NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

21 April 2016 at Skipton House, SE1 6LH

Present:

Name	Capacity
Dr Mark Taylor (Chair)	Chair; items 2a, 3a, 4a, & 4b.
Dr Patrick Coyle (Vice Chair)	Chair; items 4c-e.
Dr Kambiz Boomla	
Professor Jennifer Kurinczuk	Absent for items 3a & 4a
Mr C Marc Taylor	
Mrs Hannah Chambers	Lay
Dr William Bernal	
Ms Kim Kingan	
Mr David Smallacombe	
Professor Barry Evans	

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	Head of Confidentiality Advice Service, HRA
Ms Diane Pryce	Senior Confidentiality Advisor, HRA
Dr Janet Messer	Director of Research Systems, Standards, & HRA Approval
Dr Harvey Marcovich	(New CAG member, observing)
Dr Martin Andrew	(New CAG member, observing)
Mr Christopher Ward	Senior Confidentiality Advisor, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies were received.

Potential interests were declared for agenda item 3a by Professor Kurinczuk and Mr Smallacombe as both have conducted work in this area; the group agreed that these did not constitute a conflict of interest.

2. ITEMS FOR CONSIDERATION

a. CAG 2-03 (a) Application for transfer of data from the Health and Social Care Information Centre (HSCIC) to commissioning organisation Accredited Safe Havens (ASH). Follow-up responses to additional dataset inclusion.

The Group were supportive in principle of the amendment submitted by NHS England when it had previously been considered (see February 2016 sub-committee minutes). This sought the inclusion of the following datasets to CAG 2-03 (a)/2013: Mental Health Minimum Data set (MHMDS), Mental Health Learning Disabilities Data set (MHLDDS), Mental Health Service Data set (MHSDS) (once available) and the Maternity Services Data Set (MSDS).

Members had recommended conditional support, with the caveat that appropriate patient notification materials were of prime importance, combined with the ability of patients to be informed and to provide an objection if they choose, particularly if there were any concerns about any mental health issues becoming more widely known. Satisfactory responses had not previously been provided and the applicant had been asked to resubmit a comprehensive response to all aspects. The two aspects to be clarified and the responses were as follows.

1. Applicant to provide clear information to provide assurance that relevant patient information materials are very easily available with information on how to object.

It was emphasised that 'patient notification' in this context was a principle specific to the approval provided under Regulation 5. This is separate to local data controller's responsibilities to process relevant information in accordance with the Data Protection Act (DPA) 1998. However, the outputs in relation to patient notification may be realised, partially or wholly, by effective steps taken to meet the first principle requirements under the DPA. Members reiterated that the clarifications requested related solely to the principle of 'patient notification' under the support provided by Regulation 5, and if the applicant intended to respond through data controller fair processing actions, this distinction should be made clear in future submissions to avoid the possibility of misinterpretation as the CAG is not responsible for assessing what is contextually appropriate under the provisions of the DPA.

The response paper confirmed that in order to address these points NHS England had instructed the HSCIC to update their website; this had been confirmed by the HSCIC and two links were provided as evidence to address this aspect.

The paper also confirmed that NHS England are working with the HSCIC to develop a comprehensive list of all commissioning data flows being disseminated by the HSCIC or their regional offices (DSCROs) to commissioners. It was anticipated that the list of commissioning data flows will sit within, or be linked from, the 'patient confidentiality' page and will also be linked to the 'your information' page which provides information about objecting to the dissemination of their personal data from the HSCIC. The report confirmed this work was underway and a progress report would be provided to the June 2016 meeting.

Members noted that it could be difficult for patients to understand, from the links provided, what had been supported, and comment was made about the accessibility, language and readability, and that the Health Research Authority provided published guidance on producing information for patients. It was suggested that these could be reviewed prior to the expected June submission. However, as a whole the steps to help manage issues of consistency and content as set out in the paper, and the progress report for the June 2016 meeting, were generally welcomed.

2. Confirmation as to how NHS England will ensure there are easily available, appropriate patient notification materials, for all those who will receive data under this support

The report confirmed the following:

The HSCIC are viewed as being the main source of patient information in relation to the dissemination of data for commissioning purposes and therefore NHS England will ask all CCGs to update their Privacy/Fair Processing Notices (currently displayed on their website) to include a direct link to the HSCIC webpage. CCGs will be required to add the same wording included in the HSCICs 'Your info' webpage to their websites to ensure that patients are provided with clear and consistent advice. The steps NHS England are taking are set out below:

1. A request will be sent out by the 22 April 2016 to all Clinical Commissioning Groups (CCGs)(via their CSU IG service provider where appropriate) asking them to update their Privacy/Fair Processing Notices with information on what type of data they process for commissioning purposes and with information on what action patients need to take if they wish to object to their data being disseminated by the HSCIC. CCGs will be required to update their websites by the end of May 2016.

