NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group (CAG)

04 August 2016, Skipton House, London

Present:

Member	Capacity
Dr Martin Andrew	Expert
Dr Kambiz Boomla	Expert
Dr Malcolm Booth	Expert
Dr Tony Calland	Vice-Chair (Chair for items 1 – 4)
Ms Hannah Chambers	Lay
Dr Patrick Coyle	Vice-Chair (Chair for items 5 – 8)
Dr Katie Harron	Expert
Dr Rachel Knowles (item 7 by phone)	Expert
Dr Harvey Marcovitch	Expert
Ms Diana Robbins	Lay

Also in attendance:

Present	Capacity
Ms Juliana Araújo	Observer - HRA
Ms Natasha Dunkley	Head of Confidentiality Advice Service, HRA
Ms Carolyn Halliwell	Observer - HRA
Ms Rachel Katzenellenbogen	Observer - HRA
Ms Helen Poole	Observer - HRA
Dr Janet Messer (item 7)	Director of Research Systems, Standards & HRA Approval Programme, HRA
Mr Stephen Robinson (from item 6a to 6d	Corporate Secretary, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies were received. Welcomes were extended to the HRA staff observers who were attending as part of the HRA Technical Talent Management programme. No declarations of interest were identified in advance or declared at the meeting.

Members welcomed Mr Robinson, the decision-maker on behalf of the Health Research Authority decision-maker who was joining to to hear the discussions leading to the CAG recommendations in relation to research applications.

No declarations of interest were made.

2. APPROVAL DECISIONS

The following approval decisions were confirmed:

Secretary of State for Health approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice recommendations provided by the CAG in relation to the 30 June 2016 and 13 July 2016 meeting applications. It was noted that there had been a change to the previous representative who approved applications on behalf of the SofS due to internal organisational change.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 30 June 2016 and 13 July 2016 meeting applications.

Members were advised that there had been some delays in the CAT receiving final approval decisions for both research and non-research following the CAG recommendations due to availability and staffing issues. This issue had not been resolved.

3. ITEMS FOR CONSIDERATION

a. 'Annual Review: PIAG 4-07(t)/2002 - Arnold Lodge Admission Cohort: Reconvictions and Intervening Treatment (ALACRITy); ECC 4-15(b)/2009 - Extension: Long-term follow-up of a regional secure unit admission cohort 1983-2011.

This item was considered by the CAG as it has arisen in relation to the previous consideration of 15/CAG/0199; An extension of the Arnold Lodge Admission Cohort Reconvictions and Intervening Treatment (ALACRITy) study: 1983-2013 at the November 2015 CAG meeting. It had been identified that an annual report had not been submitted for the 2002 and 2009 applications and as the new submission sought to utilise data collected under these references, members considered it important that the applicants provide a clear update on status and conditions of support first.

Context

Following consideration of item 15/CAG/0199, members had advised that an annual review should be submitted against the two applications above, prior to consideration of any future applications.

Following a meeting to clarify a number of issues the annual review was considered as a consequence of this advice. The annual review provided an update against three conditions.

1. Support was provided for a retrospective cohort, deceased persons and those lost to follow-up.

   The report confirmed the above, and set out an intention to submit a new application to include patients up to 30 June 2013.

2. Consent should be explored and consent sought from those in contact with the service prospectively.

   The review confirmed that the study had previously been placed on hold due to staffing resources. As a consequence, it was confirmed that there had not been opportunity to undertake activities relating to this condition in the interim period. However, the applicants provided an update on the activities undertaken to explore and test consent as a result of the 2015 outcome. This included devising a questionnaire for clinicians to test on their patients and allowed for generalisability of consent issues across the patient groups. A summary of these conclusions were provided. The review also provided an update on activity undertaken with a Steering Group

3. Efforts should be made to improve user participation to assist in uptake of consent arrangements

The review indicated that this had been explored through a Steering Group and a patient information leaflet developed with the Steering Group comment.

Members welcomed the responses and engagement with the conditions of support. Members were informed that the applicants were intending to submit an application to the September 2016 meeting that was intended to replace these references, and to take into account the considerations of 15/CAG/0199. It was agreed that support should be recommended for an interim period of three months to take account of a new submission.

