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

November 2021

1. New Applications

a. 21/CAG/0095 - IMplementation of the Preterm Birth Surveillance PAthway: a RealisT evaluation (including a realist literature scope)

Name	Capacity
Professor Barry Evans	CAG member
Dr Katie Harron	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from King's College London set out the purpose of medical research that seeks to identify and understand the features of successful and unsuccessful implementation of the Preterm Birth Surveillance Pathway (PBP).

In the UK, 1 in 13 babies are born pre-term, defined as before 37 weeks of pregnancy. Currently, women at risk of preterm birth receive different care depending on the hospital they're treated at. Some women are offered specialist care in a preterm birth prevention clinic, however many do not receive any specialist care. NHS England has published some guidance on how to standardise care across the UK and this new guidance has developed a pathway called the Preterm Birth Surveillance Pathway (PBP). This pathway states that midwives should assess every pregnant woman for the risk of having a preterm birth by asking questions about her medical history and determining whether she is at high, intermediate or low risk of a preterm birth. If a woman is assessed as being at high or intermediate risk that she should be referred to a special preterm birth prevention clinic. These clinics can offer additional tests and, depending on the results, decide which women may need further help, such as admission to hospital to help prevent the preterm birth.

The applicants will investigate to what extent and in what contexts the PBP is implemented through a realist evaluation, including a realist literature scope (a theory-driven and interpretive type of literature review). The guidance recommending the PBP was published in March 2019 and maternity providers should have implemented this by April 2020. The applicants seek to undertake this research as hospitals begin implementation in order to track the intended and unintended outcomes of pathway implementation, explore implementation facilitators and barriers so sustainability of the pathway is likely, and develop theories on how to improve implementation at different hospitals. A set of recommendations for improving the implementation of the PBP can then be provided.

Hospital staff at participating trusts will access confidential patient information within their IT system and remove patient names and all records for patients who have opted-out. Members of the research team from King's College London, who are not members of the direct care team, will then access the data onsite, under the supervision of a member of the sites' local team in order to pseudonymise the data. The hospital staff will be provided with a record that links the personal information to study participant information number, used to identify duplicated entries and allow data checking/validation. This will be kept locally only on secure NHS servers. Pseudonymised data will be sent securely centrally to King's College London through an established NHS electronic network. Linkage of different datasets will be done centrally based in the study participant information number.

The applicants will also conduct interviews with staff members and patients at each site. Patients will be identified and approached by the clinical care team. Observations of patient care will also be undertaken by the direct care team. The researchers will only have access to confidential patient information for patients who have consented to the sharing of their information. This is outside the scope of the support sought.

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	Women who booked their pregnancy between 1st March 2018 – 31st October 2021 at the three participating trusts. 60,900 patients will be included in the data collection. 60 participants in total, half staff and half patients, will be included in the interview arm, which is outside the scope of support.
Data sources	1. Patient records at: a. Leeds Teaching Hospitals NHS Trust b. Homerton University Hospital NHS Foundation Trust c. Yeovil District Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID number 3. Date of birth
Identifiers required for analysis purposes	No identifiers will be retained for analysis.

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. **Further clarification needs to be provided on the pseudonymisation and anonymisation processes that will be followed.**

The applicants provided a revised data flow diagram, which was reviewed and accepted by the CAG.

2. **Further information on how the linkages conducted within King's College London will be carried out is needed:**

    a. **The identifiers needed to conduct the linkages within King's College London need to be clarified and an explanation provided on how the linkage will be undertaken if the re-identification key is held within the participating trusts only.**

The applicants advised that the pseudo algorithm is designed so that the same patients get the same pseudo. Therefore, the data linkage will be done using this generated pseudo, which means that the re-identification key will not need to be used for the linkage.

    b. **The specific datasets that will be linked to within King's College London need to be named.**

The names of the datasets that will be linked are different as each hospital uses different systems. Yeovil uses TrakCare and Neonatal Badgernet. Leeds uses K2, PAS/K2 and Neonatal Badgernet. Homerton use Cerner EPR and Neonatal Badgernet.

    c. **Further information also needs to be provided on the variables that will be extracted.**

The applicants provided further details on the variables that would be extracted.

    d. **The meaning of maternity' and 'neonatal' admin and routine datasets needs to be explained.**

The applicant advised that the maternity datasets are used by clinicians to store information about a woman's pregnancy and delivery. These include booking and delivery forms.

