Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

17 May at 10:30 at Barlow House, M1 3DZ

Present:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Tony Calland MBE (Item 3.a. only)	Yes	Chair
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	Lay Member
Dr Rachel Knowles	Yes	
Mr Andrew Melville	Yes	Lay Member
Ms Clare Sanderson	Yes	Alternate Vice-Chair
Dr Murat Soncul	Yes	Alternate Vice-Chair
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley (Item 3.a. only)	Head of Confidentiality Advice Service
Mr Stephen Tebbutt (Item 3.a. only)	Head of Corporate Governance
Dr Vicky Chico (item 4 only)	Lecturer in Law, University of Sheffield
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

Mr Steve Tebbutt, Head of Corporate Governance, was welcomed to the CAG meeting for agenda item 3.a. only.

Dr Vicky Chico, Lecturer in Law at the University of Sheffield, was welcomed to the CAG meeting for agenda item 4 only.

Apologies

There were no apologies for absence received.

Declarations of Interest

The following interests were declared:

18/CAG/0088: Ms Clare Sanderson advised the Group of a possible conflict of interest in the item due to potential future activity with the applicants, which could not be fully disclosed because of commercial sensitives. Ms Sanderson did not participate in the discussion of the item; however, remained present within the meeting as there was no direct conflict with the application being considered.

2. APPROVAL DECISIONS

The following decisions were taken in relations to the relevant CAG recommendations.

Secretary of State for Health and Social Care Approval 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 **19 April 2018** meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the **19 April 2018** meeting applications.

In relation to application reference 18/CAG/0052, which was considered at the Precedent Set Review for March 2018, the decision-maker agreed with the advice given by the CAG in relation to this application. This specific application was a BPSU study focussing on children with Chronic Fatigue Syndrome or Myalgic Encephalitis – the decision-maker highlighted that there was currently a heightened interest in this disease area. As such, the HRA decision-maker added an additional recommendation to the outcome that the applicants should look to strengthen their patient and public involvement and engagement activity as the project progressed. This was added as recommendation only and did not change the outcome or request for further information raised by the CAG.

3. EDUCATION ITEM

a. General Data Protection Regulation (GDPR) – led by Dr Vicky Chico

The Chair welcomed, Dr Vicky Chico, Lecturer in Law at the University of Sheffield, to the meeting. Dr Chico presented an educational item on the forthcoming General Data Protection Regulation to the CAG.

Dr Chico was thanked for her attendance at left the meeting.

4. NEW APPLICATIONS – Non-Research

a. 18/CAG/0083 – National Ophthalmology Database (NOD) Audit

Context

Purpose of Application

This application from the Royal College of Ophthalmologists, on behalf of the Healthcare Quality Improvement Partnership (HQIP) set out the medical purpose of clinical audit which consists of consists of a national cataract audit in England and Wales, as well as a feasibility study for the collection of cataract patient reported outcome measures (PROMs).

The audit was initially funded for three years from 01/09/2014 to 31/08/2017, during which pseudonymised data only was collected. The audit programme has now been extended for a further two years from 01/09/2017 through to 31/08/2019, during which a change to the methodology is proposed to enable confidential patient information to be collected as part of the audit programme. It is explained that by collecting confidential patient information, the applicants will be able to:

- Check the completeness of extracted data from providers by cross checking patient ID against NHS Digital data for individual cataract operations done by each centre,
- Link patients' data if collected at different centres and track patients moving between providers for 2nd eyes (R/L) or operations by another provider to deal with complications,
- Match the patient's postcode to the English and Welsh indices of social deprivation.

The Royal College of Ophthalmologists has been commissioned by HQIP to provide the audit. Data processing for the audit has been sub-contracted to Gloucester Hospitals NHS Foundation Trust (GHNHSFT).

There is a feasibility element to the project around the collection of PROMs data from patients which will be operated at 5-10 sites who are providing data to the audit.

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

Confidential Patient Information Requested

Cohort

- All adult patients in England & Wales undergoing cataract surgery, between 01/09/2017 to 31/08/2019.
- Sample size is not known; however, 420,000 cataract operations were undertaken across England and Wales in the last audit reporting period (2016/17).

