NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

08 June 2017 at Skipton House, SE1 6LH

Group Members:

Name	*Present*	*Notes*
Dr William Bernal	Yes	
Ms Sophie Brannan	Yes	
Dr Tony Calland	Yes	Vice Chair
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	
Professor Jennifer Kurinczuk	Yes	
Mrs Diana Robbins	Yes	
Dr Mark Taylor	Yes	Chair

Also in attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor
Ms Eve Riley (Item 3a only)	In Attendance – via telephone	Associate Director-Research & Governance, HQIP
Dr Carolina Arevalo (Item 3a only)	In Attendance– via telephone	NJR Associate Director - Operations & Contracts, HQIP
Mr Mike Swanson (Item 3a only)	In Attendance– via telephone	Northgate
Ms Sue Hogarth (Item 4b only)	In Attendance	Public Health Consultant, Tower Hamlets Together
Mr Krish Thiru (Item 4b only)	In Attendance	Public Health Intelligence Manager, London Borough of Tower Hamlets
Mr Stephenson Robinson (Item 6a only)	In Attendance	Corporate Secretary, HRA

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies were noted for the meeting.

Dr Lorna Fraser declared a conflict of interest with the application, noting that the main applicant had previously been her PhD Supervisor. The CAG agreed that there was a potential conflict of interest. Dr Fraser did not participate in discussions around the proposal.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State for Health Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 11 May 2017 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 11 May 2017 meeting applications.

3. ITEMS FOR CONSIDERATION

a. PIAG 2-05 (j)/2006 NJR amendment

Amendment Request

The letter and supporting responses set out an amendment to the existing support in place, specifically to the data linkage element. This support would provide the satisfactory legal basis by which NHS Digital could continue to provide all episode data for a given set of OPCS4 codes in order to continue to be able to identify procedures missing from the NJR dataset. The inability to identify procedures not in the NJR database could potentially compromise patient safety.

The linkage activity is undertaken by Northgate Public Services (NPS), contracted by the Healthcare Quality Improvement Partnership (HQIP), as the NJR's data processor. Once created, the pseudo-anonymised data set is passed to the University of Bristol (as the NJR's statistical analysis contractor) and used for agreed analysis

Each year an application is submitted to NHS Digital (NHSD) for HES, ONS, and PROMs data so that it can be linked to patient identifiable data at the record level. The request to NHS Digital is to provide episode and operation data for a specific set of OPCS4 codes used in hip, knee, shoulder, elbow, and ankle joint replacement. The requested data includes patient identifiable data so that it can be linked to data held by the NJR. The purpose of this linkage is to create an annual, pseudo-anonymised data set that can be used for research and analysis. Aggregated data and outcomes are published in the NJR's Annual Report, publications (including the Lancet, the British Medical Journal, and the Journal of Bone and Joint Surgery), and directly to stakeholders via the NJR's online stakeholder reporting services.

Confidentiality Advisory Group Advice

The Chair welcomed Ms Eve Riley, Associate Director-Research & Governance (NJR), Healthcare Quality Improvement Partnership (HQIP), Dr Carolina Arevalo, NJR Associate Director - Operations & Contracts, HQIP, and Mike Swanson, Northgate, to the meeting via teleconference.

Background to Amendment Submission

The CAG was unclear from the documentation provided to support the submission what had occurred to bring about the necessity of the amendment to clarify the scope of the existing support. The applicants explained that historically an application was made to NHS Digital each year for information from HES, PROMS and ONS data in relation to OPCS4 codes which are supplied by the NJR. NHS Digital had historically provided a complete dataset in relation to these specified codes to enable record linkages with the NJR for patients who had provided consent or for whom consent status was not known. The requirement for the amendment was due to concerns which had been raised by NHS Digital around sending confidential patient identifiable information to Northgate in relation to patients who did not have an NJR record or for whom the consent status was unknown as there was potential for these individuals to be identified. Members clarified that records were not linked for patients who had registered dissent and it was confirmed that type 2 objections would be respected.

The applicants further advised that whilst time pressures existed in their processes, data had not been readily provided by NHS Digital to enable Northgate to undertake the activity it had been commissioned to do on behalf of HQIP. It was clarified that the last application for data from NHS Digital had been made in December 2015 from which no data had been received.

Public Interest

The Group agreed that there was an overriding patient safety issue in relation to the previous years' data which had not yet been processed by the NJR. Members agreed that support was recommended in relation to the transfer of confidential patient information for all patients with the relevant OPCS4 codes from NHS Digital to Northgate for the period of 2014 to 2016. The CAG acknowledged that there was limited time available before the request for data in relation 2017 would be submitted and it was unlikely that an alternative process would be agreed in this timeframe. It was recommended that support be extended to cover the data collection in relation to 2017 also. The CAG confirmed that there was an overriding patient safety interest which supported the rationale to extend support to these data flows to enable facilitation of the linkage and analysis of the outstanding years of data.

Data Flows

The CAG queried why the dataflow for the project was established for the transfer of confidential patient information from NHS Digital to the NJR for linkage as it commented that dataflow in the opposite direction was the standard. The applicants clarified the data linkage for the NJR had been undertaken by Northgate on behalf of HQIP since 2006, since which time complex and intelligent algorithms have been developed to facilitate the data linkage. It was further added that in the previous four years, only one dataset had been received from NHS Digital.

Whilst the applicants agreed that whilst the algorithms which had been developed could be shared with NHS Digital, due to the delays which had been encountered in receiving the non-linked files, there was concern around how long the linkage process may take. The applicants were also unclear whether the full linkage algorithm would be utilised, which would affect the quality of overall dataset.

The applicants confirmed that the process to receive data from PEDW was the same and no issues had been encountered in the transfer of data in connection with Welsh patients.

Members queried whether it was possible for data linkage to continue to be undertaken by the NJR; however, only in relation to those patients who have a record within the NJR dataset. NHS Digital would only supply confidential patient information in relation to those patients who had a confirmed record within the NJR dataset. The applicants advised that, in this process, data would not be supplied in relation to those patients who had been overlooked for inclusion within the NJR. Members suggested that patient-level de-identified data could still be provided for all patients with the relevant OPCS4 codes. The applicants stated

that support was not currently in place to support this dataflow. It was acknowledged that whilst possible, the applicants were reluctant to pursue this due to the cost and time implications involved with cleaning up the linked de-personalised data received from NHS Digital.

The Group queried whether there was scope for the applicants to send a historical dataset which had already been successfully linked using the NJR algorithm to NHS Digital in order to test the linkage capabilities. It was explained that discussion around this would need to be held with the wider team in order to seek authority for this additional activity; however, it was noted that support for the retention of data gathered up to the end of 2016 would expire at the end of June 2017, so any additional processing of identifiable data would need to be undertaken with haste.

Members considered this process and it was agreed that an extension to the support in place for historic datasets was recommended to enable a test linkage activity to be undertaken with NHS Digital in relation to this historic dataset. The applicants would be expected to provide details of the outcome of this trial at the next annual review stage. If the outcome of the linkage is positive, it would be expected that arrangements were made for NHS Digital to undertake the required data linkage moving forward.

Patient Objection

It is a long-standing position of the CAG that any explicit objection raised by a patient in connection with an activity supported under the Regulations is respected in all but the most extreme circumstances. In line with this, Members requested further information around the consent arrangements which were put to patients in relation to the NJR. In particular, it was queried whether the consent process was explicit around the data flows which were required in relation to the Registry and whether there was scope for a patient to believe that they had either explicitly consented or dissented to the data sharing from NHS Digital to the NJR. The applicants confirmed that the exact data sharing arrangements were not explicit in the consenting process as it was not known whether there would requirement in future to change the data sets with linkage is required. The applicants explained that a proportionate approach is taken in relation to the information provided to patients because of the potential future change and as such, it was not possible for a patient to believe they had dissented to the sharing of data from NHS Digital to the NJR.