The neonatal datasets are used by clinicians to store information about a baby once he or she is born.

Hospitals use different electronic systems to store the maternity and neonatal data. Yeovil uses a system called 'Trakcare' for its maternity system, Leeds uses a system called 'k2' for its maternity system, and Homerton uses a system called 'Cerner EPR'. All three sites (Yeovil, Leeds and Homerton) use the same system, 'Neonatal Badgernet' to store their neonatal data.

e. **The data flows also need to be made clear in the data flow diagram.**

The applicants provided a revised data flow diagram, which was reviewed and accepted by the CAG.

The CAG noted the information above and raised no further queries.

3. **The patient notification materials require revisions to address the use of 'pseudonymisation' and 'anonymisation' so that they are used consistently and in line with the responses given to the queries above.**

An updated poster was provided. This was reviewed and accepted by the CAG.

4. **Further details need to be provided on the exit strategy;**

a. **Clarification needs to be provided on when confidential patient information will no longer be processed. This deadline for processing needs to align with the deadline for patients' objections, 01 July 2022.**

The applicant confirmed that identifiable data will not be processed once Naomi Carlisle and the data manager have left the local sites. The applicant explained that women will be able to opt-out until Naomi Carlisle and the data manager have left the local sites. The deadline for processing therefore aligns with the deadline for patients' objections, and also with when the study will be publicised for a final time on local Mumsnet pages.

b. **The research data that needs to be retained for 10 years needs to be specified.**

The non-identifiable pseudonymised data sets that were used for analysis will be archived and stored (not processed) for 10 years after the study has ended. This is to ensure scientific integrity.

The CAG noted the information above 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 30 June 2021.**

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

   The NHS Digital **2020/21** DSPT reviews for **Leeds Teaching Hospitals NHS Trust and Homerton University Hospital NHS Foundation Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (27 July 2021).

   The NHS Digital **2020/21** DSPT review for **Yeovil District Hospital NHS Foundation Trust** was confirmed as '**Standards Met'** by email to the CAG inbox (05 November 2021).

b. 21/CAG/0147 - 2021 NHS Adult Inpatient Main Stage Survey – Mixed Methods

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Rose Payne	CAG member
Mr Dan Roulstone	CAG member

Dr Pauline Lyseight-Jones	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2021 NHS Adult Inpatient Survey.

The Adult Inpatient Survey is the most established survey within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The 2021 Adult Inpatient survey will be the nineteenth carried out to date, and the second mainstage to be completed using a mixed method approach, following a pilot of the approach during 2019 and the first mainstage during 2021. The NHS Patient Survey programme is used to help the CQC understand what patients think of the NHS healthcare services they use. The results from the Adult Inpatient Survey will help to assess NHS performance and the CQC will use the findings for regulatory activities such as monitoring ongoing compliance and reviews. Trusts will also use the findings to monitor performance, and to drive improvements and initiatives at a local level.

All eligible trusts (137) will be asked to conduct the survey, with preparations expected to begin in the autumn of 2021 and fieldwork expected to start from January 2022. All trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey.

The 2021 Adult Inpatient Survey will be managed and coordinated by Ipsos MORI in their role as the Coordination Centre for Mixed Methods. The survey will follow the same mixed method approach as the 2020 Adult Inpatient Survey, which was developed and tested during the 2019 Adult Inpatient Pilot Study, and completed in 2021 with a response rate of 45.9%, which is consistent with other surveys in the NPSP. The applicants anticipate that the vast majority of trusts involved will opt to use an approved survey contractor, either Picker, Quality Health, Patient Perspective, to facilitate the sending of surveys.

	Mode of contact

Contact 1	Postal letter inviting the patient to take part online
Contact 1.1	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 2	In week 2, a reminder letter will be sent to non-responders
Contact 2.2	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 3	Final, postal reminder sent, along with a paper questionnaire

A recommendation for class 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	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital. A list of reasons for exclusion, such as deceased patients and those under 16 years of age at the time of sampling, was included in the application.
Data sources	2. Electronic patient records with acute and specialist trusts in England.

