NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

19th February 2015 at 9am – 5pm at Skipton House, SE1 6LH

Present:

Name	Capacity and items present for
Dr Mark Taylor (Chair)	
Dr Kambiz Boomla	
Dr Patrick Coyle (Vice Chair)	Chair for item 5A
Dr Robert Carr	Not present for item 2A
Dr Tony Calland MBE (Vice Chair)	Chair for item 4A
Mr Anthony Kane	Lay
Mr C Marc Taylor	
Ms Clare Sanderson	
Professor Jennifer Kurinczuk	Not present for item 4A
Dr Murat Soncul	
Professor Barry Evans	Not present for item 4A
Dr Miranda Wolpert	Not present for item 2A, 6A, 6B, 7A, 8A, 9A
Mrs Hannah Chambers	Lay

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Ms. Amy Ford	Senior Confidentiality Advisor, HRA
Ms. Catherine Chesham	Deputy Regional Manager, HRA (observing)
Ms. Naaz Nathoo	REC Manager, HRA (observing)
Mr Hayden Thomas	NHS England, Item 2A
Mr Andrew Ashworth	NHS England, Item 2A
Ms Ming Tang	NHS England, Item 2A
Ms Lan-Ho Man	Department for Communities and Local Government, Item 5A

Mr Rod Hill	Department for Communities and Local Government, Item 5A
Ms Miriam Minty	Department for Communities and Local Government, Item 5A

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies were received from Ms Gillian Wells and Professor Julia Hippisley-Cox.

The following declarations of interest were made:

Professor Jennifer Kurinczuk declared an interest in item 4A. As an existing data controller for the BINOCAR datasets she had been involved in discussions with the applicant in relation to the arrangements for the transfer of legacy data and had submitted information about the application to CAG. Professor Kurinczuk left the room for the discussion of this item.

Professor Barry Evans declared an interest in item 4A as the application was submitted from his employer. Professor Evans left the room for the discussion of this item.

Dr Mark Taylor declared an interest as a member of Independent Information Governance Oversight Panel (IIGOP) who had provided public comment on the information governance issues faced by item 5A. Dr Taylor stayed in the room for the discussion but stepped out of the Chair role.

Ms Clare Sanderson clarified that she did not consider that she had a conflict of interest with item 2A or any NHS England items. Previously Ms Sanderson had been commissioned to undertake work on behalf of NHS England, however this had now concluded.

2. FOR CONSIDERATION

a) Update report and extension request

Application for transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH) [CAG 2-03(a)/2013]

Disclosure of commissioning data sets and GP data for risk stratification purposes to data processors working on behalf of GPs [CAG 7-04(a)/2013]

Application for transfer of data from the HSCIC to commissioning organisation accredited safe heavens: inclusion of invoice validation as a purpose within CAG 2-03 (a)/2013 [CAG 7-07(a)/2013]

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

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

Members welcomed and thanked Ms Ming Tang, Mr Hayden Thomas and Mr Andrew Ashworth for their thoughtful comments and noted their constructive engagement with the considerations of the Regulations, the CAG and Confidentiality Advice Team.

Support had previously been provided to enable continuation of these activities until 30 April 2015, subject to a report to be considered at the January 2015 CAG meeting. Report submission was deferred until the February CAG meeting. The purpose of the item discussion was to:

1. Consider the supporting documentation providing an update on all referenced activities.
2. Consider the proposed duration extension for a further two years.

Confidentiality Advisory Group advice

As a whole, members welcomed the report and supporting documentation and it appeared that where it was possible, activities were proceeding as planned.

It was agreed that continuing support should initially be provided for a 12 month period with an interim report on progression at 6 months (October 2015). In light of the available information considered and discussions, members agreed that this should be subject to information being provided back to CAG as discussed at the meeting. Current support was due to expire on 30 April 2015 therefore members advised that an updated project plan with detail on timescales for key milestones and phases, an update on patient notification and objection handling and review of accuracy of information on the HSCIC and NHS England websites to be provided back to CAG prior to 30 April 2015 to enable the extension to come into effect.

All previous specific and standard conditions of support remain applicable, noting the addition of the condition of support below:

Specific conditions of support

1. All specified information to be provided to the CAG for review prior to 30 April 2015 and provision of an update report in October 2015.