The following patient identifiable data will be extracted from the EMR systems and databases of participating centres in England & Wales and transferred to Gloucester Hospitals NHS Foundation Trust (GHNHSFT):

- NHS Number,
- Date of birth,
- Person Gender Current (Sex),
- Ethnic category (where available),
- Post Code of Usual Address – to calculate IMD.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, through the management of health and social care services, via clinical audit. It was acknowledged that the audit had initially been funded for three years from 01/09/2014 to 31/08/2017, during which pseudonymised data only was collected.

This application had been submitted following the extension to the audit programme for a further two years from 01/09/2017 to 31/08/2019, with a proposed change to the methodology to enable confidential patient information to be collected. It was stated within the application that the proposed change to the audit methodology, to include confidential patient information within the data collection, would enable analysis of case ascertainment, tracking of patients moving between services for the provision of treatment on a second eye, follow-up any treatment for complications and enable socio-economic analysis of the patient sample.

The proposed change to the audit methodology was considered. Members were unclear from the information included within the application what additional purposes would be served by moving towards the collection of confidential patient information within the audit programme. Whilst it was stated that confidential patient information would be requested from NHS Digital and NHS Wales Informatics Service (NWIS) in relation to Trusts/Health Boards participating in the audit, it was unclear how this information would be used to improve the outputs of the audit. It was agreed that further justification was required from the applicants to support the change to the audit methodology and to explain what additional benefits would be achieved from the processing of confidential patient information which were not possible from aggregated data only. This was required to justify the public interest in the proposed activity proceeding with support under the Regulations.

The Group discussed how aggregated data could be used as a practicable alternative to achieve the wider analysis of case ascertainment. As an example, it was suggested that, by compiling an aggregated list of number of procedures per Trust included within the audit submission and comparing this with an aggregated list, provided by NHS Digital, of the number of procedures performed at each Trust site, the applicants would be able to challenge individual Trusts that show significant discrepancies between the figures. Members commented that it would be helpful to understand the current ascertainment of the audit programme against the actual number of cataract operations which are undertaken in England and Wales. This would clarify whether there was actually an issue with the data collected via the audit which required resolution. It was also agreed that further rationale was required to explain how the applicants would utilise confidential patient information to improve reporting via the audit programme as it did not appear that there would be any follow-up with individual Trusts following supply of information from wider NHS organisations.

Members noted that patient postcode was requested to enable socio-economic analysis of the patient cohort to be undertaken; however, the application did not describe what analysis would be carried out and further information was required to justify the requirement for this information.

The Group agreed that this additional clarification and justification was required before any recommendation of support for the activity could be considered as the public interest in the audit programme progressing via the proposed changed methodology was unclear.

Practicable Alternatives

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

- Feasibility of consent

The Group acknowledged that consent was not feasible for the audit programme due to the potential size of the patient cohort to be included.

- Use of anonymised/pseudonymised data

It was recognised that the audit programme had operated for three years on the basis of collecting pseudonymised patient level data only. As discussed previously, the CAG was unclear what additional benefits would be achieved from the audit programme by moving to the collection of confidential patient information. Further information was requested.

Justification of Identifiers

Members agreed that a stronger justification would need to be provided to support the collection of confidential patient information for the audit programme. Further information was requested.

Data Flows

The applicants had clarified in response to queries that confidential patient information would not be shared with NHS Digital for linkage with HES. It was confirmed that the applicants intended to apply to NHS Digital to request confidential patient information for all patients undergoing cataract surgery at participating Trusts during the audit period. The rationale to support the proposed data flow was unclear. The applicants were asked to consider the proposed methodology and consider ways to minimise the flow of confidential patient information. It is also requested that contact is made with NHS Digital and NHS Wales Informatics Service to discuss the proposed activity and seek agreement in principle.

