Minutes of the meeting of the Confidentiality Advisory Group

19 August 2021 – held via zoom

Present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member
Dr Rachel Knowles	CAG member
Professor Sara Randall	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	**Position (or reason for attending)**
Ms Katy Cassidy	Confidentiality Advisor

Ms Caroline Watchurst	Confidentiality Advisor
Mr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Ms Gemma Oakes	HRA Approvals Specialist (Observer)

1. Introduction, apologies and declarations of interest

Apologies were received from Mr Andrew Melville, Mr Marc Taylor and Mrs Diana Robbins.

2. Support decisions

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **22 July 2021** meeting applications.

3. New applications

a. 21/CAG/0117 – CCP-Cancer UK

Context

Purpose of application

This application from University of Liverpool set out the purpose of medical research that seeks to determine the Covid-1 9 fatality rate within the cancer population and to identify factors associated with poor outcomes from Covid-19 in patients with cancer.

Limited information is currently available on the risks posed by Covid-19 to patients with cancer. The applicants aim to understand the presentation, management and outcomes of cancer patients with Covid-19. The influence of cancer type and treatment will be explored, as well as comparing the outcomes of cancer and non-

cancer patients. The information collected may also help inform practice for future outbreaks and to develop guidelines with regard to the care and management of cancer patients with viruses such as Covid-19 and similar infectious diseases.

The applicants will conduct a prospective observational cohort study to collect a cancer specific dataset from patients enrolled into the ISARIC CCP-UK study (IRAS 126600) study for patients with cancer. The CCP Cancer UK study will be run as a companion study to the ISARIC CCP-UK study. The ISARIC CCP-UK study is described by the applicants as the key national protocol for characterising COVID19 in the UK population. Participants included in the ISARIC CCP-UK study with an accompanying diagnosis of cancer will have additional cancer data provided for the CCP Cancer UK study, from participating research sites. Three tiers of patients are involved in the ISARIC CCP-UK study. Patients in Tier 0 are recruited into ISARIC CCP-UK under the COPI Notice, while patients and Tiers 1 and 2 were consented. Participants on the ISARIC CCP-UK study who fall into the subset of COVID19 patients with a diagnosis of cancer, either through the ISARIC CCP-UK CRF, or through linkage to cancer registries, will be identified and data collection completed by local research teams. Data from linkages will also be carried out with the National Cancer Registration and Analysis Service (NCRAS), the Welsh Cancer Intelligence & Surveillance Unit (WCISU), PHSISD and NICR.

The ISARIC CCP-UK entire cohort data is stored within the Scottish National Safehaven (as part of that study already). The data controller for the study (University of Oxford) have agreed, via Data Sharing Agreement, that this data can be accessed via approved researchers for the purposes of the CCP Cancer UK study.

Researchers at the University of Edinburgh will identify patients within the ISARIC CCP-UK data who have a history of cancer as recorded on the CCP-UK case report forms. The researchers will remove all fields, except for the ISARIC CCP-UK study ID, NHS number, date of birth and sex and will transfer the above data to the University of Liverpool so that the CCP Cancer UK REDCap database can be populated with the patient records of eligible patients. Staff from the local research teams will log into the CCP Cancer UK REDCap database to complete the CCP Cancer UK datasets for their patients, using local medical records. The University of Liverpool will then pseudonymise the data, leaving the ISARIC CCP-UK study ID only, and will send the pseudonymised data to the PHS Scottish National Safe Haven.

The University of Edinburgh will securely transfer all ISARIC CCP-UK patient IDs and NHS numbers to Public Health England for data linkage to the National Cancer Registration and Analysis Service (NCRAS). NCRAS will remove all identifiers apart from the ISARIC CCP-UK study ID and return the pseudonymised dataset to the PHS Scottish National Safe Haven.

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	5000 patients who are recruited into the ISARIC CCP-UK who are identified as having cancer, alongside Covid-19. The applicants note that 20,000 patients are estimated to be eligible, but funding is only is place for the completion of records for 5000 patients.
Data sources	1. University of Oxford 2. NCRAS, held by Public Health England 3. Patient information from trusts contributing to the ISARIC CCP-UK study, input by trust staff into REDCap.
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. CCP-UK study ID
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority to transition the study to support under Regulation 5.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants advised that it is not practicable to seek consent as the majority of patients will be recruited into Tier 0 of the ISARIC CCP-UK study, which is not consented, and the applicants will not have the opportunity to contact patients to seek consent for data collection for the CCP Cancer UK study.

