NHS
Health Research Authority

# Minutes of the meeting of the Confidentiality Advisory Group

## 13 July 2017 at Skipton House, SE1 6LH

### Group Members:

| *Name* | *Present* | *Notes* |
|---|---|---|
| Dr Kambiz Boomla | Yes | |
| Dr Tony Calland | Yes | Vice Chair |
| Ms Hannah Chambers | Yes | Lay Member |
| Dr Patrick Coyle | Yes | Vice Chair |
| Professor Barry Evans | Yes | |
| Mr Anthony Kane | Yes | Lay Member |
| Professor Jennifer Kurinczuk | Yes | |
| Dr Harvey Marcovitch | Yes | |
| Mrs Diana Robbins | Yes | Lay Member |
| Mr Marc Taylor | Yes | |

### Also in attendance:

| *Name* | *Present* | *Notes* |
|---|---|---|
| Miss Kathryn Murray | In Attendance | Senior Confidentiality Advisor |
| Ms Natasha Dunkley | In Attendance | Head of the Confidentiality Advice Service |
| Dr Victoria Chico (Item 3 only) | In Attendance | Lecturer in Law, University of Sheffield |
| Ms Amanda Hunn (Item 3 only) | In Attendance | Joint Head of Policy, HRA |
| Mr Stephen Robinson (Items 6a and b only) | In Attendance | Corporate Secretary, HRA |

## 1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introduction

The Group welcomed the attendance of Dr Victoria Chico, Lecturer in Law, University of Sheffield. Dr Chico was attending the meeting to lead an education item providing of the findings of public and patient focus groups which had been held in 2016. Ms Amanda Hunn, HRA Joint Head of Policy, was also welcomed to the meeting to present on the same agenda item, having been part of the team, together with Dr Chico, who had led the focus groups.

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

Dr Tony Calland advised that he had previously been a Member of the Welsh Information Governance Board. Whilst it was acknowledged that this was not a true conflict of interest, as the applicant was not a Welsh entity, it was agreed that this should be recorded within the minutes relating to the application.

Dr Patrick Coyle noted that he was currently Acting Chair for the Welsh Information Governance Board. It was again agreed that this did not constitute a true declaration of interest for the previous reasons acknowledged; however, it was agreed that this should be formally recorded in the minutes.

No other interests were declared.

## 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 08 June 2017 meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 08 June 2017 meeting applications.

## 3. EDUCATION ITEMS

**a. Attitudes towards use of NHS Data for mixed public (health) and private (commercial) purposes – A report from focus groups carried out in 2016.**

The Chair welcomed Dr Victoria Chico, Lecturer in Law from the University of Sheffield, and Ms Amanda Hunn, HRA Joint Head of Policy, to the CAG meeting.

Dr Chico led the Group through a report presentation on the above subject.

The Chair thanked Dr Chico and Ms Hunn for their attendance and they left the meeting.

## 4. RESUBMITTED APPLICATIONS – Non-research

### a. 17CAG0113 – CHC Data Access (Previously 17CAG0080)

**Context**

Purpose of Application

This non-research application, submitted by Liaison Financial Services, stated that several Clinical Commissioning Groups (CCGs) have voiced to the applicant their concerns about the rising spend on Continuing Healthcare (CHC) and the increasing pressure to manage and control this spend. These difficulties were specified to include duplicate payments, overcharging for revised care packages, recharges from Local Authorities and charges for deceased patients.

A recommendation for class 4 and 6 support was requested to enable the disclosure of data from NHS Digital to the applicant, on behalf of the CCGs.

Confidential Patient Information Requested

Cohort

The applicants confirmed that the patient cohort encompasses approximately 14,000 patients across 27 CCGs (which are named within the application). This covered all patients who were registered with the CCGs as follows:

- Have died since April 2013 to present,
- Have had an inpatient stay since April 2013,
- All patients registered within the CCGs boundaries since April 2013.

The following items of confidential patient information are required for the activity described:

- NHS Number – validation and analysis (provided by CCGs and shared with NHS Digital to enable linkage and supply of the below details),
- Date of death – validation and analysis,
- Hospital admission date - analysis
- Hospital discharge date – analysis,
- GP/CCG details – validation and analysis.

**Confidentiality Advisory Group Advice**

The Group acknowledged that the application was a resubmission of 17CAG0080, which was considered at the CAG meeting held on 11 May 2017, where it was issued with a deferred outcome, due to insufficient information being present to enable a recommendation to be provided on the application.

As part of the resubmission, the applicant had provided a covering letter responding to the request for further information which was issued at the previous review, which formed the focus of this review.

