Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

02 May 2019 at Skipton House, SE1 6LH

Present:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair
Dr Patrick Coyle	Yes	Vice Chair
Dr Liliane Field	Yes	
Dr Lorna Fraser	Yes	
Mr. Myer Glickman	Yes	
Dr Katie Harron	Yes	
Dr Simon Kolstoe	No	Apologies received
Professor Jennifer Kurinczuk	Yes	
Dr Harvey Marcovitch	Yes	
Mr Andrew Melville	Yes	Lay Member
Ms Clare Sanderson	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	Confidentiality Advisor
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor

Ms Dawn Monaghan (Item 3.a. only)	Head of Data Sharing and Privacy at NHS England, Head of Strategic IG at NHS Digital and Director Information Governance Alliance
Mr John Farendon (Item 3.a. only)	Senior Programme Lead, NHS England LHCR Programme

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Chair welcomed Dawn Monaghan, Head of Data Sharing and Privacy at NHS England, Head of Strategic IG at NHS Digital and Director Information Governance Alliance together with John Farendon, Senior Programme Leave, NHS England LHCR Programme to the CAG meeting. The external guests attended for agenda item 3.a. only.

The CAG thanked the guests for their attendance to deliver the educational item.

Apologies

Apologies were received from Dr Simon Kolstoe in advance of the meeting.

Declarations of Interest

- Professor Jennifer Kurinczuk noted that agenda item 4.d. (19/CAG/0054) had been submitted by her appointing organisation – University of Oxford; however, this was from the Orthopaedic Department with which she has no involvement. This was noted for transparency purposes but determined not to be a true conflict of interest so no further action was required.

- Dr Lorna Fraser noted that she had previously worked in the same office as the named applicant for agenda item 4.b. (19/CAG/0069). Dr Fraser was not assigned to actively review this application and it was agreed she would remain out of discussions.

2. SUPPORT DECISIONS

Secretary of State for Health and Social Care 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 **07 March 2019** meeting applications.

Health Research Authority Support Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **07 March 2019** meeting applications.

3. EDUCATION ITEM

a. Local Health and Care Record (LHCR) – Journeys

Ms Dawn Monaghan and Mr John Farendon delivered an educational item to the CAG around the Local Health and Care Record Journeys for information.

4. NEW APPLICATIONS – Research

a. 19/CAG/0071 - Retropubic Tape versus Transobturator Tape: 10-year follow up study

Context

Purpose of application

This application from the University Hospital Plymouth NHS Trust set out the purpose of medical research which aims to undertake a 10-year follow-up of women who were enrolled on the MONARC study. The MONARC study was a consented trial which undertook a comparison of retropubic tension free vaginal tape (TVT) with the transobtruator tape procedure (TOT) as surgical treatments for stress urinary incontinence (SUI). Comparison of these two procedures in the MONARC trial demonstrated similar success rates and patient satisfaction at one year follow up. However, it was indicated that long-term outcome data on the safety and efficacy of these two procedures remained lacking.

The application set out the intent to undertake an evaluation of the outcomes for patients from the MONARC trial. The primary outcome, as per the original study, is cure of stress urinary incontinence at ten years, and this would be established via patient reported outcomes. In addition, emphasis will be placed on secondary objectives including change in quality of life, *de novo* symptoms, including overactive bladder, recurrent urinary tract infections, urinary retention, and long-term complications as examples.

Reason for application

It was confirmed that postal questionnaires were sent to all study participants, consisting of 180 patients, to undertake a ten-year follow-up of the original MONARC trial. Of critical note was that from these 180 participants, 63 participants had not responded and had not actively provided consent to the follow-up consent request, and two participants were confirmed to be deceased. The application sought support to process the confidential patient information related to the 63 non-responders, and the two deceased patients, on the basis that the original 63 participants had failed to respond to the request for consent.

A recommendation for class 1, 5 and 6 support was requested to cover activities as described in the application in relation to the non-responders and deceased patients. The original application was only considered by a research ethics committee as it was intended to be undertaken on a consented basis. It was understood that an amendment to the REC had been made for ethical review.

Confidential patient information requested

Cohort

The application to process confidential patient information without consent extended specifically to 63 non-responders and two deceased patients. The following items of confidential patient information were specified to facilitate sample validation and linkage: name, NHS Number and date of birth.

Confidentiality Advisory Group advice

The CAG was assured that the application defined an appropriate medical purpose of medical research. Members also recognised the use of prosthetic mesh in repair following certain gynaecological procedures was an area of wider interest in the healthcare environment.

However, in its review of an application, the CAG firstly considers the legal restrictions set out in Section 251 NHS Act which sets out how the Health Service (Control of Patient Information) Regulations 2002 should be interpreted, plus any restrictions. The CAG identified two key areas where the application did not appear to adequately address the regulatory restrictions set out in these Statutory Instruments as follows:

1. Compliance with Data Protection legislation

2. How the specific application to CAG would achieve the stated aims and demonstrate a public interest.

These issues are set out in further detail below.

