Health Research Authority

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

March 2022

1. New Applications

a. 21/CAG/0156 – Understanding SARS-CoV-2 infection, immunity and its duration in care home staff and residents in the UK (VIVALDI STUDY)

Name	Capacity
Ms Clare Sanderson	CAG vice chair
Professor Lorna Fraser	CAG member
Dr Martin Andrew	CAG member

Context

Purpose of application

This application from University College London (with the controller for the activity confirmed to be University College London) set out the purpose of medical research which aims to find how many care home staff and residents have been infected with COVID-19, to inform decisions around the best approach to COVID-19 testing in the future.

By testing around 6500 staff and 5000 residents across >100 care homes in England, the study will estimate the proportion who have been infected with COVID-19 in the past and have antibodies, and the proportion who are infected now. These tests will be repeated over time to learn how COVID-19 spreads in care homes and how long the antibody response lasts and whether this helps to prevent re-infection with the virus. In those who are currently infected, information will also be collected on who is experiencing symptoms to help to understand how this affects spread of infection within care homes. Information about how infection spreads between care homes, the community and hospitals will be sought by linking the information collected to national data on hospital admissions and deaths.

Support is requested to allow the disclosure of confidential patient information for care home data managers to upload lists of residents, participating care home staff, and data on symptoms to the NHS Azure system held by NHS England. This is only for care homes where the research team cannot retrieve pseudonymised data directly from surveillance datasets that are already held in NHS Foundry.

A recommendation for class 4 and 5 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

Cohort	Residents and staff in nursing and residential homes in England aged 18 yrs to 110 yrs who have not consented via the blood sampling element of the study. This will comprise of approximately 60,000 individuals until April 2023. Between April 2023 and April 2024, the applicants plan to continue data linkage for those individuals who are already taking part in the study. Data will be collected from 230 for-profit and 100 not-for-profit care homes. The researchers anticipate that there will be 40,000 participants from for-profit and 20,000 from not-for-profit care homes.
Data sources	1. Care homes - Care home records - Care home dataset (capacity tracker) 2. NHS Digital - Care home testing dataset (Pillar 2)

	- Hospital Episode Statistics (Admitted Patient Care) – Hospital Episode Statistics (Accident & Emergency) – ONS Death Certificates – National Immunisation Dataset 3. UK Health Security Agency - National Covid-19 testing database (Pillar 1) - Second Generation Surveillance System (SGSS) - Care Home outbreak dataset
Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. NHS number 4. Address
Identifiers required for analysis purposes	1. None
Additional information	Wherever possible NHS numbers are used to create the pseudo-identifier enabling linkage between datasets. However, many care homes do not hold NHS numbers for their residents which means a substantial proportion of blood test results and PCR test results cannot be matched using this method. A further challenge is that NHS records are often not updated when residents move into a care home which means demographic details such as resident address may not be accurate. The applicants state that because of the challenges of obtaining NHS numbers, they are using a wide range of other personal identifiers to try to match care home staff and residents to their NHS number. The combination of identifiers increases the likelihood that NHSE can achieve a deterministic match to NHS number using their linkage algorithm. This minimises the amount of data that is lost from the study.

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. To provide a justification for continuing to collect and link data beyond the end of the COPI Notice period.

When we submitted our CAG application in November 2021 we anticipated that it was highly likely that a new COVID-19 variant would emerge and there would be a need for ongoing surveillance of COVID-19 in care homes beyond the expiry of the COPI notice on 31/03/2022. These concerns have been borne out by the emergence of the Omicron variant in December 2021, which has led to a major increase in infections and outbreaks in care homes in England. It is highly likely that new COVID-19 variants will emerge in the future.

In order to respond to current and emerging COVID-19 variants, it is essential that we can continue to monitor infection trends and associated outcomes (e.g. hospital admissions, death) in vulnerable care home residents and staff to inform policy decisions regarding the need for (and timing of) vaccine boosters. In addition, policy makers are currently trying to balance the need to protect residents and staff from infection against the negative consequences of disease control measures such as self-isolation and testing, which are impacting heavily on staffing capacity and have a very detrimental impact on residents physical and mental health and well-being. The ability to make good decisions is strongly enhanced by access to high quality data on the risk and outcomes of infection. The VIVALDI study is the largest national study of COVID-19 in care homes and hence is a key source of this information for policymakers.

The CAG was content with this explanation.

2. To provide confirmation that staff consent to take part in the study would be taken at induction, and if not, to provide a justification why not.

We agree that it would be preferable to obtain informed consent from staff to take part in the study, however the workload associated with obtaining informed consent from staff is considerable, and it would fall to care home managers who are already under significant pressure due to COVID-19. In addition, there would need to be a rolling programme of consent because of high staff turnover. The consent process could not be devolved to the research team (team is small and doesn't have direct access to staff members), and we do not have resources to fund an external organisation to run the consent process. In the longer term (beyond 12 months) we are committed to working with providers and staff to agree on an acceptable mechanism to share data with staff for research and surveillance, but this cannot be established on a short timescale.

We have consulted with our care provider research partners to assess their views on the feasibility of obtaining individual level informed consent from April 2022 onwards (emails attached to this submission) and include their comments below:

Mr James Robson, Change Delivery Director, who has overseen delivery of the VIVALDI study at 100 Four Seasons Healthcare Group care homes made the following comments: “Following our discussion on Friday please see below a summary of the significant challenge obtaining consent would be particularly in the current climate. In an ideal scenario we would obtain informed consent from all staff to enable use of their data for research on COVID-19. However, our experiences in the VIVALDI study have demonstrated that it is extremely onerous to manage the consent process across the 200+ care homes that we manage. We employ approximately 9,000 staff in our care homes and the task of obtaining informed consent would fall to care home managers who are already under immense pressure due to staff sickness absence and the pandemic. It is not feasible in our opinion for the research team to obtain informed consent because a) they are a small team and b) they do not have direct access to staff in each care home. When we previously coordinated a process to obtain informed consent for blood sampling in a subset of care home staff and residents in VIVALDI, we appointed a project manager to oversee this process who was funded by the research study. This post was funded by exception to support the pandemic response, and we do not have access to further funding for this role. As a result, it would not be possible for Four Seasons to oversee the process of obtaining informed consent from individual staff members for data sharing.” Chris Pearson who has overseen delivery of the study at 30 HC-One homes expressed concerns about the feasibility of consenting all staff for use of their pseudonymised data by the Vivaldi study in view of the large workload associated with this. “Care home managers and staff are currently experiencing significant time constraints due to staffing issues, high infection rates and outbreaks within homes, and new policy changes that require rapid implementation. In addition, in view of high staff turnover, consent would have to be performed on a regular basis which would be unachievable given existing pressures for the homes.” He also expressed concerns about the appropriateness of collecting NHS numbers from staff members as their employer.

We have also spoken with several care-home managers to discuss the feasibility of taking informed consent for study participation. Although they all said that staff and residents felt that they had benefited from and were keen to continue taking part in research, they did not feel that consenting all staff and residents would be feasible.

