NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

15 January 2015 at 10:15am – 5pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Patrick Coyle	Chair for items 3, 4, 5, 6, 7 and 8
Dr Tony Calland	Chair for items 1 and 2
Dr Kambiz Boomla	
Dr Robert Carr	Items 2a and 2b
Ms Hannah Chambers	Lay
Professor Barry Evans	Items 2a, 2b, 2c, 3a, 3c, 3d and 4a
Professor Julia Hippisley-Cox	
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	Items 2a and 2b
Ms Clare Sanderson	Items 2a and 2b
Dr Murat Soncul	
Mr C Marc Taylor	
Ms Gillian Wells	
Dr Miranda Wolpert	Items 2a, 2b, 2d, 3a and 3b only

Also in attendance:

Name	Position (or reason for attending) and items present for
Ms Natasha Dunkley	Confidentiality Advice Manager, Health Research Authority
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, Health Research Authority
Mr John Robinson	Confidentiality Advisor, Health Research Authority (Item 3b)
Mrs Nana Baffoe	Confidentiality Advisory Group Assistant, Health Research Authority
Dr Aumran Tahir	North West London Clinical Commissioning Groups Collaborative (Item 2a)

Mr David Stone	North West London Clinical Commissioning Groups Collaborative (Item 2a)
Ms Sonia Patel	North West London Clinical Commissioning Groups Collaborative (Item 2a)
Dr Robert Kyffin	Public Health England (Item 2d)
Ms Sarah Stevens	Public Health England (Item 2d)
Ms Alex Bell	Health and Social Care Information Centre (HSCIC), Observer
Mr Ben Redclift	Health Research Authority, Observer (items 2a and 2b)
Dr Ian Goodman	(by phone) North West London Clinical Commissioning Groups Collaborative (Item 2a)
Mr Andrew Norman	(by phone) South London Commissioning Support Unit (Item 2a)

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introduction

The Chair welcomed observers from the Health Research Authority and the Health and Social Care Information Centre (HSCIC) to the meeting.

The Chair welcomed Mrs Nana Baffoe and informed members that Mrs Baffoe had recently joined the Confidentiality Advice Team as the Confidentiality Advisory Group Assistant.

Apologies

Apologies were received from Dr Mark Taylor.

Declarations of Interest

The following declarations of interest were received:

Items 2d

Professor Barry Evans declared an interest in item 2d as the application was from his employer. Professor Evans was not present for the discussion of item 2d and did not receive papers for this item.

Professor Jennifer Kurinczuk declared an interest in item 2 as she held an honorary contract with PHE and was involved in providing data from the existing BINOCAR registers to the new PHE register.

2. NEW APPLICATIONS – NON RESEARCH

a) CAG 10-02(a)/2015 North West London Whole Systems Integrated Care Programme

This commissioning application set out details to achieve the following purposes: to create a North West London population segmentation model that identified care needs by

population, develop a joint health and social care commissioning framework through integrated capitated budgets, and to formalise collaborative working across health and social care providers into Accountable Care Partnerships which were intended to support the design of personalised and co-ordinated care. Support was sought to enable the extraction of patient level GP data to link with data currently processed under CAG 2-03 (a)/2013.

The application was made by Brent CCG on behalf of eight CCGs in North West London, and the processing had been subcontracted to South East London CSU. It was noted that this was the second Pioneer application considered by CAG; however, this differed in terms of a reduced set of purposes and corresponding identifiers. It was anticipated to cover adult patients from the 2.1 million population in North West London.

Confidentiality Advisory Group advice recommendation

Members welcomed and thanked the attendees for providing considered responses to the questions prior to and during the meeting. It was agreed that this activity fulfilled a relevant medical purpose and would help the public benefit through seeking to ensure the most effective use of resources to support joined-up care provision.

A summary of the discussion and the advice recommendation from the CAG is set out below.

Communication and public confidence

Members raised a number of questions around information provision; how and when this would take place. Attendees provided an update that this application had been submitted in the context of a number of years of engagement with patients and that individual communications were not planned at this stage and would form part of a later phase. The view was expressed that as personal data would be processed for a time limited period of two hours that to undertake individual communications could be considered disproportionate.

Members discussed the current climate and public perceptions over the appropriate handling of data. It was emphasised that the advisory role of the CAG was to support public confidence in appropriate uses of data so that there are 'no surprises' over data processing. Members expressed the view that patients should have an opportunity to understand how their patient information is used and be given opportunity to register an objection, prior to any data flowing. In terms of the CAG recommendation the focus was therefore not on the amount of time personal data would be processed, but the fact data would be flowing without patients being aware in the first instance until later in the programme.

While welcoming the principle that individual communications were intended to be sent in phase two of the programme, and that a pilot approach would be followed to test penetration of communications, CAG discussed the point that when support under these Regulations is recommended, this is usually on the basis that information will be provided to patients in advance of any data starting to flow. It was therefore stated that it would be important to maintain this consistency of approach within the Pioneers as a whole; this was discussed with attendees and members concluded that there were unable to identify an overwhelming reason why individual communications could not be undertaken prior to this data flow taking place.

Members therefore advised and sought feedback on the feasibility of bringing forward the phase two individual communications and combining these with the initial patient

information. For example, the initial letter could provide information on the broader programme, and also include details of this proposed data flow. It was understood that this would require a clearer idea of future plans but members agreed that these could be phrased so that potential uses would be broadly understood. It was also advised that these communications should provide for a right and mechanism to manage patient objection.