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 acknowledged that the steering group which had been established for the audit programme included four patient and public representatives from the Royal National Institute of Blind People (RNIB), the Patients Association and the Royal College of Ophthalmologists Lay advisory group. The steering group is scheduled to meet twice a year and is responsible for the oversight and management of the audit programme. It was commented that the detail included within the application did not provide any detail around interaction with the patient and public representatives around the proposed change to the audit programme. Members agreed that further information should be provided around any activity which was carried out in this area, together with the feedback provided from the representatives, to assist with the establishment of a public interest in the proposed methodology change.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The Group agreed that the patient materials which would support the audit programme were of high-standard and provided clear information about the audit and how data would be used together with a clear pathway for opt-out. It was commented that the involvement of NHS Digital and NWIS was not included in the documentation, which may require revision should any changes be proposed to the data flows be made.

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. It was noted that a self-assessed scores for Gloucester Hospitals NHS Foundation Trust and Medisoft Limited had been published in respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. Contact should be made with NHS Digital to progress this element.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further Information Required (Summary)

1. Further justification is require to support the proposed change to the audit methodology as it unclear why confidential patient information is required to achieve the audit aims. The following points should be addressed within the response:
    a. Clarify the current ascertainment of the audit in relation to the number of cataract operations which are carried out, to highlight the issues with the current methodology,
    b. Clarify why aggregated data provided by NHS Digital would not be sufficient to address the case ascertainment issues,
    c. Provide further information to explain how confidential patient information will be used to improve the audit programme, which could not otherwise be achieved,
    d. Explain what additional public interest will be achieved via the processing of confidential patient information within the audit,
    e. Provide further detail around the analyses which are proposed of the audit data and what the potential benefits would be achieved from this work.
2. The proposed data flows via NHS Digital and NHS Wales Informative Service should be considered as part of the revised application, in order to minimise the flow of confidential patient information. An overview of the methodology should be provided as part of the revised application, together with confirmation of agreement in principle from these organisations as data controllers for HES/PEDW of their involvement in the study.
3. Provide further detail around the engagement activity which was undertaken with the patient and public representatives around the proposed change to the audit methodology, together with an overview of the feedback provided to support the public interest in the activity.
4. Revisions should be made to the participant information materials, as necessary, should any changes be made to the data flows involved with NHS Digital/NWIS.
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

5. NEW APPLICATIONS – Research

a. 18/CAG/0079 – Safety and Experiences of Medical and Surgical In-Patients with Severe Mental Illness

Context

Purpose of Application

This application from the Oxford Brookes University set out the purpose of medical research which aims to explore the experiences of service users with severe mental illness (SMI) on medical and surgical wards in acute general hospitals.

The project has two phases, the first of which is for the CAG consideration which involves secondary analysis of incident data and patient survey data. The applicant will access patient safety incident reports for incidents within 2016 in order to create a listing report which will include mental health diagnoses of the patients together with details of the incident. The applicant will also be requesting data from the Inpatient Survey 2016 from the CQC to support the analysis – this data release is out of scope for the CAG consideration as the extract will not include any confidential patient information. The second phase of the project will include semi-structured interviews with patients, which will be conducted on a consented basis and is out of scope for the CAG.

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

Confidential Patient Information Requested

Cohort

- Patients aged 19-64 diagnosed with a serious mental illness, who have had a medical or surgical inpatient experience in an NHS hospital in England in the last two years.
- The applicant will be accessing all patient safety incident reports from 2016; mental health diagnosis will be confirmed to enable the focus sample of patients with serious mental illness to be identified.
- Patients without a mental health diagnosis will form a comparison cohort.

The following items of confidential patient information are required to link information from the patient safety incident reports (DATIX system) with information from the electronic patient records system, in order to establish mental health diagnosis:

- NHS Number – sample validation and linkage,
- Hospital Number – sample validation and linkage,
- Sex – analysis,
- Age (at time of discharge) – analysis.

Confidentiality Advisory Group Advice

Members considered the application and supporting documentation which had been provided in connection with this proposal. It was acknowledged that the remit under which the CAG can advise is defined in section 251 of the NHS Act 2006 and its Regulations.

The application stated that in order to achieve the study aims, the main applicant required access to two data sources: patient incident reports via the DATIX system and electronic patient records in order to link with a mental health diagnosis. The application stated that the main applicant had access to these datasets within her role as the Patient Experience Manager at Oxford University Hospitals NHS Foundation Trust.

