NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

15 May at 10:30 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair) (acted as Chair for item 7)	
Dr Robert Carr (items 1-4 only)	
Dr Tony Calland MBE (Vice Chair)	
Mr Anthony Kane	Lay
Mr C Marc Taylor	
Ms Clare Sanderson	
Ms Gillian Wells (Alternative Vice Chair)	Lay
Professor Julia Hippisley-Cox	
Professor Jennifer Kurinczuk	
Dr Murat Soncul	
Professor Barry Evans	
Professor Ann Jacoby	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Joan Kirkbride	Director of Operations, HRA
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Mr John Robinson	Confidentiality Advisor, HRA
Mr Stephen Robinson	Corporate Secretary, HRA
Mr David Evans	Expert advisor – Data Protection, Information Commissioner's Office
Ms Victoria Cetinkaya	Observer – Data Protection, Information Commissioner's Office

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

The Chair welcomed Ms Victoria Cetinkaya who would be assisting Mr David Evans in providing expert advice in relation to Data Protection issues. The Chair expressed his gratitude to the ICO for permitting a representative to observe and provide advice to the CAG meeting, and noted that this link increased resilience in this area.

Mr Stephen Robinson attended in his capacity as the HRA approver for research applications.

Apologies

Apologies were received from Dr Miranda Wolpert.

Declarations of interest

The following interests were declared:

Ms Gillian Wells declared a competing interest with item 4a with respect to ASH work as vice chair of one Clinical Commissioning Group and lay member of another.

Professor Julia Hippisley-Cox:

- Did not receive CPRD papers and left the room for item 4b in order to avoid any perception of a competing interest given her role with QResearch.
- Declared a competing interest in relation to one of the applications discussed under item 4a, CAG 7-04 (a)/2013 Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs, as a director of ClinRisk Limited who provided one of the risk prediction software tools referred to in the application. She attended to provide expert advice to Members on the capabilities of the software, and highlight related issues, but did not participate in the advice given by the CAG for this item.
- Declared a competing interest in relation to item 6a as the application was from Nottingham City Council where she worked as a GP. She did not participate in the advice given by the CAG for this item.

Ms Clare Sanderson:

- Ms Sanderson declared a possible interest in item 4a [CAG 7-04 (a)/2013] as she had been providing information governance advice, in her professional capacity, to one of the suppliers that provides risk stratification software to a number of clinical commissioning groups. This interest was noted and it was agreed that this did not prevent Ms Sanderson from participating in the discussion of the item; this was also raised with the attending applicants.

2. MINUTES OF THE MEETING HELD ON 10 April 2014

The minutes were discussed at the meeting on the 16 May 2014.

3. CAG OFFICE REPORT

The office report and matters arising were discussed at the meeting on the 16 May 2014.

4. ITEMS FOR CONSIDERATION

a. NHS England commissioning applications – conditions of support update & duration extension

Transfer of data from the HSCIC to commissioning organisation Accredited Safe Havens (ASH) [CAG 2-03 (a)/2013]

Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs[CAG 7-04(a)/2013]

Invoice validation within NHS England within the Commissioning Support Units controlled environment (for Finance) on behalf of Clinical Commissioning Groups[CAG 7-07 (a-c)/2013]

An update report was provided in accordance with the specific conditions of support specified for each of the applications. In addition to providing the update report, a duration extension to the existing support was submitted; the rationale cited for the duration extensions were summarised as follows:

Duration extension rationale

1. CAG 2-03 (a)/2013 ASH

Establishment of new Regulations to support ASH processing was noted to be the exit strategy from support under Regulation 5. The timetable for this new regulation establishment was unlikely to align with the current expiry dates for application approval and it was indicated that continuing support would be critical to maintaining business as usual activity. The need for a managed transition to the end state including development of standards for ASHs and extending the existing support would take account of any delays to development of new Regulations.

