NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

22 October 2015 at Skipton House, SE1 6LH

Present:

Name	*Capacity*
Dr Mark Taylor	Chair
Dr Kambiz Boomla (to item 5E)	
Dr Tony Calland	Vice-Chair
Ms Hannah Chambers	Lay
Dr Patrick Coyle	Vice-Chair
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	
Ms Clare Sanderson	
Dr Murat Soncul	
Mr Marc Taylor	
Ms Gillian Wells	Alternative Vice-Chair
Dr Miranda Wolpert	

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Mr Ben Redclift	Confidentiality Advisor, HRA
Mr Stephen Robinson	Corporate Secretary, HRA
Dr Rachel Knowles	Observer (future CAG member)
Dr Lorna Fraser	Observer (future CAG member)
Mr David Smallacombe	Observer (future CAG member)
Mr Andrew Melville	Observer (future CAG member)

Ms Kim Kingan	Observer (future CAG member)
Dr William Bernal	Observer (future CAG member)
Ms Sophie Brannan	Observer (future CAG member)

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Dr Robert Carr, Professor Julia Hippisley-Cox and Professor Barry Evans. Members were informed that Professor Evans had taken a break in service to undertake work in Sierra Leone.

Welcomes were extended to the seven new CAG members that had recently been appointed and who would take up their appointments from 01 November 2015. These members were attending the meeting in an observer capacity prior to formally attending their first meeting on 05 November 2015 in Manchester.

The following interests were declared:

- Professor Jennifer Kurinczuk – item 5a. Professor Kurinczuk was not present for the discussion or final recommendation as she was named on the application.
- Dr Rachel Knowles – item 5c. It was agreed that although an observer, Dr Knowles would leave the room at time of this discussion due to preference.
- Dr Wolpert identified a potential conflict in relation to item 5 D, but it was agreed that there was no vested interest; the declaration would be noted with no further action taken.

The Chair opened by thanking members for their support and noted the issues experienced over the papers. The resource issues were acknowledged and member patience had been appreciated.

2. ITEMS FOR CONSIDERATION

a. CAG 5-05 (a)/2014 Southend on Sea Integrated Care Pioneer Update report

This non-research application, originally submitted by the Department of Health on behalf of Southend CCG and Southend Borough Council, was provided with support in March 2015. The overarching purpose was to enable the linkage of social care data with risk stratified commissioning data sets as part of integrated care, although access to social care data was excluded from CAG consideration as this was stated to be undertaken on the basis of consent. The application also set out the purpose of planning and assessing care interventions across health and social care needs for individual service users.

In order to comply with their conditional support, the applicant was asked to provide an update on progress, issues, patient objections and communications.

The report confirmed that the communications plan had been refined and assured in accordance with the conditions of approval, with further engagement from user groups and support from the LMC. Parallel to implementing the communications plan was the development of the technical solution to ensure data was extracted appropriately and shared in accordance with the agreed conditions. The report confirmed that as of October 2015 there were 22 information sharing agreements signed. Five GP practices had declined to sign an agreement and this represented 14% of the total patient population in Southend, whilst a further eight are working with CCG staff to complete the required agreements. Many of the practices which are

declining to sign the agreement first reported concerns during the initial period of negative publicity. This was when patients attended some practices in the borough to request further information or raise concerns as a result of stories published in national or local papers. It appears some GPs and practice managers were unnerved by this publicity – and the reaction of some patients - to such a degree that the CCG was unable to reassure them, even by providing accurate information about the scheme and its intentions.

Members noted this progress and agreed that the applicants had some work to undertake to regain professional confidence in some aspects, which was not surprising to members as it had been anticipated that sharing of data with councils was likely to lead to some anxiety within GPs. It was felt that this was a relatively high percentage and questions were raised about engagement with the CCG Patient reference Group and whether these could assist in appropriate communications to help relevant persons understand the data flows and to allay concerns.

In particular, members noted that the applicants had moved to a reactive communications plan for handling in light of media interest. When support was provided, this was conditional upon a proactive communications plan and it was advised that the expectation was for this proactive communications to continue, in light of recent learning, and any deviation from this proactive communications plan must be clearly justified.

Members noted that support had come into effect from 13 April 2015, and that support had been provided for a period of 12 months. It appeared that the applicant was operating under a misunderstanding that support commenced from the time period when data began to flow under this support. Members emphasised that support was from date of final approval, and should the applicant require an extension then they should follow the usual process of a duration extension, to be considered at an appropriate meeting.

