Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

18 October 2018 at Barlow House, 4 Minshull Street, Manchester, M1 3DZ

Present:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Professor William Bernal	Yes	
Ms Sophie Brannan	Yes	Lay Member
Dr Tony Calland MBE	Yes	Chair
Dr Patrick Coyle	Yes	Vice Chair
Mr. David Evans	Yes	
Mr Anthony Kane	Yes	Lay Member
Professor Jennifer Kurinczuk	Yes	
Dr Harvey Marcovitch	Yes	
Mr Andrew Melville	Yes	Lay Member
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

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

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

There were no apologies received for the meeting.

The following declarations of interest were made:

Agenda Item 2.d. – 18/CAG/0171

- Professor Jennifer Kurinczuk advised that two of the co-investigators named on the project are based within her department. The CAG agreed that Professor Kurinczuk could remain during discussion of the application, but would not participate in the consideration or recommendation for the project.

- Mr David Evans noted that NHS Digital, his former employer were involved in the project. The CAG agreed that this would be noted within the minutes for transparency; however, did not present a true conflict of interest and no action was required.

Agenda Item 2.g. 18/CAG/0179

- Professor Jennifer Kurinczuk confirmed that the main applicant for the project was an ex-colleague and a friend. The CAG agreed that Professor Kurinczuk could remain during the discussion of the application, but would not participate in the consideration or recommendation advice for the project.

2. APPROVAL DECISIONS

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the 20 September 2018 meeting applications. The advice in relation to two amendment applications which had been considered at this meeting remained pending and would be provided for approval in due course.

Health Research Authority Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 20 September 2018 meeting applications.

3. NEW APPLICATIONS – Research

a. 18/CAG/0157 – Evaluation of the Transition from Medium Security Services

Context

Purpose of application

This application from Nottinghamshire NHS Foundation Trust set out the purpose of medical research which aims to understand the patient's perspective around the transfer from medium secure services to lower secure hospital. The applicant intends to interview patients who were discharged from Wathwood Hospital, a medium secure hospital that is part of the Nottinghamshire NHS Foundation Trust, during the period of July 2012 to July 2017, having been detained under the Mental Health Act 2005. Support under the Regulations is required to identify an eligible patient cohort from medical records to be invited to participate in the study.

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

Confidential patient information requested

Cohort

Adult male offenders detained under the Mental Health Act 2003 at Wathwood Hospital and discharged to step-down conditions (i.e. low security, locked rehabilitation, supported accommodation) between December 2012 and December 2017. It is estimated that 100 patient records would be screened in order to recruit 15 patients to the study.

The following items of confidential patient information will be accessed from health records at Nottinghamshire NHS Foundation Trust in order to identify and facilitate invitation of eligible patients to the study:

- Name,
- NHS Number,
- Full address and postcode,
- Named clinician at discharge.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. The Group was unclear what the proposed outcomes of the study were and as such, was not assured of what patient benefit would be achieved from the study. It is a requirement, when seeking support under the Regulations to temporarily lift the common law duty of confidentiality, that the public interest from the proposed activity be justified as part of the application. Members were not assured that this justification had been provided within the application.

Practicable alternatives

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

- Feasibility of consent

The application proposed the inclusion of a retrospective patient cohort within the study. Members recognised that as this patient cohort had been discharged from the care of Wathwood Hospital, it was not feasible to seek prior consent for the processing of confidential patient information, as access to the patient records was required in order to identify and contact patients.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required to identify the patient cohort and facilitate the invitation process, which could not be otherwise achieved.

- Prospective Patient Cohort

The Group discussed the potential for the study to be operated prospectively by recruiting current patients who were being discharged from Wathwood Hospital. This had not been addressed within the application and Members were not assured that the necessity of the retrospective cohort had been justified within the application. The applicant would be required to consider the feasibility of operating the study on a prospective basis. If this was determined that this was not possible, a strong rationale to support the retrospective recruitment of past patients would need to be provided.

Justification of identifiers

The Group was unclear whether the applicant intended to trace the patient's current clinician/GP and residential address, as it appeared information was only be sought from historic records at Wathwood Hospital. Clarification would be required around this point.

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. Patients would provide consent to their participation in the study, which was the established exit strategy from support under the Regulations. The applicant had confirmed that confidential patient information for patients who decline participation or do not respond to the request would be appropriately destroyed. It was anticipated that support under the Regulations would only be required for three months; however, it was noted a pseudonymisation linkage key would be retained and Members sought clarity that this related to the consented patients only.

Patient Recruitment

- Methodology

The CAG agreed that the proposed recruitment methodology was unclear within the application and further clarification would be required as part of a revised submission to clearly articulate this process.

A contact was proposed with the patient's clinician at the time of discharge in order to seek an opinion around the appropriateness of approaching the patient about the study. Members commented that patients may have undergone several transfers of care in the intervening period since they were discharged from the secure facility. The application did not account for this possibility and it was suggested that making contact with the patient's current clinician or GP would be more appropriate. The Group commented that the patient's current clinician/GP would be able to make a better informed assessment of whether it was appropriate to approach the patient about the study.

It was also unclear whether patients who were still subject to the Mental Health Act 2003 would be included in the study. The CAG agreed that clarification was required in this area as the invitation process would differ as these patients could not be contacted at their home address.

The applicant had stated that approximately 100 patient records would be accessed in on order to recruit the required sample of 15 patients for inclusion in the study. Members were unclear whether the recruitment would be undertaken in a stepped process by sending invitations in batches until the required sample was achieved in order to limit the processing of confidential patient information and reduce the risk of incidental disclosures.

Members were unclear whether recruitment would be restricted to those who still resided within the local area as patients were being invited to participate in an interview which would be carried out at their home or at the hospital site. The Group agreed that this was an important point as, if there was to be further exclusion criteria relating to geographical location, ineligible patients should be excluded prior to the circulation of any invitation materials.

It was noted that the application did not specify whether the applicant would be checking mortality status of patients prior to sending invitations or how they would access current address details in order to facilitate the invitation process. The Group stated that if these details would be checked via the NHS Spine or Patient Demographics Service, this activity was also likely to require a recommendation of support under the Regulations to legitimise the data processing. Any revised application would need to clearly address these points, specifying whether support was required under the Regulations to legitimise these processes.

