NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

26 May 2016 at 10:00 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor	Chair, items 1—5c
Dr Tony Calland	Chair, items 6a—7c
Dr Kambiz Boomla	
Professor Jennifer Kurinczuk	For items 1—6a
Dr William Bernal	
Mr Andrew Melville	
Mr David Smallacombe	
Dr Harvey Marcovitch	
Ms Ellen Lim	
Dr Katie Harron	

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Head of Confidentiality Advice Service, HRA; item 10
Ms Diane Pryce	Senior Confidentiality Advisor, HRA; items 5c and 7a
M Ben Redclift	Confidentiality Advisor, HRA; item 7c
Mr Christopher Ward	Senior Confidentiality Advisor, HRA
Mrs Maeve Groot Bluemink	REC Observer, HRA
Ms Sadie McKeown-Keegan	REC Observer, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies were received.

Professor Kurinczuk and Dr Harron expressed conflicts of interest for 16/CAG/0058and did not participate in the discussion. Dr Marcovitch knew the Caldicott Guardian; this was agreed not to be a conflict.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) has yet to respond to all of the advice provided by the CAG in relation to the May 2016 meeting applications.

HRA approval decisions

The HRA has yet to respond to all of the advice provided by the CAG in relation to the May 2016 meeting applications.

3. ITEMS FOR CONSIDERATION

a. PIAG 1-07(c)/2004; The UK Renal Registry; breach.

This breach was reviewed in conjunction with the amendment request from the UK Renal Registry (item 4a) and the application to set up a research database (item 5a). CAG reviewed the letter received in relation to this breach (dated 20 April 2016 and 10 May 2016).

The group expressed their disappointment that so important a resource should have allowed so serious a breach, involving important and confidential data, to have occurred over so long a period of time. Of especial concern was the length of time taken before a report of the breach was submitted to CAG, at CAG's request.

A full report on the progress against remedial actions set out in the letter of the 10 May 2016 should be included in the next annual review, which is due on the 12 August 2016. This will be reviewed at a full CAG meeting and should include:

- Detail of the IG training which has been provided to the UK Renal Registry staff.
- Detail of the governance structures which have been set up to ensure that a breach of this nature is not permitted to occur again.

Members agreed that the content of this annual review should determine ongoing support for this and any related applications.

Members were also keen to stress the importance of notifying the committee in a timely fashion of any future breaches. As set out in the standard conditions of approval, 'any breaches of confidentiality/security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken/to be taken.'

4. AMENDMENTS TO APPROVED APPLICATIONS

a. PIAG 1-07(c)/2004; The UK Renal Registry; amendment.

This amendment sought to extend the current support to specifically confirm routine data linkages between UKRR and other national databases on an ongoing basis.

- NHS Blood and Transplant
- Hospital Episode Statistics (and the equivalent databases in Wales and Northern Ireland (PEDW and HSC, respectively).
- Office for National Statistics
- Public Health England

Confidentiality Advisory Group advice

This amendment was reviewed in conjunction with the breach report from the UK Renal Registry (item 3a) and the application to set up a research database (item 5a).

The members noted that the work that the UK Renal Registry was conducting was in the public interest and served a clear medical purpose, however, in the light of recently reported breach and the period of time which has passed since the original application was supported, members felt that the proposed amendment was sufficiently substantial to merit a new application.

Prior to receipt of this new application, support continues for the UK Renal Registry as described in the original application and any subsequently supported amendments.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Confidentiality Advisory Group agreed that the minimum criteria under the Regulations did not appear to have been met for this amendment, and therefore did not advise recommending support to the Secretary of State for Health.

5. RESUBMITTED APPLICATIONS

a. 16/CAG/0064 (previously 16/CAG/0020); The UK Renal Registry.

This resubmission was reviewed in conjunction with the breach report from the UK Renal Registry (item 3a) and the amendment to the same (item 4a).

