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

June 2022

1. New Applications

a. 21/CAG/0169 - DECLINE: Decisions against curative treatment for lung cancer in eligible patients

Name	
Dr Tony Calland MBE	CAG Chair
Dr Sandra Duggan	CAG member
Dr Liliane Field	CAG member
Mr. Myer Glickman OBE	CAG member
Mr Tony Kane	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member

Professor Sara Randall	CAG member
Mr Marc Taylor	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Nottingham set out the purpose of medical research that aims to identify perceived barriers to curative treatment for patients with early stage lung cancer in the East Midlands Cancer Care Network, and to identify reversible factors that can be used to improve treatment rates and hence outcomes for patients with lung cancer.

One fifth of people eligible for curative treatment of their lung cancer, don't receive that treatment. In a third of these cases, it is patient choice to refuse surgery, however the reasons why are unknown. This study will investigate the barriers experienced by both patients and clinicians treating lung cancer patients. The study will examine how to ensure more people decide to have the best possible treatment. Applicants hope that information gleaned from this study can be used to improve local services in the future.

Applicants will undertake consented interviews with both patients and clinicians. This element of the study does not require 's251' support. Additionally, analysis will be undertaken on a database. Part of the creation of this database does require 's251' support. The database will be generated from local records by the direct care team at 4 Trusts, and will include data for all people aged 18 or older and diagnosed with lung cancer between January 2016 and December 2019. This element does not require support. Each patient will be given a unique identifier, which is linked to the NHS number. The key will be retained by direct care team at each Trust. At this stage the database will contain demographics, information about the patients lung cancer, and will include date of birth and date of death as direct identifiers. Researchers from the University of Nottingham will go to each of the 4 Trusts, and will modify the date of birth, date of death, and date of diagnosis to; age at diagnosis, survival time in days, and months and year of diagnosis. This element requires support, as the researchers are not considered direct care team. The database is now pseudonymised for analysis, and this will be disclosed to the University of Nottingham. In cases where patients do not receive treatment but guidelines would have recommended it, and a reason cannot be identified from the information already collected, members of the research team will visit the local hospital to review the patients' records, looking for a reason why treatment was not given. Applicants assume this may be around 150 records in total. The researcher would have access to clinical records pertaining to the diagnosis. Some of the Trusts have electronic medical records and one uses paper notes. No confidential patient information will leave the Trusts.

A recommendation for class 1, 2, 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	For database: All people aged 18 or older and diagnosed with lung cancer between January 2016 and December 2019, at participating trusts (approximately 5000 patients) For case note review: Any patient (in the database) who did not have treatment, and researchers can't find a reason for why this would be the case from the dataset collected (approximately 150 patients)
Data sources	Hospital data from NHS trusts which refer to Nottingham University Hospitals: 1. Nottingham University Hospitals ('s251' support not required, researcher is direct care team) 2. United Lincolnshire Hospitals NHS Trust (comprising Lincoln County and Pilgrim Hospitals), 3. University Hospitals of Derby and Burton NHS Foundation Trust, 4. Sherwood Forest Hospitals NHS Foundation Trust (Kings Mill Hospital)
Identifiers required for purposes of creating the database	Support not required for the identification of the cohort, and initial extraction of the dataset, as is undertaken by direct care team. However the following data items will be viewed by researchers whilst modifying the dataset for analysis: 1. Date of birth 2. Date of death 3. Sector level postcode

	4. Gender 5. Ethnicity 6. Pseudo ID For the casenote review (of around 150 patients) researchers will read relevant clinic letters to try and identify the reason for non-adherence to guidance, and will incidentally view confidential patient information whilst undertaking this review. Between the 4 Trusts, there are both electronic and paper records.
Identifiers required for analysis purposes	1. Date of birth modified to age at diagnosis 2. Date of death – modified to survival time in days 3. Sector level postcode 4. Gender 5. Ethnicity 6. Pseudo ID This will be effectively anonymous to the research team. **a.**
Additional information	Only direct care team will have access to the key between pseudo ID and NHS number. No support required for the retention of the key. 's251' support not required in Nottingham University Hospitals NHS Trust, as the researcher is considered direct care team at this Trust.