Issues that they outlined included:

Workload: Consenting a single individual to take part in the study can take up to 30 minutes One of the smaller homes with 40 staff estimated that consenting all staff in this home would take up to 20 hours, which is a significant burden for the care homes. Three out of the four homes that we spoke to said that they would not be able to do this without assistance from external organisations such as the Clinical Research Network (CRN) or the study research team.

Working patterns: Due to patterns in shifts it can be difficult to catch care-home staff when they are on shift in order to consent them. If consenting was performed by external parties such as the CRN or the study research team it would be particularly challenging to consent all staff as they would only be able to do this at set times when staff may not be on shift therefore this would require multiple visits. It can also be difficult to find protected time to talk to staff which is something that we noted when we carried out our own care-home visit in November 2021.

Written consent versus verbal consent: Written consent can be an issue in a care-home setting. Our interviewees stated that although staff and residents were keen to take part in research, many were less enthusiastic about taking part in the original VIVALDI study once they had to provide written consent. All of the interviewees felt that a more informal consent procedure (ie verbal consent or opt out) would be feasible/suitable given the low risks associated with data collection. The home-manager who was most positive about written consent estimated that only around 50% of staff and residents would give written consent.

Staff and resident turnover: Interviewees all said that consent would not be a one-off due to high staff turnover. Keeping track of staff members that have left and new joiners would be extremely challenging and would add to the existing large workload.

The CAG was content with this explanation.

3. To create a separate poster for staff to being clear about how confidential participant information (CPI) has been used thus far under the COPI Notice, as well as future data capture.

We have created a new poster, leaflet and FAQs for staff which detail the transition from COPI to CAG. Given the difficulties of displaying detailed information on a poster we have added a link to the FAQs which will be posted on the VIVALDI study website when we transition.

Following CAG review, it advised changes to the poster to correct grammatical errors and typos. The poster should make it clear that staff are included in the study.

The leaflet and FAQs made reference to NHS England, without explaining their involvement. It was recommended that these were amended.

The CAG suggested that the FAQs are made available in paper form, so that residents of each care home could ask the care home manager for a copy of them to read.

The applicant has provided a revised poster, FAQ document and leaflet and these are now acceptable to the CAG.

4. To add a link to the FAQ document in the poster.

A link to the FAQ document was included in the poster. The CAG was content with this response.

5. To confirm that leaflets, containing the same information as the poster, will be given to all current staff and new staff, when they commence employment, and a separate leaflet provided to residents and family.

Leaflets are attached and we will ask our care home partners to distribute them to residents, families and staff members once the legal basis for processing data by our study has changed. We will also include a link to the FAQs on our study website. The CAG was content with this.

6. To amend the patient and staff information to contain cohort-specific details about the National Data Opt-Out and a local opt-out mechanism.

Following further discussions with NHS England and care providers we have decided that the simplest approach to ensure that both staff and residents are given the option to opt-out of data sharing is to use the existing NHS National Data Opt-Out (NDO) process established by NHS England. As NHS England are data processors for the VIVALDI study we have discussed this approach with them and they agree that we can continue using the process that they currently have in place. To ensure that staff, residents and their next of kin can access the data opt-out process, we have added a link to the National Data Opt-Out portal to the FAQs document and the leaflets.

The CAG noted the applicant does not propose to implement a study specific opt out and intends to just use the NDO. While we will accept this we do have concerns that this may lead patients and staff to take up their NDO option when they really only wish to be excluded from this specific study and would ask them to reconsider.

In response to the helpful suggestions from the CAG, we have developed a study-specific data opt-out system in collaboration with our colleague at NHS England, Mark Marshall, who currently processes our data. Any individual who would like to opt-out is directed to the care home manager. They will ask the individual to read the study FAQs and review the data information sheet outlining how the study team use and access data. If they would still like to opt-out, then the care home manager will ask them to complete a data opt-out form (included with this application). This form is then sent via secure email by the care home manager to the data processor at

NHSE (Mark Marshall). This person will collate a list of pseudo-IDs for people who have opted out of the study and will upload this to the COVID-19 Datastore (the Foundry) where the study datasets are linked and stored. This list will be applied to all of the Vivaldi datasets by the Vivaldi study team to ensure that these individuals have been removed. The opt-out list will be updated on a monthly basis by the data processor so that people can choose to opt-out or opt back in at any point. The emails containing personal details of individuals who have opted-out will be deleted once they have been removed from the dataset. If individuals are uncomfortable with speaking to their care home manager about their wish to opt-out, they can use the NHS Data Opt-Out system to opt-out.

We discussed this approach with senior care staff from two independent care homes on 09/02/2022, who felt that this would be both practical and acceptable to care home staff. We have also discussed it at length with Mark Marshall to ensure this approach is feasible. Following these discussions, we have updated our participant leaflets and have created the Data Information Sheet, which outlines this process. We reviewed these with the senior care staff on 24/02/2022 who felt they were clear and easy to understand but suggested providing an easy-read version with a larger font to make the content more accessible to residents. We will continue to engage with care homes after this system has been implemented, in order to make improvements as required.

The CAG did not believe that individuals wanting to opt-out should be made to read the study documentation or have to discuss with the care home manager to do so. It was felt that the FAQ document should be made available to individuals before making a decision.

7. With respect to PPI, further consultation should be conducted in the planned visits to homes and this must involve staff having some protected time to hear what is being planned (especially the use of CPI) and what is already happening.

It is not currently possible for us to visit care homes due to the large number of COVID-19 outbreaks that are taking place. It is also challenging to have detailed conversations about data sharing with staff when they are on shift. For these reasons, we are establishing a virtual group with approximately 6 care home managers to discuss our plans for data sharing and consider the best approach to explain how and why we intend to use data from staff to support the COVID-19 response. We plan to hold three meetings to cover the following themes: 1) explain how and why we are currently using data from staff without consent, 2) discuss the best ways to make staff aware of how we are using their data 3) give the virtual group the opportunity to review and improve our study materials (posters, FAQs and other materials that they recommend).

Our long-term goal is to coproduce a sustainable model with residents, families, staff and providers to enable data from staff and residents to be shared for research and surveillance on infection. The approach outlined in our CAG application represents a short-term solution to ensure that we can continue to support the pandemic response in care homes.

The CAG is still very concerned that they have not done any ‘ppi’ with any of the care home staff. It welcomed your plans to hold virtual focus groups but would encourage you to do so as soon as possible so that any concerns can be addressed before data extraction and also to seek to include some care home staff and not just managers

We sent meeting invites to 6 senior care home staff. A meeting was held with two senior care home staff from two independent care homes on 09/02/2022 to discuss the challenges of consenting staff and options for an opt-out system. Attendees felt that an opt-out system would be acceptable to staff, residents, and relatives as long as there was enough information around what the data would be used for and exactly what information would be collected. Following this meeting we developed the Data Information Sheet (as described in point 6). We held a second meeting on 24/02/22 to give care staff the opportunity to feedback to us on the content of this information sheet. The staff thought that the information was clearly presented but suggested increasing the size of the font and providing both a leaflet and a poster. We have therefore re-formatted the information in line with their suggestions and have attached it to this letter.