Identifiers required for contact purposes	4. Title 5. Initials or first name 6. Surname 7. Address fields including postcode 8. Mobile phone number 9. Patient unique identifier
Identifiers required for analysis purposes	1. Unique identifier (a three-digit Trust code and 4 digital serial number related to sampled patient) 2. Postcode 3. Trust code 4. Year of birth 5. Gender 6. Ethnic category 7. Date of admission 8. Date of discharge 9. Length of Stay 10. Treatment Function Code 11. ICD-10 Chapter Code 12. Treated as a suspected or confirmed covid-19 case 13. CCG code 14. Treatment Centre Admission 15. Admission method 16. NHS Site code-Admitted 17. NHS Site code-Discharged 18. Discharge Pathway

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 DSPT for Patient Perspective, as noted below, needs to be provided.**

The applicant provided the reviewed DSPT to the CAG inbox on 8 November 2021.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to The Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Patient and public involvement around the specific issue of processing of confidential patient information without consent needs to be conducted and fed-back to the CAG at the first annual review.

2. More work should be done with participating Trusts to encourage effective notification, and an account of this should be fed back at Annual Review.

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 **Ipsos Mori, Quality Health Ltd and the Picker Institute Europe** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 30 September 2021).

   The NHS Digital **2020/21** DSPT review for **Patient Perspective** was confirmed as **'Standards Met'** by email to the CAG inbox on 8 November 2021**.**

c. 21/CAG/0097 - PARADISE: Predicting AF after Cardiac Surgery - A Clinical Prediction Rule for Post-operative Atrial Fibrillation in Patients Undergoing Cardiac Surgery

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG Vice-Chair
Dr Sandra Duggan	CAG member
Professor Barry Evans	CAG member
Dr Rachel Knowles	CAG member

Dr Simon Kolstoe	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Mr Marc Taylor	CAG member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to develop and validate two prognostic models to predict post-operative atrial fibrillation after cardiac surgery.

Atrial Fibrillation (AF) after cardiac surgery (AFACS) is the most common complication following cardiac surgery, with an incidence between 30% and 50%. Around 35,000 patients undergoing cardiac surgery in the UK every year. AFACS is strongly associated with adverse patient outcomes, longer hospital and ICU stays, increased risk of stroke, increased risk of developing long-term AF, with associated complications and need for anticoagulation, and increased all-cause 30-day and 6-month mortality. Interventions that reduce the incidence of AFACS would have a substantial impact both on patient outcomes and cost. Current evidence therefore indicates that AFACS itself contributes to poor patient outcomes following cardiac surgery, and that tools to predict, prevent and guide treatment of AFACS are needed. There is no widely accepted prediction model currently, that reliably allows clinicians to determine the risk of a patient developing AFACS, despite multiple efforts over the past 15 years to develop one. The lack of effective pre and immediate post-operative prediction models for estimating AFACS risk has prevented the implementation of AF prophylaxis protocols. Interventions to prevent AFACS lead to decreased hospital length of stay, lower costs of hospital treatment, and decreased risk of postoperative stroke.

This is an international, multi-centre retrospective cohort study of patients who have undergone cardiac surgery. Two prognostic models will be developed, PARADISE-1 and PARADISE-2. PARADISE-1 will be conducted in the pre-operative assessment clinic and PARADISE-2 in the post-operative care unit. Both models will then be externally validated on prospectively collected data from two large UK centres and one UK clinical trial. The predictive models will be developed using data from the CALIBER and PARTNERS research databases, for which existing ethical approvals

are in place. The models will be externally validated on data collected as part of the Tight-K study and the Brigham and Women's CABG Genomics Database in the United States. Consent from participants in the Tight-K study has already been sought to use their data for related research. The applicants will apply for separate ethical approvals to use Brigham and Women's CABG (Coronary Artery Bypass Grafting) Genomics Database. The applicants will also use prospective data collected at The Liverpool Heart & Chest Hospital (LHCH) and Barts Heart Centre (BHC) to carry out validation. Data from all study databases/sites will be de-identified prior to secure transfer to Oxford.