4. RESUBMITTED APPLICATIONS

a. 16/CAG/0098 (formerly 16/CAG/0069) The full PIERS RISK PREDICTION MODEL FOR WOMEN WITH PRE-ECLAMPSIA: EXTERNAL VALIDATION, RECALIBRATION AND ADDED VALUE OF A NOVEL BIOMARKER (PLACENTAL GROWTH FACTOR)

Purpose of application

This research application from Oxford University Hospitals NHS Trust set out the purpose of seeking to assess the predictive ability of the fullPIERS model in order to identify the risks of developing complications for pregnant women with pre-eclampsia in high resourced settings so as to aid clinicians in managing such pregnancies.The hypertensive disorders of pregnancy (HDP), with pre-eclampsia being the most dangerous, complicate about 10% of pregnancies and are major contributors to maternal and perinatal morbidity and mortality. This is due to the severe complications that can result from them such as stroke, kidney failure and eclampsia for the mother, and fetal growth restriction and stillbirth for the baby. The ability to predict these adverse outcomes will aid the appropriate management and treatment by the early identification of women with higher risks of complications arising from HDP and applying timely interventions.

In order for the fullPIERS model to be introduced into clinical practice, it is necessary to assess its predictive ability in a similar population cohort other than the one in which it was developed in (external validation) and to improve the model where possible by adding new biomarkers as well as recalibrating the model if and when required for better predictive performance. In order to determine eligibility and collect relevant information for this study, patient case records of women who were admitted with hypertensive disorders of pregnancy (HDP) up to ten years ago will be screened by the researcher. The published PIERS equation will be applied to the individual eligible patient records in the validation datasets, to calculate the predicted probability of adverse outcome within 48 hours of admission. Data will be collected, entered into an anonymised database and will be used to validate the fullPIERS model to identify women at greatest risk for developing adverse maternal outcomes.

A recommendation for class 1 and 6 support was requested for the process of extracting and anonymising the information in line with the detail of the application.

Confidential patient information requested

Support was requested to allow the applicant, who was not a member of the team providing care to the cohort, access to medical records/clinical information in order to extract anonymised information for the purposes specified in the application.

Access was requested to data from medical records in relation to the year and month of birth, dates and time of hospital admission, medical history, recorded symptoms (e.g. headache, nausea) and laboratory tests (e.g. haematological, urine chemistry) and adverse outcomes such as maternal death and severe morbidity.

Confidentiality Advisory Group advice

It was noted that this was a resubmission of an application previously considered in May 2016; members had previously deferred providing a recommendation for the reasons specified in the letter dated 03 June 2016. Members considered the responses provided in the applicant letter and the discussions and conclusions are summarised below.

Public interest

Members agreed that this PhD study had a clear medical purpose, the processing of the data for this purpose would be in the public interest as the area to be studied was current and an important issue, and the outcomes were intended to provide a public benefit to the relevant population.

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

Members noted the previous justification for not conducting the study on a consented basis which centred on the records being up to ten years old. The arguments around the fact that gaining

consent would require access to the records to obtain address information and could skew the response rates were seen as persuasive. However members had not agreed that contacting patients would cause distress for the majority of cases and that similarly a proportion of records would be more recent with up-to date address information and potentially consent could be sought. Further justification for the impracticability of seeking consent had been requested by the Group.

The response confirmed that the applicants sought to process information recorded during admission of patients admitted to the Women's Centre over ten years ago; collecting data from 2006 and working backwards from this year. Members agreed that based on this year that current addresses may not be available and agreed consent would not be practicable in this instance. However, members were confused as to the precise date range as it was noted that there appeared to be inconsistencies within the dates specified in the responses and the protocol. For example, the protocol stated "*the anonymised data will come from retrospective data collected from… 1998 and 2008*" and the response letter indicated data would be collected from 2006. Members requested that the precise date range be clarified so that the scope of the requested support would be clear.

- Use of anonymised/pseudonymised data

It was noted that the approach to be taken required access to medical and clinical records in order to extract anonymised information. Practicable alternatives such as funding care teams to carry out searches, utilising the sitting in method, the clinical care team extracting the records and redacting identifiable information were considered and members agreed that the approach set out in the application was appropriate for the purposes of this support.

Justification of identifiers

Members had previously questioned the need to record date of death as this was considered to be an identifier. The response confirmed that the applicant had agreed to exclude the date and time of death and record instead whether the woman died within 48 hours of admission (primary outcome) or within 7 days of admission (secondary time point). Members welcomed this change.

Transfer of data to Canada

The response confirmed that although identifiable data would be viewed, de-identified data would be extracted and there would be no flow of identifiable information to Canada. Members noted that it would be the responsibility of the local data controller to ensure that the data extracted was genuinely anonymised, however, for the purposes of this application members welcomed this confirmation.

Patient and public engagement

Members had previously expressed some concern over the lack of service user engagement with this project and saw this as an example of a project which would benefit from user testimony confirming support from patient groups in principle for such a project on a non-consented basis. The response confirmed that the study had received support from the Thames Valley Maternity Service User Forum, which is a patient public participation group set up by the Oxford AHSN Maternity Network, the Thames Valley Maternity SCN and NDOG. The Group welcomed this update and advised that any such patient engagement should continue to be explored. For example, Members advised that the applicants should consider a suitable charity-based group or others such as Mumsnet to help promulgate the study.

