NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

04 June 2015 at 10.00am – 5.00pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Dr Robert Carr	Not present for items 1-3
Professor Barry Evans	
Ms. Clare Sanderson	
Dr Murat Soncul	
Mr C. Marc Taylor	
Ms Gillian Wells	Chair item 4A
Dr Miranda Wolpert	Via teleconference, present for items 2C, 2D, 3A, 4B and 4E

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Ms Amy Ford	Senior Confidentiality Advisor, HRA
Mr Ben Redclift	Observer, HRA, item 4D
Mr Stephen Robinson	Observer, HRA, item 4

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received from Professor Jennifer Kurinczuk, Professor Julia Hippisley-Cox, Dr Tony Calland MBE, Mr Anthony Kane, Dr Patrick Coyle and Mrs Hannah Chambers.

Declarations of interest

Professor Barry Evans declared an interest in relation to items 2C, 2D and 3A as these were submitted from his employer, Public Health England. Professor Evans confirmed that he had no direct involvement with the application and it was suggested that he remain in the room in case any points of clarification arose and to enable the applicant to better understand the outcome. Members agreed that Professor Evans should remain in the room; however he would not take part in the discussion.

Dr Mark Taylor declared an interest in item 4A as the application came from a researcher from his employer, Sheffield University. Dr Taylor remained in the room for the discussion but did not Chair the item.

2. FOR CONSIDERATION

a) National audit – exit strategy from support – update report

Due to last minute apologies, this item was deferred and it was agreed that the report submitted should be discussed with the Healthcare Quality Improvement Partnership, NHS England and the Health and Social Care Information Centre at sub-committee meeting.

Members queried whether Public Health England should be included in the discussions, given that they provided a lot of information from the cancer registries. It was agreed that Professor Barry Evans should attend the sub-group so that the issues could be understood and that it could then be determine if PHE should be involved and discussed with the relevant stakeholders.

Action: CAT to arrange a sub-committee meeting with CAG members and relevant stakeholders.

Action: CAT to update Dr Tony Calland in relation to the CAG discussion.

b) Advice request - INSIGHTS FOR CARE – research partnership between Heart of England Foundation Trust (HEFT), Merck Sharp Dohme and Deloitte [15/CAG/0146]

This request sought advice on whether the CAG agreed with the applicant assertion that due to the manner in which the information would be processed and the controls in place, that there would be no disclosure of confidential patient information (as defined within the Regulations) and therefore an application for support under Regulation 5 would not be required.

Confidentiality Advisory Group advice

The CAG welcomed the applicants for attending the meeting in person to answer specific queries. It was agreed that this was extremely helpful in clarifying the details of the advice request and context and provided additional assurance that the confidentiality considerations had been understood and thoughtfully addressed. Members were also reassured by the discussion, particularly the absolute assurance provided that there would be no possibility to onwardly provide any identifiable information, other than aggregate outputs.

In relation to the precise context described, it was confirmed that the data controller is HEFT, Deloitte will be undertaking analysis on the pseudonymised data and Merck are the sponsors/funders. Following the discussion, it was agreed that the data disclosed to Deloitte was not considered to be confidential personal information. The rationale for the view that the patient identity would not be ascertainable by those processing the information was critically based against the controls that were described to manage this data flow.

The controls specified included, although were not limited to, the following characteristics:

- Information provided to Deloitte will be pseudonymised at source
- Further data algorithms will be utilised to check that no patient confidential data is present
- Data will be transferred through secure encrypted file transfer
- Access to the information within Deloitte is strictly managed with role based access controls
- Information will be deleted upon termination of the research activity (noting members indicated this may not always be immediately possible due to research governance or publication constraints)
- Small number suppression and legal constraints were understood
- The healthcare provider would remain the data controller and control would be exercised via the governance board
- Good communications enabling patient objection/opt-out
- No free text would be extracted

Confidentiality Advisory Group advice conclusion

Members reiterated that their advice was based against the application submitted and the specific controls discussed in the meeting within the context of diabetes. It was

agreed that, as described to CAG and according to the paperwork considered on the day, that there appeared to be a practicable alternative to the receipt of confidential patient information. It was therefore concluded that the data disclosed to Deloitte was not considered to constitute confidential patient information as the identity would not be ascertainable by those in receipt of and processing data; this was solely due to the specific controls in place within the precise context described.

Members emphasised that this should not be seen as setting a precedent for future similar activities and agreed with the applicant commitment to keep the activity and controls under review, particularly if moving into a new therapeutic area.

c) Contacting National Health Application and Infrastructure Services (NHAIS) data subject for Cancer Screening Programmes in England – update report [PIAG 1-08(a)-2003]

Following the consideration of this annual review for this application at the November 2014 CAG meeting, a short update report was requested to be submitted to the June 2015 CAG meeting in relation to the outstanding issues, this report was received and discussed by CAG members. Members thanked the applicant for submitting the requested information.

Confidentiality Advisory Group advice

Physical access controls

The detail of physical access controls implemented within the National Office was provided and noted by CAG members.

Review of quality assurance function across PHE

It was noted that an independent review of the quality assurance (QA) function had been undertaken and the review and PHE response had been published. An update report was provided to CAG. This included a number of steps that would further improve the level of IG Toolkit compliance for the QA function and the measures and controls in place to protect confidentiality of the patient information processed.

New application

Members noted the assertion that as the sponsor for the application had not changed a new application was not considered to be necessary. However, given the loss of ‘organisational memory’ and the historical nature of the application, members advised that they would consider a new application to be necessary. This would ensure that

current processing arrangements and any conditions of approval were contemporary and clear.

