Minutes of the meeting of the Confidentiality Advisory Group

02 April 2020, Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Ms Sophie Brannan	Yes	CAG Member
Dr Patrick Coyle	Yes	CAG Vice-Chair
Dr Liliane Field	Yes	CAG Member
Dr Katie Harron	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Professor Jennifer Kurinczuk	Yes	CAG Member
Dr Harvey Marcovitch	Yes	CAG Member
Ms Gillian Wells	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Mr Paul Mills	Research Regulation Specialist

1. Introduction, apologies and declarations of interest

2. Support decisions

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **05 March 2020** meeting applications.

3. Consideration items

a. Re-discussion of HQIP Opt-Out Paper

The group discussed the HQIP opt-Out Paper.

4. New applications – research

a. 20/CAG/0044 – Revision Hip and Knee Replacement: Evaluation of Clinical, Psychological and Surgical Outcomes

Context

Purpose of application

This application from the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford set out the purpose of medical

research that seeks to investigate how satisfied patients are following revision hip or knee replacement, and whether the reason for surgery affected this.

Hip and knee replacement implants are designed to last a long time, but they do not last forever. A revision joint replacement is a procedure to replace an implant that is no longer functioning correctly. These procedures are major surgery because performing a joint replacement can be much more complicated the second or third time. This may be due to the presence of infection or formation of scar tissue and loss of bone over time. Around 13,000 revision operations are performed each year in the United Kingdom at a cost of up to £200 million. The majority of these procedures are successful and many cannot be avoided. Other revision procedures are discretional and depend on a discussion of risks versus benefits between a patient and their surgeon. In the discretional group, up to one-in-three patients who undergo revision surgery do not experience any benefit and the reasons for this are not well understood.

In this application, anonymised data will be obtained from several sources in the NHS that routinely collect information related to revision joint replacement. Data on Patient Reported Outcome Measures and from the National Joint Registry, alongside HES and ONS data from NHS Digital, will be collected and analysed in order to describe patient satisfaction and function following revision surgery, medical risks, and the need for further surgery and identify the factors that underpin each of these. Confidential patient information will be disclosed from the National Joint Registry (NJR) to NHS Digital for data linkage to HES, ONS and Patient Reported Outcome Measures (PROMS).

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	150,000 patients, who have undergone revision hip or knee replacement from April 2003 to the present and the procedure recorded on either HES or the National Joint Registry.
Data sources	1. The National Joint Registry, held by Northgate Public Services 2. PROMs, HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Date of death 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Group agreed that the project had a dual public interest, in seeking to improve outcomes for patients and informing the effective use of NHS resources.

Practicable alternatives

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

- **Feasibility of consent**

The applicants anticipate that 150,000 patients will be included and it was not feasible to contact such a large number of patients. Patients will have consented to the inclusion of their data in the NJR dataset. Patients who had opted-out of use of their data in research would not be included. Only de-identified data would be returned to the applicants at the University of Oxford. The Group was satisfied that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data from the NJR to PROMs, HES and ONS datasets held by NHS Digital. A pseudonymised dataset will be disclosed to the applicants. The Group accepted that this could not be done in any other way.

Cohort

The CAG noted that the start and end dates of the data collection period were unclear and asked that this was clarified.

Justification of identifiers

Support was sought for the patients date of death to be disclosed from NHS Digital to the applicants. The date of death was then retained for analysis purposes. Members queried whether the exact date of death was required, or if the age at death or year of death could be used instead and asked the applicant to clarify.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Patients gave consent to the inclusion of their data in the NJR dataset and were also asked to consent to the use of their data in research. Those who had opted-out of the inclusion of their data in research would not be included.

The Group agreed that further patient notification needed to be undertaken and suggested that a notice was placed on the NJR website. A dissent mechanism also needed to be created and information on how patients can dissent included in the patient notification.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants planned to recruit a pilot focus group, formed of approximately 10 patients, who will discuss the information patients need to make a fully informed decision about whether to undergo revision surgery and how the success of surgery should be measured. Patients involved in this pilot would also be engaged in subsequent research to provide feedback to steer the proposal and ensure it remains patient-focused.

