Health Research Authority

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

14 July 2017

Present:

Name	Capacity	Items
Dr Martin Andrew		2a, 2b
Dr William Bernal		2b
Dr Marc Taylor		1a
Mr Andrew Melville		1a, 2a
Dr Mark Taylor	Chair	1a, 2a, 2b

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0119 Steps Towards Increasing Bowel Cancer Screening Uptake

Purpose of application

This application from the University of Leeds, which would contribute to a PhD Psychology project, would pilot and test a new low-cost behaviour change intervention to increase uptake of screening in the North East of England.

The project aimed to use techniques which had been successful in improving rates of cervical cancer screening, in the area of bowel cancer screening. All participants would be sent the bowel screening cancer kit, but would be randomised to 4 conditions, comprising: the addition of a motivational-intervention sheet, a paper-based task to help plan the use of the screening kit, both of these interventions and a control group receiving treatment as usual (the standard invitation letter and screening kit alone). This had the potential to improve participation from the current low rate of 52% return, increasing rates of early detection for bowel cancer and therefore survival rates, reducing inequality in uptake, and potentially reducing cost to the NHS.

NHS Digital would receive data from the Bowel Cancer Screening Hub on eligible patients, removing any Type 2 objections and returning the list to the Hub, from where the screening

materials and randomised interventions would be sent. The Hub would return information on screening uptake and demographic characteristics for each condition to NHS Digital, who would return anonymised individual level data to the University of Leeds.

A recommendation for 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 one or more of the above purposes.

Confidential patient information requested

Access was requested to data from NE Bowel Cancer Screening Hub in relation to male and female participants aged between 60 and 74 who are eligible for bowel cancer screening and due to receive a screening invitation from the NE Bowel Cancer Screening Hub.

NHS number, date of birth and postcode would be used for linkage.

Data returned to the University of Leeds would include age at time of screening invitation and area-level measure of socio-economic deprivation (calculated by NHS Digital) as well as intervention condition, previous screening uptake and gender.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated a clear medical purpose and were satisfied that the study was of potential public benefit.

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 accept that consent would not be feasible in this case, given the sample size of approximately 20,000 patients.

- Use of anonymised/pseudonymised data

It was noted that the identifiers were required by NHS Digital in order to carry out the linkage. Anonymisation would be completed by NHS Digital prior to releasing information to the University of Leeds. Members were satisfied that data would be anonymised at the earliest possible juncture.

Justification of identifiers

As above, it was noted that NHS number, date of birth and postcode were the minimum requirements for linkage by NHS Digital.

Additional points

Patient notification

Members observed that the information sheet sent to patients did include the option to opt out of the study, however it didn't relate to the activity in question: - accessing patient contact details for linkage by NHS Digital.

Members were of the opinion that more could be done to increase patient awareness of the activity, and enable applicants to opt out before their details were passed on to NHS Digital. There were websites where patients could expect to find this information, for example the Yorkshire Cancer Website which currently contained only general statements about promoting and supporting research.

User involvement

Members agreed that the application had lacked detail in relation to user involvement. Although a research advisory panel was mentioned, it was not clear if their input had been significant. Likewise, references to in-depth interviews were not clear about who had participated and what their opinions had been. A brief mention of a pilot of the study, in the Protocol, provided no further information.

The Sub-Committee agreed the further public involvement work would be beneficial and could inform the approach to patient notification. Evidence of plans for future work to gauge the opinions of patients would be required.

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 patient notifications to raise awareness of the study and allow patients to opt out prior to the provision of their data to NHS Digital. Please describe where the notifications will be placed and how opt outs will be managed.
2. The applicant was asked to provide evidence of further PPI work to be done in order to gauge the views of patients on this use of their data.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-security-review-arrangements/ and contact Exeter.helpdesk@nhs.net with any queries.

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0121 Cancer Patient Experience Survey 2017

Purpose of application

This application from Quality Health on behalf of NHS England set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2017. This would enable comparisons between Trusts, for commissioners, providers and patients (all of whom could access the published results), would allow for monitoring of improvements in services, drive further improvements, and provide NHS England with an up to date overview of cancer patient experience across England.

