NHS
Health Research Authority
Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group

28 August 2014 between 10:00 and 17:30 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
Dr Robert Carr	
Dr Murat Soncul	
Professor Barry Evans	
Ms Hannah Chambers	Lay
Professor Ann Jacoby	

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 David Evans	Expert advisor – Data Protection, Information Commissioner's Office
Ms Gill Habicht	HRA, Head of Corporate Business (observing)
Ms Joan Kirkbride	HRA, Director of Operations and Approval (observing)
Mr Andrew Ashworth	NHS England, IG Transition Programme Director (Item 2)

Mr Hayden Thomas	NHS England, Strategic Senior IG Subject Matter Expert (Item 2)
Ms Ming Tang	NHS England, NHS England, Director - Data and Information Management Systems (Item 2)
Dr Robert Kyffin	Public Health England, Data and Information Policy and Partnerships Lead (Item 3)

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Chair welcomed Ms Gill Habicht, Head of Corporate Business and Ms Joan Kirkbride, Director of Operations and Approval who were attending the meeting as observers.

Apologies

Apologies were received from Professor Julia Hippisley-Cox, Professor Jennifer Kurinczuk and Dr Miranda Wolpert.

Declarations of interest

The following interests were declared:

Ms Clare Sanderson:

Declared a competing interest in items 2a to 2c [CAG 2-03 (a)/2013, CAG 7-04(a)/2013 and CAG 7-07 (a-c)/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 and NHS England. Ms Sanderson did not receive meeting papers, remained in the room for the discussion with the attendees for this item and left the room for the discussion in relation to the CAG advice.

Professor Barry Evans:

Declared a competing interest in item 3a to 3d [PIAG 03 (a)/2001], [PIAG 2-08 (e)/2002], [PIAG 1-08 (a)/2003], [ECC 5-05 (e)/2012], [PIAG 2-08(e)/2002] due to his role at Public Health England. Professor Evans did not receive the meeting papers, remained in the room for the discussion with the attendees for this item and left the room during the discussion in relation to CAG advice.

Dr Mark Taylor:

Declared a competing interest in item 5a as the application was submitted from his employer the University of Sheffield. Dr Tony Calland chaired the application and Dr Taylor left the room for the discussion of this item.

There were no further declarations of competing or conflicting interests.

2. ITEMS FOR CONSIDERATION

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

b. [CAG 7-04(a)/2013] Risk stratification

c. [CAG 7-07 (a-c)/2013] Invoice validation

Following the May 2014 CAG meeting these applications had been deferred pending receipt of a satisfactory responses to the questions posed in the outcome letter. A report was provided in response to the outcome letter and the applicant attended to provide further detail.

Confidentiality Advisory Group advice

Members welcomed the detailed report that provided a comprehensive update on the requested issues. The key points of discussion are summarised below.

Fair processing

It was noted that NHS England had engaged in discussions with the Information Commissioner's Office (ICO) due to a need to review the initial strategy following the pause to care.data. It was confirmed that the original plan had been to utilise the national fair processing portal proposal to be developed by the Health and Social Care Information Centre (HSCIC), however it was indicated that this development could be subject to protracted discussion and development. It was also confirmed that the pause to care.data would continue until at least October 2014 and was likely to be focused on the pathfinder initiatives.

The interim strategy, agreed with the ICO, involved updating the NHS England website to provide centralised fair processing pages on Accredited Safe Havens (ASH), risk stratification and invoice validation by end August 2014. These were confirmed to set out the uses of patient information approved under Regulation 5. This commitment was strongly welcomed.

It was also confirmed that a fair processing checklist for the purposes of risk stratification would be provided to those operating under this support. It would be targeted at GPs and designed to be accessible and straightforward. Detail was also provided on a fair processing poster that would outline the basic uses of data to support health care management within the wider NHS, set out the organisation's obligations to the individual and the patient role in helping the data controller to fulfil these obligations. An area to be set aside for local details would enable each organisation to provide details of their Caldicott Guardian and how patients could exercise their rights, for example via Subject Access Requests. The report also confirmed that the previous inaccuracy within the local patient information leaflet example regarding Health Research Authority approval had been rectified.

Members strongly welcomed the detail of the interim fair processing strategy and agreed that NHS England had clearly taken positive steps and engaged meaningfully with the ICO in order to seek to address this issue in challenging circumstances. In particular, members wished to express how welcome and positive they found this progress and commitments and agreed that NHS England was appearing to take all reasonable steps to manage this compliance aspect. It was agreed that a copy of the finalised leaflets or relevant web link should be provided to the CAG once available.

Patient objection

The report set out there that was some complexity around this area that required a coordinated approach across the NHS; in particular the issue of patient objection where the current technological infrastructure could have an impact on patient care in relation to risk stratification. The report confirmed that the Independent Information Governance Oversight Panel (IIGOP) had asked the Data Sharing Executive Group, chaired by Will Cavendish, to consider the issue and outline a strategy for the next steps. It was confirmed that until a decision is made by this Group that it would not be possible to make substantial progress on the broader issue. This was accepted by the CAG.

As an interim measure, it was confirmed that NHS England was working with risk stratification programmes to develop guidance on how to implement objections and exclusions locally, including support for GPs to explain to patients what objection means in relation to risk stratification. In addition, a 'how to' guide setting out how the three categories of codes need to interact will be developed. These categories were confirmed to be the obligations around care.data, the national programme of objection and exclusion codes and any local initiatives and coding.

End state position

It was confirmed that the intention underpinning the duration extension request to end April 2015 was for an alternative legal basis to be in place via the recent consultation on new Regulations. This was asserted to be the short to medium term exit strategy for commissioning purposes and more detail was likely to be known from November 2014. For both the medium and longer term solutions and the strategy for the Health and Social Care Information Centre to be the provider of many of the long-term strategic solutions, the commitment by NHS England to continue to work towards the reduction of reliance on personal confidential data for commissioning purposes was welcomed.

Retention

In relation to CAG 7-07 (a-c)/2013 ('invoice validation') the proposal for an interim retention period for the invoice validation backing data set of one financial year plus three months (i.e. 15 months in total) was stated to be an interim solution that would meet business needs. This proposal was accepted at the present time.

In relation to CAG 7-04 (a)/2013 ('risk stratification'), members noted that the five year retention period appeared to cover a relatively long period for those not the subject of subsequent care interventions, recognising the NHS England perspective that the process was currently innovative and time would be needed to be taken to enable learning to take place. Members commented that it was hoped this would be reviewed as learning emerged.

Confidentiality Advisory Group conclusion

Members welcomed the fact that the ICO had raised no concerns over the interim fair processing strategy, and recognised that there had been demonstrable evidence of positive steps taken. It was therefore agreed that in light of the report and positive progression that the duration extension requests in relation to all applications until 30 April 2015 should be approved. This was subject to submitting an update on all outstanding actions and commitments specified within the current report, which were currently in development, to the January 2015 CAG meeting along with the

plan to move towards the exit strategy. If it was envisaged that support may be required post-April 2015, CAG advised that any potential duration extension should also be submitted to this meeting.

Members reiterated that all existing conditions of support specified in each application approval must be complied with e.g. risk stratification applies only to existing suppliers as originally specified in the application. Please note that the previous requirement to submit an update to the CAG October 2014 meeting has been superseded by this meeting and this requirement is no longer required.

Members also reiterated their thanks to Ms Ming Tang, Mr Hayden Thomas and Mr Andrew Ashworth for their thoughtful comments and constructive engagement with the considerations of the Regulations, the CAG and Confidentiality Advice Team.

