NHS
Health Research Authority
Confidentiality Advisory Group

**Minutes of the meeting of the Confidentiality Advisory Group**

**10 April 2014 at 09:30 at Skipton House, SE1 6LH**

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**Present:**

| Name | Capacity |
|---|---|
| Dr Mark Taylor (Chair) | Lay |
| Dr Kambiz Boomla | |
| Dr Patrick Coyle (Vice Chair) | |
| Dr Robert Carr (items 1 - 5b and 7b) | |
| Dr Tony Calland MBE (Vice Chair) | |
| Mr Anthony Kane | Lay |
| Mr C Marc Taylor | |
| Ms Clare Sanderson | |
| Ms Gillian Wells (Alternative Vice Chair) | Lay |
| Professor Julia Hippisley-Cox | |
| Professor Jennifer Kurinczuk | |
| Dr Murat Soncul | |
| Professor Barry Evans | |
| Professor Ann Jacoby | |
| Dr Miranda Wolpert | |
| Mrs Hannah Chambers (items 1- 6d and 7b) | Lay |

**Also in attendance:**

| Name | Position (or reason for attending) |
|---|---|
| Ms Natasha Dunkley | Confidentiality Advice Manager, HRA |
| Ms Claire Edgeworth | Deputy Confidentiality Advice Manager, HRA |
| Mr John Robinson | Confidentiality Advisor, HRA |
| Mr Stephen Robinson | Corporate Secretary, HRA (items 5b, 7a and c) |
| Mr David Evans | Expert advisor – Data Protection, Information Commissioner's Office |
| Tamatha Webster | Research and Survey Officer (item 5a) |
| Paul Williamson | CQC User Voice Development Manager (item 5a) |
| Chris Graham | Picker Co-ordination Centre (item 5a) |

## 1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

### Welcome

The Chair welcomed Professor Ann Jacoby, Professor Barry Evans, Dr Miranda Wolpert and Mrs Hannah Chambers to the Group as new members. Members introduced themselves and provided some information in relation to their professional background and interests.

New members queried how expert, lay and lay plus members were identified and it was agreed that the policy in relation to this would be circulated.

**Action: CAT to circulate HRA definitions on lay & expert to new members**

Mr Stephen Robinson attended for item 5b and 7a and c in his capacity of approver for HRA research applications.

### Apologies

There were no apologies.

### Christopher Wiltsher

The Group expressed their sympathy to the family of Christopher Wiltsher, a former CAG member, who had recently passed away. Members agreed that Chris had made an invaluable contribution to CAG and his remarkable insight, warmth and generous nature would be remembered.

### Vice-Chair and alternate vice-Chair

The Chair informed members that interviews to appoint a Vice-Chair and alternate Vice-Chair had taken place and the decision to appoint two Vice-Chairs, Dr Tony Calland and Dr Patrick Coyle, had been made. Ms Gillian Wells had been made alternate Vice-Chair. The Chair thanked the new officers and informed the Group that each brought a different strength and perspective to the role and would support the work of the Chair as the future role of CAG was developed.

### Care Bill and role of CAG

Members were informed that the details of the increased remit of CAG following the provisions in the Care Bill to put CAG on a statutory footing were still being worked through in detail and that the Group would be kept informed of any developments as soon as possible.

### Declaration of interests

The following interests were declared:

- Dr Murat Soncul did not receive the application papers for item 6b and left the room during the discussion of this item.
- Dr Miranda Wolpert advised that she is a member of the Children's and Young People's Outcome Forum and did not contribute to the discussions of items 4a and 5a.
- Professor Julia Hippisley-Cox did not receive CPRD papers and left the room for items 6a and 6b in order to avoid any perception of a competing interest given her role with QResearch.

## 2. MINUTES OF THE MEETING HELD ON 6 MARCH 2014

The minutes were corrected on page three, final sentence of the first paragraph to state that care should be taken to ensure that CAG was not duplicating the requirements of the existing formal incident reporting processes.

Other than the change outlined above, the minutes were agreed as an accurate reflection of the discussion.

The following updates were provided in relation to the minutes of the meeting on 6 March 2014.

**ECC 6-02(FT16)/2012 – CQC 2013 Maternity Survey – security breach item in the October 2013 meeting minutes**

Ms Claire Edgeworth circulated the Health and Social Care Information Centre guidance on Serious Incident Requiring Investigation (SIRI) to Members. Members requested a copy of the internet link to the document.

Members noted that the document could be referred to in order to inform applicants of the correct process when security breaches had taken place.

**Action: Circulate HSCIC SIRI document link to members**

**National audits**

HSCIC existing audits

The Health and Social Care Information Centre had sought a six to nine month extension to respond to the letter from Ms Stanbrook. Following discussion with the SofS approver, it was agreed that the HSCIC would be contacted to explain in writing the steps involved to justify the duration extension.

**Action: CAT to contact HSCIC to seek further clarification on the steps to be taken & timescales in obtaining Directions and contractual changes required**

Automated data extraction from GP practices

Ms Claire Edgeworth confirmed that a letter would be sent to the HSCIC in order to request a meeting with members to discuss automated data extraction from GP practices.

**Themes from CAG Away Day November 2013**

It was noted that comments had been received from Members in relation to four papers circulated following the November away day. These papers included guidance in relation to demonstrating an equivalent duty of confidentiality, patient and public involvement and different approaches to consent and informing patients for audit activities.

## 3. OFFICE REPORT AND MATTERS ARISING

**For information**

Secretary of State approval decisions

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

HRA approval decisions

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

**Principle of access to patient confidential information as part of student Doctors additional studies**

Further to a Proportionate Review application in March 2014, a the Doctor on rotation across several Trusts, and wished to extract anonymised data during their rotation as part of their PhD. Members discussed whether the Doctor completing further studies could be seen to have legitimate access to patient's confidential patient information for study purposes.

Members noted that where a Doctor is accessing CPI *for their additional studies* rather than as part of their training to become a Doctor and consent will not be sought then a legal basis would be required to perform such extractions.

NIGB Ethics and Confidentiality Committee had previously issued guidance (see meeting minutes 29 March 2011):

Policy on medical students

Members were provided with a paper outlining a proposed position with regard to medical students undertaking studies as part of their training and the requirement for section 251 in these situations. Members agreed that medical students were by definition, doctors in training and that learning a complex job required all main parts of that job to be studied and practised. One aspect of this was working with confidential information and the laws and guidance which govern disclosure of that information. The Committee also discussed that the British Medical Association regarded students to be part of the medical team and that the General Medical Council could hold them accountable for their actions.

It was noted that arranging for students to take part in research or audit projects was common and encouraged by senior clinicians, universities and professional bodies. Additionally the Committee recognised that the number of medical students within the UK had sharply increased in the last decade and that a large number of these would already be involved in various audits within general or hospital practices being commonly regarded as a members of the clinical care team.

When students undertook audits they would be under the supervision of the clinician in charge and therefore it was discussed that they would remain fully responsible and should ensure that law and guidance in relation to confidentiality was followed.

The Committee agreed that:

1. That medical students attached to a senior clinician (consultant or general practitioner) should be considered part of the clinical care team when contributing to audit or research.
2. That the senior clinician would remain responsible for both the research or audit and the handling of confidential information in medical records.
3. That it would not be necessary for an application for section 251 support in these situations.

Members were advised that where a member of medical staff wishes to access confidential patient information from within their service as part of a 'out of programme' specialty training (if they were to complete a PhD for example) then seeking support may be suggested to potential applicants. This is because work on PhD is considered to be outside of specialty training programmes and as such the access they have to such data may be suspended whilst they are working on such 'out of programme' activities. It was noted that Deaneries are responsible for

determining whether a PhD constitutes being part of specialty training based on the Gold Book, which is a joint publication by the GMC and Health Education England.