Quality Health would request a list of eligible patients from participating Trusts, and would mail out surveys to patients after removing duplicates and checking to ensure no surveys were sent to the addresses of deceased patients. Quality Health would then anonymise the data.

A recommendation for class 1, 2, 5 and 6 support was requested for the process of extracting and anonymising the information, to link patient identifiable information obtained from more than one source, for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to data from NHS Trusts in relation to patients of 16 or over with a confirmed primary diagnosis of cancer discharged from the trust after an inpatient or day care episode, within the specified timeframe:

Name and full address for the mailing out of surveys

NHS number and date of birth to avoid duplication and for validation of data.

Confidentiality Advisory Group advice

Public interest

It was agreed that the application demonstrated a clear medical purpose and was potentially of public benefit, subject to satisfactory responses to the queries raised by the Precedent Set Sub-Committee.

Review pathway

The 2016 Patient Cancer Survey had been reviewed by Precedent Set Sub-Committee; although there was not an established category for the review it had been agreed that the application did not raise substantive or new concerns which would necessitate consideration by full CAG.

Survey methodology

The methodology for administering the surveys was simple in that Quality Health (QH) would request lists of eligible patients from the relevant Trusts, mail out the survey (having removed duplicates and patients known to be deceased), receive completed questionnaires and anonymise the data for subsequent use. However some questions were raised in relation to the process for removing duplicates and finding out whether patients were deceased. The current method used for identifying deceased patients was to ask Trusts to check their own records, in addition to a centralised approach whereby Quality Health would access the PDS/DBS system in order to check for address changes and whether a patient was deceased. The initial introduction of this system

had reduced the number of helpline calls from families who had received a survey for a deceased relative.

The conditional outcome from the review of the 2016 survey had set the following condition:

(a) It was acknowledged that every effort is made by Quality Health to avoid letters being sent to the wrong patient or to patients already deceased. Future applications should report on any such incidents to ensure that any system issues were avoided.
(b)

Members noted that consideration had not been given to this point in the 2017 application, and that this would be required.

In addition to this, members queried the time interval between the check being made and the mailing of the survey. There could be delays in updating the PDS system following a patient's death. A long interval between checking the system and mailing the survey would add to the risk.

Breaches

Also in relation to the 2016 survey, it was noted that four data breaches had been reported. Each related to the actions of individual trusts, who had taken responsibility for improving their systems to avoid recurrence, however members agreed that Quality Health should take action to reduce or avoid future similar problems. These actions could include clearer instructions to trusts or a change in the process to reduce the likelihood of future occurrence, and should demonstrate a pro-active approach to the avoidance of data breaches.

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 it would be impracticable and potentially distressing for patients undergoing treatment for cancer to be approached for consent by the direct care team. The survey would be sent once patients were discharged – completion of the survey would constitute implied consent, or patients could request the removal of their contact details from the mailing list at this point.

- Use of anonymised/pseudonymised data

The team noted that survey data was anonymised for future use; this was an appropriate exit strategy to avoid further reliance upon Section 251 support.

Justification of identifiers

The use of the specified identifiers was deemed appropriate for the purpose of participant identification and mailing surveys.

Additional points

Patient notification

The approach to patient notification was again considered by Quality Health to be the responsibility of individual trusts. The guidance issued by Quality Health was non-specific and did not set clear expectations. Trusts were not given any guidance on what would be appropriate for the notification, or how to describe the study and explain that the patient could opt out. Members observed that more could be done by Quality Health to support trusts in meeting this principle.

Patient engagement

It was noted that public engagement was limited. The main source of information was phone calls made to the helpline provided for patients who had received the survey. No pro-active attempts had been made to seek the views of patients on whether it was acceptable to access patient contact details for the purpose of mailing out the survey. The Cancer Patient Experience Advisory Group referred to appeared to focus on outcomes for commissioners and providers rather than patient views.

