NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

30 June at 10:00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor	Chair, items 3a-4a
Dr Tony Calland	Vice-chair, items 4b-6
Dr Kambiz Boomla	
Mr. Anthony Kane	
Professor Jennifer Kurinczuk	
Professor Barry Evans	
Ms. Hannah Chambers	
Dr Lorna Fraser	
Dr Will Bernal	
Ms Diana Robbins	
Ms Ellen Lim	
Ms Clare Sanderson	Left 16.30
Dr Patrick Coyle	Arrived 13:55

Also in attendance:

Name	Position (or reason for attending)
Ms Ming Tang	NHS England; item 3a-b
Ms Wendy Harrison	NHS England; item 3a-b
Ms Kemi Adenubi	Health & Social Care Information Centre (HSCIC) ; item 3a-b
Ms Dawn Foster	Health & Social Care Information Centre (HSCIC); item 6
Atul Patel	Technical Talent Management, HRA observer
Carla Dennehy	Technical Talent Management, HRA observer
Lauren Allen	Technical Talent Management, HRA observer
Andrea Horwood	Technical Talent Management, HRA observer
Tracy Papiccio	Technical Talent Management, HRA observer

Natasha Dunkley	Head of Confidentiality Advice Service, HRA
Diane Pryce	Senior Confidentiality Advisor, HRA
Rachel Heron	Confidentiality Advisor, HRA
Ben Redclift	Confidentiality Advisor, HRA
Christopher Ward	Senior Confidentiality Advisor, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from David Smallacombe. Dr Kambiz Boomla noted that he had offered advice to the applicant for 16/CAG/0084, the 'London Borough of Tower Hamlets Whole Systems Data Integration Project', but had no direct interest in the application. It was agreed that he should stay for the discussion, but not participate. Ms Clare Sanderson know one of the attendees (Ms Kemi Adenubi), however this was agreed not to be an interest.

The observers, above, were welcomed to the meeting.

2. APPROVAL DECISIONS

The following was shared with the CAG 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 May 2016 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the May 2016 meeting applications.

3. ITEMS FOR CONSIDERATION

Members welcomed Ms Ming Tang and Ms Wendy Harrison from NHS England and Ms Kemi Adenubi from the Health & Social Care Information Centre (HSCIC) and thanked them for their attendance to help support consideration of the items.

a. CAG 2-03(a)/2013 NHS England progress report

This update paper was considered at the CAG meeting on 30 June 2016. In this instance, this item was considered as part of the ongoing approval and to meet the specific conditions of support. No significant issues were raised during the update report that necessitated a formal recommendation to the decision-maker. The amendment request for additional datasets was considered in

conjunction, but is recorded separately as it required a formal recommendation and subsequent decision.

Update paper context

The paper provided an update against the Data Service for Commissioning programme, progress towards a de-identification solution, implementation of Type 2 objections, and the broader context. It was noted that consideration of the paper was taking place prior to the review to be imminently published by Dame Fiona Caldicott. Members welcomed this report and in particular the thoughtful comments and articulation of the issues. It was acknowledged that significant progress had been made in challenging circumstances and the applicant positive engagement with the CAG was welcomed in particular. The report requested a number of points of clarification and the clarifications provided by the CAG, where appropriate, are summarised below.

1. CAG 2-03 (a)/2013 Local Data Flows

The paper specified that the HSCIC Data Access Advisory Group (DAAG) would like clarification that the local flows can be disseminated from DSCROs to be used for the same purposes as nationally collected data (SUS and HES) under CAG 2-03(a)/2013 support. The CAG advised that they would need to understand what was covered by 'local data flows' prior to considering and identifying any formal recommendation to the decision-maker. The attendees indicated that a paper had already been written for DAAG and this could be shared with the CAG to help develop this understanding.

It was agreed that the paper (plus any other relevant information) would be submitted to the CAG. It would initially be considered virtually by all members and next steps would be confirmed after this consideration.

2. CAG 7-04 (a)/2013 Data controller relationships

The paper sought clarification on behalf of DAAG that the revised assignment for CCGs and GPs as data controllers in common would be acceptable under the existing support with data controller arrangements described (as per section 2.3 of the report). This was raised in the context of CAG 7-04 (a)/2013 'risk stratification'.

Members reiterated that it is not the responsibility of the CAG to determine what is appropriate under the provisions of the Data Protection Act (DPA) 1998. The Information Commissioner's Office (ICO) is the body responsible for issues of non-compliance with that Act. Acknowledging that any approved activity under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 and its parent Act must provide assurance that the activity is not inconsistent with the provisions of the DPA, it is the role of the CAG to receive and not provide this confirmation. Such confirmation should be agreed locally between the relevant data controllers and their own advice mechanisms. Once clarified this should be confirmed back to the CAG so that this could be appended to CAG 7-04 (a)/2013.