- Supporting Documentation

The CAG agreed that was a significant risk of incidental disclosure within the proposed recruitment methodology should the patient invitation materials be misdirected to an historic residential address. It was also noted that inadvertent disclosures had the potential to be hugely damaging for the historic patient cohort to be included, if they had not shared information about their past treatment. The recruitment materials which had been considered by the REC were reviewed, which included a participant information sheet, responsible clinician letter and a consent form. The information leaflet provided clear information around the care which invited patients would previously have received, which presented a significant risk of inadvertent disclosure of highly sensitive information. The information sheet did not appear to be accompanied by an invitation letter which raised concerns around how this information would be received and who was issuing the invitation. It was also noted that the document described the project as a service evaluation, rather than a research project, which would require revision.

Members suggested that the recruitment process could be revised to be a two-stage process, to enable an initial invitation letter to be sent using more neutral language in the first instance, to gauge interest amongst the target cohort. This would mitigate against the risks of inadvertent disclosures if the invitation was misdirected or opened by another individual. This could be followed up with the information sheet for those patients who had expressed an interest in being involved. It was also recommended that, due to the sensitive nature of the research, it would be beneficial for the invitation materials to be authored by the current treating clinician. The CAG agreed that, if the project was to proceed on the basis of recruiting a retrospective patient cohort, the recruitment process require revision to ensure this could be more closely managed. The documents used to support process would need to be carefully worded to mitigate against incidental disclosures.

The Group also considered the responsible clinician letter and agreed that this could be more precise to enable the current residential address and whether the individual was currently an inpatient to be confirmed.

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 planned a focus group which would be undertaken in October/November time to explore the views of existing patients at the Wathwood Hospital about the project. An overview of the topics to be discussed had been provided for information purposes. Members agreed that feedback from this activity would be required as part of any revised application. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 2018. Information about the study would be displayed on the relevant Trust website and a copy of this document had been provided for review. Members recognised the difficulties in operating a wider communications strategy for this study due to the difficulties in reaching this past patient population in the public environment. The Group was satisfied with the wording of the text and noted that a dissenting mechanism had been included.

It was unclear whether the applicant would be checking records at Wathwood Hospital for evidence of historically raised dissent against the use of data for research purposes. It was agreed that this point would need to be clarified.

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

The following information should be provided to allow the CAG to continue their consideration of the application. A clear covering letter would be required which addresses the below points and identifies where amendments have been made in a revised application form for ease of review.

1. Prospectively recruiting current patients as they are discharged from Wathwood Hospital appeared to present a practicable alternative to seeking support under the Regulations. Consideration should be given to this revised methodology – if proceeding on this basis, there would be no requirement to resubmit to the CAG. If it is determined that operating a prospective study was not feasible, a stronger rationale would need to be provided as part of a revised application to support the necessity of the historic patient cohort.
2. Clearer description of the proposed research outcomes is required in order to justify the public interest in the project proceeding with support under the Regulations.
3. A clearer articulation of the recruitment process would be required to address the following points:
    a. Clarify how patient's survival status would be checked ahead of circulating invitations,
    b. If recruitment will be limited to those patients who continue to reside in the locality of the Wathwood Hospital, explain how ineligible patients will be excluded prior to the invitation process,
    c. Confirm how current correspondence address would be sought,
    d. Contact should be made with the patient's current clinician/GP – clarify how this information would be accessed,
    e. Confirm whether patients who were still subject to the Mental Health Act 2003 would be included in the study. If so, provide details of how the recruitment process would differ for this sub-cohort of patients,
    f. Clarify whether recruitment would be undertaken in batch phases until the required sample size of 15 patients was achieved,
    g. A two-phase recruitment procedure should be established to enable a careful and neutrally worded invitation letter to be sent to patients to in order to gauge interest – a copy of this document should be provided for review, together with a description of how the recruitment mechanism will be operated,
    h. Invitation materials should be sent in the name of the current treating clinician – if this is not deemed to be feasible, a strong justification would be required to support this decision,
    i. The patient information leaflet should be revised to correctly refer to the project as a research study, not service evaluation,
    j. The responsible clinician should be revised to be more precise wen requesting the current residential address and inpatient status of the participants.
4. The outcome of the patient focus group should be provided for consideration by the CAG. If the responses given were negative, the CAG may take this into account when considering whether support can be recommended, or whether further action is required.
5. Patient records would be checked for evidence of historic dissent against the use of data for research purposes and confirm that this would be respected – provide confirmation that this would be addressed.
6. Confirm that the pseudonymisation linkage key which will be retained will only include information in relation to consented patients.

b. 18/CAG/0164 – Pre-hospital ECG in acute coronary syndromes: PHECG2

Context

Purpose of application

This application from Kingston University and St George's, University of London set out the purpose of medical research which aims to assess the association Pre-Hospital 12-lead electrocardiogram (PHECG) with patient outcomes, and research patient, practitioner and contextual factors contributing to the decision to record (or not) a PHECG. The Pre-Hospital 12-lead electrocardiogram (PHECG) is a simple test that helps ambulance clinicians assess patients with suspected acute coronary syndrome (heart attack), and helps to inform ongoing care, such as direct transfer to a specialist heart attack centre. All NHS emergency ambulances carry this equipment. This project builds on previous work by this team, which found that one in three eligible patients did not receive a PHECG, but those that did had a lowered risk of short-term death. Women, the elderly and people with more complex health status were less likely to receive PHECG. The dominant treatment for heart attack at the time of the earlier analysis was 'clot buster' drug therapy (fibrinolysis). This study will update that work, in the context of the shift in recent years to a more interventional strategy for treatment of heart attack (angioplasty and stents), and explore reasons for variations in practice-highlighting opportunities to improve care and outcomes.

The study will involve the use of data collected within the Myocardial Infarction National Audit Project (MINAP) dataset, collected with support as part of the National Institute for Cardiovascular Outcomes Research NICOR programme (17/CAG/0071), which is managed by Bart's Health NHS Trust, linked with ONS mortality information held by NHS Digital for the purposes of analysis.