Patient objection

Members noted objection had been indicated at the end of a long document, noting that the communications had been designed in collaboration with patients. Members queried how there would be consistency of approach if GPs are to manage this mechanism, noting that carers were also highlighted. Attendees explained that carers may be a part of the consenting and objection process, and it was clarified that the application sought access only to GP data. Members highlighted that the leaflet mentioned care providers and accepted there were different types of care, however, it was critical that patients would be made aware of the correct place to go should they wish to register an objection.

In line with the comments above, members advised that the guidance provided to the relevant care providers, and greater clarity on the appropriate routes for patients to contact should objection be made, should be supplied in a refined application form.

Data controller relationships

There was discussion over the role of the GP as data controller and the attendees explained the governance arrangements that had been established in terms of an overarching federated data governance group. Members did query how much control would be retained by GPs once data had transferred and more specific arrangements such as a formal contracts were discussed. Members questioned whether the approach taken had been tested with anyone else and agreed that the data controller arrangements should be clearly articulated and the detailed governance arrangements and controls applied, as discussed, specified within a refined application.

Support time period and exit

Members questioned the time period for which support would be required. It was clarified that the information would be processed by the South East London CSU for a short period but the precise time could not be specified untilsupport was in place to enable the data to flow. It was confirmed that access to identifiers was not required; these were necessary only for the purpose of linkage, and these would be stripped out quickly.

In terms of employing a pseudonymisation approach, it was clarified that it was hoped for system suppliers to build in de-identification facilities and it was understood this was planned for 2015-16; attendees confirmed that ultimately it would be dependent on the system suppliers. Members agreed that this was unlikely to be an option in the short-term but agreed that the feasibility for this to be a practicable option in the future should be explored and engagement/progress reported against in six months.

Scope

Members referred to the website link provided that set out detail on the overall project and it was agreed that details of this proposed data flow should be added. It was also clarified that the EMIS extract referred to within the supporting letter was a full data extract, and that this data was not currently flowing. Members noted that the application referred to re-

identification requests and questioned from whom, however it was agreed that this was an error and this would be removed. Members also questioned whether historical patient information would be extracted from current patients and sought clarity from what time period.

Confidentiality Advisory Group conclusion

Members agreed that the purpose of the activity was for a clear relevant medical purpose and there would be a public interest and benefit to proceeding. It appeared that there had been detailed consideration of the necessity and supporting arrangements and the dataset restricted as far as possible. Members agreed that providing there would be a change in the planned communication arrangements to undertake individual communications, and satisfactory resolution of the clarifications, that support would be recommended subject to the specific and standard conditions of support set out below

Clarifications:

1. Clarification over how many years' historical data of currently registered patients was intended to be extracted.

2. Feedback should be provided on the feasibility of ensuring individual communications prior to this proposed data flow taking place, combining details of this data flow and the broader programme (including right of patient objection).

3. Addition of this project/approval to broader website information.

4. Revision of the application form to address clarifications addressed at the meeting, including:

    a. Scope of application e.g. GP data extracted only from practices, no free text, removal of re-identification request detail
    b. How patient objection will be managed and the guidance provided to those managing the process to ensure consistency of approach so that assurance is provided that patients are clear on who to contact should an objection be raised.
    c. Clear specification of data controller(s) in the context of the legal status of the various bodies.
    d. Specification of the governance arrangements applied to manage the data controller relationships, including relevant extracts of the contract or other information that set out the controls.
    e. Removal of background contextual information from the application form; to be provided as separate supporting appendix.

Provisional specific conditions of support

1. Timetable for individual communications to be brought forward and combined with the patient information leaflet to explain in general terms the proposed uses and benefits, rather than specifically focusing on this data flow. Communications to be provided to the CAG in advance of issue and prior to final approval coming into effect.

2. A report to be provided in 6 months on an exit strategy from support, to include a timetable for following a pseudonymisation approach and demonstrating active engagement with system suppliers to achieve this aim.

3. Free text information will not be extracted, and information will not be re-identified.

4. Support is provided to access NHS Number and care service records.

5. The conditions of support applicable to CAG 2-03 (a)/2013 remain applicable. The applicant should ensure that there is appropriate liaison with the HSCIC and NHS England to ensure compliance with those conditions of support.

b) CAG 10-02(b)/2015 Inpatients Survey

This service evaluation application from the Care Quality Commission set out the purpose of the 2015 Inpatient Survey. The inpatient survey would include all 154 eligible trusts who would be asked to conduct the survey with preparations expected to begin in August 2015. Approximately 1,250 patients would be included at each trust.

A recommendation for class 5 and 6 support was requested to cover access to information from relevant trusts to allow surveys to be administered. Access was requested to confidential patient information including name, address and postcode.

Confidentiality Advisory Group advice

Amendments to 2015 Inpatients Survey

Members noted that repeat survey applications were normally considered via the precedent set process, however the following changes had been specified within the application which meant that it was referred to a committee meeting for review:

- Increase in sample size at individual Trusts from 850 to 1250 in order to allow statistical reliability for Trusts and look at sub-groups.
- Addition of ICD10 code (chapter code only) in order to relate the results of the survey to particular conditions.
- A pre-approach letter would be piloted.