The CAG recognised that it may not fully understand the nature of the role of the Patient Experience Manager; however, commented that it was unclear why this role would require access to a full patient medical records system, which included sensitive information in relation to mental health diagnosis, to fulfil their role. However, the CAG agreed that, as set out by the applicants within the project documentation, the application activity did not involve a breach of the common law duty of confidentiality and as such, the remit under which the CAG can advise had fallen away. This agreement was reached on the basis of the detail

supplied within the application which stated that the main applicant had legitimate access to the relevant data sources as part of her standard role.

As the application activity described did not fall within the remit under which the CAG can advise, no wider consideration of the application detail was undertaken. The Group commented that, should the application activity not have been clearly understood and revised submission be made in future, a full review of all relevant consideration points would be undertaken at that time and further queries or issues may be raised.

Confidentiality Advisory Group Advice Conclusion

The CAG recommended that support under the Regulations did not appear to be required as it was stated within the application that the proposed activity did not involve a breach of the common law duty of confidentiality.

b. 18/CAG/0084 – The epiCrypt Study - Household transmission of cryptosporidiosis v1.0

Context

Purpose of Application

This application from the University of Liverpool set out the purpose of medical research which aims to estimate the secondary spread of Cryptosporidium, which is a major contributor to human diarrhoeal illness and infection with this parasite causing over 4,000 cases of diagnosed illness in England and Wales each year, that happens in the home and identify asymptomatic infection, which might have a role in transmitting disease. In addition, risk factors and characteristics associated with secondary spread will be described, including any differences in transmission between species.

The study will identify 400 cases from NW England and Wales over the course of 2018-19, and invite them and their household to take part. Each case will complete a questionnaire and each household member will provide a stool sample. Data will be analysed to show factors associated with spread and stool samples will be genetically characterised to accurately describe patterns of transmission.

Cryptosporidium is laboratory reportable when confirmed, and cases can only be identified via surveillance. In order to identify patients/households to be invited to participate in the study, surveillance databases will be trawled by staff based at Public Health England and Public Health Wales. Staff will not have access to any wider information that they would do as part of their standard role; however, as the data will be used for a wider purpose (research), support under the Regulations is required to support this change in purpose.

For invited potential participants who do not raise an objection to the use of their data within the two weeks from invitation, confidential patient information will be passed from PHE/PHW to research nurses based at the NIHR Clinical Research Network North West Coast, in order to facilitate the invitation/recruitment process. The applying research team will not have access to any confidential patient information until consent has been provided by the patient.

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

Confidential Patient Information Requested

Cohort

- The study population is residents of North West England and Wales, 2018-19.
- Any laboratory confirmed case of Cryptosporidium isolated from one of the laboratories in NW England or Wales is eligible for initial inclusion as an index case.
- Study data will be collected for one year.

- The applicants are aiming to collect 400 index cases and their households with an approximate overall sample size of 1,000.

The following items of confidential patient information are required to facilitate the invitation process:

- Name,
- Full address and postcode,
- Date of birth – required to enable correspondence to be appropriately addressed to patient or parent/guardian,
- Telephone number – to facilitate the recruitment contact.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research, which aimed to investigate the secondary spread of Cryptosporidium. Members recognised that there was public interest in gaining a better understanding of how the disease spreads as it was attributed as the cause of over 4,000 diagnosed illnesses each year within England and Wales.

Scope of Support

This application had been submitted to the CAG for review as the applicants intended to use confidential patient information contained within surveillance data collected by Public Health England and Public Health Wales under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002, for research purposes. This application had been submitted to the CAG for consideration under Regulation 5 of the Regulations, to seek support to use the data for research purposes.

Practicable Alternatives

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

- Feasibility of consent

The Group recognised that as detection of Cryptosporidium was retrospective and undertaken by laboratory staff, there was no opportunity to consent individuals at the time of diagnosis. All patients would be approached for consent to participate in the study; however, processing of confidential patient information was required to facilitate this recruitment process. Members were assured that the recruitment process could not be otherwise facilitated.

A query was raised around the timeline for the approach to consent by the CAG, as it was unclear from the detail within the application whether patients would have been informed about the Cryptosporidium diagnosis, prior to receiving the research invitation. It was agreed that confirmation around this point was required.

