Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

07 March 2019 at Skipton House, SE1 6LH

Present:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Dr William Bernal	Yes	
Dr Tony Calland MBE	Yes	Chair
Dr Patrick Coyle	Yes	Vice Chair
Mr. David Evans	Yes	
Professor Barry Evans	Yes	
Dr Rachel Knowles	Yes	
Dr. Simon Kolstoe	Yes	
Ms Clare Sanderson	Yes	Alternate Vice Chair
Mr Marc Taylor	Yes	
Ms Gillian Wells	Yes	Lay Member

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
Dr Nilay Hepgul (Item 3.a. only)	Research Fellow, King's College London

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Chair welcomed Dr Nilay Hepgul, Research Fellow from King's College London to the CAG meeting. Dr Hepgul was in attendance to lead the Group through an education item presentation.

Apologies

No apologies for absence were received.

Declarations of Interest

- PIAG 03(a)/2001 (Agenda Item 4.a)

Dr Rachel Knowles advised in advance of the meeting that she has a professional relationship with the applicant, through her part-time role within Public Health England. Dr Knowles confirmed that she had no involvement with this specific activity. The CAG agreed Dr Knowles could remain during discussion of the item; however, could not contribute to the discussion or recommendation.

2. APPROVAL DECISIONS

Secretary of State for Health and Social Care Support Decisions

There was no consideration of non-research activity at the virtual meeting in lieu of the 07 February 2019 meeting.

Health Research Authority Support Decisions

The research application which was considered at the virtual meeting in lieu of the 07 February 2019 had not been signed-off by the HRA decision-maker at the time of the CAG meeting. Subsequent confirmation that the advice given by the CAG had been accepted was received.

3. EDUCATION ITEM

a. Public attitudes towards the use of electronic health records for research

Dr Nilay Hepgul, Research Fellow, King's College London was in attendance to lead the Group through a presentation around public attitudes to the use of electronic health records in research.

The Chair thanked Dr Hepgul for her attendance and she left the meeting.

4. CONSIDERATION ITEMS

a. PIAG 03(a)/2001 (Sub-Reference 19/CAG/0052) – National Cancer Registration and Analysis Service (NCRAS) – Annual Review of 2018 activity

Annual Review submission

The review provided an update against the previous queries the CAG had raised regarding the 2018 annual review submission. This consisted of clarifications regarding how PHE defined identifiability, the approach to transparency of information disseminated, information on the role of the Office for Data Release, and clarification of the terminology used by Public Health England when describing levels of identifiability in the data release register.

Confidentiality Advisory Group advice

Language used to describe identifiability

Members acknowledged that precise and consistent language was now being used in the public facing information. The terminology being used was defined as follows:

- 'personally identifiable' will be used to refer to 'confidential patient information' (as defined in Section 251 of the NHS Act 2006) from the cancer register;
- 'de-personalised' will be used to refer to cancer register data that has been anonymised in accordance with the ICO's Anonymisation Code of Practice; and
- 'anonymous' will be used to refer to cancer register data that has been anonymised in accordance with the Anonymisation Standard for Publishing Health & Social Care Data (ISB1523).

The Group commented that there still appeared to be a difference in the language used internally within PHE and in the external documentation; however, it was recognised that the previous request for consistency in language had related to the external documentation which had now been addressed. The CAG raised no further queries in this area.

Transfers to the Clinical Practice Research Database

The applicant had corrected references to the data release made to the Clinical Practice Research Database to state that this was de-personalised data, in line with the above confirmed defititions. It was also confirmed that a supplementary note had been added to the published data release register to clarify the data releases here. Members were assured by the response provided and raised no further queries.

Office for Data Release and Transparency

Further information had been provided around the organisational structures within PHE to support the cancer registration service. In response to the recommendation that the review and oversight process could benefit from the inclusion of lay representation, it was confirmed that an Independent Advisory Panel on Data Release (IAPDR) had been appointed. The purpose of this panel was described as providing independent advice, oversight and challenge to the PHE Data Release Advisory Board (DRAB) on releases of data to third parties via the Office of Data Release (ODR).

The Group commended the implementation of the independent oversight panel; however, its membership was unclear from the documentation provided. Members were also unclear around the relationship between the three panels and how each was involved in the decision-making process around data releases.

The CAG agreed that further information was required in this area to explain the relationship between these three panels, how each was involved in the review and approval of data releases and who was making these decisions. This should address whether there is any lay input into the decision-making process and a more general overview of how the IAPDR would function.

Members agreed that the publicly available data release register was much improved and more accessible to lay readers.

The Group was unclear whether there was an established annual review process for ongoing projects which had received a data release from the cancer registry. Clarification would be requested from the applicant.

Patient Information Materials

The applicant had provided an overview of steps which had been taken to raise the profile of the cancer registration service.

It was confirmed that the revised information leaflet which was considered by the CAG in August 2018 had now been printed and was in distribution. The Group agreed that confirmation would be sought from the applicant that a plan was in place to ensure that legacy documents had been destroyed and replaced by this new leaflet, to ensure patients were receiving the most updated information.

Members noted that the information sheet included an email and postal address to enable patients to raise an objection to the use of their data. It was suggested that, for future print runs, a contact telephone number could also be added to make the dissenting mechanism more accessible.

Ongoing work with the Teenage Cancer Trust to develop age-appropriate materials was described with the first outputs expected in April 2019. Members commended this ongoing work to develop information materials for children and young people around cancer registration. Copies of these documents would be requested for consideration.

Further work which had been undertaken in this area included direct communications with 1,700 cancer leads around the country to promote raising awareness of cancer registration with patients and in treatment centres. Work was also being undertaken to look at the treatment pathway to engage with GP practices to promote cancer registration in practices.

