NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

19 June 2014 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Lay
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair)	
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	
Dr Miranda Wolpert (Item 4b onwards)	
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Mr Stephen Robinson	Corporate Secretary, HRA (Items 2 and 4)
Ms. Mary Ann Doyle	NHS England, Programme Director (Specialised Mental Health) - Item 5d
Ms. Ming Tang	NHS England, Director - Data and Information Management Systems - Item 5d

Mr. Ray Avery	NHS England, Partnership Manager - Item 5d

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Dr Robert Carr.

The following interests were declared:

Professor Barry Evans declared a conflict of interest with item 2, Public Health England annual review, as an employee of Public Health England. Professor Evans did not take part in discussion in relation to this item.

Professor Jennifer Kurinczuk declared a conflict of interest with item 3b as she was the applicant. Professor Kurinczuk did not take part in discussion in relation to this item.

2. ANNUAL REVIEWS

a. Public Health England annual review [ECC 7-04/2010]

An overarching report from Public Health England (PHE) that provided an update and sought continuing support for the novated applications under the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent was received.

In general, members noted the difficulties involved in bringing together existing functions and establishing a new organisation and were sympathetic to these issues.

CAG was keen to receive assurance that PHE continues to establish internal mechanisms to ensure that those operating under support do so under clear guidance and understanding of the obligations, purposes and limitations of processing.

Obtaining a suitable level under the Information Governance Toolkit was a key aspect highlighted by the CAG as this is the primary method by which applicants demonstrate they have in place satisfactory security and confidentiality arrangements. Noting that PHE was undertaking a significant programme of work on this area, Members questioned, in high risk areas such as contracts and mapping of transfers, the deadlines to which this would be completed for the specific applications. Members requested that PHE review these timescales and seek to move these to an earlier time where feasible; feedback should be provided to the next CAG meeting setting out any issues if this would not be feasible.

Members were not able to identify a systematic and consistent approach to reviewing the extent of confidential patient information required in each application nor how this was assessed, and requested updated assurance from PHE on the arrangements that enable those operating under support to undertake this. It was also noted that the management of patient objection was an increasingly high priority for those operating under support, therefore the importance of having

clear structures and processes in place to support this was emphasised. As indicated in the specific reports, this appeared to be in progress therefore members requested copies of the final documentation to provide this assurance. Fair processing information was highlighted as an aspect to be reviewed, following comment from the Information Commissioner's Office (ICO) during consideration of the annual reviews. CAG advised that PHE should engage with the ICO in order to progress and to enable feedback to be provided.

Members emphasised that unless explicitly specified within an application, that there can be no onward transfer of identifiable data, under this legal support, and another legal basis must be in place to enable this. This included transfer to different 'internal' functions within PHE.

Within the report, five separate annual reviews were included for specific activities and these were considered separately and the advice outlined below. For all applications the applicant was Public Health England.

PIAG 03 (a)/2001 National Cancer Registries

Members noted that the cancer registration system in England had completed its modernisation programme to the English National Cancer Online Registration Environment (ENCORE). While the documentation asserted that there were now substantially improved controls to ensure confidentiality, data protection and information security assurance, detailed information on these controls had not been specified so the CAG were unable to comment further on this aspect. Members therefore requested further information on the specific controls in place e.g. role based access controls, audit etc.

<u>Security & confidentiality arrangements (Information Governance Toolkit (IGT)</u>

In reviewing the cancer registration IGT action plan, it was noted that the update on the improvement plan was due to be submitted to the Health & Social Care Information Centre (HSCIC) in June 2014; due to timings a detailed status update on this was not available to the CAG at the time of the meeting.

The broader organisational context was noted and acknowledged that it was clear that steps were being taken to ensure approved activities were attaining the appropriate standard of the IGT; a written narrative update provided by the HSCIC IGT team was also provided at the meeting. In referring back to previous correspondence at time of interim annual review, members expressed a concern that some of the aspects were fundamental to ensuring appropriate confidentiality and in particular, questioned the length of time to be taken to attain the minimum standard. For example:

- IGT ref 110, 302, 335 – review of contracts. The CAG expressed surprised that a deadline of 30 September was provided in the context that this was a high risk area and queried whether this could be revised for an earlier completion date.
- IGT ref 209 – members requested clarification on the legal basis under which the ad hoc transfers to commonwealth countries were taking place.

Members concluded that a detailed status update on the IGT improvement plan should be provided, as a priority, to the next CAG meeting to provide assurance that suitable standards were being maintained while the IGT level was achieved. This should include consideration of revising the timescales for contract review and set out any issues that may be preventing swift resolution. Members also advised that there should also be a similar report to the October 2014 meeting following the September PHE IGT update to the HSCIC.

Patient leaflet

Members noted that the leaflet did not appear to clearly cover data sharing and linkages, considering recent changes to the system, and requested that advice be sought from the Information Commissioner's Office to ensure that the information provided wouldnot be inconsistent with the requirements of the Data Protection Act 1998.

Patient objection

In reviewing the information provided on patient objection, it was noted that patients were referred to GPs. It was queried what advice Public Health England disseminated to providers on patient objection and noted that in light of recent public anxiety it may be prudent for Public Health England to issue appropriate reminders. It was noted that the PHE policy and procedure was intended to be finalised Q1 2014/15 therefore members requested a copy of these documents to be provided to the next CAG meeting to provide information on how patient objection is managed.

Assessment of need for identifiable data

Noting that all requests for identifiable data should be subject to a review of necessity, members questioned the prospective use of name rather than NHS Number. Accepting the need for name for name historically, members sought further justification for use of name on an ongoing basis as it was unclear at time of review.

Confidentiality Advisory Group advice conclusion

In line with the comments above, members agreed that they were currently unable to provide a recommendation as there were outstanding questions over security/confidentiality arrangements, handling of patient objection and questions over fair processing and need for identifiable data. It was advised that review be deferred to the next meeting to enable responses to be supplied.

PIAG 2-08 (e)/2001 Congenital Anomaly Register (BINOCAR): Northern Congenital Abnormality Survey (NorCAS) and West Midlands Congenital Anomaly Register (WMCAR)

It was noted that the two registers specified above, originally approved under reference PIAG 2-08 (a)/2001 had transferred under the remit of Public Health England from 01 April 2013.

Change to application

In reviewing the report detail and proposed plan for future development of the Congenital Anomalies Register (CAR), it was noted that NorCAS and WMCAR are funded until the end of 2014/15 while PHE develop the new single national CAR, which is scheduled to 'go live' at the beginning of 2015/16. This was stated to build on the existing British Isles Network of Congenital Anomalies Registers and include both NorCAS and WMCAR. In order to support the implementation of the national register, PHE is developing a single congenital anomalies data management system to enable both the collection of an integrated data set across the registers and improve the quality assurance of the information collected.

Members noted that changes to data controllers usually require a new application and this had not been requested previously as some time had been allowed to enable the transfers to take place and embed the arrangements. Based upon the information provided in the report and to reflect the arrangements specific within Public Health England, it was recommended that a new application should be submitted to cover these updated arrangements.