1. Compliance with data protection legislation

Supported applications made under section 251 NHS Act 2006 and the Health Service (Control of Patient) Information Regulations 2002 set aside only the common law duty of confidence. Where an applicant is seeking to process confidential patient information without consent in relation to living patients, the proposed activity must have an established legal basis to prevent a breach of the common law duty of confidence and must also evidence compliance with current data protection legislation. This requirement is reinforced at section 251(7) of the NHS Act 2006, which states:

> '*Regulations under this section may not make provision for or in connection with the processing of prescribed patient information in a manner inconsistent with any provision of the data protection legislation*.'

In practice, this means that an activity must demonstrate that it would not be acting inconsistently with the provisions of data protection legislation (the General Data Protection Regulation and Data Protection Act 2018), before support can be considered.

A document had been shared titled '*Managing non-response: establishing the ICO and CAG position*', with the applicant. The document set out the established position of the Information Commissioner's Office (ICO) around the management of non-response to a formal request to consent in relation to data protection legislation, and the implication of non-response when considering making an application via the CAG. The ICO is responsible for guidance and enforcement measures in relation to data protection legislation.

Accepting that the document itself referred to the Data Protection Act 1998 due to time of original development, the core issue and guidance set out within this document remain the same under previous and current data protection legislation. In summary, this guidance clarified that if a patient had been asked for consent, using consent as the condition for processing under data protection legislation, and if there was no-response then this is taken to be dissent. Non-response is not considered consent under data protection legislation. Any further processing of relevant information may therefore be non-compliant with data protection requirements if valid consent from the participant is not in place.

In response to queries, the applicant had stated that the approach for consent for the 10-year follow-up study had been made on/after 15 March 2018 when the DPA 1998 was in effect, and this condition for processing had not changed since the introduction of the GDPR. At the time, the applicant was relying upon explicit consent to legitimise processing of the relevant information under data protection legislation. Responses to queries confirmed that the applicant had not changed their condition for processing following the introduction of GDPR from 25 May 2018 and the applicant was still relying upon consent as an appropriate condition for processing under data protection legislation. The consequence of relying upon consent as the condition for processing is that data can only be processed once valid consent is in place; without valid consent data cannot be processed. The ICO

has also indicated that controllers cannot change their condition for processing personal data. Prior to the implementation of GDPR, controllers had a two-year window, from 2016, where they had the opportunity to review their bases for processing and within this time period, the condition for processing could have been changed. This option ceased on 25 May 2018. It was clear from the responses that the applicant had sought to obtain consent just prior to the introduction of current data protection legislation and had missed the window of opportunity to change their basis for processing. This has placed the applicant in the unfortunate position, as per the ICO instruction, of removing the option of seeking 'section 251 support', on the basis that a condition for processing under data protection legislation cannot be changed once relied upon.

Members sought to review if the application provided engaged any of the exceptions in this document. The *ICO Managing Non-Response Guidance* states an application to seek support under the Regulations may be appropriate where the purpose of the application can be effectively distinguished from the purposes for which patients had been asked to provide consent. However, this specific element of the guidance was not applicable in this instance as the purposes set out in the consent request and the subsequent CAG application were confirmed to remain the same.

The guidance document also states that consideration should be given to the likelihood as to whether the consent information was received by the patient. In response to queries, the applicant had stated that they had not been made aware that any 'Return to Sender' notifications had been received following distribution of the consent materials for the 10-year follow-up study. On the basis of this information, it has to been assumed that the information had been received by the patients and they had chosen not to respond. In essence, if relying upon consent and no response is received, this is regarded as dissent, and is thus a limitation when relying upon consent. Seeking 'section 251 support' would have the practical effect of effectively overruling this dissent, which would be an inappropriate use of 'section 251 support', and processing information in the face of a dissent may lead to a breach of data protection legislation.

It is noted that this is a complex area of law for which the CAG has no remit to amend in terms of the implications. It was strongly advised that advice is firstly sought from local information governance specialists and ultimately the ICO if the applicants wish to pursue this further. Further information on the operation of the GDPR is also published on the HRA website which provides useful information on the lawful bases for processing. https://www.hra.nhs.uk/hra-guidance-general-data-protection-regulation/

In conclusion, members carefully reviewed the published *ICO Managing Non-Response Guidance* against the circumstances of this case and the responses provided. It was agreed that, due to the approach for consent made by the applicant

in 2018, regardless of whether support was provided to avoid a breach of the common law duty of confidentiality, processing of the data would appear to constitute a breach of data protection legislation due to changing the condition of processing from consent to an as-yet unspecified condition. Section '251 support' cannot provide a lawful defence against a breach of data protection legislation. Compliance with data protection legislation is a statutory requirement that must be in place prior to seeking s251 support, therefore as evidence of compliance had not been provided, and it was unclear how this activity would be compliant with data protection legislation if proceeding, the CAG was unable to recommend to the HRA that support be provided due to this fundamental legal issue.