Public Interest

The Group considered the additional rationale which had been supplied by the applicants around the public interest in the application and whilst it was agreed that there was a clear benefit in ensuring that the CCGs undertook the invoice validation activity to enable overpayments to be reclaimed, the applicants had not clarified how the service being offered by Liaison was more appropriate than the existing national application in place to manage this process. Members noted this national application had been approved by the Secretary of State for Health and put in place by NHS England on behalf of all CCGs to manage the invoice validation process, therefore there would need to be a significant public interest and rationale to understand why a further, similar application, was necessary.

Members recognised that 27 CCGs had already contracted Liaison to undertake this work on their behalf; however, it was commented that this was a small proportion in terms to the number of CCGs across England and it remained unclear how this activity was being undertaken by other CCGs across the country. The Group reiterated previous concerns that the issues which had been identified with the national application for invoice validation activity were not being addressed through this proposal.

The CAG noted that their advice would be shared with NHS England as owners of the existing invoice validation application to provide information around the issues with the agreed national process which had been identified during this review.

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 applicants had provided further clarity around the patient cohort which was the focus of the invoice validation activity and it was stated that this currently encompassed around 14,000 patients. It was acknowledged that, due to the nature of the reconciliation work to be undertaken, a significant number of the patients would be deceased for whom consent was not feasible.

The applicants confirmed that the application did not cover a pilot scheme as was previously queried and identified 27 CCGs which had already contracted Liaison to undertake the invoice validation on their behalf.

The CAG acknowledged the rationale supplied by the applicants and it was confirmed that consent was not likely to be feasible for this activity.

- Use of anonymised/pseudonymised data

Noting the similarities to the existing national invoice validation application, it was accepted that some level of identifiers would be necessary to enable validation to take place.

- Integration into existing national invoice validation application

The Group recognised that the Secretary of State for Health had approved a national invoice validation application on behalf of all CCGs, that was coordinated by NHS England under application reference CAG 7-07 (a-c) 2014. It appeared to members, in light of confusion about the data controller and processor relationships, that it may be more appropriate to assess whether this activity could legitimately fall into the framework of that national application as coordinated by NHS England. This may therefore represent a practicable alternative. The content of this proposed application was considered a local variation on the terms of the existing national approval and as such, could potentially be handled as an amendment to the existing application. As the existing application had been submitted by NHS England on behalf of all CCGs and supporting CSUs, the onus was on the CCGs involved to negotiate the required amendment via NHS

England, as the application owner of the current approval. This point is linked to and further discussed below under 'Data Protection Act 1998 Compliance'.

Data Protection Act 1998 Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the Data Protection Act (DPA) 1998. Applicants must therefore demonstrate through the application that it is consistent with the DPA.

Members agreed that the response provided in this area still raised concerns around the understanding of this Act. A data controller is responsible for determining both the purpose and the manner in which information is to be processed. It was discussed that the purpose of the activity described was determined by the CCGs and Liaison were proposing to act under the instruction of the CCGs via the contractual arrangements shared, which indicated that Liaison would therefore be the data processor for the activity. While Liaison may be responsible for some elements as to how the information is to be processed, they are not responsible for the purpose and therefore cannot be considered to be data controllers. If Liaison were the data controller, this would mean they could choose to use the data in any manner in which they wish and for purposes other than invoice validation, which was understood not to be the intention. It was also flagged that data controllership is a matter of fact based on responsibility for determining purpose and manner. The Group were clear that the justification provided by the applicants to support Liaison as data controller for the activity did not fulfil the requirements of the Act and was in contradiction to the detail of the application. Members agreed that the lack of understanding in this area was critical and a determining factor in the recommendation for not supporting the application, as the relationships would determine the best way to proceed, and members clearly expressed the view they felt Liaison to be a data processor, which could enable potential integration into the national application.

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 CAG observed that there was misunderstanding within the response provided by the applicant in this area as it had been confirmed that NHS Number alone was required to undertake the proposed activity. Further queries were raised around this as it was understood that additional data items would be required to enable any overcharges to be calculated. It was identified that the wider data set detailed above under 'Confidential Patient Information Requested' was still required and would be returned by NHS Digital to enable invoice validation to be undertaken. Members voiced concerns around the lack of clarity in this area as it was noted that the statement around undertaking the activity on NHS Number alone was inaccurate.

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 identified that there was a lack of clarity provided by the applicant in response to the queries within this area as it was initially stated that patient notifications were not required for this activity as Liaison was reviewing only financial information. This had been queried further and the applicant acknowledged that patient notifications would need to be discussed with the CCGs as the most appropriate agent to inform the cohort of the activity. The Group agreed that the response provided in this area was insufficient however, more critically, it was noted that the rationale suggested that the CCGs were more accurately the data controller for the application activity as they were given the responsibility to informing the relevant patient population.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory IG toolkit compliance. It was noted that a self-assessed score of 66% had been published; however, the assessment of the submission by NHS Digital remained outstanding.