3. ANNUAL REVIEWS

a) Clinical Practice Research Datalink (CPRD) [ECC 5-05(a)/2012]

Members considered the annual review documentation submitted by the Medicines and Healthcare Regulatory products Authority (MHRA) in relation to the CPRD. This is a research activity where support is provided to the Health & Social Care Information Centre (HSCIC) who link and provide CPRD with pseudonymised information. The CPRD do not process identifiable information under the terms of this support.

Confidentiality Advisory Group advice

It was confirmed that the CPRD was neither processing nor onwardly disclosing identifiable information to appropriate recipients under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002. The documentation confirmed that this receipt and processing of free text information had been suspended until a legal basis was in place, and this was in line with the advice previously supplied by the Information Commissioner's Office. It was noted that the processing of free text information was excluded from the scope of support.

As a whole, members agreed to accept the annual review document and provide a positive recommendation to the Health Research Authority for a further period of 12 months. In reaching this conclusion, members raised the following points as summarised below.

Information Governance (IG) Toolkit

Members noted that it is a Department of Health policy requirement for any relevant entity processing identifiable information under this support to have a satisfactory information governance toolkit submission in place or appropriate alternative; in this instance the Health & Social Care Information Centre (HSCIC) are processing information on behalf of CPRD and therefore their IG Toolkit submission was supplied.

Separate to consideration of the annual review, members noted that the CPRD had not completed an IG toolkit or equivalent, and where unclear whether they were covered under the remit of the MHRA (Department of Health). While not specifically required for the purposes of this approval, members expressed the hope that by the time of next annual review the CPRD would have in place a suitable IG Toolkit submission and encouraged CPRD to progress this on the basis it is a flagship activity and processes patient information under different legal bases.

Patient notification

The review stated that the Research Ethics Committee had reviewed and approved the patient leaflets in June 2014. In reflecting on the increasing importance of appropriate patient notification and a mechanism to communicate and manage patient objection, members questioned whether the leaflets made these features clear and requested sight of these to provide assurance that these are adequately explained to patients. Members also sought follow up information specified in the 2014 annual review that had requested the applicants to report on the dissemination of these leaflets and steps taken by CPRD to assure themselves that the information had been reasonably made available to patients.

Members also requested more information in response to question 4(ii) to specify whether any complaints had been received since time of last annual review and the numbers of any patient objections that had been received since this time.

Disclosure List

Members wished to extend their thanks in particular to the Independent Scientific Advisory Committee (ISAC) team for the regular provision of the spreadsheet of disclosures and agreed this should no longer be sent to the CAG, with any such transparency and publication of disclosures to be managed by CPRD in line with public expectation.

Confidentiality Advisory Group advice conclusion

The CAG advised that support should continue for a further 12 months until 18 February 2016, subject to the following conditions:

1. Provision of patient leaflet and/or posters within 4 weeks
2. Confirmation of steps taken by CPRD to assure themselves that patient information has reasonably been made available to patients and how many patient objections have been received within the previous year since time of last annual review
3. Provision of next annual review no later than 05 January 2016

Working with CPRD

Separate to this approval and annual review, members noted that under changes to the Care Act 2014 the Health Research Authority, via the CAG, would take on additional responsibilities to advise the HSCIC on their dissemination, once appropriate resource was in place, and this would involve broadening of scope that may impact on CPRD.

As part of collaborative working, CAG asked whether CPRD would present as an education item so that its developments could be understood and to develop mutual understanding of legislative changes that may impact.

b) National Joint Registry (NJR) [PIAG 2-05(j)/2006]

This application from the Healthcare Quality Improvement Partnership set out a study which aims to produce a register of hip and knee joint replacements (and since April 2012 also elbow and shoulder joint replacements) and included linkage with Hospital Episode Statistics, Patient Episode Database for Wales and Patient Reported Outcome Measures datasets.

Confidentiality Advisory Group advice

Patients for whom consent was 'not recorded'

Members queried whether the applicant had details of those included within the 6% of patients whose consent was not recorded and whether there were particular characteristics where consent was not recorded. In particular, members queried whether the applicant had any information in relation to whether patients were in fact asked for consent or not.