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

Confidential patient information requested

Cohort

- Work Package One: Patients aged 18 years or older when admitted with heart attack between 01/01/2010 and 31/12/2016 to one of 228 participating hospitals in England, Wales and Northern Ireland. For patients with multiple admissions, only the earliest record of their ACS event will be included. Approximately 420,000 patients to be included.
- Work Package Two: Patients with confirmed diagnosis of heart attack (STEMI and nSTEMI) on MINAP database and taken to hospital by one of the three participating ambulance services (Welsh, West Midlands and South West). Approximately 1,800 patients to be included identified from patients in WP1.

The following items of confidential patient information will be released from the MINAP audit held by NICOR to NHS Digital for the purposes described:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Date of birth – sample validation,
- Date of death – sample validation and analysis,
- Postcode (northing and easting references) – analysis,
- Ambulance Job Number – sample validation and linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that gaining a better understanding of the impact of a Pre-Hospital 12-lead electrocardiogram on patients suffering acute coronary syndrome was in the public interest as there was potential to improve patient care pathways and outcomes from the findings.

Practicable alternatives

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

- Feasibility of consent

The Group was assured that consent was not feasible for the project on the basis of the patient numbers to be included, the potential for patients to be deceased and the fact that the cohort would be established from a dataset which had been established with support under the Regulations via a national audit. It was also noted that a wider of confidential patient information would be required to facilitate a consenting process.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage between data sources which could not be otherwise achieved.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the proposed activity. It was noted that the northing and easting reference of the postcode would be retained for analysis; however, it was queried whether these references would be potentially identifiable. Clarification would be requested from the applicant around this element.

Scope of Support

Members noted at Q26 of the application form it was stated that the MINAP dataset was likely to be made available to the statistical team for list cleaning prior to linkage with ONS data. It was unclear whether this element would involve access to confidential patient information. It was agreed that clarification would be sought from the applicants around this point.

The applicant had specified that support was only required for work package two at two of the participating sites, which were South Western Ambulance Services NHS Foundation Trust and West Midlands Ambulance Service NHS Foundation Trust. The Welsh Ambulance Service NHS Trust had provided confirmation that the research paramedics who would be seconded into the Trusts to facilitate the data extraction required for the research purposes would be considered as part of the direct care team and did not require the establishment of a legal basis to legitimise their access to confidential patient information. It was noted that when considering application activity, the CAG takes the perspective that a member of the care team is someone that a patient or service user would reasonably recognise to be as such, as part of delivering specific interventions as part of providing 'direct care'. Reference was also made to the definition provided by Dame Fiona Caldicott, National Data Guardian, in the Information Governance review, which stated that "*Direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers. Relevant information should be shared with them, when they have a legitimate relationship with the patient or service user*". Members were unclear how a research paramedic that was seconded solely for the purposes of undertaking data extraction for research purposes would be classified as part of the direct

care teams against these definitions. The Group was content to provide a recommendation of support to the research paramedic access to patient records; however, this requirement needed to be clearly articulated. As such, it was agreed that further clarity around the practice at the Welsh Ambulance Service NHS Trust would be requested.

The Group noted that, as part of the data extraction undertaken by the research paramedics, free text information would be extracted and disclosed for analysis. It was agreed that assurance would be requested from the applicant that appropriate training would be provided to those undertaking the extraction to ensure this did not lead to incidental disclosures of confidential patient information.

Data Flows

The Group commented that the data flows to support work package one has not been clearly described in the application or supporting data flow chart. It was agreed that the disclosure of confidential patient information from NICOR to NHS Digital had been clearly described; however, the wider data flows between NHS Digital, NICOR and Swansea University were unclear. It was agreed that a clear overview of the data flows to support work package one would be required for consideration to ensure that the scope of support required under the Regulations to legitimise this activity was clearly specified.

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 noted that the research team would be undertaking all analysis on a pseudonymised dataset. Clarification was required around when the ambulance job numbers required for linkage with patient records within work package two and the UNID MINAP reference number would be destroyed.

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 considered the activity which had been undertaken in this area. Three patient and public involvement and engagement representatives had been involved with the study from the outset and were members of the study steering committee. A further patient and public representative sits on the study management group and one is a co-applicant on the study. The study also has a social media presence and each of the patient and public members has established links with wider patient groups which will be utilised to facilitate dissemination of the project findings. Members recognised that whilst the activity in this area was limited in terms of the number of patients who had been involved, this was of a high standard and plans were in place to continue this as the study progressed. Feedback would be requested at the time of first annual review around additional activity which would had been carried out in this area. If the responses given are negative, the CAG would take this into account when considering whether support should continue, 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 Data Protection Act 2018. The applicant confirmed in response to queries that contact had been made with the NICOR support team at Barts Health NHS Trust, in order to progress a study-specific notification and dissenting mechanism. The outcome of this discussion was required prior to any final recommendation of support, together with copies of any documentation which would be used to facilitate the communications strategy for review. Members commented that any information which would be displayed on the NICOR website should be clear and easily accessible from the home page.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Clarify whether the statistical team would have access to confidential patient information during the initial access to the MINAP dataset prior to linkage with ONS.
2. The status of research paramedics at the Welsh Ambulance Services NHS Trust as members of the patient's direct care team should be reconsidered. If determined not to be part of the direct care team, response should formally request an extension of the scope of support to extend to the data processing to be undertaken at this site.
3. Provide assurance that research paramedics would be provided with appropriate training in free text extraction to ensure that confidential patient information is not incidentally disclosed.
4. Clarify whether the northing and easting postcode references which would be retained for analysis are identifiable.
5. Provide a clear overview of the data flows required to facilitate work package one. This should confirm what information is disclosed between each organisation and in what format (i.e. identifiable, pseudonymised), to ensure that the elements of this data flow which require a recommendation of support under the Regulations can be clearly identified.
6. Provide details of the project-specific notification and dissenting mechanism which has been devised with NICOR – copies of any text which will be used to facilitate this mechanism should be provided for review. This information should be easily accessible from the NICOR homepage, and a link to this detail provided.