It remains challenging to meet in person or virtually with care home staff because there are severe staffing shortages in the care sector. We asked the 2 staff members who met with us how we might ensure that staff understand how we are using their data, and make it easier for them to tell us their views on our research and use of data.

To this end, we agreed to undertake the following activities at 2 care homes over the next two months:

1) Test out holding ‘Drop-in virtual engagement meetings’ for staff, so they can talk to members of the study team, ask questions, and learn about the study. This will also give us the opportunity to gain insight into staff members’ views on how we are using their data. By being flexible about when to meet, we hope to be able to engage with a larger, more diverse group of staff.

2) Use paper-based survey questionnaires to get feedback from care home staff on our information leaflets. This will help to ensure that we are making information accessible to care home staff.

These strategies will give us the opportunity to discuss data sharing for the purposes of research with staff from different backgrounds with different levels of experience and ensure that staff members understand about the use of their data in VIVALDI. Insights from these conversations and surveys will inform our plans for the study and be used to adapt study materials as appropriate. They will also be able to highlight concerns which the study team will work to address.

The CAG was content with this, although disappointed that care home staff PPI remains targeted at senior staff rather than the main body of care home staff; however, it was appreciated that further engagement activities are planned.

8. To provide a rationale as to how data from staff and patients who leave the care home during the study period would be removed, so as not to skew the results of the research.

At the beginning of our study, we attempted to obtain dates of entry and exit for residents and staff from each care home. However, we soon realised it was quite challenging to obtain this information directly from care homes, and we could not obtain it for individuals who had not provided informed consent i.e., those not participating in the blood sampling. We have therefore used COVID-19 (which is undertaken regularly in staff and residents) as a means of identifying people who are 'active' in the care home and exclude people who have not had a recent test in our research studies. This approach is imperfect because a small proportion of residents i.e., end of life care will not be tested, but it ensures that we are not including people who have died or left the care home in our analysis. We also link to individual-level death records.

The CAG accepted that this was as much as the research team could do in the circumstances.

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. That individuals wanting to opt-out should not be made to read the study documentation or have to discuss with the care home manager to do so. The FAQ document should be made available to individuals before making a decision.

2. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

3. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5

4. Favourable opinion from REC **Received 29 May 2020**

5. 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 care homes, NHS Digital and the UK Health Security Agency is in place once support under Regulation 5 is active.**

b. 21/CAG/0148 – Postoperative vasopressor usage: a prospective observational study. Relation to Perioperative Atrial Fibrillation (AF)

Name	Capacity
Dr Murat Soncul	CAG alternate vice-chair
Dr Liliane Field	CAG member

Context

Purpose of application

This application from the University of Liverpool set out the purpose of medical research that seeks to identify the proportion of patients who develop post-operative atrial fibrillation.

Some patients develop a syndrome called vasoplegia while undergoing surgery. Vasoplegia occurs when the function of blood vessels become impaired, blood pressure falls to abnormally low levels and additional medications (vasopressors) are required to

maintain blood pressure. If vasoplegia persists after surgery, it often necessitates admission to the intensive care unit for management of vasopressors, which results in prolonged hospital stays and a greater risk of complications, including the development of atrial fibrillation (AF), an irregular heart rhythm that increases the risk of stroke and death.

The applicants seek to investigate the prevalence of post-operative AF in a non-cardiac surgical population. The study will be conducted in two parts and two cohorts will be involved. The SQUEEZE UK study will be conducted in at least 40 UK centres and the data collected in this study will be analysed as part of a worldwide study to understand the impact of vasoplegia on outcomes.

In the first part, cohort A, data will be collected from all patients who undergo surgery as hospital inpatients in order to determine the proportion who develop vasoplegia and AF, and to identify any risk factors. Suitable patients in cohort A will be identified by members of the direct care team (the perioperative anaesthetist). The clinical research team will then access confidential patient information in patient records to extract a pseudonymised dataset onto CRF 1. Additional information for patients will receive a Post-operative Vasopressor Infusion (PVI) will be collected and entered onto CRF 2. Information for patients who develop AF will be collected and entered onto CRF 3.

In phase two, cohort B, 30 patients recruited into cohort A from each participating centre who develop vasoplegia will be followed up in detail. Patients in cohort B will be identified by the clinical research team, who will then access confidential patient information in patient records to extract a pseudonymised dataset.

Support is required as, while the applicants expect that members of the direct care team will undertake processing of confidential patient information to identify patients for cohort A within some of the participating trusts, this would not be the case in all trusts. The applicants noted that one week of heavy workload would be involved, meaning that research nurses may need to process confidential patient information to recruit cohort A. A pseudonymised dataset will be extracted and entered onto the Clinical Report Forms (CRFs). The pseudonymisation key will be held by the participating trusts and Health Boards. Any re-identification of patients required will be undertaken by the Trust had submitted the information, who will retain the pseudonymisation key. The information uploaded to the ESAIC will be effectively anonymised. The anonymised dataset will be sent to University College London for analysis.

A recommendation for class 1, 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

Cohort	Cohort A: Patients aged 18 years and over at the time of surgery, who have undergone surgery and were not discharged on the day of surgery. Cohort B: Patients aged 18 years and over at the time of surgery, who have undergone surgery and were not discharged on the day of surgery, and who received an infusion of vasopressors which continues after the patient has left the operating room. 5000 patients will be included in England and Wales.
Data sources	1. Electronic patient records at 51 participating NHS Trusts and Health Boards in England and Wales.
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender 4. Study number (patient identification number)

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 study poster needs to be revised as follows:**

    a. **Further details needed to be given on the poster, including an explanation that patient hospital records will be looked at.**

The applicants explained that the poster will be made available in A3 and A4 format, the content is the same in both versions. The applicants had revised the poster to state that patient hospital records will be looked at. An updated version of the poster was provided.

b. It needs to be clearly stated that patients can dissent to the use of their information and a brief explanation of the opt-out process also needs to be included.

The applicants advised that this had been included in the revised poster.

c. A link to the website information needs to be included.

The applicants advised that the website was inactive but would be activated once support was in place.

The CAG reviewed the poster and requested that the dissent information on the poster included postal and telephone contacts, as well as email.

The CAG noted that the poster explained that "*You should be aware that contacting this email address carries the risk of you losing your anonymity*", which seemed to suggest that opting-out is a worse option than not objecting. No statement was included elsewhere on the poster that data will be anonymised, so it was unclear how patients would balance the implications of opting out or not. The CAG suggested that the quoted statement was removed from the posters and, instead, the study team have a script for anyone who contacts them that explains what identifiable data is collected in the study and when this is destroyed/anonymised.

