods of time. For reviews of rare causes of death, it is possible that new information would need to be sought for deaths as far back as 2009, therefore identifiable information would need to be retained.

4. **Provide the revised 'When your child dies' leaflet for consideration.**

The applicant provided the revised leaflet. This was reviewed and noted by the CAG.

5. **A plan for ongoing patient and public involvement and engagement activity should be provided. This should explain how the views of bereaved parents and families around the acceptability of using confidential patient information for the application purposes will be sought.**

The applicants planned to hold focus groups of bereaved parents and families to ascertain their views on the acceptability of using confidential patient information for the Child Death Review Programme. The applicants also plan to seek views on how parents could be involved in thematic reviews, the acceptability of the use of the information for research purposes (this would from part of the necessary application for approval for research work in the future) or for improving healthcare services.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support extends to non-research purposes only. Any wider use of the data retained or collected under this application for research purposes would require submission of a separate application.

2. Feedback is required at the time of first annual review from the patient and public involvement and engagement activity which has been carried out against the plan.

3. Confirmation provided from NHS Wales Informatics Service of the ongoing security assurance. **Confirmed – NWIS have confirmed the CPIP assurance report for Public Health Wales NHS Trust which has achieved a 96% assurance score.**

2. New Amendments

20/CAG/0099– Promoting vision-related quality of life (QoL): first stage development of a model for intervention from the evidence of what matters most to visually impaired children and their families

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study has support to allow a research assistant, who is not part of the clinical care team, to access confidential patient records at Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust in order to identify eligible patients. Patients are then contacted about the study to seek consent to participate. Support is in place for 150 family units to be recruited.

This amendment seeks support to increase the sample size to 200 family units, which is based on a recently completed secondary data analysis of existing data from a prior PROMs study. This amendment also seeks support for patients to additionally be identified from Moorfields Eye Hospital, in order to recruit the number of participants required in the time frame. The participant identification process and data flow at Moorfields will mirror the approach in operation at GOSH.

The amendment also includes the addition of the Impact of COVID-19 Pandemic Survey, which will increase the number of data items collected, but this is under consent, and does not impact the scope of 's251' support. Associated patient notification materials have also been provided to CAG, alongside an updated protocol.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:**

   The NHS Digital **20/21** DSPT reviews for **Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust and Moorfields eye Hospital NHS Foundation Trust** were confirmed as 'Standards Met' by email to the CAG inbox on 01 October 2021.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 12 May 2021**

19/CAG/0205 – A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease. (PD MED)

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This research from the University of Birmingham studies the long-term cost-effectiveness of 4 different classes of medication that are currently being used to treat Parkinson's disease, and is intended to provide evidence for better NICE guidance for the management of Parkinson's disease. PD MED has current support under the Regulations to link Hospital Episode Statistics (HES) data, ONS mortality data, Cancer registration data and demographics data in relation to PD MED clinical trial participants. Identifiable data is submitted to NHS Digital in order to link data to trial participants. Regulation 5 support is also in place for the disclosure of confidential patient information from NHS Digital back to the PD Med research team at the University of Birmingham

An amendment to CAG dated 6 October 2020 specified the applicant would receive outcomes from cancer registry data and mortality data between September 2018 to March 2020, and mortality data from September 2018 to March 2020. It also specified they would receive updated demographics data between October 2018 and March 2020.

This amendment is to seek support for the PD Med team at University of Birmingham to receive confidential patient information from NHS Digital in the form of outcome updates from cancer registry data and mortality data between September 2018 to the latest available data at the point of reporting. This is because the applicant reasons that this will help to answer the research questions more accurately. NHS Digital have also advised that this is normal practice, and it is very difficult for them to extract a linked dataset that has specified an end date.