Amendments to patient information

Members were pleased to note that additional text would be included within future patient information leaflets, however agreed that it was disappointing that the amended text would not be added to the patient information sheet until the end of 2015/2016 and encouraged the applicant to amend information sheets more urgently if possible.

Members advised that the patient information should include details of what aspects of data sharing it was possible to object to. Whilst it was noted that an applicant would not be able to opt out of screening, members requested that it be made clear that patients could object to further data processing for other purposes. To ensure patients were fully informed, members advised that more detailed information could be provided in relation to who data was currently being shared with and for what purpose.

Confidentiality Advisory Group advice conclusion

CAG requested that a new application, taking into consideration the advice of CAG outlined above, be submitted prior to the next annual review date. As the approval runs until 20 November 2015 it was advised that this is submitted in time for the 22 October 2015 CAG meeting.

d) National Cancer Registries Database - update report (May 2015) [PIAG 03(a)-2001]

Following the consideration of the annual review for this application at the November 2014 CAG meeting, a short update report was requested to be submitted to the June 2015 CAG meeting in relation to the outstanding issues, this report was received and discussed by CAG members. Members thanked the applicant for submitting the requested information.

Confidentiality Advisory Group advice

Patient notification and objection

Members noted that the previous report, submitted in November 2014, had explained that an engagement and consultation process had been undertaken in collaboration with Cancer Research UK to obtain the views of patients on the proposed revisions to current patient information leaflet. The outcome of this consultation was a layered approach to patient information. The applicant had confirmed that this layered approach had also been discussed with the Information Commissioners Office. The update report confirmed that the revised leaflets had been disseminated and published online; the

report confirmed that over 62,500 leaflets had been disseminated to 163 Hospital Trusts with an accompanying letter from the NCRS regional manager.

It was noted that the effectiveness of the layered approach could be measured in part by the number of 'hits' for the leaflet on the PHE website and a report in relation to this would form part of the monitoring of the effectiveness. In addition NCRS would be undertaking a survey of how NHS Trusts were ensuring that patients were made aware of the leaflet and its contents. The findings and any actions taken in response to this would be reported to CAG at the next annual review stage.

The applicant highlighted that NCRS were intending to review patient information materials every two years, however, they would commit to a more urgent review should CAG or the ICO feedback that this was necessary. Members agreed a bi-annual review of patient materials appeared to be sufficient as long as there were no substantive changes, in which case the applicant might consider reviewing the materials sooner.

It was noted that there was an established process to allow patient objection and it was confirmed that no requests had been received over the preceding 6 month period.

Confidentiality Advisory Group advice conclusion

The applicant was advised that an annual review should be submitted as usual and that this could be considered in the first instance by the Confidentiality Advice Team in line with the normal annual review process.

3. ANNUAL REVIEWS

a) National Drug Treatment Monitoring System (NDTMS) [ECC 5-05(e)/2012]

This application was from the National Treatment Agency (on behalf of Public Health England (PHE)) and detailed the continued processing of patient identifiable data within the National Drug Treatment Monitoring System for a number of purposes.

Support under the Regulations was requested in order to legitimatise the continued processing by Public Health England (PHE) of patient identifiable data for all individuals being treated for drug and alcohol misuse after the 1st April 2013. Previous consent had indicated that identifiable data would not be available to government, however, due to organisational change; NTA staff would become part of PHE on the 1st April 2013 and therefore civil servants. As PHE was not yet formally established the Regulations could not currently apply to the organisation and it was advised that PHE would need to complete administrative actions to enable any approval to come into effect.

Confidential patient information requested

Confidential patient information including initials, date of birth and gender were requested in order to de-duplicate data from a number of sources and link with data from a variety of sources including Home Office, Ministry of Justice, Department of Work and Pensions and the Department of Education.

At the review in November 2014, members requested that the applicant provide specific updates in relation to the following additional points:

1. Further information in relation to whether there is considered to be an exit strategy from support under the Regulations. If an exit strategy is identified, progress in relation to the movement towards this exit strategy should be provided at the next annual review submission.

2. An update in relation to outstanding actions arising from the Information Governance Toolkit submission should be provided at the next annual review stage.

Confidentiality Advisory Group advice

Exit strategy

It was noted that there were a number of purposes for which the dataset was used and that removing the identifiers from the historic records would reduce the value of the data collection. Ongoing support would therefore be required to enable the records retained under the old consent statement to continue to be processed. In order to mitigate this, steps had been taken to reduce the requirement for PHE staff to directly access identifiable data items, and the planned redesign of the NDTMS system would ensure that this was reduced further by the automation of routine data processing and analysis activities and implementation of enhanced technical access controls.

Members therefore agreed that there was still a continued need to access confidential patient information as specified within the original application. Members were pleased to note the improvements being made to the system and requested further information in relation to the improvements made at the next annual review stage, in particular members queried whether the implementation of pseudonymised processes might lead to an exit strategy for the retention of identifiable historical data in future.

Conditions of support

Members noted that the original conditions of support indicated the recommendation would cover patient data collected from the NHS only. Since the original approval was provided, CAG had received legal advice which confirmed that support could be provided to support the disclosure of confidential patient information in England and Wales whether or not it was generated within an NHS

or non-NHS setting. Therefore members requested that this specific condition of support was withdrawn at this time.

Confidentiality Advisory Group advice conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter, to the date specified above.

