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

26 January 2017

Due to volume of business at this meeting, these two items were considered via sub-committee review by agreement of the acting Chairs.

Application title: Risk factors for influenza-related complications in children

Cag reference: 17/CAG/0009

Member	
Dr William Bernal	
Dr Patrick Coyle	Vice-Chair
Dr Katie Harron	
Mr Anthony Kane	Lay
Ms Kim Kingan	

Purpose of application

This application from the University of Oxford set out the purpose of a study that aims to find out which children are more likely to develop further complications if they get flu or a flu-like illness. During the 2009/10 swine flu pandemic the public were advised to avoid their GP and seek advice from the National Pandemic Flu Service (NPFS). The NPFS kept records of which parents and children sought advice regarding flu or flu-like illness. The NPFS did not collect information regarding which children went on to develop further complications or required hospitalisation.

While the University of Oxford is not intending to receive identifiable information, the study would involve two different organisations processing identifiable information held or received to achieve this purpose. Support was therefore requested to provide a legal basis, in order to mitigate against a breach of confidentiality, to enable the processing of the relevant information by the two legal entities for this purpose.

A recommendation for class 1 and 6 support was requested to cover the following:

The NPFS will identify records of children who were assessed during the 2009/10 swine flu pandemic. Information from the NPFS records will then be linked to information from children's GP surgery records by NHS Digital.

Confidential patient information requested

The cohort is anticipated to be approximately 20,000 children aged 0-18 years old who had flu or a flu-like illness during the 2009/10 swine flu pandemic for which they or their parents sought advice from the National Pandemic Flu Service (NPFS). The NPFS will extract the name, address, postcode, date of birth and gender, and transfer to NHS Digital. NHS Digital will use this information to trace their NHS numbers and link the NPFS service to their GP record.

The identifiers will be removed once the two datasets are linked and the research team at the University of Oxford will not receive or access any confidential patient information.

Confidentiality Advisory Group advice

Public interest

Members agreed the application demonstrated a clear medical purpose and was seeking to identify lessons to be learned through a sample of 20,000 children and young persons who presented to the NPFS to improve future treatments and outcomes. The potential benefits were described in detail and appeared to be significant and justify the level of intrusion necessitated in the application. Members also agreed that the proposal had the potential to improve the management of children in a future influenza pandemic.

Practicable alternatives

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

- Feasibility of consent

The research team listed a number of reasons why they felt it would not be practicable to seek consent. These included highlighting that as six years had passed since the swine flu pandemic the contact details of some parents/children will have changed. Data may have been incorrectly entered by NPFS as at the time there were no quality checks carried out due to the pressurised circumstances. Additionally, the NPFS did not collect GP information from individuals and many parents/children may not recall the specific details regarding the illness/episodes of the time which may lead them to not respond to request for consent. Finally, children may well have been otherwise healthy and may not have had any regular contact with healthcare professionals which would result in them being unable to be traced.

Members agreed that for the reasons given above that consent would not be proportionately feasible given the large numbers and the fact that this cohort is from a pandemic many years ago.

- Use of anonymised/pseudonymised data

Members agreed that the processing of identifiers appeared appropriate and necessary to undertake the linkages and noted the activity would entail a single data extraction that will be retained for less than three months.

Patient and Public involvement

The application stated that there are three patient representatives interested in being involved in the delivery of the study and it is anticipated their role will be to initiate wider engagement with other patient representatives from relevant groups. They will also be involved in assisting with writing lay summaries and to help disseminate the research findings. 18 patient representatives (parents of children within the target range) were involved in advising regarding the acceptability of using patient identifiable data without consent and it was stated they were fully supportive of the study and particularly reassured that NHS Digital would be performing the data linkages and removing all patient identifiers once the linkages had been completed. The patient representatives felt that the findings of the project could considerably improve the lives of young patients in the future.

Members noted that efforts had been specified to engage suitable patient involvement and it appeared that the patient and public involvement was reasonable in this context.