It was advised that the new application should include detail on the new arrangements briefly summarised in the annual review and incorporate the plans for the new CAR, using the two registries as the baseline. Members advised that it should be written in such a way that new registries joining could be added to the application in future via amendment to the CAG if consistent standards would be applied across the system. Members advised that this application should be submitted to the 06 November 2014 meeting.

Security & confidentiality arrangements (IGT)

In reviewing the two registry information governance toolkit (IGT) action plans, it was noted that the update on the improvement plan was due to be submitted to the Health & Social Care Information Centre (HSCIC) in June 2014; due to timings a detailed status update on this was not available to the CAG at the time of the meeting.

The broader organisational context was noted and acknowledged that it was clear that steps were being taken to ensure approved activities were attaining the appropriate standard of the IG Toolkit; a written narrative update provided by the HSCIC was also raised. In referring back to previous correspondence at time of interim annual review, members expressed a concern that some of the aspects were fundamental to ensuring appropriate confidentiality and in particular, questioned the length of time to be taken to attain the acceptable standard. For example:

- IGT ref 324 – mapping of confidential data. The CAG expressed concern that data processed under the support should be known and already mapped, therefore were concerned that completion deadline was not until the end of the year. Consideration was requested on moving this timescale forwards and if not feasible, a strong rationale provided.
- IGT ref 110, 302, 335 – review of contracts. The CAG was surprised that a deadline of 30 September was provided considering this is a high risk area and queried whether this could be revised for an earlier completion date.

Members therefore concluded that a detailed status update on the IGT improvement plan should be provided, as a priority, to the next CAG meeting to provide assurance that suitable standards are being maintained. This should include consideration of revising the timescales for contract review and set out any issues that may be preventing swift resolution. Members also advised that there should also be a similar report to the October 2014 meeting following the September PHE IGT update to the HSCIC.

Confidentiality Advisory Group advice conclusion

In line with the comments above, while supportive in principle, members agreed that they were currently unable to provide a recommendation as there were outstanding questions to be clarified. It was advised that review be deferred to the next meeting to enable the documentation to be supplied. Once that the IGT aspects are satisfactorily addressed, members advised that support should be recommended to continue until 28 November 2014 to enable sufficient time for a separate application, written in line with the advice above and providing detail of existing arrangements, to be submitted for review and approval.

PIAG 1-08 (a)/2003 Contacting National Health Applications and Infrastructure Services (NHAIS) Data Subjects for Cancer Screening Programmes in England

Security & confidentiality arrangements (IGT)

In reviewing the information governance toolkit (IGT) action plans, it was noted that the update on the improvement plan was due to be submitted to the Health & Social Care Information Centre (HSCIC) in June 2014; due to timings a detailed status update on this was not available to the CAG at the time of the meeting.

The broader organisational context was noted and acknowledged that it was clear that steps were being taken to ensure approved activities were attaining the appropriate standard of the IG Toolkit; a written narrative update provided by the HSCIC was also raised. In referring back to previous correspondence at time of interim annual review, members expressed a concern that some of the aspects were fundamental to ensuring appropriate confidentiality and in particular, questioned the length of time to be taken to attain the acceptable standard. For example:

- IGT ref 324 – mapping of confidential data. The CAG expressed concern that data processed under the support should be known and already mapped, therefore were concerned that completion deadline was not until the end of the year. Consideration was requested on moving this timescale forwards and if not feasible, a strong rationale provided.

- IGT ref 110, 302, 335 – review of contracts. The CAG was surprised that a deadline of 30 September was provided considering this is a high risk area and queried whether this could be revised for an earlier completion date.

Members therefore concluded that a detailed status update on the IGT improvement plan should be provided, as a priority, to the next CAG meeting to provide assurance that suitable standards were being maintained. This should include consideration of revising the timescales for contract review and set out any issues that may be preventing swift resolution. Members also advised that there should also be a similar report to the October 2014 meeting following the September PHE IGT update to the HSCIC.

Patient information and objection

Members noted that a response to this aspect had been incorrectly provided under the section titled 'user involvement'. It was noted that the 28 page leaflet did not provide clear indication as to whom data is shared with, therefore, the CAG advised that the applicant make contact with the Information Commissioner's Office to ensure that the patient leaflet is likely to be compliant with the provisions of the Data Protection Act 1998. This written feedback should be provided back to the CAG.

Members also could not identify sufficient evidence to support the right of patient objection, and requested how this would be managed. Further information should be submitted back to the CAG to clarify this aspect.

User involvement

Members advised that this section be reviewed and completed to reflect the question.

Confidentiality Advisory Group advice conclusion

In line with the comments above, members agreed that they were currently unable to provide a recommendation as there were outstanding questions over security/confidentiality arrangements and further clarity required on patient information and objection. It was advised that review be deferred to the next meeting to enable the responses to be supplied.

ECC 5-05 (e)/2012 National Drug Treatment Monitoring System

Security & confidentiality arrangements (IGT)

In reviewing the information governance toolkit (IGT) action plans, it was noted that the update on the improvement plan was due to be submitted to the Health & Social Care Information Centre (HSCIC) in June 2014; due to timings a detailed status update on this was not available to the CAG at the time of the meeting.

The broader organisational context was noted and acknowledged that it was clear that steps were being taken to ensure approved activities were attaining the appropriate standard of the IG Toolkit; a written narrative update provided by the HSCIC was also raised. In referring back to previous correspondence at time of interim annual review, members expressed a concern that some of the

aspects were fundamental to ensuring appropriate confidentiality and in particular, questioned the length of time to be taken to attain the acceptable standard. For example:

- IGT ref 324 – mapping of confidential data. The CAG expressed concern that data processed under the support should be known and already mapped, therefore were concerned that completion deadline was not until the end of the year. Consideration was requested on moving this timescale forwards and if not feasible, a rationale provided.
- IGT ref 110, 302, 335 – review of contracts. The CAG expressed surprise that a deadline of 30 September was provided considering this is a high risk area and queried whether this could be revised for an earlier completion date.

Members therefore concluded that a detailed status update on the IGT improvement plan should be provided, as a priority, to the next CAG meeting to provide assurance that suitable standards are being maintained. This should include organisational consideration of revising the timescales for contract review and set out any issues that may be preventing swift resolution. Members also advised that there should also be a similar report to the October 2014 meeting following the September PHE IGT update to the HSCIC.

Archiving

Members noted the response to archiving data after four years and it appeared to members that archiving was taken in this context to represent ongoing retention of identifiable data, therefore further clarity was requested on whether this interpretation was correct. This concern was also echoed by the information Commissioner's Office (ICO), through written comment, therefore it was advised that the applicant engage with the ICO to check this position and that the information is being retained only for as long as necessary to ensure compliance against the Data Protection Act 1998; the ICO feedback should be provided back to the CAG.