It was further explained that NJR would use the complete data set to link with records in the NJR for those patients where consent was confirmed and for those whom consent status was not known. NHS Digital had raised concerns that the applicants would use additional data to identify those patients falling out with of the categories described. The applicants explained that whilst this was technically possible to identify patients through investigating procedure date and centre ID along with other points, this would not be undertaken. The applicants stressed that their organisation's professional reputation depended upon them abiding by the law. It was advised that if it became apparent that there was a particular centre or procedure which did not have corresponding records within the NJR, contact would be made with the relevant Trust in an attempt to drive retrospective data entry and patient consent to enable quality data to be pulled through to the NJR. The CAG was satisfied with the assurance provided by the applicant

Role of Northgate

The CAG requested clarification of the role of Northgate within the project. It was explained that the NJR is part of the National Audit Outcomes programmes commissioned by HQIP. Northgate are a sub-contractor of the NJR which acts as data processor for the registry, working closely with the University of Bristol which undertakes the data analysis. It was noted that historically, Northgate facilitated HES before this was brought back in by NHS Digital.

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 acknowledged that there were issues around the consent process which was currently operated. It was suggested that in future, if exploration of data linkage by NHS Digital proved to be unsuccessful, the consenting process would require revision. It was recommended that the participant information materials were explicit that confidential patient information would be shared with the NJR from NHS Digital regardless of formal consent from the patient. The documentation should make clear that this data flow would only be prevented through the registration of a type 2 objection with NHS Digital.

- Use of anonymised/pseudonymised data

The Group acknowledged that data linkage between the mentioned datasets was required to enable the NJR to continue to achieve the required outcomes. It was acknowledged that the additional analysis undertaken by the University of Bristol was done so on an anonymised dataset.

Justification of Identifiers

Members requested further rationale to support the requirement for confidential data items to flow to the NJR from NHS Digital. The applicants explained that the algorithm utilised by the NJR to link patient records would attempt linkage via NHS Numbers in the first instance; however, if this was not available the algorithm would stepdown to other identifiers to facilitate linkage. The applicants explained that this system could only be applied if a wider selection of patient identifiers was available to enable the working of the algorithm. The use of the sophisticated algorithm enabled a higher level of data linkage than would be achieved on NHS number alone. The applicants advised that it cannot be known prospectively which data items were required to undertake data linkage for each patient, hence the requirement for the full dataset.

The Group acknowledged that there was an interest in patients which were identified by NHS Digital that did not have a corresponding NJR record, as their data had not been notified to the registry through the useful reporting channels. It was queried whether depersonalised data was useful in relation to these missed cases. The applicants advised that these cases could not be identified until the full data linkage process against the NJR records had been undertaken.

Confidentiality Advisory Group Advice Conclusion

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

Specific Conditions of Support

1. Support was extended to cover the flow of confidential patient identifiable information in relation to all patients with the relevant OPSC4 codes for the reporting periods from 2014 up to and including 2017.
2. Assurance is provided that record linkage would only be undertaken for those patients whose consent status was confirmed as a positive and those patients where consent status was not known.
3. The following activity should be undertaken moving forward to evidence whether there is a practical alternative available to the current established data flows:
4. The duration of the support in relation to the retention of confidential patient information held for historic years of NJR records are extended from June 2016 for an additional six month period, to facilitate a test of the data linkage capabilities of NHS Digital, against a dataset which has previously undergone the NJR data linkage algorithm. A report on the outcomes of this linkage test is required at the next annual review.
5. If the above data linkage testing proves to be successful, data linkage for prospective audit data should be facilitated by NHS Digital. An amendment would be required to facilitate the change to the application.
6. If the above data linkage is found not to be a success, revisions should be made to the patient consent process which made it explicit that data flows from NHS Digital to NJR of confidential personal

information would continue, regardless of a patient's consenting status, unless a type 2 objection is raised. An amendment submission would be required for review to process these changes.

7. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Northgate Public Services, Version 14, 2016-17, reviewed grade of satisfactory at 94%).**

4. RESUBMITTED APPLICATIONS – Non-research

a. 17CAG0100 (Resubmission of 16CAG0130) – Tower Hamlets Together

Context

Purpose of Application

As one of the most deprived boroughs in England, Tower Hamlets is attempting to efficiently improve overall health outcomes while addressing health inequalities. The intention of this project is to underpin this strategy with evidence identifying the key drivers of health inequalities with respect to health status and service usage. Tower Hamlets already benefits from an integrated care dataset that links data across different settings of care: primary care, community health, mental health, secondary care and adult social care. This was established as part of the Waltham Forest, East London collaborative (WELC) Integrated Care Pioneer Programme in order to map a proposed capitated budgets model based on 14/15 data. The applicants propose to build on this good practice by linking these datasets as well as children's services data and wider determinants data, which are held and owned by the local authority.

To establish a truly integrated and pseudonymised health and social care (H&SC) dataset for the local population which combines information from both the London Borough of Tower Hamlets (LBTH) and North East London Commissioning Support Group (NEL CSU) so as to:

- define, inform and implement capitated budget for the Tower Hamlet population.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Data from the London Borough of Tower Hamlets (LBTH) and the North East London Commissioning Support Group (NEL CSU) in relation to the resident population of the London Borough of Tower Hamlets (296,000):

- NHS Number;
- Full Name;
- Full Address (including postcode);
- Date of Birth;
- Gender;
- GP Code; & Unique Property Reference Number (UPRN) [a unique alphanumeric identifier for every spatial address in Great Britain].

Confidentiality Advisory Group Advice

The Chair welcomed Ms Sue Hogarth, Public Health Consultant, Tower Hamlets Together (PMO) and Mr Krish Thiru, Public Health Intelligence Manager, London Borough of Tower Hamlets to the meeting. The applicants were in attendance to provide clarifications to any outstanding matters from the application review.

It was acknowledged that the application had been considered on two previous occasions during 2016. CAG consideration of this resubmission focussed on the points raised in the summary outcome document issued to the applicants at the previous review held on 13 October 2016.

Public Interest

The Group reiterated that projects of this type were in the public interest and the medical purpose was defined in the planning and improvement of health and social care which could be achieved from the projects outputs.

Practicable Alternatives

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

- Feasibility of consent

The CAG remained assured that consent was not feasible due to the number of participants involved in the project.

- Use of anonymised/pseudonymised data

Members commented that the applicants had stated that the project analysis would be undertaken on a pseudonymised dataset; however, it was identified that there was the intention to retain easting and northing references for patient entries, which were identifiable items. It was acknowledged that the applicants would be using the Lower Super Output Score (LSOA) for reporting. The Group agreed that the northing and easting references would need to be deleted to ensure a pseudonymised dataset was used for analysis.

Exit Strategy

The Group had previously raised concerns around the exit strategy for the project and the applicants were required to provide further information around what steps could be taken to reduce the identifiability of the data set. The resubmitted application requested support for a one year pilot project only. The applicants confirmed that identifiable information would be held for a three month period only following initial data linkage. After this time, the dataset would be depersonalised. The CAG were satisfied with the terms of the revised project and no further issues were raised in this area.

Reporting Arrangements

The CAG had requested assurances around the process by which external contractors would request project reports. It had been clarified within the revised documentation that there was no scope to request individual reports from the project. The applicants would provide a single outcome report. Members received the response and no further issues were raised with this point.

Justification of identifiers

Members remained satisfied that the identifiers requested were proportionate to perform the required data linkage.

Governance Arrangements

The CAG had previously requested further information around the governance structures for the project with particular focus around where lay representation was included. Details had been provided in the resubmission of a Steering Group, Stakeholder Council and Public and Patient Involvement Sub-Group and

whilst it was documented that lay representation was included within these groups, it was unclear from the terms of reference provided for each group whether this was accurate. The applicants explained that a HealthWatch representative was included within steering group for the overall project; however, it was felt that the order of business may be too complex for a true lay representative to be comfortably involved with. Members received the concerns but it was commented that the value and input of patients and public at this level of the project would be beneficial.

It was further advised that the Tower Hamlets Together Board had given approval to the Stakeholder Council being convened, which would include lay representation; however, this group was still in development.

The CAG noted from the documentation that there was no specific funding allocation for involvement and engagement work and requested assurance that this would be adequately resourced. It was noted that communications were included within the pilot framework; however, work is ongoing to embed these principles into the governance for the overall project. The applicants confirmed that funding had not yet been allocated but approval was in place from the Board moving forwards.

