NHS
Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

8 September 2017

Present:

Name	Capacity	Items
Mr Anthony Kane		1a, 1b
Ms Sophie Brannan		1a, 1c
Dr Patrick Coyle		1a, 1b, 1c
Ms Hannah Chambers		1b
Dr William Bernal		1c

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0133 Data quality on shared information

Purpose of application

This research study from the University of Sheffield was to be completed as part of an MSc in Health Informatics. It set out the purpose of improving communications between agencies via the electronic health record (EHR) completed by the patient's GP. The study would examine GP records for 'highlighted' information (information recorded on a summary or flagged as a problem – which is shared with other organisations). This would enable comparison between primary care practices in relation to data shared with secondary care services, quality of records and what GPs consider important and relevant to share. The information shared by primary care services would inform decisions taken by professionals and was therefore important to patient care. The study would enable an informed discussion to be had within the healthcare environment in relation to the quality of GP record keeping and information sharing and any inconsistencies between practices.

Although patient identifiable data would be accessed during the process of the data collection, the aim was to examine the process and quality of record keeping rather than to

gather data on patient diagnoses or outcomes. This is consistent with Precedent Set category 10 - Incidental disclosures of identifiable information made to an applicant who is observing practices and procedures within a health and social care setting.

A recommendation for class 1 and 6 support was requested for the process of extracting and anonymising the information, and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from participating clinics in relation to 1000 patient records of patients aged 18 to 70.

The researcher would access 'highlighted' information on the patient electronic record: information which is shared with other agencies. This extract would be anonymised onsite however the researcher wished to retain a link to the practice from which the data originated.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated a medical purpose. Previous research had found that problems with the electronic record could lead to negative consequences for 1 in 5 patients, and the applicant stated that there was little work in this area to date. Members were aware that there was frequent criticism of the effectiveness of communications between health service providers, and agreed that there was a clear public interest in undertaking this work to identify what a 'good summary' looks like and to address variations.

Practicable alternatives

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

- Feasibility of consent

Members agreed that consent was not practicable due to large numbers which would make the administrative burden disproportionate.

- Use of anonymised/pseudonymised data

Members observed that the applicant had considered the 'sitting in' method, but stated that it would not be possible due to limitations in staff resources and software. As the data harvester was a local serving GP it was agreed that the proposed level of intrusion was acceptable.

The applicant would anonymise the data onsite. The project focused on the quality of records and would not refer to individual conditions.

Justification of identifiers

Members agreed that the information to be extracted was justified for the purpose of the study. Diagnostic codes and the GP practice identifier would be included for the purpose of analysis and retained for up to 3 months. The Sub-Committee agreed that the risk of re-identification of a patient from this information was remote.

Additional points

Public involvement

Although not answered on the IRAS form, the applicant had later responded to a query about public involvement on the advice form. Members accepted this response.

Patient notification and dissent

The applicant provided a poster and leaflet to be used at each participating practice, which was reviewed by members and deemed appropriate.

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.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) 17/CAG/0144 PPH Butterfly

Context

Purpose of application

This research application from the University of Liverpool set out the purpose of testing a device designed to halt post-partum haemorrhage (PPH), as an alternative to the current invasive manual methods of treatment.

PPH is a major problem, killing 140,000 women worldwide each year. Although few women die in the UK, it can result in significant difficulties such as weakness through anaemia, delayed recovery and psychological trauma which can in turn affect bonding with the baby. This Phase 2 clinical trial aims to test a device designed to replace the standard manual method of stopping PPH. The device has already been tested in healthy volunteers; this phase would trial the device on women undergoing PPH.

In addition to testing the efficacy and safety of the device, the research would evaluate the cost of the new intervention relative to the cost of standard treatment and would collect information about the delivery and subsequent clinical pathways followed in order to do

this. To compare the new intervention with standard treatment, the researcher wished to access medical records without consent in order to identify a matched historical cohort and extract clinical information for analysis. Each study participant would be matched with two 'control' women for parity, mode of birth, blood loss, and experience of PPH to the nearest time and date 2 years prior to the study event.

To find these women, the hospital information team would search the patient record system and pass the details of eligible women to the research team (via the Hospital Records Team who would identify the patient via the hospital number, then deliver the case notes to the Research office at the hospital). The research team would access the full medical record in order to extract data.