## Applications considered via proportionate review

### CAG 1-03(PR1)/2014 British Childhood Cancer Survivor Study Case-Control Studies (v1.0)

This research application from the University of Birmingham set out the purpose of establishing case-control studies as an extension of the British Childhood Cancer Survivor Study (BCCSS) cohort (Ref: ECC 2-02(f)/2011 - 13/04/2011). The BCCSS is a long-term follow-up (i.e. cohort) study of adult survivors of childhood cancer. The nested case-control studies will focus on the risks of adverse health outcomes, including, but not limited to, cardiac disease, cerebrovascular disease, and subsequent primary neoplasms after childhood cancer and quantify the extent to which these risks are related to previous radiotherapy and chemotherapy given to treat childhood cancer. Approximately 50-70% of all cases and 15-20% of all controls included in the case-control studies are deceased. Medical records of deceased cases and controls would be accessed without consent and consent would not be sought from a legal representative. This submission has been recognised under Proportionate Review Criteria 2 - access to deceased patient data. The application was reviewed by Dr Mark Taylor (Chair), Dr Patrick Coyle and Professor Jennifer Kurinczuk.

A recommendation for class 6 support was requested to allow access to the deceased patient data.

Access was requested to full name, NHS number, Hospital ID, GP Registration, Date of Birth, Date of Death and Postcode and clinical information.

### Confidentiality Advisory Group advice

Members recognised that there is a high public interest in knowing the long-term sequelae of treatment of childhood cancer treatment for both the management of those patients and understanding the long-term consequences for healthcare services.

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 support is only being requested for deceased patients and controls and were unable to suggest an alternative to the unconsented use of identifiers that are necessary for data linkage. It was noted that the details required, particularly treatment information, would only be available from hospital and primary care notes rather than national databases.

Members agreed that it would be unreasonable to contact the living relatives of the deceased patients. It was noted that living patients will be consented.

Members noted that the identifiers requested seem appropriate for linkage directly with hospital and primary care notes.

The applicant provided reassurance to Members regarding erasing photographs securely from the camera's SD card prior leaving the hospital. Members noted that the research protocol included an assurance regarding the encryption of photographs on the laptop and securely erasure from the laptop once the photographs are transferred to the researcher's private network.

Members accepted the justification for retaining identifiers of deceased patients until the end of the study, due to the linkage that will be performed across multiple sites. The applicant confirmed that once the linkage has been completed, data will be deidentifed prior to analysis.

**CAG advice conclusion**

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised the Health Research Authority to provide a recommendation of provisional support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

As the application scope covered information generated in both England and Wales a joint approval decision would be required from the Health Research Authority (England) and the Secretary of State for Health (Wales). CAG advice would be provided to the HRA who would provide a recommendation to the SofS in relation to Welsh data.

**Health Research Authority recommendation**

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

**Specific conditions of support**

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

**CAG 1-03(PR2)/2014 National Child Development Study The 1958 British Birth Cohort Study**

This research application was for the National Child Development Study (NCDS), the second of Britain's world renowned national longitudinal birth cohort studies. It follows all those born in one week in 1958 through the course of their lives, charting the effects of experiences in early life on outcomes and achievements later on. Since 1958 information has been gathered from the cohort on eight occasions. Over time, the scope of enquiry has broadened from a strictly medical focus at birth, to encompass physical and educational development at the age of seven, physical, educational and social development at the ages of eleven and sixteen, and then to include economic development and other wider factors at ages 23, 33, 42, 46 and 50. The age 55 study is currently in the field. Future sweeps of the study are planned to take place every five years.

The ongoing success of the study depends on maintaining contact with as many study members as possible. Support is requested for two activities which will support this endeavour:

1. To supply the HSCIC with lists of 'untraced' cohort members in order that they can be matched with GP registrations and new addresses supplied. These matched individuals will be contacted and invited to continue participating in the study.
2. To continue to receive notifications from the HSCIC of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS which are used for both tracing and research purposes.

This application was considered via the proportionate review process under criteria 1 and 2 – patient recruitment and access to deceased patient data. The application as reviewed by Dr Mark Taylor (Chair), Mr Anthony Kane and Ms Clare Sanderson.

Access was requested to Name, NHS Number, date of birth, full address, postcode, date of death and cause of death.

**Confidentiality Advisory Group advice**

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

The Applicant confirmed that anonymised data will be provided to researchers under strict controls.

Members were content that the identifiers were required the specified purposes.

Members noted that the Applicant had specified that identifiable data would be retained for 10,000 years and stated that this should be reduced to 100 years subject to regular review.

Members requested that participants be advised that the Centre for Longitudinal Studies will be receiving notifications from the HSCIC and are given the opportunity to dissent, within future study dissemination.

**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 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.

As the application scope covered information generated in both England and Wales a joint approval decision would be required from the Health Research Authority (England) and the Secretary of State for Health (Wales). CAG advice would be provided to the HRA who would provide a recommendation to the SofS in relation to Welsh data.

**Health Research Authority recommendation**

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

**Specific conditions of support**

1. The retention period of identifiable data be reduced to 100 years.
2. Confirmation of suitable security arrangements via IG Toolkit submission.

**CAG 1-03(PR3)/2014 Longitudinal Study of Young People in England (LSYPE)**

This research application from Centre for Longitudinal Studies at the Institute for Education, University of London, set out the purpose of a longitudinal study, previously managed and funded by the Department of Education (DfE) from 2004 until 2012. In 2013, the Economic and Social Research Council (ESRC) took over the funding of the study and management transferred to the Centre for Longitudinal Studies (CLS).

The aim of the study is to examine how health, wealth, education, employment and attitudes are linked, how they change over time and how they can vary between different people, at different points in time.

A recommendation for class 2, 3, 4 and 6 support was requested to cover access to:

1. GP registrations and addresses from the Health and Social Care Information Centre (HSCIC) so that individuals could be contacted and invited to continue participating in the study.
2. Notification from the HSCIC of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS.

The application as reviewed by Dr Mark Taylor (Chair), Dr Kambiz Boomla and Dr Christopher Wiltsher.

Access was requested to name, address and date of death.

**Confidentiality Advisory Group advice**

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.

It was noted that individuals had previously provided consent to be part of the cohort. Members noted that it would not be possible to obtain future consent from this cohort without obtaining up to date contact details and distinguishing those who had died or left the NHS. Members therefore agreed that the request to access the data in order to seek consent was appropriate and that there appeared to be no practicable alternative.

Members noted that the final version of leaflets that would be sent to the cohort were not yet available and requested that final versions be submitted prior to final approval being given. Members advised that the applicant should ensure that any patient information materials included details of the collection of data from the Health and Social Care Information Centre (HSCIC) so that the cohort were fully informed about the potential uses of their data.

It was noted that identifiers were confined to address details necessary to write to individuals, and the fact of death or embarkation to avoid writing to those whom it is unnecessary or where it might cause distress.

**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 the application was in the public interest, 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.

**CAG 1-03(PR4)/2014 Retrospective cohort study of management and outcomes of MDR TB**

This research application from St George's, University of London set out the purpose of accessing identifiable data relating to Multidrug resistant Tuberculosis (MDRTB) on site to be anonymised for use within the project.

In this study the applicant aims to document the current treatment practices and outcomes in certain NHS sites in England for treatment of MDR TB. Information regarding, risk factors for poor outcome, adherence to treatment, management practices, side effects of medications, delays to discharge and costs of treating patients for MDR TB will be collected. The data will be used to document and compare treatment across the sites studied with the aim to improve care at each of the sites. There is currently very limited data available in England (collected for public health) regarding management practices and detailed outcomes for MDR TB treatment in this country. No information on patient monitoring, side effects and management, hospitalisation, adherence or microbiological outcomes is currently available in England. Information is required to enable physicians to assess the impact of their management and compare and learn from best practice and improve outcomes.