4. NEW APPLICATIONS – Research

a) Yorkshire Health Study [15/CAG/0114]

This application from the University of Sheffield set out the purpose of conducting a study which aims to help the NHS provide appropriate service and treatments to prevent and treat obesity in the future by collecting information on the health and weight of a representative sample of adults of all ages (16+) over the next twenty years. The research team recruited randomised GP practices to take part in the study. The appointed GP practices were required to pick randomised patients from their practice in order to send out a letter with enclosed questionnaire informing them of the study and also to consent for future contact by the research team.
The applicant was seeking support to provide the Health and Social Care Information Centre (HSCIC) with a legal basis to provide Hospital Episode Statistics (HES) data for the purposes of the study.

<u>DAAG application and consent history</u>

All patients had provided consent initially for inclusion in the study. Following the original application for linkage to HES and ONS data in December 2013, the HSCIC Data Access Advisory Group (DAAG) advised the applicant to revise the consent form prospectively and include a statement in relation to the HSCIC and write to patients who had previously provided consent to inform them of the changes to consent material. Following this outcome, the research team had been contacting the patients who had agreed to be contacted again in order to re-consent patients using the amended wording and had received a 49% response rate. From January 2014, the patients had received an invitation letter and consent form with an amended version of the DAAG recommended wording. Following contact with DAAG, the revised wording was rejected in May 2014. Therefore, since June 2014, the remaining patients who had not been contacted were receiving a questionnaire and invitation letter containing the full wording stipulated by DAAG.

The applicant sought support under the Regulations in order to link the data regardless of the form of wording used on the version of the questionnaire the patients had completed, including those who had not responded to the attempt to re-consent following December 2013.

<u>Class support requested</u>

A recommendation for class 2, 4, 5 and 6 support was requested to cover access for an authorised user to obtain and use information about past and present geographical

location, to link patient identifiable information obtained from more than once source and for auditing monitoring and analysing patient care and treatment.

Confidential Patient Information Requested

Access was requested to name, NHS number, date of birth and postcode. The applicant required to access HES and mortality data from the Health and Social Care Information Centre (HSCIC) and the Office for National Statistics (ONS) in relation to the patients within the obesity cohort on the use of resource. The applicant confirmed that confidential patient information would be provided to the HSCIC for linkage and data would flow back to the applicant in pseudonymised format.

Confidentiality Advisory Group advice

CAG thanked the applicant for attending the meeting via telephone to answer specific queries. It was agreed that this was helpful in clarifying the details of the application.

Public Interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely provide a public interest due to the need to investigate the growing levels of obesity and why it poses a major public health problem in England (including South Yorkshire) as well as much of the developed world.

Cohort groups

Members noted that due to the different approaches taken by the applicant in relation to seeking consent there were a number of different considerations depending on the specific approach taken. Therefore, members considered each cohort group individually and the advice provided in relation to each is outlined below. They also noted that the original advice from DAAG was to inform rather than seek consent from patients and this difference in interpretation by the applicant had lead CAG to take the consider support for some of the cohorts below.

1. Cohort group who provided secondary consent using DAAG approved wording

Members agreed that for those individuals in the cohort who had consented using the DAAG approved wording, access to HES data would not require support. Members noted that the consent was considered to be sufficient and therefore, outside of the scope of the Health Services (Control of Patient Information) Regulations 2002.

2. Cohort group who provided secondary consent using the consent form with revised wording that was later checked and not approved by DAAG.

Members agreed that for those individuals who had consented using the consent form which did not include the DAAG approved wording, support would be required for the purpose of linking confidential information with HES data for audit and analysis purpose. Members noted that DAAG did not consider the consent wording for this cohort to be sufficient and that category eight of the precedent set process was for applications where the wording of the original consent was not considered sufficient by

the data controller responsible for providing the information. Therefore support could be advised to provide a legal basis to access data where the data controller has indicated that support may be required to proceed as consent is not sufficient.

3. Cohort who had not yet been contacted to re-consent

Members agreed that those patients identified as part of the cohort who had not been contacted since initial recruitment would require support. Members requested that the applicant write to the cohort in order to inform them that confidential patient information would be used for the study and to confirm the local mechanisms to object to further use of data. It was advised that this cohort group was not contacted in order to re-consent, as issues in relation to non-response (outlined below under cohort group 4) may be engaged. Members noted that for this cohort, confidential patient information would be required in order to link with HES data.

4. Cohort group who had not responded to attempts to re-consent

Members noted that 6,821 patients had consented initially at recruitment stage, but had not responded to the applicant when the cohort was written to again asking for secondary consent using the DAAG approved wording. Members noted that the reason for this may be that the patient had already consented for their confidential patient information to be used within this study and may have felt that they did not need to consent again. However, members advised that the Confidentiality Advisory Group had previously sought guidance on non-response to requests for consent from the Information Commissioners Office (ICO) who had confirmed that where an attempt to rely on consent to process sensitive personal data under schedule 2 and 3 of the Data Protection Act 1998 (DPA) had been made, a subsequent attempt to rely on another schedule where individuals did not respond would not be possible under the DPA.

Members noted that as the cohort had consented previously, the Confidentiality Advice Team should seek advice from the ICO in relation to this group to determine if the continued processing of and additional access to confidential patient information as outlined within the application would be consistent with the DPA. Members noted that the CAG advice as to whether support would be permitted for this cohort would be dependent on the advice given from the ICO. The Confidentiality Advice Team will notify the applicant and provide confirmation to CAG of the ICO view once known.

5. Patients who had dissented from further use of their data

Members advised that for the patients who had explicitly dissented at any point of the consent process, there would be no legal basis in place for the further disclosure of confidential patient information. Members agreed that support for this cohort could not be recommended as patients had explicitly objected.

Application scope

Members noted that it was unclear from the response from the applicant or within the application as to whether the applicant would require data from the HSCIC for the purpose of obtaining up to date contact details for the cohort prior to contacting them or whether it was intended that this was received from Data 8 only. Members requested clarification from applicant.