**Confidentiality Advisory Group Advice Conclusion**

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

**Resubmission**

To progress, the applicant must discuss this proposed application with NHS England, to ascertain whether the activity could take place under the national invoice validation application CAG 7-07 (a-c)/2014. Should this be the case, NHS England should submit an amendment to CAG 7-07 (a-c) to enable this activity to take place.

## 5. NEW APPLICATIONS – Non-Research

### a. 17CAG0109 – DWP Request to Obtain HES Data for Specified Benefit Recipients

**Context**

Purpose of Application

This service evaluation application from the Department for Work and Pensions (DWP) proposed the linkage of information, for patients who are claiming disability benefits or premiums, to HES data held by NHS Digital. It is proposed that NHS Digital provide the DWP with dates of any hospital admissions and discharge for this cohort to enable the DWP to calculate the correct benefit. The application stated that disability benefits and payments should be stopped once a patient has been an inpatient for 28 days (individual or linked admissions).

This application covers an initial feasibility project to investigate whether the data linkage is possible and able to fulfil the applicant's requirements. This would consist of records for a retrospective sample of patients covering a six month period to be linked with HES data by NHS Digital. The data will be used by the applicants to determine whether the proposed data linkage would reduce the volume and amounts of benefit overpayments caused by either late or no notification of the hospital admission. The applicants are focussing on the six month feasibility sample in the first instance, with a view to, if the activity is found to be successful, submitting a further application for ongoing support to be in continual receipt of this information, to enable accurate and timely cessation of benefits moving forward.

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

Confidential Patient Information Requested

Cohort

All individuals in receipt of one of the following benefits: Disability Living Allowance, Attendance Allowance, Personal Independence Payment, who have had a stay or linked stay in hospital which exceeds 28 days in the six month period to be studied (proposed April – September 2017).

The following items of confidential patient identifiable information were requested for the purposes stated:

- Name – data linkage and analysis,
- Full address and postcode – data linkage and analysis,
- Date of birth – data linkage and analysis.

**Confidentiality Advisory Group Advice**

Scope and Purpose of Application

All applications must meet the minimum requirements of section 251 of the NHS Act 2006 in order for consideration to take place under the Health Service (Control of Patient Information) Regulations 2002. Review of the application raised a fundamental concern that it was not clear how this activity fell within a relevant medical purpose. Section 251 (12) of the NHS Act 2006 sets out the relevant medical purposes; the application appeared that it was intended to fall under 'management of health and social care services'.

The purpose was specified to enable the DWP to fulfil its administrative functions of paying the right amount of benefit at the right time to individuals. Applicant emphasis was placed on the DWP's legal obligation to pay correct benefits and it was asserted that should the activity prove to be successful, this would have patient benefit as it would enable the prevention of overpayments, through the DWP's being in receipt of accurate hospital admission data in a timely fashion, which would remove the distress caused by an overpayment and the subsequent action to remedy this.

In reviewing this justification, while acknowledging the importance of wider Government priorities to ensure correct payments, Members were clear that the use of patient data to achieve the intended aims would achieve no clinical medical benefit. Members therefore unanimously agreed that there was no appropriate evidence provided to justify that the activity fell within a relevant medical purpose.

It was therefore agreed that as the application did not appear to involve a clear medical purpose, that the application did not meet the minimum requirements and therefore the application was currently out of scope of the NHS Act 2006 and supporting Regulation. The Group advised that there would have to be a significant and clearly transparent justification as to how this activity was a medical purpose, and expressed the view that they were unclear as to how this would be possible.

Members commented that the sensitivities of the use of health data for this purpose, and the potential public confidence implications which surrounded the activity as described brought the public interest further into question. As the activity did not currently fall within the legal remit of the CAG, the Group agreed that further exploration of the issues below was unnecessary within the formal outcome as these issues were not the basis of the formal recommendation provided to the Secretary of State for Health as decision-maker.

In discussing this application more generally, members also supported the concerns that had been identified by colleagues at NHS Digital, evidenced within one of the wider application documents, which highlighted that the activity may lead to an increase in the number of type two objections. It was acknowledged that this had wider repercussions to the secondary use of data and its value in research and the management of health and social care services.

