Health Research Authority

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

April 2019

Present:

Name	Capacity	Items
Dr Tony Calland MBE	Chair	1.a, 1.b, 1.c.
Dr Lilianne Field	CAG Member	1.a, 1.c.
Mr Myer Glickman	CAG Member	1.b., 1.c.
Dr Simon Kolstoe	CAG Member	1.a.
Ms Diana Robbins	CAG Lay Member	1.b.

Also in attendance:

Name	Position (or reason for attending)
Miss Katy Cassidy	Confidentiality Advisor, HRA
Miss Kathryn Murray	Senior Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 19/CAG/0061 – Salford Kidney Study

Context

Purpose of application

This application from Salford Royal NHS Foundation Trust set out the purpose of medical research which aims to follow-up historic deceased participants of the CRISIS study to establish a cause of death.

The CRISIS study was a consented longitudinal study, which merged along with other kidney-based research projects, into the Salford Kidney Study. At this stage, patients were re-consented to their ongoing involvement in the refreshed project. However, there were a small number of patients who were originally recruited to the CRISIS study that were deceased at this stage for whom cause of death has not been recorded. This application has been submitted to seek support under the Regulations to legitimate the disclosure of confidential patient information from the Salford Royal

NHS Foundation Trust to NHS Digital to facilitate linkage with ONS Mortality information to establish cause of death.

A recommendation for class 1, 2, 3, 4, 5, and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

500 patients identified as part of the CRISIS study who were diagnosed with chronic kidney disease who died between 1 January 2012 and 31 January 2016.

The following items of confidential patient information will be disclosed from Salford Royal NHS Foundation Trust to NHS Digital to facilitate linkage with ONS Mortality information:

- Study ID,
- NHS Number,
- Date of birth,
- Date of death,
- Cause of death.

Confidentiality Advisory Group advice

Public interest

The Sub-Committee was satisfied that the application was for a medical purpose, which was medical research. Members noted that the overarching Salford Kidney Study was an amalgamation of several historic longitudinal research studies. The Group was assured that that the activity had a clear public interest, as understanding the cause of death for the sub-group of deceased patients was important for the overall analysis.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information 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 Group acknowledged that the patient cohort were deceased, therefore it was not possible to obtain consent. The CAG raised no concerns in this area.

- Use of anonymised/pseudonymised data

The Group accepted that confidential patient information was required to facilitate data linkage. Members raised no queries in this area.

Justification of Identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the study aims, and no queries were raised in this area.

Exit Strategy

The applicant was requesting support for a time limited basis only. Once cause of death data had been received for this cohort, there would be no further need to request information. This was a one-off request and NHS Digital did not need to retain items of confidential patient information.

The Group observed that it was unclear how long NHS Digital would retain the items of confidential patient information disclosed to them to facilitate the data linkage. Members requested that the timeframe was clarified by the applicant.

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 an unconsented activity should go ahead.

The applicant explained that the Salford Renal Research team had strong ties to the Hope Kidney Patient Association (KPA), which included a patient research focus group with whom they meet regularly. The KPA newsletter included a research section, detailing ongoing studies and disseminating the results of previous studies. The applicant explained that the study design had been reviewed by patients and carers, and adjusted according to their suggestions.

It was unclear whether any public and patient engagement had taken place around the activities taking place as part of this follow-up study, particularly the specific issue of accessing confidential patient information on deceased patients without consent.

Members considered the information given, and asked that public and patient involvement was carried out to discuss the specific issue of obtaining data on the deaths of the 500 patients, and feedback on this issue supplied to the CAG. A response was required prior to any final recommendation of support coming into effect. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The applicant explained that they will use their regular communications channels, including newsletters and social media to update patients on this activity and its importance for our research in renal disease, including regular updates on the main outcomes.

Patients had previously consented into the study. NHS Digital was facilitating the data linkage and would apply any registered opt-outs. Further data on patients who had opted out

would not be released. As the cohort were deceased there was no other mechanism that could be used to record dissent. The Group raised no concerns in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Clarify how long NHS Digital would retain the items of confidential patient information disclosed to facilitate linkage, to provide an overview of the duration of support required under the Regulations for this activity.