Justification of identifiers

Members agreed that NHS number, name, date of birth and postcode were necessary to submit to the HSCIC for data linkage purposes and for data to flow back to the applicant within pseudonymised format.

Retention

Members noted there were discrepancies within the application in relation to the retention of confidential patient information. The applicant confirmed that the application for support was for a longitudinal study and based on long term conditions and therefore, would be required to retain confidential patient information until the end of the study in 2045.

Role of Data 8

Members noted that the processor Data 8 was not incorporated within the application. The applicant provided clarification that Data 8 was a private company with a Data Processor Agreement in place to provide information on participant's change of address and confirm who had subsequently died to ensure that they were not contacted. The applicant provided confirmation that Data 8 obtained change of address and year of death details from a third party company called re-connect. Members requested clarification on Data 8's contract and security arrangements.

Merging of two Studies

Members noted that the study was previously named South Yorkshire Study and was now called Yorkshire Health Study. Members requested that the applicant provide clarification as to whether the two studies had been merged and if so the reasons behind this. The applicant confirmed that there was a need to broaden the study to conduct further analysis on obesity in alternative areas. The applicant confirmed that recruitment of participants prospectively had changed as patient recruitment and patient information materials had become more accessible online. Members noted the potential for under-representation within the cohort. The applicant had responded that under representation within studies like Yorkshire Health Study was an issue, however, to overcome this, the applicant had approached GP practices to allow a researcher to attend the practice and recruit directly. The applicant confirmed that the research team were still currently developing methods to utilise in order to prevent or limit under representation prospectively.

Information Governance Toolkit

Members noted that the applicant had not provided information on the study or organisation's Information Governance Toolkit. The applicant noted that the department did have an Information Governance Toolkit, however, it was due for an annual review shortly and the applicant was currently updating policies and processes.

Confidentiality Advisory Group advice conclusion

Cohort group who provided secondary consent using the consent form without DAAG approved wording and cohort group who had not yet been contacted to re-consent

The CAG agreed that the minimum criteria under the Regulations appeared to have been met for cohort groups outlined under 2 and 3 above and therefore advised recommending provisional support to the Health Research Authority. This recommendation is subject to a satisfactory response to the following requests for clarification and the following standard and specific conditions of support.
In order to complete the processing of this application, please respond back to the following requests for further information within ten days:

Request for clarification

1. Provide information on Data 8's contract and security arrangements.
2. In line with the application scope section above, the applicant was asked to confirm if full name and address were required from the HSCIC for the purpose of obtaining up to date contact details.

Specific conditions of support

1. The cohort group who have not yet been contacted should be written to in order to inform them about the data collection from the HSCIC and to offer an opportunity to object.
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Cohort group who had not responded to attempts to re-consent

In line with the considerations above, the CAG agreed that further information would be required from the Information Commissioners Office (ICO) in order for a recommendation under the Regulations to be provided in relation to the cohort outlined in 4 above. The further advice would be sought by the Confidentiality Advice Team.

Once received the information would be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

b) Simon Broome Familial Hypercholesterolemia Register (MR180) [15/CAG/0138]

This application from University College London set out the purpose of continuing the development of a research database and associated epidemiological study to investigate risk factors in Familial Hypercholesterolemia patients. The study will assess the extent to which the prognosis has improved due to the increase in availability and effectiveness of the lipid-modifying drug therapy and also the increased rate in which patients are identified and treated. The applicant had

previously obtained support with the condition that newly registered patients would prospectively consent for flagging via the NHS Central Register. From this period, consent forms were in place and mortality data was provided both for those who had consented and also those who were registered prior to the adoption of the consent model. The applicant would like to continue receiving mortality data; however, the Health and Social Care Information Centre (HSCIC) Data Access Advisory Group (DAAG) had advised that the applicant should seek support for the cohort who was registered prior to the consent forms being in place.

A recommendation for class 4 and 6 support was requested to cover access for an authorised user to link patient identifiable information obtained from one or more source.

Confidential patient information requested

Access was requested to NHS number, name, date of birth, date of death, GP registration and postcode.

Confidentiality Advisory Group advice

Referral from Precedent Set Committee to Full Committee

Members noted that the Precedent Set sub-committee of the Confidentiality Advisory Group was unable to give advice due to a number of significant points that were identified from the review of this application and the application was referred to a full committee due to the described complexities of data processing.

Patient Information and Notification

Members highlighted that patients had not been contacted for 20 to 25 years and there had been limited patient notification. Members advised that the applicant should visit the Information Commissioners' Office (ICO) website for further guidance on fair processing and to report back to CAG on the development and implementation of patient notification within the annual review submission.

Previous PIAG support

Members noted that support had previously been provided for mortality data to be received under the Office of National Statistics class support process and that data had been provided under this approval for a number of years. It was agreed that it was necessary to approve the amendment in order to provide support for the cohort who was registered prior to the consent forms being in place.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research

Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Provide feedback on the development and implementation of patient notification at annual review submission
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

c) The inequality of Bowel Cancer referral rates in England [15/CAG/0145]

This application from the University of Warwick set out the purpose of a retrospective observational study to investigate the variations in suspected bowel cancer referral rates across GP practices in England using statistical models to look at i) the variations in patterns of referrals over time, ii) referrals that lead to confirm diagnosis and iii) the effects of the bowel cancer screening program on the confirmed diagnosis of bowel cancer.

A recommendation for class 1, 5 and 6 support was requested to cover access to HES-ONS linked data from the HSCIC in relation to longitudinal data over the period 2003-2013 and referrals by GPs to GastroIntestinal (GI) Units.