Members advised that any duration request and annual review should include the following:

- Confirmation as to which user groups had been consulted
- Feedback on any dialogue with the CCG Patient reference Group as they should be able to assist the applicant in developing appropriate communications
- Confirmation that use of social media would not involve the disclosure of patient information
- The precise time period for which support is anticipated to be necessary as a whole
- Arising benefits to support the public interest in the activity and benefits of the Pioneer Programme as a whole.
- Detailed update on communications plan and adherence to original plan; any deviations to be justified.

In August 2015, there was an allegation from a third party of evidence suggesting that patients who chose to opt out of their patient records leaving their GP surgery to be used in the Care.data programme (using the 9Nu0 dissent code) were to have their data shared with a third party as part of this Southend application. The applicant was asked to respond to this allegation (noting this was reported at the time and refuted, namely on the grounds that the information had not yet flowed).

Members were assured that at the time of the media article, data had not flowed. Members were also assured that patient objection would be appropriately respected. As a whole, it was agreed that this was a reasonable interim report and that a detailed report, as above, should be provided at time of annual review or earlier if a duration request could be anticipated.

The Group advised that the applicant should remain mindful of the implications of an opt-in approach to consent in line with guidance produced in conjunction with the Information Commissioner's Office. The

applicants were to be reminded that if consent was originally relied upon, then there could not be reliance upon support for the same purpose if the applicant dissented.

3. RESUBMITTED APPLICATIONS

a. Holding patient identifiable data within the National Head and Neck Cancer Audit (HANA) [15/CAG/0197]

Purpose of application

This application was supported by Professor Ian Hutchinson, Ms Fran Ridout and Mr Richard Todd, QC who attended in person to discuss the activity. This application from Saving Faces, the Facial Surgery Research Foundation, set out the purpose of conducting a commissioned audit on behalf of the Healthcare Quality Improvement Partnership (HQIP). The HANA database aims to assess and improve the quality of services and the outcomes achieved by head and neck cancer treatments across the NHS. The data will provide comparative information to patients, commissioners and regulators of healthcare professionals. HANA will collect data on pre-operative health status and co-morbidity, details of the treatments provided and the principle healthcare professionals responsible, and also the development of any recognised complications following surgical and non-surgical treatments delivered within NHS hospitals.

The applicant was seeking 's251 support' in order for confidential patient information to be disclosed to Dendrite Clinical Systems Ltd for the purpose of data linkage, retaining the linked datasets (includes identifiers) as part of a database for audit purposes, and to anonymise the data prior to transfer to Saving Faces for the purpose of analysis. The applicant was also seeking s251 support in order to disclose NHS Number to the Health and Social Care Information Centre (HSCIC) for the purpose of checking mortality data to determine whether the patient was deceased and the associated cause of death.

A recommendation for class 1, 4, 6 support was requested to allow access to an authorised user for the purpose of extracting and anonymising and linking the specified patient identifiable information obtained from one or more source.

The original application, that had been reviewed at the August 2015 CAG meeting had also sought 's251 support' in order for HSCIC to disclose the DHANO historical data set, which included confidential patient information, to Dendrite Clinical Systems Ltd, for the purpose of data linkage and retaining the data within the database. These retrospective elements (the transfer of DAHNO data from HSCIC to Dendrite) had received final approval for 12 months on 25 September 2015 under reference 15/CAG/0170. Therefore this application was for the prospective elements of the study only.

Support was requested for the following purposes;

- Hospital performance – facilities and their timely availability, pastoral aspects of care
- Clinician performance - surgical skills of surgeons measured BHANO standards and the current surgeon-level reporting fields; and for the first time oncologist performance in terms of disease control and complications
- Long-term treatment outcomes – complications of treatment, disease control and survival

Confidential patient information requested

Access was requested to NHS Number, date of birth, postcode, date of death, cause of death and name.

Confidentiality Advisory Group advice

Public interest

Members noted that this was a beneficial activity in the 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 the assertion by the applicant that as near to 100% ascertainment was required in order to fulfil the purpose and therefore the seeking of consent was problematic and would jeopardise this aim. However they remained unconvinced by the argument that clinicians collecting the data would not try hard to seek consent in order to fulfil the audit. It was noted that the applicants themselves were supportive of a consented approach and the move towards a model where support would be required only for those who had not provided consent. The applicant proactively agreed and confirmed that that the feasibility of a consent-based approach would be piloted and was therefore asked to provide an update to the committee on progress with this element at next annual review stage.