<u>Purpose of application</u>

This application from The UK Renal Registry set out the purpose of:

1. Conducting research on an existing non-research database (reference: PIAG 1-07c/2004).

2. Allowing two specific one-off additional data-linkages for the purpose of research.

The proposed research would cover:

- Epidemiology, including the reporting of disease rates, treatment rates and outcomes and associations between these and practice patterns.
- Linkage to existing databases.
- Providing end-points to quality improvement initiatives, including before-and-after studies and stepped wedge cluster randomised trials in which an intervention is being rolled out, but the order in which that happens at a unit level is randomised.
- Providing end-points to other previously recruited cohort studies and trials, providing these already have the necessary permissions and consent.

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover the activity specified in the application.

Confidential patient information requested

The following information is already collected under reference PIAG 1-07(c)/2004: name, address, postcode, date of birth, NHS number, hospital number, date of death, and data from NHS Blood and Transplant relating to kidney transplantation (such as transplant waiting list status and kidney donor characteristics).

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

Practicable alternatives

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

- Feasibility of consent

The group was content that it would be unfeasible to seek specific consent from this cohort for the use of already held data for an additional purpose (research).

- Use of anonymised/pseudonymised data

The applicant will be processing already held identifiable data for release in a de-identified format for research; members were content that this was justified.

However, the group did not feel that the applicant had justified the release of full postcode. Where a researcher wishes to use identifiable information from the Renal Registry for the purpose of research, a new CAG and REC application would be required in each instance.

Justification of identifiers

The members were content that the applicant was not requesting access to any additional identifiers, over and above those already held for a non-research purpose. However, in light of a breach (PIAG 1-07(c)/2004) reported to CAG at the same meeting, the members were unable to recommend supporting processing this data for an additional purpose until the non-research component of the UK Renal Registry had been set in order.

Exit strategy

The group was satisfied that there was no additional identifiable data being held, over and above that supported under PIAG 1-07(c)/2004.

Patient notification and objection

Members were satisfied with the patient notification and objection materials provided.

Additional points

The group noted that the applicant had requested two one-off additional data linkages to support research:

- to Clinical Practice Research Datalink (CPRD) and Hospital Episode Statistics (HES) Health Technology Assessment (NIHR HTA) to test the safety and efficacy of drugs for osteoporosis in patients with kidney disease.
- to the Intensive Care National Audit and Research Centre (ICNARC) to develop better risk prediction models for patients in intensive care units.

Members were unclear if CAG support had already been granted to allow the ICNARC linkage. While members did not want to delay potentially important research they were not able to come to an opinion on the basis of the information provided. As such the members concluded that new applications should be made to cover this activity (if support is not already in place for the ICNARC linkage).

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however in light of the recently reported breach, a new submission for the non-research component of the UK Renal Registry would be required prior to confirming that the minimum criteria under the Regulations had been met. CAG therefore advised recommending provisional support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

However this recommendation did not extend to the two specific one-off additional data-linkages as set out in the application. A separate approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 should be submitted to conduct these additional linkages.

Specific conditions of support

1. Full CAG support for the resubmission of the non-research component of the UK Renal Registry (PIAG 1-07(c)/2004).
2. Confirmation that full postcode will not be released save in instances where a new separate approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 has been granted.
3. Favourable opinion from a Research Ethics Committee.

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

Once provided, the response is to be reviewed by the Confidentiality Advisory Team.

b. 16/CAG/0071 (previously 16/CAG/0052); Benchmarking clinical quality healthcare measures.

Purpose of application

This application from University Hospitals Birmingham Foundation Trust (UHB) set out the purpose of receiving monthly and annual extract of Hospital Episode Statistics (HES) and HES linked ONS (Office National Statistics) Mortality datasets from the Health and Social Care Information Centre (HSCIC). This will cover all English hospital activity.

The objective of this work is to support both University Hospitals Birmingham and other NHS Trusts and commissioners in the ongoing monitoring of clinical quality and organisational effectiveness. This purpose is fulfilled either:

- directly, i.e. the NHS Trust holds a subscription to use the HED system, or
- indirectly i.e. analytics are provided via a non-NHS organisation who holds a subscription to use aggregate small number suppressed data within the HED system. The applicant has reviewed the NHS standard (ISB 1523) relating to anonymisation and confirmed the system was compliant with this. This has also been corroborated by a recent audit from the HSCIC particularly in relation to small numbers suppression.
- through clinically-led bespoke reports based on retrospective, pseudonymised data which if requested are published in peer review journals with small numbers suppressed.