3. Clarification of scope of CAG 2-03 (a)/2013

The paper sought clarification on behalf of DAAG whether the other data sets included in CAG 2-03(a)/2013, including the subsequently approved amendments to the data sets, are included in the support for the purposes of risk stratification. Members confirmed that the information approved within CAG 2-03(a)/2013 underpins reference CAG 7-04 (a)/2013. It was noted that this had already been specified within the application documentation for this reference.

4. CAG 7-07 (a-c)/2013 – data controller and processor arrangements

The paper requested confirmation that if the CCG is procuring the services of a non-CSU third-party (LPF provider) they are able to within the approval scope, providing they meet the conditions specified within the update paper. Members confirmed that support under Regulation 5 extends to data controllers only, as any data processors (recognised as such within the provisions of the DPA) are normally acting under instruction of the data controller. As such, within this context, members could not identify any issues within the approval that would prevent the approach specified. It was noted that support related to lifting the common law duty of confidence and did not remove any other obligations. It was advised that if there are issues relating to data controller and/or processing arrangements, these should be addressed locally between the relevant data controllers or advice sought from the ICO.

5. CAG 7-04 (a)/2013 Risk Stratification Providers – clarification

Members were advised that historically an amendment had previously been submitted to include additional risk stratification suppliers due to 'administrative oversight' after the original application had received support. It had been considered by the CAG for this reason.

The paper confirmed that NHS England had received a number of requests for new service providers to be included on the register. The paper sought endorsement from CAG for NHS England to undertake an assessment of each new provider, and providing the tool uses one of the approved end-state solutions for risk stratification, they may be added to the register. The paper confirmed the benefit would involve maintaining control of the way that identifiable data is handled without restricting competition in the risk stratification supplier market.

The Group advised that it was not for CAG to 'endorse' a specific approach as its role is advisory, and while mindful of the issue members were clear that it is not the role of the CAG to consider competition issues as this would be a national policy decision generally outside the remit of the CAG advisory role within the Health Service (Control of Patient Information) Regulations 2002. However, it was noted that NHS England had maintained the Register of suppliers from commencement of the approval therefore the Group agreed that the approach specified in the amendment request would not represent a significant change to the existing approval scope, purpose and refined exit strategy; noting that the exit strategy was currently undergoing development and confirmation of approach. In particular, members were advised that discussions had been undertaken as part of the review undertaken by Dame Fiona Caldicott, and the report was expected to provide clarification on this area. Members therefore agreed that it would be appropriate for NHS England to continue to manage the addition of new suppliers within the framework of the approval scope, subject to any recommendations arising from the report and the developing exit strategy.

6. Exit strategy

Members considered the paper which described the approach to be undertaken as part of the exit strategy from reliance upon this support, and how 'anonymised in context' was being developed. Noting that the report from Dame Fiona Caldicott was due for publication shortly, which might have an impact on the definitions and working practices, members agreed that there was nothing unusual in the description that led to concern at the current time.

b. CAG 2-03(a)/2013 NHS England amendment for inclusion of IAPT dataset

Amendment scope

Following queries arising from DAAG, an amendment was submitted to enable incorporation of additional datasets within CAG 2-03 (a)/2013 and the linked references CAG 7-04 (a)/2013 and CAG 7-07 (a-c)/2013. The datasets covered the following: Improving Access to Psychological Therapies (IAPT), Diagnostic Imaging Datasets (DIDS) and Children and Young People's Health Services Dataset (CYPHS).

The amendment confirmed the scope to cover the HSCIC to make the data sets specified above available to DSCROs for de-identification and linkage to other commissioning data sets, and make this available to Commissioners (CCGs and NHS England) as part of reference CAG 2-03 (a)/2013. The update paper specified that the data sets are nationally defined and provide the minimum level of detail necessary to support service activity and quality monitoring for individuals that access the service.

Clarification of reference scope

In response to a specific request, members confirmed that the information approved within CAG 2-03(a)/2013 flowed through and underpinned reference CAG 7-04 (a)/2013. It was noted that this had already been specified within the application documentation for this reference.

Future dataset inclusion

Members queried the rationale for submitting this amendment as it appeared that the datasets could reasonably fall within the classes of information originally approved within CAG 2-03(a)/2013. In this instance, the CAG agreed that the inclusion of these datasets could reasonably be taken to fall within the high level classes of information specified already in the approved application, and agreed to recommend to the decision-maker that these datasets are already included.

Should there be future additional datasets, it was advised that these should be reviewed by the relevant parties and considered as to whether they would reasonably fall within these classes within the application documentation. This amendment request outcome should be used to help local judgements on appropriateness of formal submission to the CAG. In instances where the conclusion is that the national datasets do not fall within these classes, a short assessment of this rationale should be submitted, in addition to any formal amendment.