The British Association for Surgery of the Knee patient group has also been involved in the development of the proposal. This included recent work with the James Lind Alliance, who identified revision knee replacement as a research priority for patients. Patients would also be kept informed of the results of the application via public involvement and engagement events. The results of the study will also be disseminated to participants, made available online and disseminated through departmental social media accounts.

It was unclear whether the acceptability of processing confidential patient information without consent had been tested during patient and public involvement.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Provide further details on the patient and public involvement carried out, specifically whether the acceptability of processing confidential patient information without consent had been tested.

2. Patient notification needs to be carried out. A dissent mechanism also needs to be created and information on how patients can dissent included in the patient notification.

3. Clarify if age at death or year and month of death could be retained for analysis purposes.

4. Clarify the start and end date of the data collection period.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: Northgate Public Services (by NHS Digital email dated 07 February 2020) and NHS Digital (by NHS Digital email dated 10 June 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

b. 20/CAG/0045 - An evaluation of a water fluoridation scheme in Cumbria: A population based comparative cohort study of systemic and topical fluoride exposure

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to assess the effects and costs of systemic and topical exposure to water fluoridation following a reintroduced Water Fluoridation scheme on a cohort of contemporary children.

Tooth decay is the commonest disease of childhood. Fluoride can prevent tooth decay. Water fluoridation has a 70-year history. Unfortunately the scientific evidence demonstrating how well water fluoridation works and how cost-effective it is in the current climate of falling decay levels is lacking. A new plant opened in May 2013, giving the applicants an opportunity to study the impact of water fluoridation in West Cumbria. The applicant will investigate the effects of a new water fluoridation scheme on young children by recruiting groups of children born over the period of a year and following up over a five to six-year period. All children born from September 2014 to September 2015 were recruited and their teeth examined at 3 and 5 years of age to assess the affects of fluoridation on the deciduous teeth. The number of children who developed tooth decay in fluoridated and non-fluoridated areas.

Support is sought for the applicants to link the previously collected confidential patient information collected for the study to dental health data from NHS Business Services Authority (BSA) and HES data from NHS Digital. NHS BSA and NHS Digital had deemed the existing consent obtained in 2013 to be insufficient for this planned data linkage. The applicants also seek support to obtain anonymised data from NHS BSA for children born between September 2014 and September 2015, within the same geographic location, Cumbria East and West, as the children consented into the study.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	3200 children aged 4 -12 years and living in West Cumbria; Cornhow and Ennerdale, who were consented into the original study. Anonymised data will also be obtained for children born between September 2014 and September 2015, within the same geographic location, Cumbria East and West, as the children consented into the study.
Data sources	1. Dental Health Data held by NHS BSA 2. HES data held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode
Identifiers required for analysis purposes	1. Date of birth 2. Postcode 3. Gender

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Group agreed that there was a clear public benefit in determining whether water fluoridation was beneficial to the development of healthy teeth and that the application had a medical purpose.

Scope

Anonymised data would be requested for those who would have been eligible to take part in the study but were not approached. Members noted that this was outside the scope of s251 support as no confidential patient information would be included for this aspect of the study.

Cohort

The Group agreed that this application and the application for 20/CAG/0046 were very similar, and the main difference was that different cohorts were involved. Some information had been duplicated across the applications and it was not clear whether some of these duplications were in error. Members agreed that further information on the cohorts recruited to each application was required, including the differences between each cohort.

The Group requested clarification on which patients in the cohort would be included in the data linkage, whether this was the whole population who originally consented or only those still active in the study.

Practicable alternatives

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

- **Feasibility of consent**

Consent had been sought from children and their parents when the project began in 2013. Patients had been followed-up over a number of years. NHS BSA had advised that the existing consent did not cover the planned linkage to their data and the applicant advised that it was not possible to re-consent all individuals.

The applicants advised that they were unable to re-consent patients as they may not have up-to-date contact details for the cohort. Participants had been sent yearly questionnaires and had been seen at ages three and five. The researchers would have seen half of the cohort in September 2019 and will see the other half of the cohort before September 2020. It was not clear why consent could not be sought if the research team had been in contact so recently and members requested that further justification for not seeking consent was provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link research data for individual patients with data held by NHS BSA and NHS Digital. The Group accepted that this could not be done in any other way.