The applicants are seeking support to allow staff outside the direct care teams at LHCH and Barts Health NHS Trust to process confidential patient information in order to identify the study cohort and to compile a dataset containing information from multiple routinely-collected data sources. Confidential patient information will also be disclosed from LHCH and Barts Health NHS Trust to NHS Digital in order for the National Data Opt-Out to be applied. Pseudonymised data only will be disclosed from LHCH and Barts Health to the research team at the Nuffield Department of Clinical Neurosciences. Pseudonymised information will also be shared from the Tight-K trial, and the Brigham and Women's CABG Genomics Database and PARTNERS study in the United States to the Nuffield Department of Clinical Neurosciences.

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

Confidential patient information requested

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

Cohort	Male and female patients aged 18 years and over who were admitted to hospital for any cardiac surgery. The scope of support extends to 12,000 patients treated at LHCH and BHC, treated between 1st January 1998 to 31st December 2020, for the retrospective cohort and the 1st July 2021 to 31st July 2023 for the prospective cohort.
Data sources	3. Electronic patient records held at the Liverpool Heart and Chest NHS Foundation Trust

	4. Electronic patient records at Barts Health Centre at Barts Heath NHS Trust. 5. Pseudonymised data from: a. The Tight-K study at Barts Health NHS Trust, b. The CALIBER study at University College London, c. The Brigham and Women's CABG Genomics Database, Brigham and Women's Hospital, USA, d. The Partners Research Database (PRD), USA.
Identifiers required for linkage purposes	10. Name 11. NHS Number 12. Hospital ID number 13. Date of birth 14. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – district level 2. Age 3. Gender 4. Ethnicity

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 specific issue of the use of confidential patient information without consent needs to be discussed with a patient and public involvement group. Feedback from this discussion, including the number of those consulted and their demographics, needed to be provided.**

The applicant advised that they had met with four members of the Oxford Critical Care Patient Forum to discuss the specific issue of the use of confidential patient information without consent. All members were white British, aged between 50 and 78 years. All members were entirely supportive of the use of de-identified, confidential patient information without consent from Barts and Liverpool to validate the prognostic models.

2. **Consider whether hard copies of information about the study can be made available at participating sites and provide the outcome of these considerations.**

The applicants provided a poster, which would be displayed at the two participating sites. The CAG noted that the poster contained a link to information about the project on the University College London website, but that the privacy statement was difficult to find. The applicants provided a link to the CALIBRE privacy statement. The CAG were content with this response.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 25 August 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.

- **The NHS Digital DSPT review for Nuffield Department of Clinical Neurosciences, University of Oxford for 2020/21 was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 05 November 2021).**

- **The NHS Digital DSPT review for Barts NHS Trust for 2019/20 was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 05 November 2021).**

- **The NHS Digital DSPT review for Liverpool Heart and Chest NHS Foundation Trust for 2020/21 was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 05 November 2021).**

d. 21/CAG/0114 - Trends in the Prevalence and Complexity of Children with a Life-limiting or Life-threatening condition in Wales

Name	Capacity
Dr Malcolm Booth	CAG member
Dr Rachel Knowles	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of York set out the purpose of medical research that aims to estimate the number of children in Wales who are living with a Life-limiting or Life-threatening condition (LLC) and to assess the complexity and severity of this population to aid service planning and delivery. The applicant proposes to use Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service NWIS) as a trusted third party to undertake linkage with Welsh clinical data from Secure Anonymised Information Linkage (SAIL) databank, Paediatric Intensive CareAudit Network (PICANet) data, and data from NHS Digital.

Life-limiting conditions (LLC) are serious health conditions in which the child's life may be shortened. Children living with an LLC usually have repeated admissions to hospitals and require healthcare including palliative care for many years. A challenge in LLC research is lack of information on the severity or complexity of the child's condition. This application will link data from different sources which will be pivotal for service planning and provision.

Identifiable data from NHS Digital and PICANet from all Wales residents ageing 0 to 25 years old is sent to DHCW to be linked and for cohort identification. The data linkage will be undertaken by the SAIL Databank team and DHCW. Data for any individuals who do not meet the cohort inclusion criteria will be deleted once the cohort has been made. After linkage, data will be pseudonymised using a unique identifier that matches with SAIL datasets. This dataset will be disclosed to SAIL, alongside full date of death for those who have passed away. SAIL will then link to clinical data and modify date of death to month and year of death 6-8 weeks after receiving the dataset. 's251' support

will then no longer be required. Researchers from the University of York will have access to the pseudonymised dataset via secure remote access provided by SAIL.