Patient notification

Members reminded the applicants that under the terms of support, the focus of the Group was on the principle of 'patient notification'; the amendment form had provided an extract of the ICO website DPA notification however it had not addressed the question as to how inclusion of these datasets would be made publicly available. It was clarified that the Data Protection Act lies within the remit of the ICO, and the Group focus was separate to this. The issue of patient notification had been a question raised and addressed during the previous amendment for inclusion of datasets, and relevant information was provided in the update report and email correspondence. Members agreed that further updates against the plans to provide patient notification should be submitted at the next quarterly report.

c. PIAG 4-05(d)/2005; To access birth notification information for statistical purposes; annual review.

Purpose of application

This application from the Office for National Statistics set out the purpose of conducting a project aiming to routinely link birth notification records and vital registration records so as to maintain ongoing quality checks, and produce enhanced national statistics that will better meet the needs of the NHS, Department of Health, Department for Education, Treasury, Parliament and the public.

Confidentiality Advice Group advice

Security arrangements

A satisfactory Information Governance Toolkit score of 91% was noted and there are policies and procedures in place to enforce security arrangements, which also included appropriate training and ongoing supervision. The Confidentiality Advice Team noted that access to confidential patient information was restricted to authorised personnel for the purposes it was made available or for which section 251 support was sought.

Study Progress

The Confidentiality Advice Group noted that overall the conditions of approval continue to be met. However, they also noted that the applicant was in the process of considering a new application for this work. This was in order to address the changes which had taken place since the original application had been considered and the changes there had been to organisational structures and legal framework.

Practicable alternatives or exit strategies

The Confidentiality Advice Group noted that linkage between birth notification and civil registration of births and deaths are required for the Office for National Statistics to perform statistical analysis of this data. There was still a continued need to access confidential patient information as specified within the original application.

Members also noted that access to confidential patient information was limited to the minimum necessary personnel and that after linkage; and that statistical files were produced with the agreed identifiers.

The Group also noted that the applicant had developed posters for informing patients how birth notification data are used by the Office for National Statistics and relevant contact details. The posters have been disseminated through maternity units and are updated annually. However members felt that the poster was not particularly informative and somewhat out of date; they also felt it was unlikely to be accessible to the majority of patients.

Projected end date

The Confidentiality Advice Team noted that this study was a continuous statistical analysis and output within the Office for National Statistics portfolio of life events analysis. The confidential patient information was retained until data linkage has been completed and quality assured.

Project changes

The data controller for this data now sits within the ONS Life Events processing team; Robert Seymour is branch head, Mark Gautrey Sources manager. The purpose for ONS receiving birth notifications remains as in the original application and all data flows remain in place.

In April 2015 the source of birth notifications was transitioned from the HSCIC NN4B service to the Patient Demographic Service following an implementation project conducted by ONS and HSCIC. The replacement receiving mechanism at ONS has since proved successful in receiving and processing the notifications. The transmission of relevant information on to the civil registrations process for birth registrations continues to be provided using this IT solution.

Following the changes notified in this annual review the CAT advised that the applicant should submit a new and revised application form. This has now been received and following initial review it has been identified that an alternative legal basis for the data processing may exist.

Patient feedback and objections

It was noted that the applicant had not received any complaints or queries regarding the use of their data for the purpose of the original application.

Confidentiality Advice Team advice conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 3 months from the anniversary of the original final approval outcome letter, to the date specified above.

This was in order for the applicant to work with the Data Controller to determine whether an alternative legal basis exists. If it was determined an alternate legal basis did not exist a new application would be required.

The applicant was reminded that a new application would need to address the Health Service (Control of Patient Information) Regulations 2002. In this scenario the applicant should contact the CAT to book their application to the next available meeting.

4. NEW APPLICATIONS – Non-research

a. 16/CAG/0084; London Borough of Tower Hamlets Whole Systems Data Integration Project.

Purpose of application

As one of the most deprived boroughs in England, the London Borough of Tower Hamlets (LBTH) is attempting to efficiently improve overall health outcomes while addressing health inequalities. This application from LBTH set out the purpose of underpinning this strategy with evidence identifying the key drivers of health inequalities with respect to health status and service usage. Tower Hamlets already has an integrated care dataset that links data across different settings of care: primary care, community health, mental health, secondary care and adult social care. The applicants propose to build on this by linking these datasets as well as those holding children's services data and wider determinants data, which are held and owned by the local authority.

To establish a truly integrated and pseudonymised health and social care (H&SC) dataset for the local population which combines information from both the LBTH and North East London Commissioning Support Group (NEL CSU) so as to:

- clearly describe the health and care provided to a risk stratified Tower Hamlets population with sufficient granularity
- define, inform and implement capitated budget for the Tower Hamlet population

Once linked, the data will be pseudonymised, with only aggregated summary data being available outside the safe haven. This will comply with the NHS and ONS Information Governance rules of small numbers (<5) being converted to zero.

A recommendation for class 1, 4, 5, and 6 support was requested to allow the transfer of data from LBTH to NEL CSU.

Confidential patient information requested

Access was requested to:

- NHS Number
- Full Name
- Full Address (including postcode)
- Date of Birth
- Gender
- GP Code
- Unique Property Reference Number (UPRN)

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially 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

The group was content that it would be unfeasible to seek consent given the number of participants involved.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to perform the required linkage.

