Minutes of the meeting of the Confidentiality Advisory Group

18 February 2021 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr William Bernal	No	CAG Alternative Vice-Chair
Ms Clare Sanderson	Yes	CAG Alternative Vice-Chair
Dr Martin Andrew	Yes	CAG Member
Mr David Evans	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Dr Lorna Fraser	Yes	CAG Member
Mr Myer Glickman	No	CAG Member
Dr Katie Harron	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

The Chair welcomed all Members to the meeting, and apologies for absence were received from Dr William Bernal and Mr Myer Glickman.

The CAG noted the death of Dame Fiona Caldicott and members expressed their sadness at the loss of a wise and experienced colleague. The CAG Chair had given a statement, which was available on the HRA website.

Any declarations of interest are detailed for each application below.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **21 January 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **21 January 2021** meeting applications.

3. New Applications - Research

a. 21/CAG/0020 - The effect of age at first invitation for breast screening in the NHS Breast Screening Programme in England and Wales (AFBSS)

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to establish whether the age at women are first invited for routine mammogram affects mortality from breast cancer. NHS Digital will link further death records and cancer registrations to flagged Age at first breast screening (ABFSS) patients originally flagged on the NHS Central Register (NHSCR), and supply the outcomes to the applicants who will link these data to the dataset they already hold on 1.4 million women born in 1945-1948 in England and Wales.

This was previously supported as a non-research application in 2007; PIAG 3-05(l)/2007, however in 2018, the NHS Breast Screening Programme changed their definition of age, meaning PIAG 3-05(l)/2007 can no longer be classed as an audit of its routine practices. Therefore applicants are seeking support for this new research application to complete data analyses and to extend follow up period to include data from between 31st December 2012 and 31st December 2019 for research purposes, and replace the previous PIAG application.

In England and Wales, the NHS routinely offers breast screening every three years to all women aged 50-70 and this screening has been shown to reduce mortality from breast cancer. Although women are eligible for breast screening at the age of 50 years, in practice they are first invited for screening between the ages of 50 years and 52 years. It is not known whether this three-year range in age makes a difference to breast cancer mortality. The study aims to address this, and findings will inform screening policy and practice regarding the age at first routine mammogram.

A part of PIAG 3-05(l)/2007, data routinely collected by the NHS Breast Screening Programme on women's first invitation to routine screening were extracted from the NHAIS system in England for women born in 1945-1948. These women were flagged on the NHSCR, which enabled follow up for cause-specific mortality and cancer diagnosis up to 31st December 2012, through record linkage to death records and cancer registrations. Details of individuals in the study population have already been collected and are held securely at the University of Oxford. This database contains identifiers: name, NHS number, date of birth, postcode and a unique participant study number only.

The study population of AFBSS patients are already flagged on the NHSCR, held by NHS Digital. The same function is now carried out by the Personal Demographics Service (PDS), but as the women in the study were flagged on the NHSCR, NHS Digital will be able to trace their details using the unique participant number. Support is requested for NHS Digital to link the flagged patients to further death records and cancer registrations from the ONS Civil

Registration Mortality dataset, and Cancer Registrations Data dataset controlled by Public Health England, until 31st December 2019. These datasets are also held by NHS Digital. Deaths, cause of death and cancer incidence will be provided from NHS Digital to the applicants at University of Oxford alongside a unique study number. This data flow also requires support as date of death can be considered an identifier, and the applicants hold additional identifiers. The applicants will then link the provided outcome information to their existing dataset using the unique participant study number. The data will be pseudonymised for analysis, except full date of death which is required. Name, NHS number, date of birth, postcode and the unique participant number will be retained in a separate part of the study database. Once the study is published all identifiable data will be destroyed, and the applicants estimate that support will be required until 31st December 2024.