3. ANNUAL REVIEWS

a. PIAG 03(a)/2001 - National Cancer Registries Database

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

c. PIAG 2-08(e)/2002 Congenital Abnormality Survey (NorCAS) and West Midlands Congenital Anomaly Register (WMCAR) only

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

Following discussions that began with the National Information Governance Board (NIGB) Ethics and Confidentiality Committee in 31 October 2012 and 06 December 2012 and the subsequent formal novation of five applications to Public Health England (PHE) from 01 April 2013, an interim annual review, exceptionally agreed due to the changing organisational status, had been provided for CAG consideration on 03 October 2013. At that meeting, the CAG did not have the benefit of considering security assurance status via the Information Governance Toolkit (IGT) submission as the IGT had been submitted to the Health and Social Care Information Centre (HSCIC) on the same day of CAG consideration. Following CAG advice, the interim annual reviews received a recommendation of continuing support in October 2013 until June 2014, subject to PHE providing detailed annual reviews including a clear update on the security assurances and IGT status in June 2014. The Health and Social Care Information Centre (HSCIC) separately confirmed on 21 November 2013 that the novated activities had been confirmed as satisfactory, with associated improvement plans in place. The detail of the requirements to be provided to the June 2014 meeting were set out in the letter dated 03 December 2013.

Fuller annual review reports were subsequently submitted to the June 2014 CAG meeting. A recommendation of support was provided to ECC 1-05 (a)/2012 due to its satisfactory IGT status and different provisions as to fair processing as the cohort was primarily deceased; a recommendation was deferred in relation to the remaining four applications to enable PHE to rapidly submit information to the July 2014 CAG meeting, however, due to timing issues this information was provided for consideration in August 2014. Due to expressed member concerns around progression, PHE representation was requested to provide further context and to respond to arising queries. The meeting was attended by Dr Robert Kyffin and members welcomed this attendance in helping to clarify the issues.

Applications to be consistent with the provisions of the DPA

Members noted that it is a requirement under section 251(7) of the National Health Service Act 2006 that the processing of prescribed patient information cannot be inconsistent with any provision made by or under the Data Protection Act 1998. The first principle of the Data Protection Act 1998 required the provision of fair processing information. The issue of ensuring that there is suitable fair processing information in relation to the applications had previously been raised in December 2012, December 2013 and June 2014 and PHE had been advised to make contact with the Information Commissioner's Office (ICO) in order to progress this aspect. The expectation at the August 2014 meeting was therefore that progressive discussions would have taken place and relevant documents shared with the ICO in response to the deferral actions specified in June 2014. The ICO confirmed that limited contact had taken place and referred to email correspondence received on the date of this meeting.

While noting the background context and understandable challenges arising from the establishment of PHE, it was noted that over 16 months had passed since PHE had taken on formal responsibility for the novated applications. Members therefore considered that a greater sense of urgency should be demonstrated in order to appropriately address the issues raised. As a whole, the CAG was disappointed to note the lack of progress on this aspect of appropriate fair processing information, considering the critical importance of compliance with this aspect in relation to an approved activity. Members also discussed how PHE could be sure that a newly diagnosed cancer patient received information that their data would be held on a registry; this was in light of patient feedback provided to the CAG that had previously been flagged with PHE. Discussions indicated that PHE were instructing all Trusts to disseminate information and that there had to be a reliance on Trusts to comply with the fair processing obligations.

Following comment from the ICO that the significant number of patient records processed heightened the importance of demonstrating likely compliance with the Act, as a consequence of the current status of fair processing information the CAG noted that it had been placed in a position where it would need to draw this status to the attention of the relevant approval bodies; it was recognised that there was a possibility that this may jeopardise the status of the existing approvals.

In order to resolve this aspect, members advised that there should be separate priority discussions with the ICO and a programme on implementing appropriate fair processing information rapidly established and progressed. The CAG were clear that this may require significant resource and capacity requirements to manage effectively and consistently, therefore it was suggested that the programme plan should also include interim measures or quick wins such as updated information to be placed on websites, to be agreed with the ICO. The rationale for this approach was that as the full scope to implement appropriate fair processing information was not yet clear, it would be of benefit to employ a staged approach to fair processing so as to identify where transparency should be improved on an interim basis as the plan progresses to its end state conclusion.

Patient objection

Separate to the issue of fair processing, Members welcomed the NCRS policy on managing patient objection, although noted that an organisation-wide policy on this aspect was not in place. It was noted that in the example given that a patient would be advised to speak to a consultant however it was unclear on how the consultant would be expected to handle these situations. This was acknowledged as a reasonable point and that the approach PHE would be taking would be reviewed. The conversation indicated that there would need to be a significant amount of

organisational change to attain the position discussed with the CAG. In agreeing that a uniform approach across all applications would be unlikely, members emphasised the importance of a consistent approach across all applications and this aspect of consistency should be developed. Members also commented that the language used was rather abrupt and more could be detailed in the policy about the benefits in participating; noting that some of the applications involved a research aspect, the advantages of following the HRA guidance on patient information leaflets was suggested.

Transfer of information

Members noted from the discussion that it was confirmed that the majority of overseas transfers of identifiable data were undertaken on a consented basis. The report specified that the PHE Clinical Genetics Counselling Service received approximately 50 requests per year from geneticists based outside the UK. In relation to deceased patients, the report asserted that Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002 did not prevent international data transfers and while this controls the purpose to which cancer registry data can be put, it does not place geographical controls on its use.

Members expressed the view that while the purposes are established under Regulation 2, Regulation 2(3) states that processing of confidential patient information for the purposes specified in paragraph (1) may be undertaken by persons who (either individually or as members of a class) are a) approved by the Secretary of State and b) authorised by the person who lawfully holds the information. The CAG were therefore unclear on whether the recipients of the data, when receiving identifiable data under Regulation 2, are bodies or persons approved by the Secretary of State. The CAG therefore expressed the wish to take up the stated offer from PHE to seek further legal advice in order to clarify the position and to provide this, as stated, to the CAG as part of the report to the November 2014 meeting.

Information Governance Toolkit improvement plan

Members agreed that there was a greater sense of reassurance following the updated report, and the additional information showing the current status was helpful. Appreciating that PHE had been formed in April 2013 and allowing for a year to embed its processes, members did reiterate that it had been in existence for over 16 months and in taking on responsibility for existing applications already approved under the Regulations, members were keen to emphasise that the standards for the novated applications should rapidly attain level 2 IGT status considering the time the improvement plan had been in place, and to maintain public confidence; the stated update on this aspect in November 2014 was therefore welcomed.

Report to November 2014 meeting

During the discussion, it was noted that there had been a number of challenges for PHE in taking on responsibility for the novated applications, however it was important, in order to maintain public confidence, for appropriate standards to be documented and in place. The Group therefore welcomed the absolute verbal guarantee that a detailed report on all outstanding and planned actions, in line with the discussion, would be provided to the November 2014 meeting in line with published timescales. In relation to the outstanding requirements, it was advised that PHE must ensure that all aspects are fully addressed in this submission to enable a positive recommendation to be provided, considering the context that a recommendation has been deferred twice.

Due to timings of the IGT submission, members agreed that PHE should submit the update to the CAG in November 2014, rather than the previously specified October 2014 meeting. This was on the proviso that all aspects would be fully addressed.

Confidentiality Advisory Group advice conclusion

Based upon the current progress and the critical issue of suitable fair processing information provision, the CAG agreed that there was currently insufficient information to enable it to provide a recommendation to the approval bodies. Noting the importance of suitable fair processing information for all applications and its impact on the viability of continuing support, it was agreed that the recommendation would be deferred for a final time to enable Public Health England to provide the requested information for consideration at the 06 November 2014 meeting.

e. [PIAG 2-08(e)/2002] British Isles Network of Congenital Anomaly Registers (BINOCAR)

This annual review submission from the British Isles Network of Congenital Anomaly Registers was for a number of registers which were established to provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies by means of national, regional and disease specific registers of congenital anomalies. A recommendation for class 1, 4, 5 and 6 support was requested to cover access to congenital anomaly registers. Access was requested to mother's name, address, postcode, hospital number, NHS number and date of birth, and to baby's name, address, postcode, hospital number, NHS number, date of birth, date of death and address at conception.