Confidentiality Advisory Group advice conclusion

In line with the comments above, members agreed that they were currently unable to provide a recommendation as there were outstanding questions over security/confidentiality arrangements and further clarity required on archiving status in terms of retention of identifiable information. It was advised that a recommendation be deferred to the next meeting to enable the information to be supplied.

ECC 1-05 (a)/2012 End of Life Care Repository

The original application set out the proposal to establish a national end of life care data repository with the aims of increasing knowledge and understanding of end of life care and providing information to commissioners, service providers and the public. This application had been approved in April 2012.

Members were pleased to note that the report confirmed the End of Life Care Repository remained compliant at Level 2 or above for all of the Information Governance Toolkit 11-370 standards. The report also confirmed that the PHE office hosting the End of Life Care Repository continued to hold ISO 27001 information security management certification.

In terms of reviewing the extent of identifiers processed, it was noted that approval had been provided to enable the Repository to access linked Hospital Episode Statistics and Office of National Statistics primary care mortality database data on a quarterly basis. The data items required included lower layer super output area, four-digit postcode, establishment code of residence, an algorithmically scrambled NHS number key, and the date of death for all patients who had died in England from 2001 onwards. The report confirmed that data supplied to the Repository by the Health & Social Care Information Centre (HSCIC) had been reviewed to ensure that only pseudonymised and derived data items are included. It was confirmed that data retention and disposal is currently managed under an appropriate access agreement with the HSCIC, and any termination of this would involve the deletion of all the data held by the Repository.

Confidentiality Advisory Group advice conclusion

As a whole, the Group agreed to recommend to the Secretary of State for Health that support be provided for a further 12 months.

3. AMENDMENTS

a. CAG 6-07 (a)/2013 NHS England: Enhanced quality assurance process of the provision of NHS funded care for people with a learning disability or autistic spectrum disorder - duration amendment

This non-research application from NHS England, approved in December 2013, had set out the purpose of two distinct activities which formed part of the actions arising from the national review of events at Winterbourne View Hospital, as published in 'Transforming care: A national response to Winterbourne' (Department of Health, December 2012), and its supporting concordat. A recommendation for class 1, 4, 5 and 6 support was requested to support the following two activities:

1. Triangulation of data on NHS funded care for patients with a learning disability or autistic spectrum disorder.
2. Enhanced Quality Assurance Programme (EQAP).

Support had originally been provided to enable the quarterly data collection arising from activity 1 as specified in the approved application ('Triangulation of data') until August 2014. The quarterly data collection, known as 'Assuring Transformation' has taken place twice for two time periods, 31 December 2013 and 31 March 2014 respectively. This had enabled NHS England to report publicly on progress towards meeting the NHS Winterbourne View Concordat commitments.

Support was requested to allow the triangulation of data to be carried out in September 2014 by NHS England. The duration request indicated that NHS England was working with the Health & Social Care Information Centre (HSCIC) with the intention that they would take over the running of the data collection from the 30 September 2014 return. There was a contingency plan in place should this not prove feasible for the HSCIC, which was for NHS England to run this collection. This amendment was therefore a contingency request should the HSCIC not be able to deliver the September 2014 data collection.

Members reiterated that this was an important activity with a high public interest to help ensure the safeguarding of adults. As the application was already operating under support, and previous advice had indicated that it was important for the triangulation activity to continue as it offered a public benefit through avoiding double-counting, members considered the duration amendment and specifically that it was a contingency request.

It was noted that it would become known nearer the time whether the contingency approach of NHS England carrying out the data collection would be required. An indication as to future steps involved in managing this were outlined with the long-term aim of this data collection being integrated into a dataset collected under the HSCIC powers under the Health & Social Care Act 2012.

In questioning whether the HSCIC were aware of this request, the CAG was disappointed to note that the HSCIC had not responded to a request from the Confidentiality Advisory Team that sought to obtain clarification on whether the HSCIC were aware of the contingency application by NHS England. As the structures were evolving, members were advised that the HSCIC had clarified that all relevant application outcomes should be copied to the Caldicott Guardian and SIRO; members therefore advised that subsequent confirmation as to whether the application would need to come into operation should be jointly provided by the applicant and the Caldicott Guardian or SIRO of the HSCIC to ensure consistency of communication.

Confidentiality Advisory Group advice conclusion

In noting the public interest in this activity proceeding, Members advised that this duration amendment should be supported to enable the September 2014 data collection the respective body. This advice was given with the condition that the amendment would effectively be put on hold until a joint communication was received by NHS England and the HSCIC as to whether the application would need to come into effect.

b. ECC 5-05 (f)/2012 MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP).

(1) Maternal morbidity confidential enquiry 2014 – Maternal Post-partum Psychosis

(2) Analysis of perinatal mortality surveillance data

The original application from the University of Oxford, approved in October 2012 and advised against by the NIGB Ethics and Confidentiality Committee, had set out details of a national programme which aims to assess quality and stimulate improvement in safety and effectiveness in maternal, new-born and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events. Following a general confidential enquiry methodology, the purpose of the Programme is to monitor, through population surveillance, the frequency of deaths and review clinical practice in relation to maternal, perinatal and infant mortality and morbidity and identify risks that can be attributed to sub-optimal clinical care. These activities are intended to be completed by 2015. The application had been approved on the grounds that re-instigation of the enquiry component was considered to be an essential activity and there was a significant public interest in this activity going ahead.

The amendment request confirmed that, in line with the rolling programme, the morbidity topic for this year to be included in the 2015 report would be post-partum psychosis.

The request provided background information that psychiatric hospitalisation for major post-partum mental illness affects one in every 1,000 women following childbirth. This increases to an estimated one in two to one in four in women with a history of bipolar affective disorder or previous post-partum psychosis. It was highlighted that suicide was one of the leading causes of death reported to the maternal deaths enquiry in 2006-8; the majority of women who died had an underlying severe depressive or post-partum psychotic disorder. The letter asserted that evidence from previous confidential enquiries had shown that the failure to enquire about past psychiatric history (thus missing the opportunity to make the diagnosis) and poor management, even when the diagnosis has been made, were contributory factors in the deaths.

Approval was sought for two aspects:

1. <u>Case identification – sampled women</u>

For the applicant to receive name of hospital of admission, consultant name, patient hospital record number and date of birth from the sampled women, from the HSCIC. This was for the purpose of the applicant double-checking with each hospital whether the women identified meet the case definition. Once confirmation is received, copies of notes would be requested and sent to the applicant.

The first aspect to the request sought support to identify women falling within the following case definition:

"*Women admitted to a psychiatric unit with a post-partum psychosis who have a past history of bipolar affective disorder or post-partum psychosis following a previous pregnancy*".

The request set out that there was no easily accessible source from which women falling within this definition could be identified. Following discussions with Ms Netta Hollings (HSCIC) it had been identified that the linked Hospital Episode Statistics and Mental Health Minimum Data Set (HES-MHMDS) held by the Health & Social Care Information Centre (HSCIC) could be used to identify the sampling frame for selecting eligible women. Members considered the difficulties in identifying an appropriate source of data and advised that consent was likely to be very difficult and involve ethical considerations. It was also advised that there would be a strong public benefit in this activity taking place as this was an important area to assess, and would be likely to generate useful information in helping to identify any potential improvements to care.