The Group reviewed a video on the National Disease Registration Service website which aimed to inform patients about how and why Public Health England collects patient data. Whilst Members recognised that this was a useful and accessible tool for patients, it was commented that there were some omissions from the video which were important for patients. It was noted that the video did not differentiate between how data was used for registration and research purposes, explain that this would be made available to third parties or explain a patient's right to raise an objection to the use of their data. The CAG agreed that

a recommendation would be added that this video was updated to include this additional information.

Information had been provided about the annual conference which was held in 2018 which was well-represented by cancer groups. It was explained that of the 400 attendees at the two-day conference, 100 patients were present on funded places.

The CAG recognised the significant work which had been undertaken in this area and commended the applicant on the progress and achievements which had been made.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the applicant had demonstrated there was a continuing public interest in support continuing in its current form and therefore provided a positive recommendation to the Secretary of State for Health and Social Care and the Health Research Authority, subject to the conditions set out below.

Specific conditions of support

1. Further information is required around the relationship between the Independent Advisory Panel on Data Release (IAPDR), the Data Release Advisory Board (DRAB) and the Office of Data Release (ODR). The following points should be addressed:

a. Explain how each was involved in the review and approval of data releases,
b. Clarify which group(s) was responsible for approving data releases and the quoracy involved in this process, i.e. approved by a panel or an individual employee,
c. Clarify whether the decision-making process involved any lay input,
d. Confirm whether applicants which receive data from the registry are required to submit an annual review around the progress of the project,
e. Provide a more general overview of how the IAPDR would function, the demographics of this group and how it would feed into the established processes moving forward.

2. Confirm that steps were taken to implement a plan to fully replace legacy information sheets with new materials.

3. Confirm that future publications of the information sheet would include a contact telephone number to enable patients to raise a dissent.

4. Provide copies of the age appropriate children and young people information materials for consideration.

5. The patient-facing video which is available via the National Disease Registration website should be updated to include further information around the differing uses of patient data (registration and research), to inform patients that data would be made available to third parties and explain the right to object to the use of data. Provide details of a timeframe for these updates to be implemented.

   Response was requested within three months of the date of this outcome letter which would be considered at the next available full CAG meeting.

   The following conditions were carried forward from the previous annual review for information purposes as these points had not been applied to the recent submission:

6. The processing of confidential patient information for the purpose of genetic counselling is managed entirely by PHE without reference to advice by the CAG; therefore, further general reference to this aspect should no longer be included in future annual reviews as this is out of the scope of the CAG review.

7. Maintenance of a continuing satisfactory level of security assurance for the duration of the support, as evidenced through publication of satisfactory review by NHS Digital in relation to the current Information Governance Toolkit (and future changes under the IGT replacement). Applicant to ensure they provide complete evidence of one relevant security assurance specific to this activity in future annual reviews.

5. RESUBMITTED APPLICATIONS – Research

a. 19/CAG/0039 (Resubmission: 18/CAG/0027) – Virtual Aneurysm Screening Project

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research which aims to model outcomes of the abdominal aortic aneurysm (AAA) screening programme based upon targeting men with a history of smoking, the only risk factor proven to influence the development of AAA. The study will include the records of men included within the screening cohorts from 2013/14 to 2018/2019 from the NHS Abdominal Aortic Aneurysm Screening Programme (held by Northgate on behalf of Public Health England), which will be linked with other primary care data, HES and ONS Mortality information held by NHS Digital.

The NHS AAA Programme operates with support under Regulation 5 of the COPI Regulations (application reference: ECC 3-04(0)/2011), to enable the relevant cohort of patients to be invited for screening. The patient cohort includes all men in England in their 65th year registered with a GP. Support under the existing application extends to non-research purposes only to facilitate the screening invitation programme.

Screening outcomes (AAA or no AAA) will already be known in the smoking and non-smoking group. Secondary analysis will include testing other screening models (such as including prior cardiovascular events) and an economic, cost effectiveness analysis (using an existing economic model) for each model generated. This analysis will test the feasibility and cost-effectiveness of targeted screening for AAA in high risk groups.

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

Confidential patient information requested

Cohort

Men aged 65 – 71 years who have been invited for abdominal aortic aneurysm screening by the NHS AAA Screening Programme from April 2013 to March 2019 inclusive who consented for the use of their data in research. It is estimated that there will be approximately 1.7 million men included within the cohort.

Public Health England will provide data from The NHS National Abdominal Aortic Aneurysm Screening Programme. This will be disclosed by Northgate on behalf of Public Health England to NHS Digital to facilitate linkage with the wider sources.

Linkage will be facilitated using NHS Number only.

Confidentiality Advisory Group advice

The CAG recognised that this application was a resubmission of an application previously considered in February 2018 under reference 18/CAG/0027. The recommendation had been deferred at that time, pending further information from the applicant.

The revised submission had undergone significant changes in methodology and had appointed a new main applicant. The CAG agreed that whilst consideration of the request for further information detailed in the previously deferred outcome would be undertaken, wider consideration of the application was also required due to the applicant-led changes in methodology.

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members agreed that there was a strong medical purpose in this study proceeding as there was potential significant patient benefit to be achieved from its findings.

The applicant had explained that of the 227,543 men who were screened in the 2015/16 reporting period, only 1.1% of this cohort was actually diagnosed with AAA. The Group agreed that these figures provided significant evidence to support the necessity of a more targeted screening programme, which was the purpose of this study.

The aim of the study was to ensure those at the greatest risk from AAA could be targeted and remove the requirement of screening for patients who were not at risk but were made anxious from the screening invitation and procedure. This would also lead to wider health resource improvements for the NHS, due to a more efficient screening process.