A recommendation for class 1, 2, 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	1.4 million women born in 1945-1948 in England and Wales who were alive, on the NHAIS system; and age 50 in 1995-1998 This application is only concerned with linkages to death and cancer outcomes between 31sT December 2012 and 31st December 2019
Data sources	1. PIAG 3-05(l)/2007 dataset, held at the University of Oxford. Data collected under Regulation 5 support. 2. NHS Digital - ONS Civil Registration Mortality dataset, and Cancer Registrations Data dataset (controlled by Public Health England, but held by NHS Digital), and details of previously flagged ABFSS patients on the NHS Central Register (NHSCR).
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode

	5. Unique participant study number
Identifiers required for analysis purposes	1. Full date of death 2. date of birth modified to month and year of birth

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 Committee were however less clear about the public interest element, as it was noted that there are no secondary research questions stated as part of the CAG application, and the answer to the primary research question could potentially be answered using existing research sources. It was commented that the applicant is required to better justify access to the confidential patient information of so many people in order to assure the CAG of the public interest. The applicant is therefore asked to provide the CAG with details of other secondary research questions which may be answered using this dataset.

Legal basis of current database

The last review date for PIAG 3-05(l)/2007 was due 4 March 2016, according to the CAG register. The applicant describes due to staff movement and funding difficulties, follow-up was frozen in 2016. The data were then, and still are, held securely and confidentially in a location that cannot be accessed by researchers. However, despite this, an annual review should still have been provided for PIAG 3-05(l)/2007 annually from 4 March 2016 until now to enable the retention of identifiers. An annual review has now been submitted for PIAG 3-05(l)/2007 for CAG review, with the view of replacing this application with 21/CAG/0020 when supported. It is noted that the Chief Investigator of 21/CAG/0020 is new to the project and did not have previous oversight of the retained dataset held under PIAG 3-05(l)/2007.

The members had some queries surrounding this dataset, which will be required as part of the response to this provisional outcome. The first issue is regarding whether in fact there are any identifiers retained as part of this dataset. The application describes that this database contains identifiers: name, NHS number, date of birth, postcode and a unique participant study number. However, it was noted by the CAG alternate Vice Chair that the flagging process on NHSCR (and now using PDS) was set up in a way to enable researchers to receive pseudonymised datasets without any need to retain the identifiers themselves. The applicant should explain why the identifiers need to be retained going forward and why they could not merely rely on the Unique participant study number allocated by NHS Digital for linkage purposes.

It is also noted that the application and ongoing annual reviews do mention that identifiers are retained, so it is likely that the description of identifiers held is correct. The CAG members would like clarification regarding confirmation that identifiers are currently retained within the PIAG 3-05(l)/2007 dataset.

The second point made by the Members is that as part of the PIAG 3-05(l)/2007 application and ongoing annual reviews until 2016, the exit strategy from support was to anonymise the data after the linkage and prior to analysis. At the time point of 'freezing' follow up in 2016, it is not clear why identifiers were still retained at this point instead of anonymising. However, it is noted that the applicant for 21/CAG/0020 was not controlling PIAG 3-05(l)/2007 and she may not be able to provide the CAG with this information. It is also noted that in previous annual reviews until 2016, the applicant was extending the duration support was required for, as is often the case in national audits applications.

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 applicants are minimising the flow of identifiable information by using the NHSCR flagging system.

- **Feasibility of consent**

This study involves an historic study population of around 1.4 million women in England and Wales identified as alive and age 50 in 1995-1998. The applicants reason it is not practicable to obtain patient consent in these circumstances due to the size and historic nature of the population some of whom will have died or emigrated. The main outcome of the study is death, and these women cannot give their consent. The CAG were content with the justifications provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage from NHSCR to cancer and mortality outcomes by NHS Digital, and this cannot be undertaken with pseudonymised data. Full date of death is also required for analysis.

'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 object 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 privacy notice was provided to CAG alongside the application, with an opt out option included, which will be made available on the University website. Information about this study has now been made available on the Cancer Epidemiology Unit's website; https://www.ceu.ox.ac.uk/research/the-age-at-first-breast-screening-study This information currently does not describe the linkages or flow of identifiers, and does not offer an opt out option, but the applicants have provided an updated website text for consideration. The CAG therefore considered a patient notification website text, and the study privacy notice.

A study specific opt out option is provided on the notification and privacy notice. In addition, NHS Digital will apply the national data opt out before sending data back to the applicants.

It was commented by members that the website text notification was quite long, and that applicants should consider shortening the notification text, and discussing their notification materials with a group of patients and the public for feedback. The CAG commended the layered approach of a notification linking to a separate privacy notice, however this is only effective if the notification is concise enough.