Consent process

Members discussed the current consent process and advised that there may be a method to improve consent rates by incorporating the consent into a procedure specific consent form which included consent for surgery and consent to be included on the NJR. Members requested that the applicant continue to explore opportunities to achieve an even higher ascertainment of consent and report back at annual review stage.

Data linkages

Members noted that the application form specified that additional linkages may be undertaken and that CAG would be notified of these. Members advised that the approval covered the purposes and datasets included within the application form only and any further datasets or purposes would be subject to an amendment or further application depending on the nature of the request.

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 below. This was subject to the conditions outline within the original outcome letter and the following conditions of support:

1. Further information should be provided in relation to the details of those patients for whom consent was 'not-recorded' at the next annual review stage.
2. Further consideration of the feasibility of improving consent ascertainment should be explored in line with the comments above.
3. Linkages of additional datasets not currently specified within the application will be subject to a further amendment request.

4. DEFERRED APPLICATIONS

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

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.

Confidential patient information requested

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. Legacy data from BINOCAR registers was also requested.

Confidentiality Advisory Group advice

Members reviewed the covering letter from Dr Jem Rashbass and supporting information submitted in response to the request for further information made at the January meeting.

Legacy data arrangements

The letter outlined that PHE had informed current data controllers that they would need to ensure that there was a legal basis for the transfer of identifiable data prior to the point at which the current BINOCAR approval expired at the end of June 2015. A letter from BINOCAR was also received, members noted concern that there appeared to be some differences in understanding in relation to what would happen to the legacy data. Members agreed that it was essential that all parties were clear about the arrangements for processing legacy data and existing BINOCAR data controller's responsibilities following the transfer, in particular noting that BINOCAR would need to determine the legal basis for continuing to process confidential patient information following June if this was required.

Members advised that the applicant should ensure that there was common understanding in relation to the plan for transfer of legacy data. In order to be assured that this was the case, members requested that a joint letter be provided from PHE and BINOCAR confirming the agreed approach to the management of legacy data. Members recognised that there were some activities which the current BINOCAR data controllers may want to undertake prior to anonymising the data;

however it was agreed that these proposals would require review by CAG and subsequent decision by HRA/SofS. It was recognised that BINOCAR would need to submit their own proposals for the management of legacy data following the transfer to PHE and members agreed that a separate letter should be sent to BINOCAR in relation to this.

Separate correspondence was received from the Wolfson Institute Antenatal Screening Clinical Advisory Committee. This raised concerns in relation to the mandatory nature of the request and advised that, as a current data controller, the Wolfson Institute needed to be mindful about their responsibilities to the data subjects and to ensure that certain aspects of the transfer of data to PHE, such as the intended purposes and access arrangements, were specified prior to agreeing to this. Members asserted that an approval under the Regulations in order to process confidential patient information did not mandate the disclosure of information from existing data controllers. It was advised that the agreement from both PHE and BINOCAR as outlined above was key to ensure that the legacy data was processed and transferred appropriately and the Wolfson Institute would be informed of the CAG consideration of their letter.

Due to the importance of this mutual understanding in the transition plan, members agreed that the processing of legacy data would not be included within the current recommendation for support. The Chair for this application, Dr Tony Calland, offered to meet with the applicant in order to clarify next steps if required.

Patient notification

Members thanked the applicant for providing the fair processing plan and the draft patient information leaflet within their response. The commitment to an absolute right to opt out for any patient who objected themselves or whose parents objected on their behalf was welcomed. In addition, members noted that the applicant proposed to implement a system to contact GPs and registered clinicians to provide details of the register and right to object as patients reached the age of consent. Members reiterated the importance of ensuring that patients were informed about the data collection as they reached the age of consent, in particular as long term data retention and follow up of patients' health and treatment was proposed. Members asked that the applicant ensure that the mechanisms remained effective and report on progress at annual review stage.

Members were pleased to note that the patient information leaflet, provided in draft, was being developed in conjunction with patient focus groups. It was agreed that consent would not be possible at this stage; however members requested further information in relation to how patient information materials would be made available to parents and agreed that the applicant should continue to explore options for consent, in particular noting the commitment to the development of a web portal. The final patient information should also be submitted once available.