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

Confidential patient information requested

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

Cohort	All children and young adults aged 0-25 years old with a life-limiting condition (LLC), resident in Wales from 2003-2020. ~63,000 cases
Data sources	1. SAIL databank (linked via Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, (NWIS); • Primary Care GP (2000-2020) • Patient Episode Database for Wales (PEDW) (1997-2020) • Critical Care Dataset (2006-2020) • Emergency Department Data Set (EDDS) (2009-Present) • Outpatient (2004-2020) • Annual District Death Extract (2003-Present) • Congenital Anomaly Register and Information Service (CARIS) (1998-2019) • Welsh Cancer Intelligence and Surveillance Unit (WCISU) (1972-Present)

	6. The Paediatric Intensive Care Audit Network (PICANet) data from the University of Leeds 7. NHS Digital; • Hospital Episode Statistics (HES) (A/E; Admission; Outpatient) • Emergency Care Data Set (ECDS)
Identifiers required for linkage purposes	• NHS Digital linkage: 1. NHS Number 2. Postcode 3. Date of birth 4. Sex • PICANet linkage: 1. PICANetidentifier 2. Name 3. NHS number 4. Postcode 5. Date of birth 6. Sex
Identifiers required for analysis purposes	1. Date of death (modified to month and year) 2. Ethnicity
Additional information	Data linkage undertaken by Digital Health & Care Wales (DHCW) The pseudonymised dataset will be hosted by the Secure Anonymised Information Linkage (SAIL) databank at Swansea University. The researchers at the University will access and analyse the dataset via secure remote access provided by SAIL.

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 provided further explanation as to why it is not possible for DHCW to implement a study specific opt out.**

The applicant confirmed they have contacted the SAIL team and they confirmed that DHCW are not able to implement a study specific opt out as they are not able to manage it. The members noted this was not any further explanation than had been provided previously, but accepted that it was not in the applicants control.

2. **The website notification should be amended and an updated version provided;**
   a) **It should be clarified that parents can contact the research team to find out more about the study (not to opt out),**
   b) **Contact details for the research team should be provided.**
   c) **References to contacting SAIL regarding opt out should be removed.**
   d) **If after further explanation, it is impossible for DHCW to implement a study specific opt out option, the website notification should make it clear that parents will have to use the national data opt out if they wish to object.**

The applicants provided an updated notification which addressed points a-d above. The members requested further changes, of adding at least one other form of contact in addition to email address (phone/postal), and requested the applicant make it clearer to patients that taking the National Data Opt Out route would mean opting out of ALL research not just this specific project. The applicant updated as requested, and the Sub-Committee were satisfied with this response.

3. **Please provide evidence of NHS Digital review of the 20/21 DSPT for PICANet – University of Leeds SEED, and Secure Anonymised Information Linkage (SAIL databank), as per standard condition of support below.**

The NHS Digital DSPT review for SAIL was undertaken on 1 October 2021. The NHS Digital DSPT review for PICANet – University of Leeds SEED, has not yet been undertaken, however on the basis that PICANet have confirmed that all data will be transferred from SEED to LASER by January 2022, support is recommended for this application without the requirement for PICANet – University of Leeds SEED, as the applicant will not be able to begin processing data until after January 2022 now.

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 11 August 2021**

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

   The NHS Digital **20/21** DSPT reviews for **NHS Digital and PICANet – University of Leeds LASER** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 September 2021), and **Secure Anonymised Information Linkage (SAIL databank) 8WG95** was confirmed as '**Standards Met'** (by email to the CAG inbox on 1 October 2021)

   Digital Health & Care Wales (DHCW) has a confirmed Caldicott Principles into Practice (CPiP) Outturn report.

1. New Amendments

20/CAG/0067 – Learning Disability Mortality Review (LeDeR) programme

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities (aged 4 years and over) in England. The activity was previously given support under reference 16/CAG/0056. A new application was given support in May 2020 as the controller for the application had changed from HQIP to NHS England.

An amendment supported on 05 July 2021 replaced the University of Bristol as a data processor for web notifications, a web based platform and a linked database, coding completed review forms and redacting reviews with a new data processor; NHS South Central and West Commissioning Support Unit who are part of the Data Controller - NHS England and NHS Improvement.