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 confirm if the feasibility of automating the pseudonymisation to allow direct care team to manage the process, and reduce the amount of 's251' support required has been considered, and provide justification if this is not a practicable alternative.**

The applicant confirmed that owing to time constraints providing NHS clinical care, the direct care team would not be able to pseudonymise information on the research team's behalf, even if using a pre-prepared database. The CAG were content with this response.

2. **Please provide an updated poster which addresses the rectifications requested in this letter. Namely altering the word confidential, altering the description of CAG, and describing the QR code.**

The poster was updated and provided as per CAG advice. The Members were content with the poster provided.

3. **Please clarify if the Trust specific opt out will include the national data opt out, otherwise please confirm that the national data opt out will be applied.**

The applicant confirmed that where the National Data Opt Out is included in the patient record these patients will be excluded from the study. National Cancer Registration Opt Out and hospital specific opt out will also be respected. The Members were content with this explanation.

4. **Please undertake further Patient and Public Involvement with a number of additional cancer patients who are distinct from the funder, to ensure the use of confidential patient information without consent is acceptable to patients and the public.**

The applicants discussed the study with three additional lung cancer patients from the East Midlands. Patients were provided a written summary of DECLINE including what confidential information would be accessed, and replied through an online forum. All patients understood this would involve accessing confidential records without consent, and felt this was justified in the context of the potential benefits of the project. The Committee were content with this response.

5. **Please provide a Favourable Opinion from the REC, as per standard condition of support below.**

The REC favourable opinion was issued on 10 December 2021.

6. **Please provide evidence of NHS Digital review of the 20/21 DSPT for United Lincolnshire Hospitals NHS Trust, as per standard condition of support below.**

The DSPT review was returned to the CAG inbox on 8th June 2022.

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 10 December 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 **University Hospitals of Derby and Burton NHS Foundation Trust, and Sherwood Forest Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 December 2021)

   The NHS Digital **20/21** DSPT review for **United Lincolnshire Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (and by email to CAG inbox 08 June 2022)

b. 22/CAG/0066 - A pragmatic trial of an Artificial intelligence DRiven appOInTment maNagEment SyStem

Name	
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Harvey Marcovitch	CAG Member
Mr David Evans	CAG Member
Mr Umar Sabat	CAG Member
Mr Anthony Kane	CAG Member
Miss Katy Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from London South Bank University set out the purpose of medical research that seeks to investigate whether use of the DrDoctor appointment managing system increases the efficiency of patient appointments without compromising patient outcomes.

Managing out-patient appointments is a challenge to healthcare providers and patients, as missed appointments can lead to missed treatments and wasted capacity. Technology for improving attendance, such as DrDoctor, has been developed. This uses Artificial Intelligence to address the issues. The applicants are seeking to evaluate the efficiency of the DrDoctor technology. The technology has three main elements; a Did-Not-Attend (DNA) system which predicts how likely it is that patients will attend, a linked appointments system, which monitors the impact of appointment changes in one care pathway on other pathways, and a decision support tool which recommends the appointment type and urgency of appointment to clinical staff, based on the patient provided information.

Patients will be sampled from a single intervention site, Nottingham University Hospital Trust and a single comparator site, Imperial College Healthcare NHS Trust London. Participating NHS Trusts will disclose confidential patient information to London South Bank University (LSBU) and held within the UKFAST Secure Cloud Data Storage. Confidential patient information, containing hospital patient ID, will also be disclosed to LSBU from DrDoctor. The DrDoctor data and data from hospital trusts will be combined. LSBU will create a unique identifier and the dataset for analysis will be pseudonymised using this identifier. A separate dataset, containing confidential patient information, will be retained until the data linkages and cross references are complete. There will be three data disclosures, one pre-covid, one pre-deployment of DrDoctor and post-deployment. The two datasets will then be combined, and all items of confidential patient information removed.