Exit strategy

The Group noted that the exit strategy was unclear. The applicant had advised that the confidential patient information needed to undertake the linkage would be destroyed in line with the ethics of the application, once the analysis of linked data had taken place. Members requested clarification on when the linked file from NHS Digital would be deleted.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A patient notification strategy was not described. The Group noted that patients had consented to inclusion originally. The applicant advised that patients who contacted

the research team to request the removal of their data prior to the data linkages being undertaken would not be included.

Members advised that a patient notification strategy needed to be devised. The Group suggested that notices were included on the websites for University of Manchester website and United Utilities, and that information about the data linkages was included on the next annual questionnaire.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants provided information on planned patient and public involvement. The Group noted that the application form had not been updated in all areas since the original REC submission had been written, therefore it was unclear if the patient and public involvement described had already taken place or was planned for the future. Members agreed that patient and public involvement needed to be carried out, particularly around the processing of confidential patient information as proposed in this application.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Further information on the cohorts recruited for each application is required, including the differences between each cohort

2. Provide clarification on which patients in the cohort would be included in the data linkage, whether this was the whole population who originally consented or only those still active in the study.

3. Justification needs to be provided on why consent for the proposed data linkages cannot be sought, particularly from those who are still actively participating in the study.

4. A patient notification strategy needs to be devised. Any materials, such as posters, leaflets and website text, need to be provided for review.

5. Patient and public involvement and engagement needs to be undertaken around the proposed usage of confidential patient information as proposed in the application.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed – University of**

Manchester (by NHS Digital email dated 04 October 2019), NHS Digital (by NHS Digital email dated 10 June 2019) and NHS Business Services Authority (by NHS Digital email dated 06 September 2019) have a confirmed 'Standards Met' grade on DSPT submission 2018/19.

c. 20/CAG/0046 - An evaluation of a water fluoridation scheme in Cumbria: population based comparative cohort studies of topical fluoride exposure alone

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to assess the effects and costs of systemic and topical exposure to water fluoridation following a reintroduced Water Fluoridation scheme on a cohort of contemporary children.

Tooth decay is the commonest disease of childhood. Fluoride can prevent tooth decay. Water fluoridation has a 70-year history. Unfortunately, the scientific evidence demonstrating how well water fluoridation works and how cost-effective it is in the current climate of falling decay levels is lacking. A new plant opened in May 2013, giving the applicants an opportunity to study the impact of water fluoridation in West Cumbria. The applicant will investigate the effects of a new water fluoridation scheme on young children by recruiting groups of children born over the period of a year and following up over a five to six-year period. All children born from September 2014 to September 2015 were recruited and their teeth examined at 3 and 5 years of age to assess the effects of fluoridation on the deciduous teeth. The number of children who developed tooth decay in fluoridated and non-fluoridated areas.

Support is sought for the applicants to link the previously collected confidential patient information collected for the study to dental health data from NHS Business Services Authority (BSA) and HES data from NHS Digital. NHS BSA and NHS Digital had deemed the existing consent obtained in 2013 to be insufficient for this planned data linkage. The applicants also seek support to obtain anonymised data from NHS BSA for children born between September 2014 and September 2015, within the same geographic location, Cumbria East and West, as the children consented into the study.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	3200 children aged 4 -12 years and living in West Cumbria; Cornhow and Ennerdale
Data sources	1. Dental Health Data held by NHS BSA 2. HES data held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Date of birth 2. Postcode 3. Gender

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Group agreed that there was a clear public benefit in determining whether water fluoridation was beneficial to the development of healthy teeth and that the application had a medical purpose.

Scope

Anonymised data would be requested for those who would have been eligible to take part in the study but were not approached. Members noted that this was outside the scope of s251 support as no confidential patient information would be included for this aspect of the study.

Cohort

The Group agreed that this application and the application for 20/CAG/0045 were very similar, and the main difference was that different cohorts were involved. Some information had been duplicated across the applications and it was not clear whether some of these duplications were in error. Members agreed that further information on the cohorts recruited to each application was required, including the differences between each cohort

The Group requested clarification on which patients in the cohort would be included in the data linkage, whether this was the whole population who originally consented or only those still active in the study.