Members additionally noted that in relation to the two deceased patients the Data Protection Act 2018 would not be applicable. As such, access to these two patients would not be constrained by data protection legislation as is the case for the 63 participants. Members advised that support could theoretically be provided for the two deceased patients to provide a lawful basis to avoid a breach of the common law duty of confidence, but they appreciated that this was not likely to provide a significant amount of information of value to the applicant in isolation.

2. Public Interest

A further minimum requirement which must be evidenced is how the proposed activity satisfies the public interest, as set out in section 251(1)(b) of the NHS Act 2006.

Members noted that within both the initial MONARC trial and the subsequent 10-year follow-up study, the primary outcome measure was cure of stress urinary incontinence, defined by patient-reported outcome measures collected by questionnaires completed by participants. As these data were patient reported and could not be collected from information which was recorded in patient medical records, the Group was unclear how this primary objective could be achieved by the proposed methodology, as this outcome was dependent upon the patient providing their individual feedback.

The Group agreed that, in principle, there was a public interest in undertaking a longer-term follow-up comparing outcomes between retropubic tension free vaginal tape (TVT) with the transobtruator tape procedure (TOT) in treatment for stress urinary incontinence. However, a primary concern of the group was that it did not appear that the specific objectives of the follow-up study could be achieved by the proposed methodology.

The CAG cannot recommend support for an activity where it does not demonstrate that the minimum requirements within the Regulations had been met. On the basis that it was unclear how the primary study objectives could be achieved through follow-up via patient records, Members did not identify sufficient evidence that a clear public interest had been demonstrated within the application. As the CAG is

legally constrained from recommending support under the Regulations where the minimum threshold required under section 251 of the NHS Act 2006 and its Regulations had not been met, Members recommended that the application was not supported.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that whilst it was, in principle, very supportive of research being undertaken in this area, it noted that separate to its advisory function it is legally constrained from recommending support where an application does not demonstrate that it meets the minimum threshold under the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002.

Members emphasised that the primary issue was one of data protection compliance, and members were unsure how the applicant could progress this element due to the factual and legal requirements of data protection legislation and published guidance. This element would have to be adequately addressed before any further consideration, if appropriate, by the CAG could take place in relation to this element.

The Group also noted that the approach of patient reported measures for outcomes, while not being able to obtain this information directly from non-responders, was not currently in the public interest using the methodology currently described.

On this basis, the CAG advised the Health Research Authority that the application should not be supported on the grounds that the minimum requirements of the relevant legislation had not been met.

b. 19/CAG/0069 - Care quality outcomes of heart attack patients in Yorkshire and Humber

Context

<u>Purpose of application</u>

This application from the University of Leeds set out the purpose of medical research through the establishment of a research database for which the primary purpose will be to improve the care of heart attack patients in Yorkshire and Humber. Data will be collected from 13 hospital Trusts within the Yorkshire and Humber region to enable the assessment of the care provided and patient outcomes.

The purpose of the database is to enable assessment of hospital performance against the National Service Framework for Coronary Heart Disease. It will collect data on patients who have been hospitalised with a heart attack (STEMI or NSTEMI) to include socio-demographic information, admission information, clinical features

and investigations, medical history, drug treatment in-hospital and at discharge, clinical complications, and interventional treatments.

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

Confidential patient information requested

Cohort

Patients who have been hospitalised with a heart attack (STEMI or NSTEMI) within 13 hospital Trusts throughout the Yorkshire and Humber area from 01/09/2019 to 31/07/2024.

The following items of confidential patient information are requested for the purposes as specified below:

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

Confidentiality Advisory Group advice

Public interest

The CAG recognised that the application had been submitted as a research database application, which would fall within the scope of medical research as a medical purpose. Members were assured that undertaking further research into patients who have suffered cardiac arrest would achieve a wider public interest. However, wider issues had been identified with the proposal which Members agreed made it difficult to assess whether the threshold had been met against these minimum requirements for applications seeking support under the Regulations.

Purpose of Application

The application had described both non-research and research purposes for which the data would be collected. Whilst the applicant had provided confirmation that this application had been submitted to seek support for the research purposes, members commented that there was confusion within the document which made it difficult to ascertain what the applicant was trying to achieve through the research database.

The CAG agreed that as the purpose and intended outcomes of the research database could not be clearly understood, it was unable to provide a recommendation of support for the proposal. Should the applicant wish to proceed with a revised submission, this would need to clearly extract the research-based

purposes of the overarching project and set out clear objectives that the research database was intended to achieve.