Justification of identifiers

Insufficient information had been provided about the health and social care data for which support was requested; nor was the analytical approach which would be taken to the identifiers, and thus the extent to which they were justified, clear. This was felt to be particularly important given the extent of data for which support was requested. The applicants should set out how they have satisfied themselves as to the scientific validity of the proposed project. A full list of the data items should also be provided (setting out from where each will be sourced, how processed, how retained, in what form, and by whom). Each dataset, including the healthcare dataset, should be accompanied by an explanation as to the question it will help to answer, and how it will be utilised to achieve this.

Members noted that neither National Insurance (NI) number nor date of death was included in the list of identifiers listed in section (m) of the form but NI number was included in the list of data items to be deleted in the section indicating how the data would be de-identified. The extent to which other data items which may constitute identifiers (for example, the 'Noise complaints, untidy gardens, household waste' data item, which includes a grid reference) would be dealt with was also unclear.

Members were also unsure as to whether the Unique Property Reference Number (UPRN) was being retained for spatial analysis. If it is not, the applicant should clarify how it will be de-identified as there was an implication that it would be de-identified but the details of how this would be achieved were not given. If it, or any other identifiers will be retained, this should be clearly set out in the application and justified.

With reference to CAG's remit under the relevant regulations and legislation the applicant should set out precisely which data items they are seeking support for and the legal basis under which any other items are being processed. This should be noted on the list of identifiers, as above.

Exit strategy

The application was ambiguous as to whether a one-off linkage or an annual linkage was proposed. This should be clarified in any future resubmission. CAG were however satisfied with the exit strategy as set out, with the pseudonymised Whole Systems Dataset being held for five years and confidential client data being processed for up to three months post-linkage, in order to allow time to check, and then pseudonymised.

Patient notification and objection

Members commended the patient notification materials and the patient and public involvement which had taken place.

The mechanism for opt out, however, caused the members some concern as, once opted out, participants would not be able to change their minds and opt back in. This was felt to be possibly coercive as individuals might not wish to take so decisive a step.

Additional points

NEL CSU is a stage 1 ASH for the purpose of receiving commissioning datasets under CAG 2-03(a)/2013; CAG 7/04(a)/2013 and CAG 7-07(a-c)/2013. The purposes set out in this application are not covered by the support the above projects have received.

The group was unclear the period of time which would be covered by the data being linked. This should be clarified.

The data processors were unclear – the CSU and DSCRO were, for example, conflated in the submission papers. This should be explained in any future submission. The CAG was unclear if the CSU's would have access to sufficient identifiers to enable the linkages set out in the application. Any future submission should make clear the legal basis on which CSUs have access to the identifiers required for linkage purposes, particularly if these extend beyond NHS number alone.

The applicant should also note that members were unclear as to whether CSUs can act as data controllers.

The submission made minimal reference to the CCGs and any future submission should set out how they are involved in the project.

Confidentiality Advisory Group advice conclusion

Members understood the principle of the application and were supportive of it. However, in line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. The applicant should provide evidence as to how they have satisfied themselves of the scientific validity of the application.

2. A full list of the data items, including the healthcare dataset, (setting out where they will be sourced from, how processed, how retained, in what form, by whom, and which support is requested for) should be provided. Each dataset should be accompanied by an explanation as to the question it will help to answer, and how it will be utilised to achieve this.
3. Clarification as to the period of time covered by the data being linked.
4. The application should be clear as to what identifiers are being processed, which retained, and under what legal basis this will be conducted. The application should also be clear as to who will be processing which data items.
5. The applicant should set out the legal basis for any identifiable data which is held in the CSU.
6. Clarification should be provided as to what involvement the CCGs will have with the project.
7. Confirmation should be provided that NEL CSU is not already covered by the existing support for CAG 2-03(a)/2013; CAG 7/04(a)/2013 and CAG 7-07(a-c)/2013 for the purposes set out in this application. Support for this will need to be sought as part of any future application.
8. It was unclear from the application whether a one-off linkage or an annual linkage was proposed. This should be clarified in any future resubmission.
9. The applicants are asked to consider the possibility of allowing individuals to opt back in, having opted out, or to provide a strong justification as to why this would not be reasonably practicable.
10. To clearly identify who the data controller(s) is/are and who the data processor(s) is/are.

A new submission should be provided to the CAG if the applicant wishes to take this project forward. Once received, this will be reviewed at the next available CAG meeting.

5. NEW APPLICATIONS – Research

a. 16/CAG/0083; Use of 3-Dimensional Aortic Root Assessment by Multidetector Computed Tomography to Determine Valve Sizing in Transcatheter Aortic Valve Implantation.

This application from the St Georges University Hospitals Foundation Trust set out the purpose to improve the rates of Paravalvular leak (PVL) in in Transcatheter aortic valve implantation (TAVI) by an improved sizing of the aortic annulus using Multi-slice Computed Tomography (MDCT).