The level of data that can be viewed within the online analytical system depends on the access level of the named individual user and which organisation they are working for. Any modules within the system that use ONS data are not accessible to non-NHS users.

In summary, the types of users/data requestors and access controls in place are as follows:

- Non-NHS User: Access to aggregate level small number supressed analytics only formed using HES APC, OP or A&E data (but NOT ONS data).
- NHS but non-Hospital User: Access to aggregate level small number supressed analytics only formed using HES APC, OP, A&E and/or ONS linked data.
- NHS Hospital User: Access to aggregate level small number supressed analytics only formed using HES APC, OP, A&E or ONS linked data unless Caldicott authorisation is in place to allow access to low level details and/or sensitive items for their own organisation only.

Patient information is only available to organisations who deliver the care and only if Caldicott Guardian approval has been received from that same organisation. In such instances a summary (but not all fields present in the raw HES or ONS data) will be provided at spell or patient level.

A recommendation for class 4, 5, and 6 support was requested to cover access to identifiable patient information in order to conduct root cause analyses, both for internal governance and also to provide assurance to external regulatory authorities across a range of key indicators (ie. HSMR, SHMI).

Confidential patient information requested

Access was requested to allow the disclosure of confidential patient information from the HSCIC to UHB, and from UHB to trusts who subscribe to this service.

- All APC, OP, AE and CC HES data.
- All ONS Mortality data (HES linked).

All fields are required to derive clinically relevant indicators of quality of care.

Confidential items as below are required for:

- HES: Local patient ID

To facilitate case note review so patients of concern identified in the analysis can be linked to the organisation's PAS system. Only made available to organisations which delivered that episode of care and who have appropriate Caldicott governance in place.

- HES-ONS: Date of death
- HES-ONS: Cause of death
- HES-ONS: Place of death

To enable understanding of care pathways and post-discharge outcomes linked to care received at the specific healthcare organisation.

- HES: Consultant GMC code

To deliver consultant revalidation and appraisal information to support informative reviews of clinical processes.

- HES: GP Practice Code

To understand health requirements geographically.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

Practicable alternatives

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

- Feasibility of consent

The group was content that it would be unfeasible to seek consent from so large a group.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to conduct this project and that the records could not be redacted.

Justification of identifiers

The members concluded that the access to the identifiers requested was necessary and appropriate to achieve the purposes. However, it was only justified in relation to subscribers to this service. The CAG would not recommend support for the release of identifiable data pertaining to non-subscribing trusts.

In addition members noted that the applicant had stated that:

> 'UHB has received HES data from the HSCIC since 2009. This data has been used to provide HED customers with access to a web-based healthcare benchmarking tool. The content of the online system has developed and progressed over time in accordance with feedback from our user-group, to ensure HED delivers the most relevant benchmarking analytics to give assurance of safe, high quality care or signpost to areas of concern. Patient identifiable information is currently available in the system and widely utilised by trusts (where the episode of care took place) to link HED benchmark findings to local clinical notes, to drive service improvement.'

Members were unclear from this statement whether identifiable data items are or have been transferred to UBH, and, if so, under what legal basis. A separate letter on this matter is to be issued requesting clarification on the following points:

1. Please clarify whether identifiable HES data is or has been released to UBH.
2. If this data flow is or has taken place, please clarify the legal basis on which these disclosures are or have been made.

Exit strategy

The group was unclear when the identifiable data would be destroyed. Unless a strong justification were provided they considered that it should be retained in an identifiable form for no longer than three years.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and there is a mechanism for registering patient objection. The members noted that the applicant had not provided project-specific patient notification nor any project-specific mechanism for objection. These must be provided before the CAG will be able to recommend support.

Patient and public involvement

The group felt that much greater efforts could and should have been made to gauge patient and public opinion about the use of patients' records as described in the application. An action plan should be provided to the CAG detailing the steps that will be taken to address this going forward, and progress against this plan should be provided in the first annual review submission to the group.