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 application covered prospective data collection for patients who suffered a cardiac arrest in the Yorkshire and Humber over a five-year period. The applicant had stated it was not feasible to operate a consented model due to potential distress to patients, staffing and financial pressures, and the potential cohort size.

The Group acknowledged that the justifications provided were precedents for recommending support under the Regulations. However, it was commented that, as the proposed research database would be established on a prospective basis, there was greater opportunity to seek consent from patients. Members were not assured that the rationale was strong enough to support the activity proceeding on an unconsented basis.

- Use of anonymised/pseudonymised data

The applicants had stated that confidential patient information was required in order to facilitate wider linkages with the HES and ONS datasets held by NHS Digital. However, the additional data linkages had not been sufficiently described within the application to fall within the current request for support under the Regulations. The Group commented that, as these linkages had not been fully articulated, confidential patient information would be collated and retained for an undetermined period.

Whilst the CAG recognised that value in future planning for anticipated wider linkage, support under the Regulations could not be recommended to facilitate the collection of confidential patient for which a timescale for its further processing and linkage had not yet established. Members agreed that any revised application would need to provide a clear overview on the scope of the proposed linkages via NHS Digital, what additional information would be provided from this linkage and the timescale over which this would be undertaken.

- NICOR MINAP Audit

The Healthcare Quality Improvement Partnership (HQIP) commissions the Myocardial Ischaemia/MINAP Audit (Heart Attack Audit) via the National Cardiovascular Outcomes Research (NICOR) Programme. The Confidentiality Advice Team had queried with the applicant whether any contact had been made with NICOR to explore whether it already collected the required information as part of this audit programme.

The applicant had explained in response that the MINAP audit was not currently linked with HES and ONS data, the process for data access was often protracted and difficult to obtain and also costly.

The Group commented that the MINAP audit programme did undertake linkage with the HES and ONS datasets held by NHS Digital, in order to carry case ascertainment comparison exercises between the audit reported patients and that which is reported via standard hospital data coding. As the application did not clearly describe the intended purpose of the linkage via NHS Digital, Members were unable to assess what additional purpose the localised dataset would serve over that which was available on a national level.

The CAG agreed that, should a revised application be submitted, this would need to clearly explain what function the localised database would achieve which could not be undertaken on an extract from the existing national audit. It would also need to provide a clearer explanation of how this existing audit dataset did not provide a practicable alternative to seeking support under the Regulations for what appeared to be duplicated processing.

Justification of identifiers

Members were unable to assess whether the items of confidential patient information requested were appropriate and proportionate to the proposed activity, as the purpose of the research database had not been clearly articulated. This would be assessed at such time as a revised submission is made to the CAG for the project.

Research Database Access and Governance Arrangements

The application did not provide a clear protocol around the access and governance arrangement to manage the research database. The Group acknowledged that these points had also been further raised as outstanding by the Research Ethics Committee. Members agreed that, should a revised application be submitted for review, this would need to be supported by clear and robust protocol for managing requests to access the research database, provide an overview of the types of research proposal which would be deemed acceptable together the information around the governance arrangements for access.

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 application did not define an exit strategy from the requirement for support under the Regulations as the intention was to retain confidential patient information to facilitate wider linkages.

Members agreed that further consideration would need to be given in this area if a revised application is submitted for review, to establish a means to exit from support under the Regulations. As an example, it was suggested that a protocol could be established to anonymise data on patients who are deceased.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicant had confirmed that a close relationship had been established with a local cardiovascular patient group. However, Members were unsure from the information provided when engagement activity with this group had been undertaken and whether it was supportive of the proposed processing of confidential patient information without consent.

The Group agreed that any revised application would include a clear overview of the patient and public involvement and engagement activity which had been carried out to date, explaining how the acceptability of using confidential patient information without consent for the study aims had been tested. An overview of further planned activity should also be provided to explain the ongoing patient and public involvement in the study. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further activity is required.

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 not yet devised a communications strategy to support the database but had advised that this would be informed by the patient and public engagement activities. It was also explained that a dissenting mechanism would be operated; however, this had also not yet been devised.

The CAG agreed that any revised application would need to be supported by a clear communications strategy, together with copies of any documentation which would be used to support this. An overview of how an objection mechanism would be operated was also required, together with detail of how any dissent would be respected.

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.

The applicant had provided some information within the application and subsequent query response to evidence compliance with current data protection legislation. However, it had not been confirmed what legal basis was being relied upon for processing. Further detail would be required as part of any revised submission.

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)

The following information should be provided to allow the CAG to continue their consideration of the application. A detailed covering letter should be provided which explained how the below points have been addressed, which should be supported by a revised CAG application form and any wider amended or supplementary documents.

1. The revised application should set out the scope and objectives of the research-based activity only.

2. Further information is required to understand why it is not feasible to achieve the proposed aims via seeking an extract from the NICOR MINAP audit dataset. This should address what would be achieved by this localised database which could not be achieved using the national audit.

