Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

23 November 2017 at Barlow House, M1 3DZ

Group Members:

Name	*Present*	*Notes*
Dr Martin Andrew	Yes	
Ms Hannah Chambers	Yes	Lay
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Dr Lorna Fraser	Yes	
Ms Kim Kingan	No	Apologies received.
Dr Harvey Marcovitch	Yes	
Mr Andrew Melville	Yes	Lay
Dr Mark Taylor	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Apologies

Apologies were received in advance of the meeting from Ms Kim Kingan.

Declarations of Interest

17/CAG/0197 – Dr Lorna Fraser noted that her employing organisation, York Medical School, was involved with the application. Dr Fraser confirmed that she had not been involved with the application submission

and would not be involved in the undertaking of the project. The Group agreed that no conflict arose from the declaration and no further action was required.

2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State Approval Decisions

The CAG did not consider any non-research applications at the meeting held on 26 October 2017.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 26 October 2017 meeting applications.

3. AMENDMENTS

a. CAG 8-02 (a-c)/2014 Assuring Transformation Programme – Duration Extension Amendment Request

Context

Purpose of Application

A suite of three applications had been presented by NHS England, on behalf of Clinical Commissioning Groups, to reflect the different data flows involved in the initiative known as 'Assuring Transformation'. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of 'case management'. Case management had been defined at time of original consideration as activities by certain roles to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient's care and to ensure the appropriate support is provided.

Details around the final approval provided were set out in the letter dated 10 December 2014.

Amendment Request

The application was currently supported up to 31 March 2018. The amendment requested an extension to the duration of support in place for the application to 31 March 2020.

Confidentiality Advisory Group Advice

The applicants explained within the amendment documentation that the exit strategy which had previously been identified, collection of data via the Mental Health Services Dataset (MHSDS), remained the proposed plan for the activity. It was updated that the second release of the MHSDS was released in April 2017, within which the additional fields required for the Assuring Transformation programme were now included meaning there was now full coverage of the required data items in the MHSDS. It was explained that interim analysis had shown that some of the new fields which had been introduced were not yet being completed and the quality of data provided for others required improvement. The NHS England Learning Disability Programme Board currently relied on the data from the Assuring Transformation programme to monitor progress against the national transformation plan and to be kept up to date with the development and progress of the MHSDS. It was explained that the Board had taken the decision in September 2017 that it was not assured that the data within the MHSDS would reach the required standards by March 2018,

at which stage it had been agreed to apply for an extension to the duration of support provided under the Regulations for the Assuring Transformation Programme.

The CAG was assured that there continued to be an ongoing public interest in the application activity. It was acknowledged that the applicants had previously highlighted potential concerns around the integrity of the data which was being provided via the MHSDS in the 2016 annual review submission. It had been identified within the annual review submission that an amendment may be submitted to extend the Assuring Transformation programme; if it was determined that data collection via the MHSDS was not at the required standard.

Members commented that in providing a recommendation of support to the proposed duration extension which was requested, this would lead to a certain degree of dual processing of confidential patient information for the same purpose. It was identified; however, that this would facilitate identification of those institutions which were not completing the data return and enable direct follow-up with these organisations. The applicants had set out proposals within the amendment to explain how they planned to improve the data collection via the MHSDS. The Group commented that this follow-up should be undertaken proactively to achieve the proposed exit strategy from support under the Regulations.

The amendment requested an extension to the support in place for the application up to 31 March 2020. The applicants had indicated within the documentation that the overall programme was only expected to run until March 2019, but they were seeking an extension to March 2020, in order to mitigate any further potential issues with the data integrity within the MHSDS. The CAG stated that it could not provide a recommendation of support under the Regulations beyond the current scope of the approved programme. Members agreed that support for the amendment would be recommended to the decision-maker to 31 March 2019 only. A further amendment would be required from the applicants if a decision was taken to further extend the Assuring Transformation Programme together with supporting rationale at that time.

The Group discussed the importance of the data which had been collated by the Assuring Transformation programme and it was commented that steps should be taken assimilate this information into the MHSDS to ensure that this can be utilised in future, following the closure of the programme.