It was noted that the opt out options on the patient notification were not sufficient, as only a postal address was supplied. Multiple contact methods should be provided to enable opt out options such as email and telephone number in addition to postal address.

It was also noted that it is not usual to ask a person to provide their NHS number in order to opt out of applications. However, if this is absolutely necessary, please provide guidance on how people could find this information. (Find your NHS number - NHS (www.nhs.uk))

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 applicant has advised that the Advisory Committee on Breast Cancer Screening has lay representation, however this is a historical government department which would have been relevant at the time of the previous PIAG application, but does not seem relevant regarding this application 21/CAG/0020. The current application does not detail any Patient and Public Involvement regarding any part of the study, and specifically the acceptability of using confidential patient information without consent for the purposes described.

As a response to queries, the applicant has responded that the views of patients and the public will be gained by conducting a focus group with the Nuffield Department of Population Health's participant panel which includes members of the Million Women Study.

The Members were not content with this response, however they noted that a focus group is planned. They requested that the applicant provide a Patient and Public Involvement plan, detailing how the use of confidential patient information without consent will be explored. The CAG commented that the mentioned focus group could be used as a way to test the notification methods as previously noted. The acceptability of the use of confidential patient information without consent needs to be tested with patients and the public and feedback provided to CAG before support can be provided for the study.

Exit strategy

All data is expected to be received during 2021 and data analyses and the preparation of peer-reviewed publications will be completed a few years later. Once the study is published all identifiable data will be destroyed; the applicants estimate that support will be required until 31st December 2024.

The CAG queried whether, if justification for the applicant holding the identifiers could be made, it would be possible to delete the identifiers such as name after the dataset had been received from NHS Digital, and linkage undertaken. It is noted that date of birth is modified to month and year of birth, and that full date of death is required for analysis, however members were not clear why the remaining identifying information could not be deleted prior to 31st December 2024. Further justification is required for the ongoing retention of identifiers after linkage.

Confidentiality Advisory Group advice conclusion

The CAG 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 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, within one month.

Request for further information

1. Please provide confirmation that identifiers are currently retained within the PIAG 3-05(I)/2007 dataset, within three months from the date of this letter.

2. The exit strategy from support for PIAG 3-05(I)/2007 was to anonymise the data after the linkage and prior to analysis. At the time point of 'freezing' follow up in 2016, it is not clear why identifiers were still retained at this point instead of anonymising. Can you please clarify why identifiers were retained, within three months from the date of this letter.

3. Please explain why retained identifiers need to be processed at all by the applicant, and consider if the study could merely rely on the Unique participant study number allocated by NHS Digital for linkage, within three months from the date of this letter.

4. Please consider, if they are required, whether identifiers can be deleted after linkage and prior to analysis. If identifiers are to be retained, further justification is required for the ongoing retention of identifiers until after analysis and publication, within three months from the date of this letter.

5. Please provide the CAG with details of other secondary research questions which may be answered using this dataset, in order to persuade the CAG of the research being in the public interest, within three months from the date of this letter.

6. Please consider shortening the patient notification text for the website, and discuss the notification methods with patients and the public for feedback on these materials, and provide updated documentation to the CAG within three months from the date of this letter.

7. Please ensure that an email and telephone number are included alongside a postal address on the patient notification text for the website in order for people to opt out if they wish, and provide updated documentation to the CAG within three months from the date of this letter.

8. Please consider if it is necessary to ask for an NHS number in order to process an opt out request. If It is, please update the patient facing documentation in order to guide people in how they can find out this information. Please provide updated documentation to the CAG within three months from the date of this letter.

9. Please provide a Patient and Public Involvement plan, which includes feedback regarding the acceptability of the use of confidential patient information without consent for the purposes of the study, within three months from the date of this letter.

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. **Confirmed 12 February 2021**

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**

   The NHS Digital **19/20** DSPT review for **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health (**EE133863-MSD-NDOPH-NDPH), and the **19/20** DSPT equivalent for **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 23 February 2021)

Declarations of Interest

There were no conflicts of interest declared regarding this item.