Patients and the public should be involved in the drafting of the project-specific patient notification and project-specific mechanism for objection, as above.

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. Confirmation that identifiable data will not be held for over three years, or justification as to why de-identification in this time period is not reasonably practicable or is undesirable.
2. Confirmation that identifiable data will only be processed for subscribers to the service.
3. Provision of satisfactory patient notification materials, including a project specific patient objection mechanism.
4. Provision of a patient and public involvement plan. This is to be reported against at the first annual review.
5. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

Once provided, the response will be reviewed by the chair and original reviewers.

c. 16/CAG/0068 (previously: 16/CAG/0014); Cancer Research UK (CRUK) bowel cancer screening endorsement mailing.

Purpose of application

This application from Cancer Research UK set out the purpose of this request to facilitate two mailings of a targeted CRUK and NHS branded personalised bowel cancer screening endorsement direct mailings.

The overarching aim of the project was to increase participation of the Guaiac Faecal Occult Blood Test (gFOBT) i.e. the bowel cancer screening programme by raising awareness of the Bowel Cancer Screening Programme (BCSP) amongst the eligible population and reduce barriers to participation.

This project sets out to test the effectiveness of introducing an additional step in the bowel cancer screening programme call process (when combined with a supporting advertising campaign) on increasing participation in the BCSP.

The project was informed by 2 previous pilots in London and Wales. These found that advertising combined with direct mail (London pilot) and a highly targeted and personalised version of direct mail (Wales pilot), were effective methods of improving uptake. This project will apply learning from both previous pilot projects, and has the potential to increase uptake beyond 9% in some groups. Each of the four participating bowel cancer screening hubs has confirmed their support for the project.

A recommendation for class 4 and 6 support was requested to allow the disclosure of confidential patient information from 4 NHS Bowel Cancer Screening programme hubs to a third party data processor, Real Digital International, on a daily basis (week days only) between Monday 21 March 2016 to Friday 22 April (25 days).

Confidential patient information requested

Access was requested to; name, address, postcode and NHS number for

22,000 patients involved in this project.

Confidentiality Advisory Group advice

Public interest

On balance members were persuaded by the reasoning put forward by the applicant that the proposal was potentially in the public benefit. However, they did comment that this proposal added to the number of times patients were to be contacted about the screening programme.

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.

- Feasibility of consent

Members agreed that consent was not a practicable.

Justification of identifiers

Members agreed that the identifiers would be required to achieve the objectives of the project. However, members questioned the need for access to the NHS number.

Research Ethics

Members were unclear whether the project was in fact research and requested the applicant seeks advice from a Research Ethics Committee.

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 prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Secretary of State, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. The applicant should provide justification for the use of NHS number
2. The applicant should seek advice from the Research Ethics Committee on whether projects of this type are considered to be research

6. NEW APPLICATIONS – Non-research

a. 16/CAG/0058; National Maternity and Perinatal Audit

Purpose of application

This application from the Royal College of Obstetricians and Gynaecologists set out the purpose of delivering a new Healthcare Quality Improvement Partnership (HQIP)-commissioned national, prospective, clinical audit of maternity services in England, Scotland and Wales, in order to improve the quality of services and the outcomes achieved for mothers and newborns.

The commissioned audit programme consists of three phases of work:

1. An 'organisational survey' to collect provider-level information on service delivery and the organisation of maternity care, which will contribute to a better understanding of the care provided to pregnant women.
2. A continuous prospective clinical audit that produces information for maternity units to monitor patterns of care and maternal and perinatal outcomes.
3. A series of in-depth topic-specific, time-limited audits ('sprint audits'), predominantly focusing on specific types of maternal and neonatal outcomes.

Most maternity units in the UK already use electronic maternity information systems (MIS) to capture demographic and clinical information related to each pregnancy and delivery under their care. These databases cover antenatal booking through to postnatal care. Although each MIS collects slightly different information, there is sufficient similarity between MISs to allow a minimum dataset to be developed.

In order to collect data covering a four-year period, for the first extract the applicants will request delivery data for the two previous financial years. Data on deliveries occurring between April 2014 and March 2016 will be requested in 2016, with refreshed data extract for the 2016-17 and 2017-18 periods requested in 2017 and 2018 respectively.