2. Patient and public involvement and engagement activity should be undertaken specifically to test the acceptability of the use of confidential patient information to collate information on deceased patients without their consent. Provide details of the activity undertaken, the demographics of those involved together with an overview of the feedback provided, If the responses given are negative, the CAG would take this into account when considering whether support can be recommended, or whether any further action is required.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed: 11 February 2019).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed: NHS Digital has a satisfactory published grade on V14.1, 2017/18).**

b) 19/CAG/0065 – Causes of sixth nerve palsies in children: a retrospective study

Context

Purpose of application

This application from University Hospitals Southampton NHS Foundation Trust set out the purpose of medical research which aims to report the incidence and causes of sixth nerve palsies in children presenting to Southampton General Hospital over the past ten years. The applicants aim to highlight the most common causes of sixth nerve palsy, the most common path of presentation and other common associated signs and symptoms in order to guide future clinical practice in the UK.

Confidential patient information will be collected retrospectively, using a diagnostic search tool on the electronic record systems, E-Docs and Medisoft, used by University Hospitals Southampton and Southampton Eye Unit. Only data sufficient to answer the research question will be collected from the electronic records of eligible patients. If the

required information is not available in electronic records, paper based medical notes may be accessed. Once data has been extracted, no further access to participants notes will be needed.

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

Confidential patient information requested

Cohort

Patients under the age of 18 years old at diagnosis, diagnosed with unilateral or bilateral sixth nerve palsy between 02 January 2007 – 01 January 2017 and seen at Southampton General Hospital as an inpatient or an outpatient.

Access to the complete patient record is requested to enable the wider clinical information required for analysis to be extracted, the following specific items of confidential patient information are requested for the purposes set out below:

- Hospital number – sample validation and linkage
- Gender - analysis
- Ethnicity - analysis
- Age at diagnosis - analysis.

Confidentiality Advisory Group advice

Public interest

The Sub-Committee was satisfied that the application was for a medical purpose, which was medical research, and the intention of the applicant was to guide future clinical practice for this patient group, which was clearly in the public interest.

Cohort

The patient sample size was unclear in the application. The applicant explained that there was no published data stating the incidence of sixth nerve palsy in children and therefore it was difficult to predict the number of eligible participants. The applicant explained that, from his clinical experience, the estimated sample size would range from 50-70 patients.

The applicants intended to use a specific word search on the electronic patient record systems to highlight eligible patients. The applicants stated that it was difficult to predict how many patient records would need to be accessed in order to achieve the required number of participants.

The Group determined that further information on the size of the cohort was required. The applicant would be asked to provide a more informed estimate of the number of electronic patient records which would need to be accessed in order to identify the eligible patient cohort. This was necessary to understand the scope of support that was required under the Regulations for the project.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information 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 applicant had explained that consent was not possible due to the retrospective nature of the patient group to be included within the study. The Group accepted the justification for not obtaining consent as it would be disproportionate to attempt to contact all patients seen across the ten-year inclusion period. Members also recognised that patients may be uncontactable. No concerns were raised in this area.

- Use of anonymised/pseudonymised data

Confidential patient information was required in order to identify the patient cohort and to access records to extract clinical data for analysis. It was confirmed that confidential patient information would not be collected as part of the study. The Group raised no queries in this area.

Justification of identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the study aims, and no queries were raised in this area.

Exit strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Members acknowledged that support under the Regulations was being requested on a time limited basis to facilitate the linkage of data from patients seen within the ophthalmology department.

Hospital numbers of patients found to have the relevant condition would be stored on an excel spreadsheet on an NHS password protected computer, to avoid duplicating data collection. This spreadsheet would be deleted on completion of the study and no confidential patient information was required for the analysis.

Members were assured that this process was appropriate and raised no queries in this area.

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 an unconsented activity should go ahead. The applicant advised that they had not carried out any activity in this area, however they explained that they could give out questionnaires in the paediatric ophthalmology outpatient's department, if the Group recommended that this was done.

The Group agreed that public and patient involvement needed to be carried out, either by consulting an appropriate patient group or by questionnaires given out in the ophthalmology department. Information on the feedback received from this engagement needed to be provided to the Group for consideration, prior to any final recommendation of support coming into effect. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

The applicant advised that the study was to be advertised on a publicly accessible research database online. Written information would not be provided for eligible patients, as the applicant was concerned that this would not be useful due to the study's retrospective nature and involved patients seen under specialities other than ophthalmology. A telephone number was made available for patients to contact the study team if they wanted further information or to dissent from the study.

University Hospitals Southampton did not have a process for patients to dissent from retrospective studies. The applicant explained that, if there was a record in the notes that patients had expressed that they did not want their information used in research, then this would be respected and data would not be extracted.

The Group was dissatisfied with the process described and expressed concern that most patients would be unaware that the research database was available. Members suggested that a notice with information about the project, including how to dissent, was displayed more prominently on the Trust website, including on the ophthalmology department webpage.

