Health Research Authority

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

October 2017

Present:

Name	Capacity	Items
Mr Murat Soncul	Chair	1a, 1b, 1c, 1d
Professor Barry Evans	Reviewer	1a, 1b
Dr Will Bernal	Reviewer	1a, 1d
Dr Lorna Fraser	Reviewer	1b, 1c
Ms Hannah Chambers	Reviewer	1c, 1d
Dr Kambiz Boomla	Reviewer	1e, 2a
Mr Andrew Melville	Reviewer	2a, 1f
Professor Jenny Kurinczuk	Reviewer	1f
Mr David Smallacombe	Reviewer	1e
Ms Clare Sanderson	Chair	1e, 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/0172 Expanded Access of BlincytoÂ® in Patients with Acute Lymphoblastic Leukaemia: A Retrospective Observational Study

Context

Purpose of application

This application from OXON Epidemiology aims to characterise the population receiving the drug Blincyto in Europe, under an early access program, and to investigate outcomes and utilisation. The drug is approved in the US by the FDA, and conditionally approved by the EMA (European Medicines Agency) for the treatment of adults (and more recently children) with relapsed and/or refractory (R/R) Philadelphia chromosome-negative (Ph-) B-precursor Acute Lymphblastic Leukaemia (ALL).

Due to the high level of unmet clinical need in these patients, Amgen has been providing Blincyto via an early access program for a number of ALL subgroups who met pre-specified disease criteria in countries where such programs are permitted. The pool of eligible patients in the 6 countries is estimated to be approximately 400-500 B-precursor ALL patients.

The applicant was requesting Section 251 support for two aspects of the study:

1. To access the data of deceased patients
2. To allow research staff, who are not considered part of the direct care team, to identify and approach living patients for consent to access their medical records

A recommendation for class 1, 3 and 6 was requested for the purpose of extracting and anonymising the information, for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to:

1. Identifiers from patient's clinician to research staff, in order to contact the patient and seek consent.
2. Data from medical notes in relation to deceased patients identified by their treating clinician as taking Blincyto:

The full medical record would be accessed on-site; however the only identifiable data extracted would be date of death.

Date of birth would be truncated to month and year.

Confidentiality Advisory Group advice

Public interest

The Sub-Committee was of the opinion that the application had demonstrated a medical purpose and sufficient public interest in the stated aim of characterising the population receiving the drug Blincyto in Europe, under an early access program, and to investigate outcomes and utilisation.

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 evident that consent could not be sought from deceased patients for the use of their data. It was also accepted that it would not be practicable to seek consent from patients before accessing their data in order to contact them for consent.

- Use of anonymised/pseudonymised data

Data accessed for both of the specified purposes would be for a time-limited period only prior to either seeking consent or pseudonymising the data. It was observed that date of birth would be truncated to month and year. Members were satisfied on this point.

Justification of identifiers

Date of death would be retained for analysis. Members noted that there was precedent for this to be supported via the Precedent Set pathway, and agreed that the retention of date of death was justified.

Additional points

Patient notification and opt out

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.

While making the observation that it would be possible to notify those patients who were still living of the access to their data in order to seek consent, members agreed that this would be given as a suggestion only. Support would not be conditional on this point.

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. The applicant was asked to consider notifying living patients of the access to their data for the purpose of contacting them to seek consent, placing information in the public domain to enable them to opt out if they so wish. It was clarified that this was a suggestion and support was not conditional on this point.
2. The applicant was advised that the CAG recommendation applied to England and Wales only. Approvals should be sought from the relevant bodies for any data processing that will take place in Northern Ireland and Scotland.
3. Favourable opinion from a Research Ethics Committee. **Pending**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.

b) 17/CAG/0180 MR865 (Whitehall Study)

Context

Purpose of application

This longitudinal study at the University of Oxford set out the purpose of examining how cause-specific mortality in old age is influenced by various factors including lifestyle, socio-economic circumstances,

cardiovascular risk factors, employment grade and self-assessment of physical and mental health. Various measures including plasma or genetic markers would be completed at middle and old age, and others such as whether mortality differentials by employment grade persist into old age, would be taken in old age alone.

Background

In 2014, all applications accessing mortality, cancer or GP registration data from NHS Digital were required to re-apply in order to establish the legal basis. A Precedent Set criterion was set up for all such applications ('Class support studies'), and a shortened application form provided to applicants for this specific purpose.