Justification of identifiers

Members queried the need for the retention of the name. Members were not altogether persuaded by the stated experience of the applicant in terms of accessing computer systems to identify patients and the stated need fora secondary identifier due to incompatibility in the records held in different places. In particular, members noted that some of these experiences were in the context of direct care, which falls outside the scope of these Regulations.

However, on balance members agreed the use of the requested identifiers should be supported. This was on the basis that with the exception that they would be destroyed when no longer need for example within 6 months of date of death. Members agreed that this should be made explicit on the Patient Information Sheet

Additional points

The information being provided to patients had been reviewed by members. Members agreed that the content was satisfactory for display on a public facing website; however the information was not easy to understand form a lay perspective. Members agreed that the information being provided to participants should be re-written in plain English so as to be accessible to all participants, should refer explicitly to procedures around opt-out. Mention should also be made to the identifiers along with an explanation of why these would be required along with clarification that uses for direct care were not covered under the S251 exemption. It was also noted that HQUIP were working towards a common policy for all audits around exit strategy and that this study would be included in the discussions in HQIP around this topic

Members also re-iterated to the applicant that direct care was not covered under 251 support, for example in multidisciplinary team meetings. Similarly if a research project was initiated on the data then a new research application would be required.

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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Feedback on the discussed pilot on consent to be provided to the CAG when available or at time of annual review
2. Update on progress with moving towards an exit strategy in line with other HQIP audits should be provided at next annual review stage.
3. Exploration of, and move to, ensuring relevant identifiers are should be provided that the identifiers including the name would be destroyed when no longer need for example in the case of death.
4. Patient facing materials should be revised to be written in clear English, be specific about the identifiers being used and why and should refer explicitly to the mechanism for patients to register an objection.
5. The processing of information for the purpose of direct care is excluded from the scope of this support.
6. Any processing of data to support research purposes is excluded from the terms of this current support. A new IRAS application would be required if intending to process data for the purposes of research.
7. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **CONFIRMED 15/07/2015**

4. NEW APPLICATIONS – Non-research

a. National Lung Cancer Audit [15/CAG/0188]

Members noted that this application had been withdrawn by the applicant on 16 October 2015, prior to full CAG consideration, to enable the applicant to further ascertain the data necessity and requirements in conjunction with Public Health England following the Advice Team queries.

5. NEW APPLICATIONS – Research

a. Ethnic variations in infant mortality and other birth outcomes in England and Wales, 2006-2012 [15/CAG/0181]

Purpose of application

This application from National Perinatal Epidemiology Unit (NPEU) set out the purpose of a project-specific observational cohort study design to describe and explore differences between ethnic groups in infant mortality (deaths in the first year after birth) and other outcomes such as preterm birth. This will use linked,

routinely collected data on births and infant deaths in England and Wales in order to undertake a study of ethnic variations in infant mortality between 2006 and 2012 (approx 4.8 million births).

There will be no direct benefit to the individuals whose data is being processed however the future benefits to others, including the ethnic groups that are the focus of this research, will arise from an increased understanding of current patterns of infant mortality and of the factors associated with ethnic variations in infant mortality and adverse birth outcomes. Findings will inform service developments, potential interventions and policy aimed at improving birth outcomes and reducing inequalities in infant mortality.

Specific objectives of the study are:

- To describe ethnic variations in infant mortality (overall, by timing of death and by cause) and other birth outcomes including preterm birth, birthweight, small for gestational age (SGA), large for gestational age (LGA);
- To explore the individual and joint effects of ethnicity, area deprivation (Index of Multiple Deprivation (IMD)) and migration status (UK vs. nonUK born) on these outcomes;
- To describe ethnic and socioeconomic variations in infant mortality following preterm birth; and
- To describe ethnic variations in the incidence of sudden unexplained death in infancy (SUDI) and to explore the extent to which these variations are attributable to other factors such as preterm birth.

Confidential patient information requested

A recommendation for class 1 and 6 support was requested.

The data required for the study are held by ONS and all processing of identifiable data needed to create the study data extract will be carried out by ONS. It was confirmed that ONS would be undertaking this processing under a different legal basis and support was not requested for this aspect. The dataset received by the NPEU was stated not to contain identifiers. It was confirmed that ONS regard the dataset as identifiable because the data includes complete national coverage of all births. The application stated ONS will only release the dataset to the applicant if support under Regulation 5 is in place.