Practicable alternatives

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

- **Feasibility of consent**

Consent had been sought from children and their parents when the project began in 2013. Patients had been followed-up over a number of years. NHS BSA had advised that the existing consent did not cover the planned linkage to their data and the applicant advised that it was not possible to re-consent all individuals.

The applicants advised that they were unable to re-consent patients as they may not have up-to-date contact details for the cohort. Participants had been sent yearly questionnaires and had been seen at ages three and five. The researchers would have seen half of the cohort in September 2019 and will see the other half of the cohort before September 2020. It was not clear why consent could not be sought if the research team had been in contact so recently and members requested that further justification for not seeking consent was provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link research data for individual patients with data held by NHS BSA and NHS Digital. The Group accepted that this could not be done in any other way.

Exit strategy

The Group noted that the exit strategy was unclear. The applicant had advised that the confidential patient information needed to undertake the linkage would be destroyed in line with the ethics of the application, once the analysis of linked data had taken place. Members requested clarification on when the linked file from NHS Digital would be deleted.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and

to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A patient notification strategy was not described. The Group noted that patients had consented to inclusion originally. The applicant advised that patients who contacted the research team to request the removal of their data prior to the data linkages being undertaken would not be included.

Members advised that a patient notification strategy needed to be devised. The Group suggested that notices were included on the websites for University of Manchester website and United Utilities, and that information about the data linkages was included on the next annual questionnaire.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants provided information on planned patient and public involvement. The Group noted that the application form had not been updated in all areas since the original REC submission had been written, therefore it was unclear if the patient and public involvement described had already taken place or was planned for the future. Members agreed that patient and public involvement needed to be carried out, particularly around the processing of confidential patient information as proposed in this application. The Group suggested that this was undertaken with a small group of those who had originally consented to taking part in the study.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further

information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Further information on the cohorts recruited for each application is required, including the differences between each cohort

2. Provide clarification on which patients in the cohort would be included in the data linkage, whether this was the whole population who originally consented or only those still active in the study.

3. Justification needs to be provided on why consent for the proposed data linkages cannot be sought, particularly from those who are still actively participating in the study.

4. A patient notification strategy needs to be devised. Any materials, such as posters, leaflets and website text, need to be provided for review.

5. Patient and public involvement and engagement needs to be undertaken around the proposed usage of confidential patient information as proposed in the application.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed – University of Manchester (by NHS Digital email dated 04 October 2019), NHS Digital (by NHS Digital email dated 10 June 2019) and NHS Business Services Authority (by NHS Digital email dated 06 September 2019) have a confirmed 'Standards Met' grade on DSPT submission 2018/19.**

d. 20/CAG/0049 – PREDICT Study: RaDaR and UKRR Linked Dataset

Context

Purpose of application

This application from King's College Hospital set out the purpose of medical research which aims to create a new dataset to aid in developing a predictive tool to estimate the degree of pregnancy-associated progression and adverse pregnancy outcomes in women with CKD, including those with rare renal disease.

Moderate-severe chronic kidney disease (CKD) affects approximately 0.9 – 3.1% of women of childbearing age and is associated with higher rates of adverse pregnancy outcomes compared to healthy women. Approximately one in three women with moderate-severe kidney disease will require dialysis or lose at least 25% of kidney function within six months of delivery. It is estimated that over 1000 pregnancies per

year in the UK are affected by moderate-severe CKD. This number is set to rise due to maternal factors associated with CKD, such as obesity and advancing maternal age, and the accessibility of assisted conception. Current risk estimates for pregnancy-associated pregnancies are based on a small, single centre study examining pregnancies between 1971 and 1997, which does not reflect contemporaneous practice or enable accurate individual risk prediction. There is also no up to date information for patients with rare renal disease, including those already receiving renal replacement therapy and kidney transplants.

Two renal datasets, the National Registry of Rare Kidney Diseases (RaDaR) and the UK Renal Register (UKRR), will be linked with two pregnancy data sets, Hospital Episodes Statistics and Maternity Services Data Set, by NHS Digital. The linked data will form a new dataset, to be used to create a prediction tool to improve the accuracy of information and the communication of risk between pregnant women with CKD and their clinicians. The datasets will be linked using NHS number and date of birth and pseudonymised linked data reported to the UK Renal Registry who will further link the data with UK Renal Registry records for renal outcomes. The UK Renal Registry will then transfer an anonymised dataset to the King's College Hospital research team.