The CAG recognised that, in considering providing a recommendation of support for this activity, the previous expectations of patients to be consented for the use of their data for research purposes would be overturned. The patient and public engagement activity which had been undertaken by the applicant evidenced wide support for the project proceeding without consent; however, Members recognised that the percentage of respondents who opposed this was not insignificant. However, the Group was assured that the wider public interest which could be achieved from this proposal was so significant that the potential benefits which could be realised outweighed the indicative minority who may be opposed to the use of data in this way. On this balance, the CAG agreed to provide a recommendation of support under the Regulations.

Data Flows

The CAG acknowledged that the data flows described within this revised submission were much more streamlined than the initial application which had been considered. Processing of confidential patient information for the purposed of this research activity would now be limited to NHS Digital. The applicant at the University of Leicester would only receive a pseudonymised dataset on which analysis would be undertaken.

NHS Digital would link the patient cohort with primary care data, HES and ONS mortality datasets, which would create a more enhanced dataset than was proposed in the initial application submission, leading to more sophisticated study analysis.

Members noted that wider clinical information would be released by Northgate, processor of the NHS Abdominal Aortic Aneurysm Screening Programme, to the applicant at the University of Leicester, to be linked with the data released by NHS Digital. The Group was unclear why the complete data linkage could not be facilitated by NHS Digital. It was agreed that clarification was required from the applicant to justify the proposed data releases from the NHS Abdominal Aortic Aneurysm Screening Programme.

Practicable alternatives

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

- Feasibility of consent

The Group recognised that seeking consent from the 1.7 million patients which would be included in the study was not feasible. It was also noted that a prospective consented study was not feasible as a significant patient cohort was required to inform the analysis.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage between the AAA screening programme and wider administrative datasets held by NHS Digital which could not be otherwise achieved. No issues were raised in this area.

Justification of Identifiers

Linkage between the AAA screening programme information and wider administrative datasets held by NHS Digital would be facilitated on NHS Number alone. The CAG raised no queries in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support was requested on a time limited basis only to facilitate the one-off linkage process. The Group agreed that clarification was required from the applicant around the anticipated timeframe for this linkage process together with and the ongoing retention period for confidential patient information to be held by NHS Digital after the linkage had been completed.

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 commended the substantial work which had been undertaken by the applicant in this area in order to seek the views of a wide patient and public population around the proposed research activity. It was recognised that specific engagement had been undertaken with respect to the use of confidential patient

information from the screening programme without patient consent, when patients had previously been informed that this would be sought.

The applicant had created a video which provided an overview of the proposed activity to inform patients and the public about the research study. This was followed by a survey to seek views based on the information which had been shared. The Group agreed that this was an innovative and productive means of undertaking patient and public involvement which had produced impressive outputs. The applicant confirmed that the survey had been completed by 110 people and provided a detailed overview of the findings for consideration by the CAG.

The CAG considered the findings in relation to the specific question around the processing of confidential patient information for the purposes of this research study, without seeking consent from the men who had previously been informed within the screening programme materials, that they would be approached for consent for any use of their information in research. 84.3% of respondents were of the opinion that this was acceptable. Conversely, 12.1% of respondents had found this to be unacceptable. Members acknowledged that a significant majority was supportive of proceeding without re-consenting patients for the use of their data; however, it was recognised that those who were against this was not an insignificant minority, particularly when this percentage was extrapolated to the patient cohort which was to be included in the study.

A focus group was also held with 65 men with an abdominal aortic aneurysm and their partners as part of the applicant's 2018 patient forum. The Group acknowledged that this was a relevant patient group to be engaged around the project and the overview of the findings evidenced its support for the project to proceed without consent.

The CAG applauded the impressive scope of activity which had been carried in this area by the applicant since the initial consideration of the proposal. It was recognised that targeted activity had been carried in the form of focus groups with a relevant population, which was also supported by the wider survey-based activity. Members agreed that overall, the outputs of this work were supportive of the project proceeding on an unconsented basis and no further queries were raised.

National AAA Screening Programme – Patient Information Materials

The CAG recognised that Public Health England were responsible for the patient notification mechanism and associated information materials that supported the national AAA screening programme. As some of the aspects requiring clarification related to the information materials around the screening programme, it was agreed that PHE would be copied into the outcome.

Members noted that the information which was included in the 'Frequently Asked Questions' section on AAA screening via the NHS Choices website still provided contradictory messages around how data would be used. This initially suggested data would only be used for direct care purposes, then stated patients would be approached about any research purposes and then finally went on to explain that data would be linked via NHS Digital and shared with the applicant at the University of Leicester for research analysis. The Group commented that, as informed readers, this information was difficult to understand and appeared contradictory. It was presumed that the section around approaching patients for consent for research purposes was intended to cover projects in which patients would be active participants; however, this was not made clear.

Whilst it was recognised that updating the detail on the NHS Choices website was out of the applicant's remit to progress, this point would be included in the CAG's recommendation to ensure that this was brought to PHE's attention to be addressed prior to any final recommendation of support coming into effect.

The Group noted that there was also a lack of clarity around when consent materials for the screening programme had been amended. When the initial application was considered, consent materials dated August 2016 were considered which still made reference to seeking patient consent for research purposes. However, in the covering letter which supported the resubmitted application, reference had been made to consent materials dated 2015 which included different text.

The CAG noted that whilst making revisions to the consenting materials which supported the screening programme was out of the applicant's remit to progress, it was agreed to include this point in the recommendation to draw this to PHE's attention. This was important to ensure that any consent taken for the AAA screening programme moving forward would account for any future data-based research activities, such as this proposal, proceeding without patient consent.

Members acknowledged that the updated privacy notice which was published on the gov.uk website did provide a clear overview of the data flows to support this research project.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018. The Group recognised that the communications strategy which had been implemented to support the project was impressive. It was commented that the information which was displayed on the University of Leicester website was exemplar. A clear mechanism for patient objection had been described and the applicant had confirmed that any known or registered historic objections would also be respected. The CAG raised no concerns in this area.