It was noted that the NPEU, for a completely separate non-research purpose (reference ECC 5-05 (f)/2012), holds the national births data for 2010 onwards which overlaps in time period with this application. Hence there is the theoretical potential for the applicant to identify individuals by matching records in the two datasets. Risks to mitigate against this were stated in page 6 of the application and summarised as:

- Fair processing materials
- Receipt of grouped variables
- Technical server separation from other data sets
- Separation of staff working on the datasets for different purposes
- In future, likely for MMBRACE ONS data to be deleted

Confidentiality Advisory Group advice

The question for CAG consideration was whether this activity required a recommendation of support; namely whether the information to be received by the applicant was considered to be confidential patient information as defined within section 251 of the NHS Act 2006 (the enabling Act for these Regulations).

Members noted that CAG sought to be consistent with the Information Commissioner's Office (ICO) guidance where appropriate and referred to the ICO Anonymisation Code of Practice that specifies situations where data is disclosed within a 'limited access' environment. It appeared to members that this application appeared to follow this model of limited access specified within the ICO Code of Practice, although it appeared that ONS were requiring the applicant to receive approval under the COPI Regulations.

Noting that support under the Regulations is a measure of last resort, members questioned whether suitable controls could be put in place to mitigate against a risk of re-identification, and this question had been asked by the advice team prior to submission, with the applicant responses provided.

In considering this option, members discussed whether, in this instance, the disclosure was to an organisation or to the person. Noting the separate requirements for a legal entity and data controller under the Data Protection Act 1998, in considering this application, members advised that it would be appropriate to consider the disclosure to the person rather than the broader organisation as it appeared that there were controls specific to this activity within the organisation. Members clarified that it would be helpful to look at the context of the disclosure and possible motivations. The view was expressed that the National Perinatal Epidemiology Unit was an organisation clearly working for the public benefit, and no commercial factors could be identified.

In light of this, members advised that if a suitable data sharing agreement (or other suitable mechanism as thought locally appropriate between ONS and the applicant) was put in place and if this was broken, then this would typically be a breach of the Data Protection Act 1998 and also a breach of confidentiality. Members therefore agreed that there was a theoretical risk of re-identification and this could be effectively managed through local controls, to be agreed between the data controller and recipient.

On this basis, the CAG recommended to the Health Research Authority that support would not be required as, based on the specific context, there could be suitable local controls and measures taken to reduce the risk of re-identification and that the information disclosed was not considered to be confidential patient information.

Confidentiality Advisory Group advice conclusion

The CAG recommended that support under the Regulations did not appear to be required as the information to be disclosed was not confidential patient information, and risks of re-identification could be reduced to an appropriate level through the implementation of local controls e.g. data sharing agreement and other local restrictions.

b. Understanding the Nature and Frequency of Avoidable Significant Harm in Primary Care (Phase 2) [15/CAG/0182]

Purpose of application

This application from the University of Nottingham set out the purpose of a retrospective cohort study (over the course of 12 months) involving case note review of primary care patients to identify instances of

significant harm that are judged to be avoidable. Significant harms will include any serious adverse health events occurring during the 12 month data collection period.

It will involve 16 general practices in England in the retrospective cohort study. The total population of patients covered will be around 100,000; 2,500 patients in total across all of the practices. This sample will receive detailed retrospective case note review to identify the extent to which failures in primary health care contribute to any of these significant health problems.

The findings will be published in a report to the Department of Health, and in professional academic journals. Information will also be made available to the public and organisations/charities concerned with patient safety (using presentations/focus groups, social media, and liaison with the media).

The stated aims were:

1. To estimate the incidence of avoidable significant harm in primary care in England.
2. To quantify, describe and classify the different types of avoidable significant harm, and their severity.
3. To identify factors that, if addressed, could help reduce the incidence of avoidable significant harm in primary care in England in the future.

A recommendation for class 1, 5 and 6 support was requested to achieve the above activity and aims.

Confidential patient information requested

Access was requested to name, date of birth and NHS Number, gender, age and participating practice name.

Confidentiality Advisory Group advice

Public interest

Members noted the proposed benefits were anticipated to be, based on the findings of the research:

- To advise on the development of new measures at national and local levels, aimed at ensuring that the NHS Outcomes Framework has coverage across primary care in relation to risks of avoidable harm.
- To advise on the extent to which future assessments of avoidable harm in primary healthcare could be made more efficient through interrogation of clinical computer records.
- To advise on interventions that might help reduce the incidence of avoidable harm.

Members agreed that this this would be a valuable study and the methodology appeared appropriate.

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.