2. CAG 7-04 (a)/2013 Risk Stratification

it was indicated that work with providers had not progressed as quickly as anticipated due to actions required to meet conditions of support. The duration extension would permit a managed transition to the end state of new Regulations.

3. CAG 7-07 (a-c) 2013 Invoice validation (environments)

Further work would berequired with CCGs to implement the necessary cultural changes and amendment of local systems and further work would to be undertaken to identify necessary backing data requirements. The extension period will allow for safe transition from current arrangements and permit transfer of data and functions to fully authorised accredited safe havens.

<u>Confidentiality Advisory Group advice</u>

A lengthy discussion took place over the update reports for all applications. The key aspects from the CAG advice are summarised below and are applicable to all of the reported applications, except where actions specific to an application are specified below.

1. Fair processing (applicable to all applications): feedback report due August 2014.

It is a requirement of all approved applications that processing cannot be inconsistent with the Data Protection Act 1998. Members noted that the original intent of these applications was to utilise the fair processing approach dictated by 'care.data', which was to provide high level information with a web portal to be established by the HSCIC to provide more granular detail on processing activities (a layered approach to fair processing). Due to the pause on 'care.data', members indicated that there was a reasonable public presumption that patient information would not be flowing as there was currently no national fair processing information made available in relation to these specific applications. The ICO representative indicated that there would need to be an assessment of likely compliance with the Data Protection Act 1998 and consideration should be given to an interim strategy, although the importance of a coordinated approach was also noted.

Members agreed that there should be an urgent action for NHS England to engage with the Information Commissioner's Office to discuss the specific approaches to fair processing in light of the comments above. Members indicated that suitable fair processing would be critical to have in place as a priority as this is a minimum requirement under the existing approval, and a clear position to satisfy the obligation, accepted by the ICO, should be provided back in a report to the August CAG meeting to allow support to continue.

It was noted that the local fair processing notice provided under the risk stratification update, indicated approval had been provided for health and research purposes via approval from the Health Research Authority. It was noted that the support in place involves support provided by the Secretary of State for Health and does not cover medical research purposes as these should be the subject of individual applications, therefore the example was misleading. Comment on rectification of inaccuracies in local patient leaflets was therefore requested.

2. Patient objection (specific to risk stratification CAG 7-04(a)/2013): feedback due August 2014

Processing for the purposes of risk stratification is considered to be processing for 'secondary purposes / indirect care'. A type 1 objection registered with a GP will stop all identifiable data leaving the GP practices for secondary purposes, and this would have the consequence of preventing data flowing for risk stratification along with other secondary purposes. The previous fair processing information associated with 'care.data' has made clear that opting out of 'care.data' will not affect the care or treatment a patient receives.

However, if by opting out, a patient prevents data flowing for both 'risk stratification for commissioning' and 'risk stratification for case finding' this does not seem to be true. The result is that a patient might receive literature telling them that they can opt out without affecting care and they opt-out because they are concerned with care.data. The impact of that opt-out extends beyond the care.data programme to include, amongst other secondary purposes, risk stratification. This may have an impact upon the care they receive. Members noted that this was an issue and sought NHS England comment on this aspect. Feedback was also requested on how patient objection had been practically implemented noting that some patients have already registered their objection.

It was agreed that the CAG would also highlight this issue with IIGOP and the SofS representative.

3. End state – Regulation development (applicable to all applications)

Members were advised that the exit strategy from the current support was reliance upon new Regulations, and that consultation on new Regulations was likely to commence early June 2014

for a period of 8 weeks. Members queried whether there was further detail on this end state as it made it difficult to advise when the detail was not understood, for example, whether there would be a clear definition of an accredited safe haven, purposes, security controls and data flows. This was considered important as while it was not the applicant's responsibility to solely define the end state, the applicant was responsible for appropriately articulating the direction of travel.

Members also queried whether the new Regulations would allow for a more permissive processing environment than those currently in place for 'Stage 1 ASHs'. It appeared to members that the end state would be worked out through iterative discussion on the new Regulation development, and members expressed concern that this was an uncomfortable process and questioned what reassurances could be put in place to prevent processes that could be improved from being mirrored within new Regulations.