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 a favourable ethical opinion for the revised project was required prior to any final 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. Provide further information to explain why the complete data linkage process, including all relevant clinical data, cannot be undertaken by NHS Digital.

2. Confirm when confidential patient information will be destroyed by NHS Digital in order to clarify the exit strategy for the study.

3. Information within the 'Frequently Asked Questions' section on AAA screening on the NHS Choices website should be updated to accurately reflect how data would be used and when patients would be approached for consent for the use in research purposes. Provide a revised copy of the text and updated web link for consideration.

4. The CAG recommended that the consenting materials used to support the AAA screening programme were appropriately updated to prevent any of the issues encountered in the consideration of this application from occurring again in future.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - NHS Digital has a published satisfactory reviewed grade on V14.1, 2017/18**)

6. NEW APPLICATIONS – Research

a. 19/CAG/0024 - The Sub30 Feasibility Trial

Context

Purpose of application

This application from the Barts Health NHS Trust set out the purpose of medical research which aims to evaluate the impact of early administration of Extracorporeal Cardiopulmonary Resuscitation (ECPR) to patients suffering cardiac arrest on survival outcomes. The active study will involve the recruitment of a six patients across a 12 month study period, who will receive ECPR within 30 minutes of the call for emergency services pre-hospital admission. This study aims to assess the feasibility and safety of operating this protocol in order to inform a future larger-scale trial.

The six active patients which will be included in the trial are being recruited under the emergency research provisions of the Mental Capacity Act 2005. The applicant has stated that the request for support under the Regulations does not extend to the active cohort of patients.

The applicants intend to create a control cohort of patients as a comparator group to the active patient cohort for analysis. The research team will send matching variables based on the active patient cohort to the London Ambulance Service to enable linkage with the dispatch data and cardiac arrest database. These variables will be used to match with wider patients managed by London Ambulance Service on non-study days to provide the researchers with a comparator cohort in order facilitate analysis. Whilst the variable included

in this database have been limited, this will include date of incident, location of collapse (which may or may not be the patient's home address) and date of death as appropriate. The applicants are seeking support under the Regulations for the processing which would be undertaken by the London Ambulance Service and the subsequent disclosure of the database to the research team.

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

Confidential patient information requested

Cohort

All patients aged 18-65 years who suffer an out of hospital cardiac arrest and are attended by London Ambulance Service across the study duration (maximum 12 months) who were not included in the study as an active patient. Patients would be required to meet the standard inclusion criteria which have been established for active patient recruitment including receipt of bystander chest compressions within three minutes of collapse and remain in cardiac arrest at 20 minutes following the call to emergency services. Based on numbers of cardiac arrests attended in 2017/18, it is estimated that this patient cohort will include a maximum of 300 patients.

London Ambulance Service will perform matching on active patients based on age (closest match to five years), time of first LAS resource attendance on scene (closest match to five minutes) and presumption of the cardiac aetiology (cause) of the arrest. The following items of information will be released in relation to the matched comparator cohort:

- Location of the cardiac arrest – provided as GPS Location which will be converted into sector level postcode for analysis,
- Date of the cardiac arrest – analysis,
- Date of death – analysis,
- Age – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

Public interest

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

It was recognised that the proposal described a feasibility study, the overall aim of which was to ensure that it was possible to carry out the active intervention on patients who suffered a cardiac arrest in the community. The application to the CAG was only concerned with collecting data on a comparator control cohort of patients who suffered an out of hospital cardiac arrest during the study recruitment period but did not receive the intervention. Members recognised that the applicant had gone to great lengths to consider the ethical issues and potential risks associated with the study.

The Group was assured that there was public interest in the proposed feasibility study to ensure that it was possible to carry out the intervention in the community to ensure that any wider scale future trial was appropriately informed.

Cohort

Members commented that the majority of the application had focussed on the recruitment and management of the active cohort of six patients which would receive the intervention procedure. As such, the demographics of the comparator cohort were unclear. It had been stated in places that the comparator cohort would be matched to the active patients, which suggested only six patients would be included in this sub-group. However, elsewhere it was suggested that the control group would include all patients who were eligible for inclusion in the active trial, during the recruitment period, but were not.

The CAG agreed that a clear definition of the control cohort and estimated number of patients to be included was required to ensure that the scope of support which was recommended under the Regulations extended to the required sample.

Members recognised that the inclusion of a comparator cohort was important for the trial; however, it was unclear from the information provided exactly what information would be recorded on this sub-cohort and what analysis would be undertaken. It was agreed that further information would be requested in this area.

Practicable alternatives

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

- Feasibility of consent

The application had provided a clear rationale to support why the patients included in the active arm of the trial could not be consented; however, it was unclear if this same rationale extended to the comparator group which was the focus of the CAG application. Members agreed that further justification would be requested from the applicant to explain why seeking consent from patients included in the comparator arm was not considered to be feasible.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was required in order for the London Ambulance Service to create the matched comparator cohort required for the study analysis. The applicant explained that this analysis dataset could be potentially identifiable in combination. Members were assured that the comparator cohort could not be otherwise established and raised no queries in this area.

Justification of identifiers

The CAG commented that the patient identifiers which were required for the purposes of analysis were not standard; however, the applicant's concern that these in combination may be identifiable was accepted. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The Group agreed that clarification was required around when the anonymisation process would be carried out in order to establish an exit strategy from support under the

Regulations. It was commented that date of death and the GPS postcode location would need to be removed from the analysis dataset as part of this process.

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 undertaken a specific patient and public involvement event as part of the planning stages of the project 2017, which involved 12 patients, who were supportive of the project. A lay representative had also been appointed to the trial steering committee. The applicant had also established links with the British Heart Foundation, which was an appropriate third sector organisation to support the project.