Confidential patient information requested

Access was requested to a Hospital Episode Statistics and Office of National Statistics (HES-ONS) dataset that would include information in relation to GMC registration number which would be linked with individual clinician characteristics. Month and year of death would be required for analysis purposes.

Confidentiality Advisory Group advice

Definition of data requested

Members discussed whether the information requested could be considered as confidential patient information, noting that the unique reference number and identifiable information related to the clinician, rather than the patient. On balance, members agreed that it was possible that the data could theoretically be linked back to an individual patient, due to the combination of data items which included information about individual GPs and referrals. Therefore it was considered that this could fall within the remit of CAG.

Practicable alternatives

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

would not be practicable to obtain consent due to the size and retrospective nature of the cohort.

It was queried whether alternative methods could be adopted in order to negate the requirement to process individual GP information at all or in the same dataset as patient information and members asked whether the applicant had explored alternatives. For example, whether information in relation to GP registration be disclosed prior to other patient data to allow banding to take place and then anonymised information only linked to other patient data.

User involvement

It was noted that limited user involvement had taken place, both with patients and GPs. In particular, members advised that consultation should be undertaken with GPs to ensure that they were aware and supportive of the activity using their personal data. Further information in relation to plans to consult with GPs and patients were requested.

Patient notification

Members advised that attempts should be made to inform patients about the activity and data being processed. Further information in relation to methods that would be utilised to raise awareness of the study within the patient population was requested. In addition, members queried how patients would be provided with an opportunity to object to the processing.

Scope of application

Members requested clarification in relation to the requirement for 10 years of HES data and queried whether this could be reduced.

Retention period

Members advised that once GP data had been banded, individual level data should not be retained.

REC submission

It was noted that an application had not yet been submitted to a Research Ethics Committee and members advised that, as the application was research, it would be necessary to obtain a REC opinion for the study if support was required.

Information Governance Toolkit

Members noted that the Information Governance Toolkit had not yet been completed and advised that if support was required a satisfactory Information Governance Toolkit score would need to be in place prior to disclosure of confidential patient information.

Confidentiality Advisory Group advice conclusion

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

Further information required

The applicant was requested to provide the following information to allow the CAG to continue their consideration of the application:

1. Confirmation in relation to what alternative methods had been considered in order to remove the requirement to process individual GP information at all or in the same dataset as patient information.

2. Further information in relation to plans to consult with GPs and patients.

3. Further information in relation to methods that could be utilised to raise awareness of the study within the patient population.

4. Confirmation why 10 years of HES data would be required.

Once received it was agreed that the information would be reviewed by a sub-committee of members in the first instance.

Action: CAG to discuss studies undertaken for academic reasons and timescales for completion of course being used as evidence that alternatives are not available at a future away day.

d) Service provision in end of life Dementia care [15/CAG/0137]

This application from Princess Alice Hospice/Kingston NHS Foundation Trust set out the purpose to assess what services influence the end of life care for people with dementia. It was detailed within the application that Princess Alice hospital has seen a year on year increase in people with dementia being referred for Specialist Palliative care (SPC) a multidisciplinary approach to provide total care for patients with progressive advanced disease and their families and referral seems to occur late in the illness trajectory. However little is known about the end of life provision for these patients. This study aims to build a detailed picture of the last year of a patient's life and what service do or could influence their care.

This will be a retrospective study in 2 NHS Trusts and the Hospice to explore the everyday lives of 20 people with dementia in the last year of life. Data will be collected from deceased patient's medical notes over the last 12 months and interviews will take place with their carers. Clinicians involved in the care of patients will identify the deceased patients and carers and act as "professional consultee" to ensure carer suitability to be contacted. The researchers have contracts with the trusts to access the health records they hold to obtain the necessary data. Each study participant will be assigned a unique number at the site of data retrieval.

Analysis between the trust data and hospice data will occur at the hospice but both sources of data will have been assigned the identification number at the site of origin and no identifiable information will be removed from either site.

A recommendation for class 1 and 4 support was requested to cover access from Trusts hospital records and data within hospice records by the research team.

Confidential patient information requested

Access was requested to date of birth and date of death for data linkage.

Confidentiality Advisory Group advice

Public interest

It was noted that this research would evaluate specialist palliative care in the last 12 months of life for patients with a diagnosis of dementia with an aim to improving care. Members agreed that the study outcomes appeared to be in the public interest.

Practicable alternatives

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

It was noted that the legal representative of the deceased patients would be difficult to ascertain and that the carer or next of kin did not necessarily have right of access to deceased persons data as the duty of confidentiality would continue after death. There were therefore no practical alternatives available.

Justification of identifiers

It was noted that the specified identifiers were required in order to link to medical records.

Additional points

Members thanked the applicant for the coherent and interesting application and commended the level of service user involvement that had been undertaken.

Confidentiality Advisory Group conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being

conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

e) Preceding Paraneoplastic Encephalitis in Ovarian Cancer [15/CAG/0140]

This application for the University of Birmingham set out the purpose of an epidemiological case-control study to review the incidence of Paraneoplastic Encephalitis before the diagnosis of ovarian cancer. The study is to also examine the characteristics of the patient cohort and to identify the risk factors of developing an episode of Paraneoplastic Encephalitis in ovarian cancer. The study cohort will include all newly diagnosed cases with ovarian cancer during 1st January 2014 to 31st December 2014 from Birmingham Women's NHS Foundation Trust, Sandwell and West Birmingham Hospitals NHS Trust and Birmingham and Solihull Mental Health NHS Foundation Trust. Confidential patient information will be extracted and linked on site with NCIN Public Health England data and once data linkage has been completed, the applicant will pseudonymised the data. The control group will be matched by age and socioeconomic status and selected from the same group of cases who were diagnosed with ovarian cancer within the same time period, but did not develop Paraneoplastic encephalitis.