Specific conditions of support (Provisional)

1. Planned patient and public involvement and engagement activity should be progressed, with feedback on the actual activity undertaken provided at the time of first annual review. If the responses given were negative, this would be taken into account by the CAG when considering whether support can continue, or whether further action is required.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending**).

c. 18/CAG/0169 – Creativity: Schizophrenia's 'Missing Link'?

Context

Purpose of application

This application from Manchester Metropolitan University set out the purpose of medical research which aims to evaluate to what levels linguistic creativity, which is described as the techniques which creative writers employ, is involved in formal thought disorder, which is a set of symptoms that influence a person's ability to organise language and express ideas and it is often found in patients with schizophrenia.

The research involves questionnaires and interviews – the application has been submitted to the CAG on the basis that patients eligible to participate in the study would be identified via a medical record review. This will be undertaken by a local collaborator (Clinical Psychiatrist and Field Supervisor for the study). This individual would not be considered as part of the direct care team for all patients within the eligible sample. As such, the applicants are seeking support under the Regulations to legitimise access to patient records in order to approach the eligible cohort for consent to participate.

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

Confidential patient information requested

Cohort

Patients aged 18 – 50 years with Schizophrenia (inclusive of Formal Thought Disorder); schizophrenia (exclusive of Formal Thought Disorder). A control cohort will be included in the study; however, these will be self- nominated patients from public advert.

Access is required to the full patient record by the local collaborator in order to identify eligible patients to be invited to participate in the study. The following items of confidential patient information were requested for the purposes of sample validation and to facilitate the invitation process:

- Name,
- NHS Number,
- GP Registration,
- Date of birth.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were unclear what the proposed study outcomes were and how patient benefit would be achieved from the project. When providing a recommendation of support under the Regulations, the CAG must be assured that the proposed activity would be within the public interest in order to balance against the intrusion of patient privacy. The Group did not believe that current application had clearly articulated how the proposed study would be within the public interest. If a revised application was provided, the public interest in the activity would need to be clearly outlined.

Practicable alternatives

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

- Feasibility of consent

The Group considered the feasibility of operating the study on a prospectively consented basis. To be eligible to participate, patients must be currently prescribed Clozapine for the treatment of schizophrenia. It was understood that this treatment would require regular blood monitoring. The CAG was not assured that prospective consent was not feasible for this project as patients would be seen regularly in clinic, which would present an opportunity for study information materials to be distributed.

Members were in agreement that this revised recruitment methodology presented a practicable alternative to seeking support under the Regulations and this basis confirmed that the application could not be supported. It was stated that, should the applicant decide to resubmit the application, this would need to provide a very clear justification to support why patient recruitment cannot be managed via a direct approach.

The application was fully considered by the CAG and whilst it was not recommending support for the project, it was agreed that full details of the queries raised in discussion would be included in the outcome letter to assist the applicant should they decide to resubmit a revised application for review.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required in order to identify eligible patients, which could not be otherwise achieved. Members were not assured that access to this information outside of the direct care team has been justified.

Scope of Support

Information within the application was unclear around when searches of patient records were being undertaken. There were references to an initial search to identify patients and an extended review of patient notes which appeared to be undertaken with consent. Should a revised application be submitted, this would need a clear articulation of the elements of the study which would involve a breach of the common law duty of confidentiality for which the CAG was being asked to provide a recommendation of support.

Justification of identifiers

The Group acknowledged that the access to the full patient record would be required within the current methodology. However, Members were of the opinion that a practicable alternative to the proposed recruitment methodology existed, via prospective recruitment of patients, and did not undertake an assessment of the items of confidential patient information stated as required.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicants had approached a community organisation, the Bridge Collective, for patient and public engagement in the proposed research. From the description of this activity provided within the application, it did not appear that it had been explained that confidential patient information would be accessed in order to invite patients to participate in the study. The applicant had confirmed that from the request for views, response had only been received from one individual.

The Group commented that the activity which had been undertaken in this area to date would not be sufficient to support a resubmission of the application. If the applicant proceeded with a revised submission to the CAG, further work would need to be undertaken in this area to seek the views of an appropriate patient group, to include those with a schizophrenia diagnosis, around the acceptability of using confidential patient information without consent as required within the study. Feedback from this activity would need to be provided, together with an overview of the views expressed by the group to support the 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 Data Protection Act 2018. A communications mechanism had not been described within the application. The Group advised that, should a revised submission be made, this would need to describe how the study would be promoted in an appropriate clinical setting in order to inform patients that the project was ongoing and allow an opportunity to dissent. It was suggested that this could be facilitated by a poster within a relevant clinical setting. Confirmation that records would be checked for evidence of historical dissent was also required.

Other Points

The CAG noted that the participant invitation materials had been omitted from the application submission. Should a revised application be progressed, this documentation should be provided for consideration.

Confidentiality Advisory Group advice conclusion

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

d. 18/CAG/0171 – Epidemiological studies of the Porton Down veterans: a ten-year update of mortality and cancer incidence

Context

Purpose of application

This application from King's College London, University of Oxford and University of Lancaster set out the purpose of medical research which aimed to undertake a 10 year update of mortality and cancer incidence of the patient cohort included in the 2002-07 Porton Down Veterans study. The previous study investigated whether military veterans who were exposed to chemical agents as part of the 'human volunteer programme' at the UK government's research establishment at Porton Down, had unusual rates of cancer incidence or mortality compared to veterans who did not attend Porton Down, and the general population.

The original study was considered by the Patient Information Advisory Group (PIAG) in December 2002 and support was recommended for the project (at that time, under Section 60 of the Health and Social Care Act 2001). Within this study, the University of Oxford assembled a cohort of patients who were flagged in the NHS Central Register which comprised of c20,000 Porton Down veterans who took part in the 'human volunteer programme' between 1941 and 1989. The patient records were linked to routine data held by the Office for National Statistics to compare their pattern of deaths and cancer registrations up to 2004, with that of a comparison cohort of c20,000 non-Porton Down military veterans. The study established that, although there was a small (6%) excess of all-cause mortality, this could not be attributed to any specific exposure at Porton Down and might have been related to unmeasured factors such as smoking. There was no excess of cancers.