During collection of data the chief investigator will not collect any patient identifying data and the notes will be read on the NHS site and clinic that they belong to. The only data to be transferred will be radiography tests which will be anonymised and sent by regulated NHS routes (image exchange portal, IEP) or CD. These will be reviewed already anonymised by an independent radiologist. The site specific physician will hold a log of all patients' names and hospital numbers' in the study from his own site and this log will be kept on an NHS password protected secure computer.

Patients treated for MDR TB from 2008 onwards over the age of 10 years will be included in the study. The applicant feels it is important to include older children in the study because treatment is often taken from what is happening in adults and may not be effective or have as good outcomes and they would like to improve care in this area.

A recommendation for class 1, 5, 6 support is being requested to allow the applicant to extract anonymised data on-site regarding management practices and detailed outcomes for MDR TB treatment in England. This application was considered via the proportionate review process under criteria 3 - access to data on-site to extract anonymised or effectively pseudonymised data. The application was reviewed by Dr Mark Taylor (Chair), Dr Patrick Coyle and Dr Christopher Wiltsher.

Access was requested to hospital number and clinical information.

**Confidentiality Advisory Group advice**

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 were unable to identify other practicable alternatives to the approach proposed by the applicant.

Members acknowledged that it would be very difficult to approach the patients for consent as it was noted that many are immigrants who will have been lost to follow up and may have left the country.

It was noted that data would be fully de-identified once it had been extracted and that therefore no identifiable data would be retained.

Members suggested that the applicant give further thought to how they could ensure this data is being fairly processed.

**Confidentiality Advisory Group advice conclusion**

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

**Specific conditions of support**

1. Evidence of further consideration/demonstration that the principle of fair processing has been respected in relation to how patients are informed about the use of their records in such projects.
2. Favourable opinion from REC.
3. Confirmation of suitable security arrangements for each site via IG Toolkit submission.

**Amendments to approved applications**

**ECC 5-05(b)/2012 Life Study**

This research application from University College London detailed a birth cohort study that aimed to track the growth, development, health, wellbeing and social circumstances of over 100,000 babies. The application detailed two different components; maternity and national.

With respect to the maternity component, a recommendation for class 2, 3 and 4 support was requested to enable confidential patient information to be sent to the Health and Social Care

Information Centre (HSCIC) from maternity units, who would then write to pregnant women to invite them to an appointment. The invitation letter would include a covering letter from the NHS obstetrician from the maternity unit. Consent would be taken at the appointment for further inclusion into the study. Support was also requested to allow the retention of dates of birth, ethnicity and deprivation score for those who did not respond to invitations in order to analyse demographics of non-responders. These would be retained until response rates and characteristics had been calculated.

The national component of the study detailed recruiting women via the HSCIC using NHS central register data. The HSCIC would identify women who met the inclusion criteria and would send invitations on behalf of the researcher.

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

**Amendment request**

An amendment request was submitted on 31 January 2014 which detailed that recruitment for the maternity component (now renamed the pregnancy group) would now be undertaken by research midwives who would approach women within the maternity unit to invite them to attend a Life Study appointment. It was confirmed that the research midwives would split their time between clinical and research duties and would therefore be considered part of the clinical care team.

**Confidentiality Advisory Group advice**

The amendment requested was forwarded to CAG members who agreed that the change would mean that support would not be required for the initial recruitment of the pregnancy group as there would be no disclosure of confidential patient information outside the clinical care team.

It was noted that support would be required for later stages of the study which involved accessing data in relation to the eligible cohort, including those who did not attend an appointment. Members were advised that this aspect would be subject to a future amendment and noted that advice would be sought from the Information Commissioner's Office in relation to accessing data where a patient had chosen not to attend a Life Study appointment. Members advised that the applicant should ensure that potential participants were made aware of the uses of their data at recruitment, even if they chose not to partake in Life Study, and given an opportunity to object to any future uses of their data.

## Central Register class support applications

These are historical, pre-existing approved applications which have previously fallen within the NHS Central Register application (ECC 2-04(c)/2010) and now submitted on an individual basis. This is because the overarching NHS Central Register application is no longer required by the HSCIC following powers provided to them within the Health and Social Care Act 2012. These applications are considered by proportionate review by the Confidentiality Advice Team, following agreement from the Confidentiality Advisory Group, under criteria 15 – access to mortality, cancer or GP registration data from the NHS Central Register - class support study. The application was reviewed by Mark Taylor (Chair), Tricia Cresswell and Patrick Coyle.

**CR9/2014 Transfusion Medicine Epidemiology Review**

This surveillance application from the National CJD Research & Surveillance Unit (NCJDRSU) set out the purpose of an activity to determine whether CJD was transmissible through blood transfusion.

A recommendation for support was requested to cover access to mortality data from the NHS Central Register, maintained by the Data Linkage and Extract Service (DLES) at the Health and Social Care Information Centre. A cohort of 4,800 patients was flagged at the DLES.

It was advised that support could also be provided to give a legal basis for the disclosure of data from NCJDRSU to UK Blood Service in relation to patients with definite or probable CJD and UK Blood Services to NCJDRSU in relation to recipients of blood donations from these patients.

Confidential patient information including name, date of birth, address and postcode was requested.

**Confidentiality Advisory Group advice**

Members agreed that this activity appeared to be public health surveillance and agreed that there was a substantial public interest for this data transfer to continue.

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.

It was noted that it would be important for the purposes of the activity to ensure that as close to 100% ascertainment as possible was achieved. Members considered whether anonymised data could be used to fulfil these purposes and noted that the identifiable data items requested would be required for linkage of UK Blood and NCJDRSU data.

Members noted that a REC opinion had been submitted in support of the application but that, following checks carried out by NRES colleagues within the HRA, this had not been located as a current REC approval. Further confirmation in relation to the REC opinion was requested and the applicant was asked to contact the NRES committee responsible for the approval for confirmation that the opinion was still current.

**Confidentiality Advisory Group advice conclusion**

As the application scope covered information generated in both England and Wales a joint approval decision would be required from the Health Research Authority (England) and the Secretary of State for Health (Wales). CAG advice would be provided to the HRA who would provide a recommendation to the SofS in relation to Welsh data.

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

**Health Research Authority recommendation**

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

**Specific conditions of support**

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. Please provide confirmation from NRES that current Research Ethics Committee approval is in place or is not required.

**CR13/2014 Haemostatic Factors of Coronary Heart Disease**

This research application from the Royal Free & University College Medical School set out a long term prospective study aimed at improving the identification of men at high risk for heart attack.

A recommendation for class support was requested to cover access to mortality data from the NHS Central Register, maintained by the Data Linkage and Extract Service (DLES) at the Health and Social Care Information Centre. A cohort of 3,052 patients was flagged at the HSCIC.

**Confidentiality Advice Team advice**

The Confidentiality Advice Team 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.

It was noted that identifiable data was currently held by the applicant with consent and support was requested to obtain mortality data from the HSCIC only.

Identifiable data was held by the applicant with consent, support was requested to obtain mortality data from the HSCIC only. It was confirmed that it would not be possible to remove all identifiable data in relation to participants as information in relation to diabetes and non-fatal myocardial infarction was requested and future linkages to MINAP or hospital admissions may occur. It was advised that this recommendation of support did not cover access to future linkages other than to HSCIC mortality data and a further application should be submitted if support was required for any additional linkages.

It is a requirement of all applications that data processing is not inconsistent with the Data Protection Act 1998. The first principle requires that reasonable efforts are made to inform data subjects of the uses of their data. In line with this, it was advised that continued reasonable efforts were made to inform participants that information in relation to mortality would be accessed from the HSCIC, for example including this information on relevant websites.

It was advised that NRES confirmed that they do not have a record of the application and as such the approval may have elapsed. Confirmation from NRES that the approval remains valid was requested prior to final confirmation of support.

**Confidentiality Advisory Team advice conclusion**

As the application scope covered information generated in both England and Wales a joint approval decision would be required from the Health Research Authority (England) and the Secretary of State for Health (Wales). CAG advice would be provided to the HRA who would provide a recommendation to the SofS in relation to Welsh data.