Confidentiality Advisory Group advice

The amendment requested was considered by Vice-Chair's Action. The Vice-Chair considered that this is an appropriate amendment request to simply extend the time of the previously requested linkages up to the latest available data at the point of data extraction, and was content to recommend support.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:**

   The NHS Digital **2020/21** DSPT review for **NHS Digital and University of Birmingham** were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 19 October 2021 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 19 October 2021**

18/CAG/0185– At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University of East Anglia aims to assess whether care provided to patients with asthma, who are at greater risk of hospital admissions and dying from their condition, can be improved via a GP-practice led intervention. Support under the Regulations is currently in place to allow the disclosure of specified confidential patient

information from participating GP practices in England to Harvey Walsh prior to onward disclosure to NHS Digital for linkage with HES and ONS datasets.

This amendment sought support to extend the duration of the study in order to complete the transferral of confidential patient information from GP practices to NHS Digital via the trusted third party. The revised end of study date is 31 October 2022.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT considered the duration request reasonable and in the public interest.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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 - NHS Digital and Harvey Walsh Ltd. have confirmed Standards Met grade on the DSPT 2020/21 (By check of the DSPT tracker 20 October 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed Non-substantial 28 September 2021

20/CAG/0086 – YouScreen: A pragmatic implementation feasibility clinical trial of offering HPV self-sampling to cervical screening non-attenders within the NHS cervical screening programme in England

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to provide evidence that self-sampling can improve cervical screening coverage in England and can increase detection and treatment of high grade Cervical Intraepithelial Neoplasia. Support is in place to allow the National Health Application and Infrastructure Services (NHAIS) to transfer confidential patient information to Docmail, via North of England Commission Support Unit for mailing purposes, for NHAIS to transfer pseudonymised data to King's College London and for Clinical Commissioning Groups to access confidential patient information in order to transfer pseudonymised information to King's College London. However at the time of submission support did not extend to CCGs undertaking any processing of confidential patient information, as security assurances were not able to be established. The following condition of support was applied;

4. *This support does not extend to processing North Central London Central Commissioning Group, because satisfactory NHS Digital review of their Data Security and Protection Toolkit (DSPT) is not in place. The applicants are advised to seek 19/20 NHS Digital assurances for this organisation, and submit an amendment to add this to the scope of support once NHS Digital has satisfactorily reviewed the 19/20 submission.*

This amendment request is to include Barnet Federated GPs Ltd, Islington GP Group Ltd, Camden Health Evolution Ltd and Camden Health Partners as data processors. This is following discussions with North London Central Commissioning Group, and the other organisations processing data. There is no longer a need for North Central London Central Commissioning Group or North East London Commissioning Support Unit to be a data processor, and the following changes have been made:

- **GP Practices in Tower Hamlets & Newham**
  There is no change to the organisation processing data for GP Practices in Tower Hamlets and Newham (Clinical Effectiveness Group at QMUL).

- **GP Practices in Barnet & Islington**

For GP Practices in Barnet and Islington, during discussions with North London Central Commissioning Group it was made clear that they do not have centralised access to line level GP Practice data and were unable to process and extract the data required. Applicants plan to work with **Barnet Federated GPs** and **Islington GP Group** instead, who do have centralised access to line level data and the appropriate Data Sharing Agreements already in place with the GP Practices, therefore will be able to process, pseudonymise and transfer the data required.

- **GP Practices in Camden**
  Applicants also identified that North Central London CCG/Camden GP IT were not able to access and extract data from GP records due to the limits of their data sharing agreements in place with the GP practices in Camden. Applicants have identified that **Camden Health Evolution Ltd** and **Camden Health Partners** (formerly Haverstock Health) have centralised access to line level data and the appropriate data sharing agreements in place, and will therefore be able to process, pseudonymise and transfer the data required.