Patient objection and opt-out

It was confirmed that Information on the study would be publicised on the Oxford Safer Pregnancy Alliance (OSPREA website) which is accessible to the general public. Anyone wishing to do so would be offered to register their objection via the website, email or telephone.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the applicant had satisfactorily addressed the previous areas requiring clarification and the minimum requirements of the Regulations appeared to have been met. The CAG agreed to recommend to the Health Research Authority that this application be approved, subject to satisfying the request for clarification and specific conditions of support.

Further clarification required

1. Applicant to confirm and revise as appropriate all information to ensure clarity of the relevant year ranges the information will be collected.

Specific conditions of support

1. Date and time of death will not be extracted in line with revised approach.
2. Consideration of extending patient involvement, and to report against this at time of annual review.
3. Provision of favourable REC opinion.
4. Confirmation received directly from NHS Digital that the Information Governance Toolkit submission for Oxford University Hospitals NHS Foundation Trust is satisfactory.

5. NEW APPLICATIONS – NON-RESEARCH

a) 16/CAG/0097; Pathways of Care for young people in secure institutions (national service evaluation).

Purpose of application

This application from Central and North West London NHS Foundation Trust set out the overarching purpose of undertaking a NHS England funded service evaluation linked to CAMHS Transformation. The aim was to scope the secure institutions which currently make up the secure estate for young people, to clarify how many young people are currently detained in secure institutions in England and to identify the level of need, characteristics and pathways of care for these young people. This was indicated to be important in beginning to address the gap in knowledge in this area where service provision has grown organically without prior service evaluation, to inform commissioning needs for the Clinical Reference Group and Commissioners, consider the implications of service delivery in terms of the different legislative and funding bodies and enable discussion about whether pathways into the different secure institutions are appropriate for the young people. This service evaluation of the pathways into and needs of young people within the entire secure estate is intended to enable the overall secure service providers to consider what intervention package would be appropriate into the different secure institutions.

A recommendation for class 1, 5 and 6 support was requested to achieve the purposes set out in the application.

Confidential patient information requested

Support was requested to cover data collection in relation to all young people in secure institutions (hospitals, secure children's homes, secure training centres, young offender institutes) on a specific date (date tbc). Support was requested to allow the disclosure of confidential patient information from any prison (young offender institution or secure training centre), secure children's homes, or secure mental health wards with insufficient resource to complete the service evaluation to Central and North West London NHS Foundation Trust. Access was intended to be carried out onsite, with the relevant person to extract de-identified information. In accessing the notes, the study team would have access to any identifiers stored there.

The data items were listed in section (m) of the application form.

Confidentiality Advisory Group advice

The advice provided by the CAG is summarised below.

Public interest

Members noted that the principal aim of the study was to identify the needs of those in secure care to identify whether the current secure estate is able to meet their needs and whether they are detained in the appropriate institution under the most beneficial legislative framework, and to help assess whether the services provided are meeting needs. The public interest was indicated to be served through assessing whether the secure estate is able to meet the needs of the young people in their care, and whether specialisation of the various institutions may improve the service provision for these young people. This will enable the English secure estate to ensure that they fulfil the Children's Rights to receive appropriate therapeutic or psychosocial input to reduce their risks to themselves and/ or the public when in secure settings.

Members agreed that there was likely to be a high public interest in this evaluation.

Scope

Members raised a number of queries regarding scope as set out below.

The response in the advice form indicated the following "*there are some Trusts which may not be able to provide the personnel to collect this data and they have asked if our assistant psychologist can be provided an honorary contract from their Trust and collect the information from their notes and immediately place it pseudonymised into the overall database. This Trust is asking for CAG approval for this. We are not asking for any support but for confirmation of your approval for this process*". A later response then indicated "*in some cases, identifiable data will be processed outside the care team by the project team's assistant psychologist. As outlined above, this is not likely to be for many sites, just those with large numbers of young people, and availability for staff within the direct care team to collect data. These are the cases for which we are asking for CAG support*".

Members agreed that the language appeared to raise some inconsistencies and misunderstandings as to the remit of the CAG and the purpose of applying for support under Regulation 5 of the Health

Service (Control of Patient Information) Regulations 2002. In essence, if support is provided by the Secretary of State for Health, following advice from the CAG, this provides a legal basis to enable disclosure of relevant information to specified individuals to prevent a breach of confidence by those disclosing the information.