4. New Applications – Non-Research

a. 21/CAG/0019 - Biliary Atresia Registry (England and Wales)

Context

Purpose of application

This non-research application from Kings College Hospital NHS Foundation Trust (KCH) set out the purpose of creating a registry of all infants with biliary atresia in England and Wales from January 1999 onwards. The purpose of the registry is to monitor the outcome of the clinical management of biliary atresia. Prior to 1999, management in the UK was decentralised. Outcome surveys had shown that only the larger centres treating more than 5 cases per year had acceptable results, so it was mandated that the care of such infants was to be centralised and managed only at three large national centres in London, Birmingham and Leeds, covering patients from England and Wales. Since centralisation, there has been a dramatic improvement in national outcome.

This registry has been in existence since 1999 when the Department of Health mandated that a record be kept of all infants in England and Wales with this diagnosis. However, it has been operating without a legal basis, and this application is therefore to provide a legal basis to retain the database which has been created retrospectively, and to provide a legal basis for the data collection prospectively.

Biliary atresia is a rare, potentially life-threatening, condition of newborns characterised by persisting jaundice and the development of liver fibrosis and cirrhosis. It requires early identification and prompt surgical management to try and forestall liver failure. The registry is required to continue to provide regular, consistent and transparent monitoring of the outcomes of all infants with biliary atresia, in order to continue to improve outcomes of infants and children with this disease.

Data is collected by the direct care team in individual centres, and name and NHS number are removed. At the end of each year, confidential patient information including hospital number, date of birth and gender alongside the pseudo-Identifier and clinical information about each new patient treated in the centre for biliary atresia is transferred via a password-protected spreadsheet using NHS emails, to the central database (in KCH) together with a yearly record of outcome of all infants previously registered. These annual updates of patient management and outcome for previously registered children are then linked to baseline measures via the hospital ID. Data are stored on password-protected hospital server at KCH and only accessible by Mark Davenport, and a nominated deputy.

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	All infants diagnosed with biliary atresia and managed in one of the three national centres, from January 1999 onwards Approximately 850 infants, and more prospectively.

Data sources	Medical records at the three national centres; • Kings College Hospital, London • Birmingham Women's and Children's Hospital • Leeds Children's Hospital
Identifiers required for linkage purposes (for annual follow up)	1. Hospital ID
Identifiers retained in registry	1. Hospital ID – to allow linkage 2. DOB –for analysis 3. Maternal Postcode – for analysis 4. Gender –for analysis 5. Ethnicity – for analysis 6. Date of surgical (Kasai) intervention – for analysis 7. Clearance of jaundice – Primary outcome measure 8. Associated anomalies – for analysis 9. Type of BA – for analysis 10. Need for and date of transplant – for analysis 11. Date of death – for analysis
Identifiers required for analysis purposes	1. Maternal postcode (at time of child's birth) 2. Ethnicity 3. Associated congenital anomalies 4. Type of biliary atresia 5. Date of surgical (Kasai) intervention 6. Date of liver transplant 7. Date of death 8. Date of Birth 9. Gender
Additional information	An update of patient management and outcomes for all previously registered children is also sent annually to KCH

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services 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 Members commented that this was an appropriate medical purpose which was in the public interest, and there is no doubt that the applicant needs to retain and build on this important registry; the committee were very supportive of the registry in principle. The CAG welcome a new application as soon as possible which addresses the points detailed below, as it is recognised that a legal basis is urgently required for the retention of the confidential patient information which is already in the biliary atresia registry.

Scope

The Committee noted that a sister research application is expected for this registry, however this has not yet been submitted. It is important to keep the purposes of the non-research registry clearly defined from the research registry. It was commented that some of the purposes of the non-research registry described in the application seemed to be research related, and therefore the applicant is requested to describe the non-research purposes of the application in more detail when re-submitting. There are some tools available to aid in deciding if an application is research; Is my study research? (hra-decisiontools.org.uk) and also a document which helps define if certain activities are research or not; Microsoft Word - DefiningResearchTable_Oct2017 (hra-decisiontools.org.uk) which the applicant is advised to use as a guide.

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**

It is mentioned in the application that there is an annual flow of data to the co-ordinating centre, from each of the participating centres, but it is not clear if this is always performed on the same date each year. More information regarding this should be provided as part of a new application.