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	Patients aged 18 years and over attending renal, ophthalmology, oncology outpatient appointments at Nottingham University Hospital Trust (intervention site) and Imperial College Healthcare NHS Trust (the comparator site). Patients will be eligible for inclusion in the analysis if they enter the service within one of the sampling periods (pre-COVID, pre deployment and 3 months post final deployment). • Pre-COVID = 1st May 2019 • Pre-deployment = 1st May 2022 • Post-deployment = 1st April 2023 The applicants anticipate that 500,000 patients will be included in the cohort where confidential patient information will be processed without consent.
Data sources	1. Patient data supplied by participating trusts 2. Patient data provided by the DrDoctor Patient Engagement Platform,
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID number 3. Date of birth 4. Postcode – District Level
Identifiers required for analysis purposes	1. Postcode – District Level 2. Gender 3. Occupation 4. Ethnicity
Additional information	After data linkage, patients date of birth will be converted to age by year.

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. Details need to be provided on the legal basis under which DrDoctor is operating, taking Article 22 of UK GDPR into account.

The applicant provided a response for DrDoctor, who advised that DrDoctor acts as a data processor. The NHS Trust is the data controller and it is the data controller who needs a legal basis. The Trust would rely under Article 6(1)(e) and Article 9(2)(h) and 9(2)(j) of UK GDPR. In respect to Article 22, this does not apply since neither profiling nor a solely automated decision process is taking place here. The output of this project will supply booking teams with more information, but will not replace the need for human intervention. The CAG noted this information and raised no further queries.

2. Clarify whether confidential patient information is disclosed to DrDoctor as a separate organisation, or whether DrDoctor is software that sits on the systems of participating trusts, meaning that no confidential patient information left the trusts to flow to DrDoctor.

DrDoctor is a service provider to NHS Trusts, in the process of providing the services, DrDoctor will process confidential patient data on behalf of the Trust. However, this is not dissimilar to any other relationship a Trust will have with a tech provider. The CAG noted this information and raised no further queries.

3. If confidential patient information is disclosed to DrDoctor, clarify whether support under s251 is required for this disclosure or whether another legal basis is in place.

DrDoctor advised that support under Section 251 is not required as they will not process confidential patient information. The CAG noted this information and raised no further queries.

4. Patients approached to take part in the survey must also be informed of the use of their data and given the opportunity to remove their information.

The applicants expressed concern that adding this information to the information would potentially confuse and overwhelm participants. The applicants advised that patients who complete the survey will be are advised of the opt-out process in a separate communication.

5. The patient notification materials need to be revised as follows;

a. The timescale for opt-out needs to be made clear and patients informed of the date after which they will no longer be able to opt-out.

b. Further details need to be provided on DrDoctor and the purpose of the research.

c. The statement "The evaluation team (based at London South Bank University) has permission from the Health Research Authority to access your health records" in the Opt-Out adverts needs to be revised and the following wording was suggested, "The application was reviewed by the HRA Confidentiality Advisory Group who recommended to the HRA Decision Maker that support was given under Regulation 5 of the Control of Patient Information Regulations to allow the applicants to process confidential patient information without consent.

The applicants provided a revised Opt-Out Advert.

The CAG agreed that the wording on the Opt-Out Advert regarding the role of the CAG needed further revision and asked that the below wording was included:

The application was reviewed by the Confidentiality Advisory Group (CAG). They are part of the NHS Health Research Authority. CAG recommended that the application to allow the applicants to process confidential patient information without consent is supported. The Department of Health gave their approval. A link to Regulation 5 of the Control of Patient Information Regulations should also be included.

6. Further patient and public involvement needs to be undertaken specifically around the use of confidential patient information without consent and feedback from this provided to the CAG.

Applicants convened another PPI meeting on 17/05/22. The notes and slides from this meeting were provided.

7. Clarify how long confidential patient information will be retained in identifiable form and when the dataset would be anonymised.

Confidential patient data will be anonymised after the post deployment data has been received and merged, based on current implementation timescales for DrDoctor this will be around December 2023

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. The wording on the Opt-Out Advert needed further revision and asked that the below wording was included:

The application was reviewed by the Confidentiality Advisory Group (CAG). They are part of the NHS Health Research Authority. CAG recommended that the application to allow the applicants to process confidential patient information without consent is supported. The Department of Health gave their approval. A link to Regulation 5 of the Control of Patient Information Regulations should also be included.

