NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

14 September 2017 at Skipton House, SE1 6LH

Group Members:

Name	*Present*	*Notes*
Dr Kambiz Boomla	Yes	
Ms Hannah Chambers	Yes	Lay
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	Lay
Mrs Diana Robbins	Yes	Lay
Ms Clare Sanderson	Yes	Alternate Vice Chair
Mr Marc Taylor	Yes	
Ms Gillian Wells	Yes	Lay

Also in attendance:

Name	*Present*	*Notes*
Miss Kathryn Murray	In Attendance	Senior Confidentiality Advisor
Ms Natasha Dunkley (Items 1-4 and Item 6 onwards)	In Attendance	Head of the Confidentiality Advice Service
Mr Stephen Robinson (Items 4a, 6a and 6b only)	In Attendance	Corporate Secretary, HRA
Professor Ruth Gilbert (Item 4a only)	By Telephone	17CAG0147 – Main Applicant
Professor Jennifer Kurinczuk (Item 5a only)	By Telephone	17CAG0150 – Main Applicant

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Mr Stephen Robinson attended in his capacity as the decision-maker, on behalf of the Health Research Authority, for the research items considered by the CAG.

Apologies

No apologies were noted for the meeting.

Declarations of Interest

The Group recognised that Professor Jennifer Kurinczuk was a current member of the Confidentiality Advisory Group, and was the applicant for item 5a: 17/CAG/0150. No further action was required as this was a pre-existing declaration made upon this member's appointment; however, a formal record of this relationship was noted for the purposes of transparency in the minutes.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 13 July 2017 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 13 July 2017 meeting applications.

3. CONSIDERATION ITEMS – NHS England Application Amendments

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

Background

The original non-research application from NHS England, approved in November 2013, sought support to enable the correct commissioner to be identified to enable payment for treatment. This was requested as an interim measure and would form a part of NHS England's 'managed change' process. The application had been presented as three separate applications to reflect the different environments and controls and to primarily set out the mechanism to allow data to flow to Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs) to support invoice validation in the short term. This would allow business continuity while strategic options to reduce or remove the need for personal confidential data (PCD) were explored.

The first application (7-07(a)/2013) was intended to explore the extent of access to confidential patient data as part of this managed change process. Applications (b) and (c) reflected that this could not happen immediately and that support was needed immediately to enable appropriate payments within the system.

Amendment Request

This amendment request included the following two items:

1. To remove the requirement to respect patient objections from the flow of information to Controlled Environments for Finance (CEfE) which are required to support invoice validation. This request extended to include NHS England's demographic data which is shared with CCGs to enable their CEfF to undertake the processing of data to accurately verify the CCGs patients in line with their requirements under the Data Protection Act 1998 by ensuring that commissioners have the most up-to-date and accurate information.
2. To extend the duration of support in place for the application for a further 18 months, up to 30 September 2018.

This amendment had previously been considered by the CAG at a meeting held on 23 February 2017; however, the decision was deferred pending a request for further information.

Rationale for Amendment

It was stated that the invoice validation process is required for a significant portion of NHS treatment that falls outside of standard contracts, systems or expected patient pathways as well as resolving disputes or discrepancies in standard contracts. Key examples include non-contract activity, for patients treated out of area and nursing home payments.

The amendment specified that without access to data on all patients, regardless of their sharing preference, where patients had indicated a Type 2 objection to their data being disseminated from NHS Digital, commissioners were unable to effectively account and pay for care provided to their patients. A consequence was stated to result invoices not being paid and care not being provided, especially when high cost specialised care services are required.

The paper indicated that once proposed new Regulations are in place, it is envisaged that patient objections will not apply to this type of processing and therefore NHS England requests that to maintain financial stability, that the current requirement to respect Type 2 objections within this flow to CEfFs is removed.

The duration extension stated that this date, 30 September 2018, aligned with the anticipated implementation date for the new Regulations under section 251 of the NHS Act 2006, which were currently being drafted by the Department of Health. The extension will ensure that the effective financial management of health care services can continue in line with the established processes agreed under the current approval.

Confidentiality Advisory Group Advice

The CAG considered the further information provided by the applicants in response to the previous deferred outcome.

<u>Prevalence of Type 2 Objections</u>

The Group acknowledged that a very small number of patients had registered a type 2 objection (2.3%, or 1 in 44 patients) though it remained unclear how the current opt-out level had impacted the invoice validation scheme. The applicants had confirmed that currently, type 2 objections were being applied to the flow of confidential patient information from NHS Digital in support of the invoice validation scheme.

It was recognised that NHS England had established systems across wider commissioning services, which has enabled invoice validation to be undertaken on a pseudonymised data set. The CAG acknowledged that the request extended to specialist commissioning services only, as this involved external care providers, which required the use of confidential patient information to track patients across systems. This limited the scope of the request.

Members were of the opinion that it was unlikely that there would be a large crossover between the patient cohort with registered type 2 objections and those receiving specialist commissioning services.

As such, it was acknowledged that the scope of the amendment request was very narrow, and could not be considered to set a wider precedent in relation to the requirement to respect type 2 objections.

Respecting Type 2 Objections – Financial and Clinical Implications

The applicants clarified that, from a financial perspective, patient care was not directly affected by opting-out of data sharing as the required care would still be provided; however, the wider patient population would be affected indirectly through impacts on the local commissioning system. It was explained that if invoices cannot be correctly allocated and paid in a timely way then this presented a serious financial risk particularly in the current climate of limited resources with many commissioners having to make difficult decisions about the future funding of services and care. The NDG review also acknowledged that the public did not have particular concerns about their data being used for payment purposes.