This application was made as a result of the applicant discovering that the legal basis was not adequate for the renewal of their agreement with NHS Digital.

A recommendation for class 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 NHS Digital in relation to 19,000 men who were aged 40-69 years when originally surveyed in 1967 – 1970:

5-digit Whitehall study number to be provided to NHS Digital to enable linkage with patient cause-specific mortality and cancer registrations

Date of birth retained by the applicant in order to validate data

Date of death to be returned to the applicant from NHS Digital

Public interest

Members agreed that the application clearly demonstrated a medical purpose and public interest in examining how cause-specific mortality in old age was influenced by various factors including lifestyle, socio-economic circumstances, cardiovascular risk factors, employment grade and self-assessment of physical and mental health.

It was commented that this long-running study was an important and valuable data source which members were keen to 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 observed that the study was consented originally, but the original consent did not cover later developments in electronic sources of data.

Given that 50% of the participants had died in 1997, it was evident that reconsenting the cohort would be impracticable.

- Use of anonymised/pseudonymised data

The application stated that data linkage could be carried out by NHS Digital without identifiers, using the Whitehall study number only.

Justification of identifiers

The applicant wished to retain date of birth in order to validate mortality data (for example, if a situation should arise where the date of birth held by the applicant did not correspond to the date of birth on the death certificate) and for linkage with data in other nations such as Scotland.

Members did not consider this to be an adequate justification for the retention of date of birth, and required further justification and details of an exit strategy in order to consider this request. The applicant should explain how long they intended to retain date of birth, and what method they would use to end reliance on Section 251 support (for example consent, anonymisation/pseudonymisation or destruction of the data).

The applicant also required full date of death to be returned from NHS Digital in order to carry out their analysis.

Members were content to support retention of date of death to allow the full range of analyses to be carried out.

Additional points

Patient notification and opt out

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members considered the age of the cohort, and the fact that 50% had died by 1997, and agreed that on this occasion the principle of patient notification was not likely to be effective or relevant to the cohort.

Public involvement

In line with the considerations applied to the principle of patient notification, members agreed that the principle of public involvement was not relevant here, given the difficulties associated with engagement of this cohort in public involvement work.

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. Please provide further justification for the retention of date of birth, and give details of the exit strategy.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 1 February 2016**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V14, CTSU Nuffield Dept of Population Health, University of Oxford - confirmed published and reviewed**
   V14, NHS Digital – confirmed published and reviewed

c) 17/CAG/0181 A Population Based Study Of Genetic Predisposition And Gene-Environment Interactions In Prostate Cancer In East Anglia, Trent And West Midlands

Context

Purpose of application

This application from the University of Cambridge set out the purpose of analysing epidemiological information and biological material on a population based series of prostate cancer cases, in order to identify genetic predisposition to cancer and estimate the effects of age and gender-specific and lifestyle risk factors. It is part of a larger study entitled SEARCH, which investigates the question of genetic predisposition to a range of cancers.

This long-running study held data and blood samples with consent from study participants who had been identified by the cancer registry and had consented to provide the blood sample for the purpose of extracting DNA for genetic analyses. They had also completed a comprehensive questionnaire on lifestyle and family history of cancer. They had consented to access by the research team to their medical record and pathology material.

Section 251 support was requested under the Precedent Set criteria 'Validity of Consent', to enable the provision of data from the cancer registry via PHE to continue.

Funding for the prostate arm of the SEARCH study halted in 2013, therefore no further recruitment has taken place in the last 4 years. However, anonymised data was still used for research and updates from PHE were required to keep existing data current.

A recommendation for class 4 and 6 support was requested for the purpose of linking patient identifiable information 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 University of Cambridge in respect of patients who consented to the SEARCH trial:

Name, NHS number, Date of birth and cancer registry number would be provided to PHE for the purpose of linkage.

Clinical information would be provided to the University of Cambridge from PHE.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application demonstrated a medical purpose and significant public interest in its stated aim of identifying genetic predisposition to cancer and estimating the effects of age and gender-specific and lifestyle risk factors. The study data was an important public resource.

Scope of application

Several points had been unclear in the application; members therefore requested that the following points be clarified:

Clarification was requested as to whether access to data from NHS Digital was required or whether the request was for PHE data only.

The SEARCH study appeared to refer to the whole SEARCH study and the prostate arm interchangeably. Members requested further confirmation that the application concerned the prostate arm of the SEARCH study only, particularly as the covering letter referred also to the colorectal and multi cancer arms.