Members noted that the patient information materials which were produced for the programme had recently been updated in September 2017. It was agreed that a copy of the revised materials should be supplied at the time of next annual review for information purposes.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. The duration of support for the application activity is extended to 31 March 2019.
2. Plans to improve the quality and completeness of data submitted via the Mental Health Services Dataset (MHSDS) which were proposed within the amendment submission should be taken forward, with a view to achieving complete ascertainment within the current scope of support which is in place for the activity. An update would be required at the time of next annual review at the latest, or earlier as progress is achieved.
3. Steps should be taken to assimilate the data collected via the Assuring Transformation Programme into the MHSDS to ensure this is available for future use.
4. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – NHS Digital, Version 14, 2016/17 reviewed satisfactory).**

4. NEW APPLICATIONS – Non-Research

a. 17/CAG/0193 – UKRETS – United Kingdom Registry of Endocrine and Thyroid Surgery)

Context

Purpose of Application

This application from the British Association of Endocrine and Thyroid Surgeons sets out the purpose of a clinical audit into endocrine and thyroid surgery. The United Kingdom Registry of Endocrine and Thyroid Surgery audit was set up in 2004 to measure the quality of endocrine and thyroid surgery and to use that information to improve the quality of the surgery across the NHS for patients, commissioners and regulators of healthcare professionals. The audit outcomes also provide reassure to patients that the quality of clinical care is being actively monitored and improved. It audit has collected over 80,000 cases since its establishment in 2004.

Members of the British Association of Endocrine and Thyroid Surgeons record a number of outcome measures (as well as pre-operative and operative details) for each endocrine surgical operation performed including length of stay, mortality, voice change, hypocalcaemia (for thyroid and parathyroid surgery) and persistent disease (for parathyroid surgery). This data is transferred at the point of entry into a database which is maintained by Dendrite Ltd.

The application also stated that data will be requested from the HES dataset via NHS Digital around the number of surgical procedures undertaken; however, this would be requested in anonymised format only and would not involve the processing of confidential patient information to facilitate the data release.

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

Confidential Patient Information Requested

Cohort

All patients within England and Wales undergoing thyroid, parathyroid, adrenal or endocrine pancreatic surgery. This is approximately 8-9,000 patients per year.

The following items of confidential patient information will be entered by the direct care team into the web-based registry, maintained by Dendrite:

- NHS number (in England and Wales) – validation and follow-up of patients,
- Date of birth – validation (only available to the clinical care team) and analysis (age at procedure),
- Gender – analysis,
- Date of death (if applicable) – calculate length of stay for analysis
- Date of operation – validation and analysis.

Confidentiality Advisory Group Advice

Historic Practice

It was acknowledged that the audit had been in operation since 2004; however, it was unclear from the information provided within the application what the legal basis was under the common law duty of confidentiality to support the data processing up to this point. The Group agreed that further information was required from the applicant in relation to this point before any recommendation of support could be given to the prospective audit activity.

The applicants had provided an overview of previous correspondence between Dendrite Ltd., the data processor for the audit programme, and the Information Commissioners Office (ICO) around the audit practice at the time of set-up. It was stated that the past audit practice did not constitute a breach of the Data Protection Act 1998. The applicants further stated that this position had been regularly checked with the ICO who had provided reassurance against the original standpoint. Reference was made to a breach report which had been made to the ICO in relation to the National Bariatric Surgery Registry and the applicants stated that in this instance, the ICO advised that there was no requirement to report the data processing as a Serious Incident Requiring Investigation (SIRI). The CAG received the information which had been provided; however, it was noted that copies of this correspondence had been requested for consideration but had not yet been provided. Members agreed that sight of this historic correspondence would be required for review.

The applicants had identified in response to queries raised around the application that historically, the following items of confidential patient information were collected within the audit: date of birth, date of death and gender. Whilst it had been stated that these data items were only available to the patient's treating clinician, it was understood that these patient identifiers had been transferred to and retained by Dendrite Ltd. within the database. The Group stated that, if this understanding was correct, it appeared that confidential patient information had been disclosed outside of the direct care team. If this understanding of the historic practice was correct, Members recommended that the applicants discuss this with the ICO in the interests of transparency.

Healthcare Quality Improvement Partnership (HQIP) – Role within the Audit Programme

Members were unclear what relationship the Healthcare Quality Improvement Partnership (HQIP) had to the audit programme. The applicants had clarified that they, the British Association of Endocrine and Thyroid Surgeons, were appointed as data controller for the audit programme, rather than HQIP as with other national audit programmes. It was detailed within the application that the audit outcomes were published by HQIP on an annual basis; however, it was unclear whether HQIP commissioned the audit programme. The Group agreed that further information would be required from the applicants around these points to clarify the organisations responsible for the audit activity.

Retention of Historic Database

The Group was unclear from the detail provided within the application whether the request for support under the Regulations was intended to cover the ongoing retention of data which had been collected as part of the audit programme since its inception in 2004. Clarification was required around this point to ensure, if the CAG was of the opinion that support should be recommended to the application activity in future, this extended to all elements of the programme which required support under the Regulations. It was recognised that support under the Regulations could not be applied retrospectively to data processing which had already been undertaken.

Public Interest

The CAG acknowledged that the application defined a medical purpose through the audit of surgical procedures, which would fall within the category of the management of health and social care services. From the information provided within the application, Members were unclear whether the public interest in the activity had been clearly justified as it had been identified within the application that the audit was currently only achieving 50% case ascertainment. Further information was required from the applicants to support the public interest in the activity proceeding.