Members were sympathetic to the CCGs in these circumstances as it was acknowledged that the care which was provided under specialist commissioning was small-scale, but expensive. The CAG acknowledged the importance, for local commissioners in having a clear understanding of what care was being provided to inform effective commissioning and service planning in future.

The Group was assured that there was potentially a serious risk to direct patient care if activity in relation to invoice validation was restricted through the inability to recharge the relevant local commissioners for the care which had been provided to patients within their locality. Members recognised the findings of the NDG review which had been provided in support of the amendment request, which identified that that public did not have concerns around the use of their data for payment purposes.

It was acknowledged that the request to extend the duration of support up to 30 September 2018 was appropriate and aligned with the expected introduction of revised Regulations under section 251 of the NHS Act 2006, which would directly address this type of activity. The CAG agreed that support would be recommended for the duration extension.

The CAG stated that the recommendation of support to remove the requirement to respect type 2 objections in the flow of confidential patient information from NHS Digital in support of the invoice validation scheme would be applied to prospective data flows only and would not apply to any unaccounted invoices which were currently held within the system.

Patient Notifications and Dissent

It is a general principle of the CAG, when recommending support, 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 requirement for clear communication activities to be undertaken in the intervening period, prior to the implementation of the new opt-out model. It was agreed that a clear strategy and supporting materials would need to be developed to target the patient group which had previously registered a type 2 objection, in order to inform that it would no longer be applied this specific area. It was commented that any documentation which was devised to manage patient notifications in this area would need to be incredibly clear around the narrow scope of this support recommendation. The Group indicated that public and patient views should be sought around the information materials to test the acceptability and understanding of detail provided.

The Group acknowledged that, in future, patients would be informed that an opt-out request would not apply to data flows to support invoice activity.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG advised recommending *conditional* support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support

1. The requirement to apply to type 2 objections to the flow of confidential patient information from NHS Digital to support invoice validation of specialist commissioning services has been removed.
2. Support extends to the flow of NHS England's demographic data to the Controlled Environment for Finance for CCGs.
3. Support applies to prospective data flows only from the date of this outcome letter.
4. Support is extended up to 30 September 2018 only.
5. Patient Notifications – a report is required to the CAG within three months of the date of this outcome letter, to provide an update in relation to the following points:

a. Consider how information will be made available to the sub-group of patients, who had previously registered type 2 objections, which would no longer be respected in this specific circumstance. Provide an overview of how communications would be managed for this sub-group, providing copies of any documentation where appropriate.

b. Consult with patients and the public around the communications strategy which is devised for this sub-group of patients, to test the acceptability of the methods proposed and the suitability of any materials which are written to serve this purpose.

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

Amendment Scope

This amendment requested a change to the purpose to support the processing of pseudonymised data for the commissioning purposes as set out in the original application.

The applicants stated that the requirement to amend this application had arisen from requirements set out in the EU General Data Protection Regulations (GDPR). It is understood that under the GDPR pseudonymised data has been classified as personal data, which would require the establishment of a legal basis to enable processing to be undertaken.

Amendment Justification

The applicants stated that whilst the GDPR is supportive of processing personal data for healthcare management purposes, it is understood that there will be an essential requirement under the GDPR that patients receive assurance that data which identifies them is not being used for non-direct care purposes. The applicants explained that the ICO was currently undertaking a review of their Anonymisation Code of Practice in line with the changes to UK Data Protection legislation which will be implemented with the GDPR in May 2018.

Confidentiality Advisory Group Advice

The CAG considered the amendment request and it was noted that, until it is clear how the GDPR would be implemented in UK Law, the Group was unable to make any recommendation around the request.

Members recognised that there were likely to be wider implications of the UK legislation, in addition to how personal data is defined under the Regulation, which it would fall to the Information Commissioner to interpret, and both the law and statutory guidelines would need to be fully understood before the CAG would be in a position provide any guidance in this area.

Further to the discussions held around this agenda items, the CAG requested that follow-up be undertaken with the Information Commissioner's Office (ICO) to query an expected timeframe for release of updated anonymisation code of practice. The Head of Confidentiality Advice Service agreed to take this action forward and report back to the CAG.

The Group was sympathetic to the applicants' forward planning and it was commented that, should the position be clarified that pseudonymised data would be classified as personal data when the GDPR is implemented; a resubmission of the amendment would be received at that time.

Confidentiality Advisory Group Advice Conclusion

In line with the considerations above, the CAG agreed that there was currently insufficient information available around the implementation of the GDPR to enable a recommendation to be provided around the amendment request, and therefore advised recommending a deferred decision to the Secretary of State for Health, until the implications had been clarified nationally.

4. RESUBMITTED APPLICATIONS

a. 17CAG0147 – Employment and Receipt of Welfare Benefits before and After Renal Transplantation'

Context

Purpose of Application

This application from University College London sets out the purpose of medical research which aims to determine the change in benefits and employment in the period after, compared with before, renal transplantation. The applicants state that this is a proof of concept study that uses data from the NHS Blood and Transplant renal transplant dataset (NHSBT) and the UK Renal Registry (UKRR) linked to benefits and employment data held by the Department of Work and Pensions (DWP) for individuals who have ever received welfare benefits (except child benefits).