Members were not able to discern whether linked datasets were requested in relation to the 4700 prostate cancer participants only, or whether this data was also requested in relation to the control group of 3400 participants. Further clarification was required on this point.

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 impracticability of reconsenting the 4700 SEARCH prostate was accepted by the Sub-Committee. Consent had previously been taken, but was not considered valid for linkage to PHE data. The application was therefore submitted under the 'validity of consent' criteria.

- Use of anonymised/pseudonymised data

Members were unconvinced that Section 251 support was required, given that a cancer registration number was held for most of the participants. Data linkage could be completed using pseudonymised data. Further clarification was requested as to why support was required.

Justification of identifiers

In line with the query above, members did not consider the use of identifiers to be justified given that the linkage could take place using the cancer registration number.

Additional points

Patient notification and opt out

It was observed that patient notification and details of how to opt out were available via the website only. The demographic of the study population was older men, who would be less likely to look at the website than others. Members agreed that other methods of notification should be considered.

Public involvement

The extensive nature of the PPI work (200 participants to be interviewed by telephone) was praised, however members agreed that some feedback should be obtained prior to the beginning of the study.

Confidentiality Advisory Group advice conclusion

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

Further information required

1. **Scope of support:**
   - **a)** The applicant was asked to clarify the dataset(s) requested, and whether the request was for PHE data only or included NHS Digital data.
   - **b)** The applicant was asked to confirm whether the application refers to the prostate arm of the study only.
   - **c)** The applicant was asked to clarify whether support was required to link to datasets held for the control arm of the study, or whether support was required to link to datasets held for the participants with prostate cancer only.
   - **d)** The applicant was advised that CAG support applies to England and Wales only – separate approval should be sought for any data processing in Scotland.
2. **Practicable alternatives**: the applicant was asked to clarify why support was requested, as it appeared that linkage could be undertaken using the cancer registration number without transferred identifiers?
3. **Patient notification and opt out:** The applicant was asked to advise on alternative methods of disseminating information about the study to those who do not have internet access.
4. **Public involvement:** The applicant was asked to provide some evidence of public involvement prior to commencing the activity, to gauge the views of patients on this access to data without consent.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed.**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **University of Cambridge and PHE, v14 confirmed published and reviewed.**

d) 17/CAG/0182 SAFE TKR Study

Context

Purpose of application

This research study from the University of Warwick set out the purpose of assessing the feasibility of a randomised controlled trial to determine whether use of a tourniquet in Total Knee Replacement (TKR) surgery increases the risk of blood clot.

A tourniquet is used to interrupt the blood supply and drainage from the leg, to facilitate surgery. However, once the tourniquet is removed any blood clots that have accumulated in the leg could then return to the heart where they may then travel to the brain. This risk had not previously been examined. In order to assess the feasibility of carrying out a future RCT, the applicant would carry out a randomised controlled trial and qualitative research with consented patients, and a retrospective multi-centre cohort study.

Support was requested for the retrospective multi-centre cohort study, which would use data collected from the National Joint Registry (NJR) between April 2003 to December 2003 concerning the use of tourniquets in TKR surgery in England and Wales. This data would be linked to Hospital Episode Statistics (HES dataset) on reported blood clots, socio-demographics, co-morbidities and length of hospital stay for the TKR.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source.

Confidential patient information requested

Access was requested to the following data from NJR in relation to patients who had TKR surgery between April and December 2003:

NHS number, date of birth, gender, postcode, procedure code and local patient identifier – to be transferred to NHS Digital for linkage.

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that there was a medical purpose and public interest in the specified aim of determining whether use of a tourniquet in Total Knee Replacement (TKR) surgery increased the risk of blood clot.

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 NJR database was initially consented, however the consent had not anticipated later possibilities to link with the HES dataset. The application was therefore submitted under the Precedent Set criteria ‘validity of consent’.

It was agreed that re-consenting would not be practicable given the size of the cohort (approximately 20,000, some of whom would be deceased).

- Use of anonymised/pseudonymised data

Members were satisfied that data would be anonymised prior to transfer to Warwick University; identifiers were required for linkage only.

Justification of identifiers

The use of NHS number, date of birth and full postcode was queried, as members had been under the impression that linkage could be achieved with fewer identifiers. It was agreed that confirmation from NHS Digital that all of these identifiers were required should be a condition of support.