Participants in Tiers 1 and 2 have consented to the collection of sampling and data. The consent forms used to recruit patients to Tiers 1 and 2 of the ISARIC CCP-UK application have been provided.

The applicants also note that they will be collecting data for patients seen from the beginning of the pandemic, and a number of these patients will have been discharged from hospital care or will be deceased.

The applicants provided a response from the ISARIC CCP-UK team, explaining why consent cannot be sought from patients in Tier 0 of that application. The reason given

is the size of the cohort (approximately 214,000 patients), and that 25% of patients would have died since their data was collected.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link the data from the ISARIC CCP-UK dataset to datasets held by the National Cancer Registries, NCRAS, WCISU. This cannot be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

All patients in the CCP Cancer UK study will have been included in the ISARIC CCP-UK study. Participants in ISARIC CCP-UK fall into 3 tiers.

Participants in Tiers 1 and 2 gave consent for data and sample collection. However, the applicants note that not all participants in Tiers 1 and 2 did not initially consent to data sharing. These patients will be excluded from the CCP Cancer UK study. If Tier 1 and 2 participants decide to withdraw or not participate in data sharing, then the ISARIC CCP-UK study team will make the CCP Cancer study team aware of this.

Patients in Tier 0 were not consented to ISARIC CCP-UK. The majority of patients recruited to ISARIC CCP-UK will be in Tier 0. The applicants note that, should patient in Tier 0 become aware of the usage of their data in CCP-UK or CCP Cancer UK, then they can contact the study teams.

The applicants advised that the NHS Digital National Data Out-Out would be applied once it came into force on 30 September 2021 by using the Message Exchange for Social Care and Health (MESH). Any patients identified as having opted-out would be deleted from the CCP Cancer UK database. The recruiting hospital will also be advised that the patient has been withdrawn from the CCP Cancer UK study.

The applicants noted the difficulty in undertaking patient notification via posters and leaflets, as the majority of patients will have been discharged from their tertiary care centre and may no longer be under the care of oncology teams. In consultation with local research teams, the applicants have decided to create a general letter of notification to be placed in CCP Cancer UK patient medical notes at NHS Trusts. This could then be provided to patients who return to their NHS Trusts for ongoing clinical care. The letter would contain email, telephone and postal contact details for patients to register dissent. The applicants explained that, as processing had already begun under the COPI Notice, then the dissent would cover any processing carried out after dissent was registered. The records of dissenting patients would be deleted from the project dataset.

The applicants noted that they were working with the ISARIC CCP-UK team to update their trial website (https://isaric4c.net/) to make information about how patients can dissent more accessible.

A Privacy Notice (https://www.liverpool.ac.uk/legal/data_protection/privacy-notices/ccp-cancer-study)would also be made available on the University of Liverpool website. The applicants noted that, although the document is termed a 'Privacy Notice' it contains study-specific information, including how participants can dissent to their participation in the study via email. The applicants also noted that telephone and postal contact details could be added, if required.

The CAG agreed that the Privacy Notice needed to include a clear explanation of which patients would be included in the research. Members suggested that the Patient and Public Involvement Groups reviewed the Privacy Notice to ensure that the research and who was included was sufficiently clear. The title also needs to be revised to make it clear that this is a patient notification document, rather than a Privacy Notice.

Patient and Public Involvement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants had consulted with the Independent Cancer Patients Voice (ICPV) when designing the study. The protocol was also reviewed by representatives of the ICPV. A letter of support was provided (ICPV - CCP-Cancer Letter of support).

The CAG agreed that it was not clear whether an explicit question around the use of confidential patient information without consent, as proposed in this application, had been asked during patient and public involvement. Members agreed confirmation

needed to be provided that this issue had been discussed. The study had been running for over a year, and the CAG suggested the previous participants were included in the discussion.

Exit strategy

Patients date of birth will be converted to age at admission when input into the Scottish National Data Safehaven. The applicants would then use variables such as time to death, or until other events, to further pseudonymise the data.

The CAG noted that date of birth was included in the list of identifiers provided in Q38. Members requested clarification on when date of birth would be converted to age, and patients date of birth deleted.