The applicants explained that the website text provided information about the data collected and how and where it will be stored. Different routes for patients to request opt-out of the study were also provided. If the recruiting centre was contacted, the local PI would arrange for deletion of data for this patient.

For patients contacting the SQUEEZE UK study team for opt-out, the SQUEEZE UK team would liaise with the local recruiting centre to have the data deleted.

If patients wanted to know more about the data collected, the SQUEEZE UK study team would provide a list of data derived from the eCRF. A printout of the eCRF would be made available as part of the study documentation pack in each recruiting centre and can be offered to patients when the local centre is contacted directly about the type of data being collected.

Identifiable data will only be available at the local recruiting centre and only as part of the screening and recruitment documentation. The SQUEEZE UK and the SQUEEZE

study teams have no access to identifiable data. As outlined above, when approached with a request for opt out, the SQUEEZE UK team will contact the recruiting centre to request data elimination for this patient. Contacting local centres will happen as soon as possible, usually on the same day. The SQUEEZE UK team expect data to be destroyed within one week of having been contacted. This information about the process of how their data are being deleted will be relayed to all patients contacting the SQUEEZE UK team with the request to opt out.

A further revised poster was provided, which was reviewed and approved by the CAG.

2. **The text of the website information needs to be provided to the CAG for review.**

The applicants provided the text of the webpage. This text was reviewed and approved by the CAG.

3. **Feedback from patient and public involvement discussions that specifically include the use of confidential patient information without consent need to be provided.**

Feedback from meetings with the patient ambassador was provided.

4. **Advise how long prior to the data extraction the posters will be on display.**

The applicants advised that they would ask participating sites to display the posters for 2-4 weeks prior to starting recruitment. The exact time window would vary from centre to centre, to accommodate participating sites individual time intervals between preoperative appointments and day of surgery.

The CAG requested a commitment that that posters will be displayed at least 2 weeks before the data extraction. The applicants confirmed this.

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: Favourable Opinion issued 16 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. **Not checked due to the number of sites involved in the study. Support is recommended on the basis that it is the applicant's responsibility to ensure that the required security assurance standards have been met at each site prior to processing any confidential patient information with support under the Regulations.**

c. 22/CAG/0031 - Magnetic Foreign Body Ingestion in Children (MAGNETIC): a prospective surveillance study

Name	
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Context

Purpose of application

This application from the University Hospital Southampton NHS Foundation Trust set out the purpose of medical research that seeks to establish the incidence of ingestion of magnetic foreign body by children aged 16 years and under within the UK and Ireland.

Magnetic objects are known to be dangerous when swallowed by children, particularly when multiple magnets are ingested. Ingestion can lead to significant morbidity, including bowel obstruction, fistulation and perforation, which require emergency surgery to treat. Recent published research has shown that rates of magnetic foreign body ingestions are increasing globally. Studies from the UK have highlighted a significant burden of morbidity, but the exact scale of the problem in terms of actual incidence, burden of morbidity, risk factors and outcomes is currently unknown in the UK and Ireland. The applicants seek to conduct a prospective surveillance study across the UK and Ireland to collect data to establish the incidence rate of magnet ingestion, which investigations are best at diagnosing magnet ingestion and its complications, the

treatment modality that is most effective, and the complications that may occur as a result of magnet ingestion.

Clinicians in participating trusts will be made aware of the study and inclusion criteria through relevant research networks and organizations. Children swallowing magnetic foreign bodies will be identified on initial presentation in emergency departments, or on presentation to paediatric medical or surgical teams. Clinicians will then complete a case report form on RedCap. At this point the patient's NHS number will be collected, along with other relevant routinely collected clinical data from the patient's health record. The NHS number will be held until the end of the study and used to check for duplicate entries, as patients may move between trusts when receiving treatment. At the end of the study, duplicate entries will be removed using NHS numbers within RedCap. This anonymised dataset will then be used for analysis.

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

Confidential patient information requested

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

Cohort	Patients aged 16 years and under who attended hospital **in England or Wales** having ingested at least one magnetic foreign body - confirmed on radiology or by clinical features.
Data sources	1. Electronic and paper patient records at participating trusts.
Identifiers required for linkage purposes	1. NHS number 2. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level

Additional information	Patient sex, ethnicity, postcode and age in months at presentation will also be recorded to meet the study objectives. Data will also be collected for patients treated for ingestion of a magnetic foreign body in Scotland and Northern Ireland. The applicants will ensure that the appropriate support is in place for this data collection.

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. **It was unclear whether the applicants would obtain full postcodes or the first part of the postcode only. Members requested clarification on this. If full postcode was required, justification on why this was needed is to be provided.**

The applicants confirmed that the first part of postcodes only would be collected. The clinical team caring for the patient will be asked to use the full postcode to identify and upload the index of multiple deprivation rank and decile. They will be prompted to do this during completion of the eCRF. The full postcode will not be included in the eCRF. The CAG noted this information and raised no further queries.

2. **The CAG asked that the information on the poster was also included on the websites of participating trusts.**

The applicants advised that they had discussed this and had determined that placing opt-out information on trust websites would not be useful. Patients/parents are unlikely to read information on the hospital website, especially given the acute nature of their admission. Uploading the opt out information to every trust website in the UK will likely be difficult and time consuming given the individual nature of each hospital's IT system.

The applicants proposed to maintain their current approach of displaying opt-out information on posters in patient facing areas of participating hospitals where this information is most likely to be seen. This will be in emergency departments and parent areas on in patient wards. The CAG noted this information and 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

The following sets out the specific conditions of support.

1. Consultations with relevant organisations and patient groups are to be undertaken as the study continues and feedback from these discussions provided when submitting annual reviews.

2. Favourable opinion from a Research Ethics Committee. **Confirmed: 18 February 2022**

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 **2020/21** DSPT review for University Hospital Southampton NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (28 February 2022).

d. 22/CAG/0007 - Prison healthcare, focusing on natural and other non-natural deaths

Name	
Dr Patrick Coyle	CAG Vice Chair
Ms Rose Payne	CAG member
Professor Lorna Fraser	CAG member
Mrs Diana Robbins	CAG member

Context

Purpose of application

This application from NCEPOD set out the purpose of a confidential enquiry to review the clinical healthcare provided to prisoners.

The House of Commons Health and Social Care Committee report, 'Prison Health' which was published in 2018, reported that the Government was failing in its duty of care towards people detained in English prisons. The Select Committee recommended that the National Prison Healthcare Board worked with stakeholders to agree a definition of equivalent care and indicators to measure health inequalities between those in prison and the general population. The application has been commissioned by the Health Foundation, supported by NHS England, to review of the healthcare provided to prisoners who died in prison. The information collected will be used to highlight where care and organisation of care could be improved.

The standard NCEPOD methodology will be followed. A retrospective peer review of clinical notes will be undertaken and those involved in prisoners care will be asked to complete a questionnaire to provide their views on the care they could provide.