Additional points

Patient notification and opt out

Concern was expressed at the level of patient notification. Although the applicant had stated that many of the cohort would be deceased, and that information about the linkage and how to opt out was available online, this was considered insufficient. Members agreed that some attempts should be made to reach those who did not have access to the internet, for those of the cohort who were still living.

A query was raised in relation to the intention to notify the patient's GP of the study results. It was assumed that this referred to the pilot trial, which was a prospective, consented trial. Subject to confirmation of this point by the applicant, members were satisfied that this would not relate to the use of unconsented data.

Public engagement

Consultation with 30 patients, specifically addressing the issue of access to data without consent, was documented. In discussion, members agreed that this was adequate for the purpose of the study.

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. The applicant was asked to provide confirmation that NHS number, date of birth and postcode were all required to carry out the linkage.
2. The applicant was asked to confirm that notification to the GP of study results applied to the prospective consented cohort only.
3. Favourable opinion from a Research Ethics Committee. **Confirmed 27 January 2017.**
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **NJR and NHS Digital, both confirmed published and reviewed via NHS Digital website**.

e) 17/CAG/0160 The HOME Study

Context

Purpose of application

This NIHR-funded study from the University of Oxford set out the purpose of testing a psychiatric approach to the identification and management of psychological problems, to see if it enables faster discharge for older people on acute general hospital wards. Dementia, confusion, depression and anxiety often contribute to a longer hospital stay, but are missed in wards which focus mainly on physical symptoms. Patients would be randomly allocated to receive the usual care or usual care plus the new approach, which would involve seeing a doctor or nurse who specialises in psychological problems in the medically ill.

Support was requested in order to identify participants and subsequently seek their consent. The applicant proposed to screen patient notes as soon as possible following admission to hospital, and to approach eligible patients for consent. Researchers would be embedded within the clinical care team during the recruitment period.

Data concerning those who did not give consent to participate would be retained in order to assess the generalisability of the study findings. The applicant confirmed in response to queries that this would be pseudonymised to age and gender, and destroyed at the same time as personal data for trial participants, however further clarification may be required in relation to when the pseudonymisation will take place.

The study would take place in England and Scotland – CAG support was requested for England only.

Support was requested to allow members of the wider research team (including research nurses, practitioners, assistants or doctors) access to patient medical records in order to screen for eligibility for inclusion in the study.

Data would also be retained on those patients who do not consent to the study – date of birth, gender and reason for non-participation.

A recommendation for class 3 and 6 support is requested to select and contact patients to seek their consent, and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from patients meeting the following criteria:

- Male/Female inpatients on an acute ward at one of the three participating English sites,
- Have been admitted to hospitals non-electively,
- Be aged 65 or older,
- Be expected (by their clinical team) to remain an inpatient for at least 2 days from the time of the baseline assessment,
- Be able to give informed consent or, if unable to give informed consent, a consultee or legal representative advises that study participation is appropriate.

3,244 patients will be recruited to the study; however, it is likely that a greater number of medical records will need to be screened to identify eligible patients.

Access to the full medical record would be required to screen for eligibility against the above criteria.

Date of birth would be used to confirm age and eligibility and retained to assess the generalisability of the research.

Confidentiality Advisory Group advice

Public interest

Members agreed that the application described a strong medical purpose and that there was public benefit in the specified purpose of testing a psychiatric approach to the identification and management of psychological problems, to see if it enabled faster discharge for older people on acute general hospital wards.

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 noted that the application was to identify eligible patients in order to consent them, and agreed that consent would not be feasible until after the eligible patients had been identified. The Sub-Committee agreed that the case had been made for not asking staff to identify participants given the rapid turnaround of staff and the pressure of time and resource.

- Use of anonymised/pseudonymised data

Members commented that support was only required for a time-limited period in order to review the medical records and to approach eligible patients for their consent.

The only area of concern was the retention of information in relation to patients who had declined to give consent. It was agreed that only pseudonymised data could be retained – date of birth must be converted to age.

Justification of identifiers

In line with the discussion above, members agreed that the retention of date of birth for patients who had not given consent was not justified – only age of the patient should be retained.

Additional points

Patient notification

Members considered the poster which had been provided. The poster would be displayed on the ward and included details of how to opt out. This was deemed suitable by the Sub-Committee, although it was suggested that as many of the potential participants would be lacking capacity it would be useful to address their relatives in the information provided.

It was agreed that this suggestion could be considered by the REC in their review of the patient information.