The CAG observed that within the justification supplied by the applicants for the request for support under the Regulations, there had been limited consideration given to the potential patient and public benefit arising from the activity in terms of clinical or broader care. Members expressed concerns for the lack of understanding which came across around the importance of identifying these benefits in order to provide support to the proposed activity. It was further acknowledged that there appeared to have been little consideration given to the potential negative impact the proposed activity could have on patients. Members noted that these concerns were further emphasised by the unwillingness on behalf of the applicants to undertake any patient and public engagement activity to test or explore the proposed data linkage.

Members suggested that there appeared to have been a misunderstanding of the requirements of the NHS Act 2006 and Health Service (Control of Patient Information) Regulations 2002. Instead, the applicant had focused on the benefits that would arise in terms of the applicant organisation fulfilling its own statutory function. As such, a number of key areas of CAG consideration were not fully explored within the documentation, particularly around the requirement to operate a patient notification and objection mechanism.

In light of these comments, the Group remarked that the application activity had the potential to reduce the public confidence in both the CAG itself and its role providing independent advice around the use of patient data without consent if it received a positive recommendation in its current iteration. This could also potentially impact on the wider health service if patients and the public could not be assured that the CAG was taking a reasonable position on applications. It was unanimously agreed that the application could not receive a positive recommendation in its current format, without addressing the underpinning issues.

**Confidentiality Advisory Group Advice Conclusion**

In line with the consideration above, the CAG agreed that the minimum criteria under the NHS Act 2006 and supporting Regulation had not been met, and therefore advised the decision-maker that the application should not be supported.

**b. 17CAG0124 – National Diabetes Audit (Adults) – Wales**

**Context**

Purpose of Application

This application seeks to provide an update on the National Diabetes Audit (Adults) (NDA), which has previous Section 251 approval under application ECC 3-04 (r) 2011. NHS Digital NDA has entered a new 3 year agreement (with the possibility to extend to 5 years) with NHS England to deliver the NDA as part of the National Clinical Audit Programme. The audit has been running since 2003 with Wales joining the audit from 2007-08 onwards.

This application is for the NDA to continue in the interim in Wales under Section 251 support and along with the collection of data also includes holding, data linkages, analysing and disseminating the historical Welsh NDA data with a change of data controllership from HQIP to NHS Digital whilst we work with the Welsh Assembly Government to develop an exit strategy. The application specifically covers the transfer of data from NWIS to NHS Digital to support the primary care core audit in Wales and the secondary care core audit in Wales which flows from hospitals to NHS Digital and the associated processing and dissemination which follows. This includes linkages to PEDW, ONS mortality and support for the transition audit.

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

Confidential Patient Information Requested

Cohort

Adult patients with a diagnosis of diabetes within Wales, which was estimated at approximately 200,000 patients.

The following items of confidential patient identifiable information are collected by NHS Digital for the National Diabetes Audit for the purposes identified:

- NHS number – validation of records and linkage between data sources,
- Date of birth – used in conjunction with postcode and gender to validate NHS number then converted to year of birth and age for analysis,

- Gender – validation and analysis,
- Postcode – validation and converted into LSOA to calculate deprivation for analysis,
- Ethnicity – analysis,
- GP Practice Code – analysis/reporting,
- Date of Diabetes Diagnosis – analysis,
- Date of death – analysis.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG recognised that the medical purpose and public interest in this activity had previously been defined.

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 consent had previously been determined as unfeasible for this activity and was assured that this remained the case.

- Use of anonymised/pseudonymised data

Members commented that within the patient information materials supplied it was stated that once a patient's information was linked, their NHS Number and date of birth were deleted to anonymise the information which was held about them. The Group suggested that this was not the case as identifiers would need to be retained to enable incremental annual updates to be attributed to the relevant patient for analysis. The information within the application stated that NHS Number was utilised as the unique identifier and it was acknowledged that this was likely to be the data item retained to link patient records across annual reporting periods.

Whilst the importance of the annual incremental data was accepted, the CAG suggested that there were ways in which the NHS Number could be pseudonymised to reduce the identifiability of the dataset retained within the audit analysis file. For example, it was suggested that the same pseudonymisation code could be used each year on the NHS Numbers, to enable the update to the attributed to the correct patient through the application of the same code. Members agreed that the applicants would be required to consider this point and provide an update on their progress in this area at the time of first annual review.

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 CAG was assured that the personal identifiers requested were appropriate to enable the undertaking of the activity described.

Exit Strategy

The CAG acknowledged that the applicants had identified within the proposal that support under this application was intended to be an interim arrangement to enable the audit activity to continue, whilst NHS Digital worked with the Welsh Assembly Government to establish an exit strategy.