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

**Health Research Authority recommendation**

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

**Specific conditions of support**

1. Confirmation of suitable security arrangements via IG Toolkit submission.
2. Confirmation of favourable REC opinion in line with comments above.

3. Reasonable efforts to inform patients of ongoing data collection should be made in line with the requirements of the Data Protection Act.

## Matters Arising

### Major Internet Security Threat – the 'Heartbleed' exploit

Members queried whether the NHS Mail web interface which utilises SSL security measures had been tested to determine whether it was affected by the security exploit referred to as "Heartbleed".

### Publication of applications and outcome letters

Natasha Dunkley provided an update against progression of the expressed member wish for greater transparency of application details. It was confirmed that the preferred position of CAG is that applications and outcome letters should be published by the applicant , excluding those aspects that would be exempt from disclosure under the Freedom of Information Act 2000 with exemptions to be determined by the applicant.

The HRA had expressed that they agreed in principle to this requirement, subject to consideration of the potential impact on applicants. The Secretary of State representative asked that consideration be given to how this could be made proportionate to the type of activity being conducted.

It was confirmed that draft wording of this requirement would be discussed with the SofS representative and the Department of Health to ensure alignment, with a view to incorporating within the standard conditions of support.

It was confirmed that it would be the responsibility of the Data Controller and/or sponsoring organisation to assist individuals seeking copies of applications rather than CAG.

**Action: Suggested text to be provided to the SofS representative for review**

### Annual Reviews

Natasha Dunkley advised that in light of comments from the SofS approver and member feedback that it would be timely to review the annual review process and documentation to ensure that it was suitably robust. Volunteers to assist with this were requested and Mr Anthony Kane, Professor Julia Hippisley-Cox, Murat Soncul and Ms Clare Sanderson agreed to contribute to the review. Mr C Marc Taylor stated it would be helpful to the Sub Group to agree which types of data breaches should require the Groups consideration when reported as part of an Annual Review.

**Action: CAT and nominated members to undertake review of current annual review requirements (in line with SofS and previous CAG comments). Schedule meeting with members to discuss & refine with output to return to CAG meeting.**

### Contents of applications

Members queried whether it would be possible to ask applicants to submit a contents table with applications to ensure that documents were labelled and ordered correctly.

**Action: CAT to consider possibility if requesting a contents table from applicants.**

### Distribution of meeting papers

Members were advised that in accordance with forthcoming changes to the Standard Operating Procedures, in future all Members attending meetings will receive a copies of all applications. Lead and secondary reviewers will continue to be allocated.

The Group were advised that application documentation should be retained in accordance with guidance from the HRA.

**Action: CAT to clarify the HRA policy on retention of application documentation**

**HSCIC pseudonymisation review**

Professor Julia Hippisley-Cox informed members that the HSCIC were establishing a Pseudonymisation Steering Group as part of the next stage of the review. Professor Hippisley-Cox had been asked to be a member of the group in order to represent EMIS NUG and queried whether CAG should request to be represented on the group. Members agreed that CAG would have a clear interest in the outcome of the review but that it was important to retain CAG independence at this stage given the potential role in advising the HSCIC in future. The Chair requested further information in relation to the terms of reference of the Group and suggested that at this stage CAG discuss with the HSCIC the most appropriate way to engage with the work, which might be adopting an observer status at meetings.

## 4. ITEMS FOR CONSIDERATION

### a. National Community Child Health Database [CAG 1-04(a)/2014]

The NCCHD is a statistical database which provides NHS activity on children in Wales, and is used as a resource to support the NHS in Wales, the NHS Wales Department of the Welsh Assembly Government and other government departments. The dataset fulfils a variety of purposes, including provision of maternal and child health information, provision of immunisation information, production of analyses to support epidemiology and performance management, supporting the development and evaluation of governmental policies, and provision of extracts and analyses to support research.

**Background**

Following a request for further information from the Ethics and Confidentiality Committee, a further information had been requested by the Confidentiality Advice Team in order to ensure that support was in place for the activity. The following information was requested:

- Confirmation that the requirements of the Data Protection Act were being met as it appeared that people are not informed that these data are being held, nor provided with information on how they are being used, or that data subject rights are all being met.
- Identification of a suitable exit strategy from support under the Regulations.
- Confirmation of what patient and public involvement could be undertaken.
- Retention of postcode and date of birth.

A response to this letter was submitted on 04 February 2014.

**Confidentiality Advisory Group advice prior to meeting**

The responses were forwarded to the Chair, it was agreed that there needed to be absolute clarity about data flows, access controls and what secondary medical purposes required confidential patient information and that further clarification regarding the purposes would also enable effective communication with patients in relation to the processing. This information was requested for consideration at the April CAG meeting to ensure that the purposes and exit strategies appropriate for specific purposes were clear on an ongoing basis.

The Chair agreed that it should be recommended that support be provided for an interim period only and that the following information must be submitted to the CAG meeting.

- Confirmation of specific purposes requiring support and the identifiable data required for each of these purposes
- Further information regarding data flows; including confirmation of when and how data would be pseudonymised and access controls.
- Confirmation of how patients will be informed about the processing of their personal data and how objections will be managed.
- Confirmation of what patient and public involvement could be undertaken.

**Confidentiality Advisory Group advice following meeting review**

The responses to the above request for information were submitted to members for consideration at the meeting.

Members discussed the further information provided and commented that they would expect the applicant to submit a new application form in order to recommend continued support and ensure that the details of the application were clear on a prospective basis, noting that support had expired previously. In particular, members advised that the following issues were addressed in the new application:

- Details of patient and public involvement and assurances of how it would be ensured that this was meaningful and relevant.
- Management of patient objection should be considered and details of steps taken to ensure that opt out was respected in relation to secondary purposes should be provided. Members noted that data would have to be collected for primary care purposes.
- Whether there were alternative legal bases for certain public health activities which might mean that support was not required. Members asked for clarification on this issue although it was recognised this may not be in time for the initial submission.
- Data flows should be very clear and it should be specified where data would be accessed for a primary care purpose only. Details of the pseudonymisation exit strategy should be clear in specifying where the pseudonymisation key will be held and how it will be ensured that individuals accessing data for NCCHD purposes cannot re-identify patients.
- The applicant should consider whether any of the purposes are research. Members advised that if this was the case the applicant should make a submission to a Research Ethics Committee (REC).

Members agreed that they were supportive of the application in principle and the application could be processed via the precedent set process once received.

## 5. RESUBMISSIONS

### a. Child Inpatient and Day Case Survey [CAG 1-05(a)/2014]

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

A recommendation for class 5 and 6 support was requested to cover access to contact details of patients (children aged 0-17) who had been admitted as an inpatient or received treatment as a day case patient in June 2014. Approximately 850 patients per trust would be included.

Access was requested to name and address of patient and the patient's parent/carer.

**Background**

This application was considered by the Confidentiality Advisory Group on the 6 March 2014. The Group recommended to the Secretary of State that the application was not approved as there appeared to be a practicable alternative to the disclosure of confidentiality patient information without consent. It was advised that the applicant explore the feasibility of trusts disseminating the survey themselves and noted that this had proved to be possible in some instances.

**Resubmission**

The applicant provided a response to the above comments in a resubmission considered at the April meeting and this is summarised below.

The applicant raised the following issues in relation to this approach:

1. Limit on capacity of trusts to undertake the work.
2. Greater potential for errors and risk to confidentiality.
3. Increased costs to trusts in adopting this methodology.
4. Potential for the loss of independence of the survey.