Paravalvular leak (PVL) in Transcatheter Aortic Valve Implantation (TAVI) is frequent with moderate-to-severe PVL occurring in over 5% of cases. PVL is not well tolerated in patients with severe Aortic stenosis as the left ventricle is typically non-compliant from left ventricular hypertrophy. The researchers plan to performed detailed MDCT assessments of the aortic root and hypothesise that these detailed metrics will strongly predict PVL, and that they can be used to improve THV sizing and improve patient outcomes.

Patients will be identified from a local TAVI database. MDCT images for all patients over 18 years old who have undergone an MDCT study prior to TAVI at the hospital will be retrospectively examined along with baseline patient and procedural characteristics. It is estimated that around 100 patients will be involved in this study. Various aortic root and aortic valve measurements will be recorded. The researchers believe that the height and shape of the sinotubular junction as well as the intercommisural distance will strongly predict

the development of PVL after TAVI. Patient identifiable data will only be used for data collection. Once collected, all data will be de-identified and assigned a unique study number, in particular, imaging data will be de-identified using a DICOM anonymiser tool which removes 34 pieces of potentially identifiable patient information. If the TAVI database is incomplete on patient characteristic information e.g. presence of hypertension, the researcher plans to access the medical records at St Georges Hospital.

A recommendation for class 1, 4, 5 and 6 support was requested for the process of extracting and anonymising the information, to link patient identifiable information obtained from more than one source, for auditing monitoring patient care and treatment and to allow access to an authorised user for one or more of the above purposes. Support is requested to allow the disclosure of confidential patient information from the Trust to the researcher.

Confidential patient information requested

Access was requested to allow the disclosure of name, NHS number, and age from the TAVI database held by the hospital to the researcher along with CT imaging data, Transthoracic and transoesophageal echocardiographic imaging data and Angiographic data.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a study in the public interest with a medical purpose.

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

There was some discussion around the potential for the study to be conducted on a prospective consented basis. Members felt that given the numbers involved there might be potential for consent to be sought although as the study cohort were patients undergoing a procedure it was agreed that consent was probably not suitable in the circumstances and many of the patients would be deceased. The sample bias created by possible dissent was noted although the committee agreed that only in exceptional circumstances should sample bias be seen to override the requirement to consent the patients.

- Use of anonymised/pseudonymised data

Members noted the justification around the impossibility of anonymization by the care team as being too time consuming to be practical.

Justification of identifiers

The requirement for retention of age and date of birth was queried. Members noted that gender would not be retained for analysis. The applicant had mentioned the requirement to

access medical records in certain circumstances although it was unclear how many records were likely to be accessed in this way. No letter of recommendation from the Caldicott Guardian had been provided and the applicant response referred to contact with the Information Governance Manager. The applicant was reminded that this was not necessarily adequate if it did not represent recommendation from the Caldicott Guardian (or equivalent) at the NHS trust.

Patient Notification

It was noted that there was currently no patient notification in the study protocol.

Patient/Public involvement

Patient Public involvement was seen to be minimal as only three potential patients had been consulted and it was unclear whether these represented the cohort to be studied.

Additional points

Members agreed that there was a lack of clarity around the security arrangements of the laptop to be used to store the data and exactly when identifiable data would be moved across to storage on the laptop. It was also questioned whether pseudonymisation would be taking place if the study number was to be retained. The applicant should confirm exactly what identifiers would be held on the laptop and whether it was encrypted or not. As the student was seen to have contact details in Australia confirmation should also be provided that no identifiable data would be transferred outside the European Economic Area (EEA).

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. The applicant should demonstrate greater fair processing of patient details. The provision of study information on websites or the display of posters or information leaflets in clinics might provide evidence of fair processing to the committee.
2. The applicant should demonstrate greater public engagement if possible.
3. The applicant should provide further information about the security arrangements for storage of data on the laptop including details of what data would be stored and where the laptop will be kept.
4. The applicant should confirm the requirement for age and date of birth.
5. A letter of recommendation from the Caldicott Guardian should be provided
6. Favourable opinion from a REC should be provided.

b. **16/CAG/0081; Using Patient Data in Amyloidosis to Understand Complex Diagnosis Pathways and Treatment Patterns.**

Purpose of application

Amyloidosis is a rare life-limiting disease that can progress rapidly. Due to the rarity of amyloidosis and range of manifestations of the disease (often presenting as vague symptoms), patients often experience delays in diagnosis or may even remain undiagnosed. Delay in detection of amyloidosis may have an adverse impact on modifying the progression of the disease, even for those patients who receive therapy. Before a confirmed diagnosis of amyloidosis is finally provided to a patient, patients have often been seen by multiple physicians and may have received multiple incorrect diagnoses.