The revised Opt-Out Advert needs to be provided within one month of the issuing of this outcome letter.

2. Favourable opinion from a Research Ethics Committee. Confirmed: Favourable Opinion issued 01 April 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 reviews for Nottingham University Hospitals NHS Trust, Imperial College Healthcare NHS Trust, ICNH Ltd (DrDoctor) and UFAST were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 June 2022).

1. New Amendments

21/CAG/0085 – The Child Health Clinical Outcome Review Programme (CH-CORP)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘s251’ support for a core methodology of data collection for The Child Health Clinical Outcome Review Programme (CH-CORP). Confidential patient information regarding all eligible cases is disclosed from participating healthcare providers to the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), a sample is selected, and confidential patient information is used to follow-up with clinicians involved in the patients care by way of questionnaire (completed online in pseudonymised format), and relevant copies of

extracts from the patient’s case notes are also disclosed from treating clinicians to NCEPOD. This application also has ‘s251’ support for the described core methodology to be used to undertake the ‘Transition from child to adult services study’.

This amendment sought support for changes to the ‘Transition from child to adult services study’ sub-study only rather than the core methodology overall. The applicant sought support to extend the duration of ‘s251’ support for the sub-study until September 2023. This is an extension of 3 months, as the study has been delayed by the pandemic. The applicant also sought support for the ability to use hard copy questionnaires if they are not able to set up a primary care practice on the online questionnaire system. This is no more disclosive regarding the ‘s251’ support which is already in place. The protocol has been amended to change the word ‘hospital’ to ‘organisation’ as these data are not just from hospitals, and other minor changes have been included in the protocol. An updated data flow diagram has also been provided, to take into the use of paper questionnaires. There are no changes to data sources or flows between organisations. The updated protocol and data flow diagram have been accepted as notifications to CAG.

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 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 **2020/21** DSPT review for **National Confidential Enquiry into Patient Outcome and Death (NCEPOD)** was confirmed as '**Standards Met**' on the NHS Digital DSPT Tracker (checked 07 June 2022)

Due to the number of participating care providers involved it is the responsibility of NCEPOD on behalf of HQIP, as controller, to ensure that all organisations disclosing confidential patient information to NCEPOD meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

22/CAG/0010 – The Integration and Analysis of Data Using ARtificial InTelligence to Improve Patient Outcomes with Thoracic Diseases

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Professor William Bernal	CAG Alternate Vice-Chair

Context

Amendment request

The DART study has 's251' support to allow the disclosure of confidential patient information from participating trusts to the Oxford University Hospitals NHS Foundation Trust, for the purposes of developing an Artificial Intelligence model to aid in the diagnosis of lung cancer in pulmonary nodules identified on CT scans performed as part of the NHSE Lung Cancer Screening Programme.

This amendment sought support to amend the names of participating Trusts in the protocol, as these were initially listed incorrectly. This includes changing the Trust name of Salford Royal Foundation Trust to Northern Care Alliance NHS Foundation Trust, University Hospital of North Staffordshire to University Hospitals of North Midlands NHS Trust, West Yorkshire and Harrogate Cancer Alliance to Bradford Teaching Hospitals NHS Foundation Trust, Bradford District Care NHS Foundation Trust to Bradford Teaching Hospitals NHS Foundation Trust, and NHS Bedfordshire, Luton and Milton Keynes CCG to Luton and Dunstable University Hospital NHS Foundation Trust.

The amendment also sought support for an additional purpose to be included in the DART application, and this is to include the purpose of linking DART data with SCOOT (Sample Collection for the Integration and Analysis of Data Using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases) data. This linkage is undertaken with the consent of the SCOOT trial patients, and therefore 's251' support is not required for the linkage to be undertaken, merely to include this new purpose to the DART application. The amendment request is to combine blood biomarkers with other data to improve algorithms for the early detection and consequent treatment of lung cancer.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Alternate-Vice chair was content to support the amendment, noting that the linkage was clearly stated on the SCOOT PIS.