The members noted that the flow chart provided appeared to have arrows flowing both ways between Kings College Hospital and the other centres and requested clarity on what data (if any), is provided back to the participating centres.

- **Feasibility of consent**

The applicant has reasoned that it would not be practicable to take consent for retrospective patients as it would be logistically impossible to retrospectively identify and confirm parental permission dating back to 1999. Some have been lost to follow-up and some children have died. The CAG members accepted this justification for the retrospective cohort.

As part of the applicant's response to queries, regarding whether prospective consent could be a practicable alternative, (as it seems on average each centre would only see 14 new patients per year) the applicant commented that the registry could use a consented model moving forwards, but he had also stated that he required support for patients added to the registry prospectively. In a final response to queries the applicant confirmed that consent will not be practicable moving forwards as complete ascertainment is required in order to fulfil the purpose of the registry.

The CAG members commented that sufficient justification for complete ascertainment within the registry had not been provided, and the applicant would have to ensure a fuller argument is provided in a future application. It was noted that the applicant has stated that the registry is mandated by the Department of Health; the members viewed the press release from 1999 that was provided by the applicant, but did not take this to be sufficient justification for complete ascertainment. Whilst the CAG members noted that it is possible to make a strong argument for complete ascertainment, especially in such a small dataset, it was commented that the applicant had not made these arguments as part of the application, and this would be required as part of a new application.

If there is any possibility that consent could be a practicable alternative to providing support under the Regulations, the CAG cannot, by law, support the application. Therefore, the applicant needs to ensure that it is explained in a new application why prospective consent is not a practicable alternative, and if that reason is that complete ascertainment is required then this needs to be explained and justified clearly.

- **Use of anonymised/pseudonymised data**

In the application, the applicant has stated that pseudonymised data fulfils all the objectives of the registry. However, the data is not pseudonymised – the only identifiers removed are name and NHS number, and the data flow still contains other identifiers alongside a pseudo-identifier. The members wished to note that in this small patient group even one of the data items retained in the registry could alone identify a patient, and the dataset retained cannot be classed as a pseudonymised dataset. As part of the resubmission the applicant should understand that the dataset is not pseudonymised and contains identifiers, such as date of birth, and this is why Regulation 5 support is requested to retain the registry indefinitely.

Justification of identifiers

Confidential patient information in the form of hospital number alone is required for linkage from baseline data to annual outcome data. The applicant states that confidential patient information is also required for accurate analysis of clinical outcomes.

The CAG queried whether any other identifiers would be required for linkage - For example date of birth is often additionally used. The applicant is required to ensure it is clear in a re-submission which identifiers are required for the purposes of linkage.

It was noted that a large amount of identifiable information is retained for analysis purposes, however the justification for the retention of these identifiers has not been clearly provided. The full maternal postcode (at time of child's birth) is stated as required for analysis; however, members were not clear on why this was required, and queried if this could be modified to a less identifiable format? Full date of birth is also stated as required for analysis; however, members were not clear why this was required (if not being used for linkage), and queried if this could be altered to a less identifiable format such as month and year of birth? Other dates held in full format such as date of death and date of interventions should also be fully justified, if these are not able to be modified to a less identifiable format.

'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 object 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 applicant has provided an information sheet and a consent form in response to a request for a patient notification. As the applicant later confirmed he does not propose to consent patients prospectively, the members disregarded the consent form, and considered the information sheet as a notification leaflet.

This notification does not contain an opt out option, and as a response to queries the applicant responded that no opt out mechanism currently exists, as this would negate the mandate from the Department of Health to ensure an on-going audit of outcome in Biliary Atresia. This response also applied to the National data opt out.

The CAG commented that the notification was not fit for purpose in its current format. The leaflet should state which data items are collected and how, the legal basis of the data collection and processing needs to be explained. A link to a more detailed privacy notice should be placed within the text of the notification, to cover GDPR requirements. This more detailed privacy notice could be available on a website. It is not clear where the notification will currently be displayed. This should be clearly explained in a re-submission, for example, the notification could be displayed in the relevant clinical areas in each participating Trust, and on the Children's Liver Disease Foundation website. The members also noted that the notification document was co-branded with the Children's Liver Disease Foundation logo, but it was not clear if the charity had any input into this notification. It was commented that further patient and public involvement should be carried out regarding the notification methods, see below section for additional details.

