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

19 August 2022

Present:

Name	Role	Items
Dr Patrick Coyle	CAG Vice Chair	1a, 2a, 2b, 3a
Dr Malcolm Booth	CAG Member	1a, 3a
Dr Rachel Knowles	CAG Member	2a, 2b
Mr Umar Sabat	CAG Member	2a, 3a
Dr Pauline Lyseight-Jones	CAG Member	1a, 2b

Also in attendance:

Name	Position (or reason for attending)
Mr Will Lyse	HRA Approvals Administrator
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Consideration items – National data opt out exemption request

a. 15/CAG/0158 - The Fracture Liaison Service Database

This is a request to defer the national data opt out for 15/CAG/0158, non-research application. The Healthcare Quality Improvement Partnership (HQIP) commissions the Royal College of Physicians to undertake the fracture liaison service database (FLS-DB), which is part of the Falls and Fragility Fracture Audit Programme (FFFAP).

FLS-DB has been supported since 2015 with consistent submission of annual reviews since that time.

Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with NHS Digital outcome data.

The applicants previously submitted a request in relation to 2 non-research applications, 15/CAG/0158 and CAG 8-03(PR11)2013 (which were provided as two separate outcome letters). 15/CAG/0158 received a 'not supported' outcome as it was felt that the paper submitted mainly related to CAG 8-03(PR11)2013**,** and as such, there was not a clear patient safety argument provided. As the CAG required further information to make a decision on 15/CAG/0158, the applicant was advised to resubmit. This outcome letter relates only to the non-research activities undertaken under CAG reference 15/CAG/0158.

Confidentiality Advisory Group advice

This request was considered by Members with the provided rationale predominantly relying on bias, and technical issues. However CAG agreed that the rationale provided was not sufficient to override patients' objections for their data to be shared for secondary purposes under Regulation 5 support.

1. Deferral rationale: patient safety

Members considered the paper provided by the applicants, which had three central arguments surrounding patient safety.

Firstly, FLS-DB provides a list of patients who are missing information for follow-up. Sites use this list to find and check with patients that they are receiving the right care to protect them from more broken bones. Therefore, if the NDO is applied, many patients would potentially be left untreated for osteoporosis and face a higher risk of fracture.

Secondly, FLS-DB provides site-level benchmarks regarding critical components of care patients should receive after a fragility fracture. Applicants reason that there is a patient safety element surrounding the feedback of care received not being representative of the care actually given, and applicants argue that this process depends on the completeness of data from each site. Applicants state that osteoporosis is common in those with higher rates of social deprivation, and that disproportional exclusion of people from specific ethnic and socioeconomic backgrounds will further limit the audit's ability to monitor and support such patients' continuation with bone strengthening or fall prevention management.

Finally, given that the FFFAP sister audit, the National Hip Fracture Database (NHFD) is exempted from application of the NDO, it will not be possible to track a patients' full journey from hip fracture to secondary care and any potential reduction in a subsequent hip fracture / other fracture if the same patient is to be excluded from the FLS-DB. Applicants argue that application of the NDO has the potential to decrease the evidence base that supports the use of FLSs for osteoporosis management, potentially impacting on the commissioning of services due to data being misrepresentative.

If the applicant had 100% case ascertainment, these arguments would hold more weight. However, the applicant reported that case ascertainment is estimated at **43%**. The applicant explained that case ascertainment for the FLS-DB varies as it is a live audit with patient records being continuously added. Previous case ascertainment has been 37.1% (2019), 32.8% (2020) and 36.2% (2021). Case ascertainment for the FLS-DB is defined as the percentage of patient records submitted to the database compared with the local estimated caseload. The local estimated caseload is calculated using the 'rule of 5' – multiplying the number of patient records submitted for the associated NHFD hospital (of the FLS) by 5 to estimate the total number of fragility fractures in the local population.

With this in mind, that the applicant is already missing approximately **57**% patients annually. Therefore the CAG could not understand how applying the NDO would have any effect, as an additional **6%** of cases missing when the applicant is already missing **57%** of cases, would not appear to cause any exceptional harm to patient safety.