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 **Oxford University Hospitals NHS Foundation Trust**, and **Oxford University** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 07 June 2022)

Due to the number of participating sites where confidential patient information will be accessed, support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 10/03/2022 (re trust names) & 04/05/2022 (re SCOOT linkage)

19/CAG/0219 - Epidemiology of Pancreatic Cancer Using Longitudinal Electronic Health Record Data

Name	Capacity
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the main applicant access to confidential patient information held within the Cerner Millennium System Business Intelligence tool on site at Barts Health NHS Trust and wider disclosures of confidential patient information from NHS Discovery East London Programme to Queen Mary University of London for linkage.

In this amendment, the applicants are seeking to extend the duration of support by 18 months, until 31 December 2023. This extension is required to accommodate delays caused by the Covid-19 pandemic.

The applicants also seek to include the postcodes of patients' registered GPs. The GP postcode will be used to obtain the Lower Super Output Area (LSOA) of the practice, which will in turn be converted to index of multiple deprivation (IMD) score. The IMD score will then be used in analysis, as it has been identified as a potentially importance associative feature in investigating pancreatic cancer incidence and outcome

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team who agreed that the extension 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 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: Barts CR-UK Centre (BCC) and North East London CCG have confirmed 'Standards Met' assurance on DSPT 2020/21 (confirmed by check of the NHS Digital DSPT tracker on 08 June 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed: Confirmation that REC review was not required for this non-substantial amendment was provided on 17 May 2022.

19/CAG/0162 – Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis

Name	Capacity
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow research paramedics access to confidential patient information on site at participating ambulance Trusts to enable the eligible patient cohort to be identified, the onward disclosure to NHS Digital and access to confidential patient information at participating Trusts by research nurses.

In this amendment, the applicants are seeking to extend the duration of support by 12 months, from 30 June 2022 to 30 June 2023. The applicants' data sharing agreement with NHS Digital will also be extended to 30 June 2023.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the amendment request 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 Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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

Confirmed: The NHS Digital 2020/21 DSPT review for University of Sheffield - School of Health and Related Research, South Warwickshire NHS Foundation Trust, Doncaster & Bassetlaw Hospitals NHS Trust and The Rotherham NHS Foundation Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (confirmed by check of the NHS Digital DSPT tracker 08 June 2022).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed:** Non-Substantial REC amendment, REC review not required.

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

Name	Capacity
Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating GP practices to Public Health England so that eligible patients can be contacted to seek consent for participation in the study.

The original application stated that general practices in the South-West of England, South-West London and Yorkshire and Humber would be recruited. The applicants have received expressions of interest to participant in the study from 23 General Practices, some of which are outside the Yorkshire and Humber CRN. The applicants seek to include the West Yorkshire and Humber Clinical Research Network (CRN) as a data processor to include these additional sites. Adding these sites would increase the likelihood of meeting the applicants target of sending 100,000 invitations to patients.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the amendment 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. Favourable opinion from a Research Ethics Committee. **Confirmed:** Confirmation that REC review was not required for this non-substantial amendment was provided on 17 May 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 review for the University of Bristol and Public Health England were confirmed (confirmed by check of the NHS Digital DSPT tracker on 08 June 2022).

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

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

Context

Amendment request

The amendment sought support for the addition of patient ethnicity to data items, which is not an item of confidential patient information alone. The amendment also sought support for the removal of Rackspace as a data processor, due to Epilepsy12 Audit Data Platform Server migration back into RCPCH own environment. (Microsoft Azure is a sub-processor). The amendment also sought support for a change of physical storage location within the RCPCH for storage of Epilepsy12 files used for data processing and analysis – to the Microsoft Cloud in Microsoft UK data centres based in Cardiff, Durham and London with data back up provided at the Microsoft UK South (London) data centre.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Chair was content with the changes requested.

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, and SysGroup PLC** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 June 2022)

   The NHS Digital **21/22** DSPT reviews for **Microsoft UK** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 June 2022)

19/CAG/0214 – Understanding the scale and nature of avoidable harm in prison healthcare (Phases 2 & 3: Case note review and qualitative interviews)

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

Context

Amendment request

This study from University of Manchester aims to determine the frequency and nature of avoidable patient harm in prison healthcare. There is currently support under the Regulations for researcher access to confidential patient information within electronic and paper-based medical records, managed by a number of healthcare providers delivering services at 17 named prisons in England. This will be the records of approximately 15,000 patients. Pseudonymised information will be extracted into an electronic case report form for analysis. A previous supported amendment is in place for an additional method of remote data collection via a locally agreed protocol with each prison/healthcare provider. This will be possible via the healthcare providers who can arrange access to prison-based records through their wider Trust/organisational secure servers. The study has support in place to access SystmOne patient records.