- Use of anonymised/pseudonymised data

The recruitment process could not be achieved without access to confidential patient information.

Recruitment Process

The recruitment process which had been set out within the application form was discussed. It appeared that up to six contact attempts would be made with potential participants, which Members suggested may be excessive. It was noted that the CRN nurses would attempt to contact via telephone on three occasions

and the Group queried whether voicemail messages would be left at each occasion. Clarification around this point was required from the applicants.

Justification of Identifiers

The applicants had requested date of birth as part of the dataset to enable recruitment correspondence to be appropriately addressed to either the patient, or their parent/guardian, if the patient was a minor. Members were unclear why full date of birth was required to facilitate this element, as it suggested that patient age or confirmation of adult/child would be sufficient to direct the communications. The applicants would be asked to reconsider this element and provide a stronger rationale to justify the requirement for full date of birth if this was deemed necessary.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The Group noted that clear retention statements had been established for data which would be held by the Clinical Research Network, pending patient consent. It was acknowledged that the maximum case finding period for recruitment to the study would be one year, should complete target ascertainment not be established earlier. Clarification was required from the applicants around the overall duration of support which would be required under the Regulations to support the recruitment processes, should this extend to full duration.

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 applicants had confirmed that no activity had been undertaken or was planned within this area. Members agreed that the applicants would be required to undertake some work in this area, in order to test the acceptability of using confidential patient information without consent in order to facilitate the study recruitment procedures. It was commented that Public Health England had an established people's panel, which may be a possible channel for engagement. An overview of the activity which was undertaken, together with feedback from the panel would be required prior to any recommendation of support coming into effect. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

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

It was confirmed within the application that there would be no generic communications strategy around the study to support the targeted recruitment materials which would be sent direct to eligible patients. Members noted that Public Health England currently published information on Cryptosporidium via the gov.uk website and it was suggested that additional information could be placed on this webpage in order to promote the research programme in the wider public arena. It was also commented that it may be helpful to include this website link within the recruitment materials, should patients wish to find out further information. The Group agreed that further action was required from the applicants in this area prior to any recommendation of support coming into effect. It was suggested that the patient and public engagement activity could advise around the content of the webpage.

The targeted recruitment materials were also considered by the Group. It was noted that the initial invitation letter provided information around how a patient could dissent to further contact around the research programme; however, the patient was required return an objection slip by post. Members agreed that a

telephone number and email address should also be offered as alternative means to raise an opt-out. A revised invitation letter was 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 for processing in England or CPiP Assurance for processing in Wales. Confirmation is required around which organisations will be processing confidential patient information with support under the Regulations to enable the appropriate IG assurance to be checked.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Evidence of the favourable ethical opinion would be required prior to any final recommendation coming into place for the application.

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. Confirm that patients would be informed of the Cryptosporidium diagnosis prior to receiving the research invitation.
2. Confirm whether date of birth could be translated into age prior to the release of data to the CRN, in order to reduce the identifiability of the disclosed dataset. If full data of birth is required, stronger justification is required to support this.
3. Clarify the overall duration of support under the Regulations which is required to facilitate the recruitment process.
4. Confirm whether the CRN staff, when contacting potential participants by telephone around the project, will leave a voicemail in connection with the study.
5. Patient and Public Involvement and Engagement – work should be undertaken in this area in order to test the acceptability of using confidential patient information without consent for the project aims. It is also recommended that advice is sought from this engagement activity around what additional information could be displayed via a webpage to supplement the invitation materials. An overview of the activity undertaken in this area should be provided, together with feedback from the patient and public representatives. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.
6. A wider communications strategy should be developed to raise the profile of the study – it is suggested that this could link with the information which is already published online by PHE about Cryptosporidium. Feedback should be provided around what additional communications will be put in place, together with a draft of any information for consideration.
7. The invitation letter should be revised to include alternative contact details to facilitate patient objection. A link should also be included within the document to the webpage details referenced at point six above, to provide further information.
8. Confirm which organisations will be processing confidential patient information with support under the Regulations to enable the IG Assurance to be checked.