Members also noted that the public acceptance and political appetite for new Regulations could not be accurately predicted at this time, and questioned what other exit strategies are in place should new Regulations prove not to be publicly accepted. Clarity on the scope of the new Regulations was also requested in relation to data flowing to DCSROs and CSUs; it was acknowledged that much of this was linked to new Regulation development however a strategy should be in place for these bodies.

Further discussion indicated that there may be a need to process four identifiers (NHS Number, date of birth, postcode and Local ID) to allow linkage with social care data. Members noted that this appeared to move away from the 'Caldicott 2 review report' concept of an accredited safe haven, and noted that it would be preferable to associate the need for identifiers to certain purposes, as some datasets should be of a sufficient quality to only require access to NHS number to allow linkages. Questions were raised on whether NHS number could be pseudonymised in the ASH environment and it was confirmed that NHS Number in the clear would be required due to issues of data quality and to enable role based access controls.

Members queried the role of the HSCIC and in particular, how the central risk stratification service proposed to be provided by the HSCIC as a recommendation of the options appraisal work with the ASHs.

4. Retention (specific to CAG 7-07 (a-c) 2013 invoice validation)

Members expressed positive comments that this application activity was making evidenced steps to reduce the reliance on personal confidential data, and this was strongly welcomed and the progression praised. However, it was noted that significant progression had not been achieved in relation to clarification of a suitable retention period, and members requested that this be prioritised with a finalised retention period to be submitted to the August CAG meeting.

5. Further clarifications for submission to August 2014 meeting

The following clarification requests were also requested:

a. Risk stratification CAG 7-04(a)/2013 – exclusion of sensitive data items. A list of specifically excluded sensitive data items were provided in the original submission under Annex D. Members requested that a final standardised list of all excluded conditions should be submitted, along with feedback on whether any data from this has been inappropriately extracted and the steps taken to rectify this.

b. A statement of confirmation was requested that the data processed within CSUs and DSCROs was being processed in accordance with the purposes specified within each of the applications.

c. Clarification that there is no onward disclosure of personal confidential data, under the support provided to CAG 2-03 (a)/2013, from ASHs to third parties.

d. Specific to risk stratification, a suggestion to reduce the retention period of those with compromised health receiving an intervention due to a risk score could be that their risk stratification is transferred to the care provider organisation to be kept as part of their health records to overcome the medico-legal reason stated to justify longer retention. Comment on feasibility was requested.

e. For CAG 2-03 (a)/2013, a number of datasets were specified as falling within the scope of approval as set out in Appendix 1 of the letter. Members advised that they would like to see absolute clarity on the content of these datasets (e.g. through indicating where this information is clearly held on a website or information standard). Please provide this clarity for the August 2014 meeting.

On the basis that satisfactory responses are provided in the August CAG meeting to enable support to continue, members identified that the duration extension request should be resubmitted to the 02 October 2014 meeting via a report to include the following:

1. Final requirements for Stage 1 ASH, with particular emphasis on security arrangements and standards to be applied.

2. Table of specific and standard conditions for each application and how each has been met.

3. The ASH complexity around linkages has been recognised so to avoid any future ambiguity, the purposes must be specified within each application, with the corresponding need for identifiers mapped across to each purpose via a matrix

4. Comment on the HSCIC Pseudonymisation Review (if at a stage to allow meaningful feedback) and longer term possible options (e.g. pseudonymisation at source, DEID4LA or Regulations

It was noted that support for CAG 7-04 (a)/2013 expires in July 2014, therefore the CAG recommended that this application be extended for a short period to enable the requested clarifications to be provided to the August CAG meeting.

b. Clinical Practice Research Datalink service – annual review 2014 [ECC 5-05(a)/2012]

Members noted that this annual review had been received later than scheduled however the positive engagement with the subsequent clarification requests was welcomed. As a whole, the CAG responded positively to the annual review documentation, and in particular welcomed the transparency commitment to publish the decision-making documentation and list of data disclosures (regularly updated) to recipients.