The following registers were included within this annual report from Queen Mary University of London :

- East Midlands and South Yorkshire Congenital Anomalies Register – University of Leicester
- Wessex Antenatally Detected Anomalies Register – University Hospital Southampton NHS Foundation Trust
- Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire – University of Oxford -
- South West Congenital Anomaly Register – University Hospitals Bristol NHS Foundation Trust
- National Down Syndrome Cytogenetic Register – Queen Mary University London
- Yorkshire and the Humber Congenital Anomalies Register – University of Leeds

A separate application had been submitted in relation to the Congenital Anomaly Register and Information Service (CARIS) and therefore this was considered separately under CAG 6-06(b)/2014.

Confidentiality Advisory Group advice

This annual review was reviewed by the Confidentiality Advisory Group, rather than by the Confidentiality Advice Team as a number of other congenital anomaly registries had been submitted for review under different auspices and, in order to ensure a consistent approach, it was agreed that the annual review should be reviewed at a CAG meeting.

Submission of amended application form

Members noted that the annual review suggested a period of change for the registries, including their relationship with Public Health England and the development of a national data management system. Members advised that they would have expected a more detailed report, but noted that the uncertainties faced meant that providing further information at this stage would be difficult. With this in mind, and noting that the annual review process was currently being revised to request further details from applicants, members agreed that there was a continued public interest in data collection taking place and therefore the application should be supported until June 2015. However, due to the substantial changes over the next year a revised application form was requested in order to ensure that the future state, once known, was clear.

Members discussed that the revised submission should include further information about the following points.

Fair processing

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 limited information in relation to fair processing had been provided within the annual review and requested further information in relation to how it was ensured that patients were made aware of the registries and the processing of confidential patient information.

Patient engagement and involvement

Members highlighted that where patient information was to be used without explicit consent for purposes that were in the public interest, it was of particular importance to consult with patients to determine the acceptability of the activity and demonstrate that interest.

Members noted that two user groups were represented on the BINOCAR Management Committee but that no specific patient information was undertaken by individual registers. Members advised that where patient information was to be obtained without consent, greater efforts should be made to engage with the public and queried whether further efforts could be made in relation to this application to engage with patients and the public**.**

Practicable alternatives and reduction of identifiable data items

Members considered practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006. The annual review specified that the use of all current identifiers and potential scope for pseudonymisation would be reviewed as part of the development of the national data management system. An update on the continued requirement for all specified data items must be provided for review at this time.

Future data management system

Members requested further information in relation to the proposed data management system and the relationship with Public Health England (PHE), noting that the management system was being developed by PHE.

Confidentiality Advisory Group Advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared continued to have been met and that there was a public interest in research of this nature being conducted, and therefore advised recommending conditional support to the Health Research Authority until 20 June 2015, subject to the standard conditions of support and confirmation of satisfactory security arrangements via an Information Governance Toolkit submission. A new application should be provided to CAG prior to June 2015 to ensure continued support.

4. RESUBMITTED APPLICATIONS

a. [14/CAG/1017] Partnerships in Care Research Database

This application from Partnerships in Care detailed the creation of a research database to use for research studies to inform treatment and the planning of services. A recommendation for class 4, 5 and 6 support was requested to cover access to link records collected in relation to 935 patients from medium secure units to Hospital Episode Statistics (HES) and mortality data from the Health and Social Care Information Centre (HSCIC). Access was requested to name, address, date of birth and date of death.

Resubmission background

The application was considered at the March 2014 CAG meeting at which time a number of queries were raised and CAG advised that the application was not approved. The application was then resubmitted to the May 2014 CAG meeting and members agreed that they would need further information before a recommendation could be provided. A teleconference was set up on the 13 June 2014 to discuss the questions and responses provided by the applicant.

Following the teleconference it was agreed that the queries should be refined and resubmitted to the applicant and the applicant submitted responses to be reviewed at the August 2014 meeting.

Confidentiality Advisory Group advice

Members discussed the responses to the queries at length and agreed that currently the responses were not adequate to allow a recommendation of support to be provided. In particular, members raised concerns about the following aspects.

<u>Legality of database</u>

Members noted that assurances could not be provided in relation to the legality of the database and raised concerns about the implications of this. It was noted that the applicant had attempted to obtain clarity but that this had proved not to be possible.

<u>Alternative methodology</u>

As the legality of the existing database was unclear, members discussed at length opportunities to continue to process the data and link to data held by the Health and Social Care Information Centre (HSCIC) in a pseudonymised format. Members encouraged the applicant to engage with the HSCIC in relation to potential opportunities to carry out data

linkage in a pseudonymised format which would allow the database held by the applicant to be anonymised as soon as possible.

Members advised that if possible, identifiers should be provided to the HSCIC who could use the data to flag patients on their systems. Once flagged, data could be provided to the applicant using a unique reference number and the applicant could destroy the identifiable data held within the research database.

Members agreed that the adoption of this method would allow the database to be de-identified as soon as possible and, given the uncertainty over the legal basis, advised that the applicant should take steps to adopt this approach to ensure the risks of holding a database including identifiable data without a clear legal basis were mitigated as far as possible. It was recognised that this would require support under the Regulations in order to allow the disclosure of data to the HSCIC and members advised that if this method proved feasible, the applicant should return to CAG with a new application.

The Group went on to discuss the application in general and the following points were raised for the purposes of information and to invite reconsideration of a number of aspects if a new application were to be submitted.

Fair processing

Members noted the response to queries raised in relation to what efforts could be made to carry out fair processing and the text provided which would be displayed on the Partnerships in Care website. It was advised that the applicant revisit the text to ensure that the details of processing were fully covered and available to anyone accessing the information.

Patient objection

Members noted that the applicant had specified a process for allowing patient objection. However, members advised that this should be simplified to ensure that patient could object with relative ease. In particular members commented that patients should not have to attend a meeting or provide explicit reasons for requesting that their data be removed from the database.

Governance of database

Members advised that robust plans should be established for the governance of the research database in future, including legacy planning and a clear review process for disclosure requests.

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 and requested that the applicant explore the alternative methodology with the HSCIC.

5. NEW APPLICATIONS – Research

a. [14/CAG/1015] An analysis of linked pre-hospital and hospital data

This research application from the University of Sheffield described a study which aimed to utilise routine NHS data from a number of providers of emergency and urgent care in Yorkshire and Humber. The application described linking data to provide a coherent picture of emergency and urgent care demand for a period of 12 months. The data would be used to map the use of emergency and urgent care services in order to identify pattern of service use and outcome by different patient and demographic groups to identify groups of patients who currently utilised emergency and urgent care services in different ways and who may benefit from an alternative approach to care.

A request for class 4 and 6 support was made to allow the disclosure of confidential patient information from Yorkshire Ambulance Service and Emergency Department and inpatient Patient Administration System data to researchers within the University of Sheffield. Confidential patient information from the Yorkshire Ambulance Service and a number of NHS Trusts was requested in relation to patients using services over a 12 month period.

Name, postcode, NHS number, date of birth and date of death were requested in order to carry out linkages. It was confirmed that all identifiers were required in order to carry out linkages across ambulance data as limited data was recorded at this stage. The study was likely to include data in relation to over 1 million patients.

Confidentiality Advisory Group advice

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 agrred that consent would not be feasible in this instance noting the circumstances in which patients would be admitted to hospital. It was noted that the application specified processing identifiable data for a short period of time in order to anonymise the data.

Analysis dataset

Members discussed that incident number appeared to be included within the analysis dataset and queried whether this would allow the dataset to be re-identified. It was advised that this should be replaced with another unique reference number if possible.