EUROCAT dataflow

The applicant confirmed that these details were not currently available and that no data would be provided to EUROCAT until information governance assurances had been provided. Members requested that this information be provided as soon as possible and, as the details of this data flow were unknown, this would not be included within the current recommendation of support.

Confidentiality Advisory Group advice conclusion

National Registration Service Data

In relation to the prospective data collection from 1 April 2015 only, 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 to be met or agreed to prior to final support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.
2. Submission of a final draft of the patient information leaflet.
3. Confirmation of how patient information would be disseminated to parents/patients.
4. Support extends only to the cohort specified within the application, suspected and diagnosed cases of congenital anomaly and rare diseases in England as defined within the application.

Specific conditions of support to be reported on at annual review stage

1. Continued exploration of options for adoption of a pseudonymised approach or consent as an exit strategy.
2. Further information in relation to the development of a web portal and how it is anticipated this will be implemented and managed.
3. Report on progress and effectiveness of fair processing plan, in particular in relation to informing patients reaching the age where they are able to provide consent themselves.

Legacy data

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 in relation to the legacy datasets. The following information should be provided prior to a recommendation being confirmed:

Request for further information

1. A joint letter from PHE and BINOCAR confirming the agreed approach to the management of legacy data.

EUROCAT data flows

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 in relation to the disclosure of data to EUROCAT. The following information should be provided prior to a recommendation being confirmed:

Request for further information

1. Clarification in relation to data provided to EUROCAT.

5. RESUBMISSIONS – Non Research

a) Troubled Families Evaluation [15/CAG/0106]

This application from the National Institute of Economic and Social Research (NIESR) described the evaluation of the Troubled Families programme, commissioned by the Department for Communities and Local Government. The programme began in April 2012 and involved 120,000 families in England. 59 local authorities would take part in the evaluation.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to Hospital Episode Statistics (HES) data from the Health and Social Care Information Centre in a pseudonymised format. Name, postcode, NHS number and date of birth would be used to carry out linkages to HES data and the NIESR would retain the key to allow re-identification of HES data.

Confidentiality Advisory Group advice

Members noted that the application had been submitted to the December 2014 meeting where a number of issues had been raised. The applicant had provided a response to the issues raised in a covering letter to CAG and representatives attended the CAG meeting on 19 February 2015 in order to discuss the application. Members thanked the attendees for the informative discussion and agreed that this was helpful in the consideration of this application. A summary of the discussion and subsequent CAG advice is outlined below.

Medical purpose

At the December 2014 meeting, members had requested that the applicant provide further information in relation to the medical purpose of the activity, noting that this was a requirement of the Regulations.

The applicant provided a brief presentation which helped summarise the potential medical benefits in undertaking the evaluation and the potential impact of the programme on individuals' health and the prevalence of use of particular health services. A summary of the medical purposes of the evaluation was also included within the covering letter included with the submission.

Members asked the applicant to elaborate on the added value of the health data on the evaluation and what changes they anticipated to find as part of the evaluation of the programme. Attendees confirmed that they anticipated that the evaluation would show a reduction in use of drug and alcohol misuse services, mental health services and emergency departments. However, currently the exact variables of interest had not been specified and a high level analysis was planned with input from colleagues at the Department of Health and Public Health England.

Pseudonymised methodology

Following review of the original submission, members had requested that the applicant explore a pseudonymised methodology and provide further information in relation to why it would be necessary for NIESR to retain the key to allow re-identification of the dataset.

It was noted that one of the main purposes of retaining the key was in order to link existing cohort information to determine whether individuals had been included within the programme or were part of the control group. In addition, this would allow data linkage to occur for the purposes of a longitudinal study, which was separate to this application.

Members asked applicants if they had considered whether effectively anonymised HES data which did not include the key to allow re-identification by NIESR would suffice for the purposes of this evaluation. Members were pleased to note that the applicant had contacted the Health and Social Care Information Centre (HSCIC). It was advised that further discussion with the HSCIC should take place in order to determine whether they were able to carry out linkage to required information, such as whether an individual was part of the programme or not, which would mean that anonymised information only could be disclosed to the applicant. It was noted that it would still be necessary to determine the legal basis for the disclosure of local authority data to the HSCIC but that this was outside the remit of CAG.