2. CCGs will be asked to specifically make reference to the services included in this application within their Privacy/Fair Processing update.

3. NHS England will audit each CCGs website during June 2016 and will take action to serve notice to any CCG that has not complied with the request to update their Privacy/Fair Processing Notice.

4. CCGs will also be required to strengthen their communication with providers around their responsibilities as data controllers to provide Privacy/Fair Processing Notices to patients which specifically includes information on how patients can object to the use of their data. This requirement has already been included in the new 2017/18 commissioning contract.

5. NHS England is also strengthening its assurance role for primary care providers with the inclusion of GP IG support funding in 2016/17. A programme of audits will be implemented by the corporate IG team during 2016/17 to evaluate version 13 IG Toolkit returns and target GP practices that have not completed an IG Toolkit return or have not provided sufficient assurance around the provision of Privacy/Fair Processing information to patients.

The report confirmed that the applicant is committed to ensuring that patients are fully informed about the use of their data for commissioning purposes and being open and transparent in the use of that data. Members agreed that this was an important activity and the applicant had sought to address the clarifications, noting there were broader issues about consistency of content, and that this could be revisited at the June meeting.

Confidentiality Advisory Group recommendation

The CAG agreed to recommend to the Secretary of State for Health that the applicant had satisfactorily responded to the outstanding clarifications and the amendment should move to final approval, subject to the further action below and future review in accordance with the actions specified for CAG 2-03 (a)/2013 and linked applications.

Members noted that the data flow supported under CAG 2-03 (a) 2013 related to data flowing from the HSCIC to relevant parties, and it also supported other national data flows under other support references. Noting that it would be important for all parties to have a shared understanding, members agreed it would be important to ensure an appropriate representative from the HSCIC was present when these data flows were discussed. It was noted that NHS England would be returning in June 2016, as part of meeting the conditions of support previously communicated, to provide CAG with a detailed update against progress and an executive summary of the purposes of all applications. As the data flow reference underpinning all of these related to the HSCIC, and as the report indicated specific actions for HSCIC, it was advised that they should attend with NHS England for the June 2016 meeting.

Members raised a broader issue arising from this discussion, on whether the HSCIC could work with the Health Research Authority in terms of consistency of information provided to the public and how fair processing obligations would be met. This would be raised within the HRA.

ACTION: To flag with HRA what role it could offer to facilitate the HSCIC in terms of consistency of information provided to the public and how fair processing obligations would be met.

3. RESUBMITTED APPLICATIONS

a. 16/CAG/0056; Learning Disabilities Mortality Review (LeDeR) Programme; original reference, 16/CAG/0005.

Purpose of application

This application from University of Bristol set out the purpose of the Learning Disability Mortality Review (LeDeR) Programme as a service improvement initiative. It was commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England.

The aim of the programme was to drive improvement in the quality of service delivery for people with learning disabilities (LD) and help to reduce premature mortality and health inequalities in this population. The remit of the LeDeR Programme was primarily to support local agencies to review deaths of people with learning disabilities and to use the learning gained to make improvements in the delivery of care. The LeDeR programme will develop and roll out a standardised process for reviews to support this local delivery, and provide strategic support for its implementation. In doing so, it will be building on the well-established practice in health and social care of conducting mortality reviews as a means of improving patient care.

The anonymised mortality case reviews will be collated and evaluated by the programme team to ensure that learning is being embedded in practice. This will be reported on annually. Reports on the findings of this work will be disseminated to regulators, policy makers, commissioners, service providers, practitioners and patient and family groups with the aim of supporting changes that improve the quality and safety of care for people with learning disabilities.

This application was a re-submission of 16/CAG/0005 previously reviewed at the 14th January 2016 CAG meeting.

A recommendation for class 1, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from:

- The reporting of personal details about people with learning disabilities who have died from 1st April 2015 to 31 May 2018 to the LeDeR Programme
- Collection of detailed case information and review of health or social care case notes in order for a local reviewer to conduct a review of the death
- To share NHS numbers (or other key identifiers) with the Office for National Statistics to obtain the ICD10 codes for each person's causes of death.