The request set out a limitation to the dataset in that the diagnostic data collected was indicated to be of relatively poor quality and particular cluster codes of service use would have to be used in combination with what diagnostic information was available. The expected consequence was indicated to be that some cases would be identified that would not meet the case definition and thus over sampling would be necessary.

Members noted the expressed limitation regarding the dataset and the consequence that the applicant intended to sample 50 cases with the purpose of identifying 30 women that met the case definition. Members had sought reassurance prior to the meeting on the risk of receiving information on women who did not meet the case definition. This had been acknowledged by the applicant and confirmed that once checked if the women met the case definition, the information held would be destroyed immediately in accordance with good practice if they did not meet the case definition. The applicant had also indicated that there was a risk of eligible women being missed due to the above limitation, however, this data source was currently the most appropriate to achieve the aims of the activity.

In terms of a practicable alternative, consideration of the HSCIC facility to notify hospitals, ask them to identify the women and locally anonymise the case notes so that the applicant did not become aware of the women's identity, was set out in the request. In considering this aspect, members referred to the practical difficulties, resource required and example set out in the letter, and to two previous amendments where difficulties over local anonymisation issues had been articulated and the amendments approved on the basis that these had been shown not to be feasible. The CAG therefore advised that the practicable alternative would not be feasible in this instance.

<u>Confidentiality Advisory Group advice conclusion</u>

In conclusion, the Group agreed that the minimum criteria under the Regulations appeared to have been met in relation to this aspect of the amendment, and therefore advised recommending support, with no additional conditions, to the Secretary of State for Health.

2. Analysis of perinatal mortality surveillance data

This aspect sought approval for the transfer of identifiable information to the Department of Health Science at the University of Leicester for the purposes of analysis. Previously, the University of Leicester team analysed anonymised perinatal surveillance data.

Members noted that under the existing approval arrangements, anonymised perinatal surveillance data was transferred from the NPEU in Oxford to the Department of Health Science at the University of Leicester for the purposes of analysis. The amendment set out problems experienced over data quality provided directly by hospitals; the level of data cleaning required for analyses to be carried out and in particular, the need for various dates to calculate gestational age and other time critical items for particular events was asserted to be problematic and not practical for the analysis to proceed without the analysts, who are based in Leicester, having access to the raw data to enable on-going checking as the analysis proceeds. The change would involve the transfer of data to an encrypted laptop (minus name and NHS Number) by a staff member of the MBRRACE team and delivered personally to a member of the Leicester team.

Members considered the sensitivity of the dataset and noted that while the laptop would be encrypted, there was an inherent risk in the transit of portable media. In noting that the flow of identifiable data would be extended to the Leicester team, albeit as part of a collaboration, members were unable to identify a clear justification to demonstrate the necessity of this broadening disclosure against the original approval data flows. It was queried whether the analysis function could be brought on-site within Oxford as a methodological practicable alternative, and agreed that this should be considered via clarification. The extent of the issue should also be quantified to assist in demonstrating necessity of the proposed approach.

Confidentiality Advisory Group advice conclusion

As a whole, the Group agreed that a sufficient case had not been made to justify the necessity of changing the current analysis arrangements, and queried whether data quality issues could be addressed while on-site in Oxford. If not, greater articulation of the reasons why not should be provided to demonstrate that there is no other way to achieve the outcomes other than the proposed approach.

The CAG agreed to defer providing a recommendation on this while further justification was provided.

c. CAG 1-05 (a)/2013 CQC Child Inpatient Survey

This application from the Care Quality Commission detailed the first iteration of a national children's survey conducted as part of the national NHS patient survey programme. The survey was developed to incorporate the views of children and young people into existing national patient surveys.

A recommendation for class 5 and 6 support was requested to cover access to contact details of patients (children aged 0-17) who had been admitted as an inpatient or received treatment as a day case patient in June 2014.

Access was requested to name and address of patient.

Access to patient contact details

Members placed a number of conditions around the recommendation of support for the activity including that the parent/carer details, rather than the child, were disclosed and used for those children under the age of 13. The applicant specified that they would be unable to proceed with this condition in place and raised the following issues

- Parent/carer name is not recorded as default by all trusts, although it is recorded by some.
- Some trusts record next of kin as a default for parent, and the applicant asserted that this was likely to be problematic for 'looked after children', or where parents are separated and a child was taken to hospital by the parent who was not named as 'next of kin'.
- Some trusts recorded more than one person as next of kin, which the applicant asserted would be problematic for deciding which contact to mail the questionnaire to, or for which next of kin, the trust holds address information.
- The applicant also asserted additional concerns about the quality and accuracy of the information recorded in relation to patient/carer.

The applicant proposed that they address surveys to patients under the age of 16 to 'the parent/carer of x' for this age group as per the guidelines issued by the Market Research Society.

Members considered the further information provided by the applicant and noted that the applicant had considered the potential of accessing parent/carer, rather than child, data in detail and that evidence had been provided that this would not be feasible. Members agreed that this would not be feasible and agreed to withdraw this condition of approval.

Members advised that the suggestion that mail outs would include initial and surname of child only on envelopes was a positive step and should be adopted where possible.

In general, members commented that the CQC may wish to ensure that their code of practice specifically addressed circumstances where the data relates to a child.

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

1. Support is provided for a period of 12 months and the representativeness checking process using anonymised data outlined above should be utilised with those Trusts undertaking the dissemination of surveys themselves to determine whether this did present a feasible alternative. Strong evidence would be required that there was no practicable alternative if a further application for a future survey was submitted.

2. Confirmation of suitable security arrangements via IG Toolkit submission.

4. NEW APPLICATIONS – Research

a. 14/CAG/1005 The identification of Dynamic Risk Factors associated with Mentally Disordered Firesetting within a Mental Health Trust

This application from the University of Kent set out the purpose of a research study which aimed to establish which dynamic risk factors are associated with firesetting recidivism. The results of the study would provide information to aid professionals in the short term assessment of future firesetting behaviours.

A recommendation for class 4 and 6 support was requested to cover access to patient records in relation to cohort and control group. Approximately 200 patient records would be accessed and confidential patient information was required in order to link incident forms to patient records; identifiers will be destroyed as soon as possible following linkage.

Access was requested to name, NHS number and date of birth.

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 applicant had asserted that seeking consent in these circumstances may be distressing for the cohort. Members agreed that in these instances it would be difficult to seek consent, noting the responses provided following patient consultation and the requirement for a complete sample.

Members noted that confidential patient information would be required in order to link incident forms and that identifiers would be destroyed as soon as possible following linkage.

Data Protection Act compliance

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 noted that a generic patient information leaflet had been provided which was distributed by Kent and Medway NHS and Social Care Partnership Trust. Members noted that there were assurances within the leaflet which

suggested that anonymous information only would be provided for research purposes and that permission would be sought when identifiable data was required. Members advised that this information sheet should be updated to ensure it provided an accurate account of the potential uses of confidential patient information.