The applicants agreed that lay representation within the governance structures could be improved and advised that relevant patient groups would be consulted at appropriate times in the project to expand lay representation within the overall governance structures of the project.

NHS Discovery – Data Processor Arrangements

Members requested further information around NHS Discovery, which was now detailed as the data processor for the project. It was clarified that NHS Discovery was not a legal entity in its own right but was a consortium of GP's within the Tower Hamlets region that acted as a legal entity under the Tower Hamlets CCG. NHS Discovery was acting as data processors on behalf of the GP's, which were the data controllers. NHS Discovery would provide the data safe haven via a contracted arrangement with AIMES data centre, which provided the haven set up and infrastructure.

Patient and Public Involvement and Engagement

The Group considered the previous request to undertake actual patient and public involvement to strengthen the public interest in the project together with providing detailed onward plans to maintain a level of engagement throughout the duration of the project. It was acknowledged that a number of focus groups had been held but it appeared that the number of patients involved was relatively small. The applicants provided an overview of the work which had been undertaken to date and acknowledged that the input of patients and service users had improved the project. It was confirmed that there were three further focus groups planned.

The applicants had been asked to report any negative feedback around the project as part of the resubmission; however, there did not appear to be any information provided within the documentation. The applicants explained that they had not met any resistance to the project but reported that the only negative comments received were around the scope of the project not stretching far enough. Patients and services users involved in the focus groups had identified additional ways a project of this type could benefit them when accessing health and social care services, which could not be achieved through the current scope of the project. The applicants acknowledged that this input provided scope for any future projects and was not deemed as a negative view of the current proposal.

Evidence of local support for the project had also been supplied from the Tower Hamlets Together Chair, London Medical Committee and the Deputy Mayor and Cabinet Member for Health and Adult Services.

The CAG was assured that there was commitment to engage with patients and the public throughout the project; however, it was agreed that the involvement plans required further development to ensure that this continued throughout the duration of the project. It was agreed that support would be recommended for the project with a specific condition around further improvement in this area. Members agreed that an interim

report would be required at six months from final support coming into place to provide an update on actual activity together with an updated engagement plan moving forward. The value of the project within the community could be evidenced through wider and creative engagement and involvement techniques. It was further advised that any subsequent purposes outside this pilot project could be demonstrated by the public and patient involvement and engagement undertaken here.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members discussed the outcome report information from the patient and service user focus groups and it was noted that concerns had been raised around how the dissenting model would be facilitated; however, it did not appear that these issues had been addressed. The applicants advised that they had been in discussion with the GP Federation around this point and had also arranged a session with the PPI Sub-Group for further consideration of how this could be addressed.

The CAG queried what arrangements were in place to enable opt-out from use of Local Authority data. The applicants explained that they working with the East London GP Consortium around this issue as it had been identified that dissent was poorly recorded. It was explained that the future arrangements would involve a central data management system to enable residents to opt-out of use of data; however, in this current proposal reliance would be on existing systems.

Members received the response and it was acknowledged that the applicants were working to ensure a meaningful notification and dissent model was in operation for the project. It was agreed that support would be recommended on the basis of specific condition that work continues throughout the project to improve patient notifications and dissent, with a focus on improving the objection model for social care data.

Additional points

Members queried a reference within the documentation around a research project. It was advised that the submission was being considered for non-research purposes only and any support would not extend to additional research purposes. The applicants explained that there was currently one defined research project detailed within the documentation (Appendix C, Schedule 2); however, it was understood that this project would need to be submitted for consideration by CAG as a standalone research project. The Group received the response and were assured that the applicants were aware of the support provided and the additional submission requirements for any linked research projects.

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. Provide confirmation that the northing and easting references would be deleted from the analysis dataset.
2. Submit a final and revised application form which reflects the project as support has been recommended.

Once received, the information will be reviewed by a member of the Confidentiality Advice Team 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. If the response is satisfactory, the SofS will confirm approval.

Specific Conditions of Support (Provisional)

1. Support extends for a one year project only.
2. Lay representation within the governance structures of the project should be actively improved. A report should be provided within six months of final approval providing detail of actions which have been taken in this area and providing revised terms of reference for the various steering groups/sub-groups to include true lay representation.
3. Further work should be undertaken to improve the opt-out mechanisms available to patients and the public. Opt-outs from the use of social care data should actively be explored as part of this work. A report should be provided within six months of final approval detailing the outcome of planned engagement around this point, together with details of the improvements made to the opt-out mechanism.
4. Public and Patient Involvement and Engagement:
   a. Continue to improve and strengthen public and patient involvement and engagement with the project.
   b. Work should be undertaken to actively widen the scope of this activity and the audience it reaches to ensure a diverse population is involved,
   c. A report should be provided back within six months of final approval around actual activity together with an updated plan detailing how this will continue as the project moves forward.

   Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – NHS Discovery is covered under the IG Toolkit for AIMES – reviewed reported grade of 100% satisfactory on Version 14, 2016-17).**

b. 17CAG0090 (Resubmission of 17CAG0042) - Feasibility study to better understand the patient journey for Chronic Heart Failure amongst Salford patients

Context

Purpose of application

A client of North West E Health (NWEH) is interested in using linked and pseudonymised National Health Service data from primary and secondary care in Salford, Greater Manchester. The project aims to better understand the patient journey for Chronic Heart Failure from two years pre until five years post diagnosis, enabling a longitudinal assessment of patient characteristics, management and healthcare resource utilisation (HRU). The cohort will be identified from the Salford Integrated Record System (SIR) which is hosted by Salford Royal Hospitals NHS Trust. Confirmation has not been provided around which organisation will be undertaking ONS data linkage

The primary purposes of this project are detailed below which will help understand the patient journey:

- Establish population split between preserved Ejection Fraction (pEF) and reduced Ejection Fraction (rEF).
- Establish Heart Failure and Cardiovascular related treatments and triggers for therapy review / dose level adjustments pre and post diagnosis.
- Calculate resource utilisation pre and post diagnosis,
- Calculate 5 year mortality
- Evaluate comorbidities.

The secondary purposes for the project are:

- Establish real world adherence to NICE guidelines such as whether are all patients receiving echo, BNP (B-type natriuretic peptide) measurement and specialist referral
- Assess ejection fraction and BNP levels as indicators of disease progression,
- Determine size of population in primary care with symptomatic chronic heart failure with reduced ejection fraction.

A recommendation for class 1, 4 and 6 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

The following items of identifiable patient information will be requested from two data sources for the purposes identified below:

From Salford Integrated Record, the following data items will be provided for each patient:

1. NHS number (not available to NWEH)
2. Age
3. Gender
4. Date of Death (year and month only)
5. GP Practice Code
6. All journal data

From ONS the following data items will be provided for each patient:

1. NHS number,
2. Date of Death (year and month only)
3. Cause of death

- NHS number is used to link SIR and ONS mortality data. Once linked, the NHS number will be replaced with pseudonymised study ID before the combined data set is made available to NWEH.
- Date and cause of death are used to determine 5 year mortality.
- Date of death is requested from both data sets as an extra check quality check (increased confidence that patients have been matched successfully).
- Age, gender, GP practice code and journal data will allow analysis of resource usage for different categories of patients.

Salford Royal Hospitals NHS Trust will use the Salford Integrated Record (SIR) database to identify patients with a diagnosis of Heart Failure or a New York Heart Authority classification, or an echocardiogram from SRFT in the secondary care data. The focus will be on preserved ejection fraction patients diagnosed in primary care as these are less well studied than reduced ejection fraction patients. Study of the whole of the Salford Heart Failure population should help eliminate sampling biases present in previous studies. The sample size is estimated at approximately 7,000 patients. It is explained that all patients within the SIR database who fit the patient profile will be included.

Confidentiality Advisory Group Advice

The CAG acknowledged that the application was a resubmission of 17CAG0042, which had previously been considered at the CAG meeting held on 23 March 2017. Members considered the revised application with reference the points raised as part of the previous review as requiring further information.