A recommendation for class 1 and 6 support was requested for the purpose of extracting and anonymising the data and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from Liverpool Women's Hospital in relation to the control group: women identified from hospital records and matched to individuals within the study group for parity, mode of birth, blood loss, and experience of a PPH to the nearest time and date 2 years before.

The following data would be accessed during the identification of the control group:

- Hospital ID
- Date and time of delivery of baby
- Time of PPH
- Mortality and clinical data relating to mother and baby.

The applicant stated that baby's date of birth and time of delivery would be used only to identify the control group, and would not be used in analysis. Data would be anonymised prior to transfer to Bangor University Group.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application described a medical purpose in establishing whether the device was an improvement on the current manual method used to treat PPH, and that it was in the public interest to carry out this work and to determine the financial implications.

Practicable alternatives

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

- Feasibility of consent

Members considered the argument that to consent the historical group two years after their experience of PPH would be impracticable and would be an intrusion likely to cause distress. It was agreed that contacting participants would necessitate accessing further identifiable data in order to find them, and that some participants would experience distress on being reminded of their experience. Therefore members supported the decision not to seek consent from the historical cohort.

The HRA, in considering the feasibility of consent, asked whether a prospective design for the control arm had been considered, as this would enable the applicant to seek consent.

- Use of anonymised/pseudonymised data

Members commented that the data flows in the application were described in a contradictory fashion throughout the application, and that it had been difficult to distinguish between consented data flows (relating to the study cohort) and unconsented data flows (relating to the historical cohort, for which Section 251 support was required).

Further information was requested in relation to the data extracted from the medical records of the historical cohort. Although it was stated that the data would be anonymised before transfer to Bangor University, further clarity was required in relation to the data items to be extracted and the point at which the data would be fully anonymised.

Justification of identifiers

The Sub-Committee required a clear specification of the data flows including the data items recorded, and those to be transferred for analysis, in relation to the historical cohort, before they could comment on this aspect.

Additional points

Public Involvement

Members agreed that although the issue of no consent for historical patients had not been specifically addressed, adequate PPI work had been completed for the purpose of the study.

Patient notifications

Members agreed that reasonable efforts had been made to inform the cohort of the activity, and were satisfied with the patient notifications.

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.

Request for further information

1. The applicant was asked to provide a clear specification of the data flows including the data items recorded, and those to be transferred for analysis, in relation to the historical cohort.
2. The applicant was asked to provide justification as to why the control group was not designed prospectively, thus avoiding the requirement for Section 251 support.

c) 17/CAG/0159 Predicting flow to high acuity services from 111: Data analysis plan

Context

Purpose of application

This research application from The Behavioural Insights Team (BIT), commissioned by NHS England, set out the purpose of reducing potentially avoidable Emergency Department (ED) attendances to free up high-acuity resources. The study would focus on callers to the 111 service to determine why some of those who were told not to attend ED went on to do so in spite of this advice.

The study would consist of two parts. The first would be a quantitative analysis of data from 111 call records provided by NHS Digital as data controller in pseudonymised form (demographic data on patients and call handlers and call outcomes and call handlers). This data would be analysed to determine the characteristics of patients and call handlers most likely to lead to ED attendance after the 111 call.

For the second part of the study, qualitative analysis would be carried out on 200 recorded calls, linked to the record of service use soon after the call. Qualitative factors would include: the speed that advice is given with, opportunities to clarify the advice, planning discussions, the emotional tenor of the patient.

The sample for this would be drawn from the quantitative sample already provided by NHS Digital; all patients would have been advised not to attend ED – half would have attended nonetheless (and were subsequently coded as 'not needing treatment, advice or guidance) and half would be patients who did not attend ED. For this sample, the call recording would be requested from the 111 service provider as data controller.

BIT would be blinded to the outcomes of these calls during the qualitative analysis (i.e. they wouldn't know whether the call in question was one which led to an ED attendance). The researchers would develop coding strategies using a Grounded Theory Approach to thematically record the most salient features of these calls which were not already routinely quantified as part of the 111 process. Finally, they would compare the thematic coding of both groups in order to identify whether any of these qualitative factors could explain different outcomes in terms of where a patient seeks treatment.