This study will update mortality and cancer registration data by at least 10 years. This new data will enable the analyses carried out previously to be repeated, but with increased statistical power so a more full examination of the impact of rare exposures and outcomes at a level of detail not possible in the original study. The remit of the CAG extends to data linkage to be undertaken via NHS Digital. The application references linkages via NHS Scotland and the North Ireland Statistics and Research Agency; however, an alternate legal basis would need to be established in relation these patient groups.

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

Confidential patient information requested

Cohort

The proposed study involves the same patient cohort which was established during the original 2002-07 study. This included a cohort of Porton Down veterans' who attended the facility as part of the 'human volunteer programme' between 1941 and 1989, comprising of 18,276 individuals. A control comparison cohort was also included which comprised of individuals with a military service number adjacent to a Porton Down veteran, but did not attend the facility themselves, comprising 17,600 individuals.

The following items of confidential patient information have been identified by the applicant as being required for the study purposes:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage (where available),

- Date of birth – sample validation, linkage and analysis,
- Date of death – sample validation and linkage,
- Address – (text of address at discharge from military service),
- Postcode (District Level) – sample validation and linkage,
- Gender – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that this application defined an appropriate medical purpose, which was medical research. Members recognised that, due to the increased risk of civilian exposure to chemical weapons, building on the research which had already been undertaken on this unique cohort was very much in the public interest, to enable the quantification of longer term risks.

Practicable alternatives

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

- Feasibility of consent

The applicants explained that consent would not be feasible for the study as current contact information was not available for the patient cohort and it was also noted that a considerable proportion would be deceased. It was recognised that during the previous study which was undertaken to follow-up this patient cohort, around half of patients were deceased. The applicants explained that, due to the further time lapse, it was estimated that around two-thirds of the cohort would now be deceased. The Group was assured on this basis that it would not be feasible to operate the project on a consented basis.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage with the wider NHS administrative datasets which could not be otherwise achieved. No issues were raised in this area.

Justification of Identifiers

The CAG was satisfied that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity, with the exception of patient address, the requirement for which did not appear to be justified within the application. The applicant would be asked to provide a clear justification to support the requirement for patent address.

Data Flows

King's College London, University of Oxford and University of Lancaster were acting as joint controllers for the application activity. Members agreed that the role of King's College London had been clearly explained within the application; however, it was unclear what role the Universities of Oxford and Lancaster would undertake in the project and whether these organisations would have access to confidential patient information. The Confidentiality Advice Team explained that, in response to pre-application queries, the applicant had explained that a future amendment was likely to be submitted in relation to the wider organisations which were involved in the project. The Group acknowledged this supplementary detail and agreed that clarification would be requested from the applicant around the intended roles of the named organisations, together with confirmation around whether the University of Oxford would continue to retain any confidential patient information following the initial disclosure to King's College London.

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 acknowledged that confidential patient information would be stored separately to the wider clinical information to enable the study analysis to be undertaken on a pseudonymised dataset. It was unclear how long confidential patient information would be retained, as in the response to queries around data protection compliance, it was stated that this would be retained for the minimum period required for analysis. Eelsewhere it was noted that this may be retained for potential further follow-up in 2024. The applicants would be required to clarify the overall retention period for the confidential patient information.

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 the work which had been undertaken to ensure transparency around the project and the planned engagement activity which was to be undertaken as the project moved forward. The Group noted that no specific work had been undertaken to date to engage with an appropriate population in connection to this longer term follow-up but it was agreed that the findings which had supported the historic study remained relevant here. The applicants would be asked to progress the planned patient and public involvement and engagement activity which had been described in the application, including the establishment of the stakeholder group and the work with associated third sector organisations. Feedback around the actual activity undertaken would be required at the time of first annual review. If the responses given were negative, the CAG will take this into account when considering whether support should continue, 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 Data Protection Act 2018. The Group commended the applicants on the wide reaching communication plan which had been established to support the project. Links had been established with a number of veteran support and patient groups to promote the research, together with the supporting information which would be placed on the participating organisation websites. Members also considered the drafted newsletter which would also be circulated to promote the study. A project-specific dissenting mechanism had been included in the text, and the applicants had confirmed that any dissent would be respected. The CAG raised no queries in this area.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Justify the requirement for patient address to be included within the study dataset.
2. Confirm the roles of the three joint controllers, King's College London, University of Oxford and University of Lancaster, within the proposed application activity.
3. Clarify whether the University of Oxford will continue to have access to confidential patient information in relation to the cohort following the initial disclosure.
4. Clarify the overall duration of the confidential patient information in order to define the exit strategy for the project.

Specific conditions of support (Provisional)

1. Patient and public involvement and engagement activity should be progressed as per the plans which were detailed in the initial application. An overview of the actual activity undertaken should be provided at the time of first annual review, together with any feedback which was provided, for consideration. If the responses given were negative, the CAG will take this into account when considering whether support can continue, or whether further action is required.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – King's College London – King's Centre for Military Health Research and NHS Digital have published satisfactory reviewed grades on V14.1, 2017/18**).

e. 18/CAG/0175 – Do Invasive Dental Procedures Cause Prosthetic Joint Infections (PJI)? - The PJI Study

Context

Purpose of application

This study from the University of Sheffield set out the purpose of medical research which aims to understand whether there is a link between invasive dental procedures and prosthetic joint infections. NHS Digital will identify a patient cohort consisting of those who have been admitted with a late prosthetic joint infection via the HES database. This will be linked to dental records by the NHS Business Service Authority. The applicants will receive a pseudonymised dataset form both processors which will be linked by unique study ID for analysis.

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 individuals identified on the NHS Digital Hospital Episode Statistics database who we admitted to hospital between 01/04/2010 and 31/03/2017 with a primary or secondary discharge diagnosis consistent with a late prosthetic joint infection (LPJI). It is estimated that there will 87,000 patients included in the cohort.

The following items of confidential patient information will be released by NHS Digital to NHS Business Service Authority to facilitate linkage:

- Name,
- NHS Number,
- Date of birth,
- Postcode (Unit level),
- Address,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG recognised that the application defined an appropriate medical purpose, which was medical research. Members noted that the study would investigate the link between invasive dental procedures and late prosthetic joint infection. Due to the rise of antibiotic resistance, Members agreed that investigating whether there was merit in prescribing patients with prosthetic joints antibiotics ahead of invasive dental procedures, which was current practice in the United States (US), was within the public interest.