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. The applicant was asked to provide further information in relation to patient notification: has the usefulness of the guidance provided to trusts been assessed? Members expressed the view that a clearer statement should be provided to trusts, including website wording and leaflet description of the survey and how to opt out, to support trusts in producing the notification. The applicant was asked to advise whether there were any plans to produce further guidance, and if so to give details including the timeframe.
   If no further guidance would be produced, the applicant was asked to provide a rationale.

2. The applicant was asked to specify how many surveys were sent to the wrong patient, duplicated, or sent to a deceased patient in 2016.
3. The applicant was asked to specify the time interval between the mortality check and the mail-out of survey materials.
4. In relation to the breaches reported for the 2016 survey, the applicant was asked to advise what action would be taken by Quality Health to address the risk of future occurrences, including any lessons learned and any planning to assist trusts in the avoidance of further incidences.
5. The applicant was asked to provide further details in relation to public and patient involvement, giving consideration to whether the current opportunities for patient engagement are adequate and whether there is an effective mechanism to gauge the views of patients on this use of their data. If any future work was planned, the applicant was asked to provide details.

Specific conditions of support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-security-review-arrangements/ and contact Exeter.helpdesk@nhs.net with any queries.

b) 17/CAG/0125 All cause mortality within 12 months following hip fracture.

Purpose of application

This service evaluation application from Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences (NDORMS) at the University of Oxford aimed to investigate the causes of death in patients with hip fracture. The mortality rate was unusually high (up to 30% in the 12 months following hip fracture). In 2013 61,000 patients experienced hip fracture in England, Wales and Northern Ireland therefore a considerable number of patients were affected. The published findings would enable better follow-up care by enabling clinicians to identify patients more likely to die in the 12 months following hip fracture. Potential correlations could be made between demographic trends and causes of death, increasing awareness within the medical community of the likely risks to patients, and facilitating future research on effective follow up and preventative strategies.

The applicant requested linked data from the National Hip Fracture Database (NHFD) and ONS data held by NHS Digital. Identifiable data would be provided from NHFD to NHS Digital in order to facilitate the linkage and provide pseudonymised data to NDORMS.

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

Confidential patient information requested

Access was requested to data from NHFD in relation to patients over 60 years of age undergoing hip fracture surgery.

NHS number, date of birth, gender, postcode and unique NHFD identifier to be provided from NHFD to NHS Digital

Date of death and cause of death would be returned to Oxford University for analysis, along with age, gender and clinical data

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated a medical purpose and a strong public interest in the work.

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

Data provided by NHFD was obtained under Section 251 support. Members accepted the argument that consent would not be practicable given the size of the cohort (350,000 patients in total), and that to obtain consent for this specific activity would involve a greater disclosure of patient details.

- Use of anonymised/pseudonymised data

Members commented that the application was sparse on the detail of the data flowing directly from the NHFD to Oxford University, stating only that sensitive identifiers would be removed. This dataset would be likely to include the unit where treatment took place, the surgeon carrying out the treatment and dates of admission and surgery. Although identifiers would be replaced with a study ID, the inclusion of this data and the addition of date of death for some patients would increase the risk of re-identification.

Another area requiring clarification was the data returned from NHS Digital to Oxford – the postcode was provided to NHS Digital for linkage, but it was unclear whether the final dataset provided to Oxford contained location data.

Members agreed that the applicant should provide further detail in relation to the data items and whether they had considered ways to further reduce the risk of re-identification for example providing the dates to NHS Digital so that time intervals between events like surgery and death could be calculated, and the resulting dataset returned to Oxford University without specific dates. Any additional data, such as day of the week of surgery, could be supplied as necessary.

Justification of identifiers

Members required further information on the precise data items to be transferred to NDORMS from NHFD and NHS Digital, and justification to be provided for the use of data items such as the date of death, in order to comment on this aspect.

Additional points

Data flows

Members had requested justification for the data items to be transferred from NHFD to NDORMS. This was part of a wider query about the necessity of this data flow. Further information was requested along with the request to consider ways to reduce the identifiability of this dataset.