Members agreed that as the current information did not indicate identifiable data could be used, further efforts should be made to inform patients of this activity. Members noted the concerns raised by patients in relation to contacting them after discharge and advised that information could be displayed where the cohort potentially might see it, such as the hospital website.

Access to confidential patient information

Members queried which individuals would require access to identifiable information and asked that the applicant confirm this prior to final approval.

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.

1. Confirmation that further information about the study would be displayed on hospital website.
2. Confirmation regarding who will have access to identifiable data.
3. Favourable opinion from REC.
4. Confirmation of suitable security arrangements via IG Toolkit submission,

b. 14/CAG/1001 Critical Care Health Informatics Collaborative

This application detailed the establishment of a research database including clinical, laboratory and demographic data in relation to all patients admitted to Adult Critical Care Units across 5 NHS Trusts.

An application for support under class 1, 2, 4 and 6 was received to allow access to data from hospital systems and Hospital Episode Statistics (HES) data from the Health and Social Care Information Centre (HSCIC).

NHS number, date of birth and date of death were requested in order to carry out linkages to HES data.

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 applicant asserted that consent would be difficult as approximately 15% patients would not survive and often the patient's condition would mean that they were too unwell to consent. Members agreed that consent would be difficult in these circumstances but, noting that the data collection was prospective, queried whether there would be an opportunity to seek consent from a patient as they were discharged from hospital.

Members advised that the applicant should consider ways to ensure that data was pseudonymised as soon as possible. For example, by pseudonymising data prior to disclosure from hospital systems to the research database and restricting access to identifiable data to the HSCIC and limited research staff. Members noted the intention to carry out data linkages within UCL and advised that where possible data linkage should be undertaken within the HSCIC to ensure that the disclosure of confidential patient information would be restricted to relevant patients. Data should then be disclosed from the HSCIC and linked in a pseudonymised format if possible.

Management of research database

Members advised that where possible clinical and demographic data should be separated for storage and identifiable data only used to request further information from the HSCIC. Unique reference numbers should be assigned to clinical data and used to carry out linkages and access to identifiable data items should be restricted to a very limited number of research staff.

Members advised that data should only be disclosed to third parties where it had been demonstrated that this could lead to improvements in patient care. Further information in relation to the safeguards that were in place around data sharing was requested. In particular; a detailed description of the criteria for data sharing requests both within and outside the collaborative, how the risks of re-identification would be assessed and managed and provision of a model data sharing agreement.

Members queried the methods available to access data and sought clarity that data could only be accessed from specified IP addresses.

In addition, members advised that a register of disclosures should be established in order to keep a record of organisations receiving extracts from the database and the purposes of use. This should be publicly available to ensure transparency.

Patient information materials

Members requested copies of the patient information leaflets and further information in relation to how it would be ensured that these leaflets were provided to patients.

Patient involvement

Members advised that further patient and public involvement should be carried out to ensure that the acceptability of using confidential patient information without consent was tested specifically and to help raise awareness of the database.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, due to the issues highlighted above, further information would be required prior to confirming that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Health Research Authority to recommend that the application not be supported to the Secretary of State for Health.

c. 14/CAG/1002 ALTER-10 study: 10 year outcomes of minimally deranged serum alanine transferase in a community population.

This application from Newcastle Upon Tyne Hospitals NHS Foundation Trust detailed a study to identify the significance of a minimally abnormal result of a liver blood test and to identify if this abnormality was associated with an increased risk of mortality due to liver disease of cardiovascular disease at 10 years. In addition, the study hoped to identify whether a minimally abnormal result of a liver blood test was associated with an increased incidence of significant liver disease, type 2 diabetes and cardiovascular disease.

A request for class 5 and 6 support was received in order to access confidential patient information from a 2003 audit of liver function tests and seek further information in relation to mortality and clinical data from GP records in relation to a sample of those who are alive.

Name, NHS number, date of birth and date of death would be used to carry out data linkage. Date of birth and death would be retained for analysis purposes.

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 discussed whether consent would be feasible. It was noted that this would be difficult as this would involve contacting patients about an abnormal blood test that was taken 10 years ago and the applicant had asserted that there was a risk that this could cause distress.

Fair processing information and managing patient objection

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 noted that the applicant had advised that posters would be displayed and requested further information in relation to where these would be displayed and asked for a copy of the poster.

Members also advised that posters should include instructions in relation to registering objections and that any objections received should be respected.

Informing patient GPs

Members noted that the IRAS form indicated that GPs would not be informed about the study and sought assurance that they would be informed where GP data would be collected from practices in relation to the subset of patients.

Additional points

Retention of audit data

Members noted that the audit data had been retained for 10 years and queried whether this was standard practice and in line with the NHS code of practice in relation to Records Management. Members advised that retention periods of audit data should be reviewed in line with this to ensure that data was not retained for longer than necessary.

Publication of results

Members were of the view that the results of the study should be publicised as far as possible to patients.

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 as set out below.

1. Submission of patient information posters and confirmation of arrangements for provision of information to patients, including methods available to object to processing of confidential patient information.
2. Confirmation that GPs will be informed where data is to be collected from GP records.
3. Confirmation of suitable security arrangements via IG Toolkit submission.
4. Confirmation of a favourable Research Ethics Committee opinion.

d. 14/CAG/1003 Improving Outcomes from Out of Hospital Cardiac Arrest: The Cardiac Arrest Individual Registry and Outcomes (CAIRO) Programme (Work Package A)

This application from University Hospitals Bristol NHS Trust detailed a research programme designed to monitor and improve patient care from initial ambulance response to cardiac arrest through to hospital discharge and beyond. A comprehensive patient registry, the CAIRO database, would be established to allow linkages to be made from different data sources and to track each cardiac arrest patient from initial collapse through to hospital discharge.

The aim of this specific application was to evaluate the feasibility of setting up the CAIRO database.

Support under class 1, 4 and 6 was requested to access name, NHS number, hospital ID, date of birth and date of death. NHS number, date of birth and postcode would be retained if a patient died prior to consent being sought to carry out data linkage. Patients would be identified through South Western Ambulance Service NHS Foundation Trust, consent would be sought from surviving patients whilst still in hospital where possible and mortality data obtained from the HSCIC prior to writing to patients to seek consent once discharged from hospital.

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 demographic data was requested to allow the applicant to seek consent from those patients who survived. Consent would not be feasible for those patients who died and limited information would be collected in relation to these patients.

Members noted that identifiable data would be required in order to seek consent and request mortality data from the HSCIC.

Retention of identifiable data

Members queried how long identifiable data would be retained in relation to those patients who died and where no further information would be collected.

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

1. Confirmation of retention period for identifiable data in relation to deceased patients.
2. Confirmation of suitable security arrangements via IG Toolkit submission.
3. Confirmation of favourable Research Ethics Committee opinion.