3. Provide a stronger justification to support why the prospective data collection could not be undertaken on a consented basis.

4. Proposed data linkages to HES and ONS datasets held by NHS Digital would need to be clearly described within the application. This should set out the linkage process, the data which would be collected and the anticipated timeframe for this linkage to be undertaken.

5. Provide a clear protocol for the access, governance and management of the research database.

6. Consideration should be given to how an exit strategy from the requirement for support under the Regulations could be achieved.

7. Details of the patient and public involvement and engagement activity undertaken to date should be provided, explaining how the acceptability of using confidential patient information without consent for the study purposes was tested. Details of further planned activity in this area should also be provided.

8. A communications mechanism should be established for the study. Details of this should be provided, together with copies of any documentation to support it, for consideration. This should also incorporate a dissenting mechanism and overview of how this would be operated.

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

c. 19/CAG/0059 - National Early Inflammatory Arthritis Audit Research Database

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to establish a research database from data collected under the National Early Inflammatory Arthritis Audit, which is commissioned by the Healthcare Quality Improvements Partnership (HQIP) as part of the programme of national audits, which operates with support under the Regulations via application 18/CAG/0063.

King's College London would not receive any confidential patient information; however, support under the Regulations is required to allow the data which is collected for audit purposes to be utilised for wider research purposes. The National Early Inflammatory Arthritis Audit dataset represents the largest early inflammatory arthritis cohort of its kind globally, which the applicant states would have enormous research potential to help understand and improve the care of people presenting for the first time with inflammatory arthritis if made available for use in research.

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

Confidential patient information requested

Cohort

All patients who are included within the National Early Inflammatory Arthritis Audit programme.

The following data items will be made available within the research database collated from the information collated from the audit programme, to be made available for analysis:

- Sex,
- Ethnicity,
- Audit specific ID.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application described an appropriate medical purpose, which was medical research. Members recognised that the audit provided a rich and valuable dataset which was be a useful research resource to increase knowledge of early inflammatory arthritis. The Group further noted that proposal to utilise the audit database for research purposes was prompted by the patient panel established to support the audit. Members were assured that the proposed activity had a clear public interest.

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 audit activity operated on an unconsented basis with support under the Regulations, which made seeking consent from patients for the proposed wider research purposes difficult. The applicant had also advised that to operate the database on a consented basis would put a significant burden on clinicians and may bias the data available for research purposes. Members were assured by the rationale provided and raised no queries in this area.

- Use of anonymised/pseudonymised data

It was recognised that the research database which would be created would be anonymised. The applicant had described a robust anonymisation process which assured the Group. It was recognised that support under the Regulations was required to support the wider research purpose use of data which had been collated with support for non-research purposes. Members raised no queries in this area.

Justification of identifiers

The items of information which would be transferred to the research database were agreed to be appropriate and proportionate to facilitate research analysis. It was acknowledged that confidential patient information would only be processed to facilitate anonymisation. No queries were raised in this area.

Database Content

The applicant had stated that the research database would not include any supplementary data provided to the audit following linkage via NHS Digital with HES. The Group commented that this additional information may be useful for the wider research which would be undertaken on the database. It was agreed that clarification would be sought from the applicant around this point to clarify whether this additional information would also be made available for research purposes.

Database Access Arrangements

Members commented that the protocol which had been described to assess applications wishing to access the database was specific and clear. No queries were raised in this area.

The Group was unclear from the information which had been provided whether the non-research audit dataset which contained confidential patient information would be held on the same server as the anonymised research database. It was agreed that further clarification would be requested from the applicant in this area to ensure the appropriate physical or electronic separation of the two datasets would be in place.

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 recognised that this application had been prompted by feedback from the patient group which supported the audit programme. The applicant had also provided further detail around wider activity which was planned in this area. The Group was assured that the activity undertaken and planned was appropriate and proportionate to the application 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. Members commented that the information which had provided in this area overlapped with the patient notifications which were in place to support the non-research audit activity.

The CAG agreed that further work was required from the applicant in this area to establish a specific communications strategy and dissenting mechanism to support this additional research purpose. Clear information would need to be provided to patients around how their data would be used and offer a means of objection.

It was noted that applicant had engaged with national patient societies which may provide a wider avenue for communications with the relevant patient group. Members also commented that, due to the clear application process which had been established to facilitate access to the research database, there was potential for project-specific information to be displayed on the relevant websites. This would also be followed up with the applicant.

The applicant would be asked to provide further information in this area, together with copies of any documentation which would be used to support the communications strategy for consideration prior to any final recommendation of support coming into effect.

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.

The applicant had provided some information within the application and subsequent query response to evidence compliance with current data protection legislation. However, it had not been confirmed what legal basis was being relied upon for processing. Further confirmation would be sought from the applicant.