Public involvement

The applicant described consultation with 7 older patients who were currently in hospital as well as 5 older people who had experience of being in hospital themselves or of being carers for inpatients, as well as a Patient and Public Involvement Panel of 7 people for the study.

Members were satisfied that the views of patients had been adequately sought in relation to this use of data.

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. The applicant was advised that support was not in place for the retention of date of birth of participants who did not consent – this must be reduced to age.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 6 October 2016.**
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

V14 Royal Devon and Exeter NHS Foundation Trust confirmed published and reviewed.
V14 Oxford University Hospitals NHS Foundation Trust confirmed published and reviewed.

V14 Cambridge University Hospitals NHS Foundation Trust confirmed published and reviewed.

f) 17/CAG/0169 Investigating an organ donation intervention in primary care: a single practice feasibility study

Context

<u>Purpose of application</u>

This application from University of Bedfordshire, part-funded by NHS Blood and Transplant, aimed to test the feasibility of using U.K. primary care settings to increase registration to the NHS Organ Donor Register (NHS ODR) by asking patients if they would like to join during consultations. This could potentially address the problem of low registration to the NHS ODR (currently only 35%).

Previous research has shown that this works effectively in the USA; however as it involves additional staff time and workload it is necessary to test the feasibility of the intervention in a UK setting. The intervention consists of three elements: training staff in organ donation information, the display of leaflets and posters in the waiting room and asking patients during consultations if they wish to join the register (also called prompted-choice). A single GP practice in Luton, U.K. has agreed to run the intervention for a three-month period.

Support was requested to allow the CI access to the patient database for the GP practice in order to set up a prompt on the system which would remind staff to ask the patient about organ donation and to fill in a short questionnaire which would later be extracted by the CI. The questionnaire would not contain any identifiers. Setting up this prompt was not expected to reveal identifiable patient information; however there was a possibility that there would be some incidental disclosure. There was also a potential disclosure when extracting information from the database – although

the aim would be for the system to calculate age from date of birth, there was again a possibility of incidental disclosure.

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 this purpose.

Confidential patient information requested

Access was requested to data from Medici Medical Practice in relation to all patients registered at the practice.

Support under s251 is requested because of the possibility of incidental disclosure primarily as the researcher will be setting up prompts in the patient database for staff to use in consultation.

There was also potential for incidental disclosure of age, gender and ethnicity of patients who registered onto the tissue bank, and brief incidental disclosure of date of birth before this was converted to age (the researcher aimed to set up the database to complete this action but could not yet ascertain whether this would be effective).

Confidentiality Advisory Group advice

Public interest

Members agreed that there was a clear medical purpose and public benefit in the specified purpose of investigating the feasibility of increasing organ donor registration via direct discussion with patients in a primary care setting.

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

As the incidental disclosure could relate to any patient attending the surgery, it was agreed that seeking consent would not be feasible.

Members also accepted that it would not be possible for administrative staff to add the prompt to the system (although they did have access) as this would be a drain on staff resources. The same argument applied to the truncation of date of birth to age – clinical staff could not be expected to do this within the consultation given pressure of time.

- Use of anonymised/pseudonymised data

Members noted that the aim was to extract only pseudonymised data. Should the full date of birth remain on the data extracted, the researcher would truncate it to month and year of birth. This was considered to be an appropriate exit strategy.

Justification of identifiers

Members were satisfied that the applicant would access the minimum possible level of identifiers to complete the study.

Additional points

Patient notification

Members noted that existing dissent on patients' records would be respected, and that one of the conditions was set by the REC was that patients were notified about the research study during the consultation and given the opportunity to opt out.

However, this did not address the general principle of CAG support, which was that patient notifications should be available prior to the data access described in the application to enable patients to opt out.

The application had made some reference to a leaflet to be provided, however members queried whether there was scope to include information in the practice newsletter or on the practice website, which could further enable patients to opt out before the potential access to their data while the prompt was set up. There was also an opportunity to notify patients about the research study at the point of making an appointment for consultation, which did not appear to have been explored. Patients could be given a leaflet or online information, which would give them the opportunity to opt out of any inclusion in the questionnaire completed by staff.

Members agreed that these further actions would be recommended to the applicant, but that support would not be made conditional on this point.

Public involvement

Members commented that the involvement of the PPI group at the practice as well as external organisations (NHS British Transplant) was to be commended.

Time period of support

The exact time period had not been clearly specified. Members stipulated that support would only be in place for one year; any proposed extension must be submitted as an amendment.