The Group asked the applicant to develop a communication strategy to notify patients about the study. Members suggested that posters could be displayed in clinics, and information disseminated through the lay networks at the hospital and relevant voluntary organisations. Information on the strategy, including any new or revised documentation, needed to be provided to the CAG for consideration before final support can be given.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018.

Whilst further information had been provided by the applicant around to explain how the proposed activity was compliant with current data protection legislation, it remained unclear what legal basis for processing was being relied upon. Confirmation would be sought from the applicant.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information (Summary)

1. Provide further information around the number of patient records which would be accessed to establish the patient cohort to be included in the study to clarify the scope of support which is required under the Regulations.

2. Patient and public involvement and engagement activity should be carried out to test the acceptability of accessing confidential patient information without consent to achieve the study aims. Feedback should be provided around the activity which was undertaken, the format this took and the demographics of those involved, together with an overview of the outcome. If the responses given are negative, the CAG would take this into account when considering whether support can be recommended, or whether further action is required.

3. Mechanisms to notify patients and the public about the study and to provide a means of objection should be established. Confirmation should be provided around how this will be achieved, together with copies of any documentation which will be used to support the communications strategy, should be provided for consideration.

4. Confirm that the legal basis being relied upon processing data under the GDPR are Article 6(1)(E) – tasks in the public interest and Article 9(1)(J) – research purposes.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Confirmed: 18 February 2019).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: University Hospitals Southampton has a satisfactory reviewed score for v14.1 2017-18).**

c) 19/CAG/0067 – Can a multimarker strategy improve risk stratification and expedite discharge in patients hospitalised with chest pain?

Context

<u>Purpose of application</u>

This application from Aintree University Hospital NHS Trust set out the purpose of medical research which aims to undertake further follow-up of patients who were previously recruited to a consented trial which aimed to evaluate the effects of biomarkers found in the blood against standard investigations in patients who are

admitted to hospital with chest pains. The trial opened in 2010 and consented patients for follow-up up to five-years via hospital records and contact via the GP.

This application aims to follow-up patients via HES and ONS records at NHS Digital. Whilst the historic trial, which recruited patients between 2011 and mid-2013, operated on a fully consented basis, this consent extended to a five-year follow-up only and is no longer understood to be valid to this additional follow-up via administrative datasets held by NHS Digital.

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

Confidential patient information requested

493 patients who were previously recruited to the trial carried out at Aintree University Hospital NHS Trust following presentation with chest pain that was suspected to be cardiac in origin, but for whom heart attack had been excluded.

The following items of confidential patient information would be released from Aintree University Hospital NHS Trust to NHS Digital to facilitate linkage with the HES and ONS datasets. The wider data items would be returned for analysis:

- NHS number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Sex – sample validation, linkage and analysis,
- Date of death (DD/MM/YYYY) – analysis,
- Ethnicity – analysis,
- Dates for subsequent admissions to UK hospitals with codes for chest pain, angina, myocardial infarction or revascularisation – analysis,
- Hospital which admission took place – analysis,
- Date of death – analysis,
- Cause of death – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the proposed activity had a clear medical purpose, which was medical research. There was significant public interest in the original application, in which the applicants were attempting to find biomarkers in the blood of patients who had experienced chest pains. The proposed follow up via NHS Digital would add to the usefulness of the previous research.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information 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

Patients had been consented into the original trial. The Group agreed that the original consent form signed by participants did not provide a basis, under the common law duty confidentiality, to legitimise linkage via NHS Digital with data from HES and ONS.

The applicants explained that re-consenting for the follow-up stage was not practicable, as they were aware that 10% of the cohort were now deceased. Excluding the deceased patients would likely lead to significant bias, as these patients were more likely to be higher risk and may have experienced hospital presentation with myocardial infarction prior to mortality. Patients recruited into this study were unlikely to be under routine clinical follow up and asking patients to consent was likely to be an inconvenience and would not enhance their care. The applicants also had limited resources available in their team.

The CAG accepted that the applicants wished to avoid introducing bias, which would be the likely result of excluding data from deceased patients. It was further noted that value of the project would be diminished if the dataset was incomplete or unreliable, which was a risk if information from GPs and hospitals records only was used. The Group noted that there was a strong public interest in compiling a dataset that was as complete and accurate as possible.

The CAG accepted the rationale that re-consenting patients was not feasible and had potential to introduce bias. Members were content to provide a recommendation of support under the Regulations.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate data linkage at NHS Digital, which could not be achieved by any other means. The Group raised no concerns in this area.