The data collected from English MIS systems will be linked to Hospital Episode Statistics (HES) maternity data from 2017, pending approval from the Health and Social Care Information Centre (HSCIC) Data Linkage and Extract Service. The HES data will in turn be linked to the Office for National Statistics (ONS) birth and death register. These linkages will be repeated annually and will enable the applicants to calculate case ascertainment for English births, and to examine additional processes and outcomes of maternity and perinatal care, including maternal and neonatal hospital readmission. A similar linkage exercise is planned for the data collected from Welsh MIS systems using the Patient Episode Database for Wales (PEDW), pending approval from the Welsh Information Services Division.

Additional data linkages are planned as part of a series of topic specific 'sprint audits'. The linked MIS-HES/PEDW-ONS data will be further linked with data from the Intensive Care National Audit and Research Centre (ICNARC), the RCPCH's National Neonatal Audit Programme (NNAP) and Public Health England's surveillance systems (SCSS and LabBase2) to investigate maternal and neonatal intensive care admissions and blood-stream infections, respectively. This information will be released in a link anonymised format.

A recommendation for class 1, 4, 5, and 6 support was requested to cover disclosure of confidential patient information from English & Welsh NHS trusts to the Royal College of Obstetricians and Gynaecologists, in order to link this data with data contained in other national databases.

<u>Confidential patient information requested</u>

Access was requested to the following identifiers:

- Baby's date of birth
- Baby's time of birth

- Mother's postcode
- Mother's date of birth
- Mother's NHS number
- Baby's NHS number

Identifiers used for risk adjustment during data analysis:
- Mother's Ethnicity
- Mother's socioeconomic status (Index of multiple deprivation (IMD) category)

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

Practicable alternatives

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

- Feasibility of consent

The group was content that it would be unfeasible to seek consent from such a large group, especially for the retrospective component of this cohort.

- Use of anonymised/pseudonymised data

Members were content that identifiable data was required to perform the linkages for this study.

Justification of identifiers

The members concluded that the access to the identifiers requested was necessary and appropriate to achieve the purposes.

Exit strategy

The group noted that the contract period of the audit will be 1 June 2016 to 31 May 2019 with the possibility of a further 2 year extension.

Patient notification and objection

The members agreed that the opt-out mechanism should be reviewed in the first annual review to the committee. They recommended that the applicant seek patient and public views on how easily information on opt-out can be accessed and as to whether other mechanisms for opting-out (e-mail or telephone, for example) should be included.

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. Provision, in first annual review, of an update on the mechanisms for opting-out of the study which have been adopted as a result of patient and public engagement, as above.

7. NEW APPLICATIONS – Research

a. 16/CAG/0062; Comprehensive Patient Records for Cancer Outcomes

Purpose of application

This application from the University of Leeds set out the purpose of an element of the 'CPR for Cancer Outcomes' study, to securely link information from electronic GP and community (primary care) and hospital records. This data will provide the means to get a clearer picture of what happens to cancer patients across their cancer pathway and of the costs involved in care. The linkage is also anticipated to provide a clearer picture of patients' health before the cancer diagnosis and the impact of cancer treatment on subsequent health and wellbeing, and the associated costs.

Data will come through automated processes from two sources:

- Patient hospital records and financial data held at the Leeds Teaching Hospitals NHS Trust (LTHT) to support patient care. This is more detailed than national registry data.
- Primary care records that are opted in to ResearchOne (R1), a research database held by The Phoenix Partnership (TPP). TPP maintain electronic health records for over 5,000 UK healthcare organisations.

LTHT and TPP will provide data from records of a cohort of cancer patients and cohort of control patients. The application stated that the researcher will use an automated process to produce the non-identifiable row-level data in line with ICO and NHS standards (containing no identifiers or free text). The non-identifiable data will be encrypted and transferred to a secure environment in the University of Leeds and linked by a third discrete organisation (Integrated Research Campus, IRC). It will be linked using digest codes created using OpenPseudonymiser. Data will remain securely in the IRC with controlled access purely by the research team for this research project.