Patient notification

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.
Members noted that patient information and objection specific to this project was a potentially difficult issue given that the pandemic was some years ago and it is difficult to identify a specific method of targeting information to this group. It was noted that the activity is relying on the CPRD information and method of dealing with objection. Members agreed that this was probably the best available mechanism in these circumstances.

Research Ethics committee requirement.

It is a statutory requirement, when seeking support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent, that the research be approved by a research ethics committee.

The email provided by the sponsor was noted in addition to reference to guidance produced by the HRA that states that where information is not identifiable to the research then generally it does not require ethical review. Members clarified that while the information to be processed is not identifiable to the research team, there is processing taking place on identifiable information for the purpose of this activity, without consent. This involves a breach of confidence. In order to allow these entities to process identifiable information for this purpose, they need to have a legal basis. The purpose of submitting this application is to seek support for this legal basis to be put in place for the NFPS and the CPRD (via NHS Digital).

It is therefore advised that an application should be submitted to the Research Ethics Service as soon as possible, providing a copy of this letter as part of the submission, and a favourable ethical opinion obtained against the application submitted to the CAG. Please ensure a copy of the favourable ethical opinion is provided to the CAG when available in order to reach final approval, as support is not yet currently in effect.

Leading on from this, the issue of this guidance has been raised with the Guidance & Advice team within the HRA and they have agreed to assess where it could be made clearer, at this location, that ethical review is a statutory requirement when undertaking a research activity without consent where seeking support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002.

Additional points:

Members noted there appeared to be an error in the IRAS form where it indicates that no children are included, but the assumption was that this was a typographical error. It was also noted there were some discrepancies in specifying the sample size within the IRAS form and protocol, and this should be updated.

Confirmation of data controller.

A previous response provided in an advice form indicated that Public Health England was the data controller. However, this position did not appear to be evidenced within the application as the application form had not been signed off by Public Health England. The assumption is that the University of Oxford is the data controller, as the NFPS and NHS Digital (via CPRD) are processing their respective information based on the requirements set out by the University of Oxford. If Public Health England is confirmed to be the data controller, a letter should be supplied from PHE that sets out their agreement to the detail contained within the information and that they take

responsibility for the respective processing of identifiable information. Otherwise please review the processing relationships and provide a written response to confirm the correct bodies.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending provisional support to the Health Research Authority, subject to receiving satisfactory responses/evidence to the request for clarification and evidence of compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please ensure evidence to demonstrate compliance with the specific conditions of support are provided back to the CAG. Once received, a final approval outcome to process confidential patient information without consent can be issued.

Specific conditions of support

1. Assessment and written confirmation of the appropriate data controller and data processor relationships/entities within the context of the Data Protection Act 1998 and specifically within the context of the application.

2. Favourable opinion from a Research Ethics Committee. **Pending. Please ensure this letter is provided as part of the submission to the REC.** Submission to the REC is detailed on the HRA website.

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Pending.**

There is a published satisfactory version 13 IG Toolkit for NHS Digital. The relevant legal entity responsible for the National Pandemic Flu Service should provide evidence through the published IG Toolkit website that their submission has been reviewed as satisfactory**. Pending for the NFPS.**

Application title: **The UK National Registry of Childhood Tumours Epidemiological Study Database**

CAG reference: **17/CAG/0010**

Reviewers:

Name	Capacity
Ms Sophie Brannan	
Dr Tony Calland	Vice-Chair
Dr Lorna Fraser	
Mr Andrew Melville	Lay

Purpose of application

This research application from University of Oxford provided the following information. The UK National Registry of Childhood Tumours (NRCT) database was built up over several decades by the Childhood Cancer Research Group of the University of Oxford, and combined the administrative function as the UK cancer registry for childhood tumours with use for research into associations and risk factors for childhood cancers. The Registry function was transferred to Public Health England (for England), ISD Scotland (for Scotland) and the equivalent bodies for Wales and Northern Ireland, in April 2013. The Childhood Cancer Research Group closed in March 2014.