The Prisons and Probation Ombudsman (PPO) produce Fatal Incident reports for any prisoner who dies. The Fatal Incident reports will be accessed to identify relevant patients. These reports are in the public domain, therefore this is outside the scope of support. However, as these reviews are undertaken to varying levels of detail dependent on the nature of the death the applicants will undertake more detailed reviews, which will include review of the care provided over the previous 12 months, to assess the healthcare provided as well as the death. Information for identified patients will be linked to prison healthcare and primary care records at SystemOne, and hospital case notes if the prisoner was admitted to hospital. NHS commissioned independent clinical reviews, provided by NHS England/Health Inspectorate Wales, and coroners inquest reports will also be accessed, if available. For the in-depth peer review, extracts of case notes from hospitals and SystmOne will be scanned and sent to NCEPOD via an nhs.net email address. Questionnaires will be sent to the clinician involved in the care of the prisoner and confidential patient information is required to send this questionnaire. The data collected will be aggregated before publication and confidential patient information is only required to link data at the collection phase.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All prisoners aged 18 years and over who died between 01 January 2018 and 31 December 2020, of natural causes or other non-natural deaths. Deaths where the cause was suicide or homicide will be excluded.
Data sources	1. Fatal Incident Reports, created by the Prisons and Probation Ombudsman 2. Records of the NHS clinical review associated to the Fatal Incident Report 3. Coroner's inquest reports 4. SystmOne notes for the 12 months leading up to the death – held by Primary Care Support England 5. Patient records at the treating hospital for any acute admissions and outpatient appointments in the 12 months leading up to the death
Identifiers required for linkage purposes	1. Name 2. Sex 3. Age 4. Date of birth 5. NHS number 6. Date of death 7. Prison name 8. Hospital name 9. NHS number 10. Hospital number 11. Prisoner number 12. Date of admission – where applicable 13. Date of discharge – where applicable
Identifiers required for analysis purposes	1. Name 2. Sex 3. Date of birth 4. Prison number 5. Hospital number 6. NHS number 7. Date of death 8. Prison name 9. Hospital name 10. Date of admission

	11. Date of discharge

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 justification for using all the identifiers listed in section (j).**

The applicants agreed that patient name, date of birth and NHS number should be sufficient to confirm that the correct patient has been identified. All identifiers had been listed as the applicants were aware that they may access these this information in the case notes. The CAG noted this answer and raised no further queries.

2. **Feedback from the further patient and public involvement to be undertaken needs to be provide. This needs to cover the following areas:**

    a. **The creation of patient notification materials for the prison population, including ensuring that the information provided is easily understood by those with an average reading ability.**

The applicants advised that they had updated the poster and information leaflet to include details on all aspects of the study and added clarity about the use of confidential information being used for the case review of deceased prisoners. Initially, two separate posters had been created, one for prisons where current prisoners and their families/friends may see the information, but there was a risk of confusion as they were so similar. To reduce this risk, one poster was finalised that is applicable to all groups, covering both aspects of the study. To meet the needs of those with reduced literacy the poster and information leaflet are being converted into an easy read format.

The anonymous survey for prisoners/ex-prisoners and their families/friends was circulated through social media and all stakeholders involved. This includes a question about the use of confidential patient data for the purpose of the wider study and we have had no concerns raised about the use of data. The applicants will continue to promote this survey and monitor the responses to this. The CAG noted this answer and raised no further queries.

    b. **Specific questions on the use of confidential patient information, as proposed in the application, need to be asked during patient and public involvement.**

A question about the use of confidential patient data has been included in the survey. In addition, the applicants have created a one question survey for easy of circulation that just has this question in it. This has been circulated through the Study Advisory Group, specifically focusing on the ex-prisoner who has shared it with his contacts and he has arranged for a link to be added to the next monthly bulletin circulated by the Longford Trust, Manchester University who are undertaking a study on avoidable harm and who have access to a user group, Pact, Inquest and the Prison Reform Trust to see if any concerns are raised. There have been none so far. The applicants will continue to monitor this. The CAG noted this answer and raised no further queries.

3. **The patient notification materials intended for the prison population need to be provided for review.**

The applicants provided revised patient notification materials. These were reviewed and accepted by the CAG.

4. **The poster needs to be revised to include information about the use of confidential patient information.**

The applicants provided a revised poster. This was reviewed and accepted by the 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. 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 reviews for **NCEPOD, The Health Foundation and Primary Care Support England/The Phoenix Partnership** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 January 2022).

e. 22/CAG/0003 - Reducing time to appropriate emergency response in trauma incidents using smartphone video streaming from 999 callers: A feasibility Randomised Controlled Trial

Name	
Dr Murat Soncul	Alternate Vice Chair
Professor Lorna Fraser	CAG member
Dr Malcom Booth	CAG member
Ms Rose Payne	CAG member

Context

Purpose of application

This application from the University of Surrey sets out the purpose of medical research to explore the feasibility of conducting a future randomised controlled trial to assess the clinical and cost effectiveness of using GoodSAM live video streaming to improve targeting of emergency medical resources.

Major trauma (MT) is any injury with the potential to cause death or prolonged disability. MT is a leading cause of serious morbidity and mortality. Advanced emergency medical care provided at the scene of an accident can prevent death and improve patient outcomes. Currently, UK emergency services rely on verbal telephone information from incidents to prioritise dispatch. Previous studies have shown at up to 50% of air ambulance deployments and 25% of land ambulance dispatches are inappropriate, highlighting the limitations of decisions based on audio information only. The applicants seek to explore the use of video to improve triage and dispatch decisions. The benefits of using video in other healthcare settings is growing, e.g. for remote healthcare consultation, but evidence is sparse in relation to use in emergency response. GoodSAM uses callers' smartphone cameras to stream live footage directly to the dispatchers, offering unique opportunities to improve precision in dispatch.

This study is comprised of a feasibility trial, with embedded process evaluation and two sub-studies. In the feasibility trial, each eligible call received will be observed by research paramedics, who will collect data on the incident. They will also record the resource/dispatch decision making, noting whether any dispatch decisions are changed once the live stream is shared for calls on the intervention arm. The study research

fellow will be present for some of the intervention arm shifts and may observe incidents in order to examine barriers and facilitators to the use of GoodSAM. Following the incident, the research paramedic or research nurse will approach the casualties or their representative to seek consent for access to their medical data. If consent is given, then patient records will be accessed for up to three months after the incident.

Support is required for the main study to undertake the live streaming without patient consent. Support is also needed for the Research Paramedic to use the CAD number to locate surviving casualties and seek consent or a consultee opinion. For deceased patients, support is needed for data collection from patient records, as consent cannot be sought. The Research Paramedic will undertake observation of shifts at the London Ambulance Service, where live streaming of trauma incidents is used routinely, and will be exposed to confidential patient information when undertaking the observations. A Process Evaluation sub-study will also take place, collecting data on fidelity, acceptability and use of GoodSAM and experiences of its use. Although confidential patient information is not required for this, the research fellow may be exposed to confidential patient information incidentally.