The applicant considered the following alternative methods of distributing the survey:

1. A method which involved the trust mailing surveys and survey contractors receiving results. The applicant asserted that this is likely to jeopardise the independence of the survey and increase the risk for error.
2. Handing out surveys to patients when in treatment. The applicant asserts that it would be difficult to monitor response rates using this method, the independence of the survey may be jeopardised and the timing of the survey was crucial and this should come at the end of treatment.
3. Using parent/carer, rather than child contact details. It was suggested that this option could be explored if requested.

In addition, the applicant would make additional patient information materials available to patients and ask Trusts to provide this at discharge.

**Discussion with applicants**

Paul Williamson, CQC User Voice Development Manager, Tamatha Webster, CQC Research & Survey Officer and Chris Graham from the Picker Co-ordination centre attended the April meeting in order to discuss the resubmission with members. A summary of that discussion is included below.

1. Members thanked the attendees for agreeing to attend to the meeting and highlighted that they were very supportive the application in principle and recognised the potential benefits in undertaking the activity. Both the applicant and members agreed that they were looking to work towards the most appropriate methodology to maximise these benefits.
2. Members queried whether there were a smaller number of patients included within this survey in comparison to other national surveys and therefore whether there was an opportunity to disseminate surveys within Trusts, particularly as it appeared some Trusts were undertaking mailing of surveys themselves. The applicants confirmed that the same number of patients would be included within this survey as other national surveys. It was confirmed that there were a number of ways that the sampling could go wrong at trust level and these were often only picked up at approved contractor level. The applicant explained that very small amounts of Trusts actually chose to undertake the survey at a local level.
3. Members queried what benefits there would be in using an approved contractor. The applicant explained that the use of identifiable data at an early stage would allow checks to be made and any issues to be identified at the earliest opportunity. For example, there had been an instance of the last half of the alphabet being omitted within one submission

and this would have significant impact on the representativeness of the sample. This could not have been picked up using anonymised data. There had been instances of Trusts amending questionnaires or assigning the wrong reference number to questionnaires and the resulting data could then not be used. In addition, it was more likely that names and addresses could be mixed up leading to inadvertent disclosure of patient data. It was highlighted that there was a significant financial burden on Trusts and therefore every effort was made to ensure that the resulting data could be used.

4. Members queried how the data would be used once received to ensure that there was a public benefit in the activity taking place. It was confirmed that the data would be used in a number of ways. Risks of poor quality care in certain organisations would be identified and drive inspection priorities and establish a picture of children's services at a national level and thematic reviews undertaken using the data.
5. Members asked about the possibility of writing to parents of children, rather than children themselves. The applicant confirmed that this had been explored as an option and it had been suggested that this might be possible but that separate information should be provided for the child so that the child may respond autonomously if desired.
6. Members queried whether the patient information poster would be amended to ensure that this reflected the child survey. It was confirmed that a specific information poster in relation to the child survey would be provided.
7. Members noted that the IG toolkit return in relation to Picker had been satisfactory but relatively low and requested that an improvement plan be submitted to highlight where improvements could be made if the application was supported.
8. Members queried how opt out would be managed and why data would need to be retained if patients had opted out. It was noted that approved contractors would deal with opt out in different ways and it was advised that it be ensured that the approach was consistent across all contractors. The applicant agreed that the need to retain data after patients had opted out and a consistent approach from the approved contractors could be explored.
9. The applicant highlighted that it may be difficult to obtain data from those Trusts where patients may be most at risk and therefore it was particularly important to involve an independent contractor in these circumstances. It was advised that support had been requested as other options had been exhausted and therefore the application was made as a last resort in this instance.

**Confidentiality Advisory Group Advice**

Members agreed that there was a significant public interest in the survey taking place, however members agreed that as children's data was to be included there was a higher threshold in relation the public interest and the practicability of adopting alternatives in these circumstances.

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006. Members discussed whether, given the information provided within the resubmission and from the attendees, they would consider there to be an alternative to the disclosure of confidential patient information in this instance.

Members discussed this point at length and views were raised that surveys could be disseminated at Trust level, with checks on the representativeness of the sample being undertaken at an early stage by the coordination centre using anonymised data. The sample could be checked by the coordination centre using the sample file information only without names and dates of birth and mailing could be carried separately by the Trust. The questionnaire would include a unique reference number but no features that could identify individuals. This would allow only anonymised questionnaires to be returned to the survey contractor. In addition, members suggested that questionnaires should be printed centrally or provided in a format which would not allow Trusts to edit these. This would negate the issue of Trusts amending surveys themselves.

Some members also commented that the data held within Trust systems may be more up to date at the time of sending the surveys and therefore mean fewer mistakes would be made if mailing was carried out by the Trust. Members queried whether the survey contractor undertook any checks using the Personal Demographics Service in relation to ensuring that deceased patients and up to date addresses were included.

However, on balance, the Group agreed that identifiers did appear to be required in order to pick up on errors, noting the examples that the applicant had provided and in particular concerns around missing data from those Trusts where patients may be at most risk. It was agreed that support should be recommended for the 2014 survey on the condition that the CQC gather evidence that the above alternative of checking the sample using anonymised data would not be sufficient and this should be adopted if possible. Trusts undertaking the mailing of surveys themselves could be used to test this methodology.

Members were of the view that strong evidence would need to be provided to demonstrate that there was no practicable alternative within the next submission if the survey was repeated and support was required.

Members recommended that parent/carer details should be disclosed for those patients aged 0-12, rather than child details. It was considered that those children aged 13-17 should be written to directly.

Members requested further information in relation to the disclosure of data to the Department of Health and NHS England, in particular the requirement for respondent level data.

Members confirmed that the security arrangements for survey contractors remain the responsibility of CQC and requested further information in relation to any improvement plans that were in place.

The patient information leaflet which was specific to the survey should be submitted. Members also advised that the applicant should ensure that the covering letter was carefully worded to ensure that recipients were aware how they were being contacted and this should be on Trust headed paper.

Members sought confirmation that patient objections could be processed both at Trust level and by the survey contractor. In addition members sought confirmation that there would be a consistent approach to managing objections by survey contractors.

**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. Support is provided to access contact details for parents/carers of patients aged 0-12 and for patients aged 13-17.
2. Support is provided for a period of 12 months and the representativeness checking process using anonymised data outlined above should be utilised with those Trusts undertaking the dissemination of surveys themselves to determine whether this did present a feasible alternative. Strong evidence would be required that there was no practicable alternative if a further application for a future survey was submitted.
3. Provision of further information in relation to the disclosure of data to the Department of Health and NHS England, in particular the requirement for respondent level data.
4. Submission of the patient information materials in relation to the survey.

5. Confirmation that patient objections can be processed both at Trust level and by the survey contractor and that there will be a consistent approach to managing objections by survey contractors and details of this approach.
6. Confirmation of suitable security arrangements via IG Toolkit submission.

### b. UCL Infection database [CAG 10-08(d)/2014]

This research application detailed the establishment of a new tissue bank to undertake research in the field of infectious disease, the primary research interest of the applicants is virology, however this resource will be used more widely and it is likely that research will encompass a range of human diseases. The tissue bank will include residual diagnostic samples, which will be held anonymised (existing samples) or linked with hospital numbers for prospective samples. The collection of confidential patient information will be limited to circumstances where further sampling or investigation of patient records is required. Consent will first be sought to complete such further analysis Support was requested for project researchers to locate and invite patients in order to seek consent to participate in a project.

Access was requested to clinical data, name, address, date of birth, gender and hospital number.

#### Confidentiality Advisory Group advice

Members thanked the Applicant for providing further clarification and updates however the Group noted a number of inconsistencies between the submitted application documentation and the later updates provided to the Confidential Advice Team that prevented them from being able to give advice to the Health Research Authority.

Members were keen to hold a discussion of these points with the Applicant.

#### Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG were unable to agree that the minimum criteria under the Regulations had been met as the Group did not have enough information to advise the Health Research Authority.