Confidential patient information requested

Access was requested to information:

- Relating to people with learning disabilities: name of deceased person, date of birth, date of death, gender, NHS number, first 2 digits of postcode, ethnicity, gender, information about the circumstances leading to the death of the individual, including the person's medical history, details of diagnoses and treatments, contacts with services, the care and support that they have received prior to death, and their cause of death.
- Relating to the person's next of kin/family: name of relative/next of kin, address, and relationship to the deceased.

Confidentiality Advisory Group advice

Public interest

As previously advised members were supportive of this work and agreed this was an important area which was often neglected. There is a clear public benefit to improve the care given to people with learning difficulties more generally.

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 that consent was not possible as the cohort were deceased.

Patient notifications

Members agreed that generally the patient notifications were acceptable but were of the opinion that the language was overly sophisticated. Members recommended that the patient information was revised and that the applicant sought a review of the revised materials by the patient and public groups they have already engaged with.

Patient and public involvement

Members agreed that the patient and public engagement was good and the applicant had clearly adopted the Secretary of State for Health's commitment to putting families at the heart of this review.

Additional points

Members thanked the applicant for re-submitting this application and agreed this was a much improved application, clear and well put together. Members were of the opinion that the information providing advice about how and what to do when families did not want to participate was dealt with sensitively.

However, the application form, section S, refers to information being classified according to an appropriate level of confidentiality: public, open (within the University), confidential, strictly confidential or secret. Members were of the opinion that information was either confidential or not and were of the opinion reference to strictly confidential or secret was not needed.

The applicant also refers, section O of the application, to minimising use of data without consent, and in section X, that data will be psudonymised as soon as possible, members requested clarification on these points.

Members noted that the applicant had given a commitment to report the outcome of the review to families and noted that, in section P of the application, family members had commented in particular that they wanted assurance that bereavement signposting to be made available to families who contribute their views to the review. The families also wanted to see an emphasis on recommended and agreed service improvements being monitored and robust governance structures being put in place so that the reviews do not become an end in themselves. Members requested more detail of how this was to be achieved.

Members also noted that the opt-out, discussed in appendix 2, was in regard to the family members and not an opt-out from the use of the deceased person's information. Therefore, opt-out by a family member does not affect the information of the deceased, other than the broader information the family member may give. The applicant should ensure they have a legally defensible position for opt out from the use of any deceased individuals' information.

Members noted that following the outcome of the CIPOLD review, training for staff, in order for them to identify concerns earlier, had been developed and had been in place for over a year but noted that applicant had not indicated whether they had engaged with local service providers. Members would recommend that, if this has not already been considered, the applicant makes contact with local service providers e.g. SIRONA care and health, in order to take advantage of lessons already learnt.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Clarification about what minimising use of data means
2. Clarification about when data will be pseudonymised
3. Clarification about the approach to families when reporting about the Review

Once received the information will be reviewed by the office, in the first instance, and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

Specific conditions of support

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

4. NEW APPLICATIONS – Research

a. 16/CAG/0038; Risk Stratification tools to identify patients with advanced COPD.

Purpose of application

This application from University Hospitals of Leicester NHS Trust set out the purpose of investigating which measurements best assess the severity of Chronic Obstructive Pulmonary Disorder (COPD), and how best to use these measurements to determine how many patients have advanced disease.

The project will use health data about patients with COPD that is already recorded by GP practices in Leicester, Leicestershire, and Rutland (LLR) and which is being used to help local health organisations work out the health needs of the local population. This information cannot be used to identify an individual patient by the research team. The researchers will use this information to find out how many patients with advanced COPD are living in LLR and how best to predict their future needs for healthcare.

Background

The applicant asserted that current information sharing arrangements permit the Arden and Greater East Midlands Commissioning Support Unit (Arden and GEM CSU) to receive patient level data from LLR practice read codes via clinical system suppliers. Patient identifiable information is placed in an accredited secured data safe haven (within Arden and GEM CSU) where it is pseudonymised immediately upon receipt. This data is then linked to pseudonymised data from other NHS information systems (Secondary Uses Service (SUS)) using the NHS number as the unique identifier.

The legal basis for this information sharing and linking of datasets as specified above was stated to be established by NHS England under reference CAG 7-04(a)/2013. This approval allows disclosure of commissioning data sets (SUS) from the Health and Social Care Information Centre (HSCIC) and the disclosure of data from GP systems to a data processor (Arden and GEM CSU) working under the instruction of GPs as data controllers, to enable the preliminary processing and linkage of the data, for the non-research purpose of risk stratification.

