Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

21 February 2019, at Barlow House, Manchester

Present:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Ms Sophie Brannan	Yes	Lay Member
Dr Tony Calland	Yes	By Teleconference – Agenda items 5.b. and 5.c. only
Professor Barry Evans	Yes	
Mr. David Evans	Yes	
Dr Lorna Fraser	No	Apologies received
Mr. Myer Glickman	Yes	
Professor Jennifer Kurinczuk	Yes	
Mr Andrew Melville	Yes	Lay Member
Ms Clare Sanderson	Yes	Alternate Vice-Chair
Dr Murat Soncul	Yes	Alternate Vice-Chair (Not present for item 5.b.)

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	Confidentiality Advisor
Ms Natasha Dunkley	Head of Confidentiality Advice Service (Not present for 5.a)
Miss Kathryn Murray	Senior Confidentiality Advisor
Ms Shirley Murphy	External Observer
Ms Emily Vereker	External Observer

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

The Chair welcomed Ms Shirley Murphy and Ms Emily Vereker, colleagues from the Republic of Ireland, to the CAG meeting.

Apologies for absence were noted from Dr Lorna Fraser.

The following declarations of interest were noted:

- Item 5.b: 19/CAG/0032 – the Confidentiality Advice Team noted Dr Murat Soncul was conflicted on this item as this involved South London and Maudsley NHS Foundation Trust, where Dr Soncul is employed at Head of Information Governance. No papers were shared with Dr Soncul ahead of the CAG Meeting and he took leave of the meeting during discussion of the item.

2. SUPPORT DECISIONS

Secretary of State Support Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the **24 January 2019** meeting applications.

HRA Support Decisions

The HRA agreed with the advice provided by the CAG in relation to the 24 January 2019 meeting applications.

3. AMENDMENTS – Non-Research

a. CAG 5-07(f)/2013 (Amendment Sub-Reference: 19/CAG/0036) – National Vascular Registry

Context

Background to the Application

The National Vascular Registry (NVR) is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme.

The NVR collects data on patients undergoing five vascular procedures: aortic aneurysm repair, carotid endarterectomy, lower limb bypass, lower limb angioplasty/stent, and lower limb amputation. These procedures may be performed after a person is admitted as an emergency or as an elective patient.

The Registry currently operates on a mixed methodology – patients who are undergoing elective surgery are included in the registry on a consented basis. Patients who undergo emergency surgery are included on the Registry with support under the Regulations. Support came into effect from 06 December 2013.

Amendment Request

The amendment seeks support to extend the scope of the support under the Regulations to include patients who are undergoing elective surgery, so the collection of all information within the Registry would be operated with support under the Regulations.

The amendment would only impact on new patients eligible for inclusion in the Registry after the point that the submission receives support under the Regulations – if this is recommended.

Confidentiality Advisory Group advice

Public interest

The CAG acknowledged that the audit work of the National Vascular Registry (NVR) was within the public interest. However, the applicant explained that there was significant variation in the quality of data entered into the audit with patient consent in relation to those undergoing elective procedures. It was explained that whilst the NVR achieved an overall consent rate of approximately 75%, this differed between NHS Trusts, with some reporting a consent rate of less than 5%.

Members recognised that the variation had the potential to substantially impact the effectiveness of the audit as the analysis would be undertaken on incomplete and non-representative data which could not be relied upon to influence changes in patient care and treatment. The Group identified that, on this basis of this evidence, there was public interest in the proposed request to extend the scope of support under the Regulations to include those patients undergoing elective procedures. However, the CAG recognised that it could not provide a recommendation of support under the Regulations for an activity where a practicable alternative existed, which was further considered below.

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 noted that overall the NVR achieved a consent rate of approximately 75%, which it was agreed was a high-level, when comparing against other consent-based activities and did evidence that seeking consent was feasible for the majority of procedures.

The amendment request had sought a change to the overall methodology for the audit to move to all elective procedures being included within the audit on the basis of support under the Regulations. Members commented that this request did not account for those Trusts which were successfully obtaining consent from patients undergoing elective procedures for the inclusion of their data within the audit.

The CAG considered whether there would be scope to include a mixed-methods model in relation to the elective patient cohort, whereby support under the Regulations could be extended to those patients who were not approached for their consent around inclusion in the audit. However, in this circumstance, Members were unclear what incentive there would be for Trusts to continue attempting to seek consent from patients, if they were able to rely on support under the Regulations. It was also commented that this would penalise those Trusts which were actively seeking consent from patients.

It was unclear from the information provided what the perceived barriers to obtaining consent were in those Trusts with a low attrition rate, whether this was that patients were not being approached for consent, or that consent was being declined. Members commented that if the approach for consent was not being made, this raised concerns around how the applicant would be assured that, if support was in place under the Regulations to collect information on elective procedures, patients were being informed about the audit and being provided with an opportunity to dissent.

The Group queried whether there were opportunities to influence practice in these Trusts to improve the consenting rate. It was suggested that standardised consenting materials could be provided to assist clinicians with the consenting process in relation to the audit, as it was recognised that patients would need to provide some form of consent to undergo the elective procedure. It was also queried whether anonymised information around the number of procedures performed at individual Trusts could be obtained from NHS Digital in order to facilitate discussions with sites to explore the variation between the number of

elective procedures undertaken against the number of patients who were consented to inclusion in the audit.

The CAG was unable to provide a recommendation of support under the Regulations when a practicable alternative to seeking this support was feasible. Members were of the opinion that the amendment submission did not provide sufficient justification to support the request to extend the support under the Regulations to all elective procedures. On this basis, the CAG recommended that the amendment was not supported in the basis that tis existing consent process provided a practicable alternative to extending the scope of support under the Regulations to the elective patient cohort.

Should the applicant wish to submit a revised submission, this would need to be supported by a stronger justification to support why consent was no longer feasible, identifying how the situation had changed since the initial application to support this. The revised submission should also provide a response to the wider queries raised above around how the revised methodology would be balanced for those Trusts which were currently obtaining consent and an assessment of why the suggested options to improve consent rates were not permissible. It was agreed that any revised submission would need to be considered by full CAG.

- Use of anonymised/pseudonymised data

Confidential patient information was required to undertake sample validation and to facilitate linkage with wider administrative datasets held by NHS Digital, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The CAG agreed that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity and on concerns were raised 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. It was understood from the 2018 Annual review that a patient representative sat on the NVR project board; however, the amendment did not describe whether views had been sought from this individual around the change to the methodology.