Members advised that this appeared to provide an alternative to the use of identifiable information and, given the limited scope to undertake user involvement and notify patients, should be adopted at this stage if possible.

Feasibility of consent

It was noted that, given the retrospective, large cohort and timescales involved with the project, explicit consent would not be feasible.

Members advised that as the proposed further longitudinal study was using prospective data, consent should be in place to carry out further data collection for the study. It was suggested that the applicant have discussion with data controllers to determine wording for consent forms to ensure that the consent in place would allow the disclosure of the required information.

User involvement

The applicant confirmed that due to the timescales involved it would not be feasible to carry out any formal user involvement in relation to the proposed data collection. Members advised that, in circumstances such as these, where a particularly large amount of confidential patient information was being requested in relation to a potentially vulnerable cohort, asking the cohort for views about the use of their information was important.

Patient notification

The applicant provided links to privacy notices to be used and confirmed that they had consulted with the Information Commissioner's Office in relation to the requirement of the first principle of the Data Protection Act (DPA) 1998 to make reasonable efforts to inform data subjects about the use of their data. The issue for CAG, separate to that of DPA compliance, was ensuring 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 were concerned that individuals would not be explicitly informed about the processing of a large amount of sensitive data that was to be processed.

Research Ethics Committee correspondence

It was noted that the applicant had received confirmation from the Health Research Authority that the application was considered to be service evaluation. Members advised that if any aspect of the activity was considered to be research and required an application for support to process confidential patient information, this would need to be reviewed and provided with a favourable opinion from a research ethics committee.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

6. RESUBMISSIONS - Research

a) Small area profiles of health needs [15/CAG/0100]

Purpose of application

This application from University College London set out the purpose of an application for a PhD project which aimed to build on a previous study that used extracts from Hospital Episode Statistics (HES) data to assess health needs based on small area information in relation to the location of service providers. The current study aimed to assess local health needs more comprehensively by means of population profiling. A recommendation for class 1, 4 and 6 support was requested.

Confidentiality Advisory Group advice

Resubmission

This application was resubmitted following review by CAG in October 2013 where the application was deferred pending further exploration into an alternative approach and confirmation that the Health and Social Care Information Centre were supportive of the extraction of the volume of HES data required. The applicant subsequently discussed the application with the HSCIC and CAG members advised in September 2014 that the application should be resubmitted due to the length of time since the original application and that the application should be reviewed and amended to reflect the current methodology. At this stage the applicant was advised that members remained concerned about the extent of the potential disclosure, the articulation of public interest within the application and the absence of methods to notify patients about the activity and methods to respect objections.

The application was resubmitted with a covering letter addressing the points raised by members in September 2014.

Public interest

Members discussed the public interest in the activity being undertaken and agreed that the applicant should provide further information in relation to the proposed uses of the results in order to demonstrate how this could impact on patient care. They reiterated that this was particularly important due to the extent of HES data required. Members noted that data in relation to all HES records would be required in order to carry out the analysis.

Proposed methodology

Members were pleased to note that the HSCIC had confirmed that it would be feasible to apply the software within the HSCIC which would negate the need for surname to be disclosed to the applicant. It was also noted that significant efforts had

been made to reduce the identifiability of the dataset by reducing the requirement for GRIDLINK to lower super output area.

Members noted that the applicant had been asked to explore the feasibility of undertaking analysis at the HSCIC via the proposed Secure Data Facility service. A response had yet to be received from the HSCIC. However, members noted that carrying out analysis at the Secure Data Facility would mean that the disclosure of an exceptionally large amount of HES data would be avoided and agreed that this alternative should continue to be explored with the HSCIC. If this proved to be available at the time that the applicant was to receive the HES data, this methodology should be adopted as an alternative. Members noted that the applicant would need to apply to the HSCIC to receive the data as soon as possible and advised that the applicant proceed with this process but, in line with the above, if the Secure Data Facility would be available within 3 months then the HES data should not be transferred to the applicant but the applicant should carry out the analysis with the HSCIC Secure Data Facility.