The application stated that it was theoretically possible for the general practices involved in this study to provide anonymised versions of the patients' records (e.g. by printing these out and removing all identifiable

information, or doing similar electronically). This approach had been undertaken in previous smaller scale studies but the applicant confirmed it would be time-consuming for practices to anonymise records in this way, and it would be beyond the limits of feasibility for the current study. Also, requiring general practices to anonymise records on behalf of the research team would seriously reduce the proportion of practices willing to take part in the study (and therefore mean that the findings would be at serious risk of not being representative of general practices in England) which is an important objective for the Department of Health which is funding this study.

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.

As a whole, members were generally satisfied with the application, although noting that an unfavourable ethical opinion had been provided and there would need to be evidence of a favourable ethical review as this was a mandatory requirement for medical research applications. Comments were raised about the patient leaflet and importance of ensuring it did not unnecessarily cause concern with the practice population if their practice had been selected, and that sufficient time should be given to enable information to be disseminated and opportunity for objection to be made. Comments were made that patient participation could be explored further and this should be progressed and reported against at time of annual review.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Pending**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. This should cover all entities and bodies processing confidential patient information e.g. University of Nottingham and the University of Cardiff (who would be supplying the technical infrastructure)
3. Patient information leaflet to be updated so that content does not lead to concern or undermine public confidence in the practice.
4. Data to be retained in identifiable form for no longer than 7 years.
5. At least 6 weeks should be provided to enable patient information to be shared and patients given opportunity to dissent, prior to any access to identifiable data.
6. Improved patient participation e.g. through GP patient participation group, and this should be reported against at time of annual review.
7. Any relevant dissent must be respected.
8. Confirmation of the specific time period for which confidential patient information will be processed, and hence how long support will be required.

c. National Study of HIV in Pregnancy and childhood [15/CAG/0190] (Note previous reference of 15/CAG/0153

It was noted that this submission differed from typical submissions, in that there had been previous discussions with the CAG following the submission at the July 2015 CAG meeting. The outcome dated 23

July 2015 had confirmed the HRA decision that parts of the original protocol relating to the BPSU and flagging aspects had been previously included within reference PIAG/BPSU 2-10 (a)/2005, and that:

- The surveillance aspects of the application were not supported, on the basis that there was an alternative legal basis for the data flows under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002.

- The research aspects of the application were deferred; further information had been requested from the applicant as outlined below.

The applicant had been asked to provide further information focusing solely on the research elements. A covering letter and expanded research protocol to meet this requirement was provided and considered at the meeting on 22 October 2015. It was noted that any outcomes should be read by data controllers in conjunction with the letter dated 23 July 2015.

A recommendation for class 5 and 6 support was requested to achieve the activity specified in the application.

Confidentiality Advisory Group advice

Scope

Members had previously noted that support was requested for research purposes as this purpose was excluded under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002. It was previously agreed that the applicant should submit an outline of the specific research purposes and the data flows associated with these to help determine whether CAG should consider support under Regulation 5. The applicant had been asked to ensure that all uses of identifiable data for research purposes were justified and where possible reduce the amount of identifiers required to assist the CAG in determining whether

a) general support for research purposes would be appropriate because the purposes of data flows were so intertwined, or

b) secondary access to anonymised data only would be sufficient for the primary research purposes and applications to access identifiable data for research purposes could then be made on a case by case basis as required.

Justification of identifiers:

Members advised that the use of identifiers appeared appropriate and this information was needed to link mother and child records.

Patient notification and objection

It was noted that the data flows were closely entwined and there would be issues around differentiating between surveillance and research purposes. Views were expressed by members that primarily this was a surveillance system and therefore unlikely that consent would be asked for these surveillance purposes (for data flowing under Regulation 3). It was also noted that the applicant had indicated that one possible strategy would be to use the NSHPC website to provide information stating that patients are entitled to register their objection to their personal data being used for research purposes. The applicant would provide information on how to register such an objection, and in the event of an individual doing so, they would seek to flag their record in order to exclude their data from research analyses where feasible, if the patient can

provide sufficient identifiers to enable the applicant to identify the correct record.

Members welcomed this proposal and noted it was important to recognise that it is a standard condition of support under Regulation 5 that patient dissent should be respected. It was therefore agreed that the applicants should explore the feasibility of a mechanism in order to manage this aspect, and should report in detail on direction of travel and progression at time of next annual review.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and the CAG therefore advised recommending provisional support to the Secretary of State for Health, subject to satisfactory resolution of and compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Provisions of a report detailing direction of travel and progress in ensuring management of dissent for research purposes to be included in next annual review.