The CAG agreed that activity should be undertaken in this area in order to seek the views of a relevant patient group around the proposed change to methodology. Any revised submission of the amendment should be supported by the outputs of this activity. An overview of the activity carried out and the feedback provided should be included as part of any revised amendment submission. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended for the extension to the scope of support under the Regulations, 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. A revised patient information leaflet had been provided which would be rolled out if the amendment was supported.

Members commented that the section entitled ‘Patient Consent’ did not appear appropriate, as in the event that the amendment was supported, no patients would be providing their consent to the inclusion of their data in the NVR. It was commented that, if a single information sheet was intended to provide information to a retrospective cohort also, it may be beneficial to include sub-headings to separate out information for those who underwent an elective procedure prior to the change in methodology and those after, to ensure

that this is clear. It was agreed that any revised submission of the amendment would need to be supported by a revised information leaflet.

The Group reiterated concerns around what assurance the applicants would that patients undergoing elective procedures were being provided with an information sheet about the NVR. The applicant would be required to address this point as part of any revised submission.

The CAG suggested that a wider communications strategy could be implemented to support the change of data collection methodology, including the provision of posters to be displayed in participating Trusts. The applicant would be asked to consider this as part of any revised submission.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the amendment to the existing application was not supported.

Resubmission

If you consider that the issues raised by the CAG can be addressed, a resubmission can be made. A new amendment should be submitted with a covering letter detailing any revisions which have been made to the request and how the issues raised are addressed. This should be supported by any supplementary documentation. This revised submission would be considered by at a full CAG meeting.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Provide a stronger rationale to support why consent is no longer considered a feasible practicable alternative in relation to the sub-cohort of patients undergoing elective procedures. Consideration should be given to the following points in this response:

    a. Clarify what has changed since the inception of the NVR that now means seeking consent from the elective patient cohort is no longer feasible,
    b. Explain what the perceived barriers are to seeking consent within those Trusts with a low attrition rate, i.e. clinicians not approaching, patients declining,
    c. Further information would be required to explain how a move to data collection with support under the Regulations for the elective patient cohort would be implemented within those Trusts who are successfully obtaining consent and thus evidencing that there is a feasible practicable alternative,
    d. Consider whether there were opportunities to improve the uptake of consent, i.e. through the provision of uniform consenting materials, seeking anonymised data from NHS Digital around the number of procedures being carried out in order to inform discussions with Trusts around the attrition rate.

2. Patient and public involvement and engagement activity should be undertaken to explore views around the acceptability of the proposed change to the data collection methods. An overview should be provided around the activity undertaken and the feedback provided. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended for the extension to the scope of support under the Regulations, or whether further actions are necessary.

3. The patient information leaflet should be revised to more accurately explain the data collection methodology for the NVR has been changed, providing clear information for the timeframe for the two data collection methods.

4. A wider communications strategy should be devised for the audit – the revised amendment should be supported by further information around this, together with copies of any documentation which would be used to facilitate this.

4. RESUBMITTED APPLICATIONS – Research

a. 19/CAG/0009 (Previously: CAG 4-09(a)/2013) - TRIPHIC (Translation Research in Pulmonary Hypertension at Imperial College) project - Renewal

Context

Background to Submission

The TRIPHIC research database received a recommendation of support under the Regulations on 18 September 2013. The purpose of the project was to establish a research database from established datasets at Imperial College Healthcare Trust which were linked with datasets at NHS Digital (then the HSCIC). The database included information on approximately 2000 patients who had been referred to the National Pulmonary Hypertension Service at Imperial over the preceding decade.

Purpose of this Application

This application from Imperial College Healthcare NHS Trust set out the purpose of medical research through the ongoing retention of the TRIPHIC research database for further five year duration in line with the refreshed research database application which had been submitted for ethical review, in line with NHS REC Standard Operating Procedure requirements.

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

Confidential patient information requested

Support under the Regulations currently extends to the following sub-cohorts of patients:

Living patients who previously donated biological samples and were then discharged prior to the introduction of TRIPHIC (n=374),
Living patients with CMR images who were also discharged (n=177),
A further 550 patients remain under care of the Pulmonary Hypertension Service and are being approached directly, seeking face-to-face TRIPHIC consent during clinical follow-up.

The following items of confidential patient information are required for the purposes set out:

NHS Number – sample validation and linkage,
Date of birth – sample validation, linkage and analysis,
Date of death – sample validation, linkage and analysis,
Sex – analysis,
Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the project defined an appropriate medical purpose, which was medical research. The increased morbidity and mortality in patients with pulmonary hypertension was recognised by Members, who were assured that there continued to be an ongoing public interest in the database's

activity. The Group was content to provide a recommendation of support to extend the duration of support for the application activity for a further five years.

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 refreshed application provided an overview of the applicant's planned activity to move away from support under the Regulations, which focussed on seeking consent from patients for their ongoing inclusion in the database. The application described a number of sub-groups of patients, some of which remained under the active care of the Pulmonary Hypertension service, who would be approached for consent within a standard clinical follow-up appointment, some who had been discharged from the care of the service and a cohort which is known to be deceased.

For patients who remain within the active care of the service, it was explained that a member of the current clinical care team would approach for consent as part of a standard clinical appointment. The consenting materials to support this process were provided for information purposes and Members agreed that the documentation was clear. It was confirmed that to date, less than 3% of patients had declined participation and there had been no withdrawals from the database.

The applicant proposed approaching those patients who were no longer under the active care of the pulmonary hypertension team via a postal consent mechanism. This sub-group would include patients who had previously been approached for some level of consent and a sub-group who had not had any previous approach. Whilst the CAG recognised that it was not within its remit to provide guidance around a consenting mechanism, Members wanted to be sure that the applicant was familiar with the established Information Commissioner's Office (ICO) guidance around managing non-response. This explained that where a patient has been formally approached to provide their consent to a specific activity, but had declined consent either actively, or had not responded to the approach for consent, this should be accepted as dissent. It also confirmed that where a patient has been approached for consent and either declined or not responded to this request, support could not be sought under the Regulations to legitimise processing of confidential patient information.

The implications of this established guidance within the scope of this application would be that any patient included in the TRIPHIC database that was approached for consent but did not reply, would need to be treated as having declined consent and removed from the database.

The Group noted that the invitation materials to support the approach to these sub-groups had not been provided within the application so it was unclear whether this was intended to be a formal consenting process or an opt-out mechanism.

Members agreed that further information was required from the applicants to ensure that the potential impact of non-response had been considered and any contact approach was appropriately designed. A link to the guidance would be provided for information purposes. Response would be required to explain how any contact arrangements were in line with the guidance. Sight the supporting documentation would also be required.

It was further queried whether the patient's vital status would be checked prior to approaching for consent. Clarification would be sought from the applicant around this point and how this would be facilitated.