Members agreed that the specified changes were acceptable and noted that the ICD10 code would relate to chapter code only. Members advised that they would need strong further justification if there was an intention to access lower level ICD10 codes in future, noting the increase in the sensitivity of the dataset with the inclusion of clinical codings.

Patient information and objection

Members reviewed the survey and patient letters provided; it was advised that it should be made clear that patient could object to receiving the survey and how they could express this wish. In addition, it should be clear that patients could object to receiving any information in relation to future surveys at a local level.

Sharing information

Members queried why individual level data needed to be shared with the Department of Health and NHS England; it was advised that if individual level data was shared this should be clear within the information provided to patients with the survey. Members advised that where possible individual level data should not be shared and analysis undertaken within the survey coordination centre.

Additional patients and survey questions for local use

Members advised that where Trusts were using surveys for their own purposes and disclosing additional patient information specifically for local surveys it should be ensured that a legal basis was established and clear data sharing contracts were in place to establish the data controller/processor relationship.

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. This was 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. Please confirm why it is necessary to share the respondent level data with NHS England and Department of Health.

Once received the information would be reviewed by a sub-committee of members in the first instance.**Specific conditions of support**

1. Information in surveys and patient letters should be provided which informs patient about the right to object to future and current surveys and that their information will be shared with other organisations such as NHS England and Department of Health.

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

c) CAG 10-02(c)/2015 Private Healthcare Information Network – HES Linkage to Private HES

This service evaluation application from Private Healthcare Information Network (PHIN) set out the purpose of an activity which aimed to significantly improve the measurement and understanding of core clinical indicators for patients receiving private treatment, to support proper regulation of the private healthcare industry and provide a more informed patient choice.

A recommendation for class 4, 5 and 6 support was requested to cover access to information from private healthcare providers and allow linkage to Hospital Episodes Statistics (HES) data using pseudonymised data. Pseudonymised data only would be disclosed from the Health and Social Care Information Centre (HSCIC). Confidential patient information including name, postcode, NHS number, date of birth and date of death would be sent to the HSCIC for linkage purposes.

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 noted the example consent forms provided and the email from the applicant which asserted that consent forms were owned by the health care providers and they had limited control over the content. Members agreed that the current consent forms would not be explicit enough to rely on these to provide a legal basis for the data flow. Members advised that PHIN should continue to explore the feasibility of consent with health care providers at it was recognised that this presented an exit strategy from the use of confidential patient information without consent.

Patient communication

Whilst consent aspects were explored members advised that the applicant draft privacy notices for use in hospitals and provide these to health care providers. The privacy notices should include information about the data flows specified within the application. The notices should make clear how patients could object to the use of their 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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The applicant should continue to explore the feasibility of a consent based approach as an exit strategy from support under the Regulations.

2. The applicant should ensure that privacy notices are drafted for use in relevant hospitals to ensure that patients are informed about the data collection.

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

d) CAG 10-02(d)/2015 Public Health England National Congenital Anomaly and Rare Disease Registration Service

This application from Public Health England set out the purpose of the establishment of a national registry to provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies and rare diseases for the population of England.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to confidential patient information. Access was requested to a variety of sources including cytogenetic laboratories, post mortem laboratories, ultrasound departments, delivery suites, computerised obstetric notes, ONS data, Personal Demographics Service and other outcome datasets. Name, postcode, NHS number and data of death were requested in order to carry out linkages, collect follow up data and to ensure the correct individual was identified.

Confidentiality Advisory Group advice

Members thanked the representatives from PHE for attending the meeting and agreed that the discussion was helpful and informative. In particular the discussion clarified the anticipated issues in relation to the transition of the current local registers into PHE.

Transfer of existing BINOCAR registers

The applicant advised that it was intended to transfer the existing BINOCAR register staff into Public Health England by the 1st April 2015 via TUPE and that the consultation period for this transfer had begun. It was advised that the data management system would be in place by the 1st April 2015 and that the transfer of legacy data and prospective data collection would take place following this. It was confirmed that a separate Information Governance Toolkit return would be submitted in relation to the data management system and this would need to be in place by 1st April 2015.

Members queried how local registries currently processing data under the BINOCAR approval (PIAG 2-08(e)/2002) would manage the legacy data collected within their own systems after the transfer of data from those registries had taken place. It was advised that the individual organisations responsible for the current registers would remain data controllers for the legacy data held within their own systems. Members noted that it was unclear whether the data would continue to be processed in an identifiable format and advised that if this was the case the legal basis for the continued processing of this legacy data would need to be determined. It was agreed that the current named applicant for the BINOCAR application should be copied into this outcome to alert the BINOCAR data controllers of this issue, noting that the current BINOCAR application expired on 20 June 2015.

Transition timescales

Members noted that support for the current approval under CAG 9(PS2)/2014 for the West Midlands Congenital Anomaly Register (WMCAR) and the Northern Congenital Abnormality Survey (NoRCAS) would need to be extended to ensure that the existing approval for these two registers that had already transferred into PHE were maintained. It was agreed that this separate application should be extended in line with the other BINOCAR application until 20 June 2015 to allow transition arrangements and legacy data arrangements to be finalised.