Patient notification

Members advised that the applicant should make some efforts to inform patients about the processing, whilst this did not mean individual notification to patients, public notices should be made available on HSCIC and UCL websites at a minimum. This information should include details of methods to allow patients to object to the processing via the HSCIC and this objection must 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. Demonstration of how it is anticipated the results of the application will be used to improve patient care.

2. Continuation of exploring the potential to use the HSCIC Secure Data Facility and to confirm when this will be available.

3. confirmation of what information will be publically available about the study including the agreed process for respecting patient objection.

b) CSD THIN database [15/CAG/0101]

Purpose of the application

This research application from The Health Improvement Network Ltd (THIN) described a research database which contained pseudonymised data from patients who are registered with GP site who participate in the THIN scheme.

A recommendation for class 1, 2 and 6 support was requested to access confidential patient information from GP Practices to THIN in the form of free text data. As doctors could record additional information within this field it was confirmed that the data may contain identifiable information such as name and telephone numbers.

Confidentiality Advisory Group advice

Resubmission

This application was considered by CAG in October 2014 and the applicant was advised to explore the proposed alternative of a technical solution that anonymised free text data at source. It was noted that there was a cost and time constraint on the solution. However, members did not consider that this negated the alternative from being used in this scenario.

The resubmitted documentation requested that members reconsider the advice in the short term whilst the applicant worked towards the alternative, further information in relation to the public interest in the activity taking place and the proposed user involvement was also provided.

Practicable alternatives

Members noted that the applicant sought short term support whilst the alternative was adopted and agreed that the steps taken by the applicant to move towards the alternative were positive. However, members agreed that there was insufficient evidence that the detriment of not collecting the free text information for 6 months whilst the alternative was explored would mean that support should be recommended in the interim. Members noted that once the technical solution had been developed it would be possible to collect free text information retrospectively in an anonymised form. Members therefore advised that the applicant continue to pursue the alternative and that support should not be recommended in the interim.

User involvement

Members advised that, although support was not recommended, user involvement was important and that the applicant should continue to make efforts to ensure that views of patients were incorporated into the design of the research database.

Patient notification

The revised patient information leaflets were provided and members noted that the particular phrase raised at previous review had not been removed. Members reiterated the importance of ensuring that clear and accessible information was available in relation to the processing to ensure transparency and noting the requirement of the first principle of the Data Protection Act 1998 to make reasonable efforts to inform patients. It was also noted that the leaflets were not available in Welsh and members advised that these should be introduced in welsh practices.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations did not appear to have been met, and therefore advised that the application was not supported.

7. NEW APPLICATIONS

a) ENCEPH UK Prospective Cohort Study [15/CAG/0105]

Purpose of application

This application from University of Liverpool set out the purpose of a research study which aims to study the clinical predictors of encephalitis and of poor outcome, better understand those outcomes in terms of cognitive function, quality of life and costs and develop the means of intervening to improve patient outcome. Medical notes would be reviewed to see if there is any pattern to the presenting features of encephalitis and to see what treatment has been given.

There was a consented aspect of the study which did not require review.

A recommendation for class 1 and 6 support was requested to cover access to medical records of deceased patients.

Confidential patient information requested

Access was requested to medical records in relation to deceased patients from hospital sites to a researcher from the University of Liverpool. The researcher would undertake a review of medical records onsite and extract relevant clinical information onto the clinical record form.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was important research into a serious medical condition and therefore there was a public interest and medical purpose in the activity being undertaken.

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 patients whom the data referred to were deceased and that it would be important to include these patients given the outcome. The medical records were likely to be complex and therefore members agreed that it would be necessary for the specified researcher to access the information in order to complete the case report form.

Cohort

Members were unclear what the age group for the cohort would be, it was noted that the protocol and the IRAS form specified different age ranges. One stated patients over 1 month would be included and the other patients over 16 years of age.

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. In line with the comments above, to confirm the age group included within the study.
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.

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

Purpose of application

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

Confidential patient information requested

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

Alternative methodology

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 some of the data collection was prospective and that some services already obtained some form of consent. It was therefore requested that the applicant provide further information in relation to why some form of consent could not be obtained for the prospective data collection. It was noted that consent in relation to the retrospective cohort would not be feasible.