Noting this applicant considered this activity to be a service evaluation, Members highlighted that provision of an honorary research contract did not provide a legal basis, in its own right, to enable access to identifiable patient information. Applicants apply via the CAG as part of the process to obtain a legal basis to prevent the breach of confidentiality that would otherwise take place in providing access to those who would not already have legitimate access to the information during the course of normal patient care. For someone to access patient identifiable information without consent there should be a clear legal basis e.g. consent or support under Regulation 5.

In light of the position regarding honorary research contracts and for the purposes of the application under consideration, the CAG was of the understanding that support was being sought to enable the assistant psychologist to access patient identifiable information where data would not be extracted by a member of the care team. This however raised questions for CAG as to whom support would apply to as a later response made mention of a research assistant. Members advised that this should be clarified so that scope was clear.

Members also queried the method of extraction that would be undertaken, and requested greater clarity as to the process that would be followed and by whom. The application indicated that the "'*sitting in method' relates to this process that as the service evaluation is across many sites the assistant psychologist / research assistant, is employed by the Trust / University which is coordinating the overall service evaluation and not in the direct care team for most of the sites*". However, members were not entirely clear on the precise process and requested that the methodology of extraction should be specified.

Members requested clarification on which sites would not be able to undertake the data extraction, so as to be clear as to the precise scope for which support would be applicable. The application had indicated there would be limited sites but members requested greater specificity.

<u>Practicable alternatives</u>

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

Although support is sought to collect data in a limited number of sites, noting that these sites had not been specified, the application indicated that it is not practicable to seek consent in these sites. This was asserted to be because the large numbers of young people detained at these sites (e.g. 300+ on one site) would mean that seeking consent from each of these young people during the short project timeframe would be impracticable. Members agreed that consent was not likely to be practicable.

- Use of anonymised/pseudonymised data

It was noted that the proposed methodology involved researcher access to identifiable case records on-site; this was indicated to be where there was no staff capacity to undertake themselves. This approach would mean that as a consequence this would involve physical access to identifiable information.

Patient and public involvement

The applicant indicated that there was a parent representative on the steering committee who had provided input into the questionnaires used and would inform the interpretation of the analyses.

Data Protection responses

While the CAG is not responsible for assessing compliance with the Data Protection Act (DPA) 1998, it must be assured that the activity is not inconsistent with the principles of the DPA. It appeared to members that the response to the first principle was annotated and not final and this should be completed with the correct information.

Patient notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The response confirmed that the data will be collected by the direct care team in the majority of cases, and the project team's assistant psychologist would be involved in this process in a very small number of services. For these few services, the applicant will ask if they would like to place information sheets about the project on notice boards / visible spaces. This will also provide details of how to opt out, should any young person wish to do so.

While supportive in principle, members advised that further information should be provided on the mechanism for respecting patient objection. For example, what information will be provided and how will the objection be processed and managed. Members advised that a more detailed response should be provided or alternatively, if the applicant was of the view that a mechanism for patient objection should not be put in place then a strong case should be put forward.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle of access to identify physical and mental health issues, and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the requests for clarification and compliance with the specific and standard conditions of support as set out below. Members advised that in this instance, it may be beneficial to arrange a teleconference to discuss these issues and to facilitate the response.

Clarification request

The clarifications should be read in the context of the CAG advice above.

1. Members were unclear as to the precise scope of support that was requested and requested clarification on the following:
    a. It was indicated that a small number of sites may not be able to provide resource; applicant to clarify which sites are not able to provide resource.
    b. How many researchers are seeking support, for example, is support requested for the assistant psychologist only, or a research assistant?
    c. Clarification as to the methodology of the data extraction
    d. Clarification as to the relevant population; it was noted that there may be young people in a secure unit due to criminal activity with no mental health issues, therefore members questioned whether the cohort would be confined solely to those with mental health issues only, or whether it would be broader. At present, members were supportive of extracting medical information relevant to mental health only.
    e. Further robust information on the information to be provided and the mechanism that could be put in place to manage objection, or alternatively to provide a robust view as to why a mechanism for patient objection should not be implemented.
    f. Confirm the schedule two and three condition applicable under the Data Protection Act 1998 in relation to the first principle.

Specific conditions of support

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

6. NEW APPLICATIONS – RESEARCH

a) 16/CAG/0094 Reducing misdiagnosis of urinary tract infection in older adults.

Purpose of application

This application from University Hospitals Birmingham NHS Foundation Trust set out the purpose of investigating urinary tract infection (UTI). UTI is the second most common clinical reason for antibiotic treatment in primary and secondary care. The NICE quality standard for the diagnosis of UTIs for adults over 65 years states that diagnosis and treatment should be based on a full clinical assessment. However, clinicians have highlighted that these guidelines are not always followed in hospitals and that, in particular, urinary dipsticks (reagent strip tests) are commonly employed inappropriately or in isolation, leading to high rates of false positive results. An estimated 40% of cases of UTI in over 65 year olds are misdiagnosed, leading to over-prescribing of antibiotics. This has detrimental consequences to the patient and contributes to the emergence of antibiotic resistance.