- Use of anonymised/pseudonymised data

Members were assured that confidential patient information was required to facilitate linkage of patient records which could not be otherwise achieved.

Justification of identifiers

The Group queried whether there was a need to continue to retain confidential patient information in relation the sub-group of patients known to be deceased. It was agreed that the applicant would be required to provide further justification to support this ongoing retention.

It was unclear whether the application form provided has cited all items of confidential patient information necessary to facilitate the follow-up consenting process. Clarification would be sought from the applicant around this point.

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. Members considered the update in relation to patient and public involvement and engagement with the study which was provided in the 2019 annual review submission. The applicants explained that they had been unable to recruit a patient or relative/partner to participate on the TRIPHIC Steering Committee, due to logistical issues around travel. Detail was provided around wider initiatives which had been employed to encourage patient and public involvement in the research, including invitations to join the NIHR-Wellcome Trust-Imperial Clinical Research Facility patient and public involvement group and the Facility's open events and meetings (online and in person).

The Group recognised that the work which had been undertaken by the applicants to increase interaction in this area. As the existing application was subject to a condition of support around improving patient and public involvement, the Group agreed that this would be carried forward on to the new application. Updates would be required at the time of annual review around further initiatives which had been put in place to improve activity in this area and the finding of this.

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 Group recognised that during the consideration of the initial application, it was explained that living patients would receive a copy of the Hammersmith Pulmonary Hypertension Research (HAMPHR) newsletter. It was unclear whether this communications strategy was still in operation.

Members agreed that queries would be raised with the applicant around any wider communications strategies which were in place to promote the TRIPHIC database in the public arena to support the direct correspondence about ongoing study involvement.

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.

In order to complete the processing of this application, please respond back to the following request for further information within one month. A detailed covering letter should be provided together with any supporting documentation for review.

Request for further information (Summary)

1. Further consideration should be given to how the approach to retrospectively included patients around their ingoing inclusion in the TRIPHIC database should be made.
    a. The ICO guidance around managing non-response should be considered – this can be found on the HRA website at the following link: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/

    b. A clear overview of how this approach would be made, whether this would seek formal consent or opt-out and how the methodology was in line with the above guidance would be required.

    c. Copies of any documentation to support this process should also be provided for consideration.

2. Confirm whether, and how, the vital status of patients would be checked prior to any approach being made about involvement in the database.

3. Consider whether the items confidential patient information requested within the application are sufficient to facilitate the approach to patients.

4. Provide details of any wider study communications strategy which is promoting the database with patients and the wider public.

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, the HRA will confirm approval.

Specific conditions of support (Provisional)

1. All pre-existing conditions of support related to 17/CAG/0024 remain applicable.
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received four weeks before 18/09/2019, and then on an annual basis to this schedule.
3. Favourable opinion from a Research Ethics Committee (**Pending**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Imperial College Healthcare NHS Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

5. NEW APPLICATIONS – Research

a. 19/CAG/0035 – Updating cancer survival index trends for England and Wales to 2016

Context

Purpose of application

This application from the London School of Hygiene and Tropical Medicine set out medical research which aims to update trends in the index of survival from all cancers combined in England and Wales, up to 10 years after diagnosis. The purpose is to assess progress in survival up to 10 years after cancer diagnosis, for all cancers combined, since the index was last published for patients who had been diagnosed up to 2010, as part of Cancer Research UK's (CRUK) research strategy launch in 2014. CRUK has set a target of improving 10 year survival in England and Wales for all cancer combined to 75% by 2030.

The proposed study will be an update of previous research which has been carried out by the same research team and will update the index of cancer survival for patients who received a first primary cancer diagnosis from 1971 to 2016. Information relating to patients in England would be provided by the National Cancer Registration and Analysis Service (NCRAS) at Public Health England. Information relating to patients in Wales would be provided by Welsh Cancer Intelligence and Surveillance Unit (WCISU).

Confidential patient information will be transferred to the London School of Hygiene and Tropical Medicine for analysis.

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

Confidential patient information requested

Cohort

All adult patients aged 15 – 99 years, who were diagnosed with a first, primary invasive cancer from 1971 to 2016. The study involves a complete population-based set of cancer patient data which is expected to include over 10 million patients.

The following items of confidential patient information are required for the purposes of sample validation and analysis:

- Date of birth,
- Date of death,
- Date of cancer diagnosis,
- Sex.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised the applicant had an established precedent is undertaking cancer survival analysis of this type and were assured of the ongoing public interest in this activity proceeding.

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 was assured that consent was not feasible for the study due to the inclusion of over 10 million patients' records in the study. No issues were raised in this area.

- Use of anonymised/pseudonymised data

Exact dates were required to facilitate the calculations which informed analysis. The applicant had provided a helpful paper to support this determination. The CAG was assured that the proposed activity could not be achieved via the processing of anonymised or pseudonymised data and raised no queries in this area.

Justification of identifiers

The CAG recognised that the items of confidential patient information requested had been reduced from previous iterations of the study. It was agreed that the patient identifiers requested appeared appropriate and proportionate to the proposed activity and no further 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 applicant had

explained that a de-identified dataset would be created for analysis purposes. Members were however unclear when confidential patient information would be destroyed in order to facilitate an exit from the requirement for support under the Regulations. It appeared that confidential patient information would be retained for 10 year duration and the Group was unclear why this was necessary.

The CAG agreed that further clarification would be sought from the applicant in this area in order to gain a clearer understanding of the proposed retention period for confidential patient information and the justification to support this, together with the agreed exit strategy from support under the Regulations.

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 CAG recognised that the Cancer Survival Group had an established external Patient Advisory Panel which supported its research program. It was explained within the application that as the current iteration of the proposed research had only been commissioned in December 2018, it had not yet been possible to engage with the Panel about the proposal; however, this was planned.

Members agreed that feedback from the interaction with the Patient Advisory Panel would be helpful to understand any feedback it had provided around the study, the use of confidential patient information without consent in order to facilitate the study and any guidance which was provided around the dissemination of the research findings. The outputs of the initial activity which is already planned in this area would be required prior to any final recommendation of support coming into effect for the activity. If the responses given were negative, the CAG will take this into account when considering whether support should be recommended, or whether further actions are necessary.

The Group further commented that it would be helpful to understand the demographics of the Patient Advisory Panel and details around the membership would be requested from the applicant.

The CAG acknowledged that the applicant led a wide programme of work which operated with support under the Regulations. Feedback around the user involvement activity which had been carried out was provided as standard within the annual review submission. Members noted that a number of the wider projects managed by the applicant were due an annual review submission in the near future. The CAG agreed these submissions would be considered together at the next available full CAG meeting, to allow wider consideration of the activity which is carried out in this area to support the work of the Cancer Survival Group.