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements for the bodies processing personal data under this support via Information Governance Toolkit (IGT) submission.

d. Outcomes of adolescents transitioning from children's ADHD services 15/CAG/0192

Purpose of application

This application from Central Manchester University Hospitals NHS Foundation Trust set out the purpose of a follow-up for a group of adolescents (100) discharged from ADHD services at the age of 18 years. It is hypothesised that there will be a relationship between discharge from child ADHD services and an increasing incidence of young people presenting in crisis situations having disengaged from adult ADHD services.

It aims to identify the following:

- Is there an association between discharge from child ADHD services and increased incidence of young people presenting in crisis situations and within the criminal justice system, substance misuse services and social care services?

- Outputs will inform the next study, which will add to the growing body of knowledge which is aiming to improve CAMHS to Adult Mental Health Service (AMHS) transitional services.

A recommendation for class 1 and 6 support was requested to cover the activity specified in the application

Confidential patient information requested

ADHD nurses at the 5 sites (Salford, Emerge, North, South and Central Manchester as per the protocol) will identify the potential participants. Following the opt-out consent process, the Chief Investigator will collect follow-up data for participants whom have not exercised the opt-out option.

The cohort will be aged 18-21 and are adolescents who were discharged from the five ADHD services (Salford, Emerge, North, South and Central Manchester) at the age of 18yrs between the two year period from 01/04/12 to 01/04/14.The ADHD nurses from each site will write to 50 participants from each site to obtain a sample of 20 from each site after the opt-out option. The applicant will obtain follow-up date from / access the records of these 100 patients from the following data bases: CAMHS(CORC) Adult psychiatry and liaison service (AMIGOS AND ICIS), Adult ADHD service, criminal justice system, substance misuse service and social care database. This access is indicated to be provided via organisational approval and outside of CAG scope to provide support

Support was requested to enable disclosure of NHS Number and name to the Chief Investigator to enable the linkages. Gender and occupation would be retained for analysis purposes.

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a public interest in this activity as this area was lacking in services and knowing what happens would be important.

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

It was agreed that the reasons provided for why consent would not be feasible were valid in the circumstances and consent would be very difficult for this particular cohort in light of the research to be undertaken; in this instance would not be a practicable alternative.

- Use of anonymised/pseudonymised data

It was agreed that identifiers would be necessary in order to undertake linkage activity.

Justification of identifiers

Members agreed that the identifiers specified seemed reasonable, however it was queried whether these would be sufficient to maintain accurate data linkage and whether use of date of birth or postcode would be required to ensure integrity of data linkage. It was concluded that the applicant should have assessed the identifiers necessary to ensure accurate linkage, and that the applicant could raise this following this outcome if of a subsequent view that the specified identifiers were not sufficient.

Additional points

While not a condition of support, members expressed the view that service user involvement appeared to be limited and strongly recommended improving this where feasible.

Members also reviewed the retention period specified and requested that the storage and retention be clearly explained in the invitation letter, and that the applicant must ensure they remain compliant with the provisions of the Data Protection Act 1998; further aspect on this aspect can be sought from the Information Commissioner's Office.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and recommended provisional support, subject to satisfying the outstanding specific conditions of support. It 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.

Specific conditions of support

1. Clarification that the identifiers requested are sufficient to achieve the linkage purposes
2. Where access to data sources (e.g. criminal justice system) is indicated to be provided via organisational approval, access to these will not be undertaken under this approval, namely Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002
3. Provision of a favourable opinion letter from a Research Ethics Committee - pending.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via satisfactory Information Governance Toolkit (IGT) submission.

e. The DESiGN Trial Detection of small for gestational age fetus (SGA) 15/CAG/0195

Purpose of application

This application from King's College London set out the following purpose. The Growth Assessment Programme (GAP) aims to improve the identification of small babies by considering maternal characteristics such as size and ethnicity when assessing growth. Evidence from only observational studies suggest that GAP is better at identifying babies at risk. However, a key concern is that adjustment for maternal ethnicity, some very small or very large babies might be missed or wrongly identified. Correct identification of small babies is fundamental as appropriate management and follow up reduces their risk of a stillbirth. Therefore, a well- designed clinical trial is needed to assess if GAP is better in identifying small babies.

Hospitals are randomised, rather than individual women who will receive the care allocated to their hospital avoiding contamination of the intervention. All maternity units in the trial will introduce the GAP programme eventually, but one group will use GAP immediately, while the other group will delay implementation of GAP. The time before the introduction of GAP in the delayed arm means the applicant can compare maternity units using GAP with those continuing with usual care.