Public engagement

The level of public engagement was considered limited by the Sub-Committee. Although Oxford University was in touch with patient groups, none had commented on this specific proposal. Further PPI work would be required and details of the work and a schedule should be provided.

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. The applicant was asked to specify the data items to be transferred from NHFD to NDORMS
2. The applicant was asked to clarify the necessity for the data flow from NHFD to NDORMS, as specified in 1) above. The applicant was asked to provide a justification for the receipt of

precise dates rather than calculation of time intervals, which could be calculated by NHS Digital and provided along with any necessary additional data.

3. The applicant was asked to provide details of any further PPI work to be done, including a timescale for completion of the work.

Specific conditions of support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-security-review-arrangements/ and contact Exeter.helpdesk@nhs.net with any queries.

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

28 July 2017

Present:

Name	Capacity	Items
Dr Malcolm Booth		1a,
Mr Anthony Kane		1a, 2b
Ms Kim Kingan		1b, 2b
Ms Clare Sanderson	Chair	1a, 1b, 2a

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0117 - Prevalence and characteristics of fractures in preterm infants presenting to Accident and Emergency: A retrospective study

Context

Purpose of application

This study from the University of Sheffield set out the purpose of determining if pre-term birth was a major cause for childhood fractures. The research team would look at whether there were any differences in clinical (including imaging) features of fractures presenting in accidental and inflicted injury in preterm children up to the age of 2. This would increase knowledge in this area, and was envisaged to be of particular use to doctors when deciding if a fracture with no other obvious explanation in a pre-term child was caused by accidental or inflicted injury.

The applicants proposed to collect information from records of physical examinations, blood tests and x-ray features of fractures in preterm children. Medical records of 'term' children would also be studied to compare the presentation of accidental and inflicted fractures to see if there were any differences.

The initial list of eligible patients would be obtained from the coding office at the hospital. Data would be collected on-site and anonymised, however it would be necessary to share data between sites in order to identify children who had been treated at both sites. This process would be managed by Dr Amakah Offiah. Each of the two other named members of the research team would work at one of the sites to identify participants, and would send NHS number, name and date of birth to Dr Offiah to enable her to identify the duplicates. Following this, a study number for these participants would be provided to both researchers.

The full medical record would be accessed onsite by the researchers in order to extract anonymised information for analysis.

A recommendation for class 1 and 6 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 clinical notes at Sheffield Children's Hospital Accident and Emergency Department and Jessop Hospital in relation to children (both term and preterm) below the age of 2, who have had either accidental or inflicted fractures and are otherwise healthy (selected from lists of children born at these sites between 2005 and 2015).

NHS number, name and date of birth would be accessed by one named researcher for participants from both sites in order to remove duplicate between sites and to check that the child was within the correct age range.

Clinical notes would be accessed on-site to extract the data in anonymised form.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated a medical purpose and would appear to be in the public interest; however some doubts were raised in relation to the methodology. As data would be taken from two hospitals only, there could be pre-term babies from Jessops that had been treated at other hospitals and therefore would be missed – likewise, there could be children treated for fractures at Sheffield Children's Hospital that were pre-term at a different hospital (rather than Jessops).

These factors could impact the findings, which if inaccurate would call into question the public interest in the study.

After discussion, members agreed that the scientific method and assurances in relation to the validity of the findings had been reviewed by the Research Ethics Committee (REC), and that the CAG could accept assurance from the REC on this matter.

Time period of support

It appeared that the full length of time for which patient data could be held would be 9 months: - for the first 6 months, the student at each site would collect data, and following this Ms Offiah would take an additional 3 months to validate the information, remove duplicates and return an anonymised file. Members requested confirmation on this point.

Scope of support

In relation to the study methodology, members also questioned whether access would be required to data regarding fractures for later than 2015, to cover babies born in 2015 who would not be 2 until 2017. A response to this query would be required to clarify the scope.