A recommendation for class 4 and 6 support was requested to cover access to an authorised user for the purpose of linking confidential patient information from Birmingham Women's NHS Foundation Trust, Sandwell and West Birmingham Hospitals NHS Trust and Birmingham and Solihull Mental Health NHS Foundation Trust and also NCIN Public Health England.

<u>Confidential patient information requested</u>

Access was requested to NHS number, date of birth, date of death and ethnicity. The applicant would require access to hospital medical records in order to review pathology reports, radiology reports and clinical summaries concerning the clinical symptomatology in each episode. The applicant confirmed that the identifiers will be removed once the data has been pseudonymised.

Confidentiality Advisory Group advice

Precedent Set Sub-Committee Referral to Full Committee

The Precedent Set sub-committee were unable to give advice due to a number of significant points that were identified from the review of this application. The members agreed to refer the application to a full committee for further consideration.

Public Interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely provide a public interest due to the need to investigate the incidence of Paraneoplastic Encephalitis before the diagnosis of ovarian cancer, to examine the characteristics of the patient cohort and to identify the risk factors of developing an episode of Paraneoplastic Encephalitis in ovarian cancer.

Practicable Alternatives

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

Members noted that the sole utilisation of HES data as a practical alternative would not be possible as it was necessary for the applicant to access hospital records in order to identify symptoms and examine characteristics. Members agreed incidence of symptomology could not be identified through the HES data on its own.

Members highlighted that the applicant is medically qualified in Hong Kong and would be able to identify the symptoms and characteristics of Paraneoplastic Encephalitis. However, members requested assurance that the applicant will be supervised by the clinical supervisor at all times when accessing and processing confidential patient information.

Confidentiality Advisory Group advice conclusion

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

Specific Conditions of Support

1. Provide assurance that the applicant will be supervised by the clinical supervisor at all times when accessing and processing confidential patient information.

2. Favourable opinion from a Research Ethics Committee.

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT)

submission for Sandwell and West Birmingham Hospitals NHS Trust and Birmingham and Solihull Mental Health NHS Foundation Trust.

5. NEW APPLICATIONS – Non-Research

a) National Prostate Cancer Audit – PROMSPREMS [15/CAG/0143]

This application from Royal College of Surgeons, sponsored by the Healthcare Quality Improvement Partnership, set out the purpose of collecting Patient Reported Outcomes Measures (PROMS) and Patient Reported Experience Measures (PREMS) data in response to patients who underwent radical treatment between 1 April and 31 March 2016 and 1 April 2016 and 31 March 2017 who are candidates for radical treatment for whom the National Prostate Cancer Audit (NPCA) has complete data for.

A recommendation for class 4 and 6 support was requested to cover access by Quality Health to patient name and address from the National Cancer Registration Service (NCRS) in order to send out surveys and NHS number and date of birth are requested to ensure that patient sample and survey response data are accurately matched.

Quality Health would send out postal questionnaires to patients and carry out mortality checks using DBS.

Confidential patient information requested

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

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a clear public interest in survey activities such as this taking place as part of the audit.

Practicable alternatives

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

Members agreed that it would not be feasible for Trusts to disseminate the patient survey themselves for the reasons outlined within the application form and noted that the justification provided had been accepted for previous survey applications.

Justification of identifiers

Members agreed that the identifiers requested for the purposes of disseminating surveys were appropriate and required.
Members queried whether age would suffice rather than month/year of birth for analysis purposes.

Data flow to NPCA

Members noted that the data flow to the NPCA secure database environment was anonymised and queried how the applicant would ensure this was the case noting that a unique NPCA identifier and month/year of birth were included and that the data would be linked to NPCA data. Members were of the view that this disclosure could not be considered to be anonymised given the potential to link to other NPCA data.

Survey cover letter

Members noted that previous national surveys had been sent with a cover letter on NHS Trust headed paper and agreed that if this was possible this approach should be adopted and cover letters on NHS Trust headed paper should be included with the survey.

Patient information

Members advised that the information provided to patients in relation to the use of survey responses should be as clear and transparent as possible and include information about where address information was obtained from, any future linkages to datasets and which organisations data would be shared with. The information provided should also ensure that the process for objecting to the use of data or from receipt of further surveys was as clear and straightforward as possible.

Patient notification

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. In addition, separate to that of Data Protection compliance, CAG need to be assured that there was appropriate information provided so as to increase public confidence in uses of data where this takes place without consent. This appropriately differs from the ICO role.

Members noted that the patient cohort were either currently undergoing treatment or would be in the future and therefore there was opportunity to inform patients about the survey at a local level. It was advised that the applicant ensure that Trust Caldicott

Guardians were informed about the survey to ensure that they could meet their responsibilities to inform patients about the use of their data. It was suggested that posters could be displayed within Trusts in order to meet this requirement and the applicant should provide confirmation what methods would be used to inform patients.

Retention

Members requested further information in relation to the arrangements for the retention of name and address information and whether it was proposed that this would be retained by Quality Health for those patients who responded to the survey. Members queried how long it was anticipated that this data would be retained and advised that if this went beyond the length of the survey the data should not be retained by Quality Health.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Secretary of State, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant was asked to confirm whether age, rather than month/year of birth would suffice for analysis purposes?
2. Confirmation whether the data flow to NPCA will be anonymised.
3. The information provided to patients should be explain all data flows, purposes and methods to register objection. The applicant was asked to revise the wording included on the patient information.
4. Please confirm what efforts will be made to inform patients about the survey.
5. Please confirm the retention arrangements for identifiable data in relation to patients who have responded to the survey.