This amendment sought support for applicants to access SystmOne patient records in an additional format. Currently, live SystmOne patient records are accessed remotely by study nurses and GPs. The amendment is to include the possibility of accessing the 'frozen' SystmOne record (i.e., the record saved in PDF format so that it can viewed on the secure drive without requiring the remote access. This will be for patients from the Enhanced Sample (ES), approximately 7,000 records.

This amendment has been requested as applicants are experiencing ongoing issues with accessing live SystmOne remotely, which is resulting in lost screening time and additional costs to the study. Despite ongoing efforts with the various IT teams to resolve the issues (error messages, being unable to connect, system freezing), the system is still not wholly reliable. The frozen pdf record will still remain on the organisations server, and will not leave that server. There is therefore no change to the ‘s251’ supported data flows.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs’ Action. The Chair recommended support for this amendment. It was commented that the system is being used by the same people as previously supported, and the prison health system certainly has a high 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:

   Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 17 May 2022

21/CAG/0090 – Paediatric Intensive Care Audit Network (Non research application) – PICANet

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

Context

Amendment request

This application has 's251' support to allow the disclosure of confidential patient information from participating English and Welsh PICUs and transport teams to the University of Leeds for the non-research purposes of the national clinical audit of the Paediatric Intensive Care services.

This amendment seeks support to include a new pilot data collection, that mirrors how PICANet currently works, regarding children admitted to seven level 2 paediatric critical care 'PCC' units, (sometimes referred to as 'High Dependency Units") in England to test the feasibility and quality of data collection. PICANet currently only

collects data on children admitted to PICUs, however there are children outside of PICU who receive level 1 or 2 paediatric critical care and data for these children are not nationally captured in a standardised clinical audit. Therefore NHS England has commissioned PICANet to undertake a two-year project to pilot the collection of personal, organisational, and clinical data on children admitted to seven level 2 PCC Units. The units participating in the pilot are; University Hospitals Coventry and Warwickshire NHS Trust, University Hospitals of Derby and Burton NHS Trust, Hull University Teaching Hospitals NHS Trust, Gloucestershire Royal Hospital – Gloucestershire Hospitals NHS Foundation Trust, Liverpool Alder Hey – Alder Hey Children's NHS Foundation Trust, James Cook University Hospital – South Tees Hospitals NHS Foundation Trust, University Hospital Southampton NHS Foundation Trust.

The 'pilot level 2' data collection will mirror the current PICANet methodology, collecting the same items of confidential patient information. There will be a slightly amendment clinical data collection based on the differing types of treatment that are given in level 2 PCCs. The additional items are, for example, observations recorded on admission for the national Paediatric Early Warning Score and interventions that are delivered on Level 2 critical care (which is the expansion that the CAG amendment addresses).

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice Chair was content to recommend support for this amendment request, noting that this is a pilot of bringing some paediatric critical care departments that are not at present designated as PICUs into the PICANet audit. The applicants will be collecting similar data with no change in the identifiers already supported. The Vice Chair commented that this seems appropriate, as many infants are receiving similar care in these PCCs, and is an extension of very valuable work.

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 Confidentiality Advisory Group that the relevant Data Security and Protection

Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

The NHS Digital **20/21** DSPT reviews for **University of Leeds - LASER** (8KM29) and **University of Leicester College of Life Sciences** (EE133832-CMBSP) were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 22 June 2022)

Due to the number of participating PICUs/transport providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs (or CPiPs for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

PIAG 2-07(c)/2004 – Manchester Self-Harm Project

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

Context

Amendment request

The Manchester Self-Harm Project has been running since 1997, and supported by PIAG in 2004. Data collection is ongoing, and the applicants have been seeking amendments to cover the inclusion of new cohorts of patient data to be submitted for mortality follow-up via NHS Digital.