The CAG commented that the issues around inaccuracy of the FLS-DB due to the denominator including patients who opt out in the NHFD sample as the audit has been granted exemption from the NDO whilst the numerator will not include patients who have opted out seems moot, noting that the practice of multiplying the known fractures by 5 has not been justified as evidence based, so appears also to be open to significant inaccuracy.

The Members stated that as the case ascertainment is so low, the arguments that the application of NDO will make a sufficiently great difference to patient safety to justify overriding the patients' expressed wish to opt-out of the use of their data is not made.

Therefore given the lack of evidence and justification on direct impact on patient safety, members agreed that they could not override patient rights to disapply the NDO.

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. Regarding the FLS-DB specifically, the applicant reasons that disproportional exclusion of people from specific ethnic and socioeconomic backgrounds, will limit the audit's ability to monitor and support such patients' continuation with bone strengthening or fall prevention management. The data opt out figures from NHS digital show that 50 to 70 year olds (~6%) opt out at a higher rate than the national average (5.4%). The figures also show that women opt out more often than men, and these individuals are the individuals more highly represented in FLS-DB.

As per the above reasoning surrounding case ascertainment, the CAG were agreed that the bias arguments provided do not hold any weight, because the applicant is already missing **57%** of their cases, and the CAG did not feel that an additional **6%** of missing cases was a good justification.

The Members were therefore not convinced that the NDO would cause an additional significant amount of bias, which was enough to justify overriding patient rights to disapply the NDO.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Given members felt a sufficient rationale as to why patient safety would be impacted by the NDO was not provided, CAG recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request to not be supported.

2.New Precedent Set Review Applications – Research

a. 22/CAG/0110 - Venous Thromboembolism Risk (VTE) Risk after COVID-19 Vaccination

Context

Purpose of application

This application from Shrewsbury and Telford Hospital NHS Trust (with the controller for the activity confirmed to be the same) set out the purpose of medical research which aims to determine whether there is a significant increase in the incidence of blood clots in patients who have received at least 2 doses of the COVID-19 vaccine and who at the same time sustain a hip fracture for which they had surgery.

As there seems to be an increased risk of blood clots in the legs and lungs in patients who have received vaccination for COVID-19, and the established risk of blood clots in patients who sustain hip fractures, the study is aimed at determining if there is a significant increase in the incidence of blood clots in patients who have received at least 2 doses of the COVID-19 vaccine and who at the same time sustain a hip fracture for which they had surgery.

Support is requested to allow the disclosure of confidential patient information from the Shrewsbury and Telford Hospital NHS Trust to NHS Digital for the purpose of obtaining the vaccination status of 200 individuals aged 60 years and over who either, had hip fracture and were operated on between September and November 2021 (those who had not yet been fully vaccinated against COVID), while the next set of 100 patients will be those who sustained hip fractures between February and April 2022 (those that have had the second dose of COVID vaccine). This will be linked to demographic data by NHS Digital via NHS number, and an anonymised dataset provided for analysis.

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

Confidential patient information requested

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

Cohort	200 patients aged 60 years and over. The first set of 100 patients will be selected from patients who had hip fracture and were operated on

	between September and November 2021 (those who had not yet been fully vaccinated against COVID), while the next set of 100 patients will be those who sustained hip fractures between February and April 2022 (those that have had the second dose of COVID vaccine).
Data sources	NHS site NHS medical records NHS Digital National Vaccine Database
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	None

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.

CAG considered that the breach of confidentiality was not currently in the public's interest. Although the applicant received a Favourable Opinion from the Research Ethics Committee (REC), this was because the risk of harm to participants was minimal. The CAG role is to recommend that patients' rights under the common law are removed. There must be a very high possibility that there will be meaningful findings that will benefit patients for this to happen. Following discussion between CAG and REC chairs,

CAG decided that the application as it stood, probably would not produce findings that would benefit patients, so was not sufficiently in the public interest to remove the rights of patients under the common law duty of confidentiality. Therefore, the study is unable to receive support at this time and would therefore have to be deferred.