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

Confidential Patient Information Requested

Cohort

The cohort for inclusion will be all patients over the age of 18 years who have undergone renal transplant from 2002 through to 2016. The applicants estimate that there will be between 20,000 and 30,000 renal patient's data linked during the project.

The following items of confidential patient identifiable data are required for the purposes as defined below. These data items will be supplied by the NHS Blood and Transplant service and the UK Renal Registry to the Department of Work and Pensions to facilitate linkage with benefits data.

- Name – data linkage,

- Date of birth – data linkage,
- Unit level postcode – data linkage and retained for geographical analysis,
- Sex – data linkage and analysis,
- Ethnicity – for analysis.

Confidentiality Advisory Group Advice

The Group recognised that this application was a resubmission of application 17CAG0056, which was considered at the CAG meeting on 27 April 2017. The previous submission was not supported as the CAG was not assured that the activity defined a medical purpose. The applicants had provided a revised application and covering letter addressing the concerns and issues raised by the CAG under the previous review.

The applicant, Professor Ruth Gilbert, attended the meeting by telephone to respond to application queries.

Public Interest

The Group considered the representations which had been provided by the applicant around the medical purpose of the activity. It was acknowledged that the project intended to study the functional status of patients both pre and post-transplant to better understand whether renal transplantation had any impact on an individual's ability to work. Members conceded that, from a clinician's perspective, gaining knowledge around whether patients were usually able to return to work following a renal transplantation would be important to assist with elective surgical decision-making. It was identified that there was public interest in being able to provide an evidenced position in this area to patients considering treatment pathways including renal transplantation. The CAG also recognised that returning to work could contribute to the post-surgical wellbeing of the patient cohort.

Members discussed the proof of concept element of the project which aimed to test whether data linkage was possible between NHS data and that held by the Department of Work and Pensions. It was recognised that there was past precedent in the proposed linkage with the benefits dataset maintained by the DWP and as such, proof of methodology was not considered as support of the medical purpose in the study.

The applicants had made reference within the revised documentation to an ongoing renal study which involved approximately 7,000 consented patients. Members requested further information around this existing project and whether there was potential that it could deliver similar findings. It was clarified that the established project was a self-reported quality of life study only which did not include a retrospective review around changes in employment status. It was further confirmed that this existing study did not take receipt of benefits into account at any stage. The CAG noted that the applicant's proposed study defined a wider scope than the established project, focussing on the patient before and after transplantation and it was acknowledged that the findings would be unique to this proposal. It was further identified that this proposal was presented at the first part of a wider programme of research.

The Group was assured from the additional information which had been presented by the applicants that the proposed activity did define a medical purpose through medical research.

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 by the applicant's rationale that consent was not feasible for this project.

- Use of anonymised/pseudonymised data

Members acknowledged that processing of confidential patient identifiable information was required to enable facilitate the data linkage within the project.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

The Group was assured that the identifiable data items were appropriate to the activity proposed. It was recognised that the Department for Work and Pensions dataset, as a database generated outside the health environment, did not include NHS Number. As such, the applicants had tailored the identifiers required to enable linkage with data items available within the benefits dataset.

Data Flows

The Group expressed some concerns around the proposed data flows in the study, as it was acknowledged that confidential patient information would be shared with the Department for Work and Pensions to facilitate data linkage. It was queried whether there was an alternative methodology available, by sharing data with a trusted third party to undertake the data linkage, as an example. The applicants confirmed that this was not feasible, as it would involve sharing the complete benefits dataset with the third party, which would involve a larger disclosure of personal information. It was also confirmed that no clinical information would be shared with the Department of Work and Pensions – it was noted that they would only be aware that the information had been provided from a renal database. Members accepted the information provided and agreed that there was no other methodology available to deliver the data without sharing confidential patient information with the Department of Work and Pensions. It was also unclear whether the Department of Work and Pensions would have a legal basis by which to do this, if it had been possible.

Data Retention

The application suggested that the Department for Work and Pensions would need to retain the dataset containing confidential patient information for a period of 12 months following data linkage. Members were unclear of the rationale to support this extended retention. It was agreed that the retention period would need to be revised or stronger justification provided to support this extended period.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The applicants had provided the minutes of a recent patient engagement event which had been undertaken as part of the application submission. Members considered the information and it was noted that, as written, those patients who had been involved did not appear wholly supportive of the project. Further explanation of the engagement event and the outcomes were requested. The applicant advised that there had initially been a lack of understanding by the patients present around the limited identifiable dataset which would be shared with the Department of Work and Pensions to facilitate the linkage and also the anonymised analysis which would be undertaken. It was advised that when this has been fully explained, the patients present were much more supportive of the proposal than had been presented within the minutes. The applicant advised that there was a further patient engagement event scheduled and confirmed that she had also been invited to speak at an event around the project.

Members recognised the additional information provided and it was commented that, whilst this did provide a more positive position from patients in support of the activity, further formal evidence was required as proof of the public support for the project. The Group agreed that additional written feedback was required from the future engagement events to demonstrate that the relevant patient group was supportive of the purpose of the activity and the methodology proposed. Members commented that this formal feedback would need to be provided as part of a resubmission as patient support for the project had to be evidenced before a recommendation of support could be considered for the activity.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 acknowledged that project would be advertised on the UK Renal Registry and Administrative Data Research Network websites. It was noted that a sample of website text had been included as part of the previous application; however, a revised document was not put forward with the current proposal. Members had reviewed information which was available via the UK Renal Registry and the NHS Blood and Transplant Service websites, as it was acknowledged that these organisations were providing the patient identifiers for the project. It was commented that there did not appear to be reference to the sharing of health data with non-NHS organisations on these websites. Members advised that the website information would need to be updated to advise patients that these organisations were sharing confidential patient information with non-health organisations for research purposes.