## 6. NEW APPLICATIONS – Non-research

### a. Extraction, linkage and anonymisation of Islington GP data to hospital admission data

The application 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. The outputs from the analysis would be used to inform commissioning and strategic decision making by Health and Wellbeing partners in Islington. Findings would directly inform the Joint Strategic Needs Assessment which would form the basis of the local Health and Wellbeing Strategy, and to evaluate public health interventions. Specific analysis would also directly inform the work of the Clinical Commissioning Group (CCG) and the implementation of the local primary care strategy. Tailored outputs will also be sent back to individual GP practices so that where appropriate, they can also take steps to improve the quality of their patient care and management.

#### Confidentiality Advisory Group advice

This application from the London Borough of Islington set out the purposes of a previously approved application (reference ECC 3-03 (b)/2012). The support previously provided under that reference indicated in the letter dated 11 June 2012 that support would be provided to 31 March 2013 as the organisational structures would be changing and at the time, it was unclear who would be the appropriate statutory successor body to Islington PCT, particularly as it was known that some public health responsibilities would be moving into local authorities. The original approval also established, as a condition of support, that advice from the HSCIC should be

sought and implemented to manage any disclosive risk due to the richness of the dataset. Prior to this recent submission, the Health & Social Care Information Centre had been contacted to provide advice and this application reflected these suggested structures.

This new application was originally considered under the proportionate review criteria (repeat application) however, members advised that they would be unable to provide a recommendation via proportionate review as the proposed processing structures would set a precedent and any applications setting a precedent must be considered by the full CAG. It also raised issues previously considered by the CAG with regards to commissioning in the new structures in England.

Members agreed that the purposes and aims were clearly laudable. It was also noted that there are a number of wider initiatives taking place such as 'care.data' and changes to commissioning activities established by NHS England. Members expressed the concern that while these new national processes are implemented and embedded, that caution should be taken that applications do not seek to circumvent the proper rollout of these initiatives while public confidence in the appropriate handling of data is strengthened.

Members noted that the application requested access to full postcode from GP IT systems for each patient so that geographical analysis and impact of the wider determinants of health could be undertaken through linkage with Lower Super Output Area (LSOA). Previously an anonymised data extract for public health analysis had been utilised via the King's Fund Combined Tool, however it was confirmed that this tool was no longer available in Islington and there was now a need to extract the data directly from GP systems.

Members questioned the need for full postcode as it was their understanding that EMIS could output LSOA, and requested that the applicants explore this further with EMIS to ascertain the feasibility of this. It was the understanding of the Group that partial postcode could be sufficient to obtain LSOA so this should be considered after liaison with the system supplier.

It was confirmed that NHS number would be required to enable linkage of GP data to hospital admissions data. The purpose of this was to inform commissioning strategies and intentions, reduce hospital admissions (making best use of resources), bring care closer to home, and to generally improve patient outcomes and quality of care.

The application additionally requested access to a number of sensitive data items, including demographic data (gender, age, ethnicity, occupation), smoking status, alcohol consumption, key health conditions such as mental health problems, autism and learning disabilities (excluding sexual health and HIV/AIDS status). It was indicated that this data had previously been used in analyses of anonymised GP datasets and from local hospital admissions data for analysis to inform commissioning, public health and service delivery, but these were not currently linked.

It was noted that the responses to queries referred to 'weakly pseudonymised' data and this had derived from other NHS England documentation. It was indicated that this is not a standardised term and its definition is ambiguous. Members therefore requested that there be a clear statement of what this means in terms of specific identifiers held within a dataset as it was not completely clear. It was also emphasised that NHS Number is not a pseudonym and can be more accurately categorised as an administrative identifier, so to refer as such is misleading.

It is a requirement that support can only be provided where it is demonstrated that there is no other practicable alternative. It was agreed that consent was likely not to be feasible due to the large numbers involved (218,000+). Members were however mindful that this application covered access to a comprehensive dataset containing a number of sensitive items prior to anonymisation.

Members assessed the approach that information would be extracted from GP systems by EMIS and the output supplied to the North East London CSU as a Stage 1 Accredited Safe Haven to carry out the linkages. Members reviewed the response that acknowledged the longer term

solution would be to work with the HSCIC to identify whether they could use their existing statutory powers to carry out this activity, and support was being sought while this was explored. Should it be confirmed that this is not possible then a solution involving pseudonymisation at source would be fully explored and if achievable, implemented.

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 should be explored with the relevant suppliers with specific information on the costs and technical challenges. 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.

In reviewing this leaflet, members expressed the concern that the leaflet was not entirely reflective of the application proposal and how data processed for 'secondary uses' takes place. While the leaflet captures much detail around the sharing of information for those involved in the direct care of the patient, in terms of secondary uses it relates primarily to processing of anonymised data, and does not reflect that there is processing and sharing of identifiable data to enable this anonymisation to take place. Members advised that the patient leaflet could be much clearer and accurate on uses of data.

Members noted that the applicant organisation had experienced some information governance issues in 2012-13 and therefore sought assurance that these issues had been properly addressed and that they would be appropriate custodians of the data.

**Confidentiality Advisory Group advice conclusion**

Members agreed that there was currently insufficient evidence to demonstrate that pseudonymisation at source would not be a feasible option, and therefore the requirement to show that there is no other practicable alternative to seeking support had not been achieved. Members also advised that the case for access to full postcode had not yet been made in light of technological ability to output LSOA, and the feasibility of this should be explored. Accuracy issues in the patient leaflet raised questions over compliance to the fair processing requirement under the Data Protection Act 1998, and this aspect should be reassessed. Engagement with the HSCIC and details of this would also need to be developed.

Following the consideration of the application, the CAG expressed the view that while public confidence in 'care.data' was being rebuilt, it could place the approver in a difficult position if applications for the same type of activity were supported during this 'listening period and while acceptance was embedded, also noting the public commitment that information collected under care.data would not be subject to 'section 251 approval' in the first instance.

Members were particularly mindful that care.data was being debated at a national level whereas applications submitted directly to the CAG did not have the benefit of this broader consideration, and the view was expressed that this could potentially undermine the role of the CAG if seen to be recommending support for similar activities while public confidence is being established.

It was understood that this would be a decision for the approver and CAG thought it would be helpful to flag this now before a comprehensive application was received, noting that the CAG can remain mindful of external policy considerations and initiatives, but when considering applications will focus on the Regulation framework whereas the approvers can take into account other considerations.

**Action: Issue to be flagged to the SofS approver and feedback provided to the CAG**

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

This non-research 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.

**Confidentiality Advisory Group advice**

Members queried whether identifiable or pseudonymised data was currently held within Lambeth Datanet. If identifiable data (NHS number) was held, members queried what the legal basis for this data collection was.

Members advised that they would be unable to provide support for access to the Lambeth Datanet if identifiable data was held without a clear legal basis and therefore the information was vital. If this assurance could not be provided members advised that they would only be able to support a method which did not use data from Lambeth Datanet.

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 the applicant's response to the query from the Confidentiality Advice Team that the applicant had confirmed it would be possible to pseudonymise GP practice data at source. Members queried whether access to GP practice notes would be required by individuals who were not part of the care team at any stage in order to establish the extraction method or whether this could be done automatically using a GP system supplier. Members advised that the applicant consult with GP system suppliers if this had not already been undertaken.

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.

Members noted that the applicant had completed the decision tool available on the HRA website in relation to defining whether the application could be considered to be research. It was noted that the applicant had provided information that the results would not be generalisable and members queried whether this was the case as it appeared that this would be applied to the Lambeth population in the future.

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. Members advised that it should be ensured that efforts were made to inform patients of the potential uses of their personal data and this should include specific information in relation to activities of this nature.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met as a practicable alternative existed and advised that the applicant explore the alternatives outlined in the advice above.