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 rationale supplied by the applicants to support why consent was not feasible for this audit programme focussed on the additional burden this would add to the clinicians involved in patient treatment and the difficulties in providing a uniform process due to the differing consenting practices which would be in place across Trusts within England and Wales which would be providing data to the audit programme. The Group considered this rationale; however, it was acknowledged that the endocrine and thyroid surgical procedures were generally elective and it would be anticipated that the consent required for this would be undertaken at pre-operative clinic. In light of this, the CAG agreed that it was not assured by the rationale provided by the applicants that consent could not be achieved for the audit programme, though it was acknowledged that a period of support under the Regulations was initially likely, whilst the applicants progressed with the consenting model.

Members considered the patient notification system and it was acknowledged that patients would be provided a copy of the information leaflet which referenced the right to opt-out of data collection for the audit purposes. It was suggested that, if patients will be provided with the leaflet for consideration and enabled with an opportunity to opt-out, this contact with patients could be formalised to include a consenting process. The Group acknowledged that there would be a lead-in period required in order to formalise this process and was minded, if a recommendation of support was to be extended to the application activity, to make recommendation on a time-limited basis as consent was achievable as a practicable alternative to seeking support under the Regulations for the activity. It was recognised that moving towards a consented model was in keeping with recent precedent of recommendations of support which the CAG had advised against similar application activity.

- Use of anonymised/pseudonymised data

It was acknowledged that access to confidential patient information was required to facilitate linkage and validate the sample, as well as enabling patients which undergo multiple procedures to be followed through the audit. The CAG was assured that these actions could not be undertaken without processing confidential patient information.

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 were satisfied that the identifiers which had been requested by the applicants were appropriate and justified in order to achieve the activity as set out in the application.

Proposed Future Data Linkage

It had been advised within the application that the future direction of the audit programme may look to link with wider oncological outcomes from cancer surgery, which was not currently part of the application scope. Members noted this potential intention and explained that any proposed future linkage would need to be submitted as an amendment to the proposal, should it reach a recommendation of support for the activity. The CAG acknowledged that potential future linkages had not been fully described within the application; however, it recommended that the applicants reconsider the data items which were proposed to be retained to facilitate this. Past experience suggested that linkage with national datasets would require additional items of data to supplement NHS Number in order to facilitate linkage.

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 an informal survey had been undertaken with patients around the proposed audit activity and the results reported were in the majority very supportive of the activing. Members further identified that the applicants had engaged with relevant charity organisations and patient groups which were invited to attend the UKRETS annual meeting. The CAG was assured that the involvement and engagement activity was relevant and appropriate to the proposed activity. The applicants had identified that they would continue engage with these groups as the audit programme progressed and Members agreed that feedback from this activity would be required, if the project reached a recommendation of support, at the time of annual review. If the responses given from the engagement activity were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

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 submitted an information leaflet which facilitated patient notification. Within the flowchart which supported the study, it stated that this was provided to patients to enable questions to be raised about the audit programme and to facilitate objection. Members considered the supporting detail around this which was included at section (p) of the application form, where it was written that the leaflet would be promoted by surgical units and also be available to download from the audit website. The Group commented that it was unclear whether every patient undergoing relevant surgery would receive the information sheet and agreed that confirmation around this was required.

When considering the content of the document, Members agreed that information in relation to the patient's right to opt-out of the programme should be made more prominent earlier in the document. It was also agreed that the document would benefit from revision to make this more accessible to all patients and it was agreed that this rewrite would be well-informed by engagement with patients. The applicants had raised concerns around the requirement to include reference to the collection of date of death within the information sheet, as this was an incredibly rare outcome, but may cause distress amongst patients. The Group considered this request and it was agreed that, rather than refer directly to date of death, the document should provide an explanation that the audit would collect information around the clinical outcomes of the surgical procedures. It was also noted that the document should advise that patient's NHS number will be collated as this was not currently referenced. The CAG agreed that an updated information sheet should be supplied for consideration by Members.

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 Secretary of State, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for Further Information

1. Historic Practice of the Audit Programme – further clarification is required around the history of the activity as follows:
    a. Confirm under what legal basis in relation the common law duty of confidentiality confidential patient information has been processed to facilitate the audit programme,
    b. Provide a copy of the historic correspondence with the Information Commissioner's Office (ICO) around the audit programme in which they clarified that the data processing which had been undertaken did not involve a breach of the Data Protection Act 1998,

c. Clarify whether confidential patient information (date of birth, date of death and gender) has been retained by Dendrite Ltd. in relation to the patients (circa. 80,000) which had already been entered into the audit programme database. If this is the case, it is recommended that this data retention is discussed with the ICO in the interests of transparency and to ensure compliance against the DPA.