5. NEW APPLICATIONS – Non-research

a. CAG 4-05(a)/2014 Community wide requirement to reduce mortality rates in North Lincolnshire

This application from North Lincolnshire Clinical Commissioning Group set out the purpose of obtaining details of deceased patients in order to review primary care medical files and identify root causes. The overall aim was to improve service provisions and reduce mortality rates.

A recommendation for class 1, 4 and 6 support was requested for Northern Lincolnshire and Goole Foundation Trust to identify those patients who died between April 2013 and March 2014. This information would be provided to the Medical Director who would carry out a case note review of records from local GP practices. Initially those patients falling into the Summary Hospital-level Mortality Indicator (SHMI) would be reviewed.

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 cohort in question would be deceased.

It was noted that the application specified that limited redaction of identifiers at GP surgeries would be possible and members agreed that the access to identifiable data items should be restricted as far as GP systems allowed.

Extent of request for data

Members noted that an email had been received from the applicant on the 19 June which detailed a number of data items which would be required from the Trust in addition to demographic details specified within the application form. Members agreed that a complete list of data items should be submitted with further justification regarding why the additional data was required from the Trust.

The email also suggested that data would be requested in relation to prospective, as well as retrospective, deaths and members requested confirmation of the data years requested. In addition, members noted that review would initially take place on those patients falling into the Summary Hospital-level Mortality Indicator (SHMI) and members requested confirmation that only information in relation to these patients would be required.

Informing the public

Members noted that the cohort in question would be deceased but advised that some efforts should be made to inform the public that reviews of GP records were being undertaken.

Data extraction and transfer

Members requested further information in relation to how data would be extracted and transferred whilst in the possession of the Medical Director.

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 recommending provisional support to the Secretary of State for Health, subject to a satisfactory response to the following request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for clarification

1. Confirm what data items and data years would be required from the Trust and justification for the requested data.

2. Confirm the data transfer and extraction methods whilst data is in possession of the Medical Director.

Specific conditions of support

1. Please ensure that efforts are made to inform the public that the review is taking place, for example by displaying posters within GP practices.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

b. CAG 4-05(b)/2014 Improving Offender Healthcare: Health Needs Assessment Project

c. CAG 4-05(c)/2014 Improving Offender Healthcare: Escort and Bedwatch Audit

These applications from NHS England set out the purpose of a review of service user health records, including referral information, clinical information recorded on the Prison Electronic Patient System and clinical presentations.

The aim of the Healthcare Needs Assessment project was to determine the population health issues, leading to agreed priorities and resource allocation and improving health and reducing inequalities.

The aim of the Escort and Bedwatch project was to carry out a review of clinical activity associated with referrals of service users to receive treatment within a secondary care setting. The review would focus on a specific time frame to review the treatment and carer of service user pathways to determine if the service user could have been more appropriately treated within an offender healthcare setting and what developments would be required to provide care closer to home

A recommendation for classes 1, 5 and 6 support was requested to cover access to medical records onsite in order to extract pseudonymised information.

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 queried whether it would be possible for prison healthcare teams to undertake data extraction themselves and provide pseudonymised data to contractors. It was noted that the query responses in relation to the Escort and Bedwatch application appeared to suggest that the Prison Healthcare Manager would carry out data extraction and members queried whether data would therefore be pseudonymised prior to disclosure to contractors.

When considering whether consent would be feasible, Members discussed that it appeared to be possible to obtain consent from patients through prison staff, noting that the majority could be located and that contact details would be available within records.

Members were of the view that the applicant should explore these alternatives in detail for both applications to determine if another approach would be possible.

Patient information materials

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 discussed the patient information leaflet provided and noted that it was quite generic. Members advised that information specific to this activity should be provided where possible.

Patient involvement

Members noted that patients had been consulted in relation to the potential outcomes of the review but that there did not appear to have been any consultation in relation to the acceptability of the use of confidential patient information without consent. It was advised that specific questions in relation to this aspect should be raised to ensure that patients have an opportunity to express their views.

Data access controls

Members commented that there was limited information in relation to who would have access to records and how it would be ensured that appropriate controls were in place, noting that the extent of the potential disclosure was significant and that auditors would have access to the entire record as there were no controls within the system to limit this. Members agreed that further detail in relation to the third party contractors, data processing contracts and confidentiality contracts would be required.

Terminology

Members requested that the applicant ensure that consistent terminology was used and that an explanation of the understanding of the terms anonymised and pseudonymised were included so the data flows within the application were clear.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met as a potential practicable alternative to the use of confidential patient information without consent had been identified.

d. CAG 4-05 (d)/2014 Enhanced quality assurance process of the provision of NHS-funded care for people with a learning disability or autistic spectrum disorder

The application set out a proposal for NHS England to effectively case manage the care of patients, who require secure mental health care or child and adolescent mental health services. This would involve access by the case management team to the Secure Mental Health System currently hosted by Cheshire and Merseyside CSU and extracts from the child and adolescent mental health data set as described in section (i) of the application.

Mary Ann Doyle, Programme Director (Specialised Mental Health), Ming Tang, Director - Data and Information Management Systems and Ray Avery, Partnership Manager attended from NHS England to discuss the application.

Members agreed that this was an important activity with a high public interest to help ensure the appropriate safeguarding of adults. It was also noted that the intention was for this activity to be included in a forthcoming consultation on new Regulations to provide a permanent legal basis for this activity.

Members agreed that the application raised issues over the definition and boundaries of care and indirect care, and in particular, issues around mental capacity, consent and patient objection. The supporting case studies were felt to be focused on primarily direct care, therefore, as support cannot be provided for the purpose of providing direct care and treatment to an individual, members reiterated that the applicants would need to be extremely clear on where these boundaries were drawn, with a general shared understanding of this issue within those operating

under the support. The CAG sought clarity on how this activity was taking place at present, and it was confirmed that it was currently being undertaken on grounds of public interest.

In discussing consent, members sought clarity that on whether consent would be sought where feasible, however, the responses at the meeting were not as clear as expected. Instances of provider conflict of interest were discussed and issues around patient capacity were detailed, however, members were clear that support under Regulation 5 could not be relied upon to process information where a patient lacks capacity. In these instances, another legal basis would have to be relied upon.

It was noted that advice had been sought from the Information Commissioner's Office on consent and patient objection, however, it was noted that the advice provided related solely to the Data Protection Act 1998 as this is within the remit of the ICO. Unfortunately, it appeared as though the advice had been misinterpreted and conflated with the right of patient objection under confidentiality. It is important to note that under current confidentiality aspects that right of patient objection has a lower threshold for patients to enable this than under the Data Protection Act 1998, and it is important not to confuse the two aspects of confidentiality and data protection within the documentation.

Discussions identified that there was no intention to seek neither consent nor opt-out, therefore members queried how a situation would be handled if a patient chose to make an objection. The applicants advised that this was likely not to be in the clinical interest of the patient therefore the CAG advised that this position would need to be made explicit within the application, noting that the NHS Constitution provides for this right to be explained to patients where the situation arises. Members were very clear that should this be the case, reliance upon this support could not happen in the face of patient objection.