This amendment sought support to include additional cohorts of patients, up to and including people who presented to hospital for self-harm in 2021. Additional mortality follow-up for these individuals is required from NHS Digital.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Vice-Chair was content to recommend support for this amendment, noting that It is an important piece of work for monitoring the care of people who self harm and suicide prevention. However, because of the length of time since the study first received support, no further amendments will be considered without an entire refreshed application. This will ensure that the CAG and the applicant are clear on the scope of 's251' support required for the application, and that all processes are up to date with regards to any changes in information governance since the application was first supported.

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 review for The **University of Manchester – Manchester Self-Harm Project (8D594)** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 13 June 2022)

CAG 7-04(a)/2013– Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The current application has relied on Regulation 5 support since January 2014 to provide a legal basis for GP data and secondary care data (from NHS Digital) to be linked by "approved organisations". Doing so enables GPs to identify at risk patients and allows for targeted interventions to be made as early as possible (risk stratification). NHS England manages the application on behalf of GPs/ Clinical Commissioning Groups (CCGs), who are the data controllers.

This administrative amendment is to meet the requirements of the Health and Care Act 2022, which has resulted in the replacement of Clinical Commissioning Groups (CCGs) with Integrated Care Boards (ICBs). In this amendment, the applicants requested to amend the data controllers from the CCGs listed in the application to ICBs, from 01 July 2022, when CCGs will be replaced by ICBs as new legal entities, taking on the commissioning responsibilities. NHS England will continue to manage the application on behalf of the ICBs/GP's.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair. The Chair was content to recommend support for this administrative amendment, and understood that NHS England would still manage the application on behalf of the ICBs.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending continued 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. This amendment comes into effect from 01 July 2022.

2. The CAG agreed that conditions applied as part of the annual review outcome letter (letter dated 19 May 2022) remain. These conditions are provided below as confirmation.

3. Any request to extend support post 30 September 2022 should be done as part of a revised submission to be considered at a full CAG meeting. The applicants are advised to check the CAG meeting dates and apply in sufficient time to allow an outcome to be issued prior to 30 September 2022, by 31 August 2022 at the latest.

The new application should address the following:

a) Clarity on the scope of support requested, both in terms of dataflows and purposes

b) Clear communication strategy with examples of patent notification materials

c) Detail on how local patient objection mechanisms will be managed, and clarity that the National Data Opt Out will be applied.

d) Evidence that risk stratification suppliers have had DSPT submissions verified by NHS Digital.

e) A comprehensive monitoring plan to ensure local activities remain within the scope of support

f) Detail, with anticipated timescales, of a clear exit strategy from Regulation 5 support

g) Demonstrable evidence of the improved outcomes and benefits that risk stratification has had to date.

h) Consideration whether change in legal entities from CCGs to ICBs impacts risk stratification and how.

1. CAG 7-07(a)/2013 - Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013

2.CAG 7-07(b)/2013 - Invoice validation within Clinical Commissioning Groups (CCGs) Controlled Environment for Finance (CEfF).

3.CAG 7-07(c)/2013 - Invoice validation within NHS England within the Commissioning Support Units Controlled Environment (for Finance) (CEfF) on behalf of Clinical Commissioning Groups

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Amendment request

The current application has relied on Regulation 5 support since November 2013 to provide a legal basis for data to flow to Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs), to enable the correct commissioner to be identified to allow payment for treatment (invoice validation). This application is managed by NHS England, on behalf of the CCGs, who are the data controllers.

This administrative amendment is to meet the requirements of the Health and Care Act 2022, which has resulted in the replacement of Clinical Commissioning Groups (CCGs) with Integrated Care Boards (ICBs). In this amendment, the applicants requested to amend the data controllers from the CCGs listed in the application to ICBs, from 01 July 2022, when CCGs will be replaced by ICBs as new legal entities, taking on the commissioning responsibilities. NHS England will continue to manage the application on behalf of the ICBs.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair. The Chair was content to recommend support for this administrative amendment, and understood that NHS England would still manage the application on behalf of the ICBs.