2. Further rationale is required to support to the public interest in the audit activity. The following points should be considered in the response:
   a. Specific reference should be made to the current ascertainment rate of the audit and what steps will be put in place to improve this in order to produce an effective national programme.
3. Clarification is required around the role of Health Quality Improvement Programme (HQIP) in the audit activity. Response is required to the following issues:
   a. Confirm whether the audit programme is commissioned and funded by HQIP,
   b. If so, clarify who is acting as data controller for the application activity.
4. Scope of Support – clarify whether the request for support under the Regulations is intended to extend to the retention of the audit database to date.
5. Patient Notifications and Dissent – further information is required around how the audit programme will be promoted to patients and within the public domain together with the materials used to achieve this communications. Further response is required as follows:
   a. Provide further information around how information for the audit is provided to patients.
      i. This should include clarification around whether every patient who undergoes thyroid or other endocrine surgery will receive a copy of the information leaflet,
      ii. How the website is promoted – though it was referenced that electronic materials alone were not a sufficient notification system.
   b. The patient information leaflet requires further revision as follows:
      i. The information around the patient's right to opt-out should be made more prominent and brought forward to an earlier place within the information sheet,
      ii. Date of death does not need to be directly referenced in the document; however, patients should be informed that wider clinical outcomes from the surgical procedure would also be collated as part of the audit,
      iii. The document should advice that NHS Number will be collected,
      iv. It was agreed that the document required revision to make the text more accessible to the wider patient audience. It was recommended that patients were approached to assist with this revision,
      v. The revised document should be submitted for consideration by the CAG.

Specific Conditions of Support (Provisional)

1. Support under the Regulations would be extended on a time-limited basis whilst work is undertaken to progress to a fully-consented model for inclusion within the audit programme. An update would be required at the time of annual review around the activity which has been undertaken to progress with the consenting model.
2. Patient and Public Engagement and Involvement – ongoing work should be undertaken with the relevant charities and patient groups which were referenced with the application as the audit programme continues. A report would be required at the time of first annual review around the activity which had been undertaken here, together with any relevant feedback. If the responses provided from the patient and public involvement and engagement activity were negative, the CAG would take this into account when considering whether support for the activity could continue or whether any additional actions are required.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – Dendrite Ltd. shows a reviewed satisfactory grade on Version 14, 2016/17)**.

5. NEW APPLICATIONS – Research

a. 17/CAG/0194 – SUMMIT Study

Context

Purpose of application

This study from University College London sets out the purpose of medical research to investigate the feasibility of introducing low dose computed tomography (LDCT) screening to a group of adults at high risk of lung cancer. Potential participants will be identified from their GP records by a member of the UCLH study team, attending individual practices, as current or ex-smokers between the ages of 55 and 80 years. Potential participants will be sent an invitation letter. A sub-group of patients will also be sent a separate paper questionnaire on screening uptake. Potential participants' information, including age, sex, ethnicity, smoking status, and index of multiple deprivation score and rank, will be collected and linked to LHC attendance data. By analysing those who attend and those who do not, the applicants hope to understand what factors might influence whether or not a participant attends a LHC. Uptake is one of the primary objectives for this study and it is essential to understanding the population impact of a future UK LDCT screening programme. The application has been made to the CAG in order to allow the research team access to GP record systems in order to identify and invite potential participants to the study.

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

Confidential Patient Information Requested

Cohort

1. Individuals aged 55 to 80 years within the North Central and North East London area, who meet either of the following criteria:
a. Have a history of at least 30 pack years of smoking (or at least 20 years duration), and if former smokers, have quit in the past 15 years
b. 6-year lung cancer risk of $\geq$1.3%.

Approximately 50-75,000 patients from 600 GP practices will be invited to recruit 25,000 participants. If the enrolment figure is not achieved, the applicants state that there are further 25-50,000 patients in the geographical region who will be eligible. The applicants have requested support for collection and storage of data to extend up to a maximum of 100,000 individuals but will ensure this is kept to as few as possible to achieve the target recruitment.

In addition, all individuals eligible for invitation to the initial Lung Health Check appointment will be included in the uptake study (pseudonymised data on demographic characteristics and smoking status, and the screening uptake and behaviour questionnaire).

The following items of confidential patient information will be extracted from GP records:

- Full Name and Title – to facilitate invitation,
- Date of Birth – translated to age for analysis,
- Full Address – to facilitate invitation,
- NHS Number – for linkage (undertake with consent),
- Gender – analysis,
- Ethnicity – analysis.