This amendment also therefore represents a response to condition 4 of the conditional support provided in August 2020.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs action. The Chair recommended support for additional data processors in order to undertake the work of inviting the eligible population for self-cervical screening. The Chair also confirmed this amendment constitutes a satisfactory response to condition 4 from outcome letter dated 27 August 2020.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:** The NHS Digital **20/21** DSPT reviews for **Camden Health Evolution LTD (DL7), Barnet Federated GPs LTD, Islington GP Group LTD, Camden Health Partners, NHS Digital, CFH Docmail, North of England CSU, Clinical Effectiveness Group at QMUL, and** were

confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 21 October 2021, and by email from NHS Digital 15 October 2021 (re DL7))

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 4 October 2021**

ECC 1-06(c)/2011 - National Oesophago-Gastric Cancer Audit

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The NHS Digital and Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons (RCS) has been commissioned to undertake work as part of the National Oesophago-Gastric Cancer Audit (NOGCA) programme, which is one of the Health Quality Improvement Partnership (HQIP) commissioned national clinical audits.

The Audit would like to access Cancer Waiting Times (CWT) data from Public Health England (PHE) for all OG cancer patients diagnosed since 2012. This will include patients identified in NOGCA and patients with a relevant diagnosis code in the CWT data.

NOGCA has existing support for linkage to other PHE datasets and expects that the requested CWT data will follow the same path as all other PHE data used by the Audit. The data flow is: NHS Digital sent PHE a cohort approved by the CEU. PHE carry out the data linkage. The linked data will be sent from PHE to the CEU.

NOGCA has demonstrated many improvements in the care and outcomes for OG cancer patients since 2012. However, recent Audit data have identified that a large proportion of patients may be experiencing excessive waits for treatment. The NOGCA dataset captures four key dates along the patient pathway for patients who receive a diagnosis of OG cancer, but these dates do

not enable replication of the official CWTs as the applicants cannot identify periods which are not included in the calculation of national standards. Furthermore, NOGCA data are available only for those referrals that result in a diagnosis of OG cancer, and do not provide information about previous referrals, which may not have resulted in a diagnosis of OG cancer, and may therefore not reflect a patient's path to diagnosis. Linkage of the NOGCA dataset to the CWT dataset will enable the Audit to describe patterns of waiting times along the OG cancer care pathway, and to validate the dates captured in Audit data. CWT data will also provide the Audit with details about those referrals for suspected cancer which do not result in a diagnosis of OG cancer, and provide a more detailed picture of the care pathway leading up to diagnosis.

NOGCA would also like to link Audit data to outpatient data and the emergency care dataset (ECDS) from Hospital Episode Statistics (HES) and Patient Episode Database for Wales (PEDW). The applicants are seeking access to data from both the ECDS and HES datasets from 2011 onwards. This will complement the existing approval for linkage to HES and PEDW Admitted Patient Care (APC) data, and the requested HES data will follow the same path as the APC data currently used by the Audit.

Access to the ECDS and Outpatient data from HES and PEDW is in the public interest, as it will enable NOGCA to look in detail at earlier and later stages of the care pathway for patients with OG cancer in England and Wales, including looking at diagnostic pathways, cancer surveillance, and emergency department presentations. This work will support improvements in these aspects of patient care. Specifically, outpatient data will enable NOGCA to look earlier in patient pathways to identify the number of visits and types of procedures patients have undergone prior to being diagnosed with OG cancer. This will help the Audit to evaluate whether patients are being diagnosed in a timely and appropriate manner.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the application was in the public interest.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and

therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: The NHS Digital 2020/21 DSPT reviews for NHS Digital and Public Health England were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (27 September 2021).

ECC 1-03(d)/2021– National Bowel Cancer Audit

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The NHS Digital and Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons (RCS) has been commissioned to undertake work as part of the National Bowel Cancer Audit (NBOCA) programme, which is one of the Health Quality Improvement Partnership (HQIP) commissioned national clinical audits.

This amendment has been submitted so that the NBOCA audit can access Cancer Waiting Times (CWT) data from Public Health England (PHE) for all

bowel cancer patients. This will include patients identified in NBOCA and those with the relevant diagnosis code in CWT data.