Members also requested confirmation whether date of death would be retained within the analysis dataset and queried whether this could be reduced to month and year of death. If full date of death was required members requested further information in relation to why this was necessary.

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 posters

would be displayed within hospitals and queried whether further efforts could be made to inform 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 research of this nature being conducted, and therefore advised recommending conditional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Fair processing information should be displayed on the Trust websites in relation to the data collection.
2. Date of death should be reduced to month and year only for analysis purposes.
3. It was advised that incident number should be replaced with another unique reference number within the dataset retained for analysis.
4. Favourable opinion from Research Ethics Committee.
5. Confirmation of suitable security arrangements via IG Toolkit submission

6. NEW APPLICATIONS – Non-research

a. [CAG 6-06(a)/2014] Welsh Cancer Intelligence and Surveillance Unit (WCISU)

This application from Public Health Wales set out the purpose of a population-based national cancer register for Wales.

WCISU's role was to provide cancer-specific health intelligence for public health and population health action related to:

- Root causes of poor health and health inequalities
- Population health improvement
- Disease prevention
- Population health needs assessment
- Health care service planning
- Evaluation, research and development.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to confidential patient information from sources including general hospitals, cancer centres, hospices, private hospitals, cancer screening programmes, other cancer registers, primary care, nursing homes and death certificates. Access was requested to data from multiple sources in relation to patients within Wales diagnosed with cancer. Name, postcode, NHS number, date of birth and date of death were requested in order to carry out linkage of data from multiple sources over long time periods.

Confidentiality Advisory Group advice

Disclosure of confidential patient information

Members advised that any disclosure of identifiable data to third parties should be subject to another application to CAG and onwards disclosure was not included within this application.

Patient objection

Members agreed that the patient information leaflet was clear but noted that there were limited options to allow a patient to opt out of the registry. Members requested that the applicant ensure that there was more than one method to allow patient objection and that this was reflected within the patient information leaflet.

Justification for identifiers and exit strategy

It was advised that the applicant should continue to review the requirement for the extent of identifiers requested; in particular members queried the ongoing use of patient name. Members advised that once a patient was deceased it should be feasible to remove identifiers once all linkages had taken place.

Members requested that the applicant continue to explore ways to reduce the identifiers required for the specified purposes in line with the requirement to reduce identifiers as far as possible and adopt an exit strategy from the use of confidential patient information without consent. The applicant would be asked to report on progress at annual review stage.

Extent of data requested

Members discussed that it should be ensured that the scope of the application was clear and requested that the applicant provide confirmation in relation to the datasets that may be required from various sources.

Information leaflet for NHS staff

Members noted that the confidentiality leaflet for NHS staff did not specify that NHS number and date of birth were potential identifiers and advised that this should be updated to make this clear to ensure that data including these data items was processed accordingly.

Security

Members noted that a Memorandum of Understanding (MoU) was currently being developed between the Department of Health (DH) and NHS Wales Informatics Service (NWIS) to confirm that the Caldicott Principles into Practice (C-PIP) provided equivalent security assurance. Once the MoU was in place, the HSCIC could confirm satisfactory security assurance for the purposes 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 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.

Specific conditions of support

1. Any onward disclosure of confidential patient information to third parties should be subject to a further application for support.

2. Further options to allow patient objection should be established and included within the patient information leaflet.
3. The applicant must continue to review the requirement to process identifiable data and report on alternatives or reduction of identifiers explored at annual review stage.
4. Confirmation of the data sources and types of data requested from each source.
5. The staff confidentiality leaflet should be amended to reflect that date of birth and NHS number could be potential identifiers.
6. Confirmation of suitable security arrangements, which would need to be confirmed following the establishment of a MoU between DH and NWIS

b. [CAG 6-06(b)/2014] Congenital anomaly register and information service for Wales (CARIS)

This application from Public Health Wales set out the purpose of a systematic collection, registration and publication of population level data of congenital anomalies in Wales. The data would be used to assess patterns of anomalies, possible clusters of anomalies and their causes, antenatal screening and other healthcare interventions and health service provision for affected babies and children.

A recommendation for class 3, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from a number of different sources to Public Health Wales. Confidential patient information from a range of sources was requested in relation to any fetus or baby who had or was suspected of having a congenital anomaly and whose mother was normally resident in Wales at time of birth. Data items including mother and baby name, postcode, NHS number, date of birth and date of death and father name were requested.

Confidentiality Advisory Group advice

Members noted that this application detailed the CARIS register which had previously had support under the BINOCAR overarching application (PIAG 2-08(e)/2002) and that Public Health Wales had submitted a separate application given changes within other registries covered within the application and their relationship with Public Health England.

Members agreed, in line with the overarching BINOCAR application, that there was a strong public interest in the processing of confidential patient information for this purpose.

<u>EUROCAT</u>

Members noted that the application did not include reference to the disclosure of data to EUROCAT, but that confirmation had been provided to the Confidentiality Advice Team that data transfers would take place as detailed within the BINOCAR application. Members sought further information from the applicant in relation to the exact nature of data flows to EUROCAT that needed to be included within the support provided.

<u>Practicable alternatives</u>

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006. Members discussed that consent would not be feasible due to practical complexities of the patient pathway and agreed that the identifiers requested had been justified.

Fair processing

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 agreed that the fair processing information provided within the application was clear. However, it was noted that this was aimed at parents and that as the application specified that data would be retained indefinitely efforts should be made to inform children as well as parents, in particular as they became adults. Members requested further information from the applicant in relation to how this longer term issue could be addressed.

Scope of application

Members noted that the application listed a number of data sources and requested further information about the extent of information required and methods of access for each data source.

Exit strategy

It was noted that the applicant specified that indefinite retention of data was required, whilst members agreed that it may be necessary to retain data, it was advised that the applicant should continue to review the requirement to collect and retain the specified identifiers on an ongoing basis to move away from the requirement to process identifiable data without consent.

Security

Members noted that a Memorandum of Understanding (MoU) was currently being developed between the Department of Health (DH) and NHS Wales Informatics Service (NWIS) to confirm that the Caldicott Principles into Practice (C-PIP) provided satisfactory security assurances. Once the MoU was in place, the HSCIC could confirm satisfactory security assurance for the purposes 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 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.

Specific conditions of support

1. Confirmation of the nature of data flows to the EUROCAT register.
2. Further information in relation to the provision of fair processing in the long term to ensure that children and adults were informed of the long term retention of their data.
3. Confirmation of the methods of access to data sources and the extent of data collected from each.
4. Continued review of the requirement for the use of confidential patient information and the retention of identifiable data items. This should be reported on at annual review stage.
5. Confirmation of suitable security arrangements, which would need to be confirmed following the establishment of a MoU between DH and NWIS

c. [CAG 6-06(c)/2014] Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP)

This application from Public Health Wales set out the purpose of the Wales Abdominal Aortic Aneurysm Screening Programme (WAAASP), a public health screening programme which aimed to reduce mortality by 50% by 2015.

A recommendation for class 4, 5 and 6 support was requested to cover access to confidential patient information from the Welsh Demographic Service to Public Health Wales in order to send invitations for screening. Data would be held on the Abdominal Aortic Aneurysm Screening Information System. In addition, data was requested from the Public Health Mortality Files, Patient Episode Database for Wales and the National Vascular Registry in order to determine outcomes within 30 days and 1 year of treatment for all men invited to take part in screening.

The application also sought information in relation to patients who had aortic aneurysms not detected by screening from ONS mortality data and various NHS organisations. Access was requested to name, postcode, NHS number, date of birth and date of death.

Confidentiality Advisory Group advice

Non-responders and Data Protection Act 1998 compliance

It was noted that support was requested in order to allow consent to be sought from patients who subsequently attended screening and those who did not respond to the invitation. Members agreed that there was a clear justification for retaining data in relation to these patients.