Wider linkage will be undertaken via NHS Digital with HES and cancer registries but only for those patients who consent to participate in the trial so this is out of scope of the request for Regulation support.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined a medical purpose through medical research. The Group considered the public interest in the activity and it was commented that implementation of the screening programme into the NHS environment would bring about public benefit through the potential for earlier cancer diagnosis. Members discussed the recent announcement in the press that, following the success of the Manchester Lung Health Check Pilot, NHS England had confirmed that the mobile lung cancer screening units would be rolled out across other areas of England, including London. The Group was unclear how this proposed research study would complement rollout of the same technology as a national screening programme. It was further noted from the patient facing documentation which had been submitted alongside the application that patients would only be eligible for the low dose CT scan if they agreed to undergo the wider study procedures. The Group agreed that further information would be required from the applicants in this area, as it was noted that patients should be made aware if they are able to access the same screening procedures, without needing to undergo the wider trial procedures.

Members recognised that the study was funded by an American company, Grail Inc.; however, what was unclear from the documentation was whether this organisation were funding all trial procedures, including the mobile screening units, or whether elements of the project were facilitated by the NHS. The secondary objectives for the study appeared to be linked to finding a biomarker for lung cancer within the blood samples taken from patients. This element of the study was being undertaken by Grail Inc. The CAG agreed that it was important to understand these details in order to understand the overall public interest in the study as it was unclear whether the study results would be shared widely and what the publication arrangements were. It was also commented that patients should be made aware of the commercial interests in the project. The Group agreed that further information was required in this area prior to considering whether support could be recommended for the project.

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 proposal was a participant identification study, whereby confidential patient information would be accessed with support under the Regulations in order to identify the cohort of patients to be invited to participate in the trial. The applicants had explained that consent was not feasible from the outset due to the number of patients which would need to be invited to undergo a Lung Health Check in order to achieve the required sample size of 25,000 patients. All patients that attend for the screening will provide formal consent to participate in the study. The Group was assured by the rationale to support why seeking consent prior to the processing of confidential patient information was not feasible in this instance.

- Use of anonymised/pseudonymised data

The CAG recognised that access to confidential patient information was required in order to invite patients to participate in the trial.

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 requested were appropriate and proportionate to undertake the proposed activity.

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. For eligible patients who attend a Lung Health Check and are eligible to participate in the study, formal consent would be taken and this was the established exit strategy from support under the Regulations.

For patients who are invited to participate, but which do not respond, the applicants intended to retain confidential patient information for a period of 15 months, which mirrored the overall recruitment period for the trial. Within this time period, up to three communications about the project would be sent. Members considered the proposed retention period of 15 months to be quite extensive and it was agreed that this should be reduced to a period of six months, unless a stronger justification could be provided by the applicants.

The applicants had stated that they intended to retain data on all patients which were invited to the lung health check. The Group considered the third sub-group of patients, which had attended a lung health appointment but had been found to be ineligible for enrolment in the study and were not offered the low dose CT screening scan. Members were unclear why this patient cohort could not be informed of the project and provide consent for the retention of their demographic and basic clinical data within the study database, being that they were present at the appointment. Further rationale would be required to justify why this was not feasible.

Data Storage and Access Arrangements

It was identified within the application that the applicants intended to store trial data on Amazon Web Services servers, rather than NHS or University servers as would usually be expected. Members were not assured by the rationale supplied by the applicants to explain why these data storage arrangements had been chosen over the usual storage on NHS/University servers. The examples of other large-scale research which used Amazon data storage which had been referenced by the applicants were both American projects. The CAG requested further rationale to support why NHS or University systems could not be used for this specific project, as it was acknowledged that this was the standard in past submissions from the applying organisations.

The CAG considered the information which had been provided describing how the Amazon Web Services fit into the UK health care environment; however, it was commented that evidence of assurance, when recommending support under the Regulations, was taken from a satisfactory IG toolkit submission, which was still pending. It was queried where the Amazon servers were located on which it was proposed that study data would be held and clarification would be required from the applicants.

The Group considered the wider information around the use of Amazon Web Services and it was queried what the data controllership arrangements were for information which was stored on the Amazon cloud, as it was suggested in some of the supporting literature that responsibility was shared with Amazon, which did not appear appropriate. Further information was required around these arrangements.

The CAG noted that there was potential for software support engineers from GRAIL Inc. to access confidential patient information, if there was an issue with the software which required resolution. Members recognised that this organisation were based outside of the EEA and as such, would not be able to access confidential patient information with support under the Regulations. It was further commented that it was unclear why engineers involved in the maintenance of the IT software would need access to the raw data which was retained in the database. Having considered these points, the CAG agreed that clarification was required around why it should be necessary for GRAIL Inc. employees to have access to confidential patient information and where the data would be held if that were necessary.