This application from Royal Free Foundation Trust set out the purpose of building a research platform for patients with amyloidosis. Management of all UK patients with amyloidosis is via the National Amyloidosis Centre (NAC) based at the Royal Free Hospital, although other aspects of their medical care are also be provided locally to the patient in secondary care and tertiary care centres.

1. HSCIC shares pseudonymised, non-sensitive standard monthly subscription extracts of HES Admitted Patient Care, A&E and Outpatient data with IMS Health (in line with the existing data license).
2. The NAC generates a study ID for each patient managed at the NAC. The NAC will send this and the NHS number to the HSCIC.
3. The HSCIC supplements the NAC NHS number list with pseudonymised patient IDs, which are aligned to the HES extract IMS receives in step 1. This supplemented list (comprised of pseudonymised patient IDs and study ID) is then returned to the NAC.
4. Thereafter all research activities will be conducted on de-identified data at IMS. The HES linked data will not leave IMS Health.

Although there is a consent system has been in place since 2006, with a provision to ask all current patients whether they agree for their data to be used for research, there are patients who have been lost to follow up or who are deceased, where it has not been possible to ask for consent. In addition patients present in the database prior to 2006 will not have been asked this specific question. Due to the limited size of the cohorts of interest, identification of clinically meaningful and significant precursors/prognostic factors relies heavily on maximising the full historic records available.

All patients that have refused consent for their data to be used for non-clinical purposes will be excluded from the NAC dataset. Only aggregated non-patient level output will be shared. Tables of less than 5 patients will be suppressed and no data will be published that could lead to identification of a patient (even after their death).

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover the transfer of identifiable data to the HSCIC for those patients for whom there is not an alternative legal basis for this processing.

Confidential patient information requested

Support was requested to cover the transfer of identifiable data (NHS number) relating to those Amyloidosis patients for whom consent is not in place to cover this, from the Royal Free to the HSCIC for processing in order to provide the required output.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially 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

The group was content that it would be unfeasible to seek consent, especially where some of the subjects will have died and the majority of the data is retrospective.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to perform the required linkage.

Justification of identifiers

CAG was satisfied that the number of identifiers was appropriate and justified.

Exit strategy

The group noted that the applicant was proposing a one-off linkage and that thereafter support would not be required.

Patient notification and objection

Members were unclear as to how the patient information materials were to be accessed by participants and requested that the applicant explain this. The notification materials should be as accessible as possible and the applicant was invited to consider how this was to be achieved (on websites, for example, or on posters)

They also noted that no mention was made of the transfer of NHS number to the HSCIC. This should be corrected and the updated notification materials provided to CAG for review.

Additional points

To ensure that they properly honour the withholding of consent of the 8% of patients since 2006 who have declined the use of their data for research – the researchers propose to share these patients' NHS numbers with the HSCIC as well in order to gain pseudonymised patients IDs (as per step 2 & 3 above). This will allow the researchers to ensure that they also exclude them from the HES component of the analysis dataset. Members were content with this approach to ensuring that these individuals' wishes are 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 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. Provision of an explanation as to how the patient notification materials will be made as accessible as possible.
2. Provision of revised patient notification materials explaining that NHS number will be transferred to the HSCIC.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once provided, the response will be reviewed by a sub-committee of the CAG.

c. **16/CAG/0082; Residual tumour size to predict progression in paediatric LGG (v1).**

Purpose of application

Low grade gliomas (LGG) account for 35% of all paediatric brain tumours. They are benign tumours made up of different subtypes and clinical features. In children, recurrence or progression may occur causing clinical symptoms and requiring further treatment, particularly if the tumour is not completely removed. Often residual tumour is left, which is documented by imaging after surgery. In a considerable proportion of these children (45-65%) further growth occurs and further treatment is required. If the tumour is completely removed however, recurrence is rare.

All children are followed-up with imaging at regular intervals to detect recurrence. This is a considerable burden on families and requires significant resources. There is a lack of evidence as to the features of a tumour that can predict recurrence or progression.

This application from Birmingham Children's Hospital set out the purpose of retrospectively studying the clinical and imaging characteristics of children with a diagnosis of low-grade glioma treated at Birmingham Children's Hospital to determine possible predictors of disease relapse and progression. Data will be analysed to detect a cut-off residual tumour size that can predict tumour progression. The timing of any progression from initial surgery will also be determined. From these, a guideline for surveillance imaging will be produced, suggesting the optimal frequency of scanning based on a patient's risk of recurrence.

A recommendation for class 1, 4, 5, and 6 support was requested to cover access to records in relation to ~100 under sixteen years old who have been treated for a low grade gliomas between the years 2002 to 2015.

Confidential patient information requested

In reviewing the notes, the researchers would have access to name, postcode, NHS number, date of birth, date of death, and any other confidential information contained in the record.

Only Date of Birth & Date of Death will be retained for analysis.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially 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

The group was content that it would be unfeasible to seek consent, especially as the majority of the data is retrospective.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to identify and link the various records. The care team are not resourced to collect the data on the applicant's behalf.