Additional Points

The application was supported by a letter from the Healthcare Quality Improvements Partnership (HQIP) as controller for the audit activity, confirming its support to the proposed research activity. However, it was noted that the letter referenced the British Society of Rheumatology as the processor, not Kings College London. It was agreed that clarification would be sought from HQIP that it was supportive of the application proceeding under Kings College London. Clarity would also be sought around whether HQIP or Kings College London would be the controller for the research database.

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 which addressed the below points, together with any revised or supplementary documentation for review.

Request for further information (Summary)

1. Clarify whether the research database would also include the supplementary health care information provided to the audit by NHS Digital and NHS Wales Informatics Service following linkage with HES and PEDW.

2. A specific communications mechanism should be established separate from the audit which relates solely to the additional research purposes described in this application. This should also describe a specific and separate dissenting mechanism for research purposes. Consideration should be given to linking

with wider charitable organisations to promote the study and the placement of project-specific information materials on the relevant websites.

3. Clarify what mechanisms would be put in place to either physically or electronically separate the identifiable audit data from the anonymised research database.

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

5. Provide further assurance from HQIP that it is supportive of the establishment of the research database at Kings College London. Confirm which organisation would have responsibility as controller for the database.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit submission (**Pending**).

d. 19/CAG/0054 - An evaluation of knee arthroplasty fixation

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertake a comparison of outcomes for patients undergoing cemented versus uncemented knee replacements in England.

The patient cohort will be identified by the National Joint Registry(NJR), which is a national audit programme commissioned by the Healthcare Quality Improvement Partnership. The NJR operates partially with support under the Regulations, via application 18/CAG/0146 and on a consented basis.

Northgate, processor for the NJR, will identify the relevant patient cohort within their dataset. Pseudonymised data from the NJR dataset will be disclosed to the applicant, with a corresponding NJR ID. Northgate will simultaneously disclose confidential patient information, together with NJR ID, to NHS Digital in order to facilitate linkage with the HES and ONS datasets, to collate inpatient data, patient reported outcome measures and mortality data. NHS Digital would disclose a pseudonymised linked dataset, with NJR ID back to the applicant. This would be linked with data from the NJR to create a pseudonymised data set for analysis. The applicant will see receive additional information on patients within the wider UK nations who underwent a knee replacement within the

study timeframe; however, this data will be provided in an anonymised format and will not be linked with wider datasets. This wider cohort is out of scope of the CAG application.

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

Confidential patient information requested

Cohort

All patients who have undergone a knee replacement since 01 April 2003 to 31 December 2018 who are registered within the National Joint Registry. Sample size is estimated at 1,087,611 patients. Data linkage will only be facilitated for patients in England.

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

- Surname – linkage,
- NHS Number – linkage,
- Date of birth – linkage,
- Postcode – linkage,
- Sex – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research.

The applicants had explained that over 100,000 knee replacements were performed annually in the United Kingdom, and this number was expected to increase six times by 2030. Up to one fifth of patients experienced persistent pain and were unsatisfied. The number of patients requiring repeat surgery had doubled in recent years. Knee replacements can be secured using cement or without cement (non-cemented). Cement is most commonly used, but it is not known which is better. The applicants are seeking to determine which method leads to a better outcome. The Group agreed that gaining a greater understanding in this area was clearly within the public interest.

Data Flows and Linkage

The Group noted that the applicants had described two methods by which data linkage could be undertaken.

In the first method, Northgate Public Services would send the applicant de-identified data on patients who had a knee replacement. Northgate would simultaneously disclose confidential patient information to NHS Digital to undertake the linkage to HES and ONS. The linked data was then de-identified and returned to the applicant, who merged this with the previously received dataset using the NJR ID number. The applicants would only have access to the de-identified data.

In the second method, Northgate Public Services identified all suitable patients. Confidential patient information would then be disclosed to NHS Digital to be linked with HES and ONS data. NHS Digital then returned the de-identified data to Northgate, to enable the linkage to the full NJR dataset and with the HES dataset. Access to the de-identified dataset would then be facilitated via a data portal.

The Group determined that data flows and access described in the first method appeared to be good practice and would restrict unnecessary access to wider clinical information. The CAG recommended that the data linkage for the study proceeded via this methodology.

Scope of Support

The application contained references to Patient Reported Outcomes (PROMS) but it had not been made explicit that this information would be requested. The items to be included needed to be made explicit so the scope of support was clear. The applicant would be asked to clarify which datasets NHS Digital would be linking the patient cohort to.

Cohort

The applicant had stated in the advice form that only those patients who were included on the NJR on the basis of informed consent would be included in the data linkage for this study. However, as all patients would be included in this project on an unconsented basis, the Group agreed that, if necessary for the purposes of the study analysis, the patient cohort for this study could extend to all eligible patients who were included on the NJR. The applicant would be asked to clarify the cohort.