The Group acknowledged that the study had been funded by the United States Department of Health and Human Services; however, it was recognised that the findings of the research would provide a patient benefit in England also, and raised no concerns in this area.

Practicable alternatives

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

- Feasibility of consent

The applicants explained that consent was not feasible for the project due to the size of the retrospective cohort to be included in the study, the potential for patients to be deceased and the requirement for a wider disclosure of confidential patient information in order to operate a consented model. The CAG was assured by the rationale provided and raised no issues in this area.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage between the HES and dental services datasets, which could not be otherwise achieved. 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 the proposed application activity 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. It was unclear from the application when data held in relation to the cohort would be destroyed by NHS Digital and the NHS Business Services Authority. It was noted that Q52 of the CAG application stated that personal data would be stored for five years following the end of the study; however, it appeared that this related to the pseudonymised dataset which would be utilised for analysis. Members agreed that clarification of the timescales for the destruction of this information in order to establish an exit strategy from the required support under the Regulations.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicants had not undertaken any patient or public involvement or engagement activity in order to test the acceptability of using confidential patient information for the study purposes. A reference had been made historic work which had been undertaken by the same research team in relation to CAG application 17/CAG/0076. Whilst also concerned with risks associated with invasive dental procedures, this historic application was focused on the following critical medical conditions: infective

endocarditis (IE), myocardial infarction (MI), stroke, pulmonary embolus (PE) and spontaneous pre-term-birth (SPTB).

The detail included within the application did not explain how the historic patient and public engagement activity remained relevant to the focus of this new research project. The CAG agreed that further information would be required from the applicant to explain how this previous work was relevant to the proposed research topic, or undertake further work with an appropriate patient group to test the acceptability of using confidential patient information as described for the specific application purposes. If the responses given were negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 2018. The application did not describe any project-specific communication strategy to raise the profile of the study in the public domain, or a mechanism by which a patient could raise an objection to the use of their data for these purposes.

Members discussed this aspect and were of the view that reasonable attempts could be made to make information about this study publicly available, in addition to providing a right of objection for those who may choose to exercise this. Members advised that relevant information should be placed in the public domain on this study, via the University website, that includes this right of objection, and the steps that would be taken to achieve this should be provided back to the CAG.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for the NHS Business Services Authority had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by 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 information provided by the applicant at Q57 of the application form in response to the principles of the DPA 1998 was received; however, it was noted that as this legislation had now been superseded, the detail provided did not fully address the requirements of the GDPR and DPA 2018. Further information would be requested from the applicant to show specific compliance with Article 5(1) – principles (a)-(f) of the GDPR 2018. Specific confirmation is required around the lawful basis for processing (see Article 6) data which is being relied upon to evidence compliance against Article 5(1)(a).

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. Confirm when confidential patient information in relation to the project will be destroyed by NHS Digital and NHS Business Services Authority.
2. Clarify what information will be retained for the five year period following the close of the study.
3. Further information is required around the patient and public involvement and engagement activity for the study as follows:
   a. Either provide further information to justify how the activity which was undertaken for historic project which has been cited as precedent for this application (17/CAG/0076) was relevant to proposed patient population, i.e. those with prosthetic joints, or:
   b. Undertake patient and public involvement and engagement activity with a relevant patient population in order to explore the acceptability of using confidential patient information for the study purposes. An overview of the actual activity undertaken, together details of the feedback provided, would be required.
4. A communications strategy to promote the study within the public arena should be devised which also describes a mechanism by which a patient can object to the use of their data within the study. Details of how the study would be promoted, together with copies of the documentation, are required for review.
5. Provide further information to explain how the project is compliant with Article 5(1) – principles (a)-(f) of the GDPR 2018. Specific confirmation is required around the lawful basis for processing (see Article 6) data which is being relied upon to evidence compliance against Article 5(1)(a).

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 29 August 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending – NHS Business Services Authority has not been reviewed on V14.1, 2017/18, NHS Digital have a published satisfactory reviewed grade on V14.1, 2017/18**).

f. 18/CAG/0176 – Feasibility Study for Take Home Naloxone Kits: TIME

Context

Purpose of application

This application from Swansea University set out the purpose of medical research which aims to investigate the impact of the distribution of Take Home Naloxone kits on the reduction of deaths from opioid overdose. Naloxone is a medicine that reverses opioid drug overdoses and is routinely used by paramedics and doctors in emergency settings. There are schemes in the UK and in other countries where naloxone is included in 'kits' which are given to drug users, along with brief training in how to use them. These 'Take Home Naloxone' (THN) kits contain a dose of naloxone, a means of administering this dose, and written/graphic instructions. Despite the increasing popularity of THN kits, very little is known about the relative harms and benefits of this intervention, especially on a population level.

The proposed study will investigate whether it is possible for paramedics and emergency department doctors and nurses to give out THN kits to drug users and if data could be collected in a future trial to determine whether this method of distributing THN reduces deaths from overdose. The study will be carried out in four areas of the UK – in two areas, THN kits will be given to patients who are at risk of overdose via the emergency department and the ambulance service. Information will be collected about deaths, overdoses, and related emergency ambulance calls and emergency department attendances and admissions. This information will be compared with figures from the further two areas where THN is not distributed in this way.

Consent will not be taken from patients within the study – the application has been submitted to the CAG in order to seek support under the Regulations to legitimise access to confidential patient information by

members of the research team in order to facilitate follow-up via NHS administrative datasets held by NHS Digital (for English sites) and Secure Anonymised Information Linkage (SAIL) databank and NHS Wales Informatics Service (NWIS) (for Welsh sites).

The study also involves and qualitative interview element which will be operated on a consented basis and is out of scope of the application to the CAG.

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

Confidential patient information requested

Cohort

- For the intervention, the patient cohort will include adult (18 years of age or over) patients attended for overdose or acute intoxication, as well as those attended for opioid use related problems such as needle site injuries/infections or falls/other injury related to opioid intoxication.
- For comparison group, the patient cohort will include adult (18 years of age or over) opioid users at high risk of fatal opioid overdose who make up a wider peer group and may overlap with those eligible to receive the intervention.
- Approximately 1,520 patients will be included, 760 across the intervention sites and 760 at the control sites. The study is scheduled to run from 01/09/2018 to 01/09/2019.