Justification of identifiers

CAG was satisfied that the number of identifiers was appropriate and justified.

Exit strategy

The group noted that the applicant was intended to complete the project by 31/08/2016 for submission as MSc dissertation.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and there is a mechanism for registering patient objection. The applicant will be required to produce suitable notification materials and a mechanism for opt out. These materials should be available on the trust website and posters signposting them should be provided for the clinics.

Patient and public involvement

Members noted that no patient or public involvement had taken place. It was agreed that support would be conditional on provision of the outcomes of an adequate patient and public involvement exercise (through charities or through the trust).

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. Provision of suitable notification materials and a mechanism for opt out.
2. Confirmation that the patient notification will be available on the trust website and that posters signposting this will be provided for the clinics.
3. Provision of the outcomes of patient and public involvement.
4. Favourable opinion from a Research Ethics Committee.
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once provided, the response will be reviewed by a sub-committee of the CAG.

6. HSCIC Dissemination Framework consideration

Consideration of this item was undertaken as part of the HRA CAG new role under the Care Act 2014 to provide advice, broadly, to the HSCIC on its dissemination activities.

Discussion summary
Members welcomed the attendance of Ms Dawn Foster, Head of IG, HSCIC, who attended to support consideration of the HSCIC Data dissemination Framework version 0.20 and discussion. The following summarises the key points, and CAG advice.

Referral criteria to the CAG.

CAG noted the referral criteria were a critical aspect to enable CAG to deliver its function (as per the information provided on the HRA website on this function), and confirmed that this was not present in version 0.14 nor version 0.20 and there was some concern expressed around this lack of progression. This was expected to set out the what, why, when, how and who and would involve joint working; it was questioned who was responsible for authoring this aspect as this had been unclear, and an indication as to timescales. The anticipated role of the CAG, as set out in its advice against v0.14 was discussed and confirmed.

Ms Foster agreed the referral criteria was not present and advised the following:

- Publication of the current draft Framework by the HSCIC was imminent
- The intention was to review the Framework three months post-publication, then annually or as required.
- Criteria was being developed as part of 'IGARD transition' and formed a specific part of the transition programme; the transition to IGARD was expected to be in the autumn and criteria expected to be in place at the same time.
- Mr Peter Hall was expected to be leading this work aspect due to overall responsibility for DAAG and transition.
- Criteria for DAAG considerations also to be revised

CAG advised the following:

- A placeholder should be inserted into the published document to clearly reflect that this referral criteria was not yet in place, so as to avoid creating a misleading impression to its intended audience of the function, and the CAG role within this.
- The referral criteria should map the scope of the framework against the scope of the CAG remit as this was currently unclear within the current version. CAG expressed the view that many of the comments as to scope as contained in its advice against v0.14 had not been addressed and advised that this be reviewed by the relevant party.

- CAG would like to positively engage with this development, and it would also be helpful for CAG to understand the criteria of DAAG assessments. It was suggested that it may be helpful to reach out to the Chair of DAAG, and this was agreed to be a helpful approach. Ms Foster would provide Ms Dunkley with details of the transition programme in order to make contact, and Dr Taylor would seek to contact Dr Bailey.

Future advice requests

Members sought an indication of potential anticipated advice requests. The following was confirmed:

- Any requests for advice arising from the HSCIC expected to be very low
- There had been no cases considered in DAAG recently that would have warranted an advice referral.

CAG advised the following:

- Whether any consideration had been given to thematic assessment of typical cases considered by DAAG in their dashboard. For example, whether any positions had been taken that led to an undue delay for recipients in receiving data, which in turn would impact on the Framework.
- It was unclear currently why there were no anticipated plans to seek advice and it would be helpful for the CAG to understand this.
- CAG was also mindful to ensure that any advice requests were appropriately routed under its function via the Care Act 2014, and not handled as part of its business under the COPI Regulations.

Dissemination framework general comments

- CAG advised that it did not appear that the overall scope of the Framework was clear, and how this mapped across to the referral criteria; no feedback had been provided by the HSCIC in relation to this specific feedback provided against v0.14
- Referral criteria not yet developed and a placeholder should be inserted to make clear not yet in place
- Errors in name of the CAG within Framework; references should be amended to read HRA Confidentiality Advisory Group (CAG)
- Current role of CAG as described in section 5 should be amended in line with draft text provided separately to ensure the focus is on the CAG remit under the Care Act 2014 as this is of most relevance in relation to the purpose of the Dissemination Framework.
- Appeared that a significant amount of detail was not present in the Framework in terms of underpinning processes and operation; noting there were some broader external issues impacting on some policy aspects. It was advised that it was important to seek to gain public confidence through this document.

7. **MINUTES OF THE MEETING HELD ON 26 May 2016**

The minutes of the meeting held on the 26 May 2016 were agreed as an accurate record.

The subcommittee minutes (30 April 2016; 17 May 2016; 06 June 2016; 08 June 2016) and precedent set minutes (20 May 2016) were also agreed to be an accurate record.