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	Patients aged 0 and up who are casualties involved in a category 1 or 2 trauma incident. 834 is the total sample size, approximately 250/300 will be included under support. 999 callers who reported the incident (general public or friends/family of the casualty) – outside the scope of support, unless they are also casualties. NHS staff – outside the scope of support
Data sources	1. Computer Aided Despatch (CAD) system at the South East Coast Ambulance Service NHS Foundation Trust and London Ambulance Service

	NHS Trust Ambulance Trust; and live collection of data whilst observing eligible calls. 2. Patient records at 12 hospitals trusts: a. Frimley Health NHS Foundation Trust b. Ashford and St Peter's Hospitals NHS Foundation Trust c. Surrey and Sussex Healthcare NHS Trust d. Royal Surrey NHS foundation Trust e. East Kent Hospitals University NHS Foundation Trust f. University hospitals Sussex NHS foundation trust (Brighton, St Richards, Worthing, conquest) g. Maidstone and Tunbridge Wells NHS Trust h. Medway NHS Foundation Trust i. Dartford and Gravesham NHS Trust j. St Georges University Hospitals NHS Foundation Trust k. Kings College Hospital NHS Foundation Trust l. University Hospital Southampton NHS Foundation Trust East of England Ambulance Trust – only involved in the sub-study of staff wellbeing, which is outside the scope of support.
Identifiers required for linkage purposes	1. Hospital ID number 2. CAD number 3. Age 4. Sex
Identifiers required for analysis purposes	1. Age 2. Sex

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. **A patient notification strategy needs to be created and the documents provided to the CAG for review.**

The applicants advised that a patient notification strategy had been created. The text to be displayed in the notification was provided. The posters will be displayed in emergency departments.

The text for the social media campaign will be sent out via twitter accounts at SECAmb, KSS Air Ambulance, and the University of Surrey School of Health Sciences. The CAG noted this information and raised no further queries.

2. **Clarify why patients name is not collected and whether this is required.**

The applicant explained that patient names are not always recorded in trauma incidents in the pre-hospital setting, so the researchers may not have access to their names until they are in hospital. The CAD (computer aided dispatch) number is the ID that would link the incident to the patient. Patient names were not required, other than for use during the consent process. The CAG noted this information and 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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 24 January 2022**

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 reviews for London Ambulance Service NHS Trust, University of Surrey and the South East Coast Ambulance Service NHS Foundation Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 February 2022).

2. New Amendments

a. 17/CAG/0145 – Outcomes of Drug Coated Balloon Angioplasty, A UK Real Life Experience from 2009 to 2015

Name	Capacity
Dr Murat Soncul	CAG Alternative Vice-Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The amendment seeks support to extend the duration of support to 23 December 2031, to allow applicants to follow up patients long term in terms of mortality and re-hospitalizations, as originally specified in the application. 's251' support was originally provided on the basis that '*data from the Trust database would be linked with NICOR (National Institute for Cardiovascular Outcomes Research) data to enable recording of any follow-up events for at least 12 months following the procedure'.* However this was not specified as any particular end time. The applicant is now clarifying that they will be recording follow up events from received from NICOR and NHS Digital until 2031

Additionally, there have been extensive delays to receiving the required data from the applicants data sources. The applicant confirms there is no change to the data sources or cohort requested.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Alternate Vice-Chair agreed with the duration extension and clarifications provided by the amendment.

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 review for **Norwich and Norfolk University Hospital NHS Foundation Trust** and **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (confirmed by email to CAG inbox 08 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Within scope of original REC application**

b. 20/CAG/0009 – The Cambridge Cohort - Mammography East-Anglia Digital Imaging Archive (CC-MEDIA)

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

Context

Amendment request

This research database created by the University of Cambridge, contains mammographic images to be used as a resource for the development, testing and creation of artificial intelligence algorithms. There is currently support in place to allow research staff to undertake the processing of confidential patient information from patient records at Cambridge University Hospitals NHS Foundation Trust, in order to provide the applicants at the University of Cambridge with an anonymised dataset.

This amendment sought support for a number of changes to the database. The patient notification materials have been updated, and the applicants are updating their methods of transferring clinical data and imaging data. This amendment provides further clarity

regarding the inclusion of high / moderate risk women – clarifying that women who are classed as high or moderate risk with an increased frequency of locally commissioned screening will be included. The amendment sought support for clinical staff or medical students to help with data collection from Electronic Health Records, to fill in gaps from NBSS clinical meta-data, however this is not an extension of support, as the applicant already has support for research staff to undertake the processing of confidential patient information from patient records. This amendment sought support to use the Trial Database for radiology breast imaging training. The amendment also provided updated dissemination plans for results and outputs, and included an updated protocol. None of the above described changes involve any further disclosures of confidential patient information without consent.

This amendment also sought support to 'update fields for clinical meta-data extraction'. The applicant confirmed that no additional support is required to collect any more items of confidential patient information. However, 's251' support is required for the additional new data flows of NHS Number, Hospital ID number and Date of birth and trial ID from Cambridge University Hospitals NHS Foundation Trust, and from the additional site Norfolk and Norwich University Hospital NHS Foundation Trust to NHS Digital. NHS Digital will link with National Cancer Registration and Analysis Service (NCRAS) and Screening Histories Information Manager (SHIM) in order to disclose a pseudonymised dataset back to the applicants at Cambridge University Hospitals NHS Foundation Trust, and additionally to Norfolk and Norwich University Hospital NHS Foundation Trust, which will contain additional clinical cancer fields.

Support is also sought to disclose NHS Number, Hospital ID number and Date of birth and trial ID from Cambridge University Hospitals NHS Foundation Trust to the informatics team at Addenbrookes in order for them to link with EPIC and for them to disclose a pseudonymised dataset back to the applicants at Cambridge University Hospitals NHS Foundation Trust, containing additional fields for cancer risk prediction. These changes are requested in order to aid the development of risk prediction models.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair, who was supportive of this amendment request.