Members acknowledged that the applicant had also sought the views of the London Branch of Jehovahs Witnesses around the specific elements of the clinical intervention as part of the planning phase.

The Group was assured that the activity which had been undertaken this area was appropriate and proportionate to the proposed feasibility study and raised no further issues 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 reviewed the study webpage which had been established. It was recognised that the applicant was in the process of making revisions to the site to make information more accessible to the various interested readers, with a particular focus of separating out information which was intended for patients and the public.

Members commented that the information which was available focussed mainly on those who would be recruited to the active patient cohort. It was agreed that further information should be made available around those who would be included in the comparator group, together with providing a means for individuals to raise a dissent to the use of their information in this sub-group.

The applicant had established an opt-out mechanism to prevent patients from being recruited to the active patient cohort, should they suffer an out of hospital cardiac arrest during the recruitment period. This would involve issuing a steel bracelet for the individual to wear, which would prevent this person receiving the intervention in the unlikely event that they did suffer a cardiac arrest. It had been confirmed that any patient who registered a dissent to be recruited to the active trial, would also be excluded from the comparator cohort.

The applicant was also in the process of finalising trial information leaflets and posters. Members agreed that sight of these documents was required 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. Confirmation was required from the applicant that the legal basis' being relied up on for data processing in relation to the GDPR were Article 6(1)(E) – tasks in the public interest and for special category data, Article 9(1)(J) – research purposes.

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. Provide a clear definition of the comparator control sub-group of patients which form the basis of the application to the CAG. This should also provide an estimate on the cohort size.

2. Clarify what information will be collated on the comparator cohort and how this would be utilised in the overarching study analysis.

3. Provide specific justification to explain why it is not feasible to seek consent from the comparator cohort.

4. Confirm when the anonymisation process would be carried out in order to establish an exit strategy from support under the Regulations. It was noted that date of death and the GPS postcode would need to be removed as part of this process.

5. The study website should include specific information around the comparator sub-cohort of patients which would be included in the study, together with details of how patients can object to the use of their data in this manner. Provide drafted text to be displayed for information purposes.

6. Provide copies of the trial information sheets and posters for review.

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

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Ambulance London Service NHS Trust and Barts Health NHS Trust both have published satisfactory reviewed grades on V14.1, 2017/18**).

b. 19/CAG/0038 - Evaluation of eToC service and interventions provided to T2DM patients

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research which aims to evaluate the impact of the electronic transfer of care (eToC) service which includes community pharmacy care/interventions on hospital re-admission rate in patients with type 2 diabetes mellitus (T2DM).

The main applicant will identify two patients cohorts from records onsite at Newcastle upon Tyne Hospitals NHS Foundation Trust: the first will be patients with type 2 diabetes mellitus who were re-admitted to hospital following intervention by a community pharmacist, the second will be patients with type 2 diabetes mellitus who were readmitted to hospital with no intervention from a community pharmacist. These patients will be identified from an anonymised database the main applicant created within a previous research study.

These established patient and control cohorts will then be used to undertake a retrospective analysis on the impact of the electronic referral and community pharmacy interventions on re-admission rate and length of hospital stay. Access to confidential patient information contained in patient medical records is required to enable extract of relevant clinical information required for analysis. All records will be accessed on site at Newcastle upon Tyne Hospitals NHS Foundation Trust. Only pseudonymised information would be extracted from patient records.

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

Confidential patient information requested

Cohort

Patients aged 18 and over with type 2 diabetes mellitus, who were referred via the transfer of care service to community pharmacists across the 2018 calendar year by the Newcastle upon Tyne Hospitals NHS Foundation Trust, regardless of whether they subsequently received an intervention under the service. The patient sample includes 1,154 patients.

The applicant holds Hospital Number within an anonymised database created in a previous study. This reference will be used to access patient medical records within the hospital. Access to the full record is required; however, pseudonymised data only will be extracted for analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the project defined an appropriate medical purpose which was medical research. Members recognised that there was wider interest in the impact of community pharmacies in the management of patient healthcare and were in agreement that there was a public interest in the proposal.

Practicable alternatives

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

- Feasibility of consent

The Group commented that there was some confusion within the application around the consent patients had provided in relation to the electronic transfer of care (eToC) service. It was unclear whether this extended to the direct care purposes only, or supplementary research and evaluation of the service. The consent materials to support the eToC service had not been provided as part of the submission to enable consideration of this point.

The CAG cannot recommend support under the Regulations to an activity where there is a feasible practicable alternative available to prevent a breach of the common law duty of confidentiality. As it was unclear from the application whether consent had already been taken from patients to support an evaluation of the service, the Group agreed that the recommendation under the Regulations would be deferred.

An assessment would need to be undertaken by the applicant together with the Trust to determine whether the consent patients had provided around the eToC service extended beyond direct care purposes to the research and evaluation of the service. If it is determined that consent did not extend to these additional purposes, a revised application would be welcomed to seek support under the Regulations to legitimise the proposed data access. The revised submission should clearly describe the activities for which patients had consented together with the wider access and processing of data which the CAG was being asked to consider in relation to the research study. Copies of the information and consent materials should also be provided to support the application. A clear rationale would also be required to explain why it would not be feasible to seek further consent for the purposes of the project.

- Local Clinical Audit

The Group considered the classification of the project as a research study. It was suggested that the scope of the proposed activity may fall within the scope of a local clinical audit. Activities which are defined as local clinical audit do not require a recommendation of support under the Regulations, providing specific criteria are met. Members agreed that the applicant would be directed to the publicly available guidance in this area to enable an assessment to be undertaken together with the Trust of the proposed activity to determine whether this fall would within the scope of a local clinical audit.