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 National Joint Registry operated on a mixed model, with some patients having provided consent for their inclusion, whilst others were added to the registry with support under the Regulations. Members commented that it appeared that there was some confusion within the application around the

consent which had been provided by patients for their inclusion in NJR and the wider processing confidential patient information necessary for this study.

The CAG noted that the estimated sample size included one million patients and, whilst some were included on the NJR on a consented basis, this did not extend to the data linkage for this specific study. Further information was required from the applicant to explain why consent would not be feasible for this project.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the linkage process. Analysis will be undertaken on a pseudonymised dataset only.

The applicant has explained in the advice form that wider clinical information is required for the study analysis which is not currently available from the NJR, hence the project-specific linkage needs to be undertaken. No issues were raised in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the required linkage and raised no queries in this area.

Exit Strategy

The Group advised that the first method of data linkage was recommended to be used. Data analysis would take place within 12 months of the data being made available. It was unclear how long the data linkage process would take. The Group recommended that option one was used. The data analysis would take place within 12 months of the data being made available. The dataset was pseudonymised.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out.

Prior to the CAG meeting, the Confidentiality Advice Team had requested further information on the patient and public involvement carried out, including whether the specific issues of the data linkages and sharing of confidential patient information had been discussed. In response, the applicant provided information about the events that had been carried out and confirmed that the sharing of confidential patient information without consent had been specifically discussed.

The Group noted the information provided and was assured that this activity was appropriate and proportionate to the proposed study. No further queries were raised 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 Group noted that information about the project would be displayed on the websites for the Nuffield Department of Orthopaedics and the National Joint Registry. Members noted that many patients included in the NJR had given consent and were likely to keep up to date with the website.

The Group agreed that the NJR needed to be more involved in the process of patient notification and dissent. The NJR had access to the confidential patient information, so were better placed to facilitate the dissent process. The information available to patients needed to make it clear that they were able to dissent from the study.

Those who wanted to dissent were advised to contact the study team. The Group asked that this was amended to request that objections were raised with the National Joint Registry directly. Information about the study and how to dissent from it needed to be included on the NJR at least six weeks prior to the start of the data collection period. Sight of the final text to be displayed also needed to be submitted to the Group for review.

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.

The applicant had provided some information within the application and subsequent query response to evidence compliance with current data protection legislation. However, it had not been confirmed what legal basis was being relied upon for processing. Further confirmation would be sought from the applicant.

Other Points

The Group noted that the applicants had answered “no” to Q11 of the application filter page. Members noted that this appeared to be an error, as this did not account for the processing which would be undertaken by NHS Digital on behalf of the applicant. However, it was recognised that a complete CAG application had

been submitted. The Group agreed that the applicant would be asked to clarify that this was an error.

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 to address the below points, together with any revised or supplementary documentation.

Request for further information

1. The Group recommended that the first data linkage methodology, which involved de-identified data being released by Northgate and NHS Digital to the applicant for linkage via a study reference number, was operated for the study. Confirmation of this would be required prior to any final recommendation of support coming into effect.

2. Confirm which datasets NHS Digital will be linking with the patient cohort.

3. Provide justification to explain why it is not feasible to seek consent for this study.

4. Clarify the scope of the patient cohort which would be identified by Northgate for inclusion in the study.

5. The dissent process needs to be revised as follows;
    a. Patients should be advised to contact the National Joint Registry directly in order to register their dissent,
    b. Confirm how any dissent raised would be respected,
    c. Information about the study and how to dissent needs to be included on the NJR website at least six weeks before the data collection starts,
    d. Copies of all website text would need to be provided for review.

6. Clarify that the response provided to Q11 of application filter page, which stated that confidential patient information would not be accessed outside of the care team without consent, was in error.

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee **(Pending).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via the Data Security and Protection Toolkit submission **(Confirmed – NHS Digital has a reviewed "standards met" grade on the Data Security and Protection Toolkit).**

e. 19/CAG/0073 - Characteristics of Children with Pneumococcal Meningitis

Context

Purpose of application

This application from Public Health England set out the purpose of medical research which aims to identify the incidence of pneumococcal meningitis in children across the UK and Ireland. Streptococcus pneumoniae (also known as the pneumococcus) is one of the major causes of bacterial meningitis (inflammation of the lining of the brain) in the world. It causes severe disability and death. In developed countries such as the UK, up to a third of survivors of pneumococcal meningitis may develop disabilities such as deafness, blindness, epilepsy and cerebral palsy.

This study is run through the British Paediatric Surveillance Unit (BPSU) "Orange Card" notification scheme. The BPSU methodology has received support in principle from the CAG. All paediatricians (including paediatric intensivists) in the UK are sent a monthly email asking if they have seen any cases that match the definition of currently running studies. The BPSU informs the research team of potential cases and the team will approach the notifying clinician for further details. The study will run a 13-month reporting period.