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 were assured that the activity which had been undertaken in this area was relevant and proportionate to the proposed trial. It was recognised that the trial steering Committee had lay representation and there would be ongoing engagement with patient and public involvement members around the interpretation of the trial results. The CAG was satisfied with this ongoing representation and raised no further queries 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 stated that it was not possible to operate a patient notification system for the project, as this would potentially create an increased workload for the GP practices participating in the trial, through ineligible individuals enquiring about the study. The CAG was not assured by this rationale and it was agreed that a study-specific notification system was required for the trial, in order to promote the study within participating GP practices and allow patients to register a dissent against researchers accessing their confidential patient information for research purposes. It was commented that the communications strategy for the project should be designed in such a way that information is displayed in practices in advance of data extraction, so patients can opt-out in advance of their data being accessed. Members commented that the information materials would need to make the research purposes clear, to ensure that those who have opted out of contact around research would understand they would not be invited to undergo a lung health check. It was further commented that it should be made clear that raising an objection to the project was in relation to research only and not national screening programmes. The CAG agreed that sight of the documentation would be required before any recommendation of support could be given for the project.

The Group considered the invitation letter which patients would receive around the lung health check. It was agreed that the document required some revision to clearly explain to the recipient that non-response to the invitation would lead to ongoing retention of their data for the specific time period, to enable those who object to this to raise a formal objection. It was noted that the document also directed patients to the study website for further information and Members agreed it would be helpful to see the content of these pages to see what additional information was being provided to patients.

The Group reviewed the wider patient information and consent materials which had been shared for information purposes. Whilst it was acknowledged that consideration of these documents was the responsibility of the REC, Members identified that NHS Digital had been incorrectly referenced as the Health and Social Care Information Centre, which was an outdated reference. It was recommended that the applicants correct this in the final study documentation.

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 evidence of submission of an IG toolkit for Amazon Web Services could not be found. 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 against Version 14, 2016/17 of the IG toolkit. This would need to be addressed by the applicant together with the external data storage provider.

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. Evidence of the favourable ethical opinion would need to be supplied before any recommendation of support could be extended to the project.

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 thorough the application that it is consistent with the DPA. It was advised for information purposes that confidential patient information could not be transferred outside the EEA with support under the Regulations. As it was the intention to send study data to the USA, the applicants were reminded that this could only be actioned with the individual's formal consent to do so.

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 (Summary)

The following information should be provided to allow the CAG to continue their consideration of the application. This should be submitted in the form of a detailed covering letter, together with any supporting documentation and a revised CAG application form. Details provided below are a summary of the wider considerations detailed above the in the advice section.

1. Further information is required in order to establish the public interest in the application activity – provide response to the below points:
    a. Clarify how the proposed research study will fit in with the roll out of low dose CT scanning as a national screening programme,
    b. Provide further detail around what elements of the study are funded by Grail Inc. and what involvement the NHS has in these,
    c. Provide an overview of the publication arrangements for the trial results.
2. Retention of data for non-responders – the duration that confidential patient information is retained on patients who do not respond to the invitation should be reduced to six months. Provide confirmation to this and revise documentation accordingly, or provide a stronger rationale to justify the extended 15 months retention period.
3. Retention of demographic and clinical data for ineligible patients who attend the lung health check – this patient group should be asked to provide consent for the retention of the data gathered about them to the point at which they were deemed ineligible for inclusion in the full trial – provide confirmation to this point and submit the revised documentation necessary to support this revision. Alternatively, further rationale should be provided to support why these individuals cannot be consented for the retention of data which had been gathered about them to this point.
4. Data storage arrangements – further information is required around the data storage arrangements for the trial as follows:
    a. Provide further rationale to support why Amazon Web Services had been chosen for data storage facilities, over the standard NHS or University servers,
    b. Clarify where the Amazon Web Services servers are located,
    c. Confirm what the data controllership arrangements are in respect of data which is stored via Amazon Web Services,
    d. Provide further information around why it would be necessary for employees of Grail Inc. to access confidential patient information when undertaking maintenance work on the database.

Clarification was also required around where the data would held which would be accessed by the GRAIL Inc. staff.

5. Patient Notification and Dissent – a system should be established to promote the study in the relevant public domain in order to inform potential individuals of the project and facilitate objections. The following points should be addressed:
   a. Study-specific information should be displayed in participating GP practices to promote the trial activity,
   b. Information should be displayed with a lead-in time ahead of data extraction, to enable patients to register an objection against the trial and prevent their data being shared with the research team,
   c. Documentation should make it clear that the activity is for research purposes and that any objection raised would be in connection to the research project, not the national screening programmes,
   d. Copies of the documentation to be used to facilitate this programme are required for consideration by the CAG, together with an overview of the communications plan detailing how this would be carried out,
   e. Study website text should also be provided for consideration.
6. Submit a revised patient invitation letter to address the following points:
   a. Clearly inform patients that non-response to the letter, in either a positive or negative manner, would still result in their confidential patient information being retained by the research team. Clear guidance should be given around how an individual can object to this.
7. Evidence of a favourable ethical opinion from an NHS REC is required.
8. Evidence of a satisfactory NHS IG Toolkit submission, as reviewed by NHS Digital, is required in relation all organisations which will be receiving or processing confidential patient information with support under the Regulations. Assurance in relation to Amazon Web Services remains outstanding.