Members queried whether the applicant had considered whether the linkages could be undertaken using a pseudonymised methodology such as that adopted within SAIL. It was unclear whether this alternative would still require support. However, members noted that this would allow linkages to be undertaken in a pseudonymised format and mean that anonymised information only would be accessed for analysis purposes.

Identifiers for analysis purposes

Members noted that full date of birth appeared to be required for analysis purposes and requested further information in relation to why this was required.

Scope of application

Members requested that the applicant specify which datasets were included within the application and were classed as confidential patient information.

Patient notification

Whether consent proved to be feasible for the prospective cohort or not, members advised that it was important to ensure that information in relation to the processing was publically available. Where possible this should be provided at a local level to patients receiving treatment, however a layered approach could be adopted by displaying information on relevant websites as well. This information should include details of how to object and it should be ensured that this is respected.

User involvement

Members noted that some user involvement had been undertaken; however, given the extent of the data collection, members agreed that further efforts could be made to inform patients. Members asked that the applicant ensure further user involvement was undertaken and provide further information in relation to a user involvement plan.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Confirmation why consent could not be sought from patients prospectively via services.
2. Confirmation whether the applicant has considered carrying out linkages via the SAIL service,
3. Confirmation whether full date of birth would be retained in the analysis datasets and why this was necessary.
4. Confirmation which datasets included confidential patient information and were therefore included within the application scope.
5. Confirmation of what information would be provided to notify the patients about the processing.
6. Further information in relation to the user involvement to be undertaken in relation to the application.

The following conditions were recommended, these were subject to change pending the responses to the request for further information above.

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.

8. NEW APPLICATIONS – Non-research

a) ICARE [15/CAG/0107]

This application from University of Central Lancashire set out the purpose of exploring whether the recognition of, and response to, out of hospital cardiac arrest by English ambulance services can be improved.

1. Identifying the tape recorded call handler conversations that resulted in a particular range of ambulance service response categories for suspected out of hospital cardiac arrest.

2. Identifying the tape recorded call handler conversations that resulted in a particular range of ambulance service response categories not related to out of hospital cardiac arrest.

3. Listening to conversations and identify the key “indicator” words from the person who made the call that were highly indicative of out of hospital cardiac arrest.

4. Listening to conversations and identify the key “indicator” words from the person who made the call to explore if similar key “indicator” words are used for both out of hospital cardiac arrest and non-cardiac arrest related conditions.

The application specified that results from the study could lead to the more accurate identification of patients in, and at risk of cardiac arrest, which may impact on out of hospital cardiac arrest survival.

A recommendation for class 1, 5 and 6 support was requested to cover access to data from the North West Ambulance Service in relation to 999 calls.

<u>Confidential patient information requested</u>

Access was requested to recordings of 999 calls from the North West Ambulance Service.

Confidentiality Advisory Group advice

Research definition

Members noted that the application had been submitted as a non-research application and some views were raised that the activity appeared to be research. Members requested further information in relation to how the applicant had determined that the activity was not considered to be research. It was advised that if the application was research, a research ethics committee application would need to be submitted.

Cohort size and application scope

Members requested confirmation of the number of calls included within the study to ensure that the scope of the application was understood. In addition, members noted that references were made to matching hospital data and queried whether the applicant was also requesting support to allow access to this data in identifiable form in order to carry out linkages. If support was required for this aspect, members advised that the application form should be amended and this would need to be submitted as an amendment to the current application.

Patient notification

Members advised that it was important to ensure that information in relation to the processing was available to patients and that notices should be displayed on relevant websites. This should also include information in relation to how patient could object to processing.

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. Please confirm how the application was defined as non-research
2. Please ensure that information in relation to the processing is displayed on relevant websites and this includes details of how to object.
3. Please confirm the scope of the application and cohort size in line with the above.

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

9. AMENDMENTS TO APPROVED APPLICATIONS

a) Advancing Quality (AQ) Programme [ECC 5-03 (a-c)/ 2010]

This application specifically requested access to records from the MINAP database for the purpose of monitoring adherence to clinical standards for Acute Myocardial Infarction (AMI) patients in the North West. The cohort would involve those patients, aged 18 and over, who had been discharged with an AMI diagnosis from a North West hospital participating in the AQ programme between October 2008 and December 2013. Section 251 support had been requested to permit the AQ programme access to admission records in the form of admitted patient care commissioning data set records, and access to records from the MINAP database. In particular, access was requested to the following data items: NHS Number for record linkage across datasets, local patient identifier, date of birth, patient postcode and gender. The final four items were requested to facilitate record linkage where NHS Number was not available. ECC 5-03(a)/2010, ECC 5-03(b)/2010, ECC 5-03(c)/2010 were considered by the Committee together.