A recommendation for class 1, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	An estimated 750 pregnant women with CKD
Data sources	1. National Registry of Rare Kidney Diseases, held by the Renal Association and the UK Renal Registry, held by the Renal Association 2. HES and Maternity Services Dataset at NHS Digital

Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members agreed that the potential benefits that the predictive tool could bring to women with chronic kidney disease was in public interest.

Practicable alternatives

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

- **Feasibility of consent**

The group felt that the applicant reasons for not seeking consent were justifiable. However, it was noted that the application stated "*Women have provided consent to*

participate in Radar for use of their data in future research. Their consent in this study is implicit." Members acknowledged that participants had provided consent to participate in RaDaR, however, members wished to make it clear that implied consent did not provide a legal basis under the common law duty of confidentiality to process identifiable information for research purposes. In addition, Members wished to place on record that consent for use of data in future research, does not extend to linking with other datasets,

- **Use of anonymised/pseudonymised data**

Members considered the need for use of confidential patient information and agreed that their use is merited. It was noted that the dataset would be anonymised at the earliest opportunity and that the research team would not have access to confidential patient information.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The group understand that no patient notification materials for the study have been provided, and there was no description of notification plans within the application. Members agreed that the study team cannot rely on the original consent as a form of notification.

Whilst it was noted that the research team will respect any dissent from the original study, members agreed that service users should still be provided with an opportunity to dissent from the current research. It was also commented that members would expect NHS Digital to apply the National Data Opt Out.

The group agreed that the research team should put in place a notification procedure, which should include the opportunity to dissent (including email address, postal address and telephone details available for opt out). The research team should detail this procedure to the group, as well as providing notification materials for consideration.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

Several members identified inconsistencies within the application about the Patient and Public Involvement and Engagement. The response to question 15-1 implies that the involvement will be undertaken after this study around the introduction of the tool, and no patient and public involvement and engagement has been undertaken for this study. However, the response to question 15-2 indicates the research team have discussed using patient identifiable data without consent with two Kidney patient groups. Further, the protocol does not indicate that either of the above have been done, but that a patient representative has inputted into the design of the study.

The group wishes the applicants to clarify exactly what Patient and Public Involvement and Engagement has been undertaken for this study. If the response to question 15-2 is correct, members wanted to know how many people this was discussed with, and a list of the questions that were asked. If no Patient and Public Involvement and Engagement has been undertaken for the study, the group want to see some meaningful exercises undertaken before support is given, which should include asking for views on linkage without consent.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all the requests for further information, within one month.

Request for further information

1. Provide details of the patient notification methods to be used, including where the notification will be placed.

2. Provide the patient notification materials to be used, which should include detail on how patients can opt out (including email address, postal address and telephone details)

3. Clarify what Patient and Public Involvement and Engagement in preparation for this research, addressing the inconsistencies in the information.

    a. If Patient and Public Involvement and Engagement has been undertaken, confirm how many people were involved, and detail the questions asked of them.

    b. If no Patient and Public Involvement and Engagement has been undertaken, please undertake some meaningful exercises (including asking for views on linkage without consent). Please provide the group with the outcomes, as well as the number of people involved and the questions asked.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed**

e. 20/CAG/0054 – Screening for Hypertension in the Inpatient Environment (SHINE): A Diagnostic Accuracy Cohort Study

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to determine the optimal in-hospital blood pressure threshold above which to undertake community ambulatory blood pressure monitoring to detect hypertension.