### c. Case Register for Rampton Hospital [CAG 1-06(c)/2014]

The application from Nottinghamshire Healthcare NHS Trust set out the purpose of establishing a register of patients at Rampton Hospital (for patients admitted from 01 January 2013) to identify whether interventions are effective in preventing re-offending once a patient returns to the community. Linkages to mortality data from the HSCIC and Ministry of Justice database (to identify post discharge offending) would take place via the Applied Information Department within Rampton and identifiers would be removed from the dataset prior to anonymised disclosure to researcher recipients.

Access to the Ministry of Justice database is out with the remit of section 251 of the NHS Act 2006 and was not considered by the CAG.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to a confidential patient information including date of death.

**Confidentiality Advisory Group advice**

Members noted that the applicant had previously received pre-application advice under the purview of the NIGB Ethics and Confidentiality Committee. Correspondence had also taken place prior to the meeting date and an application had been advised to enable member consideration as to whether support would be appropriate. Members agreed that a breach of confidentiality would take place and this was an appropriate activity for which support would be applicable.

Members were of the view that the purposes were valid and the predicted outcomes would have a public benefit. As a whole, members were broadly supportive of the application activity and agreed to provide a positive recommendation of support, subject to clarifying the activity type, further consideration to be given to patient opt-out, and clarifying specific points.

Members queried whether this activity could be considered to be service evaluation or research as there appeared to be research aspects to the activity. It was advised that a decision on this classification should be sought from the Health Research Authority via its online decision tool or through dialogue with the NRES advisors. A view was also expressed that undertaking ethical review via a REC established to look specifically at this type of activity would add to the methodological rigour of the application. Such evidence of engagement should be provided back to the CAG.

Members reviewed the patient leaflet and identified that no right of opt-out was provided for within the documentation. It was understood that section 10 of the Data Protection Act 1998 provides for an individual to request a data controller to cease processing of their personal data where it is shown to cause or is likely to cause substantial and unwarranted damage or distress.

One of the conditions of support under section 251 of the NHS Act 2006, applicable to approved applications under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002, is that there should be a mechanism to handle and respect patient objection and opt-out, <u>without</u> the need to show substantial and unwarranted damage or distress. In effect, the approval to lift the common law duty of confidentiality provides a higher standard than that of the Data Protection Act 1998 in relation to patient opt-out.

In this instance, it was agreed that the characteristics of the cohort make this balance a particularly challenging one. In light of this, members advised that the applicant consider inclusion of the right of opt-out, with the caveat that substantial and unwarranted damage or distress would need to be demonstrated by the data subject. Noting that review of the application was based on the information provided, members concluded that further detail would need to be provided on patient opt-out in light of this comment before providing a final recommendation.

Leading on from the point above and to support the preferred position, members suggested that the following be reflected in the response:

- The strength of the benefits of the activity would be critical to balancing the benefits of the outcomes against removal of privacy rights as members considered that this aspect needed greater strengthening. In particular, members questioned whether there was any evidence that could be provided to demonstrate that the methodology being pursued would achieve the intended outcomes and that the approach was scientifically robust.
- In considering applications, the CAG encourages applicants to seek meaningful patient engagement and involvement on using information without consent, as it provides a patient perspective on the balance considerations. In line with this, and subject to the clarification response (3), members recommended that Patient Council documented views be sought on the specific issue of opt-out and options set out in this letter. The Group indicated that if the Counsel expresses the view that opt-out should not be offered, then views on the benefits of the data collection should be articulated in this context.
- The response back to the CAG should capture these views so as to better demonstrate the benefits to proceeding.

Additionally, members sought clarification on the points below:

1. Clarification whether the application covers data generated in England and Wales, or England only
2. The understanding of the CAG is that it cannot recommend support where the reason given for not seeking consent is lack of capacity as this should be handled under the provisions of the Mental Capacity Act. It should be confirmed that where capacity is not in place then the applicants will follow the provisions set out within this Act and Regulations
3. Patient Counsel – members sought clarity on the composition of the members e.g. forensic, service users
4. Members sought clarity on the cohort boundaries within the scope of the application as there appeared to be confusion between date of admission and date of release.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG agreed to provide a positive recommendation of provisional support, subject to satisfactory responses to the points above. It was advised that the applicant consider these and provide a detailed response; this response will be reviewed by the original members outside of the full CAG meeting schedule.

**d. Access to MIDAS for the What About Youth? 2014 survey [CAG 1-06(d)/2014]**

This service evaluation application from the Health and Social Care Information Centre (HSCIC) on behalf of Ipsos Mori, set out the purpose of a survey (What About Youth?) which aimed to collect information on young people (15 years old) at a local authority or national level. Data from the survey would be used to help local authorities' planning for health improvement initiatives and measuring progress across a range of health behaviours.

A recommendation for class 5 and 6 support was requested to cover access to contact details of 300,000 patients from the Medical Research Information Service (MRIS), Integrated Database and Administration System (MIDAS) being disclosed to Ipsos Mori for the purposes of distributing What About Youth? Survey.

Access was requested to name, address, postcode and date of birth

**Confidentiality Advisory Group advice**

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 there was a potential alternative to the use of confidential patient information by using contact details held on the National Pupil Database (NPD) to send surveys. It was noted that the application specified that this would not be as effective as using MIDAS as there were concerns that the data seemed to be less accurate and that the NPD did not include all independent school pupils. Following further research into the NPD members agreed that, although some independent schools were omitted from this data, this appeared to be a minority of independent schools and that it was possible that parents and schools had specifically chose to opt out and this could have been to prevent contact details being used by third parties. Members suggested that given the number of schools not included on the NPD was likely to be small, separate approaches could be made to individual schools to ask them to disseminate surveys if there were concerns that the sample would not be representative.

The Group agreed that as there was little evidence to support the assertion that the survey could not be undertaken using the NPD, they could not recommend support to the application as a practicable alternative appeared to exist.

The Group went on to discuss the application in general and the following points are for the purposes of information and to invite reconsideration of a number of aspects in relation to the application which the Group considered to be necessary. The points raised are not conditions as support was not recommended and it is not suggested that addressing these points would constitute grounds for a resubmission.

The Group reviewed the specified survey methodology and noted that a number of follow ups were planned in order to ensure that response rates were as high as possible. Members commented that the extent of these follow ups appeared to be excessive and were particularly concerned that face to face contact was planned without consent; this appeared to be particularly intrusive. Members agreed that 1 follow up letter only should be sent to non-responders and no attempts should be made to call or meet individuals without prior consent.

Members noted that question 72 of the survey questionnaire requested that an individual consent to further contact and were unsure how this would be facilitated given that the responses were supposed to be anonymous. Members suggested that question 72 be removed and that the applicant ensure that it would not be possible to link returned questionnaires back to individuals.

It was noted that the application stated that information provided would be made available to a “range of agencies and professionals”. Members agreed that further consideration should be given in relation to who information would be provided to and for what purposes as these appeared to be very broad and needed to be defined. Members advised that it should be ensured that any disclosed information should be fully anonymised to protect the privacy of survey respondents and noted that the application included reference to information in relation to postcode being disclosed to third parties which, in conjunction with age and gender, could be used to identify individuals.

Members were unsure why full date of birth would be required and suggested that this should not be disclosed unless justified to ensure that the requested data was not excessive.

Members noted that provisions within the Children Act 2004 allowed the establishment of databases for set purposes and suggested that this application demonstrated the gap and need to establish a proper framework for contacting children, with safeguards in place that take into account lessons from previous experiences of databases in this area. Members advised that the potential for a more appropriate legal basis for this kind of activity under the Act could usefully be explored with the Department of Health.

Members were of the view that there was a potential that this could be considered research and noted the response from the HRA NRES in relation to the requirement for REC review. It was agreed that if the application was resubmitted this would be discussed with NRES to ensure there was clarity in relation to this point.

It was noted that a pilot survey had taken place and was reported within the submission. Members queried whether confidential patient information had been disclosed for this activity and if so under what legal basis.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met as there was a practicable alternative to the use of confidential patient information without consent. The application also raised a number of concerns which are highlighted above and the Group recommended that these be addressed before an alternative was pursued in practice.