This is due to concerns noted by the CAG regarding the scientific validity of this study. CAG was concerned that two thirds of the adult population had received 2 doses of COVID vaccine by 18 July 2021. This meant that Group 1 may have contained a significant proportion of fully vaccinated individuals.

Secondly, the Sub-Committee noted that patients who have had COVID infection may be at higher risk. The members noted that the COVID infection was not considered in data collection, nor in estimating the sample size/expected 10-fold difference between groups.

Furthermore, patients with previous deep vein thrombosis or pulmonary embolism (DVT/PE) were at higher risk. The CAG noted that this was not mentioned in the data collection or protocol.

The fact that different vaccines may have different likelihood of clots. The CAG noted that this was not mentioned in analysis.

CAG noted the REC comments that the findings within such a restricted sample size might misinform changes in practice. CAG agreed that it would be worth revisiting the power calculation for the sample size, bearing in mind the factors listed above. Further independent statistical advice should be sought.

The applicant is encouraged to consider the above points in any resubmission.

Scope

The scope of support did not appear to be clear through the application.

The CAG requested clarity regarding what specifically needed support. The CAG assumed that it was the two flows of data – from the Trust to NHS Digital (NHS number) and the return flow (NHS number plus vaccine data); however please could the applicant clarify.

Data Items Collected

The CAG noted that the lists of variables to be collected varies. Within the IRAS form it lists the following: age, sex, NHS number, diagnosis, operation type, weight, height, comorbidities, and length of stay. However, at Q37/38 gender was not ticked as

required for identification or analysis. Furthermore, at Q38 the postcode was required for analysis, however, CAG was unsure why. The applicant is asked to clarify these points.

The CAG noted that within the Protocol, there was a mention of residential status being collected. The applicant is asked to clarify.

The CAG also noted additional data items on page 6 of the protocol which were not mentioned in the IRAS form. These include AMT and prophylaxis for DVT/PE.

Furthermore, the CRF was not provided, and CAG wondered if this had the definitive list of data to be collected.

The applicant is asked to be consistent and clear about the variables being collected, in any resubmission.

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.

- **Minimising flows of identifiable information**

The minimal amount of CPI is being used, as NHS Digital require the NHS number in order to link demographic data to vaccination status. The applicant has confirmed that Q38 of the CAG form was completed in error, and postcode is not required for analysis.

The CAG was not clear on the point at which the dataset would be anonymised.

Please could the research team clarify whether the dataset would be anonymised and that the NHS Number lookup list would be destroyed at the point after vaccine data has been added to the clinical dataset and before analysis by the clinical care team?

'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.

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 patient notification strategy has not been devised to avoid alarming patients that the COVID vaccine could cause blood clots in them. A national data opt-out will apply to this application using the methods described in this link - https://digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out/check-for-national-data-opt-outs-service - after obtaining the NHS numbers of the patients for the study.

The CAG did not agree that a notification would be too distressing for patients and make them concerned that the vaccination could cause blood clots. Therefore, CAG requested the research team to explain the study and allow study specific opt out and apply the National Data Opt-Out.

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.

Three patients, whose data would be used in the study, had been consulted about the use of their data without consent, via a questionnaire. All responded positively to allowing their data to be used. The questionnaire and the responses were enclosed with the application. The research department also plan to organize a more comprehensive questionnaire with at least 10 patients. The CAG were supportive of this approach, as they felt that the PPI group was too small and was misleading, as the survey did not fully describe what the study team proposed to do. It could also be read as these patients agreeing to their data being used. The CAG requested the research team conduct further PPI with a survey that clearly explained the study and with at least 10 patients as proposed.

Exit strategy

Once NHS Digital has added the vaccination status to the patients' demographic data, the NHS number will be removed, and an anonymised dataset provided for analysis.