A recommendation for class Class 1, 4 and 6 support, for the purpose of extracting and anonymising the information, to link patient identifiable data obtained from more than one source, and to allow access to an authorised user for the above purposes.

Confidential patient information requested

Access was requested to the disclosure of RAIDR data from NHS Data Services for Commissioners Regional Office (DSCRO) and from 111 services to NHS Digital, to allow a flow of linked pseudonymised data to the study team.

Following this, call records and linked data on subsequent ED attendance for 200 of these patients would be requested from the relevant 111 service for qualitative analysis of the call.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application described a worthwhile project which would be in the public interest. A medical purpose had been evidenced.

Practicable alternatives

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

- Feasibility of consent

Members were satisfied that consent was not practicable, due to the potential for bias to the study.

- Use of anonymised/pseudonymised data

Members were satisfied that access to identifiable data in order to listen to recordings of 111 calls was required for the purpose of the study. Access to this data was limited to a short time period; no identifiable data would be removed from the site.

Justification of identifiers

It was accepted that removing the identifiers from the call would result in the researchers being unable to assess important aspects of the call including establishment of a rapport

between caller and call handler, therefore access to all identifiable data disclosed during the call was justified.

Additional points

Public involvement

Although the applicant had not considered consultation with the public to be necessary for the activity described in the application, as patients would expect their calls to the 111 service to be listened to as part of audits of the service, members did not concur. The activity constituted a breach of the common-law duty of patient confidence and as such, all the usual CAG considerations applied. This was the case whether or not the researcher would re-allocate the call if it transpired that they knew the caller personally (another justification which had been provided within the application).

Therefore, public involvement work should be carried out to gauge the views of patients and the public in relation to non-NHS staff from BIT being able to access recordings of 111 conversations concerning clinical matters.

Patient notifications and objections

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.

As above, the Sub-Committee did not concur with the view that the usual CAG principle of patient notification and right of objection should be set aside for this activity. Public notification of the activity should be provided, allowing patients the opportunity to opt out. Copies of the patient notification should be provided to the Sub-Committee along with a description of how opt-outs would be respected.

Legal basis for flow of data from service providers to NHS Digital.

Members asked for further information regarding the legal basis for the flow of 111 pathway data to NHS Digital.

The applicant confirmed that data was routinely transferred from 111 service providers to DSCROs under s259(1) of the Health and Social Care Act 2012. This section also provided a legal basis for the linkage between the 111 pathway data and the SUS data.

Members accepted that a legal basis was in place for the 111 pathway data to flow from service providers to NHS Digital, and for this data to be linked with outcome datasets using NHS number. Provided SUS data was considered an outcome dataset, then support from the CAG was not required for this aspect of the study.

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.

Request for further information

3. Patient notifications to be provided along with method for respecting dissent
4. Public involvement requirement to be met and feedback provided to the Sub-Committee.

Specific conditions of support

1. Confirmation of Data Protection Registration was requested for VOCARE and London Ambulance Service.
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
   VOCARE – confirmed

   London Ambulance Service - required.

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

22 September 2017

Present:

Name	Capacity	Items
Dr Rachel Knowles		1a, 1b
Dr Mark Taylor	Chair	1a, 1b, 1c
Ms Gillian Wells		1a, 1b
Ms Diana Robbins		1c
I		1c

Also in attendance:

Name	Position (or reason for attending)
Ms Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0155 ARDA

Context

Purpose of application

This application from the Royal Liverpool and Broadgreen University Hospitals NHS Trust set out the purpose of developing a binary clinical decision tool to help patients and surgeons decide on the best treatment strategy for abdominal aortic aneurysm (AAA), based on the Aneurysm Repair Decision Aid (ARDA), which the study also sought to validate.

AAA is a ballooning of the main artery supplying the body; if this grows and ruptures, 80% of patients will die. However, there are risks associated with repair of the artery. ARDA, a custom-designed computer programme, provides information on the expected AAA growth rate and risk of rupture, the chance a patient will need AAA repair, the chance of the patient surviving the repair and the length of time of survival (5 or 10 years). The development of a binary clinical decision tool based on this programme could potentially maximise patient survival and facilitate cost-effective use of resources.