Amendment request

The applicant requested support to enable collection of data prospectively on an ongoing basis.

Confidentiality Advisory Group advice

<u>Practicable alternatives</u>

Members noted the assertions that the cost of seeking consent meant that this was not a practicable alternative. However, members were unsure of the impact of up to £16,000 per year and agreed that further information in relation to why this cost meant that consent was not practicable and that this was a disproportionate cost should be provided.

Members queried what the additional benefits were to using national audit data for these purposes. Members agreed that without further information they could not support the continued data collection without consent given that there appeared to be national datasets that were collected and could be used for the purposes. Members advised that if there were additional benefits the applicant should evidence these in a new application and specify how the benefits would be achieved from the local linkage activities.

Members also advised that pseudonymisation at source could be a potential exit strategy and requested that the applicant explore the feasibility of pseudonymising datasets prior to disclosure and linking using anonymised data only.

Data controller changes

Members noted that the application form referenced the PCT as data controller and that an amended application would ensure that the current arrangements and responsibilities were detailed.

10. MINUTES OF THE MEETING HELD ON 15 January 2014

The minutes were agreed as an accurate record of the meeting.

11. CHAIR'S REPORT

The Chair provided an update report on recent events attended as part of his role as CAG Chair.

12. 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 January 2015 meeting applications.

HRA approval decisions

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

Presentations and training events

REC training

The Deputy Confidentiality Advice Manager was invited to attend the London Surrey Borders Research Ethics Committee (REC) meeting on 14 January and the REC regional training day in Leicester on 23 January to provide training to REC members regarding the work of the Confidentiality Advisory Group.

Operational updates

HARP

The CAG HARP database (an application management database) went live on Monday 9th February, members were informed that this would be used to manage all new applications, both research and non-research, starting from the February 2015 meeting.

IRAS

The Confidentiality Advice Team (CAT) informed members that work had been undertaken with the HRA systems team in relation to amendments to the IRAS form. It was confirmed that the change to remove references to NIGB will be included on the next release of IRAS in April 2015. CAT will work with the Systems Team to confirm requirements. The changes would be reflected on IRAS applications created after April.

Guidance

Members were informed that guidance for CAG applicants and potential applicants in relation to reducing the disclosure of confidential patient information (previously practicable alternatives guidance) would be published at the beginning of March 2015, initially as a consultation in use to allow detailed feedback to be collected.

Amendments

Pre-hospital Risk Stratification using a Modified Thrombolysis in Myocardial Infarction (PRISM-TIMI) Score – A Medical Record Review 14/CAG/1023

This application from St George's, University of London set out the purpose of determining whether using a novel pre-hospital risk stratification tool (The Modified Thrombolysis in Myocardial Infarction Risk Score) is better than the current methods used by paramedics in the London Ambulance Service at assessing the severity of a heart attack that a patient is suffering.

A recommendation for 1, 4, 5 and 6 support is being requested to perform a data linkage between ambulance and hospital records.

Access was requested to name, date of birth, gender and date of admission

Amendment request

This amendmenCAG PS Review dates 2015t request detailed extending the data period from 04/03/13 - 01/09/14 to 04/03/13 - 31/12/14 in order to ensure that sufficient patients were recruited to the study.

The amendment request was considered by the Confidentiality Advice Team (CAT) as a time extension to the data period only. It was noted that the amount of patients included within the study would not increase.

Secondment Report

Dr Mark Taylor attended a presentation of the draft outputs of the Sciencewise project on Identifying and Recruiting Participants for Health Research. The results would be released later in the year.

Members were informed that a project plan has been developed for the Information Governance workstream for HRA Approvals. Dr Mark Taylor reported that work was being undertaken to develop a first draft of questions for discussion with colleagues from R&D later this month.

13. ANY OTHER BUSINESS

No other business was discussed