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 **20/21** NHS Digital DSPT review for **Cambridge University Hospitals NHS Foundation Trust (RGT)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 December 2021)

   The **20/21** NHS Digital DSPT review for **Norfolk & Norwich University Hospitals NHS Foundation Trust** (RM1) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (Confirmed by email to the CAG inbox 08 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 December 2021**

c. 19/CAG/0060 – Lancashire ANCA Vasculitis and Glomerulonephritis Study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to review the epidemiology and outcomes of patients with small vessel vasculitis from a single centre by undertaking a retrospective observational study to help address current knowledge gaps. Support is in place to allow the chief investigator access to confidential patient information contained in patient medical records onsite at Lancashire Teaching Hospitals NHS Foundation Trust to facilitate linkage and to extract relevant clinical information required for analysis

This amendment sought support to change the Chief investigator from Dr Adam Morris to Dr Lauren Floyd.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team (CAT), 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 review for **Lancashire Teaching Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 March 2022**

d. 21/CAG/0155 – Using patient records to identify potential participants for the fourth National Survey of Sexual Attitudes and Lifestyles (Natsal-4)

Name	**Capacity**
Dr Murat Soncul	CAG alternative vice-chair
Dr Tony Calland MBE	CAG Chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow NHS Digital to identify a sample of eligible patients from the Demographics service and Hospital Episode Statistics (HES), and to allow the disclosure of confidential patient information from NHS Digital to NatCen. NatCen will then send the mail merge files to Formara, a sub-processor who will carry out print and dispatch, in order for Formara to send out invitation letters to eligible patients, and to allow onwards disclosure of confidential patient information to interviewers. NatCen will also send confidential patient information to interviewers' electronic devices and Formara will send confidential patient information (paper address forms) to NatCen interviewers home addresses. The support also extends to allowing record-level fieldwork recruitment outcomes containing confidential patient information to be transferred back from interviewers' devices to NatCen.

The original application only included patients from England. The applicants are now seeking to extend the study to include patients from Wales. Patient records held in the Welsh Demographics dataset, held by Digital Health and Care Wales. An updated data flow diagram as provided. The same study design, sampling methods and patient information materials will be used as in the existing support. The timeframe is the same as the original application and support will be required until 01 October 2024.

Confidentiality Advisory Group advice

The amendment requested was considered by the CAG. The CAG 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 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 reviews for NatCen Social Research and NHS Digital, and the 2021/21 DSPT review for Formara Limited, were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 March 2022).

A C-PiP report for DHCW for 2020/21 is in place, alongside an improvement plan for 2021/22

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 20 January 2022 (amendment)**

e. 18/CAG/0141 – classifying structure and joint features in extremities using statistical learning methods to assist diagnosis

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to develop automated data-driven software to assist with diagnosis of disorders in joint extremities, and has 's251' support to allow the research team access to confidential patient information within NHS PACS database at Imperial NHS Trust to enable anonymised scans and associated clinical data to be exported for analysis.

This amendment sought support for the change of Chief Investigator from Professor Justin Cobb to Mr Gareth Jones.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that this was a minor change and did not impact on the aims of the study or the scope of support.

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 review for **Imperial College London Health Care Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (confirmed by email to the CAG inbox 14 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 19 August 2020**

f. 15/CAG/0163 – Risk modelling for quality improvement in the critically ill: making best use of routinely available data

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the Intensive Care National Audit & Research Centre (ICNARC) has conducted research to understand the risk factors for, and the consequences of critical illness. The applicant currently has support for various data linkages, which have already been carried out. However support is still required under the Regulations until the point that the data has been pseudonymised.

This amendment sought an extension to support up to 31 December 2022. This is to ensure the applicants still have support until the point at which they are able to pseudonymise the dataset.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. The CAT team understand the reasons for requesting a duration amendment and raised no queries with the 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 2021/22 DSPT review for **Intensive Care National Audit & Research Centre (ICNARC**) was confirmed as 'Standards Met' by a check of the DSPT tracker (18 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 18 February 2022**

g. 21/CAG/0182 – PriDem: Best Practice in Primary Care Led Dementia Support

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application, to test the feasibility and implementation of the best practice care model developed by the PriDem programme, has 's251' support to allow members of the research team to access confidential patient information held in patient records at the participating GP practices in order to identify suitable patients to be invited into the study, and for research staff to conduct a care plan audit, using patient records at participating GP practices.

This amendment sought support to include 3 further participating GP surgeries as participating sites, and data processors for the application, to ensure the applicants are able to meet their recruitment target. These are;

1. St Andrews Medical Practice
2. Jesmond Health Partnership (alternative name of the surgery-osborne road)
3. Roseworth Surgery

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment, noting the size of the cohort will not be increased.

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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 09 March 2022

h. CAG 9-08 (e) /2014 – The EPIC-Norfolk prospective population study

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

Context

Amendment request

This application from the University of Cambridge detailed an existing cohort study of 25,639 patients aged between 40-79 in 1993-97 with cancer and/or chronic disease. Patients were originally recruited on a consented basis via GP practices. Support under the Regulations was requested for continued access to confidential patient information (HES data, GP data and death and cancer registration data) in order to follow up the cohort.

This amendment sought support to include the National Diabetes Audit held at NHS Digital, as an additional data source. With changes and restructuring of organisations holding health data, the applicants have found that some data is not available through the data sources supported in the original outcome letter.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair considered the addition of this one further data source will enhance the accuracy of the applicants data on type 2 diabetes, which is an important part of the study and will not increase their use of confidential patient information or the identifiability of patients in the study.

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 **University of Cambridge (School of Clinical Medicine), and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 February 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 09 March 2022**

i. 21/CAG/0123 – RE-BLEED: A digital platform for identifying bleeding patients – a feasibility study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application to test whether a digital platform can efficiently identify patients who have suffered a bleeding event, has 's251' support to allow members of the research team to access confidential patient information for patients identified as having met the study criteria, so that patients can be approached for consent.

The prospective cohort that applicants currently have ‘s251’ support for is; Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01 October 2021 and 01 February 2022.

This amendment sought support to change the dates for the prospective cohort, due to delays caused by covid-19. Therefore the prospective cohort that applicants will now have ‘s251’ support for is; Adults aged 16-110 years of age who were admitted to, or attended the emergency department at, Oxford University Hospitals NHS Trust between 01 October 2021 and 31 August 2022.

The applicant confirmed that the number of patients in the cohort is not increasing, and that only the dates of the cohort screening are changing.

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. See section below titled ‘security assurance requirements’ for further information. **Confirmed:** The NHS Digital **2020/21** DSPT review for **Oxford University Hospitals NHS Foundation Trust** is confirmed (by check of the NHS Digital DSPT tracker on 18 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 21 February 2022

j. 17/CAG/0150 – National Perinatal Mortality Review Tool (PMRT)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The amendment requested an extension to the duration of support to 31 September 2022. This duration reflected the funding extension which had been agreed with the Healthcare Quality Improvement Partnership (HQIP), evidence of which was provided within the amendment submission.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). No queries were raised regarding this duration 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 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 **20/21** DSPT review for **University of Oxford – Medical Sciences Division – Nuffield Department of Population Health** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 18 March 2022)

k. 17/CAG/0184 – UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The amendment requested an extension to the duration of support to 31 March 2025. This duration reflected the contract extension which had been agreed with the Healthcare Quality Improvement Partnership (HQIP).

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). No queries were raised regarding this duration 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 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 **20/21** DSPT reviews for **Royal College of Paediatrics & Child Health, Net Solving Limited, Rackspace Ltd and SysGroup PLC** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 18 March 2022)

I. 20/CAG/0034 – Detecting clinical deterioration in respiratory hospital patients using machine learning

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for researchers from the University of Nottingham to access confidential patient information held in electronic and paper records at Nottingham University Hospitals NHS Trust, in order to extract an anonymised dataset for analysis.