The members also noted that there did not seem to be any notification methods suitable for older children or young adults which could be important for this type of registry. The applicant is advised to develop these for a future application.

The CAG members noted that no opt out option had been provided, but felt the applicant had not provided a strong enough justification for this. For a re-submission, the applicant should develop an opt out method, including how to implement the national data opt out, or provide a strong justification linked to the argument for full ascertainment.

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.

Though individual parents or patients have not been approached, the applicant has provided a letter of support from the Children's Liver Disease Foundation. The letter is supportive and the use of confidential patient information without consent is explicitly mentioned.

The Committee was not content with the supportive letter as evidence of sufficient patient and public involvement. It was commented that the applicant could ask for the charity to connect him with some patients and parents in order to run a focus group. This can be undertaken in any format, including zoom or teams and does not have to be restricted to face to face. The CAG also suggested creating a steering committee for the registry which included lay representation. It was also noted that as part of the supportive letter, the charity seemed to be requesting better link up with the applicant regarding the registry, and the CAG were therefore not convinced that the applicant was engaged enough even with the charity, and especially not with individual patients or parents.

Further Patient and Public Involvement and Engagement is required to be undertaken as part of a re-submission, and patients and parents should be asked specifically about the acceptability of this use of the confidential patient information without consent, and this should include their opinions on the level of confidential patient information retained. The focus group should be asked for feedback surrounding newly developed notification materials. Parent and patient opinions should also be sought regarding whether an opt out should be offered, and their feedback should inform any justifications around complete ascertainment.

Exit strategy

Support was requested for an ongoing registry – Biliary atresia patients are never cured of their disease and require life-long out-patient based care often in the centre that originally treated them. There is a continual need for liver transplantation in these patients even if they reach early adulthood. Members were content with the exit strategy described, as this is in line with other national registries. However, at the point support is provided, this is usually given for an initial period of five years, and would also be subject to submitting an annual review each year.

Independent audit

As part of the press release from 1999 that was provided by the applicant, the members noted that the press release mentioned an 'independent audit'. However, it is also noted that the applicant is part of the clinical team at Kings College Hospital, one of the three specialist centres. Therefore, the members were not clear if this application for a biliary atresia registry was the mentioned independent audit, and if so, were not clear on how it fulfils the criteria of

providing an independent audit. It was also commented that 1999 was over 20 years ago, and it was felt that some more up to date documentation should be provided regarding this mandate.

Additional data collection; NHS number

Conversely to some of the other advice, the members advised that the applicant should be encouraged to consider the collection of additional confidential patient information in the form of the NHS number of participants. This is to enable linkage to other datasets in the future, if this was required.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Secretary of State for Health and Social Care recommended that the application was deferred. The Secretary of State for Health and Social Care additionally requested the applicant provide the document from 1999 which mandates KCL to establish the registry and details what the registry should cover.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Clearly define the non-research purposes for which the registry will be used, and ensure this is distinct from the research purpose of the sister research application to be submitted.

2. Provide a clear justification as to why complete ascertainment is required, in order to explain why consent is not a practicable alternative for prospective patients.

3. As part of the re-submission, ensure terminology surrounding the dataset retained is correct, in that this dataset is identifiable and cannot be classed as pseudonymous.

4. Please explain if the annual data capture from participating sites is always collected on the same date each year.

5. Please confirm if hospital number alone is required for linkage, or if any other identifiers are additionally required.

6. Please consider if any identifiers retained for analysis can be modified to a less identifiable format, and if not please provide clearer justifications for the retention of identifiers for analysis, such as mothers postcode, date of birth, date of death, and other dates required in full format.

7. Please re-develop patient notification leaflets as described in this letter. These should include separate information for older children or young adults. The applicant should make it clear where these notifications will be displayed, and ensure that a layered approach is in place, linking to a more detailed GDPR privacy notice.

8. The applicant should develop an opt out method, including how to implement the national data opt out, or provide a strong justification for not implementing an opt out option.