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. It was advised that the applicant should ensure that the consequences of not responding were made very clear to patients to ensure that the fair processing requirements of the Data Protection Act 1998 were met.

In addition, members advised that if explicit consent were sought for the use of data at invitation stage the continued processing of data in relation to non-responders would not be consistent with the DPA. As the applicant had sought to rely on consent, they could not then rely on another Schedule 3 condition within the DPA for the processing of sensitive personal data. The applicant was advised that they should be cautious about seeking consent for use of data at the point of initial contact as data linkages could not then be undertaken for non-responders.

Members requested that the applicant amend the invitation letter and patient information leaflet to be clear about the consequences of not responding to the invitation and the continued processing of confidential patient information.

Patient objection

A separate but related issue to fair processing was raised in relation to patient objection. Members advised that as the application requested the continued processing of confidential patient information in relation to non-responders, clear methods to allow for patient objection must be provided. Details of this should be included within patient information materials provided with invitations.

Privacy Advisory Committee (PAC) advice

Members noted the letter from the applicant referring to advice provided by the Welsh Privacy Advisory Committee in relation to the requirement to inform GP practices. It was advised that this was not within the remit of CAG as this data flow would be carried out following patients attendance at screening and therefore with consent. However, members advised that although outside remit this was clearly an important issue and the applicant should seek further advice in relation to this.

Research use

Members advised that if data in relation to non-responders was to be used for research purposes in future the applicant should submit an amendment to the application.

Security

Members noted that a Memorandum of Understanding (MoU) was currently being developed between the Department of Health (DH) and NHS Wales Informatics Service (NWIS) to confirm that the Caldicott Principles into Practice (C-PIP) provided equivalent security assurance. Once the MoU was in place, the HSCIC could confirm satisfactory security assurance for the purposes 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 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 and request for further documents as set out below.

Specific conditions of support

1. Provision of revised patient information in line with issues outlined above in relation to non-responders and patient objection.
2. Confirmation of suitable security arrangements, which would be confirmed following the establishment of a MoU between DH and NWIS.

7. MINUTES OF THE MEETING HELD ON 24 JULY 2014

The minutes were agreed as an accurate record.

8. CAG OFFICE REPORT

For information

Secretary of State approval decisions

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

HRA approval decisions

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

General updates

HRA Decision tool – 'is it research' & generalizability

Members provided feedback on their experience of the HRA decision tool 'is it research' following discussion at the July 2014 meeting. This was fed through to the Head of Partnerships and Chief Executive; the comments were positively received and considered to be timely. As the development of the decision tool was linked to the Research Governance Framework and this is currently undergoing preparatory revision in preparation for the HRA transfer to Non-Departmental Public Body status, there is agreement in principle for the decision tool, specifically in relation to the question of generalisability, to be reviewed from September 2014 onwards once new organisational structures are in place to take forward this piece of work. It was likely that further CAG input may be requested nearer the time.

Academy of Medical Sciences - Data in Safe Havens

The Academy of Medical Sciences had published a report of a workshop that took place in March 2014. This was a well-attended, thoughtful workshop that sought to look at examples of definitions, different existing models and challenges facing the research community, particularly the importance of maintaining and developing public confidence of research and its benefits.

HRA-CAG-HFEA Memorandum of Understanding

This document that sets out the operational management of applications to access the Human Fertilisation and Embryology Association (HFEA) Research Register underwent revision to reflect the new role of CAG within the HRA and has received internal approval via the Executive Management Team following. Members were informed that it would shortly be published on the HRA website.

'Future role of CAG' – Data sharing Principles workshop

Members were informed that a meeting took place on 12 August 2014 between the HRA and HSCIC to initiate discussions on how the CAG was proposed to provide advice to the HSCIC under Schedule 8 of the Care Act 2014.

It was attended by Peter Hall, Dr Martin Severs, Alan Hassey, Garry Coleman and Malcolm Oswald (HSCIC), Jennifer Byrom (DH, project manager), Joan Kirkbride, Gill Habicht, Natasha Dunkley (HRA) and Dr Mark Taylor, Dr Patrick Coyle and Ms Gillian Wells, (HRA CAG). Case studies were provided as an initial discussion point, however, it was identified that there would be a need for the HSCIC to clearly identify its own existing or developing policies and procedures as a starting point. The draft document created the impression that potential onwards referral to CAG were currently on issues of uncertainty or questions over the scope of the Health & Social Care Act 2012; as the latter involved questions of legal interpretation. It was identified that the CAG is not constituted to provide legal advice, and another internal mechanism would need to be in place for the HSCIC to resolve questions of legality.

In particular, members noted that a provisional timescale for the advice coming into effect was from January 2015, although the HSCIC indicated that this was intended to be a phased approach and may not commence at that time. The HRA raised a number of issues; notably that resource

was a key risk as currently scope was unclear and it would be difficult to appropriately recruit for an unknown activity at the current time. DH advised that a ministerial submission would be made to cover the issue and options for resourcing. The HRA raised a further concern that while there was a public expectation for the CAG to take on the new advisory role, timescales were short to achieve this. It was also highlighted that the HSCIC had published information on the Data Access Request Service section of their website indicating that in November there would be a service level agreement with the CAG with associated timescales. Noting that this statement had not been agreed, this was flagged with Garry Coleman at the HSCIC to rectify.

HSCIC publication of information

Members were advised that it has been noted that the HSCIC had published information that had not been accurate as to the CAG new role under Schedule 7, 8(1)(c) of the Care Act 2014. Recent examples were the description of the Ethics and Confidentiality Committee and Data Monitoring sub-Group in the Partridge Review, discussions in the Health Select Committee and publication of information on their website e.g. the Data Access Request Service that sets out service level agreement and associated timescale with the CAG in November 2014. An addendum had been added to the Partridge Report that clarifies the roles at the time; the HRA wrote to the Health Select Committee to provide a formal note of the role of the HRA and the CAG and in terms of the website the inaccuracy has been formally flagged with the Head of Information Governance and Head of Data Management Services.

Applications considered via proportionate review

14/CAG/1014 Clinical presentation of enterovirus infection in children, and disease-causing enterovirus serotypes in the UK.

This research application from University Hospital Southampton NHS Foundation Trust was for a retrospective study of existing microbiological and clinical data to capture the spectrum of clinical presentation of enterovirus infections in children who have received care at the University Hospital Southampton (UHS) NHS Foundation Trust and describe any associations between enterovirus serotype and clinical presentation. The Applicant also sought to compare local serotype data with national serotype data provided by Public Health England.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source. Access was requested to hospital number, gender and clinical information. This application as reviewed by a Precedent Sub Group consisting of Dr Mark Taylor (Chair), Dr Murat Soncul and Ms Gillian Wells.

Confidentiality Advisory Group advice

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 consent would be feasible and queried why consent could not be sought, given the small cohort covering only a two year period. The Applicant responded that they considered that it was not appropriate to contact the parents of these children to obtain consent retrospectively. It was noted by the Applicant, having provided clinical care for several of those cases that whilst the majority of patients recovered fully, some children may have had a fatal outcome as a direct result of an enterovirus infection. The Applicant stated that it would not be in the best interest of those families to be contacted by the study team,

as this could bring back memories of a very traumatic period in their life and may cause significant emotional distress. Members accepted this explanation and recognised that it would be distressing for parents of deceased children to be contacted about this research.

Fair processing

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 queried what arrangements were in place to ensure that fair processing obligations were respected. The Applicant advised that due to the short-lasting nature of enterovirus infections, children with this infection would not receive ongoing healthcare. The Applicant was unable to identify any parental support groups or organisations that focus on enterovirus infections. Members acknowledged the lack of continuing contact with the parents and children and lack of any known support groups that would make it difficult for the Applicant to fulfil the fair processing obligations of the Data Protection Act 1998.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Favourable opinion from REC.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

14/CAG/1009 Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest

This research application from the University of Warwick set out the purpose of a trial to work out how safe and effective adrenaline is as a treatment for patients who suffer out of hospital cardiac arrest. Data in relation to 8,000 patients who had been treated for cardiac arrest was requested. All surviving patients would be invited to take part in the follow up and consent obtained to access data. A recommendation for class 1, 2, 4 and 6 support was requested to cover access to confidential patient information in order to identify patients to seek consent from and to access mortality, HES, ICNARC and NICOR data in relation to deceased patients.