The confidential patient information required to facilitate linkage at the University of Edinburgh, the University of Liverpool and NCRAS, would be deleted from the ISARIC CCP-UK study database once the linkage to routinely collected data was complete.

The applicants estimated that the data collection and linkages would be completed by March 2022.

The answer to Q53 stated that research data will be retained for 15 years. Members requested confirmation that this retained dataset did not contain any items of confidential patient information.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Support under Regulation 5 of the Health Service (Control of Patient Information Regulations) 2002 needs to be in place for the ISARIC/WHO Clinical Characterisation Protocol (IRAS 126600), before support for this application comes into effect.

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

3. Provide clarification on when patients' date of birth is converted to age, and when patients date of birth is deleted.

4. Provide confirmation that the research dataset, which would be retained for 15 years, does not contain any items of confidential patient information.

5. Further patient and public involvement needs to be undertaken around the use of confidential patient information without consent, as proposed in this application and feedback provided to the CAG.

6. The Privacy Notice needs to include a clear explanation of which patients are included in the research. The Patient and Public Involvement Groups should review the Privacy Notice to ensure that the research and who is included is sufficiently clear. The title also needs to be revised to make it clear that this is a patient notification document.

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

8. Favourable opinion from REC **Received 11 August 2020**

9. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information (The University of Oxford and the University of Liverpool) is in place once support under Regulation 5 is active.** See below for further details.

b. 21/CAG/0106 - TRIM: What Triage model is safest and most effective for the management of 999 callers with suspected COVID-19? A linked outcome study

Context

Purpose of application

This application from Swansea University set out the purpose of medical research that seeks to determine which ambulance service triage model is safest and most effective for the management of 999 calls with suspected Covid-19.

The COVID-19 epidemic in the UK has caused surges in 999 calls from people concerned about possible coronavirus symptoms including fever and shortness of breath. As an example, the London Ambulance Service has recorded receiving three times its usual number of 999 calls each day for a sustained period. Ambulance Services need to triage calls to determine whether to dispatch a vehicle to conduct a face to face assessment and, if attended, whether the patient needs to be treated in hospital. The triage is key to identifying patients who need to be treated in hospital. Under-triaging may result in patient harm, while over-triaging may result in the unnecessary conveyance of patients to hospital. Different models of triage are used across the UK and there is a lack of evidence on which model of triage works best for patients and the NHS in a pandemic situation.

The applicants have already undertaken a survey of all ambulance services and now seek to use linked-anonymised data to evaluate models used to triage and manage emergency ambulance service care for patients with Covid-19 who call 999 in England. Four ambulance services will be identified, alongside one large general hospital in each services catchment area, apart from the Yorkshire Ambulance Trust, which will be working with two trusts in order to ensure coverage of all age groups.

Two cohorts will be involved, a forwards cohort and a backwards cohort:

For the forwards cohort, the participating hospital trusts will disclose confidential patient information to their linked ambulance service, so that linkage of the hospital and ambulance data can be undertaken. The ambulance trusts will then disclose confidential patient information to NHS Digital for linkage to the Covid-19 Hospitalisation in England Surveillance System (CHESS), ECDS, Civil Registration – Deaths, and HES datasets. A pseudonymised dataset will then be disclosed to the research team at the University of Swansea. Separately, the participating ambulance trusts will transfer pseudonymised data to the research team at the University of Swansea.

For the backwards cohort, participating ambulance service trusts will identify suitable patients and their confidential patient information is disclosed directly to NHS Digital, with no linkage to hospital trust data. A pseudonymised dataset will then be disclosed to the research team at the University of Swansea. Separately, the participating ambulance trusts will transfer pseudonymised data to the research team at the University of Swansea.

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

The applicant had indicated that class 1 support was required. Following discussion, the CAG determined that class 1 support was not needed, as the extraction and anonymisation of information will be undertaken by those considered to be members of the direct care team.

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	Forwards cohort: Patients who made a 999 call classified as suspected COVID-19 by a selected ambulance service, between 01 March 1 2020 and 31 August 2020 Backwards cohort: Patients who were diagnosed with COVID-19 in specified hospitals within the catchment areas of study ambulance services, again between 08 March 2020 and 7 September 2020. The applicants estimate that 80,000 patients will be included.