Members agreed that the patient notification material for the project would need to be carefully managed, to ensure that the information provided was clear and transparent about the data sharing which would be carried out for the project; however, it was important that the documents did not inaccurately present the project as an investigation into benefit claims. The CAG agreed that the websites of the NHS organisations involved in the project would need to include project specific notifications on their websites, which clearly articulated that identifiable data would be shared with Department of Work and Pensions. The Group was satisfied with the dissenting model which had been described within the application, acknowledging that the information materials that remained outstanding would form the basis of the objection mechanism.

Additional Points

Members commented that, if a recommendation of support was considered for the activity in future, ensuring public confidence in the project would be a key concern. It was agreed that evidence would need to be provided of the data sharing agreement with the Department of Work and Pensions, which should clearly state that the confidential patient information has been shared for the purposes as defined in the application and cannot be used for anything further.

Confidentiality Advisory Group Advice Conclusion

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

Further Information Required

1. Public and Patient Involvement and Engagement – further feedback is required to evidence that there is patient support for the project. The following points should be addressed:
   a. Provide formal feedback from the scheduled patient engagement events to evidence that there is patient support for the project.
   b. It should be clear from the response provided that the patient groups approached clearly understood the project, including the proposed methodology and intention to share identifiable

data with the Department of Work and Pensions, together with the intended outcomes and outputs from the study.

c. Detail should be included around the nature of the engagement activity, how the project was presented, and the number of patients involved. An overview of the discussion, any queries/concerns raised and how these were addressed should be provided with the overall outcome of the sessions.

2. Patient Notifications – the information which will be put into the public domain to inform patients and members of the public about the project requires further revision. The following points should be addressed:
   a. Provide revised copies of the website text around the project for consideration.
   b. The notification materials would need to clearly explain the project aims and methodology and should be transparent in stating that confidential patient information would be shared with the Department of Work and Pensions, to facilitate the data linkage required for the study analysis.
   c. Work should be undertaken with the UK Renal Registry and NHS Blood and Transplant Service, to ensure that information available on their websites clearly explained that confidential patient information would be shared with non-health organisations for research purposes.
3. Provide stronger justification to support the requirement for the Department of Work and Pensions to retain confidential patient information for a period of 12 months following linkage. If this retention period can be reduced, confirm the shorter retention duration.
4. Provide assurance that the data sharing agreement established with the Department of Working Pensions will clearly articulate that the confidential patient information has been shared for the application purposes only and cannot be utilised for any further purposes.

5. NEW APPLICATIONS – Non-Research

a. 17CAG0150 National Perinatal Mortality Review Tool (PMRT)

Context

Purpose of Application

This application from the National Perinatal Epidemiology Unit at the University of Oxford sets out the purpose of establishing a clinical audit tool, the 'National Perinatal Mortality Review Tool' to enable high quality, local, standardised, multi-disciplinary reviews of all late fetal losses, stillbirths, neonatal deaths, all deaths on neonatal units and infant deaths with the review for each individual being used for multiple purposes (e.g. serious incident reviews, Child Death Overview Panels etc.) on the principle of 'review once, review well'.

The PMRT collaboration led by the MBRRACE-UK collaboration has been commissioned to develop and support the implementation of the National Perinatal Mortality Review Tool (PMRT) on behalf of the Department of Health (England) and the Welsh and Scottish Governments. The PMRT will be wholly integrated with the MBRRACE-UK perinatal mortality surveillance data collection in order to minimise the burden on clinical staff and thus maximise its uptake; both systems are concerned with the same group of babies and have the goal of reducing the national perinatal mortality rate.

Local reviews should be carried out as part of standard clinical care and staff in Trusts/Health Boards and do not require the consent of parents before a review is undertaken. During the process of using the PMRT to conduct local reviews of care, identifiable and clinical information will be collected and generated. Section 251 support is sought specifically to enable this information to be held without parental consent on the MBRRACE-UK servers. Support was also required to support the applicants to undertake analysis on the improvements made to the perinatal mortality review process following the implementation of the tool.

User testing of the PMRT is required with 'live' data before all the review questions and data items have been finally defined. For this testing, the applicants will ask NHS staff to use 'real' cases, but will be provided with dummy identifiers. This will allow staff to test the review questions and data without disclosing

the identity of individuals. Given the extent of clinical details involved in the review, support under the Regulations is requested to cover this user testing phase, as well as wider deployment of the tool, as it cannot be confirmed that the data would be anonymous.

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

Confidential Patient Information Requested

Cohort

All mothers whose pregnancy results in a:

- Late fetal loss (babies born at 22-23 weeks gestation not showing any signs of life at birth)
- Stillbirth (all babies born at 24+ weeks gestation not showing any signs of life at birth)

All mothers and their babies:

- Where the baby dies on a neonatal unit and/or before reaching their first birthday (infant deaths).

The following items of confidential patient information are required and will be entered into the web-based system by local staff at the Trust/Health Board responsible for the patient care:

Mothers' details: full name, DOB, ethnicity, NHS number, postcode and clinical information relevant to her care during her pregnancy, labour, birth, postnatal care, bereavement care, follow-up and the causes and circumstances surrounding the death of her baby.