Previously, this activity used to operate under Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002 from 2002 – 2013 and reporting was undertaken under the overarching umbrella of the UKACR. However, since transfer of the relevant registries from April 2013, the legal basis needed to be clearly put in place for continued processing. Pre-application advice was provided in 2015. It was subsequently explained that the delay in submitting an application was due to CCRG staff illness at the time of database transfer (hence approvals not addressed at the time), limited resources subsequently available and prolonged negotiations with the Office for National Statistics over mortality data held in the dataset.

It was stated that a legacy copy of the NRCT database was transferred within the University to the Richard Doll Centenary Archive (RDCA) of the Nuffield Department of Population Health, and is currently held in the Cancer Epidemiology Unit. The application indicated the database had been approved in 2012 by NRES Committee South Central- Oxford B as a Research Database (ref 12/SC/0532). Specific updates had not been provided to the CAG or its predecessor body.

The cover letter confirmed that the database includes data collected in the 1960s onwards, under the regulatory requirements of the times. With the closure of the CCRG, the applicant has been unable to locate all documentation for all of the earlier approvals. The

documentation stated that the ONS agreed (August 2015) that they will act on the basis that approvals were valid at the time for collection and use of data provided by them (mortality, birth records).

A recommendation for class 2, 5 and 6 support, under Regulation 5, was requested to enable the existing data held in the NRCT database to be retained and established as a research database under a clear legal basis and utilised under the new custodianship of the database. The database was built up over several decades and is to be used to provide de-identified information to researchers for use in approved, by the Data Access Oversight Committee, studies.

Confidential patient information requested

The following was specified.

- Identifiers requested to be held on the database: Initials, full name, address, NHS Number, date/year of birth, date of death, postcode (unit level), gender, ethnicity and occupation.
- Identifiers required for validation/linkage: Name, NHS Number, date of birth, date of death, postcode (unit level), grid references and derived address point/codepoint references.
- Identifiers required for analysis: Name, date of birth, date of death, postcode (unit level), grid references and derived address point/codepoint references, gender, ethnicity, occupation.

It was clarified for research analyses that de-identified analysis datasets are produced and researchers will not be provided with access to identifiable data.

Confidentiality Advisory Group advice

It was noted that detailed pre-application advice had been provided in June 2015, and this application had built upon this advice in the form of a final submission.

Public interest

Members agreed this application entailed a clear medical purpose and could be a potentially valuable source of nearly 100,000 children with cancer diagnosed in the UK. However, members advised that they were unable to clearly locate an example of 'good' work in the form of a publication, medical advance or research. The expectation from members was that examples should be provided of any public benefits that had arisen in the past that had utilised this dataset. Members agreed that provision of examples of past public benefits would provide a strong justification to assist in determining the value of continued retention of the dataset, considering the scope of data processed without consent.

Practicable alternatives

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

- Feasibility of consent

Members noted that consent was not previously obtained from the 98,000 children with cancer. In noting the applicant view that it would be both impractical and undesirable to seek to re-contact survivors and bereaved patients, members agreed that it would not be practicable to seek consent in relation to those children who had been diagnosed with cancer.

- Reduced identifiability/alternative approach

In following on from their discussions in relation to the public interest, members noted that they would like to have a greater understanding of the public benefits that have arisen from use of this database first, before considering this aspect. In particular, the CAG requested information about the use of the database before it ceased and an estimate of the expected usage in the future.

It was also suggested that there may be a practicable alternative through utilisation of the databases held by Pubic Health England (PHE) and those available in the Devolved Administrations.

Members noted there are several cancer registries which exist independently from the national PHE cancer registration system. They exist because they tend to contain more detailed data than is collected by PHE. However members were not clear, in the context of the NCRT, in relation to the children with cancer in their dataset, what is different to the data held by PHE (PHE data is also continuing whereas the NRCT holds complete data up to 2010). Noting that the NCRT holds full UK data it was suggested researchers could obtain the data from all four nations if necessary. Members therefore requested a more convincing argument for retaining a second copy of identifiable data that is held in a different location from PHE.

<u>Scope and future linkages</u>

Members identified that they were being asked to recommend support for the continued retention of the identifiable data on the cases with cancer. It was noted that data on controls had been obtained from publicly available sources. Members advised that continued processing of data held on control children was currently out of its scope, on the basis that the original data collection originated from publicly available sources and would not have been covered under Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002 as the control cohort would not have been diagnosed with cancer.