Public interest

Members agreed that there was a clear public interest in the continued data collection in relation to congenital anomalies and rare diseases within England, it was noted that the

original BINOCAR application which currently included 7 local registers had received continued approval since 2002 (PIAG 2-08(e)/2002).

Parent and patient communication

Members noted and discussed at length the assertions that consent would not be feasible at the time of inclusion onto the register and concerns around the potential bias created by seeking consent. Members queried whether options such as informing all women at the point of entry on the register and allowing opt out at this stage had been considered. The applicants noted that this was something that the previous BINOCAR applicant had been unable to achieve. However, members requested that further exploration into informing parents and allowing opt out consent should take place and further justification as to why this approach would not be possible should be identified.

In addition, members noted that data would be retained and continue to be collected in relation to patients throughout their lives and queried how it would be ensured that patients were informed about the register and offered the opportunity to opt out as they became older and able to consent for themselves. In particular, members noted that there would be a hard to reach cohort who did not continue to receive medical treatment.

Members noted that the patient information leaflet was not yet finalised and agreed that a copy of this would be required before any final approval was provided.

Pseudonymised approach

The proposed dataset included a number of identifiable data items including name and address and that the applicant proposed indefinite data retention. Members requested the applicant continue to explore practical methods for pursuing a pseudonymised approach where possible. Whilst this may not currently be feasible, members were of the view that this should continue to be explored, along with other options such as consent, to ensure that an alternative to or the reduction of processing of confidential patient information without consent was identified where possible.

EUROCAT

Members requested further information in relation to the data flow to EUROCAT including what data items were sent and processing arrangements. The applicants confirmed that they were seeking further information and assurance in relation to the arrangements for EUROCAT.

Web portal

Members noted the future web portal which would allow patients to access and submit their own information. It was anticipated that this would increase data quality and allow patients to remain in control of their information. Members requested further information in relation to the web portal, noting that it was based on the cancer registries web portal pilot, including how patients would be alerted to its existence.

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 following information should be provided to allow the CAG to continue their consideration of the application:

1. Confirmation of the applicants understanding of the continued processing of legacy data by current BINOCAR data controllers and confirmation that current data controllers have been informed of the requirement to clarify retention arrangements for legacy datasets and seek further support where required.

2. In line with comments above in relation to informing patients, exploration and information in relation to the potential to inform parents (at the point of data being entered onto the register) and patients (when able to consent for themselves) and allow opt out.

3. Clarification in relation to data provided to EUROCAT.

It was agreed that this additional information should be submitted to the next CAG meeting to allow a recommendation to be made.

If the recommendation was favourable CAG identified that the following conditions would be recommended, these would be subject to change depending on the review of further information at the February meeting.

Provisional specific conditions of support

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

2. Submission of clear and coherent patient information leaflets.

3. Continued exploration of options for adoption of a pseudonymised approach or consent as an exit strategy.

4. Further information in relation to the development of a web portal and how it is anticipated this will be implemented and managed should be submitted.

3. NEW APPLICATIONS – Research

a. 15/CAG/0005 Research to identify measures of quality and safety of healthcare

This application from Imperial College London set out the purpose of the establishment of two databases. The first database would include a monthly and annual pseudonymised extract of Hospital Episode Statistics (HES) from the Health and Social Care Information Centre (HSCIC) on English NHS hospitals for the purpose of research. Data from this

database would be provided to the Dr Foster Unit at Imperial College in a pseudonymised format.

The second database would hold a limited set of identifiable fields including NHS number, local patient identifier and date of death to allow acute provider trusts to identify their own patients contributing to mortality alerts or other quality and safety alerts for the purpose of case note audits and mortality reviews.

A recommendation for class 4 and 6 support was requested to cover disclosure of confidential patient information from the Health and Social Care Information Centre (HSCIC) to Imperial College London.

Access was requested to monthly and annual extracts of HES, including Hospital Consultant Code, General Practitioner Code and Referring Practitioner Code and NHS number, Local Patient ID (LOPATID) and date of death (these three data items would be included on the second database only)

Confidentiality Advisory Group advice

Public interest

Members agreed that the activities carried out within the current application (PIAG 2-07(d)/2007) and continued within this submission provided a significant public benefit and a number of high-quality outputs.

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 a pseudonymised approach had been adopted for the research database aspect of the application and agreed that this was a positive step and noted the improvement on the previous application. No patient identifiers would be required for the research database.

It was noted that three identifiers (NHS number, local patient ID and date of death) would be required for the second database in order to carry out the re-identification service to Trusts.

A potential future exit strategy was highlighted by the applicants which suggested that the HSCIC may offer a re-identification service at some stage. Members asked that the applicant continue to pursue this alternative and requested anticipated timescales in relation to when the HSCIC would be able to offer this service.

Extent of confidential patient information requested

As outlined above, members noted that three identifiers would be required within the second database in order for the specified re-identification service to be provided to Trusts. However members queried, given that the service was not provided to all Trusts, whether the applicant could receive identifiers only for deceased patients treated in the 119 Trusts already purchasing this service from Imperial College London. This would ensure that identifiable data was only received where it was strictly necessary.

The requirement for date of death in order to calculate mortality indicators was noted and members queried whether it would be possible for the HSCIC to calculate 30, 60 and 90

day indicators on behalf of the applicant instead of receiving the full date of death. The requirement for ethnicity and GP Practitioner Code was discussed and it was agreed that further justification in relation to the justification for these data items should be provided, in particular it was noted that ethnicity was removed prior to use.