Babies details: full name, DOB, NHS number, postcode, ethnicity, birth weight, gestational age at birth, sex, place of birth, date of death, place of death, cause of death and clinical information relevant to the care of the baby at birth, on the neonatal unit and any other locations the baby was cared for prior to death.

Confidentiality Advisory Group Advice

The applicant, Professor Jennifer Kurinczuk, attended the meeting by telephone to respond to application queries.

Additional information submitted by third party.

As part of the consideration of the application, information had previously been submitted by the Perinatal Institute in 2016 regarding the applicability of the duty of candour in relation to this specific application. As no relevant application was being considered by the CAG at that time, the CAG had agreed it would not be appropriate to consider the papers without the context of an application submitted under the COPI Regulations. Members had noted that when this application would be received that the information provided by the Perinatal Institute would be provided to the CAG.

The first paper, dated 30 November 2016, set out the views of the Perinatal Institute, a national not-for-profit organisation based in Birmingham, on the appropriateness of exemption from the obligation to obtain patient consent when reviewing adverse outcomes within maternity care, in the context of the Duty of Candour guidelines which had come into force in 2015. It was stated that the Perinatal Institute has an interest because they have developed software and associated training for standardised clinical outcome reviews of adverse outcomes, which requires informing parents of the review, encourages input of their perspective on events, and helps clinicians to formulate feedback to parents of immediate concern, as well as of relevance for future pregnancies.

Members noted that an away day had taken place in October 2016, and as reported in the minutes of 31 October 2016, the CAG had been pleased to welcome Bertie Leigh, an experienced lawyer with

Hempsons, to lead a discussion on the duty of candour. Mr Leigh was very clear that it was sufficient for CAG to consider whether, in the circumstances, there is a practicable alternative without considering the implications of that for an organisation's duty of candour. He provided a firm steer that it was not appropriate for CAG to express a view, when reviewing an application for support under the Health Service (Control of Patient Information) Regulations 2002, on whether any organisation was satisfying its own responsibilities regarding the duty of candour.

An addendum paper was also submitted dated January 2017 that proposed that the duty of candour meant that recommending support under the COPI Regulations would be contrary to CAG's own Principles of Advice. Members noted that this document had previously been withdrawn on the basis it had been developed under the remit of the National Information Governance Board and therefore required review and revision, and this was ongoing as part of general CAG development activities. Finally, the paper provided a link to the application website and their plans on patient involvement.

Public Interest

The CAG was assured that the proposed activity defined a clear medical purpose which was in the public interest.

Scope of Support

The Group queried whether the proposed application activity would require the establishment of a legal basis to avoid a breach of the common law of confidentiality. The CAG considered arrangements under the Data Protection Act 1998 and a query was raised around whether HQIP were appropriately classified as data controller for the project, or if this responsibility remained with the Trusts and Health Boards which were entering data into the perinatal mortality review tool. The applicant was asked to confirm the data controller for the programme of activity and to provide further clarity around the necessity of establishing of a legal basis to prevent the proposed activity from being in breach of the common law of confidentiality.

The applicant confirmed that the data controller for the activity was HQIP. It was explained that under their contracting arrangements with HQIP, the applicants would be undertaking analysis of the data collated via the review tool, to audit any improvements which were made following its implementation. The purpose and manner in which data would be processed to facilitate this audit and analysis activity was instructed by HQIP, as the data controller for the activity. The applicant further explained that use of confidential patient information was required to facilitate this analysis, and as such, the disclosure of confidential patient data from the participating Trusts and Health Boards and subsequent processing by themselves as applicants, required the establishment of a legal basis to prevent there being a breach of the common law duty of confidentiality.

The CAG received the response and was assured that the proposed activity required the establishment of a legal basis to avoid a breach of the common law duty of confidentiality. Members were content to provide a recommendation of support under the Regulations to cover this activity.

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 considered the rationale which had been supplied by the applicants to support the assertion that consent was not feasible for this project. It was recognised that consent was not required from the parents to enable the direct care team to begin the local review into the child's death and the care which had been provided. The issue of consent was in relation to specific use of the review tool and transfer of associated data to the MBRRACE-UK server.

It was recognised that the public, patient and parent engagement activity which had been undertaken provided support for the project proceeding on an unconsented basis. The applicants had provided detail within the application around the data collection for the linked MBRRACE-UK study within Northern Ireland, where in the absence of an equivalent to section 251 of the NHS Act 2006, data collection was operated on a fully consented basis. It stated that less than 50% of eligible cases are reported via the MBRRACE-UK system within Northern Ireland, with one of the reasons cited as staff and clinicians not wanting to approach bereaved parents to seek consent.

The applicants had stated that there was currently an ongoing research study, the PARENTS study, which was investigating directly with bereaved parents how best to approach the discussions about review and how best to garner perspectives around their care. It was noted that this study was due to report in mid-2019 and the applicants confirmed that they would be utilising the findings to guide the development of materials to support Trust and Health Board staff in having conversations about reviews, whether and how consent to use the PMRT might be obtained.

The CAG received and considered information from a third-party who had stated that the Duty of Candour by which all health professionals were bound, presented a formal opportunity at which consent for the perinatal mortality review could be taken from the parents. The third-party stated that the local clinician's requirement to comply with the Duty of Candour made consent a practicable alternative for the proposed activity.