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. Members commented that the application did not appear to describe a patient notification mechanism. It was suggested that the information could be displayed on the London School of Hygiene and Tropical Medicine, Cancer Research UK, Public Health England and Welsh Cancer Intelligence and Surveillance Unit websites to promote the study in the public domain and inform patients how the applicants would be using confidential patient information within the study.

The project was relying upon the opt-out mechanisms which were operated by the national cancer registration services which were the data sources for the project. The CAG acknowledged that the limited items of confidential patient information which were provided to the applicants for such a significant patient cohort would not be sufficient to enable an individual to be identified and removed from the study database. On this basis, Members were assured, on this basis, that the operation of a project-specific dissenting mechanism would not be feasible. It was agreed that any patient notification materials which were drafted for the project would need to be direct patients to the established dissenting mechanisms within the cancer registries.

Other Points

It was noted that the application did not appear to be supported by a written recommendation from the Caldicott Guardian (or organisational equivalent). As this was a mandatory document for applications seeking support under the Regulations, this would be requested as part of the provisionally supported outcome.

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 (Summary)

1. Further information is required to understand the proposed exit strategy from the requirement for support under the Regulations:

    a. Clarify how long confidential patient information would be retained and provide a justification for this,
    b. Confirm the intended exit strategy from support under the Regulations.

2. Provide an overview of the demographics of the Patient Advisory Panel.

3. The proposed engagement with the Patient Advisory Panel should be undertaken and feedback provided around the nature of the activity, how the acceptability of using confidential patient information without consent was tested and how the study results should be disseminated. Feedback from the initial planned activity would be required prior to any final recommendation of support coming into effect.

4. Provide details of the communication strategy which is in place to promote the study in the public arena, together with any supporting documentation which will be used to facilitate this. Documentation should provide relevant links to the established objection mechanisms operated by the cancer registries.

5. Provide a written recommendation from the Caldicott Guardian (or organisational equivalent) to support the application, required as part of the mandatory study documentation.

Specific conditions of support (Provisional)

5. Favourable opinion from a Research Ethics Committee (**Pending**).
6. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Cancer Survival Group at London School of Hygiene and Tropical Medical has a satisfactory reviewed grade on V14.1, 2017/18**).

b. 19/CAG/0032 – Camden and Islington: Clinical Record Interactive Search (C&I CRIS) Linkage with Hospital Episode Statistics (HES) and Civil Registration Mortality Data

Context

Purpose of application

This application from Camden and Islington NHS Trust set out the purpose of medical research which aims to establish a research database linking the mental health records of patients treated within the Camden and Islington NHS Foundation Trust area with Hospital Episodes Statistics (HES) and ONS Mortality Data held by NHS Digital. The resulting database would be used to explore the link between mental and physical health, with specific emphasis on gaining understanding around the reduced life expectancy for patients diagnosed with a severe mental illness.

The Camden and Islington Research Database is already established and contains mental health data generated within the boroughs of Camden and Islington. This database was established using the South London and Maudsley NHS Foundation Trust (SLaM) Clinical Records Interactive Search (CRIS) methodology in 2012. South London and Maudsley NHS Foundation Trust acts as processor for the Camden and Islington CRIS Research Database.

Confidential patient information in relation to patients treated by mental health services in the Camden and Islington boroughs will be disclosed by South London and Maudsley NHS Foundation Trust (SLaM) Clinical Data Linkage Service (CLDS) to NHS Digital in order to facilitate linkage with Hospital Episodes Database and ONS mortality data. This information will be supplemented by anonymised information from HES and ONS relating to patients within the named London boroughs who were not detailed within the existing mental health database.

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 treated at the Camden and Islington NHS Foundation Trust from 2008 onwards. It is estimated that 140,000 patients were included in the Camden and Islington NHS Foundation Trust CRIS database.

The following items of confidential patient information are required for the purposes set out below:

- Full name – sample validation and linkage,
- NHS number – sample validation and linkage,
- Date of birth– sample validation and linkage,
- Sex – sample validation, linkage and analysis,
- Postcode – sample validation, linkage and analysis,
- Date of death – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Member recognised that exploring the relationship between physical and mental health was within the public interest and had the potential to improve care and treatment for patients.

Background to the Camden and Islington CRIS Database

South London and Maudsley NHS Foundation Trust has an established Clinical Record Interactive Search (CRIS) database which is maintained in-house by the Trust and contains information on its patients. Following guidance provided by the National Information Governance Board (NIGB), it was determined that the establishment of the SLaM CRIS database did not involve a breach of the common law duty of confidentiality, as confidential patient information was not being disclosed outside of the Trust. On this

basis, a recommendation of support under the Health Service (Control of Patient Information) Regulations 2002 was not required for the creation of the SLaM CRIS database.

The proposed application form explained that Camden and Islington CRIS research database, established in 2014, was modelled on the South London and Maudsley NHS Foundation Trust (SLaM) CRIS (Clinical Record Interactive Search) database.

The application explained that the C&I CRIS database was held by South London and Maudsley NHS Foundation Trust (SLaM), which acted as processor on behalf of Camden and Islington NHS Foundation Trust and University College London. Confidential patient information is included within the C&I CRIS database which is held by SLaM.

Members were unclear what lawful basis was being relied upon, in relation to the common law duty of confidentiality, to legitimise the initial disclosure and ongoing retention of confidential patient information from Camden and Islington NHS Trust to South London and Maudsley NHS Foundation Trust. Queries had been raised in advance of the meeting by the Confidentiality Advice Team in this area; however, the response did not provide the required clarity in this area. The applicant had provided a copy of a data processing agreement between the two Trusts within the response; however, this document was incomplete and did not provide the assurance required by the CAG to legitimise the data processing.

The Group was unable to provide a recommendation of support under the Regulations to an activity when the lawful basis of datasets involved is unclear. On this basis, the recommendation around support under the Regulations was deferred pending further information from the applicant in this area. It was agreed that an updated data flow chart would be required as part of a revised submission which showed all data flows involved in the creation of Camden and Islington NHS Foundation Trust CRIS database, together with the study-specific data flows, identifying the legal basis in relation to current data protection legislation for each flow together with the basis being relied upon to prevent a breach of the common law duty of confidentiality.

Broader Elements of the Application

Members accepted that the CAG was currently unable to provide a recommendation as to whether support could be recommended due to the outstanding issues detailed above. However, notwithstanding this outstanding fundamental point, The Group considered the application as a whole and agreed it would be helpful to raise points for the applicant to review to inform a revised submission.