Members discussed the continued use of anonymised sexual health data and suggested that this was removed from the request as it was not possible to link this to any further data. If anonymised sexual health data was required members requested further justification for this.

Members noted that the application included reference to receiving data from ONS and National Joint Registry (NJR) as well as the HSCIC and requested that the applicant be specific in relation to which data sources were included within the research database.

Data retention

Members noted that retrospective data within the research database would be irreversibly pseudonymised and all data received on an ongoing basis would be pseudonymised.

In relation to the second database, members sought further justification at this stage in relation to why it was necessary to retain the data in identifiable format for three years. It was suggested that the dataset was irreversibly pseudonymised as soon as possible and members requested further information in relation to when this would be possible and how this would be achieved. In addition, members requested further information in relation to the current arrangements for historical data and confirmation that the applicant did not hold the key for pseudonymisation and therefore were unable to re-identify previously pseudonymised datasets.

Application purpose

Members agreed that it should be ensured that the research database was used only for medical research purposes. Within the second database, identifiable data would only be used by the trusts purchasing the re-identification service to allow them to view data on their own patients.

User involvement

Members were pleased to note that consultation with a focus group had taken place and specific questions in relation to the use of confidential patient information had been raised. Members suggested that further patient involvement could be sought in relation to the monitoring and governance of the database and requested that the applicant consider how this could be implemented. The suggestion that the applicant would explore with the patient group the usefulness of producing information leaflets to distribute to patients via hospitals was welcomed and encouraged to ensure that as clear information as possible was available to ensure transparency. Members advised that any information provided to patients should be clear in relation to registering objections and as coherent as possible to ensure the activity and processing was fully understood.

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 Health Research Authority and Secretary of State. The recommendation of support was subject to satisfactory responses to the request for

clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for further information

1. Further justification should be provided for the use of General Practitioner Code and ethnicity. (Research and non-research databases)

2. Confirmation in relation to the precise data sources required for each database. (Research and non-research databases)

3. Confirmation whether the applicant could receive identifiers limited to deceased patients treated in those Trusts which used the service provided only. (Non-research database only)

4. Confirmation whether the HSCIC could provide mortality indicators in time intervals rather than full date of death. (Non-research database only)

5. Confirmation in relation to how long the applicant intends to retain data in identifiable format on the second database and further information on the pseudonymisation process should be provided. Any specified timescale for retention should be justified. (Non-research database only)

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.

The following conditions were recommended, it was revised that these were subject to change depending on the review of further information provided in response to the clarification request above.

Provisional specific conditions of support

1. Data in relation to sexually transmitted infections, HIV and termination of pregnancies should not be disclosed to Imperial College London unless further justification for the receipt of this data is provided for review by CAG and approved under the Regulations.

2. The research database must be used for medical research purposes only.

3. It should be ensured that historical data processed under PIAG 2-07(d)/2007 is irreversibly pseudonymised in line with this application. This should be carried out as soon as possible and in line with the response to clarification request 5 above.

4. Consultation with the patient group on the governance and monitoring of the databases should be explored on an ongoing basis and reported at annual review stage.

5. It should be ensured that all patient information is as coherent as possible with clear instructions to allow patient objection.

6. Further possibilities to inform patients should be explored in conjunction with the patient group and further information provided at annual review stage.

7. Favourable opinion from a Research Ethics Committee.

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

b) 15/CAG/0003 Comparison of bleeding after ACS between ticagrelor and clopidogrel

This application from Aintree University Hospitals NHS Foundation Trust set out the purpose of conducting a study of patients who had been treated for Acute Coronary Syndrome (ACS) with either ticagrelor or clopidogrel and corresponding patient bleeding. The study would involve six Mersey network sites in the review of patient records for the last 2,500 patients who received clopidogrel for ACS as a new prescription prior to a change in guidelines, and then the same review would be conducted on the last 2,500 ticagrelor patients. Hospital Episode Statistics (HES) data would be flagged to identify relevant patient admissions and mortality data would be collected to supplement/confirm locally held information. Access was requested to hospital number, patient demographics, date of birth, date of death, gender, cause of death and clinical data as outlined within the application.

A recommendation for class 1, 4 and 6 support was requested to cover access to link patient identifiable information obtained from more than one source and anonymise the information.

Confidentiality Advisory Group advice

Public interest

Members considered the public interest of this application and noted that study sought to investigate the potential risk of increased bleeding with ticagrelor. It was understood that there was no increase in fatal bleeding when ticagrelor was used when this drug was investigated within the referenced PLATO trial.

Members were not clear as to the evidence to suggest that there was a greater risk of fatal bleeding with ticagrelor and therefore requested that the applicant provide further information as to the rationale for this application.

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. The applicant's explanation as to why it was not possible to seek consent from patients was noted, however members were not convinced that consent would not be possible as it was understood that patients would need to spend some time in hospital or have clinical follow up appointments. It was queried whether this could provide an opportunity to contact them about this research. The

applicant was therefore requested to provide a further justification as to why consent was not feasible.

User involvement

It was noted that the applicant had not been in contact with patients regarding this study. The Group agreed that they would have expected to see some engagement with patients to include any feedback they may have had in relation to the use of confidential patient information within the study. It was suggested that patient and public involvement may also assist in demonstrating public interest and acceptance of this study.