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 for organisations processing data in England and NHS Wales Informatics Service CPIP Assurance for organisations processing in Wales (**Pending**).

c. 18/CAG/0085 – Investigating the use of 'frailty' on death certificates and admission

Context

Purpose of Application

This application from Sheffield Hallam University set out the purpose of medical research which is a preliminary study to investigate the use of the term 'frailty' and whether the use in case records is consistent with the use on death certificates. Frailty is a significant factor in the morbidity and mortality of older people. Frailty has been defined as "…a distinctive health state related to the ageing process in which multiple body systems gradually lose their in-built reserves" (BGS, 2014a) and is a recognised syndrome in the UK. Increasing numbers of older people are admitted to hospital with acute problems and are either admitted with frailty or become frail after admission. Frailty affects clinical outcomes and may be a cause of death but is not an inevitable consequence of ageing. This leads to questions of how frailty might be detected and prevented in an inpatient population.

The project will involve a retrospective case note review of patient records at Sheffield Teaching Hospitals NHS Foundation Trust. The Bereavement Services Manager will identify the patient cohort for inclusion from the hospital database of recorded deaths – this initial identification is out of scope for the CAG application, as the individual has legitimate access to this information. Patient names and hospital numbers will be used to request patient records in order to capture wider clinical information. Support is sought under the Regulations to support the disclosure of this information to the applicant and legitimise access to the patient cohort medical records in order to extract the pseudonymised dataset required for analysis.

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

Confidential Patient Information Requested

Cohort

- Patients who died within Sheffield Teaching Hospitals NHS Foundation Trust during the six month period between the beginning of January 2017 and the end of June 2017, who had the term frail/frailty or associated synonyms recorded on their death certificate. The sample size is estimated to include 301 patients.

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

- Name – validation and identification of cohort,
- Hospital number– validation and identification of cohort,
- Date of birth – to note age at event for analysis,
- Date of death – sample validation (ensure death occurred within study inclusion period),
- Postcode (District Level) – analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, through medical research, which aimed to investigate the use of the term frailty and whether this was consistent across

patient records and death certificates. Members recognised that frailty was currently an area of interest within hospitals and was satisfied that there was public interest in this feasibility study proceeding.

Practicable Alternatives

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

- Feasibility of consent

The Group accepted that consent was not feasible for the project as the patient cohort for inclusion was deceased.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was required in order to access patient records to extract the information required for analysis. Members were assured that this 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 raised no issues 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 Group commented that the patient and public involvement and engagement activity which had been undertaken was limited to two patients; however, it was agreed that as this proposal was only for the feasibility study, the activity was sufficient. Members stated that, should the applicants look to undertake a follow-up study, wider activity would be required in this area. It was explained that frailty was a comorbidity which was identified with a wide range of illnesses, which provided opportunity for varied patient engagement.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members recognised that direct notification was not possible as the patient cohort was deceased; however, it was agreed that information could be displayed on the Trust website in the interests of transparency in order to raise the profile of the research activity. Confirmation that information would be made available was required prior to any recommendation of support coming into effect.

The applicants had stated within response to queries that the Trust did not have a mechanism for recording dissent from patients around the use of their data for purposes wider than direct care, so evidence of historic dissent could not be checked for patients whose data would be included in the study. Members remarked that it seemed unusual that the Trust would not have an established mechanism to record this information as there was national policy in this area. It was agreed that clarity would be sought around this point to ensure that there was no facility to check patient records for evidence of historic dissent.

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. It was noted that a self-assessed scores for Sheffield Teaching Hospitals NHS Foundation Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. Contact should be made with NHS Digital to progress this item.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Confirmation of the favourable ethical opinion is required prior to any recommendation of support coming into effect.

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. Confirm that information materials will be displayed on the Trust website in order to promote the research within the wider public arena.
2. Confirm that, despite national policy in this area, the Trust does not operate a mechanism to record patients' dissent against the wider use of data for purposes in addition to direct care.

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 (**Pending**).

d. 18/CAG/0086 – Sydenham's Chorea Surveillance Study v1

Context

Purpose of Application

This application from the University of Exeter Medical School set out the purpose of medical research using the established British Paediatric Surveillance Unit (BPSU) and Child and Adolescent Psychiatry Surveillance System (CAPSS) methodology to investigate incidence of Sydenham's chorea, which is a disease affecting the brain that usually occurs in children and adolescents and causes abnormal movements, emotional and behavioural symptoms. The condition is associated with prior infection with the bacteria streptococcus and may severely impact on the child's ability to carry out activities of daily living such as dressing, walking or writing.