NBOCA has demonstrated many improvements in the care and outcomes for bowel cancer patients since 2012. It has informed NICE Guidelines on Colorectal Cancer Care and driven local quality improvement initiatives across England and Wales. However, there is concern that patients are experiencing excessive waits for treatment. The NBOCA dataset captures referral source but does not collect key dates along the patient pathway, such as date of referral, date of decision to treat and date of MDT discussion. Furthermore, NBOCA data are available only for those referrals that result in a diagnosis of bowel cancer, and do not provide information about previous referrals, which may not have resulted in a diagnosis of bowel cancer.

Linkage of the NBOCA dataset to the CWT dataset will enable the Audit to describe patterns of waiting times along the bowel cancer care pathway. CWT data will also provide the Audit with details about those referrals for suspected cancer which do not results in a diagnosis of bowel cancer and provide a more detailed picture of the care pathway leading up to diagnosis.

NBOCA has existing support for linkage to other datasets held by PHE and anticipates that the same process will be followed for this linkage. The process is; NHS Digital send PHE a cohort approved by the CEU and PHE undertake the linkages. The linked dataset, plus the CWT data for any patients with bowel cancer who do not appear in the audit dataset, will be sent directly from PHE to the CEU. The amendment is expected to be required for the duration of the Audit Programme.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the amendment was in the public interest.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: The NHS Digital 2020/21 DSPT reviews for NHS Digital and Public Health England were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (27 September 2021).

ECC 1-06(c)/2011– Gastro-Intestinal Cancer Audit Program (Oesophago-gastric cancer)

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Intensive Care National Audit and Research Centre (ICNARC) to NHS Digital, NWIS (now known as Digital Health and Care Wales), NICOR at Barts Health NHS Trust, SSNAP at King's College London and the UKRR at the Renal Association, for the purposes of time limited linkage with clinical datasets in order for pseudonymised linked datasets to be disclosed to the applicants at the University of Oxford, and for the return of full date of death from NHS Digital and NWIS to the University of Oxford.

In this amendment, the applicants are seeking to clarify the data products and the duration of the data that is required from NHS Digital. The applicants advised that the application had been reviewed by IGARD at NHS Digital, who agreed in principle but asked for explicit clarity around the timescales of the prior data used to assess the prior co-morbidities of patients admitted to ICU

The study design requires assessment of comorbidities prior to the ICU admission. An accepted method is to capture coding data from the 5 years prior to the ICU admission on a per patient level. The 5 years of prior health care data on each patient

is required so that the study can compare patients in terms of their pre-existing illnesses.

This approach is based on existing best practice and published research, but was not clearly defined in version 2 of the protocol. An updated protocol was provided, which had been revised to define the timescale and to make it clear that linkage to the Maternity Services Data Set (MSDS) the Emergency Care Data Set (ECDS) and Hospital Episode Statistics: Accident and Emergency through NHS Digital are required as part of the study. These data sources are not new to the study design and their use was discussed in a previous CAG amendment.

A new data flow diagram, patient notification and privacy statement were also provided.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG suggested that some minor changes were made to the Patient Notification document. These changes were accepted by the applicant.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. 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: The NHS Digital 2020/21 DSPT reviews for University of Oxford - Nuffield Department of Clinical Neurosciences - Critical Care Research Group, ICNARC, NICOR (Barts Health NHS Trust), The Renal Association, and SSNAP (King's College London) were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (23 September 2021)

3. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed **15 September 2021.**

4. Annual Review Approvals

ECC 3-03(c)/2012	Manchester Cancer Research Centre Biobank - collection of tissue, blood and urine for cancer research
20/CAG/0086	YouScreen: A pragmatic implementation feasibility clinical trial of offering HPV self-sampling to cervical screening non-attenders within the NHS cervical screening programme in England
ECC 2-03 (c) /2012	National Paediatric Diabetes Audit (NPDA)
18/CAG/0100	ORION-4
ECC 7-04(j)/2010	Long term risks of paediatric fluoroscopic cardiology
20/CAG/0110	Understanding the epidemiology in the transition from neonatal to paediatric care: a data linkage
16/CAG/0033	The Fenland Study – Phase 2
19/CAG/0200	PROFILE Study
15/CAG/0158	Fracture Liaison Service Database
ECC 8-04(b)/2013	Road Accident In-Depth Studies (RAIDS)
PIAG 4-09(k)/2003	Effectiveness of prostate cancer screening study; Evaluating population-based screening for localised prostate cancer in the United Kingdom
PIAG 1-05(f)/2006	Effectiveness of prostate cancer screening study; Evaluating population-based screening for localised prostate cancer in the United Kingdom
20/CAG/0116	NCEPOD
20/CAG/0071	Birmingham and Lambeth Liver Evaluation Testing Strategies (BALLETS) follow-up study.
15/CAG/0139	Life course pathways to ageing in the MRC National Survey of Health and Development
ECC 4-03(g)/2012	General Health & Hospital Admissions in Children Born after ART: A Population Based Linkage Study
16/CAG/0121	Epidemiology of Cancer after solid Organ Transplantation (EpCOT)
19/CAG/0118	The Robert Lane Tissue Bank (RLTB/previously Orchid Research Tissue Bank) - Collection of Genitourinary tissue
CAG 8-03 (PR9)/2013	National Prostate Cancer Audit
19/CAG/0035	Updating cancer survival index trends for England and Wales to 2018
19/CAG/0033	A multi-point survey to investigate the incidence and outcome of patients who doctors or nurses feel are unlikely to leave hospital alive from intensive care and the rate of agreement between doctors and bedside nurse

PIAG 4-08(b)/2003	National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
20/CAG/0080	Investigating whether elevated C-reactive protein is associated with probable depression in paediatric Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)
19/CAG/0117	IMS Health and HES Data Linkage
20/CAG/0081	Investigating whether elevated C-reactive protein is associated with probable depression in paediatric Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME)
CAG 5-07(d)/2013	National Emergency Laparotomy Audit
18/CAG/0184	Using National Congenital Heart Diseases Audit data to explore the impact of non-medical risk factors on late post-operative outcomes for children with complex congenital heart defects.
CR20/2014	Caerphilly Ischaemic Heart Disease Study, Speedwell Study Longitudinal Study of Ischaemic Heart Disease, Early Life Origins Of Insulin Resistance, Mortality And Cancer In Christs Hospital School Cohort
16/CAG/0043	British Association of Dermatologists Biologic Interventions Register (BADBIR)
19/CAG/0210	Discovery and Analysis Of Novel Biomarkers In Urological Diseases (DIAMOND STUDY)
17/CAG/0125	All-cause mortality within 12 months following Hip Fracture
19/CAG/0205	PD MED – A Large randomised assessment of the relative costeffectiveness of different classes of drugs for Parkinson's disease
20/CAG/0057	Incidence of psychosis and measures of psychotic experiences within the ALSPAC
20/CAG/0044	Revision Hip and Knee Replacement: Evaluation of Clinical, Psychological and Surgical Outcomes
19/CAG/0013	Cerebrovascular accident and acute coronary syndrome and peri-operative outcomes study
20/CAG/0138	Avon CAP: A Pan-Pandemic Respiratory Infection Surveillance Study [COVID-19],
20/CAG/0073	Assessing the cancer risks due to occupational exposure to styrene
CR4/2014	Asbestos Workers Survey
20/CAG/0103	National Haemophilia Database (NHD)
17/CAG/0048	Long-term follow-up of the East London Sickle Cell Disease Neonatal Cohort
18/CAG/0180	LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement.
18/CAG/0146	National Joint Registry
CAG 1-07(c)2014	Long-term effects of whole blood and platelet donation

20/CAG/0097	Breast Cancer Metastasis
20/CAG/0099	Promoting vision-related quality of life (QoL): first stage development of a model for intervention from the evidence of what matters most to visually impaired children and their families

Signed – Chair

Date

Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson, Dr Will Bernal and Mr Murat Soncul

07/02/2022

Signed – Confidentiality Advice Team

Date

07/02/2022

KM Cassidy