Communication with patients and objection

The Group agreed that if consent were not feasible, efforts should be made to raise general awareness of the use of data and to provide a process for respect where patients may not wish for their data to be included. Members requested further consideration from the applicant to demonstrate how they would attempt to raise awareness of this study and to outline how patient objections would be respected.

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 following information should be provided to allow the CAG to continue their consideration of the application:

1. Further information and justification to demonstrate the public interest in this application.

2. Further information and explanation as to the reasons for why consent was not considered to be feasible. Where further information is provided to demonstrate this then consideration as to what measures may be considered to both raise awareness of this study and to allow for patients to object of their data being included should also be provided.

3. A user involvement plan to ensure the involvement of patients, patient groups or the public within the study.

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

c) 15/CAG/0004 Chronic Conditions to Education

This application from University College London (UCL) set out the purpose of a project which sought to undertake linkage between HES and National Pupil Database data using the Health and Social Care Information Centre (HSCIC). The study aimed to inform policy about the impact of supportive service provision outside healthcare on emergency hospital admissions and

examine patterns of provision from education and out-of-home care for all children in local populations.

A recommendation for class 4 and 6 support was requested to cover access to HES-ONS linked data. The HSCIC would use the Personal Demographics Service (PDS) to locate accurate NHS number for the cohort to link to HES-ONS data.

Name, postcode, NHS number, date of birth and date of death would be used by the HSCIC to carry out linkages. A pseudonymised version of this dataset would be disclosed to UCL for analysis.

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 noted that the information provided to UCL appeared to be pseudonymised. Members noted that identifiable data would be required within the HSCIC in order to carry out the linkage of datasets. However, there was a disclosure of identifiable data from the Department of Education and therefore the legal basis for this transfer would need to be clear. This fell outside the remit of the Regulations as this was limited to confidential patient information.

As the dataset disclosed from the HSCIC appeared to be anonymised, members sought assurance that this was the case and advised that if this was correct it would appear that support would not be required as there was no disclosure of confidential patient information in this instance. In order to be certain, members asked for confirmation of how the applicant defined pseudonymised data and what safeguards were in place to ensure that identification of individuals would not be possible. In particular, assurances that unique ID numbers, such as pupil ID, would not be disclosed were requested.

Application to research ethics committee

Members noted that the applicant had corresponded with the National Research Ethics Committee and it had been advised that a research ethics committee opinion would not be required for this specific application. Members reiterated the requirement for all research applications under the Regulations to obtain a favourable research ethics committee opinion and that the applicant could ask that this was reviewed on a discretionary basis. It was agreed that if support was required, which would depend on the further information provided, the applicant should make this request. The Confidentiality Advice Team could provide assistance to help facilitate this process if required.

Extent of dataset requested

It was noted that the dataset was extensive and members agreed that if confidential patient information was required strong justification would be needed to access data in relation to the cohort size specified. Members advised that the applicant consider a case control study using a smaller cohort size. In addition, members queried what time period of data was required and whether extracts would be required on an ongoing annual basis or whether the specified data extraction would be completed once only.

Data retention

Members queried why the applicant needed to retain data for a period of 3 years and requested further clarification in relation to data retention requirements and how these has been determined.

Data sharing agreement

Members noted that data sharing agreements would be in place and requested that copies of these were submitted.

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 following information should be provided to allow the CAG to continue their consideration of the application:

1. Confirmation of how pseudonymised data was defined by the applicant and what safeguards would be in place to ensure that identification of individuals would not be possible. This should include copies of data sharing agreements.

2. Provision of further justification regarding the calculation of cohort size for this study, noting that the cohort size is exceptionally large.

3. Confirmation regarding what time period data was requested for and how frequently extracts would be required.

4. Confirmation of how long the dataset would be retained and why this was required.

Once received the information would be reviewed by a sub-committee of members.

d) 15/CAG/0001 Access to Healthcare and Impact on Health Inequalities

This application from University of Leeds set out the purpose of a study which aimed to investigate the relationship between distance/transport accessibility to healthcare services and health inequalities. The study would focus on patients with Rheumatoid Arthritis and Osteoarthritis.

A recommendation for class 2 and 6 support was requested to cover access to Hospital Episode Statistics (HES) data from the Health and Social Care Information Centre (HSCIC) in relation to hospital appointments for Osteoarthritis or Rheumatoid Arthritis across a 3 year period (approximately 20,811 per year). Confidential patient information was also requested from NatCen in relation to the English Longitudinal on Aging (ELSA) cohort (approximately 3,300). Access was requested to the datasets including postcode by a researcher at the University of Leeds.

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 noted the letter from the HSCIC which confirmed that the HSCIC was unable to provide a service to calculate distances and travel times from patients' home addresses to service provider location.

Members commented that it would be encouraging if the applicant was able to visit the HSCIC in order to provide training to HSCIC staff to apply the software which would allow them to apply this without disclosing identifiable information. Members recognised that this may not be feasible but requested that the applicant explore the option and utilise if this did present a practicable alternative.

Members supported the suggestion that the applicant should first receive a file containing postcode and other limited information to allow the applicant to apply the relevant software. The postcode data should then be destroyed and linkage to the second file, including clinical information, should be carried out using a pseudonymised method. It was noted that the HSCIC had confirmed that this approach would be possible.