Members queried whether there was potential for an exit strategy from support under the Regulations to be established via Section 255 of the Health and Social Care 2012. It was stated here at Section 255 (1) that 'Any person (including a devolved authority) may request the Information Centre to establish and operate a system for the collection or analysis of information of a description specified in the request'. The Group agreed that the applicants would need to explore the potential of establishing an exit strategy from support under the COPI Regulations via Section 255 of the Health and Social Care Act 2012 and provide a report back on the feasibility of this at the time of first annual review.

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.

Members acknowledged that there was an extensive programme of patient and public involvement and engagement which had previously been established in connection with the diabetes audit and were assured that this was ongoing.

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.

Whilst Members acknowledged that the patient notification materials had previously been considered, it was agreed that the resubmission of this application provided an opportunity to review the suitability of the documents. It was suggested that some of the language could be revised to make this more accessible to all readers. An example was given that 'enduring' could be replaced with 'long-lasting'. It was also noted that the previously mentioned reference to the anonymisation of patient upon linkage would need to be checked for accuracy. The Group agreed that the revisions could be made upon translation to the Welsh language and clarification of the revisions made would be accepted at the time of first annual review.

Additional Points

The CAG acknowledged that support under the historic application for this activity had lapsed on 16 June 2017. It was acknowledged that as data collection for the audit was undertaken on an annual basis, it was unlikely that any data had been processed in the interim without an established legal basis; however, Members agreed it was appropriate to formally acknowledge the lapse in support within the outcome letter.

**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. Exit Strategy – provide a report at first annual review around progress made towards the establishment of an exit strategy from support under the Regulations. Consideration should be given to Section 255 of the Health and Social Care Act 2012 in these deliberations.
2. Identifiability of Retained Dataset – provide a report at first annual review around the progress which has been made to reduce the identifiability of the data retained for analysis. Consideration should be given to the above suggested point around utilising the same pseudonymisation key each year on NHS Number.

3. Patient Notifications – provide a report at first annual review around the revisions made to patient information materials. Consideration should be given to the following points:
    a. Revision of the language to make content more accessible to all readers,
    b. Within the section entitled 'How is the information used?', revise the reference to data being anonymised following linkage.
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - NHS Digital Version 14 (2016-17) 92% satisfactory).**

## 6. NEW APPLICATIONS – Research

### a. 17CAG0105 – Cardiovascular Markers of Stroke

**Context**

Purpose of Application

This application from Leeds Teaching Hospitals NHS Trust set out the purpose of medical research investigating the diagnostic yield of cardiac monitoring in the identification of atrial fibrillation in stroke patients. The project aims to review all patients admitted to Leeds Teaching Hospitals Trust with a diagnosis of ischaemic stroke between 2014 and 2015. The applicants will record the co-existing medical conditions of the patient cohort together with the cardiac investigations that were performed to create a detailed stroke database. With this data, the aim is to determine the diagnostic yield of cardiac monitoring in the diagnosis of atrial arrhythmia, look for any cardiac markers which may predict recurrent events and determine whether current risk scores such as CHA2DS2VASc could be used to identify those patients in sinus rhythm who go on to develop an ischaemic stroke.

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

Confidential Patient Information Requested

Cohort

The patient cohort for inclusion is all patients who were admitted to Leeds Teaching Hospitals NHS Trust with a diagnosis of ischaemic stroke between 01/01/2014 and 31/12/2015. This cohort encompasses 1,812 admissions (including 126 recurrent episodes).

The following items of confidential patient information are required for the purposes identified:

- NHS number – data linkage,
- Study ID – data linkage,
- Sex – analysis,
- Patient age – at stroke event – analysis,
- Ethnicity – analysis.

**Confidentiality Advisory Group Advice**

Public Interest

The application described a medical purpose through the potential to improve patient care for stroke patients through testing the use of risk calculations in a wider patient population which may improve the ability to predict stroke risk, which the Group agreed was in the public interest.

Practicable Alternatives

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

- Feasibility of consent

The applicants had clarified that a proportion of the patient cohort would be deceased and for those who were living, a wider disclosure would be required in order to make an approach for consent than that which was required to enable the project to proceed. Members were assured from the rationale provided that consent was not feasible for the proposed activity.

- Use of anonymised/pseudonymised data

The applicants had identified that analysis would be undertaken on an anonymous data set; however, Members commented that this data set would contain gender, ethnicity and age at the stroke event. The Group considered the risk of re-identification from this data. It was acknowledged that the patient population within the proposed geographical area was quite diverse and Members were assured that the identifiability risk was minimal.

Justification of Identifiers

The CAG was satisfied that the patient identifiers requested were the minimum required to undertake the relevant data linkage and those retained for analysis were pertinent to the study aims.