The BPSU and CAPPS methodologies have received support in principle from the CAG.

Through the established BPSU orange card and CAPSS yellow card reporting systems, clinicians will report all children and young people with symptoms of Sydenham's chorea in their service in the UK and Ireland. The reporting period will be two years for the paediatric element and one year for the psychiatric

component. For each reported case clinicians will be asked to complete 12 and 24 month follow-up questionnaires after initial notification. The questionnaires have been approved by the BPSU and CAPSS Executive Committees and contain minimal patient identifiable information necessary to allow for case verification, matching and removing duplicate notifications and provide essential clinical research data.

The project extends to the UK and the Republic of Ireland; however, the CAG support would extend to England and Wales only. The applicant has been advised to seek alternative arrangements for data processing in the wider countries involved in data collection.

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

Confidential Patient Information Requested

Cohort

- Paediatric study run through the BPSU – children and young people aged 0-16 years presenting to the reporting clinician for the first time with a first episode of confirmed Sydenham's chorea.
- Psychiatric study run through the CAPSS – children and young people aged 0-16 years with confirmed Sydenham's chorea presenting to the reporting clinician for the first time within the current episode of care with psychiatric symptoms with an onset or exacerbation coinciding with or following the first episode of Sydenham's chorea.
- It is estimated that 100 patients will be reported into the study.

The following items of confidential patient information will be disclosed by the treating clinicians to Devon Partnership NHS Trust, for the purposes set out below:

- NHS number – validation and linkage,
- Hospital Number – validation and linkage,
- Postcode (sector level) – recoded as region for analysis,
- Sex – validation and analysis,
- Ethnicity – validation and analysis.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research, which aimed to investigate the incidence of Sydenham's chorea via the established BPSU and CAPPS methodologies. Members recognised the public interest in the activity proceeding as gaining wider knowledge of this rare condition would be of benefit.

Practicable Alternatives

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

- Feasibility of consent

The Group recognised the accepted rationale for activity proceeding via the BPSU and CAPPS methodologies on an unconsented basis, which was that, due to the rarity of the conditions being studied, operating a consented model had the potential to introduce bias and effect case ascertainment as patients would need to return to clinic specifically for consenting purposes. Members were assured that this rationale applied in the circumstances of the proposed research.

- Use of anonymised/pseudonymised data

It was acknowledged that minimal identifiers were required to validate the patient sample and undertake follow-up of reported patients. Members were assured that this could not otherwise be achieved and raised no further issues in this area.

Justification of Identifiers

The CAG agreed that the items of confidential patient information requested were the minimum proportionate amount required to achieve the study aims.

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 Group recognised that there were established links with the Sydenham's Chorea Association, a charitable organisation which was supportive of the project. It was also acknowledged that there were patient representatives involved in the project who would take the lead in disseminating research findings. Members were assured that the activity in this area was appropriate and proportionate to the proposed study and raised no further issues.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998. Members were satisfied with the information materials which had been drafted to support the project and raised no issues in this area.

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. It was noted that a self-assessed scores for Devon Partnership NHS Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. Contact should be made with NHS Digital to progress this item.

Confidentiality Advisory Group Advice Conclusion

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

Request for Further Information

1. Confirmation of the NHS Digital review of Devon Partnership NHS Trust's Version 14.1, 2017/18, Information Governance Toolkit submission.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 14 May 2018)**.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending**).

6. MINUTES OF THE MEETING HELD ON 19 APRIL 2018

The minutes of the meeting held on 19 April 2018 were received and ratified as an accurate record of proceedings with no required revisions.

7. CAG CHAIR REPORT

The Chairman's report was received by the Group with no queries.

8. EDUCATION ITEMS (2018/19)

The Group discussed potential educational items for the remainder of the financial year, which were recorded for follow-up by the Confidentiality Advice Team.

9. ANY OTHER BUSINESS

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