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. Support is in place until 26 October (one year from the date of this letter). Any extension to the time period must be submitted as an amendment for CAG support.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 3 November 2017.**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission

2. NEW PRECEDENT SET REVIEW APPLICATIONS – NON RESEARCH

a) 17/CAG/0174 UTMoST Study

Context

Purpose of application

This study from Big Health Data Group at Oxford University, funded by the NIHR with a Health Technology Assessment Programme Grant, set out the purpose of improving information available on the choice between Unicompartmental Knee Replacement (UKR) or Total Knee Replacement (TKR), particularly in relation to risks and benefits (comparative costs and effects). In order to do this an existing dataset from an ongoing RCT (TOPKAT) would be used alongside data relating to patients who were not eligible for the TOPKAT study, in order to validate the results of this trial and to broaden the scope of data collection to include patients with co-morbidities.

Patients with co-morbidities ('ASA grade 3 or worse'), who were not eligible for the TOPKAT trial, comprised 17% of those undergoing knee replacement surgery, and their omission was significant given the association between co-morbidities and both post-operative complications and mortality, and subsequent costs associated. Therefore there was public benefit in improving on the TOPKAT study to ensure that results were generalizable to this population as well as improving the validity of the original study by adding follow-up data from a longer period.

Support was requested to allow disclosure of data from the NJR to NHS Digital to enable linkage with HES-PROMS data before returning a pseudonymised dataset to Oxford University.

Confidential patient information requested

Access was requested to:

NHS number

Date of birth

Gender

Postcode

Unique NJR identifier

(to be provided to NHS Digital for linkage)

Pseudonymised data (containing NJR identifier) would be transferred to Oxford University

Confidentiality Advisory Group advice

Public interest

Members accepted that there was a strong medical purpose and public benefit in the specified purpose of improving information available to patients on the choice between Unicompartmental Knee Replacement (UKR) or Total Knee Replacement (TKR). The proposed analysis of costs and benefits would be useful to individual patients and the NHS as a whole in terms of potential efficiency savings.

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 the cohort was too large for consent to be a practicable alternative, and noted that only pseudonymised data would be returned to the applicant.

- Use of anonymised/pseudonymised data

It was understood that the data would be pseudonymised at the earliest point. Members agreed that the timescale for pseudonymisation was reasonable, and that this formed an appropriate exit strategy.

Justification of identifiers

The identifiers listed were deemed to be justified for the purpose of linkage by NHS Digital.

Additional points

Purpose of application

On reading the application, members had observed that the activity was beyond that of service evaluation and that the results could be generalizable outside the study population, and therefore argued that the study may have been wrongly categorised as non-research.

Queries had been raised by the CAT in relation to this point. The applicant had responded that previous similar applications had been considered as non-research. The CAT confirmed that the previous applications had been similar in purpose and method, and provided additional evidence in relation to a previous application. Although accepted that there was a debate to be had in relation to whether or not the activity constituted research, it was noted that the study involved pseudonymised data alone. The applicant was evaluating outcomes rather than carrying out any intervention with participants. On this basis, and on the evidence that this question had been debated before within the CAG, it was agreed to follow precedent and proceed with the application as non-research.

Public involvement

Members commented that the applicant had taken PPI seriously, with some individual and charity involvement. Members requested feedback on the progress of this work at annual review, with particular reference to the development of links with suitable charities during the course of the study in addition to disseminating the findings through the charities at the end of the study.

Patient notifications

This was the only area of concern identified in the review of the application.

While it was recognised that it would not be possible to respect dissent once pseudonymisation had occurred, members did not accept the statement in the application that patient notification and opt out was unfeasible.

The NJR and Big Health Data Group websites both contained general information on the ways in which personal data was used, including linkages. Members acknowledged that it would be difficult to include details about the specific study on these websites; however the possibility of notifying patients via charity or other websites should be investigated. Patients could then express dissent before their information was transferred to NHS Digital for linkage.

It was agreed that further information was required on this point before the final recommendation could be issued.

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. The applicant was asked to provide further information in relation to patient notification and opt out, and provide the relevant notification along with an explanation of where it will be placed and how dissent will be respected. If this is not possible, please provide a fuller justification as to why not.

Specific conditions of support

1. The applicant was asked to report back at annual review on the progress of public involvement work, with particular reference to the development of links with suitable charities during the course of the study.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.