Data Sources

The Group recognised that the applicants had liaised with The Phoenix Partnership around the use of primary care data which was held within the ResearchOne database. It was understood that this was an opt-in database, so GPs were aware that the data would be utilised for research purposes. Members were unclear whether the applicants had engaged with GPs in the locality around the use of primary care for this project. It was agreed that clarification around this point was required.

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 CAG considered the patient and public engagement activity which had been undertaken and whilst it was acknowledged that this was limited to five patients, Members agreed that the activity was appropriate to the proposal. It was recognised that the concerns raised by the patients involved had been addressed. The Group agreed plans for further engagement as the project moved forward would be required, which would be reported back at first annual review.

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.

The CAG considered the description supplied by the applicants around how and where patient notifications in relation to the study would be displayed; however, it was noted that copies of the documentation had not

been supplied for review. Members agreed that sight of the relevant documentation was required before a recommendation of support could be given.

The Group acknowledged that the applicants intended to make patient notifications available for a time ahead of the data linkage being carried out, to enable any patients to raise objection. It was not clear what mechanism was in place for patients to raise an objection or how this would be respected. Members agreed that further clarification was required in this area before a recommendation of support could be given.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory IG toolkit compliance. It was noted that IG Toolkit arrangements remained outstanding for The Phoenix Partnership. 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.

The CAG acknowledged that confirmation of The Phoenix Partnership's Data Protection Registration also remained outstanding and confirmation was required before a recommendation of support could be given.

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. It was recognised that the overall project had received a favourable ethical opinion from the Leeds East REC; however, Members commented that REC approval of the patient notification materials was required and further clarification would be required that this was in place prior to a recommendation of support being made.

**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. Response should be provided within one month from the date of the outcome being provided.

**Further Information Required**

1. Clarify whether there has been any engagement with local GPs around the use of primary care data within the project. If so, provide details of what engagement has taken place and how. If not, clarify why there has not been any activity undertaken in this area.
2. Public and Patient Engagement and Involvement – provide details of plans activity in this area as the study progresses. Consideration should be given around how and when patients and the public will be involved with the project.
3. Patient Notifications and Dissent – provide the following information in this area:
    a. Sight of the notification materials to be used, to include the website text and the poster to be displayed,
    b. The documentation should include clear information around how a patient can raise dissent accounting for different mechanisms i.e. in person, telephone, email,
    c. Provide a clear description of how the dissent process will be managed and by whom. Clarification is also required around the lead time given to patients to raise an objection before data linkage is undertaken and at what stage dissent could no longer be respected,
    d. Confirmation of REC Favourable Opinion for the patient notification materials.
4. Security Assurance – the following information is required in relation to The Phoenix Partnership:
    a. Confirmation of IG Toolkit Assurance at Version 14, 2016/17,

b. Confirmation of Data Protection Registration.

Once received, the information will be reviewed by a sub-committee of the original reviewing 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.

**Specific Conditions of Support (Provisional)**

1. Patient and Public Involvement and Engagement – provide a report back at first annual review around the additional activity which has taken place, following plans agreed via point two above.
2. Favourable opinion from a Research Ethics Committee. **(Leeds East REC issued a favourable opinion on 16 March 2017. Further clarification is required as detailed above).**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Leeds Teaching Hospitals NHS Trust shows a reviewed reported grade of 78% satisfactory on Version 14, 2016-17. Clarification remains outstanding for The Phoenix Partnership).**

## b. 17CAG0107 – Waldenstroms Macroglobulinaemia (WM) UK Registry

**Context**

Purpose of Application

This application from University College London Hospitals NHS Foundation Trust set out the purpose of the establishment of a research database focussing on Waldenstroms Macroglobulinaemia (WM), a rare blood cancer caused by genetic changes in the cells of the immune system (called B cells) which affects over 400 patients per year in the UK. The optimum way of treating this disease is under investigation, as new therapies become available, but a clear picture of the disease in the UK is lacking. The project intends to address this through the establishment of a robust database of patients which can be utilised in the improvement of patient outcomes. The database will be managed by Dendrite Ltd.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described within the application.

Confidential Patient Information Requested

Cohort

All patients with a diagnosis Waldenstroms Macroglobulinaemia (WM) or an associated condition who are patients at clinical sites registered with Dendrite as registry centres. It was identified that there would approximately 420 patients added to the registry over the next two years.

The following items of confidential patient identifiable data are required for the purposes stated:

- Full name – establishment of record
- NHS number – validation and linkage,
- Hospital ID – establishment of record,
- Date of birth – linkage and analysis,
- Date of death – linkage, survival calculation and analysis,
- Gender – analysis,
- Ethnicity – analysis,
- Postcode (district level) – validation and analysis,
- Local hospital name and address – validation and analysis.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG agreed that the application defined a medical purpose through the establishment of a national resource which will assist with future clinical trial design and enable analysis of the various treatment pathways for patients as there is not currently a standard therapy for WM. Members agreed that this activity was in the public interest as this was a little understood cancer which required further investigation.