The applicants are seeking to extend the duration of support until 31st March 2023. The Principal Investigator has recently received a no-cost extension of the MRC Clinical Academic Research Partnership Award, which will enable the extension of the duration of the study.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the extension of the application duration was 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:** The NHS Digital 2020/21 DSPT reviews for the **University of Nottingham and Nottingham University Hospitals NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 March 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 February 2022**

m. 21/CAG/0136 – National Drug & Alcohol Treatment Monitoring System (NDTMS) & Criminal Justice Intervention Teams (CJIT) [replacing and extending National Drug Treatment Monitoring System collection ECC 5-05(e)/2012]

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Office for Health Improvement and Disparities (OHID) within the Department for Health and Social Care (DHSC) set out the purpose of continued processing of confidential patient information within The National Drug Treatment Monitoring System (NDTMS), post the dissolution of Public Health England (PHE). The NDTMS collects information with the consent of the users of drug and alcohol treatment services across England to assess the need for services and to support the commissioning, planning and provision of effective treatment services and interventions. 's251' support is currently in place (among other elements) for the continued processing of confidential patient information by the Office for Health Improvement and Disparities (OHID) within Department for Health and Social Care (DHSC) regarding the

National Drug Treatment Monitoring System (NDTMS) consented cohorts, including those consented between 1 October 2021 and 6 April 2022. Consent is given by data subjects to share data from treatment/service providers with PHE, despite (as of 1st October 2021) PHE becoming OHID within DHSC. This 's251' support is in place specifically to give applicants the time required to alter their consent materials.

This amendment sought support to extend the end date of 's251' support, for this specific National Drug Treatment Monitoring System consented cohort, specifically post PHE dissolution, from 30 September 2021 – 6 April 2022, to 30 September 2021 - 1st October 2022, in order to give the applicants more time to properly develop the new consent materials.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Vice Chair was content to recommend support for this amendment.

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. See section below titled 'security assurance requirements' for further information. **Confirmed:** The NHS Digital **20/21** DSPT reviews for **PHE, and NDEC at the University of Manchester** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 23 March 2022). UKHSA will supersede PHE when security assurances are in place, however application can be supported using PHE DSPT until UKHSA DSPT is in place.

n. 21/CAG/0007 - National Neonatal Audit Programme (NNAP) data flow

Name	Capacity
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support for the disclosure of confidential patient information contained in the BadgerNet system, for Clevermed Ltd to extract confidential patient information in a dataset and further disclosure to the RCPCH Azure hosting infrastructure.

The applicants are seeking to extend the duration of support until 31 March 2025. The Healthcare Quality Improvement Partnership (HQIP) have awarded the Royal College of Paediatrics and Child Health (RCPCH) the contract to deliver the National Neonatal Audit Programme (NNAP) for a further three years from 1 April 2022 to 31 March 2025.

The applicants also seek to revise the inclusion criteria, to include babies admitted within the NNAP reporting calendar year, instead of including babies discharged within the calendar year.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the amendment was in the public interest.

Confidentiality Advice Team 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 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 Royal College of Paediatrics & Child Health and Clevermed Ltd were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 03 March 2022).

3. Annual Review Approvals

15/CAG/0138	Simon Broome Familial Hypercholesterolaemia Register (MR180)
15/CAG/0163	Risk modelling in the critically ill Version 1.0
15/CAG/0196	TIGAR
19/CAG/0042	ATD Study v1.0
18/CAG/0119	CPR Workstream 5: PROMs
PIAG 2-07(c)/2004	Manchester Self-Harm Project
19/CAG/0111	Cambridge Blood and Stem Cell Biobank
15/CAG/0119	MBRRACE_UK
17/CAG/0033	BSRBRRA
17/CAG/0145	DCB Norwich
17/CAG/0071	National Cardiac Audit Programme
20/CAG/0095	Gender-specific outcomes post transcatheter aortic valve implantation
18/CAG/0141	Bone Imaging Statistical Learning
CAG 9-08(d)/2014	BioAID Version 1
20/CAG/0028	Small Area Health Statistics Unit Research Database - 2020 CAG
19/CAG/0214	Avoidable harm in prison healthcare
ECC 8-05(f)/2010	National Neonatal Research Database
CAG 9-08(b)/2013	Linkage of readmissions to birth data
20/CAG/0107	Childhood outcomes after perinatal brain injury v1

16/CAG/0122	Long term follow up of asymptomatic carotid surgery trial (acst-1)
17/CAG/0011	Genetic mechanisms in polyposis of the bowel.
CAG 9-08(e)/2014	The EPIC-Norfolk prospective population study
16/CAG/0024	ADDITION - 10 year follow up (IRAS ID160001)
16/CAG/0026	ADDITION Plus 10 Year Follow Up
16/CAG/0050	ECG Diabetic foot ulcer pilot
16/CAG/0033	The Fenland Study - Phase 2
ECC 6-02(FT3)/2012	Stroke National Audit Programme (SSNAP)
19/CAG/0205	PD MED
ECC 6-05(e)/2012	An ongoing case-control study to evaluate the NHS Breast Screening Programme (NHSBSP)
ECC 1-03(d)/2012	The National Bowel Cancer Audit
20/CAG/0148	Evaluating alternative protocols for identifying and managing patients with familial hypercholesterolaemia: cost-effectiveness analysis with qualitative study
18/CAG/0207	DELIRIUM-PD
21/CAG/0010	Peritoneal Mesothelioma TMA
21/CAG/0026	High intensity treatment at the end of life in children with cancer
19/CAG/0154	Differential diagnosis in the acute care setting
18/CAG/0184	Long term outcome with congenital heart disease
18/CAG/0063	National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis Clinical Audit
17/CAG/0010	NRCT Research Database V1.0
19/CAG/0079	IBIS-I Epidemiological Cohort Study
18/CAG/0021	The incidence of hydroxychloroquine retinopathy in the United Kingdom
19/CAG/0189	Barts Gynae Tissue Bank (10/H0304/14 Renewal)

CAG 9-08(c)/2014	MesobanK Retrospective Sample Collection
19/CAG/0160	BRCOH - Evaluation of the NHS Breast Screening Programme
18/CAG/0003	FAST- Febuxostat versus Allopurinol Streamlined Trial V 19.0
19/CAG/0047	Risk assessment tool for self-harm in prisoners.
19/CAG/0001	NACAP Paediatric Asthma Audit
15/CAG/0120	National investigation into suicide in children and young people

Minutes signed off as accurate by correspondence from:-

Signed – Officers of CAG	Date
Dr Patrick Coyle, CAG Vice Chair	*19 April 2022*
Dr Murat Soncul, CAG Alternate Vice Chair	*19 April 2022*
Ms Clare Sanderson, CAG Alternate Vice Chair	*19 April 2022*

Signed – Confidentiality Advice Team	Date
Ms Laura Gordon, Confidentiality Advisory Group Assistant	*06 May 2022*