Recommendation

1. It is recommended that participant information materials are revised to update the references to the Health and Social Care Information Centre (HSCIC) to NHS Digital.

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

b. 17/CAG/0197 – Bowel Scope Screening: Interventions to Increase Uptake In Yorkshire

Context

Purpose of Application

This application from University College London sets out the purpose of medical research which aims to investigate whether GP practice based interventions can help increase the uptake of bowel scope screening in Hull and other parts of Yorkshire. Over a six month period, individuals due to receive their NHS Bowel Scope Screening invitation (identified through GPs) will be randomly be assigned to one of three groups with attendance monitored and compared between groups:

1. Usual care: no contact from GPs.
2. Primer and self-referral letter: A letter advising of the future delivery of a BSS invitation will be sent by the individual's GP, along with a locally tailored leaflet explaining the test. If the practice receives notice that an individual did not attend their appointment, a letter highlighting the self-referral process will be sent.
3. Primer and patient navigation: As above, a letter and leaflet will be sent ahead of the NHS BSS invitation. If the practice receives notice that an individual did not attend their appointment, a call to the individual will be made. This call will aim to identify and address personal barriers to uptake and, if appropriate, help arrange a new appointment. If no telephone contact is possible, a self-referral letter will be sent.

Support under the Regulations is required to facilitate groups two and three as the additional patient contacts which are detailed in these two options will involve sharing confidential patient information outside the direct care team without consent.

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

Confidential Patient Information Requested

Cohort

1. Patients aged between 55 years and 21 days and 55 years and 48 days at the time they are enrolled in the study, who are registered with a GP practice participating in the trial.
2. Patients will be excluded from inclusion in the study if they:
   a. Have had their large bowel removed.
   b. Have a stoma bag to collect their stool.
   c. Are currently being treated for inflammatory bowel disease (i.e. ulcerative colitis, Crohn's disease, etc.).
   d. Are awaiting heart surgery or who have had heart surgery in the last three months.
   e. Have been diagnosed with cancer (any type) in the last 12 months.
   f. Are registered on their GPs clinical system as a type II objector/opt out.

The following items of confidential patient information are requested from the patient's GP record:

- Full name – to enable intervention materials to be sent,
- Full Address – to enable intervention materials to be sent,
- NHS Number – to facilitate linkage via NHS Digital,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that that the application defined a medical purpose through medical research. Members were satisfied that there was a public interest in the overall activity as there was the potential to increase uptake of bowel screening by using the trial intervention methods.

Scope of Support

The CAG considered the application activity and it was noted that there were three elements of the project which appeared to present a breach of the common law duty of confidentiality which would require support under the Regulations in order to legitimise the processing of confidential patient information.

The first element was the sharing of confidential patient information from GP practices with MailaDoc to facilitate the circulation of the intervention materials on behalf of the research team. The applicants had requested that support be extended to cover this activity. Members were in agreement that this represented a breach of the common law duty of confidentiality and support would be required under the Regulations to legitimise the data processing to facilitate this activity.

The second element of the project activity involved GP practices sharing NHS Number with NHS Digital to facilitate longer term follow-up of the patients participating within the trial. The applicants were currently seeking clarity from NHS Digital as to whether they required the establishment of a legal basis to legitimise the data processing for this activity. The CAG agreed that the outcome of the engagement with NHS Digital was required before any recommendation of support could be extended for the project under the Regulations.

The third element of the application activity which appeared to present a breach of the common law duty of confidentiality was around the role of the Research Nurse and Research Assistant who would be appointed by Hull York Medical School to work within the participating GP practices to facilitate contact with patients around the project. The applicants had stated these individuals would have honorary contracts to work within the GP practices as part of the direct care team and such, did not require support under the Regulations to legitimise their access to confidential patient information without prior patient consent. The CAG considered this rationale and it was acknowledged that in certain circumstances, Research Nurses were legitimately part of the direct care; however, being appointed by honorary contract was not sufficient to legitimise the relationship with the patients. The Group recognised that the Research Nurse and Assistant who were involved in the study were being appointed solely for the purposes of the research which did not present a legitimate relationship with the patients involved.

When considering an application, the CAG takes the perspective that a member of the direct care team is someone that a patient or service user would reasonably recognise to be as such, by delivering specific interventions as part of providing 'direct care'. This view is informed by detail within the publication 'Information Governance Review' (March 2013), authored by Dame Fiona Caldicott, the National Data Guardian, which states "*Direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers. Relevant information should be shared with them, when they have a legitimate relationship with the patient or service user*". The Group recommended that the applicants reconsider the position in relation to this element of the application activity.