Communication with patients

Members requested that efforts should be made to inform patients where possible, in particular noting that the ELSA cohort was contacted regularly.

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. The applicant should explore whether it would be feasible to provide relevant training to HSCIC staff to allow them to apply the relevant software on their behalf and utilise this option if available.

2. Favourable opinion from a Research Ethics Committee.

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

4. **AMENDMENTS TO APPROVED APPLICATIONS**

a) PIAG 4-07(c)/2002 PICANET

This research application from the University of Leicester set out the purpose of establishing a nationwide research database of paediatric intensive care (PIC). This national database (PICANet) would hold secure and confidential high quality data on all PIC activity, casemix, structure and utilisation in England and Wales. A recommendation for class 5 support was requested to cover access to PIC data. Confidential patient information including name, address, postcode, NHS number, date of birth, sex and ethnicity was requested from NHS Trusts and the Health and Social Care Information Centre (HSCIC_.

The amendment request sought to amend the original PICANET application to reflect that the data controller was now the University of Leeds.

Confidentiality Advisory Group advice

Data controller change

Members agreed that they were supportive of the proposed amendment to the application. It was noted that the purposes and data flows specified within the application would not change.

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. Whilst it was noted that consent had been piloted previously and local processes meant that consent had not been feasible via the clinical care teams, the approval had been in place for over ten years and, with this in mind, members agreed that the applicant should continue to scrutinise potential alternatives to the use of confidential patient information without consent. Progress in relation to adopting consent or moving to the collection of pseudonymised information only should be reported at annual review stage.

Justification for identifiers

If a pseudonymised or consent based approach proved not to be feasible, members advised that the applicant should explore whether it would be possible to reduce the amount of confidential patient information requested, noting that a large number of identifiers, including name, were currently being processed. Members queried whether it would be possible to carry out linkage using NHS number only.

Parent/patient information leaflets

Members reviewed the parent/patient information provided and advised that the application should ensure that there was clear information about the method to object to data collection. It was advised that revised patient information should be provided as soon as possible to ensure individuals could object if they wanted to.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Continued exploration of alternatives to the use of confidential patient information or reduction of the number of identifiers required as outlined above.

2. Please ensure that all information leaflets include details of how patient may object to the processing of confidential patient information and ensure that this is respected.

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

5. MINUTES OF THE CAG MEETING HELD ON 11 DECEMBER 2014

The minutes were agreed as an accurate record, subject to amending condition 2 in relation to item 8, PIAG 2-07(d)/2007 Research to identify and publish measures of quality delivery of health by provided or by area and also to provide management information for the NHS, to ensure consistent with original conditions specified by the Patient Information Advisory Group.

6. MINUTES OF THE MEETING OF THE SUB COMMITTEE OF THE CAG HELD ON 1 DECEMBER 2014

The minutes were agreed as an accurate record, subject to format changes to reflect where items were considered by the Chair or Confidentiality Advice Team only.

7. CHAIR'S REPORT

Confidentiality Advisory Group new role

The Chair informed members that he had provided further comment upon draft 'CAG' regulations in his capacity as part of the Steering Group and that the principal intent had been to seek clarity regarding implications for current practice and enforcement. Members were informed that the current expectation was for the CAG regulations to come into force end of October and CAG would need to be in a position to deliver formal advice to the Health and Social Care Information Centre (HSCIC) by this time. Members were advised that an initial workshop to commence the activity development was scheduled for 13 February.

National Joint Registry meeting

The Chair and Deputy Confidentiality Advice Manager attended a meeting of the National Joint Registry (NJR). The NJR invited a presentation on the role of CAG and the relationship between section 251 and the role of the NJR ethics committee.

REC training

The Chair gave a presentation on the implications of restrictive access to health records for research at the NRES national REC Chair training day and gave a similar presentation the Ministry of Defence REC.

8. CONFIDENTIALITY ADVICE TEAM 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 December 2014 meeting applications.

HRA approval decisions

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

Updates on existing applications

CAG 8-02 (a)/2014 Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting

CAG 8-02 (b)/2014 Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient register and reporting.

CAG 8-02 (c)/2014 Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England)

These non-research applications from NHS England received a recommendation of provisional support at the November 2014 CAG meeting and were contingent upon satisfactory responses to clarifications and adherence to the specific and standard conditions of support. Final support was provided on 10 December 2014 until end March 2016.

The response, received 27 November 2014, addressed the outstanding clarifications as follows:

1. Review of patient leaflet to make more explicit the nature of the information being processed and feedback on review/development of leaflet for carer/relatives and how any objections may be managed

Response

It was confirmed that the current patient leaflet was being amended with a further draft that would be discussed with key advocacy and patient groups to ensure it is accessible. The response also indicated that a patient leaflet that specifically discusses the use of patient information was being developed and the intent was to produce a draft to discuss with key stakeholders by February 2015.

This commitment was welcomed. It was advised that there could be greater clarity or provision of examples of the relevant information so further review to ensure it is fully transparent as possible. It was also advised that a specific update on the discussions with key named stakeholders and patient groups and any changes made as a result of this be reported against at the interim review. The responses to patient objection and carer leaflet were addressed in the subsequent clarifications below.

2. Update of application to include explicit detail on how patient objection is intended to be managed and update to include greater detail on how fair processing compliance and the plan for implementation will be managed within the CCGs, including the standards the CCGs are expected to be compliant with.