This amendment is to replace the remaining functions of University of Bristol with new data processors; Kings College London and their sub-contractor, University of Central Lancashire (UCLAN). These new data processors are contracted to undertake analysis of the LeDeR data for the purposes of service improvement. This directly replaces the service previously provided by the University of Bristol.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no concerns about the request.

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 **Kings College London (EE133874-ROSALIND), University of Central Lancashire (EE133869-CBMS), NHS England (X24), North of England CSU (0AR), and South Central and West Commissioning Support Unit (0DF**) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 02 November 2021, and by email to the CAG inbox 02 November 2021)

20/CAG/0067 – Learning Disability Mortality Review (LeDeR) programme

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Patrick Coyle	CAG vice-chair
Professor William Bernal	CAG alternative vice-chair

Context

Amendment request

The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities (aged 4 years and over) in England. The activity was previously given support under reference

16/CAG/0056. A new application was given support in May 2020 as the controller for the application had changed from HQIP to NHS England.

This amendment is to include in LeDeR, reviews of the health and social care received by autistic people who have died. This amendment is requested due to the need for reliable data on the health inequalities faced by autistic people. There is no change to the data sources requested. Without this amendment, there will be no systematic means of learning from the deaths of most autistic people, opportunities to prevent future deaths will be missed, and the commitments in the NHS Long Term Plan and Autism Strategy will be unachievable.

This amendment has been discussed with autism charities - Autistica and the National Autistic Society (NAS), and also with the National Autism Steering Group, which is convened by NHS England and NHS Improvement's Autism Team. This steering group is comprised of a wide variety of stakeholders from across the autism community (including patient groups and lived experience advisors). Patients included in the LeDeR programme are deceased and cannot be directly informed about the use of their data. However, a communication plan is in place and public information materials will be adapted for LeDeR to reflect the change and communicate it to autistic people, families and carers.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs action. Both the Vice-Chair and the Alternate Vice Chair recommended support for this amendment. The Chairs noted that this very important audit is intended to improve care and reduce mortality, and this amendment will considerably enhance the value of LeDeR.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed**

   The NHS Digital **20/21** DSPT reviews for **Kings College London (EE133874-ROSALIND), University of Central Lancashire (EE133869-CBMS), NHS England (X24), North of England CSU (0AR), and South Central and West Commissioning Support Unit (0DF**) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 02 November 2021, and by email to the CAG inbox 02 November 2021)

21/CAG/0067 – Derivation and narrow validation of a clinical decision rule for paramedics to triage older adults with a traumatic brain injury. Short tile: Clinical Decision Rule for TBI in Older adults (CEREBRAL)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from South East Coast Ambulance Service NHS Foundation Trust set out the purpose of medical research that aims to develop and test a clinical decision rule (CDR) that paramedics could use to aid triage of patients aged 60 years or older who could be at risk of a traumatic brain injury (TBI), to a hospital with neurosurgical services onsite. Support is already in place to allow data extraction from emergency departments patient records to be undertaken by Intelligent information specialists (who are not considered part of the direct care team) at participating hospitals (part of East Kent Foundation Hospitals Trust for SELKaM Trauma network and part of University Hospitals Sussex NHS Foundation Trust for Sussex Trauma network), and for the onwards disclosure of confidential patient information to SECAmb.

This amendment is to allow data extraction from emergency departments patient records to be undertaken by a researcher (who is not considered part of the direct care team) at participating hospitals (part of East Kent Foundation Hospitals Trust for SELKaM Trauma network and part of University Hospitals Sussex NHS Foundation

Trust for Sussex Trauma network), in cases where Intelligent information specialists do not have the capacity to do so.