The following items of confidential patient information will be extracted from patient medical records held in the emergency department and ambulance service databases for the purposes stated:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage,
- Hospital ID No – sample validation and linkage,
- Date of Birth – sample validation, linkage and analysis,
- Postcode (District Level) – sample validation and linkage,
- Sex – sample validation, linkage and analysis,
- Date of death – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. The proposed study was investigating the feasibility of paramedics and emergency department staff distributing Naloxone kits to patients at risk of opioid overdose, and whether this had any impact on the numbers of deaths from opioid overdose. Members were assured that there was public interest in attempting to improve outcomes in this patient group and recognised that the findings of this feasibility study would be used inform a wider trial in future.

Practicable alternatives

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

- Feasibility of consent

The applicant stated that the study was being undertaken as emergency research and had provided explanation of the difficulties in obtaining consent. It was detailed that previous research had struggled to follow up the target patient population using traditional methods. It was further noted that the research team

had anecdotal evidence demonstrating that this patient population changed residential address often which contributed to difficulties in obtaining patient outcomes without linking with existing NHS administrative data sets.

Members were assured that consent was not feasible for patients who would be included in the study from the two comparison sites. Patients at these sites would not receive any research intervention and would be followed up as a control cohort to enable a comparison to be undertaken against the intervention sites.

The Group considered the feasibility of taking consent from patients included in the study from the intervention sites. Patients at these sites would be provided with training on how to use the Naloxone kit prior to discharge from hospital. The CAG commented that, if the patient was sufficiently engaged to receive training in the use of the kit, this may also provide an opportunity to seek consent for the study follow-up. The study was categorised as emergency research as the provision of the take home Naloxone kit was an activity which was subject to the time restrictions encountered in an emergency healthcare setting which made consenting participants to research difficult or impossible depending on specific circumstances. It was further explained that this problem was exacerbated by the fact that distributing the kit, which included training as a component, was a comparably lengthy procedure. It was acknowledged that the Research Ethics Committee (REC) had issued a favourable ethical opinion for the study, accepting the project's categorisation as an emergency research study. The CAG accepted the REC's decision around the project's categorisation as emergency research and proceeded with the review on this basis.

The feasibility of consent for patients within the intervention cohort was considered critically by Members. The unpredictable nature of this patient cohort was accepted together with the limitations on opportunities to provide treatment. The Group agreed that the potential benefits which could be achieved for this patient cohort from the proposed research were greater than the potential risks of overriding the requirement for consent to follow-up via NHS administrative datasets. The CAG was on balance content to provide a recommendation of support under the Regulations for the activity as it was recognised that consent would not be feasible for all patients within the intervention site cohort.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage with wider NHS administrative datasets, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The CAG agreed that the items of confidential patient information requested were appropriate and proportionate to support the linkage required for study analysis. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was recognised that a pseudonymised dataset would be created following linkage to be utilised for the study analysis. The Group was unclear around the intended follow-up duration of patients included in the study and agreed that clarification would be required. Members were unclear at what stage confidential patient information would be deleted from the REDCap system and by NHS Digital and NHS Wales Informatics Service. It was agreed that clarification would be sought from the applicant around the timeframes for the destruction, to provide a clear overview of when the requirement for support under the Regulations would cease.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. It was confirmed that two patient and public representatives had been involved with the trial design from an early stage. These individuals had experience of opioid use but were not currently patients and sat on the Trial Management Group. Two further representatives had been recruited to sit on

the Trial Steering Group. Ongoing engagement was planned with the PRIME Centre (Wales Centre for Primary and Emergency (including unscheduled) Care Research), including promotion via the website and social media channels and engagement with the service user group. The CAG was assured that the activity undertaken and planned in this area was proportionate and relevant to the proposed activity 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 Data Protection Act 2018. Members considered the patient-facing materials for both intervention and comparison sites which had been approved by the REC. It was recognised that the documents provided clear details around how a patient can raise an objection to the use of their information within the study. Patients in each cohort would be passed an information sheet relevant to their treating site. The Group agreed that within the section entitled 'Why do I need to know about it?', the second section could be made clearer by including the word 'medical' before information. It was recognised that the documentation needed to be updated to reflect the recruitment timeframe so this minor additional alteration would also be requested.

It was unclear whether patient records would be checked for evidence of any historic dissent against the use of information for research purposes. Confirmation was required that this would be undertaken and respected where found.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. For NHS sites in England, security assurance is evidenced by NHS Digital's review of an organisation's NHS IG Toolkit self-assessment score. For NHS sites in Wales, security assurance is provided by NHS Wales Informatics Service following completion of a Caldicott Principles into Practice (CPiP) report. Security assurance is required for each organisation which will be processing confidential patient information with support under the Regulations. This assurance would need to be in place prior to any final recommendation of support coming into effect.

It was noted that a self-assessed score for Yorkshire Ambulance Service had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website.

To enable security assurance to be checked for the wider organisations which would be processing confidential patient information with support under the Regulations, clarification of the NHS IG Toolkit submission including organisation code, was required to enable checks to be undertaken. The following organisations were identified from the application as undertaking data processing which would require a recommendation of support under the Regulations: South Western Ambulance Service Foundation Trust; Bristol Royal Infirmary Emergency Department; Hull Royal Infirmary; Northern General Hospital; REDcap.

Contact should be made with NHS Wales Informatics Service in connection to the CPiP assurance for the data processing it would be undertaking, together with the Welsh Ambulance Service Trust.

It was further noted that Swansea University would be processing confidential patient information with support under the Regulations. The institution did not appear to have an active NHS IG Toolkit submission so it was queried whether the organisation had submitted a CPiP report via NWIS. Confirmation of the relevant security assurance arrangements at Swansea University was also required.

Other Points

There appeared to have been slippage in the projected study timeframes as the application stated that the recruitment period for patients was 01/09/2018 to 01/09/2019. Clarification of the revised recruitment would be required, which would also need to be updated in the patient-facing documents.