Data sources	1. Electronic patient records at the 4 participating Ambulance Service Trusts and their partnered Hospital Trust: a. East Midlands Ambulance Service Trust, working with Queen's Medical Centre, Nottingham University Hospital Trust; b. East of England Ambulance Service Trust, working with Norfolk and Norwich University Hospitals NHS Foundation Trust; c. West Midlands Ambulance Service Trust, working with Sandwell and West Birmingham Hospitals NHS Trust d. Yorkshire Ambulance Service Trust, working with Sheffield Teaching Hospitals NHS Foundation Trust and Sheffield Children's NHS Foundation Trust. (Two trusts and needed to ensure coverage across all age groups) 2. The following datasets held by NHS Digital: a. Covid-19 Hospitalisation in England Surveillance System (CHESS) b. Emergency Care Dataset (ECDS) c. Hospital Episode Statistics (HES) d. Civil Registration - Deaths
Identifiers required for linkage purposes	4. Name 5. NHS number 6. Date of birth 7. Postcode – unit level
Identifiers required for analysis purposes	6. Date of birth 7. Date of death 8. Postcode – unit level 9. Gender 10. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Scope

The CAG requested confirmation that the mechanism of backwards linkage was undertaken by members of the direct care team, in order to clarify whether support was needed for this activity.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants advised that the volume of patients involved meant that seeking consent was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link data from the hospital trusts to the ambulance trusts, and for NHS Digital to conduct linkages to the CHESS, ECDS, HES and the Civil Registration – deaths datasets.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A Privacy Notice was provided (TRIM Patient notification Flyer England v0.4 05 08 2021). The applicants advised that the Privacy Notice is intended to be used as a patient notification document and will be placed on the websites of participating ambulance and hospital trusts.

The participating trusts will also publicise the study via their Twitter channels. These communications will include a link to the Patient Information Notice.

The applicants explained that any expressions of dissent will be respected. Participating ambulance and hospital trusts will check patient records for evidence of dissent from use of their data in research and will exclude any patients who have indicated dissent.

NHS Digital will apply the National Data Opt-Out.

The CAG agreed that a separate Privacy Notice and Patient Notification Leaflet needed to be provided. The Patient Notification needed to contain a lay description of the research, including the use of confidential patient information without consent and how patients can dissent, and a link to the Privacy Notice. This needed to be created and provided to the CAG for review within three months of the issuing of this outcome letter.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants advised that the research team included a representative from the SUPER (Service Users for Primary and Emergency care Research), a group of lay members supporting research into ambulances service policy and delivery. A second member of SUPER has been recruited into the Research Management Group for the study. Both have been involved in meetings and have contributed to the study outputs produced so far. Two further patient and public representatives have been recruited to the Study Steering Group.

The research is also supported by a Patient Advisory Panel, who have access to all the study documentation and who meet regularly to review the project.

A member of the Service Users for Primary and Emergency Care Research Group was active in all aspects of bid development, attended Research Development Group meetings, and had the opportunity to comment on all aspects of study design. They are a named co-applicant on the bid, and remains a member of TRIM's Research Management Group. A second PPI member also joined the Research Management Group and chaired TRIM's Patient Advisory Panel. Both PPI members have participated in discussions on the study's methodological approach, and support the principles outlined in this application.

Patient and Public Involvement (PPI) contributors will continue their roles on the Research Management Group, the Study Steering Group, and the Patient Advisory Panel. Each of these groups will meet quarterly until the end of the project.

Several PPI members from the Patient Advisory Panel and the Research Management Group are contributing to the qualitative analysis.

The PPI members of the Research Management Group and the qualitative analysis sub-group will be offered the opportunity to contribute to future papers and be named as authors if they do so.

The CAG requested that the applicant confirm that the use of confidential patient information without consent as proposed in this application had been discussed during patient and public involvement. Feedback from the patient and public involvement confirming this needed to be provided to the CAG within three months of the issuing of this outcome letter.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Confirmation needs to be provided that the mechanism of backwards linkage is undertaken by members of the direct care team.

2. A separate Privacy Notice and Patient Notification Leaflet need to be provided. The Patient Notification needs to contain a lay description of the research, including the use of confidential patient information without consent and how patients can dissent, and a link to the Privacy Notice.

3. Confirm that the use of confidential patient information without consent as proposed in this application had been discussed during patient and public involvement. Feedback from the patient and public involvement confirming this discussion needs to be provided.

4. Responses to the above three conditions need to be provided within three months of the issuing of this outcome letter.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 04 November 2020.**

6. 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.