The information collated via the BPSU questionnaires will also be linked with the national disease surveillance information which is collected by Public Health England to enable duplicate reported cases to be removed and enable an accurate calculation of incidence to be obtained. For cases which are recorded in the PHE database, direct follow-up will be undertaken with clinicians to enable reporting of this information for the purposes of the research study.

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

Confidential patient information requested

Cohort

Children, aged 16 years and under, diagnosed with pneumococcal meningitis across the 12 months reporting period in the UK and Ireland. It is estimated that around 100 cases will be identified in this period. The remit of the CAG extends to those cases identified in England and Wales only.

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

- NHS Number – sample validation and linkage,
- Hospital ID Number – sample validation and linkage,
- Date of birth – sample validation and analysis,
- Date of death – analysis,
- Postcode – sample validation, linkage and analysis,
- Sex – analysis,
- Ethnicity – analysis,
- Country of birth – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Pneumococcal Meningitis is one of the major causes of meningitis, and one third of survivors in the UK develop serious side effects. The applicants aim to identify incidences of meningitis in children and characteristics of children affected. The Group agreed that there was a strong public interest in the research.

Scope of Support

The applicants intended to collect information on patients in all four nations of the United Kingdom. The Group noted that the remit of the CAG only extended to England and Wales, and that the applicants would need to seek an alternative legal basis for the disclosure of confidential patient information from Scotland and Northern Ireland.

The total figure to be recruited was stated as 100 patients in 13 months or 200 in 25 months. The Group requested clarification on the duration of data collection and therefore the expected total number of cases, and on whether this figure was for England and Wales, or the whole UK, so that it was clear what support was given for.

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

Whilst Members recognised that the BPSU methodology had received support in principle, there was still a requirement for applicant to justify why, within the scope of this specific application, consent was not deemed to be feasible. The Group agreed that further rationale was required in this area to explain why it would not be feasible for the study to proceed on a consented model.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage, for sample validation purposes and to create the pseudonymised dataset required for analysis. This could not be done any other way. The Group raised no queries in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to the study aims and raised no queries in this area.

Exit Strategy

The Group requested clarification on the duration of the data collection period, as 13 months was given in some places in the application and 25 months in others. Members suggested that 13 months may be the data collection period, with an additional 12-month follow-up; however, confirmation would be sought from the applicant to ensure this was clear.

All confidential patient information was removed from the dataset before analysis. The de-identified dataset would be held for 25 years. Members requested clarification on the end-point of the study, to understand when the de-identification process would be performed.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out.

The study had been approved by the BPSU Executive Board, which included patient members. The applicant also worked closely with the Meningitis Charities, which were increasingly providing support for children with meningitis. Members and staff of the Meningitis Research Foundation (MRF) commented and provided feedback on the application form, the questionnaire and the public information leaflet. The applicants had also contacted families with children diagnosed with pneumococcal meningitis and received positive feedback.

Members observed that the patient group was small, and the activities undertaken in this area were proportionate to the size of the patient group. No further queries were raised 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 standard BPSU information leaflet had been provided. The study details would also be included on the BPSU website. Members asked if information was also available on the PHE website and, if so, that the text was provided to the CAG for review.

The Group requested clarification on where the leaflets would be made available and if this would include appropriate outpatient clinics.

The Patient Information Sheet did not adequately describe the dissent process. The Group asked that further information on how patients could dissent was provided in this document and included within the information provided on the BPSU and PHE websites. Further information would be requested from the applicant.

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.

The applicant had provided some information within the application and subsequent query response to evidence compliance with current data protection legislation. However, it had not been confirmed what legal basis was being relied upon for processing. Further confirmation would be sought from the applicant.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required 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 to address the below points, together with any revised or supplementary documentation for review.

Request for further information

1. Clarification on the length of time that the data collection period and follow-up is anticipated to last is needed.

2. Confirm the complete anticipated sample size and provide detail around how many of these patients were expected to be in England and Wales in order to clarify the scope of support required under the Regulations.

3. Confirm when the dataset would be de-identified in order to clarify when the exit strategy from support under the Regulations would be implemented.

4. Provide further information to explain why, for this specific study, it is not feasible to seek consent for the inclusion of patients within the study. The patient information leaflet should to be amended to make it explicit that patients and their families/carers are able to dissent and explain the dissent process. A revised document is required for review.

5. Confirm how and where the information leaflet would be displayed. It is specifically queried whether this would be made available in the relevant outpatient clinics. Confirm whether additional information about the study would be made available via the Public Health England website. If so, provide a copy of this text for consideration.

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

Specific conditions of support (Provisional)

1. Support extends to data generated in 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 the Data Security and Protection Toolkit submission **(Pending).**

5. MINUTES OF THE MEETING HELD ON 07 MARCH 2019

The minutes were received and agreed as an accurate record of proceedings.

6. CAG CHAIR REPORT

A report from the Chairman was received for April 2019.

7. ANY OTHER BUSINESS

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