Members noted the response to how ‘type 1 objections’ would be respected and were unclear on what this meant in practice. As it is a requirement of the existing approval that patient objections are respected, members advised that this aspect would be clarified as a specific condition of support to ensure that the applicant takes steps to ensure that the body disclosing confidential patient information (in this case to the HSCIC) has appropriate mechanisms in place to appropriately respect objection so that information is not inadvertently transferred where an objection exists. The outcome would be copied to the

HSCIC so that they would be aware of this condition of support in their capacity as recipients of identifiable data under this support.

Members also welcomed the draft patient information leaflets and questioned whether these had been reviewed by a research ethics committee and requested written clarification on this aspect. It was advised that the applicant should report the dissemination of these leaflets and steps taken to assure themselves that the information has been reasonably made available to patients, at time of next annual review.

Members reflected that the previous twelve months had been an iterative year in terms of understanding and encouraging documentation and transparency of CPRD/ISAC processes. It is anticipated that publication of the approval process documentation and controls in place should provide public assurance that datasets provided to recipients are suitably non-disclosive and where they pose a significant risk of re-identification, that they are escalated to the CAG as a standard application under Regulation 5.

In order to build upon this strong foundation and in addition to providing the 'ISAC summary of disclosures', members advised that there should be a review at approximately 6-month intervals of randomly sampled 'medium risk' disclosures, selected by the CAG, with a view to discussing how the conclusions were reached. It is recommended that the first review should take commence towards end August 2014 and I shall be in contact nearer the time to establish suitable dates.

In conclusion, the CAG agreed that the minimum criteria under the Regulations appeared to have been met and advised recommending support to the Health Research Authority and Secretary of State for Health that support should continue for a further 12 months, subject to the specific and standard conditions of support.

Specific conditions of support

1. Processing of free text data excluded from the approval scope

2. The draft patient leaflets to be reviewed by the relevant Research Ethics Committee (as this is a requirement for all research applications with an ethical opinion) and copy of the favourable notification of amendment from the REC or relevant correspondence to be provided to the CAG.

3. The applicant to ensure that the body disclosing confidential patient information (to the HSCIC) under this support has appropriate mechanisms/systems in place to appropriately respect patient objection. A status update on any patient objections received should be provided at time of next annual review.

4. CAG review of sampled 'medium-risk' disclosures at 6-month intervals to be undertaken with relevant ISAC assessors.

c. 2014 Community Mental Health Survey - Amendment to conditions of support [CAG 9-07(b)/2013]

This application from the Care Quality Commission (CQC) set out the purpose of carrying out the Community Mental Health Survey, one of the surveys within the NHS national patient survey programme. The survey data would be used by NHS trusts and Clinical

Commissioning Groups (CCG's) in local improvement activities. CQC would use data as part of its regulatory and surveillance activities and other relevant functions and data would also be shared with NHS England and the Department of Health.

A recommendation for class 5 and 6 support was requested to cover access to confidential patient data from mental health trusts providing mental health services to one of four 'approved' contractors and to the central coordinator (Picker Europe), to enable contractors to send out questionnaires.

Access was requested to name, address, year of birth, gender, ethnicity, date of last contact, CPA status and mental health care cluster code.

Background

Following consideration of the application at the January 2014 CAG meeting it was agreed that the application should be supported to allow the survey to proceed unchanged from previous applications. CAG did not recommend approval for the aspect of the application which referred to the receipt of mental health care cluster and GP practice code. Members requested that the applicant provide further justification in relation to the requirement for the mental health care cluster code and explore the feasibility of the HSCIC carrying this out using a pseudonymised linkage process.