- Use of anonymised/pseudonymised data

Members recognised that Hospital number alone would be used to identify the patient cohort; however, access to the complete medical record was required in order to extract the relevant clinical information required for the study analysis which could not be otherwise achieved. No queries were raised in this area.

- Data Extraction by the Direct Care Team

As confidential patient information was not required for the purposes of the study analysis, the Group queried whether it would be feasible for the data extraction process to be undertaken by a member of the direct care team. It was explained within the application that

the applicant had undertaken a previous study on an anonymised dataset, which evidenced that data extraction had previously been undertaken on behalf of the applicant. Members agreed that, should the applicant decide to resubmit the application, justification would need to be provided to explain why this was not a feasible alternative to seeking support under the Regulations.

Justification of identifiers

Members acknowledged that patients would be identified by Hospital Number alone and raised no issues in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicant had confirmed that a linkage key would be retained for a two year duration following data extraction. The Group noted that Hospital Number, when held outside of the Trust environment would no longer be considered identifiable and raised no concerns 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 recognised that, to date, the applicant had not undertaken any activity in this area in order to test the acceptability of using confidential patient information without consent for the purposes of the application activity.

It was agreed that, should the applicant decide to progress a revised submission, prior patient and public involvement and engagement activity would need to be carried out to support the application. Members suggested that an established patient group within the Trust could be approached for their views on the project. An overview would be required within the revised application about the activity which was undertaken, details of the group involved together with the feedback which was provided. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018. Whilst the applicant had provided details of patient dissenting mechanism in response to queries raised by the Confidentiality Advice Team in advance of the meeting, there did not appear to be a communications strategy in place to inform patients about the project and their right to object.

Members suggested that information about the study could be displayed within the diabetes outpatient clinic to promote the study. It was also commented that there would be a finite number of community pharmacies which had been involved in the eToC service and as such there was potential for information to be made available at these sites.

The Group stated that a revised application would need to describe a clear communications strategy and be supported by any documentation which would facilitate this. Further information should also be provided to explain how patient objections would be raised and respected, in light of the proposed communications strategy.

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)

Prior to making a resubmission, assessment of the proposed activity should be undertaken locally between the applicant and the Trust, as controller of the data to be accessed, to determine whether either of the following two options would provide a practicable alternative to seeking support under the Regulations.

Local Clinical Audit

1. Consider whether the scope of the proposed activity would fall within the definition of a local clinical audit.

2. Guidance around the definition of a local clinical audit can be found in the 'Determining the need for a CAG application' checklist which can be found on the HRA website at the following link: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/

3. If the proposed activity it determined to be a local clinical audit, there would be no requirement to resubmit to the CAG.

Patient Consent

1. The Trust should determine whether the scope of the patient consent taken in relation to involvement with the electronic transfer of care service extends beyond the access and processing of data for direct care purposes, to the proposed supplementary research and evaluation activities.

2. If it is determined that the existing consent extends to these additional purposes and the Trust is satisfied that this provides a lawful basis, in relation to the common law duty of confidentiality, for these activities to proceed, there would be no requirement to resubmit to the CAG.

Should these options not provide a practicable alternative to seeking support under the Regulations to support the proposed activity, a revised application would be accepted by the CAG. 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 addressed the below points, together with a revised CAG application form which reflects the responses provided.

1. A clear overview should be provided around the scope of the consent taken from patients in relation to the electronic transfer of care service, together with detailed information around the supplementary activities which be carried out for the purposes of the research project, for which the CAG is being asked to consider providing a recommendation of support under the Regulations.

2. Provide copies of any information materials and consent form from the eToC service for information purposes.

3. Justify why is not feasible to seek further consent from patients for the specific activities described in the application.

4. Justify why the data extraction process cannot be undertaken by the direct care team in order to prevent a breach of the common law duty of confidentiality.

5. Patient and public involvement and engagement activity should be carried out to test the acceptability of processing confidential patient information for the specific application purposes without consent. Details should be provided around the activity which was carried out, an overview of the patients involved together with the feedback which was provided.

6. A communications strategy should be developed in order to inform patients and the public of the proposed activity and to provide a means for an individual to raise an objection to the use of their information. Copies of any documentation which would be used to facilitate this strategy should be provided to support the application.

7. Provide a clear overview of how patients can raise an objection to the use of their information within the study.

c. 19/CAG/0042 – Antithyroid Drug (ATD) Study

Context

Purpose of application

This application from Royal Devon and Exeter NHS Trust set out the purpose of medical research which aims to follow-up patients who have suffered a reaction to anti-thyroid drugs which led to a very low white blood cell count or liver injury. The study will recruit across a two year window, in which time participating sites will be asked to report eligible patient details for a retrospective cohort across the previous ten years. Patients will also be recruited prospectively from clinic.

The application has been submitted to the CAG to facilitate the recruitment of retrospective patients and patients who are found to be deceased. The applicant has stated that the retrospective patient cohort would no longer be considered to be under the direct care of the hospital clinicians and thus support under the Regulations would be required to enable the patient recruitment process. For historical patients who are deceased, support under the Regulations is requested to access patient records to extract information to be included in the study analysis.

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

Confidential patient information requested

Cohort

All patients treated at the 11 participating sites in England and Wales who were treated with anti-thyroid drugs and suffered a severe reaction which led to a very low white blood count or liver. A two year recruiting period would be established where prospectively diagnosed patients would be recruited. A retrospective patient cohort will also be included comprising of eligible patients treated across the previous ten years.

The following items of confidential patient information are requested to facilitate the postal invitation process for the retrospective patient cohort. Wider items of clinical information would also be extracted in relation to the deceased patient cohort for analysis:

- Full name and title – facilitate invitation process,
- Full address and postcode – facilitate invitation process,
- Date of birth – accessed to confirm age eligibility and retained for analysis,
- Date of death – analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were in agreement that there was an established public interest in the application proceeding as this would assist in understanding outcomes for this rare patient cohort.