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

It was observed that the cohort of 120 was relatively small, and the need for complete ascertainment had not been evidenced within the application. However, the argument that some of the cohort would no longer be traceable, and finding them would necessitate a greater disclosure of identifiable data, was accepted by the Sub-Committee.

- Use of anonymised/pseudonymised data

Subject to confirmation of the time period of support, members were satisfied that data was anonymised within a reasonable timescale.

Justification of identifiers

Members accepted that access to the full clinical record on-site was required in order to extract and anonymise the data, and that access to name, NHS number and date of birth was required in order to identify duplicates across the two sites.

Additional points

Patient notification and opt out

Members did not consider the arrangements for patient notification to be adequate. Posters would be unlikely to reach a majority of parents, but the Sub-Committee was of the opinion that informing parents via hospital websites would be more effective. Both methods should be used, and the information placed on the websites and in the hospital clinics well in advance of the commencement of the study so that parents were able to express dissent to the inclusion of their child's data.

Furthermore, the applicant had not addressed the question of how they would eliminate those parents who had opted out on behalf of their child at the GP surgery. Clarification was requested on this point.

Public Engagement

The CAG noted that public involvement work had been described in response to queries on the application, and recommended support on the basis that this work had been carried out.

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. Time period of support: Members understood that it will take 6 months to collect the data and an additional 3 months to validate, remove duplicates and anonymise the data. Please confirm that this is correct.
2. Caldicott Guardian recommendation: Please provide a written recommendation from the Caldicott Guardian for each site, confirming that they have read the Protocol and agree to the study taking place at the site.
3. Please confirm that any data stored on the university cloud is anonymised.

4. Patient notification: Please confirm that patient notifications will be made available to parents via the clinics in the form of posters and leaflets, and on the hospital website, well in advance of the commencement of the study.
5. Opt out: Please describe how dissent registered with the GP will be respected.
6. Scope of support: Please advise whether access will be required to data regarding fractures for later than 2015, to cover babies born in 2015 who will not be 2 until 2017.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed.**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. Confirmation must be provided that v14 of the IG Toolkit is in place and has been reviewed as satisfactory. **Nottinghamshire Healthcare NHS Trust, Mental Health Services Community and Palliative Care - Confirmed published and reviewed as satisfactory via email from NHS Digital.**

2) 17/CAG/0126 - The DEPICT Study

Context

Purpose of application

This NIHR funded study set out the purpose of looking at how differences in access to paediatric intensive care (due to distance from the intensive care unit), and care provided during transport to intensive care, affect clinical outcomes and patient experience. The primary outcome would be 30 day mortality rate. Patient experience would be investigated via questionnaires (for which support was not required as they would take place under consent).

There are currently fewer than 30 paediatric intensive care units (PICUs) in the UK. This means that a critically ill child taken to their nearest hospital will need to be transferred to a PICU. Such transports are usually done by PICU retrieval teams (PICRTs), mobile teams who take specialist expertise to the child and safely transport them to a PICU.
There are national variations in how PICRTs are organised and deliver clinical care.

The study would combine data from PICANet (an international audit of paediatric intensive care which collects data on all children admitted to paediatric intensive care units (PICUs) in the UK and Ireland) and the CMP (an audit of patient outcomes from adult, general critical care units (intensive care and combined intensive care/high dependency units managed by ICNARC) covering England, Wales and Northern Ireland. Various outcome measures would be extracted, including: how long it takes a PICRT to reach the patient, how long it takes the child to reach the PICU, the seniority of clinicians performing the transport, medical procedures performed by the PICRT and any critical incidents during transport, and investigate whether any of these factors influence how likely a child is to survive. This would provide a basis to complete cost/benefit analysis and to study if and how alternative models of service delivery could improve clinical outcomes.

Identifiers would be sent from PICANet and ICNARC to NHS Digital, who would look for any records from the CMP database that were also in the PICANet database. The resulting dataset would be linked with ONS/HES data and transferred in pseudonymised form back to PICANet.