Confidential patient information requested

Support was requested to cover the disclosure of identifiable data from patient level data from GP practices within the LLR regions to Arden and GEM CSU for the additional purpose of research. The following additional data items will also be collected (not currently included in the data flow specified under CAG 7-04(a) 2013:

1. FEV1 (in L and % predicted), MRC (Medical Research Council) dyspnoea score,
2. BMI (Body Mass Index),
3. Home oxygen use,
4. Exacerbations in the preceding 12 months,
5. Prescriptions of antibiotics and steroids for exacerbations and of maintenance medications for COPD,
6. Smoking status.

The recipient will not receive an identifiable dataset; however support is requested to enable the processing of the already held dataset, to enable the de-identified dataset to be provided to the research team, for the purpose of research.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type are 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 is impracticable to seek consent for the additional purpose (research) set out in this application, due to the numbers involved.

- Use of anonymised/pseudonymised data

Members agreed that, as the data is being processed already under CAG 7-04(a)/2013, it could not further be reduced prior to being released in a de-identified form to the research team.

Justification of identifiers

The members concluded that the identifiers are already processed under CAG 7-04 (a)/2013 and, as all data will be de-identified prior to release to the research team, the processing is therefore necessary and appropriate.

Exit strategy

The group were satisfied that no additional exit strategy, over and above that described in the application CAG 7-04(a)/2013, was required.

Patient notification and objection

Members noted that the patient leaflet provided had yet to be submitted to the Research Ethics Committee. Subject to the REC's decision the group were satisfied with the information provided, however they recommended that the contact details were provided directly rather than in a link.

The group also noted that that the LLG leaflet provided contains factually incorrect information about CAG (for example, it erroneously states that the Secretary of State approves research, rather than that the Health Research Authority approves processing for research). This should be corrected.

Additional points

The group were clear that their recommendation to support the processing of data for a separate purpose should not be considered to set a precedent for any future applications of this type, and that future submissions should be routed via NHS England (as they manage the original support).

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. CAG receipt of the revised LCCG health records leaflet, correcting the factual inaccuracies about CAG and to allow greater ease for patients to register objection.
2. CAG receipt of a favourable opinion from a Research Ethics Committee for the revised patient leaflet.
3. CAG receipt of a favourable opinion from a Research Ethics Committee. **Received, letter dated 03 March 2016**
4. Support is conditional on suitable security arrangements (as evidenced by Information Governance Toolkit (IGT) submission) being in place.

Once provided, the response will be reviewed by the confidentiality advisory team.

b. 16/CAG/0037; Liaison Psychiatry: Measurement and evaluation of service types, referral patterns and outcomes (LP-MAESTRO).

Purpose of application

This application from the Leeds Institute of Health Sciences set out the purpose of the overall aim of LP-MAESTRO was to evaluate the cost-effectiveness and efficiency of particular configurations of liaison psychiatry service for specified target populations. To do this, an innovative approach based upon linking routinely collected patient-level data and using economic modelling with the resulting aggregated data will be developed and evaluated.

Liaison psychiatry involves the provision of mental health services in non-psychiatric settings, in this application in general hospitals. Liaison services exist because there are higher rates of most

mental health problems in general hospitals than there are in the general population. The two main questions asked of them are:

- do they improve outcomes for the people referred to them and
- if so can they do so in a cost-effective way?

It has also been claimed that LP saves the NHS money by reducing inappropriate use of expensive general hospital stays and treatment for people who are best helped in other ways.

The challenge in answering these questions is that liaison services vary greatly in how they are set up, in the sort of referrals they see, and in how they deliver care. Liaison psychiatry for the elderly does not cover the same ground as that for working age adults. So asking whether liaison services are cost effective is not like asking whether a cardiac surgery service is cost-effective but more like (on a smaller scale) asking if general practice is.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to allow the disclosure of confidential patient information, NHS Number, between ResearchOne (SystemOne database) and the Health and Social Care Information Centre (HSCIC) (Hospital Episode Statistics database) in order for linkage and psuedonymistaion to take place.

Confidential patient information requested

Access was requested to NHS number.

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 agreed that consent would be impracticable as the cases would not be identified, therefore the applicant would not be able to achieve this.

- Use of anonymised/pseudonymised data

Members discussed the linkage process the applicant had put forward and noted that it would appear this was to be achieved using a salt key which was to be applied at the SystemOne practice end of the process therefore, the data would be pseudonymised at source.

However, the applicant had indicated that NHS number was to be shared between ResearchOne and HSCIC in order to facilitate linkage prior to pseudonymisation taking place. Consequently members sought further clarification in order to determine if support under the regulations was required.