## 7. NEW APPLICATIONS – Research

### a. Recall and Reoffending Outcomes of Mentally Disordered Offenders (MDOs) after Discharge from a UK Medium Secure Unit [CAG 1-07(a)/2014]

This research application from Kent and Medway NHS and Social Care Partnership Trust set out the purpose of a project to provide an examination of factors that influence recall and reoffending rates in mentally disordered offenders (MDOs), to allow for the targeting of resources both prior to discharge and upon discharge.

A recommendation for class 4 and 6 support was requested to allow a researcher to access records in relation to 450 MDOs at the Trevor Gibbens Unit to collect data for analysis (including date of birth) to link to patient criminal records held on the Police National Computer (PNC).

Access was requested to name and date of birth in order to link patient data to PNC data.

**Confidentiality Advisory Group advice**

Members recognised that there was a public interest in the application.

Members requested that the Applicant seek engagement with a representative group of patients in regards to any potential concerns or issues in using data without consent.

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 only a cohort of 450 patients would be included in this research and queried whether a member of staff with legitimate access to the confidential patient information could provide a list of identifiers to the Police, who could in turn provide data back to the member of staff. If this is viable, it was suggested that the data could then be anonymised before it is passed to the researcher.

Members recognised that the Applicant may not have access to patient's current addresses and queried whether the feasibility of utilising the Health and Social Care Information Centre to trace patient's current address had been considered.

Members noted that the Kent and Medway NHS and Social Care Partnership Trust leaflet included in the application. The Group requested that an additional leaflet should be produced which was specific to this research project.

The Group recognised that letters will be sent out to patients to advise them of the research project and to enable them to dissent from their data being used within the project. Members advised that a stamped addressed envelope be included with the letter to allow patients to indicate dissent more easily.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG were unable to agree that the minimum criteria under the Regulations had been met as the Group did not have enough information to advise the Health Research Authority.

**Request for clarification**

Further to the points raised above, the Applicant was asked to:

1. Provide details of engagement with a representative group of patients in relation to the use of data without consent.
2. Confirm whether data could be anonymised prior to disclosure to the researcher.
3. Explore the feasibility of utilising the Health and Social Care Information Centre to trace patient's current address.
4. Provide an additional project specific information leaflet.
5. Consider whether a stamped addressed envelope be included with the patient letter.

**b. Yorkshire Specialist Register of Cancer in Children and Young People [CAG 1-07(b)/2014]**

This research application from the University of Leeds set out the purpose of establishing a research database that would include all individuals aged <30 years diagnosed with a malignant tumour whilst resident in the former Yorkshire and Humber SHA region from 1974 to present day. The database would be used to carry out a programme of epidemiological and applied health research investigating incidence, survival and aetiology of cancer occurring in children and young people.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to name, date of birth, date of death and postcode. In particular, to access confidential patient information both retrospectively and prospectively (as patients are diagnosed) to carry out linkage to hospital episode statistics and primary care data in line with the data flow diagram.

**Confidentiality Advisory Group advice**

Members noted that previously this specialist registry used to operate under the overarching support provided to the UKACR via Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002. Following organisational structure changes from April 2013, it was noted that correspondence had previously taken place with Public Health England prior to application consideration and the view provided that an individual application should be made. Members assessed the purposes of the application and were of the view that these purposes would reasonably fall within Regulation 2 of the Health Service (Control of Patient Information) Regulations 2002, and that the application would be considered under this regulation section.

Members indicated that provision of support to this database would enable greater context to be captured, and acknowledged that the specialist registry was a unique resource that provided developing knowledge in understanding malignancy in children. It was agreed that the purposes were worthwhile and would offer a public benefit.

Following review of the detail, members were broadly supportive in principle in recommending support to this database, subject to clarification of the points raised below.

1. Members were unable to identify a clear rationale within the application to explain why consent would not be feasible, particularly for the prospective arm of data collection. Further explanation was requested on this aspect to provide justification that there is no other practicable alternative.

2. Clarity was requested on the need for indefinite retention, particularly when the patient is deceased as there would be no further clinical intervention. If continued retention past patient death is requested then a detailed rationale should be provided.
3. Members noted that the patient information leaflet did not make clear that choosing to opt-out would not affect treatment, and members sought comment on the feasibility of making this explicit within the leaflet. In conjunction with this, it was identified that the leaflet did not make the right of opt-out explicit and comment on the feasibility of improving this aspect was also requested.
4. Members requested that assurance be submitted to confirm that the patient leaflet was in fact provided to every child.
5. It appeared to members that patient involvement appeared limited, therefore proactive steps that could be taken to improve this aspect was requested.
6. Members expressed the opinion that future uses of the database were broadly circumscribed. The response to question 21 indicated that once data leaves the SEED system the University of Leeds is no longer responsible for the safekeeping of the data. It was highlighted that the University of Leeds has a responsibility for ensuring that information is securely transferred and that appropriate controls are in place for recipients. It was requested that evidence of a robust process to consider anonymised data disclosures to recipients be provided, to include data access agreements, how anonymisation and aggregation is assured, and specific details of the controls placed on recipients.
7. Confirmation that an up to date favourable ethical opinion from a research ethics committee has been provided for this specific application. An MREC letter from 2000 and an amendment confirmation in 2012 showing a change of Chief Investigator was provided, however, it was not clear whether a specific ethical opinion relevant to this application was in place.
8. Confirmation that a satisfactory IG Toolkit submission is in place for this activity

Support, once finalised, would be subject to the following specific conditions of support:

1. Continuing satisfactory annual IG Toolkit submission for the duration of this approval
2. Scope of approval to cover only children's cases or further information about adults who were diagnosed with cancer in childhood.

**c. Long-term effects of whole blood and platelet donation [CAG 1-07(c)/2014]**

This research application from the University of Cambridge set out the purpose of establishing a large population research dataset involving blood donors enrolled with NHS Blood and Transplant. Data from NHS Blood and Transplant (NHSBT) would be linked to variety of health data. The project aims to evaluate claims about the possible risk and benefits of frequent blood donation. The application detailed a pilot activity only at this stage.

A recommendation for classes 1, 2, 4 and 6 support was requested to cover the transfer of demographic data including name, NHS number, date of birth and postcode from NHSBT to the Health and Social Care Information Centre. Pseudonymised Hospital Episode Statistics data would then be provided to the University of Cambridge.

**Confidentiality Advisory Group advice**

Members considered whether a practicable alternative to the disclosure of confidential patient information 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 the large retrospective nature of the cohort meant that seeking consent to carry out data linkage would not be feasible. However, members were of the view that NHSBT patient information leaflets could be updated in order to ensure that this activity was carried out on a consented basis in future.

Members noted that the transfer and processing of identifiers would be kept to a minimum and that the University of Cambridge would have access to pseudonymised data only. Identifiable data would be required by the HSCIC to identify relevant patient notes. Members discussed whether support would be required given that the disclosure of identifiers was to the HSCIC only who already had access to this information, however it was agreed that support could be given in this instance to provide the assurance that a legal basis for the transfer existed.

Members reviewed the patient information leaflets provided and advised that these information leaflets should be updated as soon as possible to ensure that patients were fully informed that information could be disclosed to other organisations and linked to other data for research purposes.

Members advised that any additional data linkages should be subject to an additional application and this support covered the linkage to HES data only.

**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. Consent must be obtained for prospective data collection and members advised that patient information leaflets should be updated to ensure that users of NHSBT were fully informed of the potential uses of data.
2. Support is for the pilot activity and to link to HES data only, additional applications should be made for further linkages
3. Favourable opinion from a Research Ethics Committee.

## 8. FOR DISCUSSION

The following agenda items were deferred to the May 2014 CAG meeting:

a. Registering patient objection
b. CAG statutory powers

## 9. ANY OTHER BUSINESS

There was no other business to transact and the meeting came to a close.