There are three components to the research:

Part A is a retrospective case series review of 500 patient records to extract all data from patient admissions to eventual diagnosis / discharge pertaining to the diagnosis of the UTI. Funding has been secured to recruit a research nurse to undertake this review. The nurse will be employed by the NHS / Sponsor organisation however it was confirmed that they did not form a part of the patient care team. Data extracted will be recorded anonymously on an electronic case report form (e-CRF).

No identifiable data will be shared with the core research team at Loughborough University. No identifiable data will be taken off Trust premises. It is for this aspect that support was requested.

Part B and C of the overall activity relate to interviews with clinicians (doctors, nurse and healthcare assistants) and patients. Support was not requested for these components and these were excluded from consideration by the CAG.

A recommendation for class 1 and 6 support was requested to undertake the activity specified in Part A.

Confidential patient information requested

Support was requested to allow the disclosure of confidential patient information from Birmingham Community Healthcare NHS Foundation Trust and the Royal Wolverhampton NHS Trust to a research nurse, who was not a member of the care team.

The information would relate to 500 70+ year old patients that had been admitted to either hospital site from January 2015 - June 2015. Whilst no identifiable data was intended to be extracted, the researcher would have access to name, postcode, NHS number, date of birth, date of death and any other identifiers contained in the notes. From the patient records, data will be reviewed and extracted on variables such as risk factors, treatment, co-morbidity and falls; the extracted data would be entered to a database with a unique research reference.

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a clear medical purpose and there was a public interest in this activity being undertaken.

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 asserted that consent would be difficult as it could lead to bias in the outcomes. Following consideration of the issues, members agreed that in this situation consent would be disproportionately difficult.

- Use of anonymised/pseudonymised data

Members noted that support was requested to access and then extract a pseudonymised dataset, so pseudonymisation would be considered the exit strategy. However, members agreed that further steps could be taken to reduce the potential identifiability of the data to be held on the database; this point is clarified further under ‘justification of identifiers’.

Justification of identifiers

Accepting that access to identifiable data was necessary to undertake the case note reviews, members raised questions about the data to be stored on the database to ensure that identifiability was reduced as far as possible and could still meet the needs of the activity. In particular members highlighted that date of death was an identifier and the applicant should seek to reduce the identifiability otherwise the database could not be considered de-identified. Members also queried name of ward and whether the unit could be coded for statistical purposes. It was agreed to ask the applicant to consider the necessity and potential reduction of items, and to provide this consideration or a stronger justification.

Patient and public involvement

Members indicated that the application was particularly strong on patient involvement. It was suggested that further engagement could be made by carers; however this was not specified as a condition of support although consideration would be welcomed.

Patient notification and objection

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 mechanism to respect objection. Members agreed that in line with this principle of support it would be appropriate for the applicant to provide suitable information on this activity, and requested that materials, such as a poster, should be provided to enable this principle.

Additional points

Members clarified that the support provisionally recommended related only to this pilot activity. Should the applicant wish to extend or develop the pilot aspect, this would require a new application or should seek to use an alternative legal basis.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further clarification to justify necessity and reduce identifiability of extracted data items where feasible would be required. CAG 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. Members considered that the information to be extracted could be reduced in terms of identifiability to ensure a clearly pseudonymised dataset. Please assess the data to be retained, as a whole, and consider reduction of identifiability or provide stronger justification for the current variables such as number of days after admission. In particular, this consideration to focus upon:

    a. The feasibility of converting sector level postcode to deprivation index by the research nurse at time of extraction.

b. Date of death is considered an identifier so to consider reduction e.g. age at death or significant justification for retention, noting retention would render the data held on the database identifiable.
c. Consider name of ward and whether the unit could be coded for statistical purposes

2. Please clarify that the transfer of data from the Trust to the University is using an equivalent, or better, standard of transfer as nhs.net to nhs.net standards.

Once received the information will be reviewed by a sub-committee of members in the first instance, and a recommendation and decision issued as soon as possible (subject to satisfying the specific conditions of support in parallel). At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm final approval.

Specific conditions of support

1. Provision of a favourable opinion from a Research Ethics Committee. **Pending**
2. Direct confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Pending**
3. To improve patient notification and to provide a mechanism for patient objection, information such as a poster should be developed and disseminated appropriately.

The specific conditions must be met before a final approval outcome will be issued.

b) 16/CAG/0095; Identifying genetic and environmental interactions in psychosis.