Patient notifications

Members noted that the applicant refers to the HSCIC process for managing objections and in relation to ResearchOne that GPs practices are able to opt into this database. They also state patients can opt out thelselves, but the process of how patients are to do this was not provided.

Additional points

Establishment of the TPP ResearchOne Database

Members referred to the establishment of the TPP ResearchOne Database and advice provided by the Ethics and Confidentiality Committee in a letter to the Dr Christopher J Bates dated 03 October 2012 and which was currently posted on the ResearchOne website.

The advice provided at that time of setting up the database was;

1. The application did not require a recommendation of support in order to proceed, on the basis there was no disclosure of identifiable data
2. Future linkages involving the transfer of identifiable data to or from the database should seek support before proceeding

Members noted specifically that, as summarised at the time, any linkages to HES would be undertaken using pseudonymisation software so that there was no disclosure to or from HES of identifiers.

Therefore, the group determined that NHS number was not held in the ResearchOne database, but pseudonymised at source before being passed to ResearchOne.

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 was psuedonymised in line with the ICO standard. If there 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.

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. Provide details of the opt out process for patients and how this will be made available to patients, e.g. leaflets, website etc
2. Provide clarification about the linkage process specifically to confirm if NHS number is used in the clear in the linkage process
3. If NHS number in the clear is used, provide confirmation exactly where this is held, and specifically if this is held in the ResearchOne database. If this is held in the ResearchOne database provide confirmation of the legal basis for this

4. If NHS number is pseudonymised at source before being passed to the ResearchOne database you should confirm your own assessment meets the ICO standard and if in doubt seek advice from the ICO to confirm your view

4. If data from the HSCIC is pseudonymised at source they should confirm their own assessment meets the ICO standard and if in doubt seek advice from the ICO to confirm their view

Once received the information will be reviewed by a sub-committee of members in the first instance. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

c. 16/CAG/0048; LATTE: Long-term Anastrozole vs Tamoxifen Treatment Effects.

Purpose of application

This application from Queen Mary's, University of London set out the purpose of adding data from the HSCIC to that already collected in the LATTE database.

The LATTE database (Research Ethics Committee reference 09/H1102/1+5) collects follow up information on participants in the ATAC study (under consent given for that study). ATAC was a randomised, double-blind trial comparing Arimidex alone with Nolvadex alone with Arimidex and Nolvadex in combination as adjuvant treatment in post-menopausal women with breast cancer.

There were approximately 9,500 post-menopausal women with breast cancer who participated in this trial. Of these, around 5,000 are alive and have not withdrawn consent.

A recommendation for class 4 and 6 support was requested to allow the disclosure of confidential patient information relating to approximately 5,000 breast cancer patients who took part in the ATAC trial from Queen Mary's, University of London to the HSCIC and from the HSCIC to Queen Mary's, University of London.

Confidential patient information requested

Access was requested to date of death, cause of death, evidence for breast cancer recurrence, other cancers, cerebrovascular events, heart disease, and fractures. This will be linked with identifiable data held with consent.

Confidentiality Advisory Group advice

Public interest

Members agreed that projects of this type are 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 is unfeasible to seek consent from such a large group.

- Use of anonymised/pseudonymised data

It was agreed that identifiable data is required in order to link with the HSCIC.

Justification of identifiers

Whilst identifiable data is required for linking the LATTE dataset with the HSCIC data, the members were unclear if the full set of identifiers requested was required solely for linkage. The applicant should provide confirmation of the identifiers required for linkage and justification for any identifiers requested over and above those required by the HSCIC.

Exit strategy

The group noted that this is a long-term follow up protocol and that, as such, there is necessarily a degree of ambiguity about when the project will end.

Patient and public involvement

The group felt that the applicant should have provided more information about patient and public involvement, and evidenced how this has impacted on the design and conduct of the trial. Engagement of this type, specifically with regard to the unconsented linkage with the HSCIC, should be conducted going forward and evidenced in the first annual review submitted to CAG.

Patient notification and objection

The group noted the applicant's statement that 19 patients had requested not to be included in the follow up and that this had been respected. However, the group were strongly of the opinion that better and more specific information should be available to participants as to how their data will be being used and how they could opt-out of this use.

Additional points

The group was unclear from the application if other data-linkage activities (with, for example, ONS) were proposed. The applicant should provide an updated data flow diagram showing what data will flow to and from what organisations and in what format.

The applicant had not requested class five support (for 'the audit, monitoring and analysing of the provision made by the health service for patient care and treatment'), and should confirm whether support of this class is required.