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. Clarify how the duration of the follow-up period for patients included in the study.
2. Confirm when confidential patient information will be destroyed by those processing with support under the Regulations, in order to clarify the anticipated timeframe for the project's exit strategy.
3. Update the section entitled 'Why do I need to know about it?' within the patient information sheets to explain that patients 'medical' information' may be included in the study.
4. Confirm whether patient records at treating sites will be checked for evidence of historic dissent and provide assurance that this would be respected where recorded.
5. Clarify the revised timeframe for study recruitment and update any study documentation appropriately.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 16 October 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending – see summary of requirements in text above**).

g. 18/CAG/0179 – IMMO – Improving the practice of foetal heartrate Monitoring with cardiotocography for safer childbirth V1

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research which aims to advance current knowledge of the types of errors, hazards and failure modes that may occur in the process of classifying, interpreting, and responding to, CardioTocoGraphy traces when monitoring foetal heart rate during labour.

This will be undertaken via researcher observation of staff within the clinical maternity setting – women will not be asked to consent to participate in the study. The application has been submitted for consideration by the CAG under precedent set category 10 – incidental disclosures, which may occur during the course of the staff observations. There is a further interview element to the study which will be undertaken on consented basis with staff only and is out of scope for CAG consideration.

Observations will be undertaken a three sites – one in England, which will be Sheffield Teaching Hospitals NHS Foundation Trust. The wider research sites will be based in Scotland and Northern Ireland which are out of the remit of the CAG to consider.

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

Confidential patient information requested

Cohort

The participants in the study are NHS staff members in participating maternity units who are involved in continuous electronic foetal heartrate monitoring using cardiotocography, especially midwives and obstetricians. The patients will be those receiving care from these participating individuals.

No confidential patient information is required for the purposes of the study; however, it is recognised that there will be incidental disclosures during the course of staff observation.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members were assured that increasing the knowledge base of issues which can be encountered when undertaking continuous foetal heartrate monitoring was in the public interest.

Scope of Support

Research observations would be carried out at three sites across England, Scotland and Northern Ireland. As the remit of the CAG extended to England and Wales only, the applicant would be advised that in this instance, the recommendation of support under the Regulations would extend to the site based in England only. Alternative arrangements would need to be made wider research sites.

Practicable alternatives

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

- Feasibility of consent

The applicants had explained that seeking consent from birthing mothers was not feasible as this was a potentially fraught time and was not appropriate in the particular clinical setting. This view had been supported by the patient and public involvement and engagement activity which had been undertaken in the study's planning phase.

The CAG considered the feasibility of consent in some depth and was in agreement that the presence of the researcher in a maternity suite would require some form of consent from a patient. It was noted that the circumstances around seeking consent may differ during the first and second stages of labour. It was noted that foetal heart rate monitoring during the first stages of labour maybe generally more relaxed, than if the monitoring was initiated following signs of foetal distress in later labour. It was acknowledged that in the later stages of labour, or where any concern had been raised around the infant's welfare, the situation was likely to be much more fraught and would not be conducive to undertaking a consenting process. Members accepted that it was likely that the more difficult births would be greater importance to the research findings.

The Group recognised that in certain circumstances, the applicants may be able to seek verbal consent to the observation from patients following an explanation of the reasons behind the project; however, it was noted that this was unlikely to be sufficient to meet the higher consenting threshold of current data protection legislation. Members also commented that this verbal assent was unlikely to endure if the circumstances of the patient's labour changed.

On the basis of these wider considerations, the CAG agreed on balance to provide a recommendation of support under the Regulations to cover all observations undertaken by the research team, accepting that in

some cases seeking consent to prevent a breach of the common law duty of confidentiality would be wholly inappropriate and would disrupt patient care in an emergency situation.

- Use of anonymised/pseudonymised data

The CAG recognised that the applicants did not require access to confidential patient information for the purposes of analysis; however, in undertaking the staff observations, the research team would be exposed to incidental disclosures of confidential patient information. Members were assured that information would not be recorded and acknowledged that the patients were not the focus of the research. No issues were raised in this area.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. A patient group at Cambridge University Hospitals NHS Trust had been approached during the study planning and had supported that the study should proceed without consent from patients. Further work was planned with the patient and public group at the Royal College of Obstetricians and Gynaecologists as the study progressed. The CAG was assured that the activity which had been undertaken and planned in this area was proportionate and relevant to the proposed 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 Data Protection Act 2018. The applicants had taken appropriate steps to ensure that the patient population were informed that the staff observation research was ongoing and were provided with the opportunity to dissent from having their care observed. Posters would be displayed in the maternity units, information sheets would be distributed and patients would be verbally informed of the right to dissent to observations. Members agreed the mechanism put in place to inform patients was exemplar and raised no issues with the communications strategy.

Members commented that the detail around maintaining patient confidentiality should be more prominent within the information leaflet. It was agreed that the bullet point from page three which begins 'The researchers will maintain your confidentiality…' should be moved the summary cover page to ensure this was accessible to patients.

It was also suggested that as the research team were academic doctors, it would be helpful if any name badges provided to them during the clinical observations made this clear, to ensure they were not erroneously identified as medical doctors. The Group agreed that this point did not need to be added as a formal condition of support as it was anticipated that this would be covered as part of standard procedure, but would be included in the document for information purposes.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Support extends to the research site located in England only.
2. Revise the patient information sheet to move the bullet point from page three of the document ('The researchers will maintain your confidentiality…') to the cover summary page. This should be actioned

prior to commencing observations; however, assurance can provided at the time of first annual review that this was undertaken.

3. Favourable opinion from a Research Ethics Committee (**Confirmed – 24 September 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Sheffield Teaching Hospitals NHS Foundation Trust have a published satisfactory reviewed grade V14.1, 2017/18**).

4. MINUTES OF THE MEETING HELD ON 20 September 2018

Review and approval of the minutes from the meeting held on 20 September 2018 were deferred pending resolution of the outstanding application outcomes.

5. CAG CHAIR REPORT

The CAG received a report from the Chair in respect of October 2018.

6. ANY OTHER BUSINESS

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