Scope of Support

The application had been submitted to seek support under the Regulations to link confidential patient information in relation to patients treated at the Camden and Islington NHS Foundation Trust with the HES and ONS datasets held by NHS Digital. Linked information would be returned to the South London and Maudsley NHS Foundation Trust to be linked with the wider data retained in the Camden and Islington NHS Foundation Trust CRIS database.

NHS Digital would also create a control cohort of wider patients who were resident within the Camden and Islington area which were not included in the CRIS cohort. Whilst this information would be released in an anonymised format and was out of scope of the request for support under the Regulations, Members agreed that further information should be provided around the content of this data set to understand how this would facilitate comparison with the patient cohort.

The CAG was supportive in principle to the proposed data flows and raised no queries in this area.

Cohort

Clarification around the patient cohort which was included within the Camden and Islington CRIS database had been sought by the Confidentiality Advice Team ahead of the CAG meeting. However, in there was discrepancy in the response provided around the time period over which patients had been included in the database. The CAG agreed that any revised application would need to include a clear description of the

patient cohort included in the CRIS database, whose data would be processed within the proposed linkage. This should include the inclusion dates and also an estimated patient cohort size.

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 CAG acknowledged that patient information was included in the CRIS database on an opt-out basis. Members were assured that, due to the size of the patient cohort, seeking consent for the wider linkage was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage process undertaken by NHS Digital which could not be otherwise achieved. No queries were raised in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the proposed data linkage and subsequent analysis. No issues 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 applicant had sought support under the Regulations on a time limited basis only, in order to facilitate the linkage via NHS Digital. It was confirmed that NHS Digital would retain confidential patient information for a maximum of three months following linkage to enable data accuracy checks to be undertaken, following which this would be destroyed. No issues were raised 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 Camden and Islington CRIS database has an established Oversight Committee which includes a member of the Trust service user research forum as the Committee Co-Chair. The Oversight Committee has responsibility to consider and approve all applications to use the C&I CRIS Database and coordinates dissemination activities to ensure that staff and service users are informed about the database. This included the development of information materials to raise the profile of the database and its use for research activities.

The applicants explained that the proposed data linkage was discussed with the Camden Mental Health Service User Group meeting in May 2018 and also at the CRIS Board Meeting in October 2018. Minutes from both meetings were provided for information purposes. Members considered these documents. It was noted that the minutes of the service user group did not provide evidence that the use of confidential patient information without consent was considered or that the group was supportive of the proposed activity.

The CAG agreed that as the data linkage proposed involved a significant patient cohort, further information would be required in this area to confirm that the service user group understood that the proposed linkage would involve the disclosure of confidential patient information to another organisation and provide feedback to evidence that they were supportive of this activity proceeding. 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. Members considered copies of the patient-facing materials which had been provided by the applicants to support the application. The C & I CRIS website was also accessed to understand how this information would be accessed by patients.

The Group was of the opinion that the patient's right to opt-out was not clearly described within the documentation and was also difficult to locate when reviewing information online. It was agreed that this could be more clearly described within the online text. It was also commented that the role of South London and Maudsley NHS Foundation Trust was not clearly described across the patient-facing literature. The CAG acknowledged that review of the patient-facing documentation was undertaken by the C&I CRIS Oversight Committee; however, it was commented that Members had struggled to clearly understand how the database operated, how confidential patient information was processed to create the database or the patient's right to dissent to the inclusion of their data within the database from review of the information provided. It was agreed that these issues would be raised to enable documentation to be reviewed prior to resubmission of the application.

The applicants had also provided a copy of a generic document which explained how the Trust uses patient information. It was unclear whether this was a physical document or online text. This document (titled 'Fair Processing Notice') appeared to be designed to fulfil fair processing requirements in relation to the current data protection legislation, and was thus outside of the CAG's remit to consider. However, it was noted that the document still made reference to the Data Protection Act 1998 and thus appeared to be out of date.

Members were unclear whether the information leaflet and website text was also supported by posters and other more visual information on site at the Trust to ensure the profile of the CRIS database was raised as widely as possible. This would be queried to enable any wider communication mechanisms to be described within the revised application.

Confidentiality Advisory Group advice conclusion

In line with the considerations above the CAG agreed, while supportive in principle of providing a positive recommendation of support to the proposed data linkage activity, further information is required from the applicant to clarify the basis being relied upon to prevent a breach of the common law duty of confidentiality in relation to the existing data flows which supported the Camden and Islington NHS Foundation Trust CRIS database.

Further information required (Summary)

The following information should be provided to allow the CAG to continue their consideration of the proposal. Below provides a high-level summary – detailed information is provided in the summary of deliberations provided above.

A detailed covering letter should be provided which addressed the points below, together with a revised CAG application form, and any wider supplementary documentation.

1. Confirm what lawful basis is being relied upon to support the flow of confidential patient information from Camden and Islington NHS Foundation Trust to South London and Maudsley NHS Foundation Trust, to facilitate the creation of the C&I CRIS database, to prevent a breach of the common law duty of confidentiality. If providing copies of historic documentation to support the response, please ensure these documents are complete and highlight specific sections of note.

2. A revised data flow chart should be provided which identifies all data flows involved in the C&I CRIS database and proposed data linkage, identifying at each stage where confidential patient information is flowing, the organisations involved and clarifies what basis is being relied upon to evidence compliance against current data protection legislation and to prevent a breach of the common law duty of confidentiality.

3. Confirm the patient cohort that is included within the Camden and Islington NHS Foundation Trust CRIS database and subsequent cohort which will be included in the proposed study linkage. This should include a start and end date for the cohort and estimated patient population.

4. Provide further information around what clinical information would be enclosed in the anonymised data release by NHS Digital in relation to the control cohort.

5. Further information is required to evidence that the Camden Mental Health Service User Group was supportive of the processing of confidential patient information without consent required to facilitate the proposed study linkage.

6. The content of patient-facing information materials should be considered to address the following points:

    a. The role of South London and Maudsley NHS Foundation Trust should be made clearer in the information,
    b. The patient's right to object to the use of their data within the C&I CRIS database should be made more prominent,
    c. Provide further information about any wider communications mechanisms (i.e. posters) that are used to raise the profile of the C&I CRIS Database within the Trust,
    d. The 'Fair Processing Notice' requires review to ensure that this refers to the current data protection legislation.

c. 19/CAG/0008 – TriStar ovarian cancer project (version 1)

Context

Purpose of application

This application from the Leeds Teaching Hospitals NHS Trust set out the purpose of medical research which aims to gain further understanding around the genetic blueprint defects and pathways leading to abnormal protein expressions in patients with ovarian cancer. This project aims to address both of these strategies by providing surplus archival ovarian cancer tissue samples with anonymised case-specific demographic annotations to a commercial partner who is funding the project, TriStar. In turn, TriStar will distribute this material to pharmaceutical companies actively engaged in ovarian cancer drug development programmes, whilst returning a replica of all the material collected and processed to Leeds, where it will be made available for academic research programmes.