A recommendation for class 1, 2, 5 and 6 support was requested to cover access to the information set out in the application form.

Confidential patient information requested

Access was requested to;

1. LTHT identify Leeds patients with a cancer diagnosis or relevant non-cancer control and use NHS number to generate a project specific digest (PSD1) for these records (from NHS

number and year and month of birth) using OpenPseudonymiser and an agreed project-specific salt (SALT1).
2. TPP use NHS numbers, month and year of birth to generate a project specific digest (PSD1) using OpenPseudonymiser and an agreed project-specific salt (SALT1).
3. LTHT share a list of relevant PSD1s with TPP to allow an agreed list of PSD1s to be defined. No additional data will be shared between organisations, including whether the patient is a cancer patient or control.
4. The agreed list of PSD1 is supplemented by LTHT with a date (month and year) of diagnosis or referral and shared with TPP.
5. LTHT produces a de-identified dataset (LD) for the project from their data warehouse in an encrypted file and shares that securely with University of Leeds Integrated Research Campus (UoL IRC) using secure FTP.
6. TPP produces a de-identified dataset (TD) for the project from R1 in an encrypted file and shares that securely with UoL IRC via secure upload (authenticated by IP address and login).
7. UoL IRC generate a second project specific digest (PSD2) using OpenPseudonymiser and a unique project specific salt (SALT2) to replace PSD1 on LD and TD.
8. UoL IRC links datasets LDD and TDD, generates derived and aggregated data, placing the research dataset (RD) within project specific virtual research environment.
9. Named members of research team, approved by UoL IRC allow "remote" access to the RD in the IRC
10. Research team generate research outputs.
11. IRC data services screen and approve outputs before they leave the IRC.

The applicant asserted in IRAS filter question 11 that no identifiable data would be accessed by anyone other than the care team.

Confidentiality Advisory Group advice

Public interest

Members agreed that this project was potentially in the interest of patients and the public and had a clear medical purpose.

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.

- Feasibility of consent

Members agreed that consent would not be practicable for this cohort.

- Use of anonymised/pseudonymised data

Members noted that the applicant had indicated the information requested was pseudonymised at source and was in line with ICO and NHS standards (containing no identifiers or free text).

Additional points

Members noted that the applicant had indicated throughout the application that the data requested was not identifiable and were requesting CAG to make a determination whether the data requested was identifiable.

Members considered the issue of whether the data in question was pesudonymised and concluded that it was the responsibility of the applicant to satisfy themselves whether the data will be psuedonymised in line with the ICO standard. If the applicant was not able to take the position that the data being disclosed satisfies the ICO code of practice on anonymisation then support would be required. In this instance the applicant should clearly indicate what activities support was being requested for.

Members clarified that their remit was to consider whether the application met the minimum requirements of the Health Service (Control of Patient Information) Regulations 2002.

Members agreed that in future selecting 'no' in response to IRAS filter question 11 ('Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?') should constitute grounds for invalidation.

ACTION: CAT team to add the above as invalidation criteria to internal process documents.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the applicant should make their own decision and determination whether the data requested was psueonymised in line with the ICO standard.

Further information required

Should the applicant determine the data requested was not pseydonymised in line with the ICO standard and came within the stated definition of confidential information they should submit a new application to CAG. The following information should be provided to allow the CAG to continue their consideration of the application:

1. New application to CAG
2. Rationale on how they reached their decision.

b. 16/CAG/0066; Hospital Alerting Via Electronic Noticeboard (HAVEN)

Purpose of application

Late recognition of deteriorating patients in hospitals causes treatment delays that result in increased mortality and morbidity. Despite widespread introduction of vital sign-based early warning scores, deterioration of patients can go unrecognised. Consequently, developing systems for early recognition of patients at risk of severe reversible deterioration has become a key goal for the NHS. This application from Oxford University Hospitals NHS Foundation Trust set

out the purpose of producing a hospital-wide IT system that enables a continuous risk assessment in all hospital patients, and predicts those at risk of deterioration.