The CAG raised no concerns regarding the proposed exit strategy.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. To address CAG concerns about the scientific validity of the study, namely:
    i. That Group 1 of the study population may contain a significant proportion of fully vaccinated individuals
    ii. That Covid infection would affect data collection and the sample size required for meaningful results.
    iii. That people with previous deep vein thrombosis and pulmonary embolism were at higher risk, and this had not been considered
    iv. That different vaccines may have different likelihoods of clots, and this should be taken into account during analysis.
    v. That the number of subjects to be included is unlikely to be enough to show a significant difference between the two groups, particularly bearing in mind the factors listed above. Advice should be sought from an independent statistician on this.

2. To provide clarity regarding what specifically needed support. Was this the flows of data from the Trust to NHS Digital (NHS no's) and the return flow (NHS number plus vaccine data)?

3. To clarify whether the dataset would be anonymised and that the NHS Number lookup list would be destroyed at the point after vaccine data has

been added to the clinical dataset and before analysis by the clinical care team.

4. To provide notification materials that explained the study and allowed for a study specific opt out.

5. To conduct further PPI with a survey that clearly explained the study and with at least 10 patients as proposed.

6. To review the protocol and IRAS form and be consistent and clear about the variables being collected and for what purposes.

b. 22/CAG/0119 - Cluster JIA-uveitis research database

Purpose of application

This research application from The University of Manchester sets out the medical purpose which aims to create the CLUSTER JIA-uveitis research database. Applicants require 's251' support to process identifiable clinical trial data from two previously consented trials, APTITUDE and SYCAMORE, in order to identify duplicate participants between the 2 trials, and link the patient's clinical data to their biological data. A 's251' application is required due to the original consent being judged as not sufficient to cover confidential patient information being used in further research.

The MRC funded CLUSTER Consortium is a translational collaborative consortium which aims to pool trial data to create biomarker tests to personalise treatment, find and test new treatments, and predict disease outcomes for childhood arthritis. The SYCAMORE trial was the first large randomized controlled trial (RCT) studying children with JIA-associated uveitis, followed by APTITUDE. It is important that data from these trials are included, to make the best use of data already collected.

The applicants already have a database containing pseudonymised IDs for participants in other JIA registries/studies, however, the applicants no longer plan to link SYCAMORE/APTITUDE trial patients data to other Juvenile Idiopathic Arthritis (JIA) studies as requested in 21/CAG/0124. However, some patients may still have participated in SYCAMORE and APTITUDE, and therefore in order to remove participant duplication in the datasets produced for analysis, the University of Liverpool will disclose NHS numbers and sample IDs for SYCAMORE/APTITUDE trial patients to the University of Manchester. Upon receiving the datasets, the NHS number will be pseudonymised (using the OpenPseudonymiser tool) which will allow the applicants to determine if there are any duplicate participants, matched by the pseudonymised NHS

number. Once duplicates are linked, the original study ID will be removed from the datasets, and participants will be given a CLUSTER specific ID before the data can be analysed. The applicants will also use the datasets to link the clinical data to the corresponding biological samples, using the sample ID. Once linked, the IDs will be replaced with the CLUSTER specific ID.

Researchers wishing to access the data from the CLUSTER database are required to apply to the CLUSTER Data Management Committee (DMC), and the Consortium Management Board (CMB). Only pseudonymous information is shared. Terms of reference have been provided, and the applicant has confirmed that the boards have lay representation.

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

Confidential patient information requested

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

Cohort	All participants in the SYCAMORE (n=90) and APTITUDE (n=22) trials. All participants are children diagnosed with juvenile idiopathic arthritis and active uveitis.
Data sources	1. University of Liverpool: a. APTITUDE dataset b. SYCAMORE dataset 2. University of Manchester: a. Pseudonymised CLUSTER database
Identifiers required for linkage purposes	1. NHS number 2. Sample ID number

Identifiers required for analysis purposes	1. N/A

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 Sub-Committee agreed this activity was in the public interest, noting the condition is one which is serious, and the potential loss of the original consented datasets would be detrimental to addressing research into treatments and improved outcomes for young people with the condition.