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 a revised data flow diagram with complete information as to what data will be flowing to and from what organisations. This should include information about the format in which the information will flow and how it will be stored.
2. Provision of new or revised patient notification materials containing information about the components of the research for which CAG support has been sought and information as to how patients can opt-out should they wish to.
3. It is unclear if the full set of identifiers requested is required solely for linkage. The applicant should confirm which identifiers are required by the HSCIC for linkage, and justify any additional identifiers.
4. Confirmation that information on patient and public engagement, specifically in reference to this unconsented linkage with the HSCIC, will be provided in the first annual review submitted to CAG.
5. Confirmation as to the classes of support required.
6. Favourable opinion from a Research Ethics Committee. **Letter dated 21 January 2014**
7. 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.

d. 16/CAG/0040; Validating an extended scale on the HCR-20.

Purpose of application

The 'Health, Clinical, Risk 20' (HCR-20) is the most commonly used risk assessment tool for assessing violence in the UK. Effective risk assessments help to ensure that offenders are given the correct support and treatment necessary to reduce their risk of reoffending. Previous studies have largely investigated the ability of the HCR-20 to predict violence. However, little emphasis has been placed on the HCR 20's potential ability to identify changes in risk. Understanding this would help secure hospitals and prisons to achieve one of their core aims, facilitating them to re-integrate offenders back into society by reducing their risk.

This application from East London NHS Foundation Trust set out the purpose of testing the validity of a new 7-point scale for the HCR-20 and of assessing whether it is better than the original, already validated 3-point scale at evaluating change in risk. The study will also test whether improvements on a HCR-20 score is linked to a reduction in violent behaviour.

To conduct the study, a researcher will visit 5 prisons and 5 secure units. At each site, the researcher will train the clinicians to complete the HCR-20 assessments and score them using the new 7-point scale. As part of routine clinical practice, the clinicians at the various sites will then complete the HCR-20 using both the original 3-point scale and the new, yet to be validated 7 point scale. The researcher will then visit the sites and document the HCR-20 scores, violent behaviour in the 6 months prior to the HCR-20 scoring, and any evidence of a change in risk (granted leave, moved to a more/less secure unit).

After 12 months, the researcher will re-visit the sites and collect the HCR-20 scores, document violent behaviour and document any changes in risk. This data will then be analysed by the research team to determine whether extending the scale from 3 points to 7 points is better for detecting change in risk.

A recommendation for class 1, 5, and 6 support was requested to allow the disclosure of confidential patient information from 5 prisons and 5 secure units to the research team from East London NHS Foundation Trust.

Confidential patient information requested

Healthcare data (number of violent incidents; number of progressive moves – service user moved to a unit or ward that had a lower security rating; changes in privileges due to a reduction or increase in risk) from 250 Residents of a forensic mental health unit or a prison, who have had at least one HCR-20 assessment completed, from 10 sites (5 of each).

No confidential information will be collected for this study, but the research team will, in accessing case files, have access to: name, postcode, NHS number, date of birth, & date of death

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type are 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 is unfeasible to seek consent from such a large group, especially one which posed such specific difficulties in terms of seeking consent. Seeking consent would be likely to introduce a bias into the study which would significantly lessen its value.

- Use of anonymised/pseudonymised data

Members were content that it is not reasonably practicable for members of the care team to extract the relevant data due to other commitments, and as this might introduce bias and could lead to inconsistencies within the dataset as a whole.

Justification of identifiers

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

However, members requested that the applicant provide specific assurance that absolutely no identifiable data will leave any of the sites in any form.

Exit strategy

The group noted that the study is anticipated to last two years; as such there is no proposed exit strategy.

Patient notification and objection

The group expressed their satisfaction with the patient notification and objection provided, however they did feel the poster should also include a direct contact for the research team (e-mail or telephone). If this will not be reasonably practicable, the applicant should justify this.

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. Specific assurance that absolutely no identifiable data will leave any of the sites in any form.
2. Provision of updated study poster including a contact detail for the research team or justification as to why this would not be reasonably practicable.
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 will be reviewed by the Confidentiality Advice Team.

e. 16/CAG/0051; Cancer survival in the United Kingdom (Wales).

Purpose of application

This application from London School of Hygiene & Tropical Medicine set out the purpose of estimating 5 year survival post diagnosis for patients with a first, primary, invasive cancer in Wales, with the aim of estimating the pattern of survival by age, sex and time since diagnosis.

These estimates will be incorporated into a set of survival estimates for all four UK nations, to be submitted by the Department of Health in London to the Organisation for Economic Co-operation and Development for its biennial publication 'Health At A Glance'.