Response

Updated copies of the three applications reflected the amendments as requested. The letter highlighted the following:

Patient objection

- Patient objection would be managed under the Data Protection Act 1998 and section 10 requirements and procedures on a case by case basis and involve the patients and/or their representatives. Processing would reflect the standards and processes required by the Mental Capacity Act 2005;

- Guidance was being produced by NHS England Mental Health and Learning Disabilities team for CCGs and NHS England's Area Teams about objection management and consideration.

- A leaflet for patients, advocates, carers and leaflets would be designed to help explain the objection process and how it is managed, as well as explaining the benefits of the processing to the individual patient and the wider patient cohort

It was advised that the response provided sufficient assurance that the applicants would ensure that those involved in processing information would appropriately discharge their responsibilities under this approval. A report on any expressed patient objection and how this right has been communicated should be provided at the interim review, along with copies of the guidance and updated patient and carer information.

Fair processing implementation plan

The response confirmed the following:

- CCGs would be asked to confirm that the current leaflet is provided to patients, their relatives, carers and/or advocates as part of the standards expected of organisations holding registers;

- CCGs would be asked to confirm they would provide the updated fair processing notices and would implement discussions to ensure the provider are obliged to provide details to patients or their representatives;

- Strengthening of current contractual requirements and advice to CCGs on how current contracts with providers could be used to ensure fair processing is undertaken and monitored;

- CCGs would be asked to provide details through their own websites and patient engagement programmes;

- CCGs to be asked to confirm that they have systems and procedures in place that comply with the guidance on management of patient objections;

- The fair processing material will be provided centrally with the ability to add information about local contact points and how to find out more;

- The implementation plan would outline these requirements, set timescales and will be reported to CAG in the June 2015 update.

Members welcomed this detail and advised that this provided sufficient assurance at the current time that responsibilities under the Data Protection Act 1998 would appear to be discharged appropriately. It was emphasised that the CAG had not specifically endorsed this approach as it is the data controller's responsibility to ensure they are fully compliant with the Data Protection Act 1998. Noting that much of the response referred to future activities, the expectation is that all aspects will be completed in line with these commitments and a detailed report on all these aspects was welcomed.

Security arrangements

It is a standard and separate part of the overall application process that all those processing information under support have attained a satisfactory level under the IG Toolkit, as confirmed by the Health and Social Care Information Centre (HSCIC) to the CAG, prior to any approval coming into effect. Correspondence from NHS England indicated that there had been a delay to this confirmation being received.

Due to unexpected external delay, confirmation was subsequently received on 09 December 2014 from the HSCIC Information Governance Delivery team that NHS England and the individual Area Teams had achieved a 'satisfactory with improvement plan' status. The CAG was disappointed to note a number of areas for improvement however as the HSCIC ultimately retain

responsibility for improving security assurance status, reluctantly agreed to accept the current plan for handling as the HSCIC appeared to have implemented relatively tight measures to ensure progression.

However, as the data flow to Area Teams is an explicitly defined data flow under approval reference CAG 8-02 (b)/2014, the CAG was concerned about some of the fundamental aspects to be completed in some areas, e.g. information asset register. The applicants were therefore reminded they are expected to comply in full with the standard conditions of approval, including the need to ensure that all staff processing information under this approval do not do so until they are trained in the purposes, manner and restrictions of processing as specified within the application. The CAG advised that they expected rapid progression on the outstanding areas applicable to the application data flows in line with the specific timescales, so as to increase external confidence in NHS England handling of patient information, and requested an interim update by the end of February 2015 to confirm relevant actions have been completed as specified in the improvement plan. It was strongly advised that appropriate resource be assigned to ensure any aspects outstanding, impacting on the application data flows, meet the required standard as a priority so as to prevent impact on continuing or future applications from NHS England as this issue will be revisited should existing applications seek further continuation. In light of the security aspects, the previous conditions of support were updated to include a specific action on reporting against these.

Updated specific conditions of support

1. Where a patient seeks to object to the data processing, any intent not to respect the objection must be legitimised under a different legal basis; support under the 2002 Regulations cannot be relied upon in those instances.

2. Legacy data collected prior to the date of final approval in this letter is excluded from the scope of support and an alternative legal basis will need to be established to continue processing this data. Data related to third parties, not considered to be that of the patient, is also excluded from the scope of support.

3. Written update report to be provided in six months (submit to deadline of 13 May 2015 for consideration at 04 June 2015 meeting), to include

    a. Practical application of patient objection – guidance, process, experience, handling and outcomes
    b. Updated patient and carer leaflet
    c. Progression towards exit strategy – update, plan, any potential issues.
    d. Information Governance Toolkit submission – status update on actions, impacting on the application, required to attain a satisfactory standard

4. In light of the improvement plan actions, report to be provided end February 2015 confirming all IGT aspects, impacting on the application data flows, scheduled for completion by this time have been satisfactorily completed.

Confidentiality Advisory Group advice conclusion

Based upon the responses it was agreed that sufficient information had been provided to enable a recommendation of final support to be provided.

Secondment report

The Chair provided an update on activities undertaken so far in his secondment capacity as Data Policy Advisor to the Health Research Authority (HRA). This item was noted by members.

9. ANY OTHER BUSINESS

No other business was discussed.