The primary objective of the study is:

- to determine whether implementation of the GAP programme will result in an improved antenatal detection of small infants
- to investigate the effect of the intervention on short-term maternal and neonatal outcomes
- to estimate the impact of GAP on clinical service provision and health economics.

- to assess fidelity and quality of implementation, acceptability and identify contextual factors associated with variation in outcomes of GAP

Interviews will be undertaken on a consented basis.

A recommendation for class 1, 3 and 6 support was requested to enable the activity specified in the application.

Confidential patient information requested

Data on few secondary outcomes, such as clinical detection of SGA and compliance assessment, are not routinely available in the hospital systems. To collect this data the research team will need to review notes of participants. In order to reduce the number of notes to review they will restrict the review to participants that had an SGA infant and they will need to use participant identifiers to select the notes to review.

Confidentiality Advisory Group advice

Public interest

Members noted there had been limited progress in reducing stillbirths in the UK over the last 20 years and activity to seek to investigate potential reduction of stillbirths would be in the public interest. It was also noted that the potential benefits of scans were not yet known as there was not yet enough evidence to implement fully.

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.

In reviewing the approach, members expressed the view that this activity could not be undertaken in a different way using wither consent or de-identified data.

Patient notification and objection

Members agreed that they supported the researchers and the activity, as they would be trying to produce 'gold standard' evidence and to discover the extent of compliance with the GAP programme. While noting that patients would not be able to opt out of the GAP programme itself, members noted that there would be no opportunity provided for patients to opt-out of the research use of data to inform the programme. It is a principle and standard condition of any support provided under these Regulations that there should be a mechanism in place to enable patients to register dissent and objection to be respected. While noting that this was an important activity, members were of the view that this mechanism of informing patients of the activity, and enabling them to register objection for the research use of the data could be managed via dissemination of a suitable patient leaflet.

Members advised that, providing this mechanism of objection to research use of the data was implemented via a patient leaflet, they would be very supportive of this activity. Members discussed whether providing suitable patient notification materials would lead to undue concern from a patient, but considered this could be readily managed through appropriate wording. Members were therefore of the view that objection in relation to research use of data should be implemented and respected.

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 conditional 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. There must be suitable notification of the activity to the cohort and a mechanism to enable objection in relation to the research use of the data
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

f. Whole-genome sequencing to investigate colonisation and transmission of multi-drug resistant organisms on the adult intensive care unit at Addenbrooke's Hospital [15/CAG/0189]

This application had been submitted as the relevant REC had issued an unfavourable opinion on the grounds that it appeared there would be a disclosure without consent. This application was withdrawn prior to consideration by CAG in response to advice team queries as the applicant had confirmed in writing that all processing of information would be undertaken by members of the care team that already had pre-existing legitimate access to the information. In light of the assertion that would be no onward identifiable disclosure, the application was withdrawn and the REC informed.

6. MINUTES OF THE MEETING HELD ON 17 September 2015

It was noted that the minutes from September 2015 had missed details of an application and would be provided to members once generated.

Feedback was provided on behalf of a member that sought clarification on whether the statement provided by Professor Martin Severs could be more comprehensive to reflect the discussion if the relevant meetings had taken place and the sensitivities no longer existed. It was agreed that this would be asked of Professor Severs.

Members also queried how CAG will liaise with the HSCIC on how 'Type 2' objections are to be implemented and any potential impact on applications approved under Regulation 2, 3(4) or 5 of the Health service (Control of Patient Information) Regulations 2002. The preference was that once the HSCIC implement the final outcome, that there would be a conversation with the CAG so that it could understand how this was implemented and the implications.

7. CAG OFFICE REPORT

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 17 September 2015 meeting applications.

However, a decision is yet to be provided on the Female Genital Mutilation application; the delay is likely due to issues around dissent.

Members should note that the current approver, on behalf of the Secretary of State for Health, will be moving to a new role. The replacement will be confirmed in due course.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 17 September 2015 meeting applications.

Operational and CAT advice updates

1. **Recruitment**

Following a public recruitment campaign, Dr Mark Taylor has been appointed by the Health Research Authority as CAG Chair from 15 September 2015 for a period of three years. Following the public recruitment campaign for new CAG members, seven new members have been appointed to take up the role from 01 November 2015. Biography details and pictures will shortly be made available on the website.