This application was to request data on all cancer registrations of residents in Wales, including invasive primary malignancies and those of in situ, benign or uncertain behaviour, with the date of birth, date of diagnosis and date of last known vital status, as well as the codes for the anatomic location and type (microscopic appearance) of the tumour. The data refer to adults (15 to 99 years) who were diagnosed between 1971 and 2013 and followed up to 31 December 2014.

The data was to be provided by the Wales Cancer Intelligence and Surveillance Unit for all residents in Wales who were diagnosed with a qualifying neoplasm and for whom complete follow-up information on their vital status (alive, dead, emigrated, lost to follow-up) has been linked to the underlying cancer registration.

A recommendation for class 5 and 6 support was requested to achieve the specified purposes.

Confidential patient information requested

Access was requested to postcode, NHS number, date of birth and date of death for linkage and analysis. Gender was to be utilised for analysis purposes.

Confidentiality Advisory Group advice

Public interest

Members did not feel that the applicant had fully demonstrated that this project was in the public interest, and whether the amount of data to be processed was justified, and whether this was a research activity (and not a statistical return).

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 applicant had not demonstrated that the feasibility of consent had been considered, nor had a clear justification for why consent was not practicable been put forward.

The applicant referred to the cancer registration process having support under the Regulations; *Cancer registration is exempt from the need to obtain patient consent under Section 251 of the NHS Act 2006 and under Statutory Instrument 2002/1438*. This did not provide a clear justification for not seeking consent.

- Use of anonymised/pseudonymised data

Members accepted that some identifiers would be required for linkage purposes, but the applicant should explore whether the linkage could be achieved with fewer identifiable fields.

Members discussed whether there was a practicable alternative to this proposal and in particular whether the Secure Anonymised Information Linkage Databank (SAIL) in Wales was, either doing this analysis already or were intending to do so, as this would be a practicable alternative to the proposal put forward by the applicant.

They also wanted to know how this analysis was carried out in the other home nations and, if so, whether this was under a different legal basis.

Members therefore requested that prior to the outcome letter going to the applicant, that SAIL be contacted to confirm whether a practicable alternative to the processing of confidential patient information outlined by the applicant existed.

Patient and public involvement

Members noted that the applicant had addressed this in the application to be through the findings dissemination process. They had also involved 3 cancer patients who were included in one or other of the external advisory panels involved, the advice provided by these patients was related to the appropriateness and relevance of national studies run by the applicants organisation and not specific to this application.

The applicant should demonstrate the impact of user involvement on the study design. Where there is no impact, this should be justified.

Patient notifications

Members noted that the applicant had not addressed the need to inform patients of the use of their data for this activity. Furthermore a process for opt out had not been provided other than by virtue of the national cancer registration process. No information about the project would appear to have been made available to patients currently living or receiving treatment in Wales about how they could opt out of the further use of their data.

Exit strategy

The group noted that no clear exit strategy had been put forward.

Additional points

Members were unclear whether it was the intention that the whole cohort was to be from Wales. If this was the case, how was such a cohort to be identified, particularly taking into account cross border issues?

Specifically, members discussed how border issues, for those patients who received a diagnosis in Wales but for who follow-up treatment was received in England, could affect the project and requested to know how the applicant would take account of these cases, e.g. noting there was no secondary care provision in the whole of Powys.

Members referred to section 2: 9-2 of the application and the applicants reference to; *Acquisition of these data is allowed under section 251 of the NHS act 2006 and statutory instrument 2002/1438, and we have the requisite Health Research Authority approvals to acquire these data and analyse them,* and requested what references these approvals were under and what purposes were approved.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required in order for a recommendation to be made.

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

1. Confirm whether there is a practicable alternative to this proposal i.e. whether this could be or is being carried out by the Secure Anonymised Information Linkage Databank (SAIL) in Wales
2. Confirm how this activity is carried out in England and Scotland & Northern Ireland and confirm the legal basis
3. Confirm if the activity is research or a statistical return
4. Provide a clear justification as to why consent is not practicable
5. Explore the possibility of carrying out the linkage with fewer identifiable data fields or justify why the fields are needed
6. Provide a revised plan to demonstrate how patient and public engagement will be conducted and a timeframe for this

7. Provide a revised plan about how patients are to be informed about the project and how patients will be able to opt out
8. Provide an exit strategy
9. Confirm whether it is intended that the whole cohort are to be from Wales, and if so, how this will be achieved
10. Confirm how the project would account for patients diagnosed in Wales but receiving follow-up treatment in England
11. Confirm how this is carried out in the other home nations and under what the legal basis
12. Confirm what is meant by *the requisite Health Research Authority approvals to acquire these data and analyse them* and provide the related references and detail of the purposes approved

Once received the information will be reviewed by a sub-committee of members in the first instance. If they are content with the response the application will then be considered at the next available full committee meeting.