Purpose of application

This application from Institute of Psychiatry, Psychology and Neuroscience (IoPPN) King's College London (KCL) specified that patients with psychotic disorders such as schizophrenia, usually experience early signs of psychosis for 1–5 years prior to the first episode of frank illness. This early state is known as at risk mental state (ARMS) or prodrome. Individuals with ARMS appear to be at extremely high risk of developing psychosis; about one-third will do so while two-thirds will not make a transition to psychosis and their at-risk symptoms will either stay the same or improve. It is unclear why only a subset of those who are highly vulnerable to psychosis go on to develop the illness. There is increasing evidence that aetiological models of schizophrenia need to incorporate the role of genetic, social, psychological and biological factors, and to clarify how they interact. In the European Network of National Schizophrenia Networks Studying Gene-Environment Interactions (EU-GEI), the genetic, psychological and physiological interactions in individuals at high risk of psychosis were examined. The aim being to deliver a tool that can be used to help identify genetic and environmental factors that, when they interact, predict who is more likely to develop schizophrenia.

A recommendation for class 2, 3 and 6 support was requested to undertake the activities listed in the application documentation and completed advice form.

Confidential patient information requested

The activity will involve contacting the individuals who took part in the original study at baseline in order to invite them to return for an additional follow-up which they had not consented to in the original Consent Form. Additionally, the application asserted that some of the participants have moved away and been lost to any follow-ups of the original study. The application also sought support to enable the researchers to request up-to-date contact details for any of the 'lost' participants and to contact them, where consent has not been given and to invite them to attend the newly added follow-up assessment. When participants attend the newly added follow-up assessment they will be re-consented into the study.

The following process will be followed:

- The applicants will obtain up-to-date contact information for the participant from NHS Care Records Service, NHS Trust databases or HSCIC.
- Participants will be re-contacted directly by telephone first, however a letter will be sent out to the most up-to-date postal address if there is no up-to-date contact telephone number available.
- If the research team does not receive a response from the participant, this will not be followed up.
- If previous participants are reachable either by telephone or post and contact is made with the research team, researchers will ensure that all participants provide written informed content before entering the study.

Support was requested to cover the transfer of name, address (including postcode at unit level), NHS number, date of birth, date of death, GP registration & gender will be used to verify identity, prevent inappropriate contact, contact the participant, and/or enable contact with GP's regarding up-to-date contact details. It was indicated that support would be necessary until 31 October 2021.

Confidentiality Advisory Group advice

Members noted that suitability of approaches to participants when seeking consent lay largely within the remit of the relevant Research Ethics Committee, therefore members did not consider this aspect further.

Public Interest

The CAG agreed that there was a clear medical purpose and that this activity would serve a broader public benefit and interest.

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

Members noted that there were some inconsistencies regarding the original consent, and considered whether the activity could be viewed as being in the spirit of the original consent obtained. Members noted that this was in essence a ‘consent for participation’ application, and therefore access to identifiable information was required in the first instance in order to subsequently seek consent.

- Use of anonymised/pseudonymised data

It was clear to members that access was required to identifiable information in order to contact the participants and to subsequently seek consent, and therefore processing of identifiable information was necessary.

Patient notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members noted the response provided in the advice form indicated that the applicants could add a notice to the SLaM IoPPN website and agreed that it would be unlikely that participants would look at the website. As an alternative, members welcomed the suggestion to place study specific patient notification materials, including a clear mechanism to manage objection, on a charity website such as Rethink and MIND. Members welcomed this suggestion and requested an update to be provided on dissemination routes and any patient objections received at time of annual review.

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

1. Favourable opinion from a Research Ethics Committee. **Provided.**

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 07 July 2016 (94% version 14). M**aintenance of a satisfactory IG Toolkit submission for the duration of the approval length will be required.

3. Patient notification materials to be disseminated to the specified patient groups and any patient objections respected. An update on dissemination and any issues experienced to be provided at time of annual review.

4. Confirmation at annual review of intended point the processing of confidential patient information without consent will cease.

c) 16/CAG/0091 Investigation into predictors of diagnosis in Pulmonary Arterial Hypertension (PAH) patients.

Context

This application from Sheffield Teaching Hospitals NHS Foundation Trust (STHFT) set out the purpose of investigating Pulmonary Arterial Hypertension (PAH). PAH is a disease primarily of small arteries in the lung which results in a progressive rise in lung blood pressure and heart

failure. There are several types of PAH including Idiopathic PAH and Associated PAH related to a range of disease processes, including cirrhosis, connective tissue disease, congenital heart disease, HIV infection and sickle-cell disease. Literature documents the difficulties with Pulmonary Arterial Hypertension (PAH) diagnosis which involves many different types of clinical tests, and the lengthy time it can take to diagnose the condition from the advent of a patient's first symptoms. This study aims to build a data environment for analysis in order to describe the PAH patient population in England, understand the natural history of disease and look for opportunities for improving predictive analytical methods to flag patients for diagnosis earlier.