Two Senior Confidentiality Advisors staff had been recruited to the Confidentiality Advice Team, and would join from end-October. Current focus, due to the reduced staffing, has been on maintaining business as usual operations and the new staff, once developed in role, will enable improvement activities to progress.

It is confirmed that five current member's terms of office would expire at the end of financial year. A further recruitment campaign is anticipated in the New Year

2. **Information Governance Toolkit equivalence in Wales**

A copy of the Memorandum of Understanding between the Welsh Assembly Government and NHS England has been received as part of the measures to ensure that the Welsh equivalent of the Information Governance Toolkit, Caldicott Principles into Practice (C-PiP) could be accepted as providing equivalent security assurance. The CAG had previously written to the approver to highlight the delays and was supportive of a resolution being achieved. There was a misunderstanding that the signing of the MoU was sufficient to enable CAG to recommend final support and a number of queries were received from applicants. Following correspondence with NHS Wales Information Services, both the HRA and SofS approvers have been written to on behalf of CAG to set out the current position; CAG did not have capacity or skillset to recommend how and whether an assurance mechanism would be provided to the CAG on individual C-PiP assessments, similar to the process currently in place where the HSCIC provides independent assurance to CAG. The approvers have discussed and the final decision on approach is currently with the Department of Health policy team.

Members highlighted how important it was that there be progression on this aspect considering the lengthy amount of time to produce a MoU, and it was understood that Mr Robinson was due to have a meeting with DH to discuss options.

3. **Information Governance Toolkit query - England**

The Hosted Secondary Uses view, 13-334 states 'The confidentiality of service user information is protected through use of pseudonymisation and anonymisation techniques where appropriate' & lists the attainment levels. However, Level Not Required states "NR:Support has been granted under S251 NHS Act 2006"

A concern has been raised that this seems misleading. One of the exit strategies for reliance upon 's251', or as part of the data flows, is often for the applicant to ensure that they are appropriately pseudonymising the data, so generally this means applicants must have suitable evidence to meet this requirement. It has been asked why this appears not to be a requirement for the reason that support is in place, when actually it is critical that appropriate pseudonymisation measures are in place under the approval. An interim response has been received from the HSCIC, confirming that the concern is valid and that there will be a need to amend or issue guidance. An update will be provided once received.

4. Guidance on access to data from the HSCIC

There has been a recent and significant increase in queries to the Advice team where the applicant is requesting data from the HSCIC. Discussion identified a position appeared to have been unilaterally taken that the scope of the approval provided to applicants was based upon the outcome letter content alone. Applicants were subsequently referred directly to the Advice Team or a number of queries around approval scope were sent directly by the HSCIC. Outcome letters are a direct reflection of the minutes and are therefore a summary of the CAG advice and the decision, not a replica of the application content. The HRA website confirms that queries over scope of approval by the data controller should be directed to the applicant in the first instance. The expectation is for the applicant and local data controllers to liaise effectively, with the applicant expected to share the application as requested. This position has been reiterated to the HSCIC, the queries have significantly lessened with clearer reasoning for referral, and the website will shortly be updated to help clarify this position.

As a result of a project and other partnership work the MRC Regulatory Support Centre has developed a number of resources to support health informatics research. These can be found on the following web page: http://www.mrc.ac.uk/research/facilities/regulatory-support-centre/supporting-informatics-research/. This includes guidance on '**Obtaining data from the Health and Social Care Information Centre (HSCIC) for health research**. This is a practical guide for researchers and includes tips on obtaining the necessary approvals. It will be a living document, updated regularly as HSCIC processes evolve. The HRA has provided input where relevant to CAG and will work with the MRC to update as CAG evolves as necessary.

8. ANY OTHER BUSINESS

Members noted for information a HRA position paper on 'safe harbor' that the HRA had asked be provided to all of its committees. It was noted that the precedent set review criteria already accounts for this by listing the following exclusion criteria: "*The transfer of confidential patient information outside of the European Economic Area (EEA), or to organisations who intend to use the data for commercial purposes*". Any transfer outside the EEA would therefore be considered at a full CAG meeting. Potential implications for CAG were as follows: Increased scrutiny on assertions that information is genuinely de-identified where involving transfer overseas; applicants to be directed to ICO guidance as part of demonstrating compliance with their guidance, acknowledgement that this is primarily a data protection issue.

Members were advised that NHS England had proposed a series of amendments that would require consideration. Depending on their nature, the Chair had agreed that these could initially be considered outside the full meeting schedule, with onwards referral where appropriate. Volunteers were sought to assist in this initial assessment.