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.

c. 21/CAG/0116 - UK Covid and gynaecological cancers study

Context

Purpose of application

This application from the Queen Mary University London and Barts Health NHS Trust Joint Research Office set out the purpose of an audit that seeks to evaluate the MDT decision making process for gynaecological cancer patient outcomes across the UK.

50 sites across the UK will participate in the audit. Individual sites will input pseudonymised data into a central REDCap database. The sites are responsible for maintaining a record of audit-specific patient IDs and their corresponding NHS numbers. The participating sites will be able to see data for their patients, while the audit team will only be able to access pseudonymised data from all sites. At the end of the enrolment period, which will run between March 2020 and March 2021, each site will disclose their list of project specific IDs and the corresponding NHS numbers and dates of birth to the audit team at Barts Cancer Centre at Queen Mary University London. The audit team will then disclose the patient NHS numbers and dates of birth to Public Health England for linkage to the National Cancer Registration and Analysis Service (NCRAS) and Hospital Episode Statistics (HES) datasets. A linked dataset will then be sent to the audit team at Barts Cancer Centre. A pseudonymised dataset will be used for analysis. The applicants also seek to undertake long-term follow up of patients in order to analyse long-term outcomes. Annual linkages to the NCRAS and HES datasets will be undertaken, and patients NHS numbers and dates of birth will be retained by the audit team for 5 years to facilitate this follow up.

A recommendation for class 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 discussed at Gynaecological cancer MDTs between March 2020 and March 2021, who have a diagnosis or differential diagnosis, or suspected diagnosis, or gynaecological cancer.
Data sources	4. Participating NHS Trusts 5. NCRAS and HES datasets at Public Health England
Identifiers required for linkage purposes	8. NHS number 9. Date of birth

Identifiers required for analysis purposes	No items of confidential patient information will be retained for analysis.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Scope

The CAG asked that the applicant clarify the list of hospitals in England and Wales who are involved in the study, so that the scope of support sought is clear.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants advised that consent is not feasible due to the size of the cohort. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is required for PHE to link data from the participating sites to NCRAS and HES data.

The applicants advised that it was not possible for sites to disclose confidential patient information directly to Public Health England, rather than to Barts Cancer Centre first, as many sites will not have the resources to undertake this activity. The applicants also noted the possibility that data from a proportion of patients would be lost and that having a centrally co-ordinated effort will ensure data completeness and efficiency. It will also reduce the burden on PHE, as they will have to deal with one dataset, rather than 50 separate submissions. The CAG agreed that the application could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Information will be disseminated through websites, digital and non-digital media sources as well as meetings and conferences. This will be done with the help of all stakeholders, sites, and patient groups, involving the QMUL and other relevant communications teams. Patients who may wish to object or have any queries would be able to contact the study team via email.

A Patient leaflet, Poster and website text were provided (Patient leaflet UKCOGS, Poster UKCOGS v4 and Patient-facing website UKCOGS). Telephone, email and postal contacts were provided for patients who had queries or wanted to opt-out.

The applicants explained that any objections made by patients will be respected. Telephone, email and postal contacts were provided on the patient leaflet, poster and website text for patients who had queries or wanted to opt-out.

The applicants advised that participating trusts would be asked to apply the National Data Opt-Out.

The CAG noted that the patient-facing website did not clearly explain that confidential patient information was used for data linkage. Members suggested that the wording used in the Patient Leaflet, under section ‘What information will you be recording’ was used in the website information.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants advised that UKCOGS is fully supported by the British Gynaecological Cancer Society (BGCS), the Royal College of Obstetricians and Gynaecologists (RCOG) and the National Cancer Research Institute (NCRI), the Gynaecological Cancer Clinical Studies Group and the British Association of Gynaecological Pathologists (BAGP). The applicants have worked closely with the all UK charities and patient support groups working in gynaecological cancer care; Ovacome, The Eve Appeal, Target Ovarian Cancer, Ovarian Cancer Action, Jo’s Cervical Cancer Trust and GO Girls. Letters of support from patient groups were provided. Patient representation was also included on the steering committee.

The CAG requested confirmation that it had been made clear to the patient and public involvement groups who reviewed the application that confidential patient information would be used to undertake the linkages.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Clarify the list of hospitals in England and Wales who are involved in the study.

2. The patient-facing website needs to clearly explain that confidential patient information will be used for data linkage.