The Chair extended thanks to the applicant, Dr Patricia Baker, for making herself available via telephone; however, it was acknowledged that the issues outstanding with the application were more appropriately articulated in writing.

Public Interest

The CAG commented that the public interest in the project remained unclear. It was acknowledged from the revised documentation that the applicants advised that a better understanding of the heart failure patient population would enable better service provision and outcomes for the whole patient population. It was further noted that the applicants had stated that depending on what was found during the course of the project, healthcare providers would be able to use the data to tailor service to the needs of the whole heart failure population. Members agreed that this statement was not definitive in describing the intended outputs of the project and suggested that the findings may not be useful.

No further information had been provided within the revised submission around the make-up of the Salford Integrated Record Board and confirmation was required as whether this included lay representation.

Information had been requested around the intended publication arrangements for the project outcomes as it was acknowledged that the public interest in a project could be strengthened through wider publication of analysis findings. The applicants had stated that publications would be from both a methodological and epidemiological community based prevalence perspective also providing estimates around health resource utilisation within the different heart failure patient populations. Further detail was provided in response to additional queries raised by the CAT ahead of the CAG meeting which stated that publication would be made to a peer reviewed scientific journal and it was clarified that this would be in the public domain. Members received the response; however, it was commented that further details was required around the publication strategy. Confirmation was also required around whether publications would still be made irrespective of whether the findings were deemed positive, i.e. useful, or negative. The Group further commented that as the proposal was a feasibility study, publicising whether the methodology had, or had not, been successful in establishing a patient journey through the healthcare system would alone have merit. Members agreed that further evidence of commitment to a publication scheme was required from the applicants.

The CAG had raised queries around the transparency of the project as it was understood that the unnamed external client was a pharmaceutical company, which had been referenced in the supporting letter from the Caldicott Guardian. Members remained unclear around how the client's stated aims linked with the referenced public benefit in the application. It was commented that further transparency around the identity of the external client and their purposes would be helpful in establishing the overall public interest in the project.

The Group agreed that the benefit to the wider public, which extended beyond that of the unnamed client, had not been established within the resubmission. Further work was required to establish how the public interest would be realised. It was noted that the public interest and patient benefit in the project may be strengthened by wider and more sophisticated public and patient engagement. This point is addressed further in the section below 'Public and Patient Involvement and Engagement'.

Classification of Project

The CAG had previously queried how the project had been classified as service evaluation and had requested evidence of the decision-making process. The applicants provided response which referenced the completion of the HRA decision tool around project classification. It was noted from the information which had been supplied that the findings of the project had not been classed as generalizable. Members were unclear around the response provided to this question as it appeared to contradict the definition which had been put forward in relation to the public interest in the project, which stated that the project findings would be beneficial for the heart failure population as a whole, i.e. were generalizable to a population larger than that included within the project.

The Group agreed that further guidance in this area was required to ensure that the project had been appropriately classified. An enquiry to the HRA Queries lines would be required to allow a review of the project to be undertaken by a specialist advisor. It was agreed that the outcome letter would be copied direct to the HRA Queries line to pre-empt the future contact by the applicants.

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 CAG reaffirmed its previous consideration that consent was not practicable for this project.

- Use of anonymised/pseudonymised data

The Group noted that issues around compliance with the ICO guidance around anonymisation had been raised within the below section 'Justification for Identifiers'.

Justification of identifiers

Clarification had been sought around whether retention of GP code was required. The applicants confirmed that individual GP codes were not required for the analysis but explained that GP practice codes were required. The justification for retaining practice codes was to enable analysis of whether the patient journey differed between GP practices or clusters within the overall locality.

Confirmation was also provided by the applicants that they would not be receiving transfer of free text information from GP records.

The CAG had previously expressed concerns around potential weaknesses in the level of pseudonymisation which would be achieved in the data set to be utilised for analysis, due to the extent and variety of information held on each individual patient. Whilst a response had been provided by the applicant in terms of the physical security of the data within the N3 network, it was unclear whether consideration had been given to the potential for individual to be identifiable from the information which was reported back for analysis. Further assurance was required in this area, which is addressed further in the data flow section below, with reference to the ICO guidance around anonymisation.

Clarification of Sample Size

The applicants provided confirmation that the sample size had been estimated at 7,000 patients by the Salford Integrated Record Board. This was all patients within the database with a diagnosis of Heart Failure or a New York Heart Authority classification, or an echocardiogram from Salford Royal Foundation Trust in the secondary care data. The response was received and no further clarification was required.

Data Source

The applicants had been asked to clarify under what legal basis the Salford Integrated Record Database was held. A response had been provided in relation to the principles of the Data Protection Act 1998 which were engaged to legitimise the holding. The CAG commented that there was a distinction between whole record sharing, for which the recommendation is that explicit consent is taken, and the sharing of elements of records for purpose of direct care. The Group received the response and it was noted that no clarification had been provided in relation to legal basis of the holding with reference to the common law duty of confidentiality and further clarification around this point was required.

Data Flows

The CAG acknowledged the additional information which had been provided by the applicants around the data flows within the project; however, it was agreed that confirmation was required around which organisation would be acting as the data processor for linkage with ONS data prior to any recommendation of support under the Regulations being provided.

It had been requested that the ICO guidance around anonymisation was taken into consideration by the applicants when submitting a revised data flow for the project. Members acknowledged that a link to the guidance had been include within the text description of the data linkage, it was unclear whether consideration had been given to the code of practice in terms of the classification of data which was flowing at each stage. Further clarification was required from the applicants as to how the ICO guidance around anonymisation was being applied to the data flows in the project to ensure compliance.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG commented that the email survey which had been proposed by the applicants in response to the previous request for enhanced patient notifications was more appropriately a patient engagement activity. It was explained that patient notification was not a requirement to contact individual patients, but to make information about the project publicly available in appropriate areas to enable patients to find out about the use of their data and raise an objection should they be inclined. It was acknowledged that the applicants intended to include information on the Citizen Scientist website and it was agreed that sight of any publication should be provided for consideration. Members agreed that further activity should be undertaken in this area and it was suggested that notifications could be displayed on the Salford Royal Foundation Trust website, within cardiovascular outpatient clinics and GP practices as an example.

The Group further stressed that any patient notification activity which was proposed must focus on the activities which were proposed within this application, rather than relate to the potential of any future research, which may or may not go ahead, depending on the outcomes of this project. It was also noted that the timing of notifications would need to be taken into account to ensure that there was a sufficient window for patients to raise objections, should they wish.

Members considered the dissenting mechanisms which had been put forward by the applicants and it was noted that they had an internet focus. Whilst it was acknowledged that the profile of the patient population was not known, it was likely that a proportion of the cohort was likely to be older and may not have ready access to electronic equipment. The Group agreed that further work was required in relation to the dissenting mechanism, in line with the revised patient notification strategy within which it was recommended that an alternative means to email was included for raising objection. It was also advised that further clarification was required around how the opt-out mechanism would be facilitated as it was unclear who would be applying the opt-outs to the data set.

Patient and Public Involvement and Engagement

The Group had previously requested additional information around the public and patient involvement and engagement in the project. A report of the overall findings of a telephone survey which was partially complete at the time of the previous review was requested. The applicants provided a brief report into the outcome of the survey; however, Members noted that of the 60 patients who were invited to participate, contact had only been made with nine patients. The Group agreed that the patient numbers were insufficient to provide any meaningful outcome. It was further commented that the background information which was supplied to patients in the survey referenced use of de-personalised data only, which did not

make it clear that confidential patient identifiable information would be accessed and processed to enable the required analysis dataset, which was de-personalised, to be created.

The CAG considered the additional information which had been supplied in the revised application and it was acknowledged that there appeared to be confusion around what activity would class as involvement or engagement with the public and patients and what would fall under the classification of patient notifications. Members considered the information which had been supplied in response to a request for improved patient notifications – the applicants had provided detail around a proposed email survey to gather opinions from the relevant patient cohort around the use of data. The Group raised some concerns around the content of the survey as the questions posed did not clearly articulate that patient identifiable information would be used in the project. It was also noticed that the invitation email which accompanied the survey link expressed the purpose as to help plan a research study. Members agreed that further work was required in this area to ensure that any patient engagement was transparent about the aims of this project (not the potential of a future research study) and also made it clear to the recipient that items of their identifiable information would be used in order to create the dataset which would be supplied to North West E-Health for analysis.