In order to validate ARDA and develop the clinical decision tool, support was required for access to retrospective data from the National Vascular Registry (NVR). The data would be transferred to NHS Digital who would link it with ONS mortality data before transferring a de-

dentified dataset to the research team at Royal Liverpool and Broadgreen University Hospitals for analysis.

A recommendation for class 1, 4 and 6 support was requested for the purpose of extracting and anonymising the information, to link patient identifiable information obtained from more than one source, and to allow an authorised user access for the above purposes.

Confidential patient information requested

Access was requested to data in relation to all patients included on NVR having undergone an elective AAA repair between 01/01/2012 and 31/12/2015, who were over 18 and have not undergone previous aortic surgery

The following data items would be transferred from the National Vascular Registry to NHS Digital:

- NHS number – to validate and link with mortality data
- Date of birth – to validate. This would then be truncated for analysis to MM/YY format

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a medical purpose and public interest in the defined purpose of developing a binary clinical decision tool, and validating the decision aid on which the tool would be based (the Aneurysm Repair Decision Aid ARDA).

Practicable alternatives

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

- Feasibility of consent

Members accepted the argument that to obtain consent would bias the study, given that many of the patients would be deceased and that death was the primary outcome for the study.

- Use of anonymised/pseudonymised data

Members accepted that identifiable data was required for linkage, which would be done via NHS Digital who would then de-identify the data prior to transfer to the research team for analysis.

Justification of identifiers

It was noted that the data requirements appeared minimal and therefore entailed a low level of risk.

Additional points

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 Sub-Committee raised issues in relation to the proposed notification and dissent process.

It appeared that any patient wishing to opt out would contact the researcher to have their data removed. Members queried how Professor Vallabhaneni would be able to identify the patient in order to do this, given that he would only receive de-identified data. It was agreed that the appropriate method would be for the patient to contact the NVR who could then ensure that their data was not transferred to NHS Digital in the first place. The patient notifications should be updated accordingly.

Public involvement

While commending the inclusion of a PPI member on the steering group, who was a representative of a PPI group, the Sub-Committee agreed that an additional member should be involved. These members should be regularly kept up to date with study progress so that they could feedback to the group.

Research results should be widely disseminated to consolidate the public benefit in the application.

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.

Specific conditions of support

1. The dissent process should take place via the NVR rather than the researcher, and patient notifications should be updated accordingly.
2. Public involvement on the research group should be strengthened. The Sub-Committee recommended two patient representative be regularly engaged in order to be able to update the patient group they represent
3. Favourable opinion from a Research Ethics Committee. **Confirmed**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
   Pending.

b) 17/CAG/0161 FAS

Context

Purpose of application

This research application from Leeds Teaching Hospitals NHS Trust aimed to determine the incidence in the UK and Ireland of Fetal Alcohol Syndrome (FAS), a specific condition with a clear case definition. (The study would not look at other paediatric disorders caused by alcohol exposure during pregnancy).

Fetal Alcohol Syndrome (sometimes known as FAS) is a rare condition which occurs when the developing baby is exposed to alcohol in the womb. Alcohol can cross the placenta into an unborn baby's blood stream, affecting the development of the brain, leading to challenges in learning and development. Alcohol can also affect the development of other parts of the unborn baby's body, particularly the face.

Expected benefits from the collection of accurate incidence data included an increase in clinician awareness of FAS which could aid accurate and timely diagnosis, improved education and greater awareness of FAS among health care professionals leading to more confident counselling of pregnant women regarding alcohol use. This would improve the care offered to affected children and enable prevention of the disorder in future siblings. The incidence data would also allow for the necessary resources to be allocated for the development of specialised services to diagnose and manage the disorder.

The study would use the BPSU methodology, an established methodology already approved in principle by the CAG. A reporting card system is used: every month an electronic reporting card with a list of conditions currently under surveillance is sent to consultants and other specialists, who return the card notifying the BPSU of any cases they have seen, or stating that they have not seen any cases for this condition. BPSU pass the details of clinicians who have reported cases of the relevant condition to the researcher, who will send the clinician a questionnaire for each reported case, requesting pseudonymised, clinical data to be returned for analysis.