The application indicated there was potential for future linkages such as follow-up of vital status and health of existing participants. Members advised that should there be the intention to undertake additional linkages with data held on children with cancer, and processing of the control data, this would need to be reassessed once the proposed datasets are clearly listed and a clear rationale provided via future amendment or extended application.

Members therefore sought clarity on whether support was requested for the continued holding of the information, or whether additional linkages and additional data would be received and/or linked so that the database would evolve in future. If the latter, it was

advised this would need to be considered separately once the original application had reached its final conclusion.

Justification of identifiers

Members noted that there were a large amount of identifiers proposed to be held within the database. The general principle advocated by the CAG is that there should be separation of identifiable and clinical data. While it appeared that the applicants were sensitive to the issues of small numbers when considering onwards disclosure of identifiable information, members requested that there be specific consideration of separating identifiers, and requested feedback on this aspect.

Patient notification

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members identified that given the historical nature of the dataset posed some challenges in achieving this principle. It was noted there was a website but it was unclear how any patient or carer would know this is available or how they could be directed to that web page. A leaflet regarding registration was provided but it was not clear to members how current the leaflet was (it appeared to be produced in 2006) and did not refer to the historic nature of the database. Members expressed the opinion that they would wish to see more up to date 'patient notification' materials on both the website and links with relevant organisations (including their websites) so that information is more available to patients and so there is a specific point of contact to enable them to object to the use of their data within this database. Members also advised it would be better to provide a clear method of contact, rather than referring only to the GP, so if participants wish they can make direct contact to advise if they want their details to be removed. Consideration of these issues was requested, in addition to provision of a clear plan that would enable these objectives to be achieved.

Patient and user involvement

Members noted the information provided and were of the opinion it appeared to be fairly minimal up to this point. Members agreed that they would welcome reference to at least some additional lay participation in how the database may be used. A request was made for a plan that would enable this objective to be achieved.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and they were supportive in principle, however further information would be required before confirming this position and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarifications and compliance with the provisional specific and standard conditions of support as set out below.

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

Request for further information

1. Examples should be provided of any public benefits that had arisen in the past that had utilised this dataset. Members agreed that provision of examples of past public benefits would provide a strong justification to assist in determining the value of continued retention of the dataset, considering the scope of data processed without consent.

2. It was suggested that there may be a practicable alternative through utilisation of the databases held by PHE and those available in the Devolved Administrations. Information should be provided about the use of the database before it ceased, and an estimate of the expected usage in the future.

3. Members requested a more persuasive argument for retaining a second copy of identifiable data that is held in a different location from PHE, in light of the advice and context above.

4. Members sought clarity on whether support was requested for the continued holding of the information, or whether additional linkages and additional data would be received and/or linked so that the database would evolve in future

    a. Should there be the intention to undertake additional linkages with data held on children with cancer, and processing of the control data, this would need to be reassessed once the proposed datasets are clearly listed and a clear rationale provided via future amendment or extended application.

5. Consideration of the feasibility of separating identifiable and clinical information held on the database.

6. Feedback on providing more up to date 'patient notification' materials in line with the advice provided above with improved method of making contact, or plan to set out how this will be achieved.

7. Consideration of improved lay representation/plan for achievement

Once received the information will be reviewed by the sub-committee of members in the first instance and a recommendation 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, the HRA will confirm approval to process confidential information is in effect through issuing a final approval letter.

Specific conditions of support (provisional)

1. Support applies only to the continued holding and retention of data collected on those children diagnosed with cancer. Additional linkages and information on the control cohort is currently excluded without further detailed rationale.

2. Support extends only to relevant information generated within England and Wales.

3. All research applications seeking support under Regulation 5 of these Regulations must provide evidence of a favourable ethical opinion from a Research Ethics Committee. **Received 04 February 2017**

4. Confirmation from the Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Cancer Epidemiological Unit (Oxford University) v13 reviewed grade published as satisfactory**