In terms of access to information, members sought clarity of the precise roles and it was confirmed that the CSUs would not have access to the Spine. The analyst based in Cheshire and Merseyside CSU would carry out the necessary linkages and anonymise the data and there was no expectation that any other CSUs would be involved in data processing. The discussions indicated that any further onward disclosure would be fully anonymised.

The CAG expressed some disappointment that user engagement had not been as progressive as hoped, considering the nature of the activity. Discussions highlighted that a recovery & outcomes group had been engaged with the activity, however, there was less information provided on how their input had impacted on the activity, and it was advised that this should be included. Members queried whether Young Minds could be meaningfully engaged with in relation to this activity.

<u>Confidentiality Advisory Group advice conclusion</u>

Members recognised that in these circumstances, there was likely to be no other practicable alternative to carrying out the activity, and that subject to the points made above, it was likely that the minimum threshold of the Regulations had been met. The CAG therefore recommended that provisional support should be provided to this application for a period of 12 months.

Due to the clarifications that had usefully arisen during the discussion with attendees, members advised that the application form should be updated to reflect these clarifications and submitted back to the CAG prior to a final approval letter being issued.

It was advised that the following should be provided in the refined application form:

1. Details of the exit strategy from reliance upon Regulation 5 and what this is expected to deliver.
2. Clarification in detail regarding how patient objection will be managed and handled.
3. Include an explicit statement that where a patient has objected to the processing of their data, that any subsequent processing will not be legitimised under this support and another legal basis will be relied upon.
4. Implications of advice provided by ICO in relation to Data Protection and differentiation from confidentiality to be made clear in application
5. Removal of any case studies related to direct care, or amendment to highlight where it relates to direct care, to avoid future confusion.
6. Confirmation that only one CSU is the subject of this application (Cheshire & Merseyside CSU) and any further disclosure will be genuinely pseudonymised
7. Details of planned engagement with appropriate users such as Young Minds and update on how existing engagement has impacted on the activity/linked to changes.

Providing that the revised application form was satisfactory, the CAG advised that the application should be subject to the following specific conditions of support:

1. The support specifically excludes activities related to the direct care or treatment of an individual as this falls outside the scope of the Health Service (Control of Patient Information) Regulations 2002. The function of the case manager appears to go beyond that of direct care and it is for this 'grey area' that support is provided.
2. The support covers only those named parties within the application, specifically the case manager, the administrator supporting that case manager and CSU analyst (with the analyst based in the Cheshire and Merseyside CSU).
3. Confirmation to received directly from the HSCIC that NHS England have a satisfactory IG toolkit standard, and copy of improvement plan if in place.
4. Support is provided for a period of 12 months from date of final approval.
5. Where patient objection is expressed, any subsequent processing of that patient data in the face of that objection cannot be legitimised under this support (Regulation 5) and another legal basis will need to be established. Any pre-existing patient objection cannot be overridden through this support.
6. Access to family, carer or any third party details is not information of the patient and access to this information is therefore excluded under this support; another legal basis will need to be established to process third party information.

6. MINUTES OF THE MEETING HELD ON 15 AND 16 MAY 2014

The minutes were agreed as an accurate reflection of the discussion, subject to correction of minor errors.

7. CAG OFFICE REPORT

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health agreed with all advice provided by the CAG in relation to the May 2014 meeting applications.

HRA approval decisions

The HRA agreed with all advice provided by the CAG in relation to the May 2014 meeting applications.

HARP

Members were informed that research applications submitted after the 19 May 2014 would now be processed via HARP for CAG. There will be no significant change in the short term but reference numbers for research applications would differ from those for non-research.

Standard Operating Procedures

A thorough review of the draft CAG Standard Operating Procedures was currently underway which aims to streamline the current SOPs document. Further information would be provided at the August away day.

Applications considered via Precedent Set Review

CAG 4-03(PR1)/2014 Cost-effectiveness of care for young people with eating disorders

This research application from King's College London will identify all new cases of anorexia nervosa in young people in the British Isles over a 12 month period, using the Child and Adolescent Psychiatric Surveillance System (CAPSS). At six and 12 months after each young person has been identified, the Applicant will gather follow-up information about the services each young person received and his/her health outcomes. This data will be used to estimate the cost-effectiveness of the different models of care provided to each young person and help us to explore whether increasing the provision of specialist services would benefit young people and their families and would be good value for money.

A recommendation for class 1, 2, 5 and 6 support is being requested to use patient identifiable data for case verification/matching of baseline and follow-up data, removal of duplicate notifications and the calculation of Body Mass Index (BMI). Geographical information will be used

to describe the population presenting with anorexia nervosa to identify geographical difference between models of care.

Access was requested to NHS Number, hospital number, date of birth, sex, town of residence and first half of postcode.

This application was considered via the precedent set process under criteria 5 – applications originating from CAPSS by Dr Robert Carr, Dr Patrick Coyle (Chair) and Mr C. Marc Taylor.

Members recognised that the application had a strong public interest in establishing which models of care for young people with Eating Disorders are the most cost-effective.

Members noted that the application followed the Child and Adolescent Psychiatry Surveillance System methodology, which had been supported in previous applications.

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 it was not feasible to seek consent based on the study design.

The Group noted that a number of identifiers had been requested including NHS number, and date of birth and that the Applicant asserted that those identifiers specified were required for the data linkage and validation.

Information Leaflet

Members noted that the patient information materials referenced the study but did not include clear information regarding a patient's right to opt out.

Additional points

Members suggested that the Applicant may wish in future to consider splitting the notification form so that clinicians send Section A & B with all the identifiers to CAPPS and send Section C separately with a unique CAPSS ID as the identifier.

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 recommending provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below:

1. The Information Leaflet should reference how patients can opt-out of their information being included in the study.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

CAG 4-03(PR2)2014 Prehospital Recognition of Sepsis by Ambulance Clinicians (PRoSAiC)

This research application from the University of Warwick is to produce a 'tool' to allow ambulance staff/paramedics to identify patients with sepsis so that they can be prioritised for treatment on reaching the Emergency Department. The data will be obtained retrospectively only from the West Midlands Ambulance Service NHS Foundation Trust and University Hospital North Staffordshire NHS Foundation Trust, the applying body being Warwick Medical School, Clinical Trials Unit.

A recommendation for class 4 and 6 support is being requested to use patient identifiers to link hospital and ambulance records.

Access was requested to name, hospital number, date of birth, gender and unit level postcode.

The application was considered via precedent set process under criteria 4 – time limited access to undertake record linkage/validation and to pseudonymise the data by Dr Patrick Coyle (Chair), Dr Murat Soncul and Dr Robert Carr.

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 it would not be feasible to seek consent based on the study design.

Members noted that all identifiable data will be removed once the hospital and ambulance records have been linked.

Justification of identifiers

Members noted the identifiers that were requested that the Applicant asserted that those identifiers specified were required to perform the linkage between the hospital and ambulance records.