The application has been submitted for review by the CAG to seek support under the Regulations to enable the patient cohort to be identified from records held at Leeds Teaching Hospitals NHS Trust and to facilitate the extraction of the pseudonymised data set which will be shared with the study partner TriStar. Archival diagnostic tumour samples will also be provided to the TriStar study partner – these will be linked to the pseudonymised dataset. A link file will be maintained at the hospital Trust site, to enable any returned surplus samples to be returned to the correct patient record.

Eligible patients will be identified by the main applicant in the first instance from the CoPath database (pathology diagnosis reporting software). These cases will be retrieved from the archive by a biomedical scientist appointed solely for the study purposes. The main applicant will be responsible for determining which patients from the overarching sample had sufficient diagnostic tissue stored in the archive to be eligible for inclusion in the study. The biomedical scientist will then access the PPM+ database (patient

information storage database) in order to extract the relevant clinical information to support the samples. The main applicant will retain an independent, link-anonymised database which contains the study numbers and patient identifiers.

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

Confidential patient information requested

Cohort

Female patients who received a surgical resection for a range of ovarian cancers and were treated at the Leeds Teaching Hospitals NHS Trust. 500 patients will be included in the study from existing records spanning a 25 year time period.

The following items of confidential patient information will be extracted from CoPath records to enable the identification of the associated tissue samples and to create the anonymised clinical database to be used to support analysis:

- NHS Number – sample validation and linkage,
- Date of birth – converted to years for analysis,
- Date of death – used to calculate survival time for analysis,
- Sex – sample validation,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised that the prognosis for ovarian cancer patients was poor and that any potential advances in care and treatment options was within the public interest.

The Group considered the involvement of the commercial third party Tristar as funder for the study, which would receive the pseudonymised data and patient samples from Leeds Teaching Hospitals NHS Trust for analysis. It was stated within the application that Tristar would be sharing anonymised patients samples with commercial and pharmaceutical companies which are actively engaged in ovarian cancer drug development programmes.

The Group considered the involvement of commercial partners and subsequent sharing of anonymised data with pharmaceutical companies as it was recognised that, as a generalisation, the public were more cautious when sharing data with these types of organisations. There was potential for these commercial entities to profit as a result of this data sharing. Commercial profiteering from the NHS was another area around which patients had previously expressed disapproval. Members agreed that these concerns needed to be clearly balanced against the wider potential for patient benefit to be realised.

It was recognised that Tristar would be returning a replica of all data and materials collected and processed within the study to the Leeds Teaching Hospitals NHS Foundation Trust to facilitate its own future research. Members agreed that this return of data to the NHS organisation was a positive and helped balance the public interest against potential commercial gain.

The CAG also acknowledged that the patient and public involvement and engagement activity which had been undertaken at the study design phase was supportive of the project proceeding.

A copy of the NHS REC's favourable ethical opinion had been provided as part of the application submission. Members acknowledged that the REC had raised issues with the applicant around the commercial involvement in the study. The REC had sought specific assurance that the tissue samples were

not being sold to Tristar and wider pharmaceutical or commercial entities. The REC was satisfied with the assurance provided by the applicant had issued a favourable ethical opinion at first review. The CAG recognised that confirmation of the REC's favourable ethical opinion also supported the project proceeding.

Members discussed more generally the role of commercial entities in medical advances. It was recognised that there was a reliance on these companies to facilitate drug discovery. These organisations were susceptible to financial risks when drugs failed – it was explained in the application that 90% of drugs which pass laboratory testing fail when tested with patients. The Group recognised that the balance for this was that commercial companies would benefit financially when an effective drug is discovered, which patients would subsequently benefit from.

The CAG was in agreement that the potential public interest which could be achieved from the study was balanced against the potential for commercial gain. The Leeds Teaching Hospitals NHS Trust was not disadvantaged by the involvement of Tristar, the commercial partner, as it would receive a duplicate of all data generated by Tristar to utilise in its own research. The Group was content to provide a recommendation of support for the study.

Scope of Support

The Group agreed that further information was required to clarify which elements of the overarching application activity required a recommendation of support under the Regulations. It was clear that the Biomedical Scientist's access to confidential patient information required a recommendation of support under the Regulations. However, Members were unsure whether the main applicant would be considered to be part of the direct care team and thus whether support under the Regulations was required to extend to his involvement in the study.

When considering whether an individual would be considered to be a genuine member of the direct care team, the CAG takes the perspective that this would be someone who typically provided care to the patient, in line with the definition given by the National Data Guardian within 'The Information Governance Review' (2013), with the caveat that this could also be someone that the patient would reasonably expect to the part of the care team.

Members agreed that this point would be raised with the applicant to seek assurance around his role, to ensure that support under the Regulations was only recommended for activities which specifically involved a breach of patient confidence. The Group was content to provide a recommendation of support for all activities which required it; however, support cannot be recommended when it is not required.

Cohort

The applicant had cited that 500 historic ovarian cancer patients would be included from Trust records over the previous 25 years. Members were unclear how this cohort would be established and whether support was required to enable a wider number of patient records to be accessed in order to achieve the target of 500 patients. Further information would be requested from the applicant in this area.

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 explained that due to the focus disease, it was likely that the majority of the patient cohort would be deceased, so consent was not feasible. A patient group was approached for views around approaching living patients for their consent to the use of data and tissue within the study. The patient group has advised that there was potential for the consent approach to cause undue distress amongst living patient and as such recommended that the while project proceed on an unconsented basis. The CAG

was assured by the rationale provided, and supporting evidence from the patient group, that consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Access to confidential patient information is required to enable identification of patient sample, linkage to wider records and tissue samples and to enable wider clinical information to be extracted from the patient records to support analysis, which could not be otherwise achieved. The CAG raised no concerns in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity 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. A linkage file would be retained for the duration of the study to enable any returned tissue samples to be reassigned to the correct patient, in the likely event that this occurs. The linkage file would be retained by the main applicant only. Members acknowledged that there was an outstanding query around whether this individual would be considered part of the direct care team. If it was determined that he was not, support would be required under the Regulations for the retention of the linkage key. In this instance, the Group agreed that clarification would be required from the applicant around how long this would be held.