CMP would also receive the pseudonymised list of those patients in both CMP and PICANet database, marked with the unique CMP identifier and the DEPICT study number before removing the CMP identifier and transferring this dataset to PICANet in Leicester, where the data would be analysed.

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 the above purpose.

Confidential patient information requested

Access was requested to data from PICANet and ICNARC in relation to critically ill children and young people under the age of 16 requiring emergency transport to a paediatric intensive care unit in England and Wales between 2014 and 2016 (IRAS form refers to participants identified from clinical notes – this is for the consented questionnaire aspect of the study):

NHS number, date of birth, name, postcode and unique local identifier and study number from PICANet, University of Leeds to NHS Digital.

NHS number, date of birth, postcode from ICNARC to NHS Digital (name is not available in the ICNARC dataset).

Confidentiality Advisory Group advice

Public interest

Members agreed that this appeared to be an important piece of work, with a clear public interest.

Practicable alternatives

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

- Feasibility of consent

Members agreed that consent would not be feasible given that the national audits from which the linked dataset would be drawn took place under Section 251 support. Seeking consent from this cohort of 15,000 would involve a greater disclosure in order to obtain contact details, and therefore was agreed to be impracticable.

- Use of anonymised/pseudonymised data

Members noted that the dataset returned from NHS Digital to University of Leicester for analysis would be pseudonymised, containing only the study number.

NHS Digital would follow established procedures to destroy patient identifiable data once the linkage had been completed.

Justification of identifiers

Members agreed that name, date of birth and postcode were necessary to enable NHS Digital to perform data linkage when NHS numbers were not available or did not match between the datasets, and that the data linkage to HES/ONS data was vital for achieving the research aims.

Additional points

Public Involvement

It was observed that parent co-applicants had been involved in the study design, including the data linkage part of the study, and that patient groups presented with information about the research had been supportive and considered the purpose of the research to be an important one.

Although the views of patient groups had not been specifically sought in relation to the use of identifiable data to carry out data linkage, the applicants had sought the parent co-applicants' input specifically on this subject and they had been supportive.

It was agreed that more could be done to seek patient views on this use of data, however this would not prevent the Sub-Committee from recommending support for this application. The Sub-Committee agreed that further public involvement would be a member recommendation to the applicant, rather than a requirement.

Patient notification

Although patient notification was in place for both audits from which the data was to be linked, the linkage was not explicitly mentioned. The applicant proposed to add information regarding the DEPICT study on both websites (PICANet as well as ICNARC), which would outline how their data will be used for linkage via NHS Digital. This was deemed appropriate by the Sub-Committee.

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. A recommendation was made that further public involvement work should be completed. (This was a recommendation only and support was not conditional on this point).
2. Favourable opinion from a Research Ethics Committee.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **NHS Digital – v14 confirmed published and reviewed as satisfactory.**
   PICANet – v14 not yet reviewed
   ICNARC - v14 not yet reviewed.

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0130 Colonoscopic surveillance for familial risk of colorectal cancer

Context

Purpose of application

This non-research application from London North West Healthcare NHS Trust set out the purpose of auditing and monitoring care provided to individuals at increased familial risk of colorectal cancer and developing evidence-based guidelines on the management of familial risk for the NHS.

Individuals with a family history of colorectal cancer are at increased risk of developing colorectal cancer. Familial risk of colorectal cancer may be estimated from the number of family members affected and the age at which they were diagnosed. In a small proportion genetic testing may be undertaken to diagnose inherited genetic predispositions.

The Family Cancer Clinic at St Mark's Hospital has over 3000 patients who are undergoing colonoscopic surveillance for an increased familial risk of colorectal cancer and whose clinical, molecular, genetic and family history are recorded on the Bobby Moore database as is the outcome of colonoscopic surveillance including the histopathology of polyps and cancers removed.

The applicant wishes to obtain outcome and mortality data from NHS Digital for this cohort in order to assess the effectiveness of their risk assessment methods and of colonoscopy. Complete ascertainment of cancers that develop in individuals who have undergone colonoscopic surveillance ensures that the surveillance protocol is effective and can be changed if there is a new case of cancer.