In line with previous advice provided by a representative of Hempsons Solicitors at a previous away day, the CAG was clear that in considering whether the Duty of Candour provided a practicable alternative to seeking support under the Health Service (Control of Patient Information) Regulations 2002, it was not undertaking any consideration of whether the individual Trusts and Health Boards involved in the care of the deceased infants were satisfying their own responsibilities in relation to this.

The Group commented that as there was no requirement for consent to be taken from the parents to enable the local review into the perinatal death to commence, it was unclear how the Duty of Candour presented an opportunity to seek formal consent for the overall activity. It was identified that the perinatal mortality review would need to be undertaken in order to ascertain what caused the child's death and understand whether the Duty of Candour was applicable in each case. Members were assured that the requirement to comply with the Duty of Candour did not provide a practicable alternative to seeking support under the Health Service (Control of Patient Information) Regulations 2002.

Members were assured by the extensive and cogent rationale provided by the applicants that asserted that consent was not feasible for this project. It was agreed that an update would be required at the time of first annual review around the progress of the PARENTS study and how any findings could be incorporated into this project to enable a move towards a consented model.

- Use of anonymised/pseudonymised data

It had been identified within the application that the Perinatal Mortality Review Tool had been integrated within the MBRRACE-UK perinatal mortality surveillance data collection so that common pieces of information were available for both purposes. This rationale for this was to maximise the use of the tool by the frontline clinical staff by reducing duplication of data entry through enabling data to be used for both purposes. To enable this integration, the applicants advised that the identity of the mother and her baby need to be known so it was not possible to use anonymised or pseudonymised data. Members agreed that the integration of the two functions provided a more efficient use of clinician time. The Group was assured by the rationale and it was agreed that the activity could not be undertaken on an anonymised or pseudonymised dataset.

<u>Justification of Identifiers</u>

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

The Group recognised that the review tool had been incorporated into the MBRRACE-UK methodology, in a bid to streamline processes for local staff and increase the uptake in use of the tool to guide the local reviews. As such, the patient identifiers which had been requested were aligned to those collated for the MBRRACE-UK data collection; however, additional clinical information was required. Members were assured that the identifiable data items requested were appropriate and necessary to undertake the activity which was proposed.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The Group acknowledged that the applicants had undertaken extensive and relevant public, patient and parent engagement activities in planning the study, which had strengthened the application. The relevant third sector organisations had also been involved in the planning stages. It was recognised that those approached were supportive the proposed methodology and enforced the applicants approach that the activity should proceed on an unconsented basis. Members were assured by the breadth of the work which had been undertaken and it was commented that this should be continued as the programme progresses.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 patient notification materials and it was agreed that whilst these were thorough and provided extensive and useful information to parents, the language could be improved to make the documentation more accessible to the wider audience. It was agreed that further work would need to be undertaken to revise the patient notification materials. It was recommended that the applicants engage with an appropriate patient group to ensure the revised information is accessible.

The Group recognised that there were a variety of opt-out methods provided to parents, which were accessible and appropriate.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State for Health, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. Support extends to England and Wales only.
2. Patient Notification Materials – work should be undertaken to review and revise the information materials, in order to make the language more accessible to a wider audience. A report should be provided within three months of receipt of this letter around the activity which has been undertaken, together with submission of the revised documentation for consideration. It was recommended that support from an appropriate patient group be sought to support this activity.

3. Patient, Public and Parent Involvement and Engagement – work in this area should continue as the activity progresses. A report will be required at the time of first annual review around the actual activity which has occurred, together with an updated plan for involvement and engagement for the following year.
4. Practicable Alternatives – a report should be provided at the time of first annual review around the progress and outputs from the ongoing PARENTS study and how this could be incorporated into the project, to support the move to a fully consented model for the undertaking of perinatal mortality reviews.
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University of Oxford, National Perinatal Epidemiology Unit has a published reviewed grade on Version 14 at 97% satisfactory).**

6. PRECEDENT SET APPLICATIONS

a. 17CAG0154 – Value of CEUS as a surrogate for CTA for EVAR surveillance (V1.1)

Context

Purpose of Application

This application from The Newcastle Upon Tyne Hospitals NHS Foundation Trust set out the purpose of medical research to determine whether contrast-enhanced ultrasound (CEUS) is as good as computed tomography angiography (CTA) for detecting leaks (endoleaks) from stent-grafts used to repair abdominal aortic aneurysms. The currently accepted test for detecting endoleaks is CTA, however, it gives a relatively high radiation dose to patients, it can cause damage to the kidneys in some cases, and it is more expensive than ultrasound. CEUS is a relatively new technique for detecting endoleaks but current literature suggests that it may be as good, if not better, at detecting leaks. CEUS does not give a radiation dose, the contrast does not pose a significant risk to patients' kidneys, and it is a cheaper procedure.

This research would use previously recorded data of patients who have had both CTA and CEUS during their stent graft surveillance to determine if CEUS could be used instead of CTA in the future. No new patients would be recruited for this research but existing information of patients under EVAR surveillance would be analysed.

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

Confidential Patient Information Requested

Cohort

All patients aged 18 years and over attending the Freeman Hospital, who have had a CEUS scan for EVAR surveillance and a CTA scan for EVAR surveillance within a period of 3 months of each (the order of the scans is unimportant). The project will involve 60 patients only.

The data sources required are:

- Automated RIS data search of procedure code 'UAbdoC'.
- Radiology reports of CEUS and CTA scans for patients who have undergone 'UAbdoC' examinations.
- Clinic letters and appointment summaries – used to collate the most recent height and weight information.
- Age and Gender information – extracted from the PACS.