Once received the information would be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible.

Specific conditions of support

1. In line with other national surveys, cover letters on NHS Trust headed paper should be included with the survey sent to patients.
2. It should be ensured that Caldicott Guardians at NHS Trusts were informed about the survey.

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) Getting it right first time programme [15/CAG/0144]

This application from Royal National Orthopaedic Hospital NHS Trust set out the purpose of a service evaluation project to determine the specific causes of medical negligence claims as surgical specialities through detailed case analysis from law firm data from the NHS Litigation Authority (NHSLA) panel firms. The project aims to improve the provision of patient care and the management of health services in the surgical specialities. The project aims to identify poor practice and influence national guidelines to address this poor practice.

A recommendation for classes 5 and 6 support was requested to cover access to data from NHSLA panel law firms in relation to patients who have made a claim against an NHS Trust in relation to surgical care since 2003.

Confidential patient information requested

Access was requested to patient age, NHSLA claim ID number, and description of medical negligence claim including dates of incident, date of case creation and outcome of case.

Confidentiality Advisory Group advice

Practicable alternatives

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

Members considered whether consent from patients would be possible and noted that this would not be feasible due to the retrospective nature of the data. It was noted that in order to identify correct case a unique identifier would be required and specific dates of treatment were required for analysis purposes.

Scope of application

Members considered whether the data requested would be classed as identifiable information, given that NHSLA claim ID number appeared to be the only unique identifier and that the application specified that similar data had already been obtained. It was noted that the NHSLA as data controller had advised that support should be obtained prior to access to this information and that the data from the law firms contained more detailed information in relation to the claim. It was noted that the richness of the dataset might mean that there was a risk of identifiability. On balance, members agreed that support could be recommended to ensure a legal basis to access the required data.

Patient notification

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. In addition, separate to that of Data Protection compliance, CAG need to be assured that there was appropriate information provided so as to increase public confidence in uses of data where this takes place without consent. This appropriately differs from the ICO role.

CAG noted that limited information had been provided to individuals about the potential of further use of data in relation to their claim. It was advised that efforts to inform patients should be made and that appropriate information should be displayed on the NHSLA website in relation to the project and data sharing. This notice should also provide instructions in relation to what a patient should do if they wanted to object to the use of their data. It was advised that on a prospective basis patients should be made aware that evaluations of this kind may take place and provided with the opportunity to object to data sharing when their claim was made.

Access controls

Members requested further information in relation to which individuals would have access to the requested data; this should be the minimum amount of people necessary. Further information was also requested in relation to the duty of confidentiality owed by these individuals, the information governance training that they had undertaken and the governance arrangements in place to ensure accountability to the Information Custodian.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Applicant should ensure that information in relation to the project, with details about how to object, are available on the NHSLA website.

2. Confirmation that the individuals who will access the requested data and confirm the duty of confidentiality owed by these individuals, the information governance training that they had undertaken and the governance arrangements in place to ensure accountability to the Information Custodian.

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

6. MINUTES OF THE MEETING HELD ON 30 APRIL 2015

The minutes of the meeting held on the 30 April 2015 were agreed as an accurate record subject to minor changes.

7. CAG OFFICE REPORT

For information

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the April 2015 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the April 2015 meeting applications.

External meetings and events

Ben Redclift, Confidentiality Advisor, attended the King's Health Partner's Information Governance conference titled *Digital Media in Health, social Care and Research: The Future is Now,* on 15 May 2015. Speakers included David Smith, Deputy Commissioner and Director of Data Protection, ICO and Dame Fiona Caldicott, National Data Guardian.

Amendments to approved applications

Prevention of Burns and Scalds in Children Phase 1 - CAG 1-06 (PR7)/2013

This application from the University of Cardiff described a study to evaluate a risk assessment tool designed to assess childhood burns and direct to appropriate care. The application was for the pilot study only.

The application followed on from a previous PIAG approval which was obtained in order to establish the risk assessment tool, PIAG 4-05(i)/2008 Thermal injuries in children – Version 1.

Confidential patient information requested

The application requested approval to access data in relation to patients under the age of 16 who have presented with scalds and non-scald burns at emergency departments over a 12 month period over 3 NHS Trusts. Clinical staff would complete a data collection form on

behalf of the research team who would then use identifiable details to request further information from other services such as health visitors, social workers, school nurses and children centres.

Name, hospital or NHS number and date of birth would be collected in order to carry out linkages. Identifiable data items would be removed from the database once linkages were complete.

Amendment request

An amendment to the approval was requested in order to extend the duration of data collection. Data collection will now extend to October 2015, although it is anticipated that phase 1 will be concluded earlier than this. This extension will ensure rigorous and seamless use of the burns assessment tool prior to commencement of phase 2

Confidentiality Advice Team advice

The amendment requested was forwarded to the Confidentiality Advice Team who agreed that support should be recommended for an extension to the period of data collection. It was noted that this amendment was justified on the basis that it will allow rigorous and seamless use of the burns assessment tool prior to commencement of phase 2.

Confidentiality Advice Team conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Mortality outcome in the London COPD cohort CAG 5-03 (PR3)/2013

This research application from University College London sought permission to obtain and use date and cause of death of previous participants in a consented COPD patient cohort. This cohort began in 1995 and 600-700 patients gave written informed consent to members of the study team accessing their medical notes. This consent did not explicitly include permission to link to mortality records to obtain date of death. The study team are routinely informed of date of death where the patient is still in contact with the hospital, but requested permission to use the Health and Social Care Information Centre to determine the current status of patients who are no longer in contact.