3. Confirm that it had been made clear to the patient and public involvement groups who reviewed the application that confidential patient information would be used to undertake the linkages.

4. Responses need to be provided to the above three points within three months of the issuing of this outcome letter.

5. 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.

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.

d. 21/CAG/0105 – Adherence to oral anticoagulants and statins

Context

Purpose of application

This application from the Leeds Teaching Hospitals NHS Foundation Trust set out the purpose of a service evaluation to investigate the real-world rates of non-adherence to direct oral anticoagulants (DOACs) and statins, and to improve the awareness of healthcare professionals on adherence across Leeds.

Atrial Fibrillation (AF) is the most common adult arrhythmia. One of its major complications is ischemic stroke and, therefore, individuals who are at risk are

prescribed an anticoagulant. Evidence shows that oral anticoagulants (OACs) reduce the risk of stroke by over 70%, however non-adherence to these effective therapies can translate to an increased risk of treatment failure, hospitalisations and early mortality. Direct oral anticoagulants (DOACs), which include dabigatran, rivaroxaban and edoxaban, are the most commonly prescribed OACs. According to the 2021 NICE Guidelines, DOACs are the treatment of choice for patients with AF. DOACs have many advantages over warfarin, however, as they do not require routine therapeutic monitoring, the chances of detecting non-adherence is reduced. Previous studies have shown that non-adherence to DOACs was associated with an increased risk for combined all-cause mortality and stroke. Various studies report different levels of self-reported non-adherence to OACs, but it seems to be prevalent and common among patients with atrial fibrillation. One study showed that only 55% of patients reported high level of adherence to OAC. The applicants will calculate the rates of medication adherence/non-adherence using individual repeat prescription data extracted from the two primary care patient records systems, SystmOne and Egton Medical Information Systems (EMIS). Currently, a general estimate of adherence is automatically calculated within the medical records systems, however data are not extractable from the systems. The applicants therefore need to extract confidential patient information, and then calculate the rate externally for each individual patient, to acquire objective information on real-world adherence patterns.

Confidential patient information from GP records, collected as part of routine care and services provided by the practice, will be accessed and extracted by the LTHT Pharmacist, and transferred to Leeds Teaching Hospitals NHS Foundation Trust. Access to primary care systems will be granted by GP Practices on a temporary basis for the extraction. A search has been designed by the Leeds Clinical Commissioning Group (CCG) to identify all potential patients who currently have a repeat prescription for a DOAC or a statin for at least 6 months prior to the date of data extraction and who have not objected to the project or opted-out. The LTHT Pharmacist will pseudonymise the data using OpenPseudonymiser, to ensure that patients cannot be re-identified. The pseudonymised dataset will then be used for analysis.

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

Confidential patient information requested

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

Cohort	The applicants estimate that 7,979 patients who are receiving a DOAC for treatment of AF, and 55,404 patients treated with statins for high cholesterol. Only patients who started treatment with a DOAC or statin within six months of the data of the extraction will be included. The final sample size will only be calculated during the searches performed by CCG staff when extracting the data. The applicants anticipate that a maximum of 63,383 patients will be included, however they note that the actual sample size will be lower.
Data sources	6. Electronic patient data from participating GP practices
Identifiers required for linkage purposes	The applicants advised that no identifiers were required for linkage.
Identifiers required for analysis purposes	11. Strategic report patient ID 12. Lower Layer Super Output area

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available. The CAG agreed that the application had a medical purpose and was in the public interest.

- Feasibility of consent

The applicants advised that consent was impracticable due to the size of the cohort. The GP practices taking part would need to contact patients to seek consent, which would be overly burdensome.

- Use of anonymised/pseudonymised data

The applicants advised that fully anonymised or aggregated data is not suitable as they cannot be used to calculate the Proportion of Days Covered (PDC) and Medication Possession Ratio (MPR).

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster was provided. This will be displayed in GP practices and at Leeds Teaching Hospitals NHS Foundation Trust. A Patient Information Leaflet (Appendix E) will be sent

automatically from the GP records systems via SMS, if patients have a mobile number recorded in their patient records, or by letter if no mobile number is stored. Posts will be made from the Leeds Teaching Hospitals NHS Foundation Trust Twitter and Facebook accounts to target the population of Leeds, and the Trust website will include a page dedicated to the project. This page will host the Patient Information Leaflet and the poster. The applicants are investigating whether this information can also be made available on the Leeds CCG website.