Access was requested to Name, Address, Post Code, Date of Birth, NHS Number, gender in order to carry out linkages and seek consent. Date of death, Date of birth and gender would be retained for analysis purposes.

This application was considered by via the Precedent Set under criteria 1 and 2 – applications to identify a cohort of patients and subsequently seek consent and access to deceased person's data. The sub-group consisted of Dr Mark Taylor (Chair), Dr Murat Soncul and Ms Gillian Wells.

Confidentiality Advisory Group advice

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 agreed that consent would not be practicable at the time of the arrest and therefore consent would need to be obtained following the event. To be able to do this, it was agreed that it was reasonable for the research paramedic to access records of those who recently survived cardiac arrest. It was noted that identifiable data would be required in order to seek consent, determine who may have died prior to writing to patients who were discharged without consent and to link data in relation to deceased patients.

Members advised that the applicant should anonymise information in relation to patients who were deceased and had not provided consent as soon as possible once linkages had been undertaken. Members queried why it would be necessary to retain full date of birth and death following linkages.

Seeking consent following discharge from hospital

It was noted that the application specified that HES, Intensive Care National Audit and Research Centre (ICNARC) and National Institute for Cardiovascular Outcomes Research (NICOR) data would be sought where patients were written to for consent following discharge from hospital and did not respond. Concerns were raised that this could cause issues under the Data Protection Act 1998 (DPA). It was advised that where consent had been requested but not obtained further processing of personal data may contravene the DPA.

The applicant was advised to write to those patients who were discharged to inform them that their data would be used if they did not actively opt out and only seek consent for further participation in the questionnaire and active follow up aspects of the study. If consent was requested and no response was received for the use of data, the applicant was advised that they would be unable to access further information in relation to the patient after they have written to them to seek consent.

It was noted that this would only impact a small number of participants as the majority should be approached in hospital and therefore able to indicate whether they consent or not.

Patient right to objection

Members advised that the patient right to object to further use of their data should be made clear when the researcher first visited the patient after the arrest and again in the covering letter with the later questionnaire.

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.

Specific conditions of support

1. Confirmation of why it is necessary to retain full date of birth and date of death for analysis purposes.
2. Ensure that the patient right to object to use of their data is clear within all communication.
3. Confirmation of suitable security arrangements via IG Toolkit submission.

4. Confirmation of a favourable REC opinion.

CAG 6 (PS1)/2014 Towards and earlier diagnosis of Neuroendocrine Tumours (NETs)

This service evaluation application from Hampshire Hospitals NHS Foundation Trust set out the purpose of a service evaluation project which aimed to analyse and assess patients diagnosed with colorectal (and terminal illeal) NETs identified through the NHS Bowel Cancer Screening Programme (NHS BCSP).

A recommendation for class 5 and 6 support was requested to cover access to confidential patient information from the NHS BCSP in relation to all patients who had been identified with Colorectal carcinoid or Neuroendocrine Tumours. This information would then be used to trace patients care across NHS organisations and obtain information in relation to the care provided for CR NET to date.

Access was requested to NHS number, month and year of birth and part postcode to allow linkages to take place. This application was considered via the Precedent Set process under criteria 4; time limited access to undertake record linkage/validation and to pseudonymise the data. The application was considered by Professor Barry Evans, Dr Patrick Coyle (Chair of sub-group) and Ms Clare Sanderson.

Confidentiality Advisory Group advice

Public interest

Members agreed that the activity aims were in the public interest, noting that the tumours were rare and management of these could be improved.

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 consent would be feasible and agreed that the reasons asserted within the application for not seeking consent were valid. Members considered whether pseudonymised/anonymised data could be used and it was noted that identifiable data would be required in order to carry out linkages and that analysis would be undertaken using pseudonymised data only.

Security arrangements

Members requested further information in relation to the security arrangements in place for the transfer of data and queried what procedures would be followed in relation to this. In addition, members queried how many individuals would have access to the database containing identifiable patient information.

Mortality data

Members queried whether the applicant had considered whether mortality data would be of benefit; this could be obtained from the Health and Social Care Information Centre (HSCIC). However, it was recognised that this may require additional identifiers.

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.

Specific conditions of support

1. Confirmation of what arrangements would be in place to ensure the security of the transfer of confidential patient information.
2. Confirmation of how many individuals would have access to identifiable data.
3. Confirmation whether mortality data would be of benefit to the study and whether additional identifiers would be required to obtain this from the HSCIC or Trusts.
4. Confirmation of suitable security arrangements via IG Toolkit submission.

CAG 6 (PS2)/2014 National Community Child Health Database (NCCHD) Wales

This application from NHS Wales Informatics Service set out the purpose of the National Community Child Health Dataset for Wales (NCCHD), a definitive statistical database which provided NHS activity on children in Wales. The application included a list of key purposes of the database.

A recommendation for class 1, 5 and 6 support was requested to cover access to confidential patient information for the purposes of pseudonymising the data prior to inclusion in NCCHD. Access was requested to NHS Number of Mother/Child, Mother/Child Date of Birth, Sex, Ethnicity, and Postcode in order to derive anonymised record level data.

Following consideration at the April 2014 meeting it was advised that this application could be considered via a sub-group following the Precedent Set review process. The sub-group consisted of Dr Mark Taylor (Chair), Ms Gillian Wells, Dr Patrick Coyle and Dr Tony Calland.

Confidentiality Advisory Group advice

<u>Practicable alternatives</u>

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006. Members noted that the dataset would be derived from data within the Child Health system, which was used for direct health care purposes, and one of the main purposes was to monitor activity in Wales, regional and small area trends in relation to births, maternity services and immunisation uptake, and to support service planning and public health. The applicant detailed that seeking consent would result in an unacceptable risk to the near 100% coverage required for these purposes.

Members noted that data would be pseudonymised as soon as possible and prior to entry into NCCHD. The applicant confirmed that work was in progress towards the establishment of a local pseudonymisation process that would allow items such as postcode and date of birth to be anonymised by those responsible for respective Health Board controlled Child Health systems. Once established, it was hoped that the process would mean that there would be no disclosure of

confidential patient information outside the local systems and therefore no requirement for support under the Regulations.

Members agreed that this appeared to be a positive step and that it would be beneficial to ensure that CAG were kept appraised of progress in this area. Members requested that further information in relation to key milestones should be provided to ensure that updates were provided to CAG at relevant stages.

Patient involvement

It was confirmed that a member of the Community Health Councils would sit on the Child Health Service Management Board and a key patient representative would be identified to sit on the Board through Children in Wales. Members asked for confirmation of when the patient representative would be involved and advised that this was undertaken as soon as possible. Members also agreed that it would be important to ensure that the patient representative was in touch with patient related issues relevant to the application. Members requested further information in relation to the relationship between the Child Health Service Management Board and NCCHD.

Registering patient objection

It was noted that registering patient objection for the inclusion on the Child Health system would not be possible as this was used to provide direct care, however members queried whether patient objection could be registered and respected in relation to the secondary purposes. The applicant confirmed that there was a system in place that relied on local processes. However, work was underway towards a uniform process to manage objection via the Child Health systems. Members agreed that CAG should be kept informed of progress and requested information in relation to key milestone to ensure updates were provided to CAG at relevant stages.

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 and further clarifications as set out below.