Amendment request

The amendment detailed that the research group had moved from University College London to Imperial College on 1st April 2014.

It was confirmed that patient information sheets and consent forms had been changed to reflect the amendment. It was confirmed that a REC amendment request had been submitted and approved for the specified amendment.

The applicant confirmed that there was no change in the application purposes or scope.

Confidentiality Advice Team advice

As the amendment request detailed a change in data controller and no change to the scope of the application this was considered by the Confidentiality Advice Team.

Confidentiality Advice Team conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Updates on existing applications

National investigation into suicide in children and young people 15/CAG/0120

This application was considered at the CAG meeting held on 26 March 2015 and the applicant was asked to respond to the request for further clarification as outlined below.

This application from University of Manchester set out the purpose of a multi-agency designed study combining available sources of information on cases of suicide and probable suicides in those aged 20 and under to provide a range of information at individual patient level that is currently not available. The study aims to identify the characteristics and antecedents of young person suicide and use these findings to help inform policy and safer practices with a view to reducing suicide rate in this age group.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover researcher access to confidential patient information from ONS, NHS Trusts Serious Untoward Incident reports and data held on the National Confidential Inquiry's database on individuals under the contract of mental health services prior to death. Scanned documents would be requested from participating organisations.

Confidential patient information requested

Access was requested to name, postcode, date of birth, date of death and place of death.

Confidentiality Advisory Group advice conclusion

At the meeting on 26 March members agreed to recommend provisional support, subject to a satisfactory response to the following request for information.

Request for further information

1. Please confirm why identifiable data needs to be retained for 6 years?

Applicant response

A sub-committee of members reviewed the response provided by the applicant within the letter dated 13 April 2015 and in the email dated 27 April 2015. It was confirmed that identifiable data would only be retained until the applicant was confident that all secondary data sources had been collected on a particular individuals. The data would then be anonymised and retained for 6 year.

Estimating the prevalence of problem and injecting drug use in Wales 2010-11 to 2020-21 15/CAG/0108

This application was considered at the CAG meeting held on 19 February 2015 and the applicant was asked to respond to the request for further clarification as outlined below.

This application from Public Health Wales set out the purpose of a study to provide robust prevalence estimates of problem drug use (PDU) and injecting drug use (IDU) across Wales for a ten year period.

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

1. Drug Interventions Programmes (DIP)/Integrated Offender Interventions Services (IOIS)
2. Welsh National Database for Substance Misuse (WNDSM)
3. Specialist and community-based needle and syringe programmes (NSPs)
4. Records of hospital admissions for specific ICD-10 codes

<u>Confidential patient information requested</u>

Access was requested to the dataset outlined above to cover patients treated between 2010-2021. First part of postcode, date of birth, initials and gender were requested.

Confidentiality Advisory Group advice conclusion

Following review at the February CAG meeting, members agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification as set out below. The applicant's response is summarised in bold.

Request for further information – applicant response

1. Confirmation why consent could not be sought from patients prospectively via services? **It was confirmed that all information would be collected retrospectively which meant consent would be impracticable. The applicant confirmed that only a sub-set of patients would be included within PEDW and therefore it would not be feasible to obtain consent for only a subset of patients and that consent was already obtained for patients within the Welsh National Database for Substance Misuse (WNDSM).**

2. Confirmation whether the applicant has considered carrying out linkages via the SAIL service? **The applicant confirmed that discussions had taken place with SAIL colleagues and that carrying out linkages via the SAIL service would involve increasing the number of parties and datasets involved in data linkage, with a consequent increase in the complexity of data processing.**

3. Confirmation whether full date of birth would be retained in the analysis datasets and why this is necessary. **Full date of birth would be retained in the analysis data sets in order to analyse age-related trends in substance misuse over time.**

4. Confirmation which datasets included confidential patient information and were therefore included within the application scope. **Data on hospital admissions from the Patient Episode Database for Wales (PEDW) and data on those accessing treatment captured on the Welsh National Database for Substance Misuse (WNDSM) are the two datasets including confidential patient information which are included within this application.**

5. Please confirm what information would be provided to notify the patients about the processing. **The research team will ensure that a clear lay summary of the project, including contact details for the research team and details of how to object to the use of data, is made available to all partner organisations in hard and electronic copy for disseminating to their service users as they deem appropriate.**

6. Further information in relation to the user involvement to be undertaken in relation to the application. **A service user involvement plan was included within the response.**

The response was reviewed by a sub-committee of members and it was agreed that this was satisfactory and conditional approval was therefore issued.

Secondment report

Dr Mark Taylor provided a verbal update on the activities undertaken as part of his secondment with the Health Research Authority.

Dr Taylor presented to Medical Research Council Research Governance Forum on 28 April 2015.

Dr Taylor reported that the draft IRAS Information Governance questions for the HRA approvals programme, mapping against requirements of v12 IG Toolkit, had gone out for review.

8. CHAIR'S REPORT

The Chair provided a verbal update on activities undertaken in the CAG Chair role in the past month.

The Chair had presented on the implementation of Caldicott Guardian and Health Research Authority approvals at the Annual Conference of Caldicott Guardians on 6 May 2015.

The Chair had attended a Data Access Advisory Group training day to present with the Confidentiality Advice Manager, Ms Natasha Dunkley on 5 May 2015.

Dr Taylor confirmed that a meeting with colleagues at the Information Commissioners Office (ICO) would take place on 08 June 2015 in relation to understanding the CAG perspective on patient notification and how this interacted with the Data Protection Act 1998 requirement for fair processing. Members suggested that the ICO be invited to attend to present their position to CAG as an education item.

Action: CAT to add ICO education item to the education item schedule.

9. ANY OTHER BUSINESS