Hypertension is the leading risk factor for death globally, with 12.8% of global deaths annually attributable to hypertension. Increased blood pressure measurements in the hospital setting are frequently dismissed, possibly due to clinicians attributing raised blood pressure to anxiety, pain or White Coat Hypertension. Clinicians usually expect that a patient's blood pressure will normalise following discharge, however limited data suggests that those with elevated blood pressure in hospitals frequently remain hypertensive in the community. Untreated hypertension is associated with a progressive increase in blood pressure that can become very difficult to treat. This means that hospital detection and timely management of hypertension offer an important intervention opportunity of address this major and global cause of illness and mortality. Recognition and documentation of elevated blood pressure readings in hospital is lacking, and referral for community follow-up of these patients to determine cases of persistent hypertension is low

The Oxford University Hospitals NHS Foundation Trust introduced the NIHR-funded System for Electronic Notification and Documentation (SEND) in 2015. SEND is a tailored software service, which links hospital bedside monitoring devices, including blood pressure monitors, with a tablet computer to accurately record vital observations of patients. This enables clinical researchers to access and analyse patient observation data at a population level, as well as an individual level. SEND has monitored observations for more than 100,000 patients so far and links patient observations to their Electronic Patient Record (EPR). This presents Oxford University Hospitals NHS Foundation Trust with an opportunity to screen all admitted patients for hypertension, with the potential of providing preventative medicine to patients.

The applicants intend to conduct a twelve-month prospective study. Eligible patients will be identified during their hospital admission by an algorithm run across the EPR. Selected patients will then be screened against the inclusion and exclusion criteria by members of the research team. Patients meeting these criteria will then be approached for consent to take part in the study. Support is sought for the screening of patient records for suitability prior to consent being obtained.

A recommendation for class 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients treated at Oxford University NHS Foundation Trust and identified as meeting the inclusion criteria and identified as potential participants by the SEND algorithm
Data sources	1. Electronic patient records held at Oxford University NHS Foundation Trust

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. GP Registration 5. Date of death Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender Age

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The group felt there was a public benefit to the research, as the results will provide further evidence for when to undertake community ambulatory blood pressure monitoring.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The group noted that the research team will be screening patient identifiable data, prior to approaching those eligible to participate in the study. Members queried how much patient information the research team will have access to prior to consent in terms of whether this will be the whole patient record, or a limited section. The group noted there was limited information on what will happen to the information of those patients not deemed eligible for the study, and requested further information.

- **Feasibility of consent/Practicable alternative**

Members noted that it had been considered for the clinical team to undertake this work and that this is not feasible due to limited available resources. The group commended the applicants in ensuring an application was made for support. Members also understand that it is not feasible to ask all Trust patients for consent prior to running the algorithm/the research team searching records, but that patients will be approached to consent to participate in the study if eligible.

- **Use of anonymised/pseudonymised data**

Members were content with the justifications that identifiable information is required to be able to access the patient record, as well as to enable approach to participate in the study.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where

appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Limited details were provided on what patient notification will be undertaken for this study. Whilst members noted that all patients are given general information on uses of data for research on admission to hospital, members felt that some form of patient notification should be undertaken for this study, for example, posters around the hospital.

The group also understood that patients had the opportunity to opt out of being approached for research on admission, members also felt that there should be an opt out for this study. As such, the group agreed to request for patient notification materials to be provided by the applicant, and for that notification to detail how patients can opt out, including contact details.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The group were generally satisfied with the work undertaken in this regard. Members were unclear on how representative of the participant population those approached were. However, given hypertension is wide-ranging members were content with this.

Members were unclear whether the patient representatives were asked specifically about the acceptability of external researchers screening identifiable patient information prior to consent and wished for further information on this. Members also suggested that those approached for consent could be asked for their view on the screening process, in order to inform future work.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information and actions within one month.

Request for further information

1. Provide patient notification materials to be used in the study, which should include information on how to opt out and contact details.

2. Confirm what information in the patient record the research team will have access to. Is it the whole patient record? If not, what information will they have access to.

3. What happens to the data of those patients that are ineligible? Will the identifiable data collected by the algorithm be deleted immediately? Please provide further information about this process.

4. Clarify whether patient representatives were asked about the acceptability of external researchers screening identifiable patient information prior to consent

5. Consider asking eligible patients at consent their views on the acceptability of the screening process.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending. Whilst it is noted that a REC Favourable Opinion was provided in February 2019, it appears this was given on the understanding that the applicants were not seeking s251 support at that time. It is not apparent that an amendment to the REC has since been submitted detailing the change to seeking s251 support. Please either submit an amendment to the REC, or clarify the basis of the REC opinion already given.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed.**

6. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date