8. **CAG OFFICE REPORT**

The following was reported in the May Office Report:

HSCIC – Class Action Plan

Members have been advised that the HSCIC have approached the CAT regarding a number of 'historic' applications they have which are described as Class Action studies which appear to have no legal basis for the data processing activities.

CAT were tasked with reviewing the HSCIC proposal and putting forward a handling plan to CAG. This will be circulated to all members via email ahead of the 10 June CAG meeting. Following CAG agreement CAT will contact the HSCIC to outline the approach.

CAT will update members as appropriate.

Handling of Type 2 objections

There have been a small number of queries from applicants who have been engaging with the HSCIC, in relation to the impact of Type 2 objections on their receipt of their datasets. Queries have focused upon seeking clarification on whether their support means that HSCIC have to uphold patient objection. This is likely due to the phrasing of the queries from the HSCIC. We have confirmed the CAG position that the standard condition of support to respect dissent remains unless otherwise stated. In the small number of instances where the decision has been, following CAG advice, that objection should not be respected (e.g. in safeguarding issues), it will be confirmed this would have been explicitly specified in the outcome letter.

Updates on existing applications

Notification of breach: CAG 10-02(d)/2015; National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

The advice team has been notified of a breach by Public Health England (PHE) that impacts on a dataflow approved under Regulation 5. The detail of the breach was provided as an appendix to the May 2016 office report through appropriate reporting as a 'Serious Incidents Requiring Investigation' (SIRI). The SIRI report confirms that they have undertaken an audit, completed root cause corrective actions and written to providers to ensure envelopes are properly sealed.

The view of the Advice Team is that applicant has undertaken a root cause analysis, appropriately reported to the relevant bodies and has undertaken reasonable corrective measures to mitigate against this occurrence taking place in future. It is advised that this is noted by members and sent to the HRA decision-maker for information.

University of Nottingham linked applications 'Arnold Lodge'

A meeting took place between the CAT and University of Nottingham applicants on 16 May 2016 in relation to 15/CAG/0199. The meeting had arisen as the new application had sought to use data generated from previous approvals (PIAG 2-07 (t)/2002 and PIAG 4-15 (b)/2009), and it had appeared that the applicants had not provided annual reviews nor responded to the conditions of support as part of these annual reviews. The following outcome was confirmed:

- CAG 1-07 (c)/2014 – the status of this Case Register application had been separately questioned due to a change in Chief Investigator and an annual review had not been submitted. It was confirmed that no data had yet flowed in or out due to internal staffing issues. It was agreed that this application, while approved, should go on hold so that data controllers are aware that no data should flow in relation to this application. This would be updated on the Register
- 15/CAG/0199 – the applicant advised that this reference had been intended to replace the 2002 and 2009 applications, although this intention had not been made clear at time of submission; at the time the applicant indicated that this application intended to utilise data from the previous two references. Verbal conversation indicated the applicants had undertaken work in relation to the outstanding annual review actions and they have been advised again to submit an annual review in relation to the two references, and that a new application could not be considered until this aspect had been appropriately closed down. This was accepted by the applicant. An annual review is still outstanding at time of writing.

15/CAG/0200 – 2016 Community Mental Health Survey amendment request

This came into CAT as an amendment request and in the first instance was circulated to a sub-committee of members. However, following comments from members the CAT noted that the amendment was in fact from the Central and North West London NHS Foundation Trust. The Trust had discussed their approach to carrying out the survey with CQC, the original applicant, and had adopted the same methodology as put forward by CQC in their application 15/CAG/0200. Noting the Trust is in this case the Data Controller whereas CQC are not. Following these discussions the CG for the Trust requested that this was discussed with CAG but for some reason they did this by submitting an amendment to the CQC application.

When it was identified that the Trust had submitted the amendment the CAT advised the contact at the Trust that this could not be considered as an amendment but may require an application from the trust.

However, picking up on comments from the members who looked at this, their opinion was that as the DC the Trust could manage this under suitable contractual relationship with their DP, and would not require s251 support.

This was how CAT understood things and concluded that the Trust, as the DC, could take the decision about the management of the survey without coming to CAG; this approach was confirmed with the CAG Service Manager.

9. **ANY OTHER BUSINESS**

a. Chair team

Thanks were offered to all members who had put their names forward to join the chair team. The interview panel was composed of Mark Taylor, Stephen Tebbut (the HRA Head of Corporate Governance), and Christopher Ward. Dr Patrick Coyle and Dr Tony Calland were appointed vice-chairs, and Ms Clare Sanderson and Dr Murat Soncul were appointed alternate vice chairs. The committee voiced its thanks for the hard work Ms Gillian Wells had put in over her time on the chair team.

b. CAG 10-02(d)/2015; National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)

The breach noted in the office report (above) was discussed by members, who were satisfied with the remedial action taken and agreed that no further action need to be taken from a CAG perspective.