The study design is a non-interventional retrospective database analysis of a PAH patient cohort based on data from the Pulmonary Vascular Disease Unit at Sheffield Teaching Hospitals NHS Foundation Trust (STHFT) and Hospital Episodes and Statistics (HES) data from the Health and Social Care Information Centre (HSCIC). It attempts to identify any predictive signals or markers which would allow earlier diagnosis of Pulmonary Arterial Hypertension patients and thus enable earlier right heart catheterization intervention, by analysing patient's usage pattern of hospital services ahead of a confirmed PAH diagnosis. In order to link the STHFT datasets to the Hospital Episode Statistics (HES) data, identifiable information is required to be passed from STHFT to the Health and Social Care Information Centre (HSCIC) in the form of the patient NHS number. The methodology and data flows are set out in the application.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to achieve the purposes specified in the application.

Confidential patient information requested

Support was requested to enable data from Sheffield Teaching Hospitals NHS Foundation Trust in relation to 1,907 patients suffering from PAH; anonymised information pertaining to other individuals with PAH will be provided by the HSCIC. NHS number will be used to undertake the linkages.

Confidentiality Advisory Group advice

A summary of the advice provided by the HRA Confidentiality Advisory Group (CAG) is provided below.

Public interest

Members agreed that there was a public interest in this activity being undertaken as this was a serious and progressive disease, and it was a worthwhile and important activity.

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

Members agreed that due to the numbers involved, consent was not likely to be practicable in this instance. The Group was mindful that in this instance, and due to the relative rarity of the condition, that it would be important to seek to obtain as close to 100% ascertainment as

possible. It was also important that when seeking to develop a predictive algorithm that as many steps would be taken to ensure that it was developed correctly.

- Use of anonymised/pseudonymised data

Members agreed that the methodology appeared appropriate and that due to the need for linkages to be undertaken, identifiable data would be required to enable these linkages to take place.

Justification of identifiers

Members considered that the transfer of NHS number to the HSCIC was appropriate to achieve the aims of the activity.

Patient and public involvement.

Members agreed that the involvement and engagement activities were particularly strong in this application.

Patient notification

It is a principle of the CAG that when advising support to the decision-maker, reasonable steps should be taken to ensure that the cohort is informed as to the nature of the activity and that adequate mechanisms are put in place to ensure any objection can be made and respected. Members noted the arrangements and agreed these were adequate for the purposes of this application. However, members suggested that it may be beneficial to work further with the patient and public involvement work stream to ensure that the arrangements are adequately implemented.

Additional points

Members noted commercial involvement via GSK and IMS Health however, members were assured that there would be no transfer of identifiable information to these entities and this raised no concerns for the Group. Members noted the strong track record IMS Health had in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and therefore advised recommending full support to the Health Research Authority, subject to compliance with the standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Received 29 July 2016**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmation of a satisfactory published submission was noted (version 13, 74%)**

d) 16/CAG/0092; Improving the management of drug resistant tuberculosis in the UK.

Context

This application from University College London (UCL) set out the following aims. The increase in antimicrobial resistance is a source of concern. In the UK, for example, 6.8% of the 8,500 tuberculosis patients seen in 2012 were resistant to the first-line drug isoniazid. It is of great importance to prevent the loss of current anti-tuberculosis drugs. This project aims to inform clinical knowledge and policies surrounding drug resistant patients, thus improving management and reducing transmission by a) determining the best treatments for patients with isoniazid resistant tuberculosis disease and b) exploring the relationship between treatment outcomes and the causes of drug resistance.

A recommendation for class 1, 2 5 and 6 support was requested to achieve the purposes set out in the application.

Confidential patient information requested

Support was requested to enable the disclosure of confidential patient information from Public Health England (PHE) and NHS Trusts to UCL in order to identify the correct hospital records for the collection of treatment regimen, treatment adherence, and outcome data. This will help the national and international policymakers decide the best treatment regimens for isoniazid resistant tuberculosis in the context of different resistance mutations.

This would involve the processing of name, date of birth, hospital identifier, treating hospital, treating clinician and NHS number. The data extraction process was set out in the application.

Confidentiality Advisory Group advice

The advice provided by the CAG is summarised below.

Public interest

Members agreed that the activity satisfied the relevant medical purpose and the study of antibiotic resistance was a current and important issue. It was agreed that the activity was likely to realise a public benefit and it was therefore of a high public interest.