9. The applicant should consider creating a steering committee for the registry which includes lay representation.

10. Further Patient and Public Involvement and Engagement is required to be undertaken as part of a re-submission, specifically requesting feedback on;
    - The acceptability of this use of the confidential patient information without consent;
    - Their opinions on the level of confidential patient information retained;
    - Feedback surrounding newly developed notification materials;
    - Opinions on whether an opt out should be offered.

11. Please explain if this audit is the mandated independent audit, and if so, please describe how it fulfils this purpose. Consider providing more relevant up to date evidence regarding the mandated audit.

12. Please consider including the NHS number as part of the data collected within the registry, in order to use this for potential linkage with other datasets in the future.

13. Please confirm if any data is sent back from Kings College Hospital to the participating centres, as is implied on the flow chart.

14. Please provide as part of a re-submission, the document from 1999 which mandates KCL to establish the registry and details what the registry should cover.

15. Ensure all 19/20 DSPTs have been reviewed by NHS Digital in order to provide security assurances for CAG. These organisations are; Kings College Hospital NHS Foundation Trust, 19/20 DSPT pending review, however both Birmingham Women's and Children's NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust have a 19/20 DSPT in place which has been reviewed by NHS Digital.

Once a new application is received, the information will be reviewed at the next available CAG meeting.

Declarations of Interest

There were no conflicts of interest declared regarding this item.

b. 21/CAG/0023 - Patient Experience Measure: a 'real time' survey of patients' experience of general practice

Context

Purpose of application

This application from NHS England/Improvement set out the purpose of a patient survey conducted to capture patients' experience of general practice in England.

The survey is designed to capture patients' experience of their most recent contact with their general practice, as well as gathering feedback on their experience of access to general practice overall. Surveys, such as the General Practice Patient Survey (GPPS) and Friends and Family Test (FFT), have existed for several years in general practice, however this will be the first time that a demographically representative, close to 'real time' responsive survey has been delivered. Following an appointment in general practice, a sample of patients will receive a text message directing them to complete a web-based survey, containing a number of questions which relates to their experience and whether or not this met with their expectations and needs. They will also be asked to provide some basic demographic information. The results of the survey will be analysed and then published on a monthly basis, aggregated at Primary Care Network (PCN) level, and will be used to track trends in patient experience overall and in relation to different groups of patients, improve access to general practice services and financially incentivise PCNs to improve their overall performance.

The applicants are seeking support as processing of confidential patient information is required in order to identify patients who have had an appointment in general practice and provide their mobile phone number, and to provide demographic data to facilitate sampling to ensure the data received is representative of the local population. NHS England/Improvement will hold a memorandum of understanding with the NHS BSA to develop and run the Minimum Viable Product (MVP) Patient Experience Survey. NHS Digital will extract the required confidential patient information from the General Practice Data for Planning and Research (GPDPR) on a daily basis and will then link this with patients' mobile numbers from the Personal Demographics Service (PDS). This data will then be shared with NHS BSA so that they can apply the sampling methodology to the data and send a text each day to a statistically significant sample of patients who had a general practice appointment within the previous 36-48 hours. Patients will then be sent a text with a link to the survey on a web form. A link to further information about the survey, and a privacy statement, will be included on the same page as the web form to ensure patients are clear about why and how their data is being used. Survey responses will be linked back to the individual's original data and then collated and analysed by NHS BSA before being published on a monthly basis, aggregated at PCN level. No identifiable data will be shared outside of NHS BSA.

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	Patients registered at a general practice in England, aged 16 and over, who have had an appointment with a general practice provider from 01 April 2021 onwards.
Data sources	1. The General Practice Data for Planning and Research (GPDPR) and the Personal Demographics Service (PDS), held by NHS Digital
Identifiers required for linkage purposes	1. Patient ID 2. Organisation Code 3. Patient mobile number 4. Patient date of birth 5. Patient ethnicity 6. Patient gender

	7. Patient language 8. Appointment date and time 9. Appointment attended status 10. Appointment ID 11. Appointment mode
Identifiers required for analysis purposes	All identifiers used for analysis will be on a consented basis

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services 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 CAG agreed that the application had a medical purpose and was in the public interest.