The CAG advised that the importance of continuing support would provide a clear public benefit in terms of the management of health and care services.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending continued 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. This amendment comes into effect from 01 July 2022.

2. The CAG agreed that conditions applied as part of the annual review outcome letter (letter dated 24 May 2022) remain. These conditions are provided below as confirmation.

3. Provide assurance that the organisations listed in the annual review letter dated 24 May 2022 have had their DSPT submissions assured by NHS Digital.

4. Give an anticipated timeframe for when clarity will be gained on how the change from CCGs to ICBs will impact the invoice validation application.

Following receipt of this information CAG will request a revised application within an agreed timeframe. This revised application should detail the steps to be taken to exit from support, and a timeframe as to when it is expected this will be achieved.

2. Annual Review Approvals

21/CAG/0077 (research)	Prognostic and molecular classification of breast cancer for personalised therapy
CR20/2014 (research)	Caerphilly Ischaemic Heart Disease Study, Speedwell Study Longitudinal Study of Ischaemic Heart Disease, Mortality and Cancer in Christs Hospital School Cohort
17/CAG/0103 (research)	West Midlands Regional Children's Tumour Registry
20/CAG/0151 (non research	NHS Digital and BAD: Dermatology Intervention Service and Clinical Registries
ECC 3-06(m)/2009	Prognostic Factors in Prostate Cancer for Patients treated by Watchful Waiting
16/CAG/0013	A comparison of risk scores in consecutive, unselected chest pain presentations with suspected acute coronary syndrome in the era of high sensitive Troponin
16/CAG/0029	The Empress Study – Cancer diagnosis via emergency presentation: A case-control study
19/CAG/0200	PROFILE Study – Germline genetic profiling: correlation with targeted prostate cancer screening and treatment.
ECC 3-04(k)/2011	UK Surveillance of Primary Congenital Hypothyroidism in Children
CAG 10-08(c)/2014	Intergenerational and lifecourse influences on health and mortality
CAG 1-03(PR2)/2014	1958 National Child Development Study (NCDS)
14/CAG/1006	Millennium Cohort Study (MCS)
18/CAG/0054 (research)	SUMMIT Study: Cancer screening study with or without low dose lung CT to validate a multi-cancer early detection test
17/CAG/0082 (research)	Do specialist cancer services for teenagers and young adults (TYA) add value?
ECC 8-05(d)/2011	Do specialist cancer services for teenagers and young adults (TYA) add value?
21/CAG/0056 (research)	A randomized, controlled trial to assess the clinical utility of a multi-cancer early detection (MCED) test for population screening in the United Kingdom (UK) when added to standard of care
18/CAG/0189 (research)	Helicobacter pylori Screening Study: a randomised stomach cancer prevention trial

16/CAG/0066 (research)	Hospital Alerting Via Electronic Noticeboard (HAVEN)
15/CAG/0123 (research)	aTTom: Adjuvant Tamoxifen Treatment – Offer More? (aTTom) trial
21/CAG/0067 (research)	Derivation and narrow validation of a clinical decision rule for paramedics to triage older adults with a traumatic brain injury
20/CAG/0015 (research)	Clinical outcome modelling of rapid dynamics in acute stroke with joint-detail, remote, body motion analysis
16/CAG/0048 (research)	LATTE: Long term Anastrozole vs Tamoxifen Effects
19/CAG/0196 (research)	Evaluating prescribing safety indicators embedded in computerised clinical decision support software OptimiseRx
20/CAG/0049 (research)	PREDICT Study: RaDaR and UKRR Linked Dataset
18/CAG/0066 (research)	United Kingdom Childhood Cancer Study
PIAG 1-05(j)/2007	A national population-based case-control study of the genetic, environmental and behavioural causes of breast cancer in men
19/CAG/0192 (research)	IgG4-related Orbital Disease (IgG4-ROD): A Surveillance Study
21/CAG/0049 (research)	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)
ECC 3-06(m)/2009	Prognostic Factors in Prostate Cancer for Patients treated by Watchful Waiting

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 and Professor William Bernal		*01 August 2022*
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst, HRA Confidentiality Advisor		*14 July 2022*