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

Members noted that the applicant had cited as one rationale that "*Public Health England is legislated by the National Information Governance Board to hold and analyse national surveillance data for public health purposes under Section 251 of the NHS Act 2006*". Members wished to clarify that this statement involved some misunderstanding; Public Health England have responsibility for activities conducted under Regulation 3 (excluding 3(4)) and this has been in place since 01 April 2013 through changes effected by the Department of Health. It was also noted that Regulation 3 activities specifically exclude research so members

highlighted that this was not a valid justification as to why consent would not be feasible and it could not be taken as an appropriate precedent to justify the applicant position.

Members noted the following reasons were cited as to why consent would not be feasible: contact details for participants will have changed substantially in the intervening years, especially for patients with certain risk factors. Secondly, approaching potential participants was considered likely to cause distress, particularly given stigma surrounding tuberculosis in the UK among certain communities. Thirdly, key population groups (homeless individuals, migrants, individuals who died) would be difficult or impossible to contact. Finally, given these other issues, inclusion in the dataset on the basis of consent was considered to substantially bias and thus invalidate the analyses.

As a whole, members agreed that consent was not considered to be feasible and a sufficiently compelling case had been made to justify this in this instance.

- Use of anonymised/pseudonymised data

Members highlighted that they were unclear on the precise data flows and what items would be transmitted, and were therefore unable to conclude whether there was a way to reduce identifiability or whether the data items requested were justified and necessary. It was agreed to request a data flow diagram that provided this information before reaching a recommendation on this aspect.

Data flows

Members identified that they were not altogether clear on the precise data flows, for example, who would be carrying these out, which organisation or body, and at what points data identifiability would be reduced. Members also queried to whom hospital information would be sent e.g. to a named department or a specific individual. Members therefore requested a greater level of detail so that the precise data flows, the information involved, and those involved in the processing and the stages of de-identification would be clear so that any scope of support would be clear.

Patient notification and objection

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The response highlighted some difficulties in meeting this principle but indicated that information could be placed in a hospital information sheet and details of the study are available on the UCL webpages and a secure system could be put in place within that webpage allowing ex-patients who find out the details of the study to notify the Chief Investigator that they wish to withdraw their records from it, and explaining their right to do so.

Members welcomed this commitment to meeting this principle and agreed further assurance as to this process was required. Members requested further detail on what would be the process once an objection was made and how this would be managed. A definitive statement on the steps taken to notify patients was also requested to ensure incorporated within the study.

Members also discussed how the information would be appropriately disseminated and noted that for some of the cohort, English would not be their first language or some would have no permanent residence and would potentially involve the most disadvantaged sections of society. In line with this, members expressed the view that any posters in clinics would need to meet the needs of the cohort, such as those identified above. Members therefore requested consideration as to how these challenges would be met to ensure appropriate dissemination and understanding so as to avoid any potential risks of misinterpretation.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the requests for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for further information

1. Please provide a clear data flow diagram, showing the points at which data will be collected, data transferred, identifiability at each stage and the points at which data identifiability will be reduced; including which body will be responsible for the processing at each stage.
2. Please specify the process and how objection will be managed if a patient requests to be removed from the study.
3. Further consideration of patient information materials in terms of dissemination and content to mitigate against risks of misunderstanding.

Once received the information will be reviewed by a sub-committee of members in the first instance and a CAG recommendation and final decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the Health Research Authority will confirm final approval to process confidential patient information without consent.

7. EDUCATION ITEM: Dr Janet Messer, Director of Research Systems, Standards & HRA Approval Programme

Dr Messer attended as part of the CAG programme of education items to provide a presentation on the HRA Approval Programme, and to pose questions to members on how they would see the interaction with CAG processes. It was noted that Dr Taylor was developing a series of information governance questions within the IRAS form and the Group were asked what information they considered essential for the CAG to review. Members provided a number of suggestions and thanked Dr Messer for attending. The presentation had been made available to all members.

8. MINUTES OF THE PREVIOUS MEETING

The minutes from the CAG meetings on 30 June 2016 and 13 July 2016; the precedent set review meeting from 01 July 2016 and the sub-committee meeting on 23 June 2016 were approved as accurate records, subject to minor spelling amendments.

9. ANY OTHER BUSINESS

Members were informed that an office report had not been provided due to annual leave and staff departures and that any relevant information would be provided in the next cycle.
Members noted the recent Chair's report and were asked if there were any arising questions; none were received.

Members were advised that the CAT was undertaking recruitment but was running with a number of vacancies and new staff. Members were asked to respond as soon as possible to follow-up responses to application activity so a timely response could be provided to the applicant, and to submit claim expenses as soon as possible after each meeting. Members asked whether copies of claim forms could be made available at each meeting to facilitate completion and this was agreed.

Members were thanked for their attendance and the meeting was closed.