This IT system will use routinely stored electronic data from Oxford University Hospitals NHS Foundation Trust and Portsmouth Hospitals NHS Trust (including demographics, laboratory results and vital signs) to create this continuous risk assessment. At present, these different types of data are stored in different local databases, and are not integrated or displayed in a way that supports decision making or calculation of patient risk. The project will implement a system to gather the relevant data so that it can be used to gauge risk.

Risk prediction algorithms will then be developed and validated, using the records of patients who were admitted to hospital and then admitted to an intensive care unit (ICU) after two or more days in hospital.

Data, including patient identifiers, will be exported from the source databases on a periodic basis. The export files will be transferred to the HAVEN Linkage Server directly over the Trust network or via encrypted drive. The applicant plans to set up automated processes to extract, transform and load the data into the HAVEN Linkage Server and create a linked database containing patient identifiers along with the complete dataset for each patient.

Identifiable data will not be available for analysis. Each patient will be given a Study ID as part of the extraction process. A mapping file linking hospital identifiers with the database identifier will be created which will be held on the same linkage server. When a pseudonymised copy of the data is required a scripted pseudonymisation process will be used to generate the data export.

Pseudonymised data will be received from Portsmouth Hospitals NHS Trust to link with the data from Oxford University NHS Foundation Trust

A recommendation for class 1, 4, and 6 support was requested to cover the disclosure of confidential patient information from Oxford University NHS Foundation Trust to the research team.

Confidential patient information requested

Access was requested to data from all patients admitted to Oxford University NHS Foundation Trust.

For linkage: name, postcode (unit level), NHS number, date of birth (converted to age for analysis), date of death (which will have an offset applied for analysis), & admission episode ID.

Gender and ethnicity will be retained for analysis.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

Practicable alternatives

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

- Feasibility of consent

The group was content that it would be unfeasible to seek consent from so large a group, especially where some of the subjects will have died and the majority of the data is retrospective.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to conduct this project.

Justification of identifiers

The members discussed whether the number of identifiers could be reduced by decreasing the number of data sources; however they were content that this could potentially harm the development of the tool and, as such, were justified.

Exit strategy

The group noted that the applicant considered it unlikely that support would be required beyond the formal end of the project (when the funding expires on 31st July 2018).

Patient notification and objection

Members noted that the notification materials had been designed with a strong patient and public involvement component and congratulated the research team on this.

However, the members did consider that the notification should also contain contact details (phone or e-mail) whereby individuals can opt out. The notification materials and a lay summary should also be available on the trust website.

In addition, it was noted that the patient information sheet makes mention of CAG approving studies. This is inaccurate and should be amended.

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. Provision of updated patient notification materials, including the patient information sheet (clinical, 6.3), and confirmation that these will be available on the trust website.
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.

Once provided, the response will be reviewed by the chair and original reviewers.

c. 16/CAG/0069; fullPIERS Model study v1

Purpose of application

This application from a student at Oxford University Hospitals NHS Trust, set out the purpose of a project to assess the predictive ability of the fullPIERS model to identify the risks of developing complications for pregnant women with pre-eclampsia in high resourced settings so as to aid clinicians in managing such pregnancies.

The hypertensive disorders of pregnancy (HDP), with pre-eclampsia being the most dangerous, complicate about 10% of pregnancy and are major contributors to maternal and perinatal morbidity and mortality. This is due to the severe complications that can result from them such as stroke, kidney failure and eclampsia for the mother, and fetal growth restriction and stillbirth for the baby. The ability to predict these adverse outcomes will aid the appropriate management and treatment by the early identification of women with higher risks of complications arising from HDP and applying timely interventions.