The applicant provided further information at the May 2014 CAG meeting which detailed the following as further justification for the addition of mental health cluster code:

1. To enhance survey results by cluster.
2. To enable the survey to have a greater role in contributing to service improvement.
3. To allow the survey approach to be refined to appeal to any groups found not to be responding.
4. To provide the only independently collected information of this nature that could be used for benchmarking.
5. To provide a breakdown of survey results to NHS trusts by superclass.

The following information was provided in relation to whether the HSCIC carrying out a pseudonymised linkage process:

1. The HSCIC would want to link datasets using NHS number and therefore identifiable data including mental health care cluster code would be required.
2. There would be an additional cost in using the HSCIC.
3. The role of the co-ordination centre was important and it would be necessary for the co-ordination centre to receive the data in order to carry out production of reports.

The request to include GP practice code was withdrawn.

Discussion with applicants

Paul Williamson, Karen Hallt and Nicola Vick from the CQC and Mark Walters from Picker attended the meeting in order to provide further clarification around the request.

The attendees provided a brief outline of the potential value of collecting mental health cluster code and a description of how this would be used to support the survey programme and benefit patients.

It was explained that the mental health care cluster code would not be linked to the mailing file at any stage and would be available to the co-ordination centre only with the sample file data. It would be ensured that the distribution of mental health care cluster code would be kept to a minimum and that controls would be placed around the sharing of this particularly sensitive data item.

The applicants confirmed that the alternatives in relation to collecting mental health care cluster code had been explored, such as asking respondents to provide this or the HSCIC collecting the data in a pseudonymised format, but these had proved not to be satisfactory. For example, this would not allow levels of response against different groups to be monitored and that NHS number would be required in order for the HSCIC to carry out linkage. This would result in a greater disclosure of identifiable data.

Confidentiality Advisory Group advice

Members agreed that the purposes described by attendees and within the submitted documents posed significant benefits to the survey programme and therefore patients.

Members noted that the disclosure of mental health care cluster code would be to the co-ordination centre with the sample file dataset which did not include name and address data and that controls around the further disclosure of this data item would be established. Members agreed that there did appear to be significant issues in adopting another approach and noted the concerns raised by the applicant that this would result in an even greater disclosure of identifiable data.

In line with the considerations above, CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending conditional support to the Secretary of State for Health.

Specific conditions of support

1. Confirmation of the controls that would be placed around the further disclosure of data that included mental health care cluster code.

5. RESUBMITTED APPLICATIONS

a. Partnerships in Care Research Database [CAG 2-05(a)/2014]

Members received the applicant's response to the previous outcome letter following the March 2014 CAG meeting, a number of questions and comments were made and it was agreed that a meeting should be scheduled with the applicant in order to discuss the points raised. Members were advised to provide comments to the Confidentiality Advice Team in relation to the application so that a sub-group of members could raise these with the applicant with a view to providing a recommendation of advice to the June CAG meeting.

Action: CAT to organise meeting with applicant and members to discuss CAG comments and queries.

6. NEW APPLICATIONS – NON-RESEARCH

a. Evaluation of the Nottingham City Alcohol Intensive Case Management Service [CAG 2-06(a)/2014]

This application from Nottingham City Council set out the purpose of evaluating an Intensive Alcohol Case Management and Peer Mentoring service that aimed to reduce the number of emergency department attendances and admissions into hospital relating to alcohol. Three groups would be assessed, those who attended the service and two control groups comprised of those who were eligible to attend the service but did not and those who were identified as high users of A&E.

A recommendation for class 1, 4, 5 and 6 support was requested to allow the disclosure of data from Nottingham University NHS Trust to Nottinghamshire Health Informatics Service (NHIS) who would link to emergency department admissions data at NHIS using NHS number.

Access was requested to NHS number in order to carry out data linkages only.

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.

Members considered whether it would be possible to write to the cohort in order to seek consent, however, it was recognised that the lack of response may result in significant selection bias which would have a detrimental effect on the results.