Members raised further concerns around the intended audience of the email survey as it was acknowledged that this was the same cohort which had been approached around the telephone survey so there was little confidence that adequate response would be received.

The Group noted that an intended session with a cardiovascular patient drop-in club had been postponed. It was agreed that this activity should be rescheduled and further information provided around how the engagement was managed, i.e. formal presentation, an opportunity for feedback etc., how many patients were present, what the outcomes were – both positive and negative. Further engagement could be undertaken by linking with local appropriate charities, Salford Heart Care as an example.

The CAG agreed that the applicants should consider the guidance provided here and in the above section around public interest, to ensure that meaningful patient and public involvement and engagement activity is undertaken prior to any resubmission being made. Any future resubmission should also include a clear plan of how this activity will be maintained during the project and dissemination of findings.

Additional Points

The applicants confirmed that study data would be retained for two years from receipt as it was noted that the study findings may be subject to an academic peer review.

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.

It was advised that should a new submission be made, it would need to address the points raised above, as summarised below. The detail behind the summary below is provided in the CAG advice detailed above.

Further Information Required (Summary)

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

1. Provide a clearer definition of the public interest in the project, accounting for all points raised by the CAG in the corresponding section above.
2. Further guidance should be sought around the classification of the project via the HRA Queries line (hra.queries@nhs.net).
3. Provide additional information around the publication intentions for the study findings.

4. Provide further assurance around the application of ICO's guidance around anonymisation, with particular reference to the potential identifiability of an individual from the analysis dataset due to the extent and variety of data which is included here.
5. Provide further information around the legal basis on which the Salford Integrated Record database is established in connection to the common law of confidentiality.
6. Confirm which organisation will be acting as data processor to undertake linkage of SIR records with ONS data. An entity is required to be named to enable an accurate description of what any future support under the Regulations covers to be articulated.
7. Patient Notification and Objection:
    a. Establish an enhanced plan for project-specific patient notifications, detailing how and where the project would be publicised and providing copies of any notification materials for review,
    b. Devise a project-specific opt-out mechanism and advise how this would be managed moving forward in the project.
8. Public and Patient Involvement and Engagement:
    a. Meaningful patient and public involvement and engagement should be undertaken prior to any resubmission being made,
    b. This activity should take into account all guidance detailed above from the CAG,
    c. Evidence of the activity which has been undertaken, together with a summary of findings and outputs should be included in any resubmission,
    d. A plan should also be submitted detailing how public and patient engagement will be maintained as the project progresses and findings are disseminated.

c. 17CAG0091 (Resubmission of 17CAG0041) - Feasibility study to evaluate the potential cost-effectiveness of a new drug in people with high cardiovascular risk in Salford

Context

Purpose of Application

A client of North West E Health (NWEH) is interested in understanding the overall Health Resource Utilisation of patients in Salford who have an increased risk of or documented atherosclerotic cardiovascular disease (ASCVD). The client wishes to examine how costs differ between subgroups of patients and gain a deeper insight into the patients that pose the biggest financial and healthcare burden to the economy of Greater Manchester. Salford Royal Hospitals NHS Trust (SRHT) will use the Salford Integrated Record (SIR) to identify people with ASCVD or at high risk of Cardiovascular Disease (CVD) and their healthcare resource utilisation (HRU) costs. Identification of all HRU costs will involve linking the SIR cohort data to data from regional hospitals to which these patients are likely to be referred. This data may be derived from the Secondary Uses Service (SUS) or directly from the hospitals concerned. There will be further linkage to Office of National Statistics (ONS) mortality data via an unnamed third party. NWEH will model potential cost savings for these patients if they were treated with a new drug which could lower their LDL cholesterol considerably more than conventional treatments.

A recommendation for class 1, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

Salford Royal Hospitals NHS Trust will use the SIR database to identify patients alive in Salford on 01.01.2006 (ensuring that archives pre-2008 are included in all searches) who meet specified clinical indications of cardiovascular illness/risk. The dataset will be a one-off snapshot of this cohort on the day that the extract is performed. It is estimated that there will be 150,000 patients within the cohort.

Access is requested to the following items of identifiable patient data will be required as detailed below:

- NHS number – used for linkage but not provided to the applicant in the final dataset,
- Age – for analysis,
- Gender – for analysis,
- Year and month of death – for analysis,
- Ethnicity – for analysis.

The following additional items of confidential patient information will be collated from patient records:

From SUS Payment by Results: where available:

1. Haematology data,
2. Biochemistry data,
3. Comorbidities – All comorbidities in the data (with onset date, not entry)
4. Medicines – All medicines prescribed during that episode and dose,
5. Procedures – All procedures during admission including Percutaneous Angioplasty and any imaging along with date and cost,
6. Demographics:
    a. NHS number (used to link data but returned in anonymised form)
    b. Age
    c. Gender
    d. Date of death (month and year only)
    e. Ethnicity
    f. Lower Super Output Area (for deprivation score)
7. Healthcare Resource Utilisation (HRU):
    a. Inpatient
        i. Admission date
        ii. Discharge date
        iii. Reasons for admission
        iv. Cost of admission
    b. Outpatient
        i. Outpatient visit date
        ii. Outpatient type (i.e. new or follow-up)
        iii. Outpatient speciality
        iv. Cost of outpatient visit

From ONS mortality data: where available, the following data should be provided for each patient:

8. Demographics
    a. NHS number (used to link data but returned in anonymised form)
    b. Date of death (month and year only)
    c. Cause of death

Rationale for the data items is as follows:

Data in points 1, 2, 4, 5, 7 and 8 will allow the calculation of HRU costs.
Data in points 3 and 6 will allow categorization of patients to gain a deeper insight into the patients that pose the biggest financial burden. The applicants have submitted evidence that discussions have been had with NHS Digital regarding what data are available from SUS.

Confidentiality Advisory Group Advice

The CAG acknowledged that the application was a resubmission of 17CAG0041, which had previously been considered at the CAG meeting held on 23 March 2017. Members considered the revised application with reference the points raised as part of the previous review as requiring further information.

The Chair extended thanks to the applicant, Dr Patricia Baker, for making herself available via telephone; however, it was acknowledged that the issues outstanding with the application were more appropriately articulated in writing.

Public Interest

The CAG commented that the public interest in the project remained unclear. It was acknowledged from the revised documentation that the applicants advised that the findings of this project would examine how patients with or at risk of cardiovascular illness in Greater Manchester were managed, treated and respond to treatment practices in place currently, acknowledging that these treatments affect whether patients go on to experience one or more serious cardiovascular events that may result in significant morbidities and potentially death. It was further noted that the applicants had stated that the findings of the project would be used to implement change to improve the treatment of patients, revise resource deployment and provide evidence around which medications were most beneficial in terms of cost and efficacy/safety to which patient groups in the Greater Manchester cardiovascular illness population. Members agreed that whilst there was potential for patient benefit from the study outputs, the principal beneficiary was the unknown commercial entity referenced within the documentation. It was also unclear what the wider public benefit from the project would be.

No further information had been provided within the revised submission around the make-up of the Salford Integrated Record Board and confirmation was required as whether this included lay representation.

Information had been requested around the intended publication arrangements for the project outcomes as it was acknowledged that the public interest in a project could be strengthened through wider publication of analysis findings. The applicants provided an overview of the intended publications for the project. It was queried whether these publications were going to the undertaken by North West E-Health or by the unnamed commercial clients. It was noted that an abstract in relation to the project was due for submission in early June 2017 and Members were unclear how this could be submitted when the project was not yet approved.

The CAG had raised queries around the transparency of the project as it was understood that the unnamed external client was a pharmaceutical company, which had been referenced in the supporting letter from the Caldicott Guardian. Member remained unclear around how the client's stated aims linked with the referenced public benefit in the application. It was commented that further transparency around the identity of the external client and their purposes would be helpful in establishing the overall public interest in the project.