The Group recognised that there was a very small number of patients who would suffer severe outcomes following a reaction to anti-thyroid drugs, which justified the requirement for a large patient cohort, which would recruit both retrospectively and prospectively to the study.

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 support under the Regulations was being sought in order to facilitate the recruitment process of the retrospective patient cohort in order to approach those still alive for consent. It was agreed that it was not possible to seek prior consent for this processing activity. Members further noted that a sub-cohort of patients would be deceased and consent could not be taken here. The Group was assured by the rationale provided and were content to provide a recommendation of support under the Regulations to enable this activity to proceed.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the invitation process which could not be otherwise achieved. The Group raised no issues in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity and raised no concerns in this area. Members agreed that details would be requested around the wider clinical dataset which would be included in the study database for analysis and together with submission of the electronic CRF form which would support data extraction.

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. For living patients, the exit strategy from support under the Regulations was intended to be consent. However, it was agreed that clarification was required around when confidential patient information would be destroyed in relation to patients who either decline consent or do not respond to the invitation request, in order to establish an exit from support for these sub-groups.

Members also agreed that clarification was required around when confidential patient information would be destroyed in relation to deceased patients.

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 the study had a named patient partner who had been involved with the project since its design phase and would continue to participate as a named collaborator. This individual had provided support for the proposed recruitment methodology. The CAG acknowledged the ongoing involvement of the patient collaborator in the study and raised no issues 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. Whilst Members recognised that all living patients would be directly approached to consent to their involvement in the study, there was still a requirement for a prior notification mechanism to be established to allow patients to object to being approached about the study at all. It was suggested that posters could be made available within the participating Trusts and Health Boards, which could be supported by a website notification. A lead in time would need to be advertised to allow time for patients to object to the approach about the study. This would be followed up with the applicant.

The Group considered the invitation letter which would be sent to patients. As some patients would be receiving this up to 10 years after their reaction to the medication, Members

commented that the document did not provide a clear introduction about the study and why the individual was being approached to account for this duration. It was agreed that the document should be revised to provide some additional introductory information about the study and why patients had been invited. Sight of this revised document was required prior to any final 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 security assurance requirements. Assurance is currently provided by confirmation of NHS Digital's satisfactory review of an organisation's self-assessment against Version 14.1, 2017/18 of the Information Governance toolkit for organisations in England. From April 2019, assurance will be evidenced by NHS Digital's confirmed that an organisation's submission of a Data Security and Protection Toolkit has met the equivalent level two standards of the IG Toolkit.

For sites processing confidential patient information in Wales with support under the Regulations, assurance was provided by NHS Wales Informatics Service's review of a Caldicott Principles into Practice report.

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

For the two study sites in Wales, the applicant would be advised to contact NHS Wales Informatics Service to ensure that the appropriate security assurance was in place to enable the study to proceed at these sites. This outcome letter would be copied to NHS Wales Informatics Service for information purposes. Confirmation would be required from NHS Wales Informatics Service prior to any final 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. Provide a copy of the electronic CRF form which would be used in the study, together with an overview of the wider clinical dataset which would be collated for analysis.

2. Clarify when confidential patient information held in relation to living patients who are approached for consent and either decline participation or do not respond to the request, and deceased patients would be destroyed in order to establish an exit strategy from support under the Regulations.

3. A communication strategy should be established to promote the study in the public arena prior to data being extracted for the recruitment process, to allow patients the

right to object to this approach. Provide details of how this mechanism would be operated together with copies of any documents being used to facilitate it.

4. The invitation letter should be revised to include some supplementary introductory information about the project and to explain why patients have been invited to participate. Provide a revised copy of the document for review.

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 sites in England (**Not checked – the study will be carried out across nine Trusts in England– security assurance would not be checked for all participating sites. Support is recommended on the basis that the applicant is responsible for seeking assurance that the appropriate security arrangements are in place, in line with information provided above**).
3. Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the two Health Board sites in Wales via the Caldicott Principles into Practice report (**Pending**).

d. 19/CAG/0045 – Suicide by Middle-Aged Men

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research which aims to examine the characteristics of middle-aged men who die by suicide, determine how frequently suicide is preceded by factors more often associated with suicide by men than by women, examine the role of support services and make recommendations to strengthen suicide prevention for middle-aged men. The study has been funded by the Health Quality Improvement Partnership (HQIP).

This will be a UK wide, multi-agency study. Data will be collated from various official bodies including: coroner inquest hearings, police sudden death reports, criminal justice reports, safeguarding adult reviews, National Confidential Inquiry into Suicide and Safety in Mental Health data and Serious Incident reports. Data will be extracted from these sources onto a standardised database for analysis.

The study will collect data about men aged 40-54 who died by suicide (including probable suicide) across the UK. This is the age group, in males, with the highest suicide rate in the UK. Suicides and probable suicides (undetermined deaths) will be identified from general population mortality data received by the NCISH from the Office of National Statistics (ONS; for deaths registered in England and Wales), National Records of Scotland (NRS; for deaths registered in Scotland) and the Northern Ireland Statistics and Research Agency (NISRA; for deaths registered in Northern Ireland). The application to the CAG extends to the data released by the ONS relating to patients in England and Wales only.

The study will collect data on a stratified random sample of 20% of deaths of men aged 40-54 from all suicides in this age group (approximately 1,527 per year) in a one-year period (based on dates of death between 1st January 2017 and 31st December 2017), equating to

approximately 300 deaths per year. Oversampling will be employed to take into account coroners who may not wish to participate in the study.

Supplementary information will be requested on the stratified sample from both health and non-health data sources to be utilised in analysis. The remit of the CAG extends to the disclosures from health sources only. An alternative legal basis would need to be established by the applicant to support disclosures from the non-health sources.