Request for clarification

1. Confirmation of key milestones in relation to progress towards a local pseudonymised approach.
2. Confirmation of when the patient representative from Children in Wales would be invited to sit on the Child Health Service and Management Board.
3. Further information in relation to the relationship between the Child Health Service Management Board and NCCHD.
4. Confirmation of key milestones in relation to progress towards a uniform process to manage dissent via the Child Health systems.

Specific conditions of support

1. Confirmation of satisfactory security arrangements.

2. Once timescales are confirmed in line with points 1 and 4 above, appropriate dates for the provision of progress reports should be identified.

CAG 6(PS3)/2014 Survey of the experience of patients with Neuroendocrine cancers in active treatment in specialist hospital centres in England

This service evaluation application from Quality Health on behalf of the NET Patient Foundation set out the purpose of identifying patients how have undergone Neuroendocrine tumour (NET) cancer treatment to request they complete a patient survey regarding their experiences. The patient survey is designed to examine the care and treatment received by patients with a known diagnosis of neuroendocrine cancer, who are in active treatment at a specialist centre within the NHS for this purpose. The patient experience survey is designed to identify barriers to effective diagnosis and treatment that may exist and to measure the patients perceptions of quality of care. These issues are of particular importance for NET patients as informal evidence indicates that some patients have to present many times before their condition is diagnosed accurately and treatment started.

A recommendation for class 4, 5 and 6 support was requested to cover access to link identifiable data from more than one source and for auditing, monitoring and analysing patient care and treatment. This application as reviewed by a Precedent Sub Group consisting of Dr Mark Taylor (Chair), Professor Jennifer Kurinczuk and Ms Clare Sanderson.

Confidential patient information requested

Access was requested to Name, Address, Postcode, NHS Number, Sex, Ethnic Group, Year of Birth, Admission and Discharge Dates, Admission Type, Referring CCG and ICD10 code.

Confidentiality Advisory Group advice

Public interest

Members were content that there was a public interest in exploring patients' experiences of management of neuroendocrine cancer treatments.

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 agreed that it was not feasible to seek consent before the patient survey could be sent out and that to do so would raise further confidentiality issues.

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.

Fair processing should ensure that patients are informed of how their information will be used within the survey and to be able to accommodate requests not to be included in the survey. Members requested further information in relation to the fair processing arrangements for this application.

Justification of identifiers

The specified identifiers were felt to be justified however it was noted that the retention period for these was not clearly stated within the application. Members requested that the retention period and arrangements for the destruction of identifiers be advised by the Applicant.

Additional points

The Applicant was advised that support for this application only covers England and Wales and does not apply to other jurisdictions. Members noted that whilst the front page of the survey stated that completion the questionnaire was voluntary, they requested that this should be placed at an earlier and more prominent position.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed 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 and further clarifications as set out below.

Specific conditions of support

1. An overview of the appropriate methods for meeting the fair processing requirements to inform patients of the survey was requested.
2. The questionnaire should be amended to move references to completion of the questionnaire being voluntary up to a more prominent position on the front page.
3. Confirmation of suitable security arrangements via IG Toolkit submission.

Request for clarification

5. The retention period for identifiers and the process for the destruction/anonymisation of these identifiers was requested.

Amendments to approved applications

ECC 7-05(h)/2011 CRANE Database – Epidemiology Register

This application from the Royal College of Surgeons of England set out details of a register of birth and demographic data in relation to all children born in England, Wales and Northern Ireland with the congenital abnormality of clefting of the lip/and or palate. (please note the ECC can only provide recommendations for support in relation to English and Welsh data)

A recommendation for classes 4, 5 and 6 support was requested to provide a legitimate basis to access confidential patient information in order to eliminate duplicate records and to remind centres to obtain consent.

Confidential patient information requested

Access to hospital ID, NHS number, date of birth and date of death for all children born in England and Wales was requested.

The CRANE Database has two broad aims:

1. To register birth and demographic data related to all children born in England, Wales and Northern Ireland with the congenital abnormality of clefting of the lip and / or palate (Epidemiology Register – current application).
2. To record the treatment of children and adults with a cleft lip and / or palate and the outcome of such treatment (Treatment Outcomes Database – separate application).

Amendment request

It was proposed to increase the amount of notification information being collected regarding the 'first contact'. The full set of questions would be used to generate Key Performance Indicators (KPIs) around Specialist Support in the ante-natal period and after birth. The amendment request detailed that the applicant was currently unable to report these KPIs in a timely fashion because of the inherent time lag in gaining prospective consent described in the original application. By including the additional fields as part of the 'notification data', the Applicant would be better able to evaluate screening and diagnostic programmes and the performance of cleft teams in supporting newly diagnosed cases.

Confidentiality Advisory Group advice

This amendment was reviewed by the Vice Chair who noted that the additional information being requested would not increase the potential identifiability of the data presently being collected.

Confidentiality Advisory Group conclusion

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

PIAG 2-08(e)/2002 BINOCAR

The BINOCAR application from Queen Mary University of London (QMUL) has approval to collect identifiable data on all cases of congenital anomalies within the population of England and Wales. A number of regional and disease specific registers of congenital anomalies provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies. Confidential information including mother and baby name, address, postcode, NHS number, date of birth and baby date of death were collected from a number of NHS organisations and other outcome datasets.

Amendment request

This amendment request detailed accessing information from the Health and Social Care Information Centre (HSCIC) in order to verify and confirm correct demographic details were held by the BINOCAR registers. The data items that required verification are:

- NHS number
- Patient name
- Date of birth
- Multiplicity
- Date of death (if applicable)
- Gender

- Address

It was confirmed that the data items would be submitted to the HSCIC who would then send back any changes to data sent, any data items that were missing and date of death of infant. All data would be transferred in the most secure way, either by NHS.net, encrypted files or another secure method already used by the HSCIC.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who noted that the specified amendment would enhance the quality of the dataset and did not include a request for additional data items. It was recommended that the amendment request was supported.

PIAG 1-07(d)/2004 British Regional Heart Study (Men)

This application from UCL Medical School set out a study which aims to determine both established and new risk factors responsible for the considerable variation in ischaemic heart disease and stroke in Great Britain. It is also concerned with the effects of risk factor changes and their impact on CVD events. The present aim is to continue to collect CVD-related incident morbidity for prevention and the promotion of a disability-free life in older men aged over 65 years.

The study sought to trace and contact those patients lost to the original cohort of 7735 who agreed to take part in the original study, but who have since moved.

Amendment request

An amendment request was received which detailed accessing data in relation to the cohort from the Health and Social Care Information Centre. Hospital Episode Statistics, Mental Health Minimum Dataset and Diagnostic Imaging Dataset data was requested. Data in relation to cardiovascular disease, cancer, diabetes, disabilities, dementia, and hospitalisations was of particular interest. The applicant advised that they would be seeking to access the entire record from the HSCIC for the participants in question.

Confidentiality Advisory Group advice

<u>Managing data in relation to non-responders</u>

The amendment requested was forwarded to the Chair who requested that the Information Commissioner's Office representative, Mr David Evans, provide advice in relation to the access of data for those who were living and had not responded to requests for consent. The ICO advised that in these circumstances, where consent had been sought but not provided, it would not be compliant with the Data Protection Act to continue to collect further data. Further information in relation to this guidance is provided on the HRA website http://www.hra.nhs.uk/documents/2013/09/managing-non-response-guidance-v1-2.pdf.

Therefore, as the request would not be compliant with the DPA, it was advised that those 305 patients whose consent had been requested but not gained were not included within this amendment. The ICO took the view that consent could be requested one further time from this sub-set, but that no further processing should take place without this consent.

It was advised that the applicant ensure that only the minimum amount of data required should be requested from the HSCIC and that data in relation to conditions that were not of interest should not be retained for any longer than necessary.

Extent of data requested

The Chair noted the request for the complete record and queried how this would be ensured and that all data requested was fully justified, particularly in relation to mental health data, which might be considered particularly sensitive.