Members agreed that as the scope of support which had been requested under the Regulations did not appear to extend to all activities described within the application which presented a breach of the common law duty of confidentiality, a recommendation of support could not be considered at this time. The applicants would be required to reconsider which elements of the application activity required support under the Regulations and resubmit the application detailing all elements. This was to ensure that, if a recommendation of support was extended to the application, this recommendation covered all elements of the application activity which required the establishment of a legal basis to legitimise the data processing.

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 explained that by introducing an informed consent process, this was likely to bias the sample included in the study due to the potential stigma attached to bowel scope screening. It was stated that the target patient cohort which the study aimed to help were likely not be included should a consented model be operated. Members considered the rationale provided and were assured that seeking consent for the project was not feasible on the basis of the rationale provided.

- Use of anonymised/pseudonymised data

The Group was assured that the project could not proceed without access to confidential patient information as this was required in order to post the trial intervention materials to 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 CAG was assured that the identifiers which had been requested were appropriate to undertake the application activity. Members

raised a query around the study linkage which would be undertaken by NHS Digital, which it is proposed will be via NHS number alone. It was recommended that the applicants seek confirmation from NHS Digital that the required linkage could be facilitated by NHS Number only, as past experience showed that another patient identifier was generally required.

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 applicants had stated that support under the Regulations would be required for a maximum period of 13 months, at which point analysis would be undertaken on a pseudonymised dataset. The third party mailing company which was involved in issuing intervention materials to patients would only retain confidential patient information for a maximum of 30 days, at which point it would be deleted. The CAG was assured by the processes which were in place for the project and no issues were raised in this area.

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 were undertaking further patient and public engagement activities and it was identified that the acceptability of using confidential patient information without consent for the application purposes would be discussed as part of these interactions. It was agreed that feedback from these activities would be required before any recommendation of support under the Regulations could be considered. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

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 Group acknowledged that the applicants were still in the process of developing the patient materials to be used in the project and documentation which had been provided was in a draft format. Members were satisfied with the communications plan, which included display of information on both the University College London and Yorkshire Cancer Registry websites, as well information within participating GP practices. In considering the content of the documentation, the Group agreed that the poster which had been provided for GP practices was too complex. It was suggested that a simpler documentation could be provided for display as a poster, which could be supplemented by a leaflet for interested patients to take away. It was agreed that comments would be fed back to the applicants to support the engagement work which was being undertaken with patients and the public around the redrafting of the documentation.

It was acknowledged that Type 2 objections were being applied to the patient cohort sample from the outset, of which the Group was supportive; however, it was commented that the information materials used to inform patients about the project should be clear that this objection applied to research only and invitations to the national screening programmes would still be received.

The CAG agreed that sight of the finalised documentation was required prior to any recommendation of support being 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 Information Governance toolkit compliance. It was noted that an IG Toolkit submission was underway for MailaDoc Ltd.; however, this was not yet finalised. 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. Confirmation of a favourable ethical opinion would be required prior to any recommendation of support under the Regulations coming into effect.

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 (Summary)

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

1. Clarification is required around the scope of support which is required under the Regulations, accounting for the three elements of the application which presented a breach of the common law duty of confidentiality. The outcome of interaction with NHS Digital should also be provided for information purposes.
2. Clarification should be sought from NHS Digital that the proposed data linkage can be facilitated on NHS Number alone. Provide response and if necessary, clarify any additional patient identifiers which will be required to facilitate this.
3. Patient and Public Involvement and Engagement – feedback should be provided around the activity which has been undertaken in this area, with a focus on testing the acceptability of using confidential patient information without consent for the application purposes. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended for the activity, or whether further actions are necessary.
4. Patient Notification and Dissent – sight of the final draft of documentation to be used to promote the project within the public domain is required prior to any recommendation of support being considered for the application. The following points should be taken into account:
    a. The poster for display in GP practices is too complex in its current format and would require revision to make this more accessible,
    b. It was recommended that the simplified poster is supplemented with an information leaflet which interested patients could take away,
    c. Materials should make it clear than any objection raised would be in relation to the project, rather than the overarching screening programme.
5. Assurance of NHS IG Toolkit compliance is required for MailaDoc Ltd. prior to any recommendation of support being put in place for the application activity.
6. Evidence of a favourable ethical opinion is required from an NHS REC prior to any recommendation of support being put in place for the application activity.

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

6. MINUTES OF THE MEETING HELD ON 26 OCTOBER 2017

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

7. CAG CHAIR REPORT

The Chair's Report was not available for consideration at the meeting.

8. ANY OTHER BUSINESS

No further business was raised.

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