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 applicant reasons that consent is not practicable as the SYCAMORE and APTITUDE trials finished a number of years ago and it is likely that participant contact details have changed. The Members accepted the justification provided for not seeking consent, noting this is particularly relevant for a cohort of this age group.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to Identify duplications. Sample ID is also required to link to biological data. This cannot be done in any less disclosive manner, and applicants have minimised the CPI used as far as possible. De-duplication cannot be done without NHS number, and linkage with samples cannot be done without sample ID. The Sub-Committee agreed with this justification.

'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.

The applicant reasons that each clinical trial website currently has a statement regarding re-use of participants' data and both of these sites will be updated to say that data/samples have been shared with CLUSTER and a link to the consortium website. There will be a statement on the CLUSTER website as well.

The applicant has confirmed that the following wording will be placed 1 month before disclosure, as a response to the deferred outcome:

*'The following statement was placed on the LCTC website on **/**/****.*

The CLUSTER consortium (https://www.clusterconsortium.org.uk/) are conducting further research into JIA and JIA-uveitis and have applied for approval to access your NHS number and participant ID in order to access your clinical and biological data that were collected during the SYCAMORE/APTITUDE trial. The Health Research Authority, on advice from the Confidentiality Advisory Group (CAG), has provided support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 in order to provide a legal basis to process confidential information without consent.

This information will be used to identify your participation in and link your data to other JIA studies involved in CLUSTER.

*These data will be shared with CLUSTER on **/**/****.*

If you would like to opt-out of your data being shared with CLUSTER, please contact LCTC (lctcqa@liverpool.ac.uk) on or before this date. After this date, your data will be in the possession of CLUSTER and you should contact the CLUSTER consortium (info@clusterconsortium.org.uk).'

A specific opt out option is therefore provided, 1 month before disclosure. National data opt out will not be applied, as the applicants do not have a mechanism whereby this could be applied as the data is held within University systems. The CAG noted that the above statement implied that once the SYCAMORE/APTITUDE data was disclosed to

CLUSTER, that the patients could still opt out if they wished (‘*. After this date, your data will be in the possession of CLUSTER and you should contact the CLUSTER consortium (info@clusterconsortium.org.uk).’*). The Members therefore assume that this would be possible using the sample ID, or the NHS number if Cluster was contacted prior to the deletion of this identifier. Otherwise the applicant is advised to change the statement to ensure it is clear that opt out after the disclosure may not be possible.

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 attended a CLUSTER Champions meeting December 8th, 2020. There are 7 members of the Champions group who are a mix of patients who have JIA/JIA-uveitis and parents of children with JIA/JIA-uveitis. A supportive letter has been provided from The CLUSTER Champions (Parent and Patient network within the CLUSTER study), however it references pseudonymised information. On querying during review of 21/CAG/0124, the applicant confirmed that patients supported the use of identifiable information without consent, in order to de-duplicate. There is also support from charities such as Olivia’s vision, and versus arthritis.

The Sub-Committee were content with the patient and public involvement undertaken, noting that CLUSTER Champions have been consulted appropriately for the original application and were supportive.

Exit strategy

Once NHS number is pseudonymised and deleted, and the study ID is deleted, and replaced with pseudonymous CLUSTER ID, support no longer required. The NHS number will be deleted as soon as it is run through the open pseudonymiser tool.

The sample ID will be retained until June 2044 (CLUSTER ends in June 2024, and required to keep this for 20 years post). Applicants need to retain the ID as future analyses using CLUSTER data or research audits may need to confirm which biological samples match which clinical data. Support required until this timepoint. The Sub-committee were content with this exit strategy, noting it seems appropriate for a research database.