The Chair advised that the request to access HES and MHMDS data could be supported but referred the request for MHMDS data to the July CAG meeting.

Specific conditions of support

1. The amendment request is not supported for the 305 non-responders.
2. Please confirm how it will be ensured that the requirements of the Data Protection Act are met in relation to ensuring that the data requested from HES and DID is not excessive and kept for no longer than is necessary.

Please provide further information in line with the conditions of approval above. Once received, final approval for this amendment can be issued.

PIAG 2-10(g)/2005 National Gestational Age Statistics

This application from City University set out the purpose of a project to acquire data from NHS Numbers for Babies (NN4B) notifications to produce national statistics about gestational age at birth and gestation-specific survival of babies born in 2005 and subsequent years, and to provide information about how the data provided by maternity units for the NHS Numbers for Babies notifications relate to those from birth registration and from the Maternity Hospital Episode Statistics in terms of numbers of events and consistency of common data items. This was a collaborative project between Child Health Statistics, Maternity Hospital Episode Statistics, Health Statistics and Analysis Unit, National Child Health, Department of Midwifery (City University), Confidential Enquiry into Maternal and Child Health, Regional Maternity Survey Office and the British Association of Perinatal Medicine. A recommendation for class 3, 4, 5 and 6 support was requested to cover access to birth registration data. Access was requested to baby's NHS number, mother's NHS number and postcode.

Amendment request

This amendment request detailed accessing Hospital Episode Statistics records from 2005 to 2014 from the Health and Social Care Information Centre (HSCIC). Currently, ONS provided patient identifiers from the linked birth registration- NHS Numbers for Babies (NN4B) files to HSCIC to carry out the further linkage to HES. In the previous stage of this linkage, covering data for the years 2005 to 2007, HSCIC sent to ONS only the HES records that could be linked to the file of identifiers and achieved a 91 per cent linkage rate. The amendment requested access to the unlinked HES records, with the aim of improving the linkage rate.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Vice-Chair who agreed that the amendment did not raise any further issues or seek to extend the data requested beyond what was already approved

for the linked HES data. The Vice-Chair agreed that the minimum threshold of the Regulations appeared to have been met and recommended support for the amendment.

Updates on existing applications

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

This commissioning application from NHS England was originally considered in October 2013, with the most recent update report considered in May 2014. In order to take into account the Secretary of State for Health condition of approval requirement that the applicants return to the **CAG meeting in August 2014, the approval expiry date had been extended to 12 September 2014 to enable support to continue pending consideration at the August meeting.**

CAG 7-07 (b)/2013 Invoice validation within Clinical Commissioning Groups (CCGs) controlled environment for Finance

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

NHS England sought clarification on this approved application on 23 July 2014 on the following aspect:

1. In order to validate invoices, some Clinical Commissioning Groups (CCGs) had split the function between a Controlled Environment for Finance (CEfF) within the CCG and a CEfF within the Commissioning Support Unit (CSU).
2. The second issue related to the co-ordination of functions between CCGs and set out details of the intent of some CCGs to cooperate on the validation of invoices.

Following review by the Chair and alternate vice-chair (Ms Gillian Wells) and office, it was agreed that the letter made explicit that the arrangements specified would not increase the disclosure of personal confidential data nor result in duplicate data flows, and that in each environment the controls that are required of any CEfF would apply, nor would any organisations not covered by the support have access to data they should not process. It was agreed that this clarification request was within the scope of the existing approval and no objections were raised to this activity proceeding.

CAG 1-06(a)/2014 Extraction, linkage and anonymisation of Islington GP data to hospital admission data.

This non research application from the London Borough of Islington, originally considered at the April 2014 CAG meeting, had set out details of the creation of an anonymised dataset linking Islington GP data, hospital admissions data and demographic data to enable public health (population-level) analysis. Following recommendation by the CAG, it had not received support on the basis that a practicable alternative utilising pseudonymised data could be a viable option to seeking support.

Members had assessed the approach that information would be extracted from GP systems by EMIS and the output supplied to the North East London Commissioning Support Unit (CSU) as a Stage 1 Accredited Safe Haven to carry out the linkages. The longer term solution would be to work with the Health & Social Care Information Centre (HSCIC) to identify whether they could use

their existing statutory powers to carry out this activity, and support had been sought while this was explored. Members were therefore of the view that there was insufficient evidence presented to satisfy the threshold requirement that there is no other practicable alternative. Positive engagement with the feasibility of pseudonymisation at source with the relevant suppliers had been advised, with specific information on the costs and technical challenges if not provided to be feasible. Further information was also sought on the engagement with the HSCIC as if they could carry this out under their statutory powers this would also represent a practicable alternative; timescales and progress on this aspect should be evidenced.

The Confidentiality Advice Team was informed on 01 August 2014 that the applicants had engaged with EMIS and the CSU and had identified a mechanism to pseudonymise data at source before linking as per the advice from CAG. It was also advised that they would be updating their patient information leaflets so they are clearer about how patient data will be used.
As it was confirmed that there would be no disclosure of identifiable data to the applicant due to the alternative methodology, a resubmitted application would not be pursued.

ECC 5-05 (f)/2012 MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP). Response to deferral of analysis of perinatal mortality surveillance data.

This non-research amendment request from the National Perinatal Epidemiology Unit at the University of Oxford was considered by the CAG at its July 2014 meeting. The first aspect, the sending of specific identifiers to the applicant about sampled women for the purpose of the post-partum psychosis topic case identification, by the Health & Social Care Information Centre, was approved following a positive CAG recommendation. The second aspect, involving the transfer of identifiable information for the purposes of analysis to the Leicester office, had been deferred as insufficient justification had been provided to allow a recommendation to be made. The applicant responses were considered by the original lead reviewers; Dr Mark Taylor, Dr Tony Calland, Professor Julia Hippisley-Cox and Dr Miranda Wolpert.

The response letter set out further justification including further detail on the security arrangements, the specialised nature of the team and clarity on previous access. The review group agreed that the responses were reasonable and based on this further justification, agreed to provide a positive recommendation to the Secretary of State for Health in relation to this aspect of the amendment with no additional conditions. The amendment reported in June 2014 has now received full approval to proceed in terms of support under the Health Service (Control of Patient Information) Regulations 2002.

CAG 1-06(b)/2014 Patient characteristics associated with high use of A&E in Lambeth

This application from King's College London set out the purpose of an activity to examine whether socio-demographic factors such as deprivation, ethnicity and population morbidity and mortality are associated with high use of A&E. The data would be used to help those commissioning and delivering services to engage with communities to design better and more cost effective service to suit patient needs.

A recommendation for class 4 and 6 support was requested to cover access to GP data including NHS number to link to Lambeth Datanet clinical data, annual GP consultation rate and HES data in relation to A&E attendances. The Clinical Data Linkage Service (CDLS) at the South London and Maudsley (SlaM) NHS Trust would carry out linkages. Access to NHS number was required in order to carry out linkages.

When this application was considered at the CAG meeting in April members discussed whether a methodology could be utilised whereby only pseudonymised data would be disclosed with clear data sharing agreements in place with GP practices and with the HSCIC which restricted the use of and controls placed around the pseudonymised data to ensure that data could not be re-identified. Members agreed that this approach would not require confidential patient information and presented a practicable alternative.

The applicant resubmitted the application in June 2014 and it was confirmed that a psudonymised approach to data linkage would be used. This was reviewed by Dr Tony Calland, Professor Julia Hippisley-Cox and Dr Mark Taylor As it was confirmed that there would be no disclosure of identifiable data to the applicant due to the alternative methodology; the applicant was informed that a resubmission would not be advised. Members advised that the applicant should ensure that the security safeguards in place should be equivalent to that applied to identifiable data given the rich dataset.

9. ANY OTHER BUSINESS

There was no other business.