The Group agreed that the benefit to the wider public, which extended beyond that of the unnamed client, had not been established within the resubmission. Further work was required to establish how the public interest would be realised. It was noted that the public interest and patient benefit in the project may be strengthened by wider and more sophisticated public and patient engagement. This point is addressed further in the section below 'Public and Patient Involvement and Engagement'.

Classification of Project

The CAG had previously queried how the project had been classified as service evaluation and had requested evidence of the decision-making process. The applicants provided response which referenced the completion of the HRA decision tool around project classification. It was noted from the information which had been supplied that the findings of the project had not been classed as generalizable. Members were unclear around the response provided to this question as it appeared to contradict the definition which had been put forward in relation to the public interest in the project, which stated that the project findings would be beneficial for the wider patient population as a whole, i.e. were generalizable to a population larger than that included within the project.

The Group agreed that further guidance in this area was required to ensure that the project had been appropriately classified. An enquiry to the HRA Queries lines would be required to allow a review of the project to be undertaken by a specialist advisor. It was agreed that the outcome letter would be copied direct to the HRA Queries line to pre-empt the future contact by the applicants.

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 CAG reaffirmed its previous consideration that consent was not practicable for this project.

- Use of anonymised/pseudonymised data

The Group acknowledged that the analysis would be undertaken on a pseudonymised dataset.

Justification of identifiers

The CAG reiterated that the identifiers requested appeared to be justified to enable the required data linkage. The concerns which had previously been raised around compliance with ICO guidance around anonymisation are addressed in the below section 'Data Flows'.

Data Source

The applicants had been asked to clarify under what legal basis the Salford Integrated Record Database was held. A response had been provided in relation to the principles of the Data Protection Act 1998 which were engaged to legitimise the holding. The CAG commented that there was a distinction between whole record sharing, for which the recommendation is that explicit consent is taken, and the sharing of elements of records for purpose of direct care. The Group received the response and it was noted that no clarification had been provided in relation to legal basis of the holding with reference to the common law duty of confidentiality and further clarification around this point was required.

Data Flows

The CAG acknowledged the additional information which had been provided by the applicants around the data flows within the project; however, it was agreed that confirmation was required around which organisation would be acting as the data processor for linkage with ONS and SUS data prior to any recommendation of support under the Regulations being provided.

It had been requested that the ICO guidance around anonymisation was taken into consideration by the applicants when submitting a revised data flow for the project. Members acknowledged that a link to the guidance had been include within the text description of the data linkage, it was unclear whether consideration had been given to the code of practice in terms of the classification of data which was flowing at each stage. Further clarification was required from the applicants as to how the ICO guidance around anonymisation was being applied to the data flows in the project to ensure compliance.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The CAG commented that the email survey which had been proposed by the applicants in response to the previous request for enhanced patient notifications was more appropriately a patient engagement activity. It was explained that patient notification was not a requirement to contact individual patients, but to make information about the project publicly available in appropriate areas to enable patients to find out about the use of their data and raise an objection should they be inclined. It was acknowledged that the applicants intended to include information on the Citizen Scientist website and it was agreed that sight of any publication should be provided for consideration. Members agreed that further activity should be undertaken in this area and it was suggested that notifications could be displayed on the Salford Royal Foundation Trust website, within cardiovascular outpatient clinics and GP practices as an example.

The Group further stressed that any patient notification activity which was proposed must focus on the activities which were proposed within this application, rather than relate to the potential of any future research, which may or may not go ahead, depending on the outcomes of this project. It was also noted that the timing of notifications would need to be taken into account to ensure that there was a sufficient window for patients to raise objections, should they wish.

Members considered the dissenting mechanisms which had been put forward by the applicants and it was noted that they had an internet focus. Whilst it was acknowledged that the profile of the patient population was not known, it was likely that a proportion of the cohort was likely to be older and may not have ready access to electronic equipment. The Group agreed that further work was required in relation to the dissenting mechanism, in line with the revised patient notification strategy within which it was recommended that an alternative means to email was included for raising objection. It was also advised that further clarification was required around how the opt-out mechanism would be facilitated as it was unclear who would be applying the opt-outs to the data set.

Patient and Public Involvement and Engagement

The Group had previously requested additional information around the public and patient involvement and engagement in the project. A report of the overall findings of a telephone survey which was partially complete at the time of the previous review was requested. The applicants provided a brief report into the outcome of the survey; however, Members noted that of the 60 patients who were invited to participate, contact had only been made with nine patients. The Group agreed that the patient numbers were insufficient to provide any meaningful outcome. It was further commented that the background information which was supplied to patients in the survey referenced use of de-personalised data only, which did not make it clear that confidential patient identifiable information would be accessed and processed to enable the required analysis dataset, which was de-personalised, to be created.

The CAG considered the additional information which had been supplied in the revised application and it was acknowledged that there appeared to be confusion around what activity would class as involvement or engagement with the public and patients and what would fall under the classification of patient notifications. Members considered the information which had been supplied in response to a request for improved patient notifications – the applicants had provided detail around a proposed email survey to gather opinions from the relevant patient cohort around the use of data. The Group raised some concerns around the content of the survey as the questions posed did not clearly articulate that patient identifiable information would be used in the project. It was also noticed that the invitation email which accompanied the survey link expressed the purpose as to help plan a research study. Members agreed that further work was required in this area to ensure that any patient engagement was transparent about the aims of this project (not the potential of a future research study) and also made it clear to the recipient that items of their identifiable information would be used in order to create the dataset which would be supplied to North West E-Health for analysis.

Members raised further concerns around the intended audience of the email survey as it was acknowledged that this was the same cohort which had been approached around the telephone survey so there was little confidence that adequate response would be received.

The Group noted that an intended session with a cardiovascular patient drop-in club had been postponed. It was agreed that this activity should be rescheduled and further information provided around how the engagement was managed, i.e. formal presentation, an opportunity for feedback etc., how many patients were present, what the outcomes were – both positive and negative. Further engagement could be undertaken by linking with local appropriate charities, Salford Heart Care as an example.

The CAG agreed that the applicants should consider the guidance provided here and in the above section around public interest, to ensure that meaningful patient and public involvement and engagement activity is undertaken prior to any resubmission being made. Any future resubmission should also include a clear plan of how this activity will be maintained during the project and dissemination of findings.

Additional Points

The applicants confirmed that study data would be retained for two years from receipt as it was noted that the study findings may be subject to an academic peer review.

The applicants also confirmed that the Health Economist and the University of York act as consultants to the project, providing advice and guidance on the approach towards the analysis. It was confirmed that access was not provided to confidential patient identifiable information.

Confidentiality Advisory Group advice conclusion

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

It was advised that should a new submission be made, it would need to address the points raised above, as summarised below. The detail behind the summary below is provided in the CAG advice detailed above.

Further Information Required (Summary)

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

1. Provide a clearer definition of the public interest in the project, accounting for all points raised by the CAG in the corresponding section above.
2. Further guidance should be sought around the classification of the project via the HRA Queries line (hra.queries@nhs.net).
3. Provide additional information around the publication intentions for the study findings and clarify how would be taking forward the proposals which were identified in the earlier response.
4. Provide further assurance around the application of ICO's guidance around anonymisation, with particular reference to the potential identifiability of an individual from the analysis dataset due to the extent and variety of data which is included here.
5. Provide further information around the legal basis on which the Salford Integrated Record database is established in connection to the common law of confidentiality.
6. Confirm which organisation will be acting as data processor to undertake linkage of SIR records with ONS and SUS data. An entity is required to be named to enable an accurate description of what any future support under the Regulations covers to be articulated.
7. Patient Notification and Objection:
    a. Establish an enhanced plan for project-specific patient notifications, detailing how and where the project would be publicised and providing copies of any notification materials for review,
    b. Devise a project-specific opt-out mechanism and advise how this would be managed moving forward in the project.
8. Public and Patient Involvement and Engagement:
    a. Meaningful patient and public involvement and engagement should be undertaken prior to any resubmission being made,
    b. This activity should take into account all guidance detailed above from the CAG,

c. Evidence of the activity which has been undertaken, together with a summary of findings and outputs should be included in any resubmission,
d. A plan should also be submitted detailing how public and patient engagement will be maintained as the project progresses and findings are disseminated.