The applicants advised that the GP practices will be responsible for updating their Privacy Notices, if needed, to cover the activities involved in this project. A sample Privacy Notice was provided.

The clinical code for objection will be built into the patient searches and for patients with the code in their medical records, no data will be extracted. The search will be run immediately before data extraction to ensure records are up-to-date.

The Poster and Patient Information Leaflet advise patients to contact their GP to opt-out or register dissent via the NHS App.

A person nominated by each GP Practice at the point of signing Data Sharing Agreements with LTHT will be responsible for including any notifications of objection to the medical records of each and every patient who objects, following the SMS or invite through the post to inform about this project. The nominated person within the Data Quality Team of the CCG, who will perform data extraction will monitor and report the number of patient objections, and make sure any data release has had patient information removed where a type 1 objection has been made.

The CAG noted that the poster did not include a full explanation of the study, but that it was only part of a layered approach. Members asked that a line directing patients to the Patient Information Leaflet was included in the poster. Email, telephone and postal contacts for the study team, for patients who wish to dissent or who have questions, need to be included in the poster and information leaflet.

The patient information materials need to be revised for simplicity and clarity, and revised materials submitted to the CAG.

The CAG agreed that there needed to be a gap of 6 weeks between the publication of patient information materials and the beginning of the data extraction, to allow patients sufficient time to register dissent.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants explained that they had invited the Patient, Carers and Public Involvement (PCPI) Group of LTHT to review all information related to this aspect of the project. Previously, feedback had been sought from this group only around the survey aspect of the study, which is not part of this application. Feedback from this discussion was not yet available but would be provided as soon as possible. The applicants advised that the PCPI Group consisted of patients and carers. Further details on their demographics would be provided with the feedback from the discussion.

The Senior Engagement Officer of the Leeds CCG has also been contacted to provide information of Patient Participation Groups which might have the opportunity to review the same information and provide their views. At this point, a meeting has been set up for 4th August to discuss the activity and agree on a timeframe. A report from this activity will also be sent to CAT upon completion.

The applicants provided a summary of planned activity (Appendix H v2 NIHR BRC) which had been submitted to the NIHR Leeds Biomedical Research Centre (BRC) PPI group. This replaces the planned activity involving VOICE which is referenced in the CAT Advice Form, as VOICE advised that they were unable to take part.

The Group noted the activity that had been undertaken, but that it was unclear whether opinions had been sought specifically around the use of confidential patient information without consent as proposed in this application. Members agreed that further patient and public involvement needed to be carried out around this specific issue and feedback provided to the CAG.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Patient and public involvement needs to be conducted specifically around the use of confidential patient information without consent as proposed in this application. Feedback is to be provided to the CAG.

2. A sentence directing patients to the Patient Information Leaflet needs to be included in the poster. Email, telephone and postal contacts for the study team, for patients who wish to dissent or who have questions, also need to be included in the poster and information leaflet.

3. The patient information materials need to be revised for simplicity and clarity, and revised materials submitted to the CAG.

4. The CAG agreed that there needs to be a gap of 6 weeks between the publication of patient information materials and the beginning of the data extraction, to allow patients sufficient time to register dissent.

5. Responses to the above four conditions need to be provided within three months of the issuing of this outcome letter.

6. 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.

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.

e. 21/CAG/0107 - Wales Cancer Network – hosted by Public Health Wales NHS Trust

Context

Purpose of application

This application from Public Health Wales NHS Trust set out the purpose of a patient survey to measure patients' experiences of cancer care in Wales and to compare the results against two previous surveys.

The Wales Cancer Network (WCN), Macmillan Cancer Support (MCS) and Digital Health and Care Wales (DHCW) will work with NHS Health Boards and Velindre Cancer Centre in Wales. The survey results will be used to support Macmillan Cancer Support, the Welsh Government and Wales Cancers Networks aims of improving the quality and standard of cancer care across Wales.

The survey has been run twice previously, in 2013 and 2016. The methodology is largely consistent with the previous surveys, however in this survey, data from all participating Health Boards and Velindre Cancer Centre will be submitted to DHCW and then transferred centrally from DHCW to Quality Health. Support under s251 is needed for the disclosure of confidential patient information from DHCW to Quality Health, so that Quality Health can extract the sample group and send out the surveys and reminders. Data will be processed on secure SQL servers and made available for analysis. Access to the data is managed by DHCW Data Warehouse team using NHS and SQL Server Security protocols.