Members noted that identifiable data would be required in order to carry out data linkages only and would be anonymised prior to analysis.

Consent forms

Members discussed the consent forms provided that had previously been used for an evaluation project. It was noted that 54 of the 72 service users had provided consent to take part in the evaluation project, 11 had declined, 2 had left the service before being asked, 1 had died and 4 were not asked as they lacked capacity.

Members noted that the original consent had been in verbal form and that subsequent requests to provide written consent to take part in interviews had resulted in a higher rate of non-response. Members discussed that the original evaluation included taking part in interviews, which may have affected the original response rate as individuals may not have wanted to take part because an there was an interview involved.

It was agreed that those who explicitly declined to take part when asked for verbal consent should not be included in the current evaluation. In addition, members raised concerns that some patients were not asked for consent due to capacity issues and advised that the requirements detailed within the Mental Capacity Act should be followed in these instances and that support under the Regulations could only be applied if there were reasons why these provisions could not be used. Further information should therefore be provided in relation to why this would not be feasible if support to access data in relation to these patients was required.

Data Protection Act

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. Members advised that the applicant should make efforts to inform the cohort that their data may be processed for the specified purposes. Members requested that the applicant consider what efforts could be made to inform the cohort and control groups, for example by displaying information at relevant groups, centres or GP practices.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, 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 in relation to the access to data in relation to those who provided consent previously, those who were not asked because they left the service or died prior to approach and the control groups. CAG therefore advised recommending provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

In line with the considerations above, CAG agreed that the application in relation to those patients who had declined to take part previously and those who were not asked due to mental capacity issues should not be supported at this stage.

Specific conditions of support

1. Reasonable efforts should be made to inform the cohort in line with the requirements of the Data Protection Act. The applicant was asked to confirm what actions would be taken.
2. This does not include support to access data in relation to those patients who had declined to take part previously and those who were not asked due to mental capacity issues.
3. Confirmation of suitable security arrangements via IG Toolkit submission.

7. NEW APPLICATIONS – Research

a. The AKORDD Study of Outreach in Acute Kidney Injury [CAG 2-07(a)/2014]

This application from Heart of England NHS Foundation Trust set out the purpose of a study to assess the impact of an outreach service. Data was requested in relation to a group of intervention and control patients identified by the same laboratory and treated at Birmingham Heartlands Hospital, Solihull Hospitals and Good Hope Hospital.

A recommendation for class 2, 4, 5 and 6 support was requested to access confidential patient information to identify patients to target for outreach service and collect follow up information in relation to patients (initially for 12 months via hospitals).

Access was requested to name, date of birth, Hospital ID, NHS number, postcode and date of death.

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.

Members noted that consent would not be feasible prior to access to confidential patient information as identifiable data items would be required in order to identify patients to receive an intervention. It would not be feasible to seek consent following identification given the nature of the intervention and reliance on clinical staff to carry this out promptly. Intervention patients would be contacted with details of the study following their inclusion.

Members noted that identifiable data would be required in order to identify patients to receive interventions and follow up patient outcomes.

Justification of identifiers

Members noted that a large number of identifiers had been requested in order to ensure that the correct patient was identified for the intervention and follow up data could be obtained. Members queried whether the applicant had considered whether the extent of data items to be transferred to the University could be reduced, for example why full postcode data would be required.

Retention of identifiable data for research purposes

Members queried whether the applicant had considered how long identifiers would need to be retained in relation to both groups and whether the complete set of identifiable data items would be required for the duration of the follow up period. Further information in relation to this point was requested to ensure that the applicant had considered what the minimum necessary data items and retention period would be in line with the requirements of the Data Protection Act.

Disclosure of data outside research team

It was noted that anonymised data would potentially be shared with colleagues outside the EU and members sought assurance that this would not include patient level data. Members sought further assurance that there was no intention to share identifiable data with anyone outside the immediate research team detailed within the application.