Justification of identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the study aims, and no queries were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The Group noted that confidential patient information would be kept for four months, to ensure that accurate linkage and extraction of follow up data.

The CAG acknowledged that the date of death would be provided in a true format from NHS Digital, to enable time to death calculations to be made. The applicant had stated that date of death could be pseudonymised to month and year of death after these calculations were made. Members agreed these steps should be taken to reduce the identifiability of the data set. Confirmation would to sought from the applicant.

The Group determined that the items of confidential patient information requested were reasonable, and were content with the plans for use and deletion. Members raised no queries in this area.

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 an unconsented activity should go ahead.

The applicant had explained that full discussions were had with the Aintree League of Friends, which was both a charitable body and a patient representative group. The Chairperson had been the primary contact and they had granted a favourable opinion about this research from the patient perspective.

The Group was unclear how many League members had been involved in the consultation and whether the linkage of study data to NHS Digital had been specifically discussed. Information on the feedback received from this engagement needed to be provided to the Group for consideration, prior to any final recommendation of support coming into effect. This should include details of the questions asked, an overview of who was present together with the views expressed. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 Data Protection Act and General Data Protection Regulation 2018.

The applicant intended to send a direct letter to the patient cohort, which included a contact number for patients if they wished to dissent. The CAG noted that there was a potential risk in sending out letters to surviving participants, as such a large percentage had passed away. Also, the applicants may not have up to date contact details. A clear and failsafe system needed to be created to ensure that the contact details of patients was accurate before the letters were sent.

The Group asked that information on how the applicants would ensure that the contact details were up to date was provided for review. This needed to include information on any wider disclosures of confidential patient information or updates to patient information required to facilitate the circulation of the direct mailing.

The Group determined that the notification materials provided were not sufficient and asked that amendments were made. The poster and notification letter needed to include a clear time limit for patients to register their dissent. The poster also needed to be amended to include the title of the study and to make it clear that this was for the attention of participants in the previous study, to offer them an opportunity to dissent, rather than the public.

The Group asked the applicant to further develop the communication strategy to notify patients about the study. Members suggested that posters could be displayed in the clinics of GPs who had been involved in the previous stages of the research. Information on the strategy, including any new or revised documentation, needed to be provided to the CAG for consideration before final support can be given.

Research Ethics Committee Favourable Opinion

The Group were unclear whether a favourable REC opinion was in place for the activities proposed. The original protocol had not been submitted to the CAG, and the Group noted that it was unclear what processes had been changed between the 2010 original and the amended protocol reviewed by the REC in 2012. The CAG noted that the updated protocol, dated January 2019, referred to follow-up over a five-year period and not beyond and it did not appear that this document had been referenced in any REC outcome.

The Group requested further clarification that the REC opinion was still in place, that the revised protocol had been reviewed and that the ethical opinion extended to the proposed activity.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018.

Confirmation was required from the applicant around what legal basis was being relied upon for processing in relation to the GDPR 2018.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Explain how the accuracy of patient contact details would be confirmed before the notification letters are circulated.

2. The Notification Letter needs to include a clear time limit for patients to register their dissent.

3. The following amendments to the poster are required;
   a. The title of the study needs to be included,
   b. A clear time limit for patients to register their dissent needs to be given,
   c. It needs to be made clear that the poster is for the attention of participants in the previous study, to offer them an opportunity to dissent, rather than the public.

4. Consideration should be given to widening the communications strategy to include display of the poster by GP practices. Confirmation that this will be progressed, or a strong rationale to explain why this is not possible, needs to be provided. Copies of any documentation used to support wider communications should be provided for review.

5. Further information on the public and public involvement and engagement activity carried out to test the acceptability of processing confidential patient information without consent is requested. Feedback should be provided around the activity which was undertaken, the format this took and the demographics of those involved, together with an overview of the outcome. If the responses given are negative, the CAG would take this into account when considering whether support can be recommended, or whether further action is required.

6. Evidence that the REC has given a Favourable Opinion for the follow up and data linkage aspects of the study needs to be provided.

7. Confirm that the legal basis being relied upon processing data under the GDPR are Article 6(1)(E) – tasks in the public interest and Article 9(1)(J) – research purposes.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **(Pending).**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements. **(Confirmed: NHS Digital has a confirmed 'standards met' grade on the Data Security and Protection Toolkit, which is the equivalent of a satisfactory grade on the IGTK).**