The applicants require access to the full medical record in order to extract the following information for analysis:

- Sex,
- Age (at event),
- Height and weight (to calculate BMI),
- Any limitations of the scan.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that this application defined a clear medical purpose which was in the public interest. It was recognised that the current standard care pathway was of the CT scan, which involved a significant dose of radiation for the patient. Members acknowledged that whilst the proposed study was small-scale and from the limited numbers involved, this would not lead to a change in the gold standard treatment pathway. It was commented the findings could provide an evidence-base which may lead to further research on a larger scale. The Group agreed that, to ensure that a wider public interest could be realised from the project, it would be expected that the applicant would publish the research findings.

Practicable Alternatives

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

- Feasibility of consent

The Group was not assured that consent was not feasible for the project. The sample size for the study was 60 patients only, which was a manageable cohort size from which to seek consent. There was no requirement to screen a wider collection of records to establish the sample, as this would be undertaken on an automated procedure code search. Members commented that the time limitation associated with the completion of a Masters project was not a valid reason for not seeking consent from patients for the use of their data. The CAG agreed that a stronger rationale would be required from the applicant to justify why consent was not feasible for the project.

- Use of anonymised/pseudonymised data

The applicant had provided further detail in response to queries raised around the application in advance of the meeting. It had been suggested that the data extraction could potentially be undertaken by members of the direct care team, which presented a practicable alternative to seeking support under the Regulations. This was further explored with the applicant, who advised that he had protected time, as part of the Masters course, to devote to this study. It was explained that whilst the Chief Investigator and Academic Supervisor could technically extract the anonymised data required for study, their roles and responsibilities in delivering day-to-day patient care in radiology would make it difficult for these individuals to devote their time to the study.

Members appreciated that clinicians' time was stretched; however, the CAG must be assured, when providing a recommendation of support under the Regulations, that a practicable alternative to processing confidential patient information outside the direct care without consent did not exist, as set out in section 251(4) of the NHS Act 2006. The Group was not wholly convinced that the data extraction could not be achieved via the direct care team. It was agreed that a stronger argument was required to clarify why members of the direct care team were unable to undertake this extraction.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

Members acknowledged that the study had been designed in such a way that confidential patient information was not required for analysis; however, the patient record would need to be accessed in order to extract the anonymised dataset for analysis.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

The CAG acknowledged that support under the Regulations was only required to enable the data extraction and the exit strategy was established through the use of anonymised data for analysis. Members agreed that this was appropriate to the activity proposed and would be supported, if the applicants provided a stronger justification against the possible practicable alternatives which appeared to be available to seeking support under the Regulations.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

There had been no patient or public involvement undertaken as part of the proposal which was considered. Members stated that the requirement to undertake appropriate involvement and engagement activity was an expectation of every applicant and the limitations of an educational programme was not a valid argument to bypass this requirement.

The Group suggested that a small-scale focus group could provide an appropriate level of patient engagement around the proposed activity. This would also enable the applicant to test the acceptability of accessing patient data without consent for the purposes defined, which may further support that this is not a feasible option for the project. Feedback from the patient engagement activity would be required as part of any revised application.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 there had not been any patient notification mechanism put in place for the project. It was explained that patient notification was not a requirement to seek consent from each patient whose data would be accessed during the study, but was a means of promoting the project in a publicly accessible manner by providing information about the study and details of how and by whom data would be accessed as part of the project. The information materials would also need to provide a facility for a patient to register an objection to the use of their data in the manner proposed.

Members agreed that a meaningful patient notification mechanism would need to be established for the project, with copies of any notification materials included as part of a revised submission. It was suggested that the notification materials could be reviewed as part of the patient engagement activity to test the suitability of the documentation.

Confidentiality Advisory Group Advice Conclusion

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

Further Information Required

The following information should be provided to allow the CAG to continue their consideration of the application. A detailed covering letter, addressing the following points, should be provided together with any supporting documentation.

1. Practicable Alternatives – the CAG requires further information around the practicable alternatives which have been presented, to provide assurance that these are not feasible for the project. The following points should be addressed:
    a. Patient Consent – provide a stronger argument to support the rationale that patient consent is not feasible for the project.
    b. Use of Anonymised Data – provide further rationale to support why it is not possible for the wider members of the study team, who are part of the direct care team for the patient cohort, to undertake the data extraction and anonymisation of the data required for analysis.
2. Patient and Public Involvement and Engagement – meaningful activity would need to be undertaken in this area to provide support for the project. The following points should be addressed:
    a. The acceptability of accessing confidential patient information without consent should be tested with the patient group, to provide support for the proposed activity,
    b. Drafted patient notifications should be reviewed by the patient group to confirm their suitability (see point three below),
    c. It was recommended that a small focus group could be convened to discuss the project.
3. Patient Notifications and Dissent – patient notifications, or information which will be made available to patients and members of the public, would need to be produced for the project. The following points would need to be addressed:
    a. Provide copies of any notification materials for consideration,
    b. The documentation should include a mechanism to enable a patient to raise an objection to the use of their data,
    c. An overview of how and where the information would be displayed should also be provided,
    d. An overview of how the objection mechanism will be managed would also be required, including detail of how any dissent would be respected.
4. Clarify the intended publication arrangements for the project findings.

b. 17CAG0157 – The delivery of major trauma care in England - impact and effectiveness following a whole system reorganisation.