Confidentiality Advisory Group advice conclusion

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

Request for clarification

1. Provision of further information regarding the requirement to transfer postcode to the University of Birmingham.
2. Provision of further information regarding whether data would need to be retained in relation to both groups and whether the complete set of identifiable data items would be required for the duration of the follow up period.
3. Confirmation that there is no intention to share identifiable data with anyone outside the immediate research team and that disclosure outside the EU would not include patient level data.

Specific conditions of support

1. Favourable opinion from a research ethics committee.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

b. Prevalence of Patterned Cutaneous Injuries [CAG 2-07(b)/2014]

This application from Cardiff University set out the purpose of determining the prevalence of patterned cutaneous injuries and the common types of implements used as weapons in child maltreatment. The study aimed to support efforts in creating a greater knowledge base on the mechanism of injury and the implements that cause them; the applicant specified that a detailed understanding on the types of injuries caused by implements will help clinicians in their investigations.

A recommendation for class 1, 4 and 6 support was requested to cover access to a patient image database and paediatric records within the child health department at Cardiff and Vale University Health Board in relation to patients treated over 10 years. Images would be linked to records using hospital number, the total potential population was 3000-4000.

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.

Members noted that the data collection was retrospective and that in order to obtain valid results the dataset would need to be of a significant size. Obtaining consent would therefore not be practicable for this group of patients.

It was noted that it appeared that identifiable data items would be required for a limited time period whilst data was extracted an anonymised dataset was extracted.

Justification of identifiers

Members queried whether hospital ID would be extracted from the hospital sites and if so why this would be necessary particularly as linkages would have taken place at the hospital sites. Members noted that the applicant had confirmed that age, rather than date of birth, would be extracted from sites. In line with this, members also requested further information in relation to the specified retention period of 5 years, whether this referred to anonymised data only and why this would be required.

Members noted that images would be cropped where the injury was to a child's face and requested that it be ensured that individuals could not be identified from the images taken from hospital sites.

Scope of application

Members queried who would have access to patient records and the extracted dataset and asked that the applicant specify particular individuals who would have access. In addition, members also requested that the applicant specify the hospitals included within the study.

Information security

Members requested assurance in relation to the security measures in place around the data extraction process and transport of data from the hospitals to the University.

Patient and public involvement

Members recognised that consultation with the target population of patients and parents/carers themselves would be difficult, however it was suggested that some consultation with public groups, such as the NSPCC could be carried out.

Additional points

Members sought reassurance that researchers would have DBS checks carried out.

Members advised that the publication of the results of the study should be carefully considered given the sensitivity of the information.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, 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 the Health Research Authority to provide a recommendation of provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support and further clarifications as set out below.

Health Research Authority recommendation

Following advice from the CAG, the Health Research Authority agreed to recommend provisional support to the Secretary of State for Health, in line with the conditions and clarifications highlighted by the CAG.

Request for clarification

1. Confirmation whether hospital ID will be extracted from the hospital sites and if so why this would be necessary.
2. Confirmation why it would be necessary to retain data for a period of 5 years.
3. Confirmation of who would have access to patient records and the extracted dataset and specify which particular individuals have access.
4. Confirmation of which hospitals are included within the study
5. Further information in relation to security measures in place around data extraction process and transport of data to the University should be provided.

6. Confirmation that researchers with access to identifiable data have valid DBS checks in place.

c. Impact of earlier diagnosis of intracranial tumours in children [CAG 2-07(c)/2014]

This application was considered on the 16 May due to time constraints on 15 May.

8. ANY OTHER BUSINESS

Member correspondence with Confidentiality Advice Team

The Chair explained that, in order to try and alleviate some of the pressure upon the Confidentiality Advice Team (CAT), the officers of CAG (Chair, Vice Chairs and Alternate Vice-Chair) would manage member correspondence and that all communication should be through the officers. Exceptions to this rule were recognised in the case of administrative matters, replying directly to an email from one of the CAT team and other special circumstances, such as correspondence in relation to working groups.