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. A patient group has been approached about the study within the design phase. The applicant provided an overview of the demographics of the group, the topics discussed, which included a discussion around the involvement of commercial and pharmaceutical companies in the use of the supplied tissue, for consideration by the CAG.

The patient group was supportive of the project proceeding and had expressed a view that it should be done so on an unconsented basis. The group was comfortable with the involvement of the commercial funder and data sharing with wider commercial and pharmaceutical companies.

The CAG recognised that the activity which had been undertaken in this area was appropriate and proportionate to the proposed activity. It was further commented that interacting with the patient group at the design phase of the study was key in establishing the public interest in the activity proceeding and providing assurance around the involvement of commercial and pharmaceutical companies.

Members agreed that ongoing activity in this area would be important in order to seek patient views around the study findings and subsequent dissemination. This would be added as a condition of support, with a requirement to provide feedback at the time of annual review of wider activity that had been undertaken in this area.

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 had provided a draft of text to be displayed on the Trust website, which provided details of how a patient could object to their involvement in the study. Members commented that the

content of the website text may not be accessible to a lay audience and agreed that this should be revised. It was further noted that the text inaccurately referred to CAG approval, which would need to be corrected.

The applicant stated that a six week lead-in time would be allowed for objections to be raised. Whilst Members recognised that the majority of patients within the cohort were likely to be deceased, it was agreed that this was a limited time period which should be extended to ensure that there was a meaningful time period built in to facilitate any objections. The applicant would be required to clarify the extended duration over which dissent could be raised.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, 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. Confirm whether the Chief Investigator is considered to be part of the direct care team for the patient cohort in order to establish the scope of support which is required under the Regulations.

2. If not considered to be part of the direct care team, clarify how long the Chief Investigator would retain the linkage key, in order to establish a timeframe for the exit from support under the Regulations.

3. Clarify how the 500 patients to be included in the study would be identified, including how many patient records would need to be accessed in order to achieve the target cohort of eligible patients.

4. The website site should be revised to address the following points:

    a. The language should be reviewed to ensure that this would be accessible to a lay audience,
    b. Reference to CAG Approval should be replaced with '…and the Health Research Authority at the recommendation of the Confidentiality Advisory Group…',
    c. The closing date for patient objection should be revised – the lead in time should be extended to allow meaningful period for dissent to be raised.

Specific conditions of support (Provisional)

7. Patient and public involvement and engagement activity should be undertaken on an ongoing basis in order to seek views on the study progress, findings and there subsequent dissemination. Feedback should be provided at the time of annual review around additional activity undertaken in this area and the feedback provided. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
8. Favourable opinion from a Research Ethics Committee (**Confirmed**).
9. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Leeds Teaching Hospitals NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

d. 19/CAG/0033 – Nursing and physician perception of inappropriate intensive care

Context

<u>Purpose of application</u>

This application from Taunton and Somerset NHS Foundation Trust set out the purpose of medical research which aims to evaluate what proportion of patients in intensive care receive treatment which is deemed inappropriate and determine whether doctors and nurses have differing views on what is considered inappropriate care.

The study will be operated on an observational basis whereby doctors and nurses caring for patients will be asked to complete a study questionnaire around the care they have provided to a patient in the intensive care environment and whether they believed the care provided was inappropriate. The questionnaire will be anonymously completed by the hospital staff; however, this will record details of the patient to enable follow-up at six months to confirm outcome status to enable comparison with the views expressed by clinical staff. Data will be collected on eight specified days across an eight week period, from 12 treating hospitals.

Limited follow-up information will be collected at six months following completion of clinician questionnaire – this will record the following only: mortality status at hospital discharge, mortality status at six months post-discharge, for those alive at six months: discharge destination. Contact would be made with the patient's registered GP if discharge destination is unknown from hospital records.

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

Patients aged over 18 years being treated within general, neurosurgical and cardiothoracic intensive cares throughout the South West, requiring one or more of the following organ supports: respiratory, cardiovascular or renal replacement therapy, across an eight week data collection period. It is anticipated that information in relation to 900 patients would be collected across the study duration.

The following items of confidential patient information are required for the purposes set out below:

- Name – sample validation and follow-up,
- Hospital ID – sample validation and follow-up,
- GP Registration – follow-up,
- Date of birth – sample validation and follow-up,
- Date of death – used to inform analysis dataset, though not retained,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Whilst Members recognised that there was value in understanding the difference between clinician and nurse perception of care and the survival of patients, it was commented that it was unclear what wider public interest of patient benefit would be achieved from the project. The Group agreed that further information would be requested from the applicant to clarify how the project findings would be used to patient benefit.

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 CAG recognised that the main focus of the study was around the views of treating clinicians and nurses. As the study focus was around whether the care administered was considered inappropriate, Members were assured that approaching patients or relatives for consent was not feasible due to the sensitive nature of the research topic.

Guidance had been sought around whether surviving patients should be approached at the point of the six month follow-up to provide consent to the ongoing use of their information within the study. The CAG commented that the number of patients who were likely to survive to the six month follow-up would be very small. As the breach of patient confidence had already occurred at this stage, Members were of the opinion that an approach for consent at this stage was unnecessary and it was recognised that this would involve a more significant breach of confidential patient information in order to facilitate the consenting mechanism.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the six month-up follow process which could not be otherwise achieved.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity 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. It was recognised that support under the Regulations was sought for a time limited basis only; however, the Group was unclear when confidential patient information held by the applicant would be destroyed. Confirmation would be sought from the applicant in order to establish the exit strategy from support under the Regulations.

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 application did not describe any activity in this area. Whilst Members recognised that the proposed study involved limited intrusion for patients, small-scale activity was required in this area in order to test the acceptability of using confidential patient information without consent for the proposed study aims. This would also help to establish a public interest in the proposed activity.

Feedback from the required activity would be required prior to any 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 application did not describe a communications strategy for the study or indicate how patient dissent would be respected.

Members recognised the sensitive nature of the research focus and suggested that any patient-facing documents could provide generic information around research being carried out on the ward using patient data and provide a generic opt-out. Wider information could be made available via the Trust's website.

The CAG agreed that an overview of the communications and objection mechanism together with sight of any documentation to facilitate this would be required prior to any recommendation of support coming into effect.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. Assurance is currently provided by confirmation of NHS Digital's satisfactory review of an organisation's self-assessment against Version 14.1, 2017/18 of the Information Governance toolkit.

The study will be carried out at 12 hospital Trust sites across in the South East England area. Assurance would not be checked for each individual site due to the number involved in the study. Support would be recommended on the basis that it is the applicant's responsibility to ensure that every site has the required security standards in place prior processing any confidential patient information with support under the Regulations on site.