Context

Purpose of Application

This application from the Big Health Data Group at the University of Oxford set out the purpose of service evaluation to determine the clinical and cost-effectiveness of re-organisation of trauma care services into Regional Trauma Networks (RTNs) and Major Trauma Centres (MTCs).

This request for support under section 251 of the NHS Act 2006 is required to allow linkage of the Trauma Audit and Research Network (TARN) data to Office of National Statistics (ONS) and Hospital Episodes Statistics data. Confidential patient information will be released from TARN to NHS Digital, to enable linkage with the ONS and HES datasets. All data provided to the University of Oxford will be psuedonymised data only.

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

Confidential Patient Information Requested

Cohort

Patients sustaining open fracture in England from 1989 to present day. This list will be used by NHS Digital, the trusted third party, to link to HES and ONS to generate a dataset of outcomes for patients sustaining open fracture in England.

Identifiable TARN data will be provided to NHS Digital for data linkage.

TARN will send NHS number, date of birth, gender and postcode as well as a unique TARN patient identifier (pseudonymised) for linkage.

NHS Digital data to be linked for this project are ONS date of and cause of death data and the complete HES record.

The pseudonymised data set will be returned to the team at the University of Oxford by TARN ID, with all other identifiable information removed.

Confidentiality Advisory Group Advice

Public Interest

The CAG agreed that this application defined a medical purpose which was in the public interest. Members discussed whether the activity would have been more appropriately classified as research; however, it was agreed that as the project was evaluating the standard care pathway, which had been introduced following previous research, this was appropriately categorised as a service evaluation activity.

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 was satisfied that, due to considerable number of patients included within the cohort, consent was not feasible for the project.

- Use of anonymised/pseudonymised data

Members acknowledged that the project had been designed is such a manner that the applicants would not have access to any confidential patient information; however, processing of data by NHS Digital as a trusted third party, was required to produce the dataset needed to undertake the analysis.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth.

The Group was assured that the identifiers which would be disclosed from the TARN dataset to NHS Digital to facilitate the data linkage were appropriate and justified for the activity proposed.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed.

The CAG recognised that the study had been designed in such a way that processing of confidential patient information to facilitate data linkage was undertaken by NHS Digital, as trusted third party. Support under the Regulations was time limited to facilitate the data linkage as the applicants would be undertaking analysis on a pseudonymised dataset. Members were assured that the methodology was appropriate to the activity being undertaken.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The Group agreed that the patient and public involvement and engagement activity which had been described by the applicants was appropriate and sufficient to the application activity. No further action was required in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, 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 applicants had explained that the TARN website was the principle point to display patient notifications. On reviewing the website, it was noted that the opt-out information was difficult to locate. Members agreed that the information on the website around raising an objection to the use of data would need to be made clearer.

The Group considered the drafted project-specific notification material and it was agreed that revision of the documentation would be required to ensure that this was accessible to a wider public audience.

Members commented that there was potential to promote the service evaluation programme more widely by displaying information within the trauma centres. It was agreed that further work would be required to develop further information materials to be displayed within the trauma centres.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support

1. Support extends to England and Wales only.
2. Patient Notification Mechanism – further work is required to address the following issues. A response should be provided within three months of the date of this letter, together with accompanying documentation, for consideration by a sub-committee of original reviewing Members.
    a. Review the drafted patient notification text to make this more accessible to a wider public audience,
    b. The opt-out mechanism available via the TARN website should be more clearly displayed to make this more visible to patients,

c. Patient Notification materials should be drafted for display in trauma centres to promote the activity. This could be posters and information leaflets as example. The language used should be aimed at a wide public audience.
Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - BHDG at the University of Oxford V14, reviewed satisfactory score 100%, 2017/18 and NHS Digital, V14, reviewed satisfactory score 92%, 2017/18).**

7. MINUTES OF THE MEETING HELD ON 13 JULY 2017

The minutes were agreed as an accurate record of proceedings, with no amendments raised.

8. CAT OFFICE REPORT

CAG Away Day – Overview

Members were reminded that the next CAG Away Day is scheduled for Wednesday 11 October 2017, 10.30am – 4.15pm

A draft agenda was shared with the Group for consideration, together with some logistical details around travel and accommodation requests.

CAG Research Stakeholder Event – February 2018

Further to the success of the CAG Patient and Public and Key Stakeholder event which was held in February 2016, work has begun to plan a similar event for this financial year.

It has been agreed that the event will take in February 2018 and will be held in the Manchester area. The focus of this year's event is around research stakeholders.

Initial planning has begun within the Chair team, with Dr Tony Calland taking the lead on the event. Ms Rachel Heron will be leading on the event from the CAT perspective, with support from the wider team.

CAG Minutes – August 2017

Minutes of the CAG business undertaken in August 2017 were shared for information purposes. This included the full CAG meeting on 24 August 2017, Precedent Set Sub-Committee and standard Sub-Committee business.

Expense Claims

Members were reminded of the importance of submitting expense claims in a timely fashion for expenses incurred in connection with CAG business. Submission details were provided together with a copy of the relevant expenses claim form.

9. CAG CHAIR REPORT

The Chair's Report for August 2017 had not yet been circulated at the time of the meeting.

10. ANY OTHER BUSINESS

a. Education Items

It was acknowledged that discussion of possible educational items had been added as a standing agenda item for every CAG meeting. It was suggested that a discussion around the GDPR would be helpful; however, it was acknowledged that this was already assigned to the Away Day agenda. It was agreed that a follow-up should be planned for the future to follow-up on learning ahead of the implementation of the Regulation in May 2018.

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