Data access

Researchers wishing to access the data from the CLUSTER database are required to apply to the CLUSTER Data Management Committee (DMC), and the Consortium Management Board (CMB). Only pseudonymous information is shared. Terms of reference have been provided, and the applicant has confirmed that the boards have

lay representation. The CAG were content with the way that data access would be managed.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 01 September 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 **21/22** DSPT reviews for **University of Liverpool and University of Manchester** were confirmed as 'Standards Met' by email to the CAG inbox (checked 08 September 2022)

3.New Precedent Set Review Applications – Non-Research

a. 22/CAG/0115 - Evaluation of ocular and systemic outcomes after treatment of ocular melanoma and other ocular tumours

Purpose of application

This non-research application submitted by Liverpool University Hospitals NHS Foundation Trust sets out the purpose of obtaining death notification data about patients with ocular cancers treated at the Trust, in order to audit local treatment outcomes, prognosis and mortality from the disease or other causes. The data will also be used for service evaluation such as ongoing Liverpool Uveal Melanoma Prognosticator Online (LUMPO) refinement and validation, as well as understanding the timing and nature of metastatic disease to enable clarification of screening practices. Further collaborative projects with other ocular oncology centres as well as medical oncologists may happen in the future, but any amendments to the purposes of this study will be confirmed via amendment, or new application to CAG.

Participants records were previously 'flagged' with the ONS, under a study reference MR572, which is no longer running. ONS, and more recently, NHS Digital, notified Royal Liverpool University Hospitals NHS Foundation Trust of participants' deaths (date and cause) and cancer events when they occurred. This has been completed for patients prior to September 2018. The applicant now requires 's251' in order to progress this activity for patients post September 2018.

The most common primary intraocular malignancy is uveal melanoma, with an incidence of about 7 per million per year. The chances of dying of metastatic disease within ten years increase with large tumour size, epithelioid cell type, and old age, ranging from 5% - 70%. Liverpool Ocular Oncology Service was designated a supra-regional centre in April 1997. As a specialised service there is a need to evaluate ocular and systemic outcomes after treatment of ocular melanoma and other ocular tumours as part of this service evaluation. In addition, service evaluation reports in parallel to new revised uveal melanoma guidelines will be produced to enable improvements in patient care. Regular meetings are also held with patient support groups such as Ocumel to enable such groups to better understand treatment options and outcomes.

In this application, the applicant at Liverpool University Hospitals NHS Foundation Trust will send confidential patient information to NHS Digital for all patients with ocular cancers, who have been treated at Liverpool University Hospitals NHS Trust after September 2018. This would be for approximately 250-300 patients a year, and the applicant would sent these extracts twice a year. NHS Digital would then flag these individuals, and send back linked mortality data once a month, for any deceased patients. The applicant will delete confidential patient information received 12 months after receiving it for each individual, however 's251' support will be required in an ongoing fashion for future flagging and linkages.

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 with ocular cancers, who have been treated at Liverpool University Hospitals NHS Trust after September 2018 Approximately 250-300 patients per year would be flagged to NHS Digital who would link the data and return only deceased patient information.
Data sources	1. Clinical databases at Liverpool Trust 2. NHS Digital; ONS Mortality Dataset
Identifiers required for linkage purposes	3. NHS number 4. Date of Birth Applicant has now confirmed minimum required with NHS Digital, and this is provided in separate correspondence from NHS D.
Identifiers required for analysis purposes	2. Date of death 3. Cause of death (not directly identifiable) (confirmed as part of further queries via email)
Additional information	NHS Digital provide linked outcome data back to the applicant monthly, for only deceased patients. Applicant will provide an update of the cohort for flagging to NHS Digital twice annually, in an ongoing fashion.

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 were agreed that the activity was an appropriate medical purpose which 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 applicant reasoned that consent is not practicable due to the fact this is a death notification service from NHS Digital. However support is also required for confidential patient information about the entire alive cohort of patients to be disclosed to NHS Digital, in order that they can flag the correct patients, and provide mortality notifications. Therefore the applicant was asked as part of the initial queries to justify why it is not practicable to gain consent the entire cohort prior to death. The justification provided is that it would not be practicable to gain consent from everyone at the correct time in clinic, as actually a lot of their patients are potentially seeing clinicians for a sight issue that does not have anything to do with an ocular tumour, and they would not be known to be eligible at this stage. They also need the entire cohort for the results to be meaningful. They also have mentioned that they do not want to further distress patients with this diagnosis.

