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

09 October 2020

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	1a
Dr Martin Andrew	CAG Member	1a
Ms Sophie Brannan	CAG Member	1a

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

1. New Precedent Set Review Applications – Research

a. 20/CAG/0137 - Best Care for Abdominal Emergencies - The BCAE Study. A retrospective single, centre cohort study of patients with intestinal emergencies

Context

Purpose of application

This application from Portsmouth Hospitals NHS Trust sets out the purpose of medical research that aims to improve the quality of care for all patients with an abdominal emergency, irrespective of whether they have a laparotomy or not. The study aims to provide mortality rates for different treatment options, and analysis of short and long term outcomes. The study is a single-centre retrospective cohort study, and will use data from electronic patient records collected at Portsmouth Hospitals Trust NHS as part of routine patient care.

Abdominal emergencies are common, and patients often need life-saving emergency surgery; laparotomy. This procedure is high risk with 10% mortality rate. However, patients who do not have a laparotomy are not well characterised and do not receive the prioritised care patients having surgery do, even though their condition is no less severe. There are two additional groups of patients admitted with abdominal emergencies: patients having keyhole surgery (laparoscopy) and patients for whom any treatment would be futile and would benefit most from an end of life care pathway. Further research is needed to investigate the management of all patients with intestinal emergency, to optimise care for each group of patients.

This study will use electronic hospital records from Portsmouth Hospitals NHS Trust to retrospectively identify all patients admitted with an abdominal emergency over a six year period, using ICD-10 diagnosis, OPCS-4 procedure codes from the Patient Administration System (PAS) and TheatreMan™ and National Emergency Laparotomy Audit (NELA) data, all of which is held locally at Portsmouth Hospitals NHS Trust. The cohort will be extracted from records that are collected as part of routine clinical care, by a member of staff who is not part of the direct care team.. The applicant plans to identify patient and admission characteristics of 4 groups of patients (laparotomy, laparoscopy, nonsurgical treatments, and end of life care). The confidential patient information of patients who don't meet the criteria will not be seen or extracted. The patients identified will be screened to remove those who have registered with the NHS national data opt-out. The resulting dataset will form the final study cohort. The main data extraction phase will then take place using patients' NHS numbers to extract patient demographics, (age, gender, date of death), their primary (and subsequent admissions) with

diagnoses and procedures, and their vital signs, blood tests and surgery specific data for their intervention episode into linked datasets. The linked datasets will then be pseudonymised and identifying characteristics (name, address, date of birth) replaced by a study identification number (ID), by the Portsmouth Hospitals NHS Trust research data manager before it leaves the hospital's systems. Age at first intervention will be recorded as it is required for the analysis, as will date of death. The key to the pseudonymisation will be deleted once the data has been extracted.

The pseudonymised datasets will be transferred with a Trust issued encrypted device from the Portsmouth Hospital NHS Trust research server onto the University of Portsmouth research server via a University of Portsmouth encrypted laptop. A recommendation for class 1, 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 adult patients admitted to Portsmouth Hospital NHS Trust with acute abdominal intestinal conditions over the study period (6.5 years: 01 December 2013 – 28 February 2020) Lowest age 16, no upper age limit. An approximate total of <5,800 patients with an intestinal emergency and <3,400 patients undergoing surgery. Inclusion criteria: - Must have an acute intestinal condition, based on their ICD-10 codes and OPCS-4 codes - Must be >= 16 years of age at the time of admission - Have at least one full set of vital signs recorded on the day of admission

	- Have at least one full set of routine blood tests recorded on the day of admission Exclusion criteria: - Maternity admissions during/after pregnancy - Patients admitted or undergoing intestinal surgery for a second time or more
Data sources	1. Portsmouth Hospitals NHS Trust - electronic patient records collected as part of routine patient care (will be screening all general adult wards, excluding maternity)
Identifiers required to extract electronic data and create study ID	1. Name 2. NHS Number 3. Hospital ID 4. GP registration 5. Date of Birth 6. Date of Death 7. Address (including postcode)/ or postcode alone: To be clarified with applicant as part of the request for further information. (These identifiers are extracted and used to link to clinical datasets within Portsmouth Hospital)
Identifiers required for analysis purposes	1. Date of Death
Additional information	Analysis will be undertaken by University of Portsmouth. All data will be pseudonymised at the point of extraction and the national opt-out will be applied. Identifying characteristics (name, address, date of birth) will be replaced by a study identification number (ID)

Confidentiality Advisory Group advice

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

Public interest

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

Scope of support required

The CAG noted that support is requested to allow named members of staff, who are not part of direct clinical care team, to extract the patient cohort from electronic patient records at Portsmouth Hospitals NHS Trust. This will involve screening patient admissions for intestinal emergencies, from 2013-2020, selecting the patient cohort, and linking with different clinical datasets also held at Portsmouth Hospitals NHS Trust.