5. NEW APPLICATIONS – Non-Research

a. 17/CAG/0088 – Mortality Information of Patients with Bleeding Disorders

Context

Purpose of Application

This application from UK Haemophilia Centre Doctors' Organisation set out the purpose of audit into mortality information in patients with bleeding disorders. The National Haemophilia Database was established in 1968 to improve haemophilia care, conduct research into bleeding disorders, haemophilia treatment epidemiology and complications and to facilitate healthcare planning. The database was established at a request from the Department of Health.

This application requests support to allow data linkage with NHS Digital to receive ONS mortality information for approximately 500 patients who are included within the database that are known to be deceased. There would be a quarterly data exchange thereafter to capture mortality information in relation to recently deceased patients.

The required data linkage was previously approved through the Central Register under reference MR328 'Haemophilia Mortality Data'; however, a revised application has been required for the data linkage.

A recommendation for class 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

The following items of confidential patient identifiable information are required for the purposes as described below:

- National Haemophilia Database Registration Number – unique identifier to enable linkage of returned data,
- NHS number, validation/linkage
- Forename – validation – complementary to or in the absence of an NHS Number
- Surname – validation – complementary to or in the absence of an NHS Number,
- Date of birth – analysis,
- Date of death – analysis,
- Cause of death – analysis.

Cohort

The application will be initially to cover a data gap of approximately 500 patients who are registered within the National Haemophilia Database which are known to be deceased. Following this initial sample, there will be a quarterly data linkage to capture the data into newly deceased patients within the database – it is anticipated that this will amount to around 250 patients per year.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that the application described a medical purpose through the follow up of patients with bleeding disorders, providing clinicians with accurate information around date and cause of death and whether the death could be associated with any treatment. The data linkage will also enable the applicants to fulfil their contractual requirements with NHS England. The application is in the public interest as outputs from the audit will help inform national policy, implement cost saving through providing evidence in support of products to treat bleeding disorders and the improvement of knowledge and care for this patient population.

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 CAG acknowledged the applicants admission that there had been a failure to plan for the consenting required to collect mortality information in relation to patients included within the database. Members recognised that the database had initially been established in 1968 and consenting requirements had changed considerably in this time.

The Group considered the information supplied by the applicants and it was noted that the database had been classified as consented database; however, the information materials which had been supplied suggested entry into the database was automatic and patients were required to opt-out if they had an objection. It was agreed that clarification was required around what percentage of the database was actually consented. It was further noted from the detail provided in the application that postal consent letters only received a 30% response rate and Members were unclear whether all patients were included within the database, irrespective of the consent status, or if the records related only to the 30% who had responded. Further information was needed to understand the patient population registered within the database.

The applicants had explained that they were working towards a revised consenting procedure, which would capture specific consent from newly registered patients for the collection of mortality information; however, it was acknowledged that this would not apply to those patients who were already registered within the database. Members agreed that further work would need to be undertaken by the applicants around the consenting procedure to ensure that prospective patients added to the database were fully consented for the required data linkages, including mortality information. A report would be required at first annual review around the progress of this work.

The CAG acknowledged the difficulties described by the applicants in attempting to seek further consent from the existing patients (approximately 29,000 patients) within the database and it was agreed that this was not feasible. Support would be recommended for the collection of mortality information for the life cycle of the patients already registered in the database.

- Use of anonymised/pseudonymised data

It was noted that identifiable information would be necessary to enable NHS Digital to undertake the linkages.

Justification of Identifiers

The Group was assured that the identifiers proposed were proportionate to perform the required data linkage.

Exit Strategy

Members considered the response provided by the applicants in relation to the exit strategy from requiring support under the Regulations. It was stated that date of death could not be truncated due implications within the wider database, reporting arrangements and the manpower required to undertake this. Whilst the CAG acknowledged the issues presented, it was unclear of the continued requirement to retain identifiable data in relation to deceased patients. It is a requirement for applicants, when seeking support under the Regulations, that an exit strategy is put in place to move away from the requirement for support. Members agreed that the applicants would be required to explore exit strategies and provide a report back at annual review around what progress had been in this area.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

The Group considered the patient notification materials provided and it was agreed that further work could be undertaken to improve the documentation. It was agreed that the language used could be simplified to make the information more accessible. Members also commented that the document would need to be revised around the opt-out or consenting arrangements once clarification had been received from the applicants on this issue.

The CAG also suggested that information leaflets could be displayed within the various treatment centres to the raise the profile of the database.

Patient and Public Involvement and Engagement

It is a key consideration of the CAG when recommending support for application under the Regulations that the applicants have undertaken relevant patient and public involvement and engagement in the application process to test the acceptability of using patient information without consent as described in the application.

The Group acknowledged that no direct public or patient engagement activity had been undertaken by the applicants; however, it was noted that this was discussed at the Data Management Working Party. It was agreed that feedback from this meeting was required.

Members stated that further work needed to be undertaken to improve patient and public involvement and engagement as the project progressed. It was recognised that the applicants had existing links with the Haemophilia Society, which could be utilised to improve plans in this area. It was agreed that support would be recommended with a specific condition around public and patient involvement and engagement, with a report being required at first annual review stage around actual activity which had been undertaken, together with an agreed plan moving forward.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under the Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score of had been published; however, this self-assessment had not yet been assessed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the ‘reviewed grade’ field on the IGT website.

This issue had previously been raised with the applicant and NHS Digital; however, confirmation remained outstanding.

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. Consenting Arrangements in relation to the database:
    a. Clarify whether the database is established on a consented or opt-out basis,
    b. If the database is established on a consented basis, clarify how much of the database is consented,
    c. Clarify if the database holds records for all known patients with a bleeding disorder or only those who have provided consent,
    d. If the database is established on a consented basis – revisions will be required to the patient information materials, which suggest that the database operates on an opt-out basis.

Once received, the information will be reviewed by a sub-committee of members, in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the SofS will confirm approval.

Specific Conditions of Support

1. Support extended to patients within England and Wales only.
2. Further work should be undertaken on the prospective consent process to ensure that any future patients entered into the database are done so on a fully consented basis, including the requirement for mortality information. A report should be provided at first annual review detailing what plans have been implemented in this area and progress with the revised consenting process.
3. Explore ways of truncating information in relation to deceased patients within the database in order to move away from the requirement for support under the Regulations to retain information provided by NHS Digital. Report back at first annual review detailing work which has been undertaken in this area and progress made on the exit strategy.
4. Patient and Public Involvement and Engagement:
    a. Provide a report back on any progress made in this area from discussions at the Data Management Working Party,
    b. Actively improve involvement and engagement, utilising established links with the Haemophilia Society,
    c. Provide a report back at first annual review detailing actual activity which has been undertaken together with an updated plan in relation to prospective activity.
5. Patient Notifications and Dissent:
    a. The patient notification materials require revision to make the language more accessible to the public,
    b. Information in relation to the opt-out requires revision,
    c. Patient notification materials should be displayed within the treatment centres to raise the profile of the database – copies of any materials should be supplied for consideration,
    d. A report should be provided at first annual review around the improvements made to the patient notification and dissent mechanism.
6. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Reported Grade remains outstanding).**

6. NEW APPLICATIONS – Research

a. 17/CAG/0081 – Women's Cohort Study – HES+

Context

Purpose of Application

This application from University of Leeds set out the purpose of research through the establishment of a database. The UK Women's Cohort Study was established in 1993 on a consented basis to explore links between diet, lifestyle and chronic disease, in particular cancer. Approval was granted at this from each local REC for the study to follow participants for cases of cancer and other diseases. Individual consent forms were not required by the REC's, therefore those women who returned questionnaires with a completed back page were considered to have provided consent for participation. The back page of the questionnaire informed participants that the purpose of the study was to examine "the occurrence of certain diseases such as cancer which are registered by the National Health Service" and participants were asked to provide their NHS number and GP address in order for their medical records to be accessed. The applicants hold name, date of birth and NHS number against a participant ID number from this historic consented study.