Fair Processing

Having reviewed the application in terms of the fair processing of data, Members requested that further information be published about the use of patient data within this project, including information about how patients may 'opt-out' of their information being included in this research.

As patients seen within the Accident and Emergency department may never visit the department again it was stated that therefore they would not see the poster specified in the application. It was suggested that an information leaflet be developed and be referenced in each of the organisations websites involved in the study.

It was noted that the West Midlands Ambulance Service NHS Foundation Trust did not include using personal data for research purposes within their current ICO Data Protection registration. The Applicant advised that this would be updated prior to the commencement of any research activity.

The Applicant stated that the fully authorised/signed NIGB Form would be provided with confirmation that no further changes have been made to the form since the submission of this 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 as set out below.

1. Provision of patient information leaflets that reference patients' right to opt-out of their data being included within this project.
2. Receipt of a fully authorised/signed NIGB Form based on the draft form submitted as part of the application with confirmation that there have been no further changes to the NIGB form other than the authorisations of the Declarations.
3. Confirmation that West Midlands Ambulance Service NHS Foundation Trust includes the use of data for research purposes within their ICO Data Protection Registration prior to the start of the research activity.
4. Confirmation of suitable security arrangements via IG Toolkit submission any queries.

CAG 4-03(PR3)/2014 GlyCon: Glycaemic Control of Stress Hyperglycaemia Implemented in NHS Intensive Care Units

This application from the University of Nottingham set out the purpose of a retrospective review of medical records and anonymised data extraction from seven sites based a selection of patients identified from the Intensive Care National Audit & Research Centre database.

Records will include observation charts, patients' notes, and the Case Mix Programme (CMP) database of the Intensive Care National Audit & Research Centre (ICNARC), among others. Data collected will include baseline characteristics, data about glycaemic monitoring and treatment, and outcome data. The primary outcome measure will be the effectiveness of the methods for

glycaemic control implemented, measured as the proportion of time spent within the glycaemic range 4-10 mmol/L. Secondary outcomes will be other measures of effectiveness, efficiency and safety. The degree of staff adherence to the specific recommendations of the protocols will also be explored.

The main aim of GlyCon is to explore the associations between the methods for glycaemic control of stress hyperglycaemia implemented in 7 NHS ICUs of a network of ICUs, and the time that their patients spend within pre-specified glycaemic ranges.

A recommendation for class 4 and 6 support is being requested to link identifiable data to facilitate the review of medical records.

Access was requested to NHS number, hospital number, date of birth (as age), date of death (as survival time from admission), ethnicity, admission and discharge dates and sex.

This application was considered via the proportionate review process under criteria 3 – accessing data on-site to extract anonymised or effectively pseudonymised data by Dr Tony Calland (Vice Chair), Dr Patrick Coyle (Chair) and Dr Murat Soncul,

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 it would not be feasible to seek consent based on the study design.
Justification of identifiers

The Group noted that a number of identifiers had been requested and that the Applicant asserted that those identifiers specified were required for the data extraction.

Additional points

Members suggested that the Applicant may wish to consider how carers, relatives and the public could be included in future public and patient involvement within the study.

The Applicant confirmed that they will make the leaflet, and key information about the project, available to the public and ICU patients through ICU patient associations and representatives.

The Applicant confirmed that they had contacted the Head of Patient & Public Involvement (PPI) in Nottingham University Hospitals (NUH), Katie Moore, and the lead for PPI in Intensive Care for NUH, Fiona Branch. In addition, the Applicant contacted the Intensive Care Unit Support Teams for Ex-Patients ICU steps.

The Applicant will provide ICU patient associations and representatives with hard copies of the leaflet and ask for the best method of diffusion. Soft copies of the leaflet will be available through for the study website hosted by the University main site (under development) and diffused through patient association and representative websites.

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 as set out below.

1. Favourable opinion from a Research Ethics Committee
2. Confirmation of suitable security arrangements via IG Toolkit submission.

CAG 4-03(PR4)/2014 Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM)

This application from Southampton University Hospitals NHS Foundation Trust set out the purpose of tracing current names and addresses of members of the EuroPrevall and the Cork BASELINE birth cohorts. The EuroPrevall birth cohort ('The prevalence, cost and basis of food allergy in Europe') enrolled 12,049 new-borns between 2005 and 2010 in nine countries and traced development of food allergy over the first 30 months of life; the Cork BASELINE birth cohort ('Babies After SCOPE: Evaluating the Longitudinal Impact using Neurological and Nutritional Endpoints') enrolled approximately 2000 new-borns between 2008 and 2011 and traced health status over the first 24 months.

Contact will be made regarding a clinical follow-up to re-assess the cohorts at 5-10 years of age. Follow up is comprised of collecting data on family background and allergic diseases through online questionnaires, clinical investigation with a focus on skin status, skin prick testing, determination of specific Immunoglobulin against common food and inhalant allergens, and collection of DNA. Suspicion of food allergy is further evaluated with standardized double-blind, placebo-controlled food challenges. All data will be stored in the Allergelab database to facilitate complex data analysis in a professionally networked environment.

The main goal of this project is to trace new onset of food allergy and clinical evolution of already established food allergy, determining frequencies and patterns of tolerance development. Influence of environmental and behavioural factors (e.g. diet, feeding practices) will be investigated. Secondary outcomes cover asthma, allergic rhinitis and eczema. This application covers the follow up of the UK part of the Europrevall cohort.

A recommendation for class 2, 3 and 6 support is being requested trace cohort members to inform about this follow up study.

Access was requested to name, NHS number, hospital number, Date of Birth and unit level postcode.

This application was considered via the precedent set process under criteria 1 – patient recruitment by Dr Tony Calland Dr Patrick Coyle (Chair) and Mr C. Marc Taylor.

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 further to parental consent given during the original cohort study, this application requested support to trace current names and addresses to enable parents to be approached regarding the follow-up study.

Justification of identifiers

The Group noted that a number of identifiers had been requested and that the Applicant asserted that those identifiers specified were required to trace current names and addresses to the EuroPrevall and Cork BASELINE birth cohorts.

Future contact

Members suggested that the Applicant may wish to specify that the cohort maybe contacted again in the future in the event of further follow-up studies.

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 as set out below.

1. Favourable opinion from Research Ethics Committee.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

UPDATE ON PREVIOUS APPLICATIONS

ECC 2-02(FT7)/2012 Accident and Emergency Survey

A security breach in relation to the above application was reported by Yeovil District Hospital NHS Foundation Trust for the current 2014 A&E Survey; and that names of sample members were left in the file when it was sent to the Survey Co-ordination Centre. The CQC wrote to the Trust on the 26 May and highlighted the guidance provided by the HSCIC in relation to reporting security breaches.

8. ANY OTHER BUSINESS

Transparency

Members requested an update in relation to the publication of applications and meeting transparency needs. It was noted that this would be taken forward as part of the development programme and that a number of options were being considered in order to ensure that CAG advice and decisions under the Regulations were as transparent as possible. Further information would be provided to members once available.