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

In consideration of a retrospective cohort, Members acknowledged the rationale that there could be up to six months before a patient was seen in clinic and were sympathetic of the time pressures around the establishment of the patient cohort. The Group was assured from the rationale that consent would not be feasible if the applicants were intending to include a retrospective cohort within the project. It was agreed that clarification around the cohort would be required to understand whether it was the intention to include patients with an existing diagnosis within the registry. Members were supportive in principle of making a recommendation under the Regulations for the establishment of the existing patient cohort within the database. The applicants would be required to consider ways in which consent could be gathered from this retrospective cohort at future clinical appointments and provided feedback before a recommendation could be given.

The CAG was not assured from the rationale supplied that consent was not feasible for a prospectively diagnosed patient cohort. It was recognised that the applicants had undertaken a pilot in which patients were asked to provide consent for their inclusion within a trial database and a cohort of 200 patients was established. Members were unclear around how many patients were approached to achieve this cohort and clarification was required around this point to understand the number of individuals who had dissented.

The applicants had estimated that there would be approximately 420 patients included within the database over a two year period, which would amount to approximately 20 patients at each identified site per year. The Group did not consider this cohort to be too large to make consenting unfeasible.

It was also recognised from the information which had been supplied from the WMUK Charity in support of the project, that an online poll was ran via personal email to their patient community members around the use of patient data within a registry. The document stated that 201 positive responses were received within the 48 hours which the poll was open. Members suggested that the results highlighted that this was a particularly engaged patient population, which further suggested that proceeding on a consented model would be feasible.

The CAG was not assured from the information provided that consent was not practicable for the prospective data collection. The applicants would be required to provide a stronger rationale to support the establishment of the registry on an unconsented basis, or provide confirmation that consenting arrangements would be put in place for prospectively diagnosed patients.

- Use of anonymised/pseudonymised data

The applicants had clarified that access to confidential patient information was required to enable linkage to national datasets. This would be facilitated via Dendrite Ltd, the organisation appointed to manage the database. Access to confidential patient information would be limited to the Dendrite management team and the lead research team at UCLH, which would consist of the main applicant and a registry fellow. It

was confirmed that researchers who requested access to registry information would only be provided with an anonymous data set.

The CAG expressed concerns around the ongoing retention of the confidential patient information as it was acknowledged that a substantial set of identifiers were being collated, together with extensive clinical information, which the applicants had stated were required for analysis. It was unclear whether the applicants had engaged with the data controllers for the wider national datasets with which they intended to link data. Clarification around this point was required to determine which items of confidential patient information were required to facilitate the linkage. Without this clarification, the CAG remained unclear as to whether a less identifiable data set could be compiled.

Members commented that if the requirement was to retain all items of confidential information in a complete format this would further strengthen the rationale for the registry to seek consent from patients.

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 received the justification for the identifiers requested; however, it remained unclear whether these would need to be retained in a complete format, as had been considered in the above section 'Use of anonymised/pseudonymised data'.

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 CAG acknowledged the substantial public and patient involvement in the application and it was recognised that the idea of the registry had been conceived through joint working between patients and doctors involved with the WMUK charity, which also provided strong support for the activity. Members were assured around the activity in this area. It was agreed that should a recommendation of support be given for any activity under the Regulations, a report would be required at first annual review around further work which had been carried out 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.

Members commented that the draft website text which had been provided was quite complex and would require revision to make this accessible to all readers. The applicants had identified that they were intending to prepare a poster, which it was recommended was written in accessible language. The CAG recognised that the applicants were aware further work was required around the establishment of a notification and dissenting mechanism and it was agreed that sight of additional and revised materials would be required before a recommendation of support could be provided.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed scores for both University College Hospitals London and Dendrite Ltd had been published in respect of version 14 (2016/17) of the toolkit; however, these self-assessments 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 would need to be addressed by the applicant.

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 REC review of the proposal remained outstanding and confirmation would be required in this area before a recommendation of support could be made.

**Confidentiality Advisory Group Advice Conclusion**

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below. Response should be provided within one month from the date of the outcome being provided.