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

Confidential patient information requested

Cohort

Male aged 40-54 years, who died by suicide (including probable suicide/undetermined conclusion) in any UK country between 1st January 2017 and 31st December 2017. It is estimated that 300 patients will be included in the study.

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

- Name – sample validation and linkage and analysis,
- Date of birth – sample validation and linkage and analysis,
- Date of death – sample validation and linkage and analysis,
- Place of death – sample validation and linkage,
- Postcode – sample validation and linkage and analysis,
- Sex – sample validation and linkage and analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG agreed that the application defined an appropriate medical purpose, which was medical research. Whilst Members were assured that there was public interest in gaining a wider understanding of risk factors associated with this specific patient cohort and understanding its characteristics, it was unclear how this specific project would undercover anything new which had not been presented in the wider research outputs in this area.

The Group had carried out a high-level search on an academic research paper repository and found that there had been considerable current research outputs in this area. It was unclear how the proposed study would seek to improve on or further develop the knowledge which was learned from the findings of these proposals. It was further noted that the scientific justification provided in support of the application only referenced government reports in this area. On this basis, it was unclear how the proposal fit within the scope of wider research which had been carried out in this area.

Members agreed that further information was required to understand how the outputs of this research study would be translated into benefits for future patients in order to evidence the public interest in the activity proceeding. The Group agreed that as there were queries around the public interest which would be achieved from the study, the recommendation in relation to support under the Regulations would be deferred. The revised application should

provide a clear overview of how the proposal fits into the wider scope of research which had been undertaken in this area, what the intended outputs for the project are and how these would acted upon in order to offer benefits to future patients.

Members noted that the study was funded by the Healthcare Quality Improvement Partnership (HQIP) as part of the wider scope of work being carried out by the applicant under the confidential inquiry into suicide. It was confirmed at Q21 of the application that HQIP had undertaken an independent review of the proposal. Feedback from this review should be provided within the revised application submission to assist in establishing the wider public interest in the activity. It was also noted that as the project was funded by HQIP, a letter of support for the proposal should also be provided.

Practicable alternatives

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

- Feasibility of consent

The CAG acknowledged that the target patient cohort was deceased so consent was not feasible. No issues were raised in this area.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage process between the various data sources for the study which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

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

Data Flows

It was noted that the applicant would receive transfer of information either by secure email exchange or via post. Members commented that, given the sensitivity of the information which would be transferred together with confidential patient information, postal transfer did not appear to be a particularly secure method of transfer. It was agreed that the applicant would be asked to consider this point as part of the revised submission.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was understood from the application that support under the Regulations was required to facilitate sample validation and linkage processes only. Confidential patient information would then be stripped from the resulting analysis dataset in order to establish an exit from support.

Members queried whether, given the richness of the dataset which would be created for analysis, this would ever be truly anonymised. It was agreed that this point would be raised with the applicant for consideration. The revised application should provide further

information to explain how the applicant was assured that the analysis dataset could no longer be identifiable.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The CAG recognised that the Centre for Mental Health and Safety had a dedicated lived experience service user group and has also established wider links with third sector organisations, including the Samaritans and State of Mind Sport. However, Members were unclear from the detail which had been provided around what specific activity had been undertaken to test the acceptability of using confidential patient information without consent for the purposes of this application. It was suggested that a survivor group or relative support group may be an appropriate group to engage with around the project.

The Group agreed that the revised application should provide clarity around how the applicant had explored this specific study with patients and the public, who was approached and what form the activity took together with an overview of the feedback which was provided.

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. Whilst the CAG recognised that true patient notification was not possible as the patient cohort was deceased, it was important that information was made available in the public arena to promote how patient data was being used for the study purposes in the interests of transparency.

Members recognised that the purpose of the privacy notice was to fulfil the organisation's transparency requirements in relation to data protection legislation. A project-specific website notification had also been made available. The Group commented that both documents did not appear to be intended for a lay audience. It was agreed that a revised application should be supported by an additional communication mechanism which was intended to inform patients and the public about the project.

The CAG confirmed that assurance was also required that any evidence of historic dissent recorded in a patient's record would be respected.

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 addressed the below points, together with a revised CAG application form.

1. Provide further information to explain how the proposed activity is within the public interest. The following points should be considered:
    a. Justify how the outcomes of this application will add to the body of research and academic literature in this area by referencing a systematic review or similar process,
    b. Clarify how the findings of the research would be used to prevent suicide in the future and provide wider improvements to the patient care for this at risk cohort in the future.

2. Submit a copy of the Healthcare Quality Improvement Partnership (HQIP) Independent Advisory Group review of the application.

3. Submit a letter of support from HQIP to support the proposal.

4. Consideration of the data transfer methods should be consider determine whether transfer of confidential patient information and sensitive supportive information via post was an appropriately secure transfer mechanism.

5. Consider whether, given the richness of the dataset which would be retained for analysis, this would ever be truly anonymised. Provide further information to provide assurance in this area.

6. Specific information should be provided to explain how the use of confidential patient information to achieve the study purposes has been tested with patients and the public. Details should be provided of any activity which has been carried out in this area, details of the group involved and the format this took, together with an overview of the feedback provided.

7. A project-specific notification document should be drafted which is intended to inform a lay audience about the study and provide details of how confidential patient information would be processed to achieve the aims.

8. Confirm that any evidence of historic dissent found in patient records would be respected.

7. MINUTES OF THE MEETING HELD ON 07 FEBRUARY 2019

The minutes of the virtual meeting held in lieu of the CAG meeting scheduled for 07 February 2019 were not available at the time of the CAG meeting.

8. CAG CHAIR REPORT

The Group received a report from the CAG Chair.

9. ANY OTHER BUSINESS

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