The Members accepted this justification regarding not consenting retrospective patients. However they did not consider that enough justification had been provided regarding prospective patients who could be consented as they are diagnosed. The avoidance of further distress argument is not accepted by CAG, as patients are often very willing to have this sort of information gathered for their benefit and for the benefit of future patients. The Members noted that it is possible arguments surrounding burdening the clinical teams could be made, but they have not been made as part of

the application, and therefore more justification for not seeking consent prospectively should be requested from the applicant prior to ‘s251’ support being provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage to mortality outcomes. Full date of death required for analysis. It is not possible to undertake linkage to mortality outcomes without some confidential patient information, and the members accepted this justification.

Justification of identifiers/data flow diagram

It is clear that only NHS number and DoB are needed for linkage, as confirmed by NHS Digital. The long list of identifiers in the data flow diagram are therefore not justified. the data flow diagram also does not list the organisations between which data is flowing. The members therefore requested an updated data flow diagram to match the information provided by NHS Digital, and to make clear between which organisations data is flowing.

‘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.

The applicant did not provide any patient notification with the application. As a response to queries, the applicant has responded with the Trust privacy notice. The applicant has not provided any opt out mechanism, either application specific or the National Data Opt Out (NDO). Although the applicant has responded to queries stating the link to the NDO is in the privacy notice, they have not provided specific confirmation that it will be applied to the dataset they are disclosing to NHS Digital.

The Members agreed that not seeking consent makes patient notification very important, and therefore were in agreement that the applicant is required to develop an application specific notification. The Trust privacy notice is not relevant to this application, as it is designed for a different purpose, and the processing that this

application is undertaking, with ‘s251’ as a legal basis under common law, is not described. The applicant must design a patient notification mechanism, for the retrospective group, and include the prospective group if you can justify not using consent. The CAG noted that clinic posters would be ideal, as this application is only a single centre, and possibly only a single waiting room.

As part of this patient notification, a project specific opt out mechanism should be developed, and how to opt out must be included on the notification.

The Applicant is required to confirm that the NDO will be applied prior to data being sent to NHS Digital.

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 applicant has stated that they closely collaborate with the patient support group OCUMEL, and will be in consultation with this group regarding the use of confidential patient information without consent.

The Sub-Committee were agreed that feedback was required from the patient group regarding the use of confidential patient information without consent, before support can be recommended. The applicant will also need to detail what OCUMEL stands for, and describe how many people were approached, and who these people were – ie. are they representative of the cohort? It should be made clear what information was provided to the patient and public involvement group, and patient comments and feedback should be provided to CAG.

Exit strategy

The data received for each deceased individual will be held for no longer than 12 months. The applicant has confirmed that full date of death will be deleted at 12 months after that data was received. However, NHS Digital will retain the flags in an ongoing fashion, and ‘s251 ’support is therefore required in an ongoing manner for the applicant to continue to receive mortality updates, and for the applicant to continue to update NHS Digital with new individuals in the cohort, which happens twice annually.

‘s251’ support will be provided for 5 years, and a duration amendment will be required at that time for support to continue, to ensure the application still meets current information governance legistaltion.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, within one month.

Request for further information

1. Please provide clear justification as to why it would not be practicable to seek consent for patients who will be included prospectively.

2. Please provide a new data flow diagram updating the data items for linkage and making it clear which organisations data is flowing between.

3. Please develop a patient notification which includes an application specific opt out option (for example a clinic poster)

4. Please confirm that the national Data Opt Out will be applied to the dataset prior to sending to NHS Digital.

5. Please provide feedback from patients and the public regarding the use of confidential patient information without consent.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. ‘s251’ support provided for five years in the first instance. An amendment will be required at that time to extend the duration of ‘s251’ support if required.

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 **21/22** DSPT reviews for Liverpool University Hospitals NHS Foundation Trust and NHS Digital were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 31 August 2022

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Patrick Coyle, CAG Vice-Chair		*22 September 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*22 September 2022*