In order to ensure complete ascertainment the applicant wished to flag their patients with NHS Digital in order to provide a list of cancer registrations, deaths and emigrations, in addition to contact details and GP details for patients lost to follow-up. Identifiers would be provided to NHS Digital, who would provide cancer registration data to the Family Cancer Clinic. Staff at the clinic would add any information not already recorded at the clinic, and destroy the dataset by deleting the information.

A recommendation for class 4 support was requested for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to data from NHS Digital in relation to patients undergoing colonoscopic surveillance for an increased risk of colorectal cancer.

Name, date of birth and NHS number to be supplied to NHS Digital

NHS Digital would return cancer registration data.

In cases where patients were lost to follow up, NHS Digital would return the name, date of birth, address and registered GP for the patient.

Confidentiality Advisory Group advice

Public Interest

Members agreed that the application demonstrated public interest in the intention to assess the effectiveness of their surveillance of those at risk of colorectal cancer, and to enable surveillance to be offered to patients at high risk of colorectal cancer who were lost to follow-up.

Data flows

The application stated '*Pseudonymised data is held by Professor Peter Sasieni at Queen Mary University of London'.* However, later sections in the application seemed to suggest that data was held outside the Trust. Members requested clarification on this point to enable them to fully assess the data flows and any associated risks.

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 approximately 3000 patients were undergoing colonoscopic surveillance for increased risk of colorectal cancer. Patients did consent to the inclusion of their data on the database and for their data to be linked with ONS data. Information sheets would be sent to each patient with the colonoscopy results letter, notifying them that their data would be flagged.

However, the data requested was for those lost to follow-up, who could not therefore be asked for consent, and to ensure complete ascertainment of cancer registration. It would not be possible to seek further consent prior to carrying out the linkage as the applicant could not know which patient any missing data would apply to.

Members accepted this rationale but queried whether the applicant could change the wording in their consent process to ensure explicit consent was sought for the flagging in the future, thus avoiding the need for prospective Section 251 support. It was agreed that confirmation of this would be required, as the support requested should be for historical patients only.

- Use of anonymised/pseudonymised data

It was noted that the data transferred from NHS Digital would be deleted as soon as it was added to the clinical database.

Justification of identifiers

Members accepted that identifiers were required in order to perform the linkage and to identify the patient before entering the missing data onto the database.

Additional points

Public engagement

Members observed that the application did not include any reference to Patient and Public Involvement work, although it was likely that some was undertaken with patients. As a general principle of CAG support, it was important that attempts were made to gauge the views of patients in relation to this use of their data, and that this be reported back to members. It was agreed that a report on PPI work would be requested at annual review stage.

Patient notification and opt out

The following paragraph would be included with information sheets sent to patients with their colonoscopy results

'Our patients who are undergoing surveillance colonoscopy for an increased familial risk of colorectal cancer are flagged by NHS Digital Data Access. This ensures that we are informed of any cancers that they develop and also allows us to trace patients who have not responded to an invitation for a colonoscopy.

If you do not wish to be flagged by NHS Digital please contact us at the above address, telephone number or email address.'

The Sub-Committee did not consider this paragraph to have enough detail or explanation to enable patients to make an informed choice about whether or not they wished to dissent. The terms 'flagged' and 'NHS Digital Data Access' should be explained as most patients would not understand the meaning of the terms.

Members also commented that the applicant had not described what would happen if an applicant did contact them and ask to opt out – an explanation of the method for respecting dissent would be required.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Secretary of State, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Data flows: please clarify where the pseudonymised data will be held.
2. Please undertake patient and public engagement work and report back on the results at annual review.
3. Please provide an updated version of the paragraph to be added to patient information sheets and the website, ensuring that it clearly explains what is meant by flagging, and how this is carried out.
4. Please explain how dissent will be respected.
5. Please clarify whether consent will be sought from prospective patients, and whether the support required is for the historical cohort only.

Specific conditions of support

1. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V14 confirmed published and reviewed as satisfactory.**