**Request for Further Information**

1. Cohort – further information is required around the cohort for inclusion in the registry as follows:
    a. Clarify whether it is intended that a retrospective cohort of patients with an existing diagnosis of Waldenstroms Macroglobulinaemia (WM) would be included within the registry, or if it is intended to include only those patients who were prospectively diagnosed.
    b. If it is intended to include a retrospective cohort, clarify how many patients this encompassed,
    c. If the retrospective cohort were established within the registry on an unconsented basis, consider ways in which consent could be sought from this patient group at future clinical appointments as an exit strategy from requiring support under the Regulations.
2. Feasibility of consent for prospective patients – the CAG was not assured that consent was not practicable for prospectively diagnosed patients. Provide further stronger rationale to support why consent cannot be taken for patients who are prospectively diagnosed for inclusion on the registry. Alternatively, provide confirmation that prospectively patients would be managed via a consented process.
3. Linkage with national datasets – clarify whether the data controllers for the named national datasets had been approached around the proposed data linkage. If so, clarify the outcomes of these discussions and clarification around which items of confidential patient information are required to facilitate the data linkage.
4. Identifiability of the data set – provide response around the following points:
    a. Consider whether all items of confidential patient information are required to be retained in a complete format and provide response, including further justification to support this where necessary.
    b. Consider whether specific patient identifiers could be removed from the data set or translated into less identifiable formats once calculations had been undertaken, i.e. date of birth removed and/or truncated to MM/YY format once age at diagnosis had been calculated.
5. Patient Notifications and Dissent – provide further consideration and response to the following points:
    a. The draft website text requires revision to make this more accessible to all readers,
    b. Sight of wider patient notifications would be required, e.g. poster,
    c. Further information would be required around how the dissent mechanism would be managed including detail around how patients would raise a dissent (website, phone, email etc.) how this would be managed and by whom.
6. Confirmation of IG Toolkit assurance is required for both University College Hospitals London and Dendrite Ltd. on version 14, 2016-17.
7. Confirmation of a REC Favourable Opinion.

Once received, the information will be reviewed by a sub-committee of the original reviewing 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.

**Specific Conditions of Support (Provisional)**

1. Support extends to England and Wales only.
2. Public and Patient Involvement and Engagement – provide a report at first annual review around further activity which has been undertaken in this area, together with updated plans moving forward.
3. Favourable opinion from a Research Ethics Committee. **(Pending).**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Pending).**

## 6. MINUTES OF THE MEETING HELD ON 08 JUNE 2017

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

## 7. CAT OFFICE REPORT

The Confidentiality Advice Team Office Report for June 2017 was circulated ahead of the CAG meeting. The following key points were noted.

**Ellen Lim – Resignation**

Following an extended break in service from the CAG, Ellen has tendered her resignation as CAG Member, due to family commitments and work pressures. Thanks were extended to Ellen from the CAT and the CAG for her input and support during her time as member.

**Meetings**

**CareCERT Design Authority Meeting – Wednesday 28 June 2017**

This is a working group established to look at the replacement of the Information Governance Toolkit. The key outcome from the above meeting was confirmation around the security assurance requirements for this financial year (2017-18). It was clarified at the meeting that Version 14.1 of the NHS IG Toolkit was the expected standard to be completed for this financial year 2017/18. Assurance for CAG application purposes would be compliance against Version 14, 2016/17.

**Wider Updates**

**ICO View on Google DeepMind**

The ICO published its view of the interaction between the Royal Free London NHS Foundation Trust and Google DeepMind. The report covers the following key points:

- Lack of a lawful basis because of the failure to satisfy the common law duty of confidence
- Lack of fairness and transparency
- The Royal Free being unable to argue a case for relying on a Schedule 2 condition to justify their processing.
- Apparent failure of the Royal Free to produce a case for processing sensitive personal data by relying on Sch 3 para 8 of the DPA (which provides for the processing of such data without consent where it is for broadly defined medical purposes).
- Strong criticism for not undertaking a Privacy Impact Assessment (PIA)
- Probable implications for prior consultation/approval by the ICO under the GDPR

- Despite the scale of the breach (1.6m records) the ICO stopped short of formal legal Enforcement action (for now) with the Royal Free being required to sign an undertaking.

## 8. CAG CHAIR REPORT

The Chair's Report for June 2017 was circulated ahead of the meeting. Members received the report and no issues were raised.

## 9. ANY OTHER BUSINESS

### a. Education Items

The Chair has requested that a standing agenda item around education items being reintroduced to the CAG meeting agenda. This purpose was to allow the Group to discuss requirements and suggest topics for forthcoming agenda items.

Two suggested items were raised at the meeting. The first was the operational implications of the forthcoming General Data Protection Regulation (GDPR). A further request was raised in relation to a presentation which was given at the CAG meeting held on 22 June 2017 by Mr Martin Severs, NHS Digital around anonymisation. It was suggested that the CAG may benefit from a wider discussion of the presentation.

The suggestions were recorded by the CAT to be taken forward for discussion with the Chair team outside of the meeting.

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