Data on births would be obtained from the ONS and relevant agencies in Scotland and Wales to inform estimates of birth prevalence (this would be anonymous data).

Class 1, 2, 4 and 6 support was requested for the process of extracting and anonymising the information, to obtain and use information about past or present geographical location, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for the above purposes.

Confidential patient information requested

Access was requested to data from paediatric clinicians in relation to all children up to the age of 16th birthday presenting with clinical signs of fetal alcohol syndrome as outlined in the case definition.

Date of birth, sex, ethnic group, first half of postcode (district), NHS number (or equivalent), hospital number are collected.

Sector level postcode, ethnicity, and gender are retained for analysis.

Confidentiality Advisory Group advice

Public interest

Members considered the application to demonstrate a medical purpose and clear public benefit in determining the rates of Foetal Alcohol Syndrome, leading to potential improvements in clinician awareness, prevention and treatment of the disorder.

Data security

It was observed that in response to queries from the CAT, the applicants had stated that they would destroy all data at 36 months rather than anonymise it. This contradicted the information given on the IRAS form, and was not the usual procedure as data should be retained to ensure research transparency and integrity.

The Sub-Committee requested clarification on this point.

In addition to this, there were some contradictions in the Protocol: on page 5 it was stated that the UCL Data Safe Haven server would be used, on page 11 the DCC based at Leeds University Hospital for data collection and storage. Clarification was required in relation to this point.

The CAG also requested further information about the statement on page 17, that the 'Rickets' investigator would be notified of cases – full details of this disclosure were required.

Once these clarifications had been made, it could be ensured that appropriate security assurances were in place for each site before recommending support.

Practicable alternatives

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

- Feasibility of consent

Members noted that the study followed the BPSU methodology, which had been approved in principle by the CAG for the study of rare conditions where complete ascertainment was essential to achieve the study aims. Therefore consent was agreed to be unfeasible.

- Use of anonymised/pseudonymised data

Members were assured that the data would be pseudonymised before transfer. Further clarification was required in relation to the anonymisation of data at the end of data collection.

Justification of identifiers

Members were satisfied that identifiers would be kept to a minimum and not retained beyond 36 months, but required clarification on whether the data would subsequently be anonymised or destroyed.

Additional points

Public involvement

It was noted that public involvement work had been undertaken with members of the public and key charities. The Sub-Committee raised no concerns in relation to the level of public engagement, but emphasised the importance of sharing the findings in order to maximise benefit to clinicians and in turn patients.

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.

Request for further information

1. The applicant was asked to provide further information on data security as outlined in the relevant section above. Clarification was required in relation to: where data processing will take place, and arrangements for notification of the disorder.
2. The applicant was advised that CAG support applied to **England and Wales only**, and that applications should be made to the relevant authority to cover data processing in Ireland.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Pending.**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
Leeds University: V14 confirmed published and reviewed as satisfactory.

IG Toolkit required for all sites where identifiable data would be processed, including Ireland.

c) 17/CAG/0162 Reminders for Bowel Scope Screening non-participants

Context

Purpose of application

This research study application from UCL set out the purpose of testing whether the inclusion of a GP endorsement to the '12 months' reminder letter' can improve uptake of Bowel Scope Screening (BSS) among previous non-participants

Bowel cancer is a major public health concern in England, accounting for one in every eight cancer incidences and one in every ten cancer deaths. Bowel Scope Screening (BSS), also known as Flexible Sigmoidoscopy (FS) screening, helps prevent bowel cancer by locating and removing small, benign growths called 'polyps' from the bowel wall before they can become cancerous. Uptake of BSS is currently less than half of the invited population, which means that the estimated life-saving benefits of BSS are not being realised. Any improvement in uptake would justify the initial spending to encourage people to undergo screening.

Previously collected evidence showed that repeat invitations increased uptake of screening programmes by 8%. In previous studies, the applicant had demonstrated that reminders prompting non-participants were not only feasible, but effective in BSS. The present study aims to extend the evaluation of these reminders by testing the impact of adding a general practice endorsement to the letter – something which has been shown to be effective for other types of screening.