In order for the fullPIERS model to be introduced into clinical practice, it is necessary to assess its predictive ability in a similar population cohort other than the one in which it was developed in (external validation) and to improve the model where possible by adding new biomarkers as well as recalibrating the model if and when required for better predictive performance. In order to determine eligibility and collect relevant information for this study, patient case records, of women who were admitted with HDP up to ten years ago, obtained through routine clinical care, will be screened by the researcher. The published PIERS equation will be applied to the individual eligible patient records in the validation datasets, to calculate the predicted probability of adverse outcome within 48 hours of admission. Data will be collected and entered into an anonymized database and will be used to validate the fullPIERS model to identify women at greatest risk for developing adverse maternal outcomes. The principle research objective will be to determine whether the fullPIERS model can be used to predict adverse maternal outcomes within 48h of admission in women presenting with pre-eclampsia and other HDPs in different centres (external validation). In addition, the applicant wishes to discover whether the fullPIERS model can be used to predict adverse maternal outcomes at two other time points, (a) within one week of admission and (b) at any time, in women presenting with pre-eclampsia and other HDPs. Finally, they also wish to assess whether the predictive ability of the fullPIERS model could be improved by incorporating new biomarkers such as the Placental Growth Factor (PlGF)

A recommendation for class 1 and 6 support was requested for the process of extracting and anonymising the information and for one or more of the above purposes.

Confidential patient information requested

Access was requested to data from medical records in relation to the year and month of birth, dates and time of hospital admission, medical history, recorded symptoms (e.g. headache, nausea) and laboratory tests (e.g. haematological, urine chemistry) and adverse outcomes such as maternal death and severe morbidity.

Confidentiality Advisory Group advice

Public interest

Members agreed that this study had medical benefit to the patient population. The public interest in this project was not fully clear from the 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.

- Feasibility of consent

Members noted the applicant's justification for not conducting the study on a consented basis which centred on the records being up to 10 years old. The arguments around the fact that gaining consent would require access to the records to obtain address information and could skew the response rates were seen as persuasive. However members did not agree that contacting patients would cause distress for the majority of cases and that similarly a proportion of records would be more recent records with up-to date address information and no reason consent could not be sought. Further justification for the impracticability of seeking consent was required by the committee.

- Use of anonymised/pseudonymised data

It was noted that identifiable data was required in order to assess the tool. However members were not fully persuaded that the researcher represented the only person with knowledge of the tool and therefore that disclosure to someone outside the direct care team was justified.

Justification of identifiers

Members felt some anxiety over the lack of service user engagement with this project and saw this as an example of a project which would benefit from user testimony confirming support from patient groups in principle for such a project on a non-consented basis. It was felt a relatively simple sample of service users or further patient involvement could provide justification for the reasons for non-consent to the committee.

There was a lack of clarity over who would be overseeing the data collection process and exactly what data would be sent to Canada. Members required further details of the senior person responsible for the management of the study.

It was similarly not clear why date of death was required.

It was noted that reference had been made to the PELICAN study. Members asked for further information about this study, details of the consent process and view of the consent form.

Additional points

Information available about the study for patients was minimal and the method of opt-out was not clear.

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 patient information is required with clear details of how patients may opt-out to uses of their data.
2. Clarification was requested over the data going to Canada.
3. Clarification was requested on who would be taking overall responsibility for the project.
4. Strong justification should be provided on why the study could not be conducted on a consented basis.
5. Evidence should be provided from user groups or patient public participation groups that they supported the project.
6. Further information should be provided on the PELICAN study and consent process.
7. Justification should be provided on the requirement to collect date of death.

Once received, the information will be reviewed at the next available CAG meeting.

12. MINUTES OF THE MEETING HELD ON 21 April 2016

The minutes dated 21 April were agreed as an accurate record, subject to a clerical correction on page 4.

The precedent set subcommittee minutes dated 26 May were agreed as an accurate record.

The subcommittee minutes dated 28 April already incorporated member comment and were agreed as an accurate record.

13. EDUCATION LOG

Notes were taken of member's suggestions with regards to training and will be entered onto the education log.

Arising from this, discussion was had as to the CAG position with regards to journals requesting 'raw' data. It was agreed that the group who are putting together a protocol for handling this should be contacted by the Chair to determine whether there is cause for concern.

ACTION: MT to contact the group who are putting together a protocol for handling access to raw data by journals to determine if there is cause for concern

14. ANY OTHER BUSINESS

The chair led a brief discussion about implied consent. Broadly, this should be understood to be consent which is implied through conduct (rather that written or verbal consent). As such, to evidence it, one has to be able to point to conduct which affords reasonable grounds for supposing consent has taken place.