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. Further information is required from the applicant to evidence how the proposed activity is compliant with the principles of the GDPR detailed at Article 5(1) – principles (a)-(f), including confirmation of the lawful basis being relied upon for processing in relation to data (Article 6) and special category data (Article 9).

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 (Summary)

1. Provide further information to explain how the findings of the proposed study will be used in order to identify the overarching public interest in the application activity.

2. Confirm when confidential patient information collected would be destroyed in order to establish an exit strategy from support under Regulations.

3. Patient and public involvement and engagement activity should be carried out in order to seek views around the acceptability of using confidential patient information without consent to achieve the study aims. An overview of the activity undertaken should be provided, details about the demographics of the group involved and feedback provided.

4. Explain how a communications and objections mechanism would be operated for the study and provide copies of any documentation used to facilitate this.

5. Provide further information to evidence how the proposed activity is compliant with the principles of the General Data Protection Regulations detailed at Article 5(1) – principles (a)-(f), including confirmation of the lawful basis being relied upon for processing in relation to data (Article 6) and special category data (Article 9).

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Not checked – the study will be carried out across 12 Trusts – security assurance would not be checked for all participating sites. Support is recommended on the basis that the applicant is responsible for seeking assurance that the appropriate security arrangements are in place, in line with information provided above**).

e. 19/CAG/0019 - Button Battery

Context

Purpose of application

This application from the Leeds Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to investigate the prevalence and severity of injury caused to children who have accidentally ingested or inhaled button batteries. Button batteries are small, round batteries used to power devices such as toys and greetings cards.

The study will operate via the approved BPSU methodology: the BPSU 'orange card' reporting system, which is approved in principle by the CAG. All UK and Ireland paediatricians participate in the compulsory reporting system over a 13 month period, where they are asked to return a card to BPSU stating whether or not they have observed a case of the disease under observation (in this case button battery ingestion or inhalation). BPSU then provides details of clinicians who have reported a case of the disease to the research team, who send a questionnaire for the clinician to fill in.

The study consists of single questionnaire which will be returned by the treating clinician. Limited confidential patient information would be collected to facilitate sample validation and to remove any duplicate entries, following which confidential patient information would be destroyed.

The BPSU methodology covers the UK and Republic of Ireland; however, the remit of the CAG extends to information generated in England and Wales only. The applicant will need to make alternative arrangements for the wider nations involved in the study. The applicant has confirmed that an application is being made to the PBPP in Scotland.

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

Confidential patient information requested

Cohort

Any presentation of any child under the age of 16 years who has ingested or aspirated a button battery of any description requiring hospital admission including those that were admitted for only observation across the 13 month reporting period. It is anticipated that 300 cases will be reported to the study.

The following items of confidential patient information are requested for the purposes set out below:

- NHS Number – sample validation,
- Date of birth – sample validation and analysis,
- Date of death – analysis,
- Postcode (district level) – sample validation and analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that the developing the knowledge base around the prevalence and severity of injury cause by the ingestion of button batteries was within the public interest as electrical devices were becoming increasingly accessible to children and young people.

Scope of Support

The application proposed a 13 month reporting period for the study; however, the applicant had stated that if they did not receive sufficient reporting in this timeframe, the reporting period may be extended. The CAG noted that an extension to the reporting period would need to be submitted as an amendment in a sufficiently timely manner to enable processing head of the end of the supported reporting period.

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 stated that consent was not feasible due to the requirement for complete case ascertainment. The Group acknowledged that the project had been accepted by the BPSU panel to operate via the established methodology, which helped establish a public interest in the study proceeding. However, it was agreed that the application did not provide a strong enough rationale for support why consent was not feasible for this particular study.

- Use of anonymised/pseudonymised data

The CAG was assured that confidential patient information was required to facilitate sample validation and removal of duplicate entries, to ensure an accurate prevalence of incidence could be reported. No issues were raised in this area.

- Use of Hospital Episode Statistics Database

The Group acknowledged that the HES database held by NHS Digital only recorded ingestion of a foreign body and was unable to provide data on a specific type, i.e. button battery. It was accepted that this did not provide a practicable alternative to the proposed study methodology.

Justification of identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the application activity. No issues were raised 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 application was reviewed by the BPSU scientific committee, which included lay membership, and is a standard requirement for applications seeking to use the BPSU methodology. The Royal Society for the Prevention of Accidents had been involved in the design of the study questionnaire. The study has also received support from the Child Accident Prevention Trust.

The applicant explained that a parent focus group was facilitated with the mothers of toddlers and infants, which was supportive of the study. The CAG agreed that the activity undertaken in this area was appropriate and proportionate to the proposed study and raised no queries in this area.

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 had confirmed that patient information leaflets would be provided to participating sights. This would be supplemented by information on the BPSU and Leeds Teaching Hospitals NHS Foundation Trust websites. The documents were still being drafted and sight would be required prior to any final recommendation of support.

The Group commended the networks which had been established with the Royal Society for the Prevention of Accidents and the Child Accident Prevention Trust. It was queried whether these networks could be utilised to promote the study to a wider audience via their websites. The applicant would be asked to explore this option and provide copies of any wider notification text for consideration.

Reference had been made to the National Data Opt-Out within the application form. It was noted that implementation of the National Data Opt-Out was being rolled out gradually and currently NHS Digital was the only organisation which is mandated to apply this. Members commented that as NHS Digital was not involved within the application, the National Data Opt-Out would not apply in this instance. It was agreed that a clear overview of how a patient objection mechanism would be operated for the study would be required.

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 (Summary)

1. Provide a stronger justification to support why operating a consented model is not feasible for the study.

2. Provide copies of the patient information leaflet and text to be displayed on the BPSU and Leeds Teaching Hospitals NHS Foundation Trust websites.

3. Explore the potential of extending the patient notification mechanism through the display of information via wider linked organisations website. Confirm whether this is feasible and provide copies of any text which would be displayed.

4. Explain how a patient objection mechanism would be operated for the study.

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, the HRA will confirm approval.

Specific conditions of support (Provisional)

1. Support extends to England and Wales only.
2. Favourable opinion from a Research Ethics Committee (**Pending**).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Leeds Teaching Hospitals NHS Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

6. MINUTES OF THE MEETING HELD ON 24 JANUARY 2019

The minutes of the meeting held on the 24 January 2019 were shared in draft format for consideration. It was noted that an item remained pending with the Confidentiality Advice Team which required resolution prior to formal sign-off of the meeting minutes.

7. CAG CHAIR REPORT

A report from the Chairman was received by the Members.

8. ANY OTHER BUSINESS

No further business was raised. The Chair thanked Members for their time and the meeting was closed.