ACTION: CAT team to consider whether handling of responses to the above warrants a change to process to ensure consistency of decision-making.

5. MINUTES OF THE MEETING HELD ON 17 March 2016

The minutes were agreed as an accurate record, subject to a correction to the action on page 25 (which should have read 'Chair Team to investigate whether help should be offered to the Royal College of Surgeons') and a correction to the discussion on page 33 (which should have read 'It was noted that CRUK and Macmillan were undertaking a review of communications with cancer patients about registrations. Following communication with the Chair, CAG offered to seek a volunteer member to participate in this review if it was considered helpful.'). CRUK and Macmillan have yet to respond to this offer.

On investigation, it was agreed that the action relating to 16/CAG/0044 ('to investigate whether help should be offered to the Royal College of Surgeons') should not be taken forward as the application it refers to was not from the Royal College of Surgeons.

The minutes of the 4 April 2016 sub-committee had been ratified by the original reviewers and were confirmed as an accurate record.

The minutes of the 21 April 2016 precedent set meeting had been ratified by the original reviewers and were confirmed as an accurate record subject to a clerical correction.

6. CAG OFFICE REPORT

Previously a new office & chair report was circulated at each new meeting and the office report included in the minutes. This has been complicated by the addition of the Manchester CAG meeting and the need to ensure consistency of information to all members.

Chair and office reports will now be circulated to all members by e-mail on the first working day of the month. The Secretary of State for Health and Health Research Authority approval decisions

will be moved from the office report to the standard agenda. Each set of minutes will thereby contain an up to date record of these decisions.

The chair and office report will be tabled at any CAG meetings that month, with any pertinent discussion minuted. However the office report will only be included in the first set of minutes produced that month.

7. ANY OTHER BUSINESS

Away day discussion on interim position: handling of Type 2 objections

The CAG had undertaken an induction for newly joined members and an away day session the day beforehand. It had been noted that the SofS had issued a Direction that day to the Health & Social Care Information Centre to require the management of 'Type 2 objections'. Members had discussed the potential impact as this condition had been waived in a limited number of circumstances, and primarily around safeguarding concerns, and feedback was sought from members to develop a position in the event that requests were received from applicants to waive condition 8 of the standard conditions of approval. The following interim position was agreed:

- The CAG is not expecting to revisit any recommendations to waive condition of support 8.
- However, in exceptional circumstances it will be prepared to hear an appropriate request, if the applicant can demonstrate a significant detrimental impact and a substantial public interest.
- The CAG will consider any such assertions at a full CAG meeting. It was agreed that any applicant proposing this approach would be expected to provide a compelling argument and the threshold would be high.
- However, the CAG will not consider any requests to reconsider the general position of the support until CAG as a committee has an understanding of what is contained within the forthcoming report to be published by the National Data Guardian. The reason for this interim position is so that the future direction of travel can be taken into account in the CAG recommendation, and if the recommendation deviates from this general direction, for the CAG to explicitly recognise this when providing advice to the decision-maker.

For the members who were not present, this position would be circulated via the minutes and Chair's report and further comment invited; it was noted this was a unanimously agreed interim position by all members present at the discussion.

MRIS SUSPENDED STUDIES

The CAT informed the group that they had received a briefing note from the HSCIC about a proposal they had put forward regarding a number of medical research studies who were originally part of the HSCIC's class action support and as a result of changes in legislation no longer have a legal basis to receive data from the HSCIC. These changes have resulted in the HSCIC stopping the provision of data to these applicants.

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The briefing note was also intended to provide assurances on the potential number of applicants to CAG as a result of these changes. The figures provided were based on the 'worst case scenario' if all the applicants submitted an application for S251 support. It was thought that a number may decide to take a different approach e.g. changing to a pseudonymised output, which may not require S251 support. It was also noted that 10 applicants had confirmed to the HSCIC they no longer require data and had destroyed the data they held.

ACTION; CAT, Diane Pryce, will draft a handling plan which will be shared with members for their agreement.

Education Items

This is a new addition to the agenda and is intended as a reminder to CAG members to raise any education items. These will be noted and a log kept to inform future away days and education items at meetings; they will not be formally minuted

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date