Support is also requested to allow the disclosure of confidential patient information from Portsmouth Hospitals NHS Trust to University of Portsmouth for the purposes of transferring the pseudonymised dataset for analysis. This is because date of death is considered an identifier. Although the applicant has agreed that support is required for this transfer, there seemed to be some ambiguity in their responses as to whether the transferred dataset could be considered anonymous or pseudonymous. The applicant did not consider security assurances were required for the University of Portsmouth, answering:

'*The University of Portsmouth does not require a DSPT as it is only processing pseudonymised patient data, with date of death the only identifier to be kept in the pseudonymised data set.'*

The CAG members confirmed that as date of death is considered an identifier, support is required for the transfer of the pseudonymous dataset from Portsmouth Hospitals NHS Trust to University of Portsmouth. University of Portsmouth will therefore require security assurances in place before support can be provided, and support will be required for as long as the date of death is retained in full format.

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**

Individual patient consent will not be sought, and data will be collected retrospectively from electronic patient notes of approximately 5,800 patients. The applicants have stated that to seek retrospective consent from this number of people would not be practicable. Additionally, 10% of the cohort will be deceased; these patients cannot provide consent, however their data is essential for the study. The CAG agreed with these justifications.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information to correctly identify the cohort and to link internally with other hospital datasets. The Sub-Committee were content that the use of identifiers for these purposes was justified. Date of death is the only identifier kept for analysis, which applicants explain is crucial to perform seasonal analysis over different time frames. The CAG considered that the use of date of death for analysis was justified. All other identifiers will be removed, and the dataset pseudonymised. The key will be destroyed at the point of data extraction.

The CAG were not content however with the applicants arguments for retaining the full date of death for 10 years after analysis, and this will be expanded on in the 'Exit strategy' section.

The Members also required some clarification surrounding whether full address was required for creating the cohort and linking with internal datasets. They requested confirmation whether postcode only was required, or if this was indeed full address.

- **Minimising flows of identifiable information**

It was noted by the CAG members that the study requires support for identification of the cohort, as this step was being undertaken by somebody who was not part of the clinical team. The members were not clear why it was not possible for the Chief Investigator, who is a consultant surgeon at the trust, and part of the direct care team, to identify the cohort and perform the internal linkages. Support under Regulation 5 would only be required for the transfer of date of

death. Justification is required as to why this alternative is not practicable, and this has been added as a request for further information.

Exit strategy

As date of death is considered to be a potential identifier, and the CAG have agreed with the justification used regarding keeping date of death for analysis, support is required until the expected end of analysis; 31 May 2021. The applicant has stated that the study team are required to retain the full date of death for 10 years post analysis, however the CAG members were not persuaded that 'trust policy' is a convincing argument for storing full date of death for 10 years. The applicants are therefore required to provide a convincing justification as to why date of death cannot be changed after analysis to a less identifiable format, and this has been added as a request for further information.

'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 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 Data Protection Act 2018.

The applicant has provided to the CAG a study website and poster. A plain English summary as a patient notification mechanism has also been provided which the applicant advises the NIHR will use to share information about the study with patients. However there is no detail on any of these 3 notifications regarding the proposed methods of data collection, specifically without patient consent, and the opt out mechanism is currently the national data opt out only. The applicant has advised he is happy to change these, but the updated versions have as yet not been provided to CAG.

The CAG commented that the website content is not yet suitable. They considered the 'plain English summary' to be confusing, and did not explain how data is collected, or provide a study specific opt out mechanism. The Group commented that the poster should explain that researchers pseudonymise the data at the hospital site. The study specific opt-out info additionally needs to be on the poster, as well as contact details for the researchers. They advised that the website content, 'plain English summary', and study poster should be updated to be more readable, include details of a study specific dissent mechanism, and they suggested

lay review of the materials by the PPI groups. These materials are required by CAG, and have been added as requests for further information.

The CAG did not consider that the national data opt out should be the only dissent mechanism for the study. However, they felt it was appropriate to apply it additionally, alongside a study specific opt out mechanism. The CAG also needed clarification on whether it was currently operational at Portsmouth Hospitals NHS Trust.

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 described consulting several PPI groups, to discuss using patient data without consent, all of which were supportive. The CAG were content with the PPI undertaken.

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 Health Research Authority that the activity be provisionally supported. However, further information and actions 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 requests for further information, and actions required to meet the specific conditions of support where indicated, within one month from the date of this letter.

Request for further information

1. Clarify if full address or postcode alone is required for identification of the cohort and linking with internal clinical databases?

2. Provide justification for why it is not practicable for the CI to identify the study cohort and perform internal linkages, and so avoid a breach in the common law duty if confidentiality?

3. Provide a full justification as to why full date of death cannot be changed after analysis to a less identifiable format?

4. Ensure that a study specific dissent mechanism is in place for the study

5. The patient notification materials (website, 'plain English summary' and poster) need review to ensure it is clear to a lay person how data is collected. The materials need to clearly show that the data is pseudonymised at the hospital site. The notification materials also need to contain a clear study specific dissent mechanism, and be provided to CAG for review.

6. Please confirm if the national data opt out is currently in operation at Portsmouth Hospitals NHS Trust.

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 and the outstanding actions listed in the specific conditions of support are met, 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. Favourable opinion from a Research Ethics Committee. **Pending.**

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. **Pending –**

    - **The NHS Digital 2019/20 DSPT review for Portsmouth Hospitals NHS Trust (RHU) was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 22 October 2020).**

- **The NHS Digital DSPT review for University of Portsmouth is pending.**

Declarations of Interest

There were no declarations of interest.

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date