This application proposes the establishment of a new database, which will be generated from the existing cohort held by the applicants as part of the UK Women's Cohort Study. The new database will hold the existing dietary information collated as part of the UK Women's Cohort Study and will be linked with HES and ODR data held by NHS Digital. The applicants propose the disclosure of confidential patient identifiable data from the established cohort to the University of Leeds Integrated Research Campus (IRC). The IRC will then send this information to NHS Digital in order for the dataset to be linked with HES and ODR data for the cohort. This will be returned by NHS Digital to the IRC, whereby the research team will access the information via a Virtual Research Environment.

A recommendation for class 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The cohort is already established and will include all participants within the existing UK Women's Cohort Study, which amounts to 35,372 women.

Confidential patient identifiable information will be transferred from the University of Leeds Nutrition Epidemiology Group UK Women's Cohort data holding to the IRC platform within the University of Leeds to enable the set-up of this new proposed database. Data will then be shared with NHS Digital for linkage and returned to the University of Leeds.

The following items of confidential patient information will be required to facilitate the data linkage to be undertaken by NHS Digital:

- NHS number,
- Date of birth,
- Participant ID.

Confidentiality Advisory Group advice

Public Interest

The CAG agreed that the application presented a strong medical purpose through the continued follow-up of the unique patient population. It was acknowledged that the applicants had published extensively in relation to the UK Women's Cohort Study and the public interest in ongoing research remained strong.

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 it was not feasible to attempt to re-consent the existing cohort; however, concerns around the validity of the original consent were raised. This issue was explored further within the section entitled 'UK Women's Cohort Study – Validity of Consent'.

- Use of anonymised/pseudonymised data

The CAG acknowledged that whilst the dataset which would be used for analysis would be stripped of patient identifiers, as there was the intention to maintain a link to the identifiable records which were held within the main UK Women's Cohort Study database, which would be stored within the same secure platform, the proposed database would continue to be considered identifiable.

Justification of Identifiers

The CAG was assured that the items of identifiable data were justified to enable NHS Digital to undertake the required data linkage.

UK Women's Cohort Study – Validity of Consent

On reviewing the information provided by the applicants from a historic DAAG review in relation to HES linkage, Members noted that the implied consent which had initially been taken from the participants of the UK Women's Cohort Study had been for a 10 year study. This previous study was established in 1995 and as such, the initial consent provided had expired. The CAG agreed that clarification was required from the applicants around the current legal basis which supported the continued retention of data in relation to participants in the UK Women's Cohort Study, as it was understood from the documentation that there was reliance on the original consent. Members further noted from the application that the original study continued to receive ONS data in relation to the participants. It was agreed that clarification of the ongoing legal basis to support this data linkage was also required.

Members acknowledged that an application had been considered by the Ethics and Confidentiality Committee under application reference ECC 6-05(e)/2011 for which support was recommended, following receipt of the aforementioned guidance from DAAG. The Group acknowledged that this project was outside of the remit of the initial 10 year study and it was queried whether there had been any further data linkage since 2005.

The Group advised that a recommendation for further use of and linkage with the information held within the UK Women's Cohort Study database could not be recommended until clarification had been provided around these points. It was also agreed that sight of the original documentation was required to aid understanding of what was originally proposed to participants.

Scope of Support

Members noted that the queries which had been identified around the current legal basis for the retention of information from the original UK Women's Cohort Study may impact on the scope of support under the Regulations which had been requested by the applicants. The applicants would be asked to confirm what the request for support under the Regulations within this submission was being asked to include.

Patient and Public Involvement and Engagement

It is a key consideration of the CAG when recommending support for application under the Regulations that the applicants have undertaken relevant patient and public involvement and engagement in the application process to test the acceptability of using patient information without consent as described in the application.

The applicants had made reference to a participant user group which had been established in connection with the main UK Women's Cohort Study; however, it unclear from the information provided whether this group had been convened since its first meeting in April 2014. Further information had been provided around the engagement with one individual around the application process. Members agreed that the level of patient and public involvement and engagement was insufficient in relation to the project proposed. It was commented that true engagement with public and patients was particularly important as the original consent provided for the UK Women's Cohort Study had expired.

The CAG agreed that a public and patient involvement and engagement plan would need to be provided detailing what activity was proposed. This overview would be required before any recommendation of support could be given. The applicants would be required to report back at first annual review around actual activity undertaken, together with a revised plan for involvement and engagement moving forward. Members acknowledged that the applicants had previously advised the REC that improvements could be made in this area.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members considered the information which had been provided in this area in response to queries raised by the Confidentiality Advice Team in advance of the meeting. From the information provided, it appeared that the patient notification and dissent system had been confused with the process for handling complaints. It was acknowledged that there was the intention to publicise the project on two named websites; however, the draft of the advertisement that had been provided was brief.

The Group agreed that further work was required from the applicants to improve the patient notification and dissent system. A detailed plan of how and where patient notifications would be made available, together with sight of any documentation would be required before any recommendation of support could be given. It was also agreed that a clear description of a dissenting model would be required together with detail around how this would be managed.

Research Ethics Committee – Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Members acknowledged that the application to the Sheffield REC had been issued with a provisional opinion at the time of the CAG review. Confirmation that a favourable ethical opinion was in place for the project was required prior to a recommendation of support being issued.

Additional Points

Members queried a comment which was included within the transcription of discussion at the REC meeting. The REC had asked for clarification around the third party organisation which was undertaking linkage with the HES database and in the response it was suggested that this would be undertaken at the University of Leeds. Clarification was sought that HES linkage would be undertaken by NHS Digital.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, 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. UK Women's Cohort Study – validity of consent:
   a. Confirm under what legal basis the UK Women's Cohort Study database continues to be retained,
   b. Clarify under what legal basis this database continues to receive ONS data from NHS Digital,
   c. Confirm if the UK Women's Cohort Study database has been linked with any additional sources since the expiration of the original consent in 2005,
   d. Provide a copy of the original questionnaire supplied in 1995, which provided an overview of what the study involved for participants if they returned the document and implied consent for participation.
2. Provide a clear description of what this request for support under the Regulations is required to cover.
3. Patient and Public Involvement and Engagement:
   a. Provide a detailed plan for public and patient involvement and engagement activity which will be undertaken as the project progresses.
4. Patient Notifications and Dissent:
   a. Provide detailed information around how and where patient notifications in relation to the project will be displayed,
   b. Submit copies of any notifications for consideration,
   c. Clarify the dissenting mechanism for the project, together with details of how any objection raised would be managed.
5. Provide confirmation that data linkage with HES data would be undertaken by NHS Digital.

Specific Conditions of Support (Provisional)

1. Support was extended to England and Wales only.
2. A report would be required at first annual review around the actual activity which had been undertaken to engage and involve public and the patients within the project. An updated plan of activity would also be required at this time detailing the proposed involvement and engagement activities moving forward.
3. Favourable opinion from a Research Ethics Committee. (**Confirmed – received 21/06/2017**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed - University of Leeds Integrated Research Centre shows a reported published score of 88% satisfactory on Version 14, 2016/17).**

6. MINUTES OF THE MEETING HELD ON 11 MAY 2017

The Chair raised a query around the information which had been included around the publication of advice to NHS Digital which had been raised under agenda point five of the previous minutes. A request was

made that the minutes were amended to state that information around discussions with NHS Digital should be published in the current location ‘in the interim period’ whilst the new website was being prepared. The revision was noted and the minutes were revised. The minutes were otherwise agreed as an accurate record, with no additional changes requested.

7. CAG OFFICE REPORT

The CAT reported that the Office report would be circulated the following week for information.

8. CAG CHAIR REPORT

The Chair had confirmed there was no additional business to record and as such, there was no Chair’s report for April 2017.

9. ANY OTHER BUSINESS

The Chair informed the Members present that he would be stepping down as Chair of the CAG with effect from December 2017, following a decision to accept a job offer in a different country. It was explained that plans would move forward to begin the appointment process for a successor in due course, which all Members would be informed of. Members present took the opportunity to thank the Chair for his support and commitment to the CAG.

The Chair thanked members for their time and consideration and the meeting was concluded.