NHS Digital would identify non-responders to the initial BSS invitation and remove Type II objectors. They would then randomise these patients to two groups – one would receive the standard reminder (usually sent by London North West Healthcare NHS Trust bowel screening hub at NHS Digital, on behalf of PHE), and the other group would receive the GP-endorsed reminder.

Support was requested to allow NHS Digital to disclose identifiers to Docmail to enable them to send the reminders via an automated system.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source and to allow access to an authorised user for this purpose.

Confidential patient information requested

Access was requested to the following data from NHS Digital in relation to patients who had not responded to the first screening invitation:

- Name, NHS number, postcode.
- Name of GP for the intervention group.

No identifiers were required for analysis. UCL would receive data from NHS Digital concerning the number of patients from each group who acted upon the reminder invitations, and the gender of the patient (as a gender gap had been identified in uptake of bowel screening).

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that the application demonstrated a public interest in working towards improvements in uptake of Bowel Scope Screening, which could ultimately save lives.

Practicable alternatives

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

- Feasibility of consent

The applicant stated that they had previously conducted another study to improve bowel cancer screening uptake using patient consent. This had resulted in confusion to participants, who were unsure whether they were taking part in research or being provided with a type of care, and had decreased the number of patients who took part in screening. To avoid such negative effects, the researcher felt that not seeking consent was justified.

In addition, seeking consent would involve a greater disclosure in order to send out invitations to participate in the research, prior to sending invitations to participate in the screening programme. This would not be practicable in terms of resources.

Members accepted these arguments and made no further comment.

- Use of anonymised/pseudonymised data

Although members accepted that full address and GP details were required in order to mail out invitations, they were not convinced that these needed to be disclosed to Docmail in order for them to administer the sending of invitation letters.

In response to queries on the advice form, the applicant had stated that NHS Digital would not be able to mail out the GP-endorsed reminders, and that Docmail were best placed to assess the validity of the addresses. Members queried this rationale, and requested evidence that NHS Digital had been asked whether they could complete the mail-out, as well as further details regarding validation of addresses. It was particularly important to explore this avenue given that the GP-endorsement could become standard practice if it was proven that the intervention was successful.

Justification of identifiers

Members disputed whether the disclosure of patient identifiers to NHS Digital was justified in terms of a lack of practicable alternatives, as above.

Additional points

Patient notifications

Members considered the method of patient notification (via the UCL website) to be appropriate, but stipulated that study-specific information about the data linkage and how to opt out should be included.

Public involvement

After discussion, members agreed that the public involvement work already completed was adequate. It was recommended that ongoing public involvement work be completed to continue to monitor the views of patients and the public in relation to the public interest and acceptability of continuing to access patient data without consent.

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.

Request for further information

1. The applicant was asked to provide confirmation that NHS Digital have been asked whether they could complete the mail-out.
2. The applicant was asked to provide further justification as to why Docmail are better placed to assess the validity of addresses.
3. The applicant was asked to provide copies of patient notification text for the website including details of how to opt out of the study prior to the sending of invitation letters.

Specific conditions of support

1. The Sub-Committee recommended that further public involvement work be carried out during the study (please note that this is a recommendation only, and support is not conditional on this point)
2. Favourable opinion from a Research Ethics Committee. **Confirmed**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V14 confirmed published and reviewed for NHS Digital**
   V14 not in place for Docmail

d) 17/CAG/0164 A case control study to investigate transmissions for sporadic STEC infections in England

Context

Purpose of application

This research application from the University of East Anglia set out the purpose of identifying the most common sources of Shiga-toxin E. coli (STEC) infections in order to reduce their incidence. STEC infections are a public health concern due to the low infectious dose required for infection and the severity of the infection and associated complications. There were no recent case-control studies; an updated study was required to reflect improved detection methods and surveillance and identify current sources of infection. Recent analysis of STEC infections from Public Health England identified that while the number of infections per year remained relatively steady, those that can be attributed to food sources were falling. There was a need to identify the other transmission pathways so that preventative measures could be introduced so that the overall numbers decreased.

STEC became a notifiable illness in 2009, enabling PHE to access information on potential causes/exposures on a vast majority of identified cases. As part of national surveillance, cases will already have been identified from having provided stool samples that demonstrate the presence of STEC bacteria, and have completed a questionnaire about foods consumed and activities undertaken in the week prior to infection. Controls would be identified via NHS Digital from a database of individuals in England registered with a GP, who could be matched with cases as listed above.