This amendment is also to include Medway Maritime Hospital NHS Foundation Trust as a new study site and data processor.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. As support under Regulation 5 is already in place for individuals outside of the direct care team to access the records, the CAT 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

1. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 November 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: **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 the following organisations have been assessed as 'standards met' by NHS Digital;**
    - **South East Coast Ambulance Service NHS Foundation Trust**
    - **King's College Hospital**
    - **East Kent Foundation Hospitals Trust**
    - **University Hospitals Sussex NHS Foundation Trust (new merged Trust, should currently be covered by the below;**
    - **Brighton & Sussex university Hospital NHS Trust and**
    - **Western Sussex Hospitals NHS Trust**
    - **Medway Maritime Hospital NHS Foundation Trust**

21/CAG/0049 – Do Safe and Well Visits delivered by the Fire and Rescue service reduce falls and improve quality of life among older people? A randomised controlled trial (FIREFLI)

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Exeter database held by NHS E&I to the Humberside Fire and Rescue Service, via NHS Digital's PCRM, so that suitable patients can be approached for consent to take part in the study. The support also covered the potential exposure of research staff to confidential patient information when assisting with the mailing of recruitment packs.

In the initial application the applicants also sought to include the Kent Fire and Rescue Service. As the Kent Fire and Rescue Service were experiencing difficulties in completing their DSPT, the Service was removed from the application. The applicants are now seeking to include this Fire Service in the application.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team who raised no queries regarding this amendment. The Sub-Committee who considered the original application were content for this fire service to be included.

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 York, Humberside Fire and Rescue Service** and **Kent Fire and Rescue Service** are confirmed as '**Standards Met'** by email to the CAG inbox (11 November 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **The Favourable Opinion issued by the REC included the Kent Fire and Rescue Services' involvement.**

21/CAG/0049 – Do Safe and Well Visits delivered by the Fire and Rescue service reduce falls and improve quality of life among older people? A randomised controlled trial (FIREFLI)

Name	Capacity
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Exeter database held by NHS E&I to the Humberside Fire and Rescue Service, and Kent Fire and Rescue Service, via NHS Digital's PCRM, so that suitable patients can be approached for consent to take part in the study. The support also covered the potential exposure of research staff to confidential patient information when assisting with the mailing of recruitment packs.

This amendment sought support to extend the study duration until March 2024. This takes into account delays caused by the pandemic.

This amendment also updated the REC with changes suggested and supported by the CAG as part of the response to both the provisional outcome, and also the conditional outcome, and therefore CAG does not need to re-review these.

Other elements of the amendment related to the consented cohort only, and are not relevant for CAG. The updated protocol and other study documents have been provided.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding the extension of the study duration. The other changes made have been previously supported by CAG as responses to provisional and conditional outcomes.

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 York, Humberside Fire and Rescue Service** and **Kent Fire and Rescue Service** are confirmed as '**Standards Met'** by email to the CAG inbox (11 November 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 October 2021**

20/CAG/0138 - Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study

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

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from North Bristol NHS Trust and University Hospitals Bristol and Weston NHS Foundation Trust to the University of Bristol.

In this amendment, the applicants are seeking support to record the details of any serious/significant adverse event resulting from administration of the BNT162b2 vaccination against COVID-19 (manufactured by Pfizer), which is revealed to a member of the research team during the course of the Avon CAP study.

For patients in the non-consented arm, should the applicants find information relating to a serious/significant adverse event following a patient receiving the Pfizer vaccination when reviewing patient records, this information will be collected onto the Avon CAP database.

The applicants noted that these adverse events should be reported under the Yellow Card MHRA system, but often are not due to lack of knowledge about the system. The applicants are unable to report the reactions via the Yellow Card MRHA system themselves. However, they will make Pfizer aware of the adverse event.

In this amendment, the applicants also seek to change the patient facing documents for patients in the consented arm of the Avon CAP study. As the consented arm of the study is outside of the CAG remit, the revised documents have been noted but no review undertaken.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment had a medical purpose and 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

1. 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 NHS Digital 2020/21 DSPT review for University of Bristol (Bristol Medical School), University Hospitals Bristol and the Weston NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 11 October 2021).

   The NHS Digital 2020/21 DSPT review for North Bristol NHS Trust was confirmed as 'Qualified Assurance – Trust has not achieved 95% staff undertaking security awareness training' on the NHS Digital DSPT Tracker (checked 11 October 2021). Please note the specific condition of support. All staff at organisation that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.

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

20/CAG/0111 - Under 16 Cancer Patient Experience Survey 2020-2023

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from NHS Principal Treatment Centres (PTCs), delivering

children's cancer care and treatment in England, to Picker Europe Ltd, in order to facilitate the Under 16 Cancer Patient Experience Survey 2020-2023. The fieldwork for the first iteration of the Under 16 Cancer Patient Experience Survey (U16 CPES) 2020 is complete, and the planning for the 2021 survey is underway.