Once the activity data has been extracted, the latest demographic data and fact of death will be incorporated from the data held in the national Patient Demographic Service at DCHW before being sent via the NHS Wales' Secure File Sharing Portal to Quality Health. Quality Health will then check and deduplicate the data set. 24 hours before each survey or reminder is sent, DHCW will run a death check using the national Patient Demographic Service and will send a list of deceased patients to Quality Health via the NHS Wales Secure File Sharing Portal. Quality Health will remove these patients from the mailing list before the send-out.

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

<u>Confidential patient information requested</u>

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	Adult inpatients and day case patients, with a histologically confirmed primary diagnosis of cancer, who were admitted to an acute or specialist NHS Hospital in Wales between 1 January 2020 and 31 December 2020.

	Approximately 11,000 patients will be included.
Data sources	7. Participating NHS Health Boards in Wales 8. Patient Demographic Service data held by Digital Health and Care Wales (DHCW)
Identifiers required for linkage purposes	10. NHS Number 11. Name 12. Full address and postcode 13. Sex 14. Ethnic Group 15. Year of birth
Identifiers required for analysis purposes	13. Full address and postcode 14. Sex 15. Ethnic Group 16. Year of birth

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants advised that consent was impracticable as it would be difficult to obtain patient contact details and seek consent without there being a breach in the common law duty of confidentiality. Care has been taken with the invitation letters to state that completion of the survey is voluntary and to advise patients that they can opt-out of receiving reminder letters.

The applicants noted that patients would not be able to make a truly informed choice on whether to take part without seeing the survey. The survey also contained a reminder that participation is voluntary.

- Use of anonymised/pseudonymised data

Staff at Quality Health require access to confidential patient information in order to send out the surveys. DHCW require access to confidential patient information in order to understand the death checks. These activities cannot be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

For the 2016 Wales Cancer Patient Experience Survey, a detailed communications plan was undertaken around the launch of the survey. This involved key stakeholders, Welsh Government, CEOs, MDs, cancer leads, lead cancer nurses and patient experience managers. Social media was used and posters were also produced and placed in high visibility hospital site areas. A similar plan will be run this time around.

For this survey the covering letter, first and second reminder letter, and questionnaire front cover will emphasise that participation in the survey is entirely voluntary. They will provide details about the basis upon which the information will be held and processed and provide details of how to opt out of the survey.

The first and second reminder letter, and questionnaire front cover emphasise that participation in the survey is entirely voluntary. Details are provided about the basis upon which the information will be held and processed and provide details of how to opt out of the survey.

A freephone telephone number was provided, for patients to opt-out of receiving any further reminder letters. The freepost envelope used to return the survey can also be used to register dissent. Patients can also register dissent via the landing page of the online survey and by email.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants held two online consultation events in August and November 2020 with stakeholders, including clinicians, cancer leads, patient experience leads, service users and representatives from cancer charities. An update on the survey progress was given, which included a thorough review of each of the sections within the survey. Feedback was sought on what worked well or what may need to be amended. Findings from these events were written up and used to inform the survey design.

In-depth interviews were also held with cancer patients, including Welsh speakers. Patients were identified via the patient experience lead at Macmillan. The patients were asked to give their views and feedback on the survey, and to share any additional experiences of their care during the pandemic.

Amendments had been made to the survey around the language used to describe healthcare professionals. A free text box, asking for patient experiences during the pandemic, was included.

The applicants provided reports of the work carried out with key stakeholders and patients when developing the questionnaire.

The CAG noted that it was unclear whether the processing of confidential patient information as proposed in this application had been discussed during the patient and

public involvement. The Group asked that confirmation that this issue had been discussed was provided, alongside written feedback from the activities undertaken.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Provide confirmation that the specific issue of the processing of confidential patient information as proposed in the application had been discussed, alongside written feedback from the activities undertaken.

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 **Quality Health Ltd** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker.

The CPIP Out-turn report for 2021/22 for Digital Health and Care Wales is confirmed.

4. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Minutes signed off as accurate via correspondence by Chair Dr Tony Calland MBE and Alternate Vice Chair Dr Murat Soncul	12/10/2021

Signed – Confidentiality Advice Team	Date
KM Cassidy	12/10/2021