Support was requested to allow the disclosure of this information from NHS Digital to PHE to allow PHE to contact the identified control group and ask them to complete the questionnaire. The questionnaire would not contain identifiable data, therefore would be returned directly to the University of East Anglia from the participant.

Support was also requested for staff at PHE to identify cases from the database held by PHE, match them to controls and provide a pseudonymised dataset to UEA for the purpose of the study. PHE would retain the 'key' matching data to controls.

A recommendation for Class 1, 2, 3 and 6 support was requested for the purpose of extracting and anonymising the information, to obtain and use information about present or past geographical location, to select and contact patients to seek their consent and to allow access to an authorised user for the above purposes.

Confidential patient information requested

Access was requested to:

1. Data from PHE in relation to patients on the national surveillance database held by PHE, comprising identified cases with a STEC-positive fecal sample and a copy of their enhanced surveillance questionnaire available on the PHE database.

2. Data from NHS Digital in relation to: randomly chosen patients (or parents where the patients were are children), fulfilling age frequency matching to cases, from a database by NHS Digital of individuals in England registered with a GP.

3. Data transferred to PHE from NHS Digital would include the following details for the purpose of matching controls to identified cases and sending invitation letters and questionnaires:

- Name
- Date of birth
- Full address including postcode

The following details would be accessed from the surveillance database at PHE:

- Name
- Address
- Gender
- Ethnicity
- Status of STEC infection
- Lab sample number and results of lab analysis

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated a strong public interest given the severity of the infections and the public interest in tracing their sources. It was clear that research in this area was overdue.

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 Sub-Committee noted that owners of the STEC data would not be consented or informed about the use of their data, or be offered the opportunity to see the results, in contrast with the consented control group.

The application stated that seeking consent would be 'inefficient'. While taking into account the fact that the sample size was not prohibitively large, it was agreed that due to its retrospective nature and the way that data had been collected, seeking consent would be impracticable. The argument that seeking consent could introduce bias into the study was also accepted.

Those contacted to participate in the study as controls would not consent for the initial access to their data in order to seek consent; again it was agreed that this was justified in relation to the aims of the study and the difficulty of notifying patients before writing to them.

Members therefore agreed that seeking consent in relation to either of these activities would be impracticable.

- Use of anonymised/pseudonymised data

The application stated that full DOB would be truncated to month and year, and that pseudonymisation of case data would occur two to three times during the course of the study to reduce the length of time that staff would be accessing personally identifiable information. A similar method would be used for the controls as well; numbers could be greater depending on response rate, therefore pseudonymisation could occur more frequently.

The Sub-Committee was content to recommend support based on these undertakings to pseudonymise the data.

Justification of identifiers

The identifiers used were deemed appropriate for the purpose outlined within the application.

Additional points

Patient notification

Although it was recognised that there would be limited opportunity to notify patients prior to sending out the invitations letters (for the control group), it was agreed that information should be placed on the PHE website to ensure that patients did have the opportunity to opt out of being sent the study invitations.

Public involvement

Members stressed the importance of PPI work given that the STEC sample would be unconsented. The examples of PPI work given appeared limited, consisting of only two members of the public.

The Sub-Committee agreed that a PPI group should be set up to gauge reactions to the use of data in this study, giving advice on the materials used and views on the value of the results relative to the breach of patient confidence involved in using the data. This would mitigate the lack of consent, ensuring that patients/members of the public had been consulted on this use of identifiable patient data without consent.

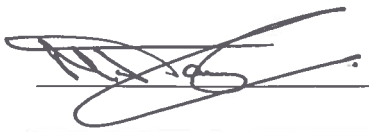
This work should continue alongside the study, and be reported back to the CAG at annual review.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. PPI group to be set up, to input their views specifically on the use of data as the study develops. This should be reported back at annual review.
2. Favourable opinion from a Research Ethics Committee. **Confirmed.**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed: v14 published and reviewed for both NHS Digital and PHE.**



26/10/17.

Signed – Officers of CAG

Date

K. Murray.

26/10/2017

Signed – Confidentiality Advice Team

Date