The applicants are seeking to amend the data items to include the ICD-O-3 4 and the ICD-O-3 morphology code, in addition to the ICD-10 and ICD-11 codes. This change to include the ICD-O codes will enable applicants to improve the way cancer grouping is presented to trusts at a national level.

The applicants also seek to use a new online sampling checking platform. Trusts will still be able to submit their patient sample lists using the secure file transfer platform (FTP), as with the first wave of the U16 CPES survey (2020) that ran this year. However, the applicants would also like to provide trusts with the option of using a secure online sample checking platform. This platform is hosted by Picker Institute Europe and performs a number of automatic checks on the sample list, thus improving checking accuracy and reducing the amount of time trusts need to be engaged with questions about their samples. This platform is in use across other national patient experience surveys, including the National Cancer Patient Experience survey, and the NHS Staff Survey, with positive feedback being received from trusts.

The applicants also seek to send the survey type, trust name and site name to Greens Ltd to improve the efficiency of the survey mailings. This will allow the Patient Reference Number to be shortened, improving efficiency as survey recipients need to refer this number when making queries about the survey and reduce the quality checking time needed between sending the patient sample list to Greens and mailing out the surveys.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that the revisions made would lead to more efficient running of the survey, which 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 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 – Picker Institute Europe and Greens Ltd has a confirmed 'Standards Met' grade on DSPT submission 2020/21 by check of the NHS Digital email dated 28 October 2021)

2. Annual Review Approvals

ECC 3-04(i)/2011	Global surveillance of cancer survival (CONCORD programme)
16/CAG/0049	National Cohort Study of late effects of Hodgkin lymphoma treatments
ECC 1-05(b)/2012	ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage
15/CAG/0143	National Prostate Cancer Audit (NPCA) Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs)
19/CAG/0192	IgG4-related Orbital Disease (IgG4-ROD): A Surveillance Study
17/CAG/0058	National Chronic Kidney Disease Audit
19/CAG/0200	PROFILE Study
CAG 5-07(d)/2013	National Emergency Laparotomy Audit
ECC 1-03(FT2)/2010	Prospective Study of Outcomes in Sporadic versus Hereditary breast cancer (POSH)
20/CAG/0056	Maternal smoking during pregnancy and intellectual disability

20/CAG/0155	Community Mental Health Survey 2021
20/CAG/0085	2020 NHS Adult Inpatient Main Stage Survey – Mixed Methods
20/CAG/0021	Breast Reconstruction: Investigating long-term clinical and cost-effectiveness in the National Mastectomy and Breast Reconstruction Audit cohort
20/CAG/0049	PREDICT Study: RaDaR and UKRR Linked Dataset
CR17/2014	Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers
PIAG 3-07(j)/2002	Long-term consequences of chronic diseases and their treatments
19/CAG/0119	MATTS (Major Trauma Triage Study)
19/CAG/0185	Understanding Multidisciplinary approaches and Parental Input in perinatal mortality Review
20/CAG/0136	A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach
20/CAG/0045	An evaluation of a water fluoridation scheme in Cumbria: A population based comparative cohort study of systemic and topical fluoride exposure
20/CAG/0046	An evaluation of a water fluoridation scheme in Cumbria: population based comparative cohort studies of topical fluoride exposure alone
20/CAG/0069	C&I CRIS Linkage with HES and Mortality
20/CAG/0056	Maternal smoking during pregnancy and intellectual disability
19/CAG/0115	Suspected Stroke Clinical and radiological data base (SSCRaD)
19/CAG/0146	The TIGHT-K STUDY. Dysrhythmias on the cardiac intensive care unit - does maintenance of high-normal serum potassium levels matter?

PIAG 3-04(FT3)/2006	Multicentre randomised controlled trial of ‘once only’ flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality
18/CAG/0008	Sight-threatening chemical injury study in association with the British Ophthalmological Surveillance Unit

Signed – Chair	Date
Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson, Dr Will Bernal and Mr Murat Soncul	07/02/2022

Signed – Confidentiality Advice Team KM Cassidy	Date 07/02/2022