Patient expectations of confidentiality

The main concern of the CAG was the patients' expectations on how their mobile number would be used. Patients would have given their contact details to their GP surgery and may not expect these details to be passed on to NHS BSA. Some may also not expect or not want to receive text messages due to concerns over safeguarding. Members agreed that the sampling methodology will need to be provided with the resubmitted application, so that the CAG can review the methodology to be used.

Scope

NHS Digital would link to the Patient Demographics Services (PDS) in order to obtain patients' mobile numbers. Patients' details and telephone number will be transferred to NHS Business Services Authority (BSA), who will apply the sampling methodology.

The application cited that 1 million GP appointments were undertaken every day. The CAG noted that details for a large number of patients would be passed from NHS Digital to NHS BSA on a daily basis, many of whom would not be contacted. Members asked for clarification on how many patients would have their details transferred to NHS BSA every day and how many of those would be selected to be contacted each day.

The CAG asked whether it was possible for NHS Digital to apply the sampling methodology, so that only the details of those selected were passed to NHS BSA, reducing the disclosure of confidential patient information.

Members noted that NFR12, on page 12 of the GP appointment questionnaire - final report, referred to potential linkages to further details about the appointment. The CAG asked that the meaning of this reference was clarified and whether explicit consent would be sought from patients for this linkage.

The data flow diagram indicated a flow of information back to GPs. Members queried whether this will be aggregated data and that there was no risk of re-identification by GPs.

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 explained that all patients over the age of 16 registered with a GP practice in England could potentially be included. Over 1 million GP appointments and it would be impracticable to ask each patient to opt-in to receiving the survey when attending, as this would be a burden on the staff within practices. The applicants noted that not every patient would be invited to complete the survey, meaning that patients may consent but then not be contacted. The applicants also noted a potential for bias, as practices could potentially 'self-select' patients who they wished to be surveyed. Patients would instead be given the opportunity to opt-out

when they received the text. The CAG agreed that consent to enable the survey request to be sent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is needed for NHS Digital to identify suitable patients and ensure that the contact details are correct. NHS BSA require the contact details in order to text patients with the survey details. The CAG noted that mobile numbers were not usually considered to be confidential patient information. If patients' NHS number was not transferred, then the only direct identifier that would be shared from NHS Digital to NHS BSA was patients' dates of birth. The CAG asked if it was possible for NHS Digital to convert dates of birth to age. The data flow from NHS Digital to NHS BSA would then be pseudonymised, which would mean that support under s251 may not be required.

- **'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 object and a 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 will be informed about the survey, and their right to opt out should they wish, via a range of communications materials including posters for display in practice, information for patient information screens, information to be added to practice websites, a script and FAQs to be shared with practice teams which will help inform their conversations with patients about the survey.

Patients will have the right to opt out of any further survey requests at any time by replying with the word 'STOP' when the text message is received. NHS BSA will maintain a list of all individuals who have opted out and this will be applied to the raw data during the sampling process.

A list of those patients who have requested to opt out of subsequent contact will be held by NHS BSA and applied to future data during the sampling stage to ensure that patients who have requested to opt out do not receive any more text requests.

The CAG asked whether NHS Digital would apply the National Data Opt-Out, prior to sending patient details to NHS BSA.

The CAG asked that the notification materials, such as posters and leaflets, were provided with a resubmitted application.

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 applicant explained that NHS BSA and Deloitte have consulted patients during the discovery phase of this project.

IPSOS Mori is currently undertaking cognitive testing of the survey questions with groups of patients (around 40) covering a range of demographics. Patients are also being asked to give their views on whether they would have any issue with the NHS using their data in this way. To date, no significant concerns have been highlighted and patients appear to be comfortable with use of contact and other identifiable data to support improvement in the NHS. Cognitive testing is due to end on 31 January 2021 when all feedback will be collated and the survey questions amended in response to this process of evaluation.

Further consultation with patients will take place during the ‘prototype’ phase using NHSX patient engagement groups.

Following prototype testing, a month-long proof of concept process which aims to involve around 70 practices and to provide a further opportunity to test the approach with patients in a ‘live’ environment, will be undertaken. As part of a ‘go live’ or ‘no go live’ decision making process, the proof of concept will test technical delivery, content of the survey and communications and engagement. Feedback from patients will be a critical aspect of this process.

A comprehensive communications and engagement strategy, which informs all key stakeholders about the patient experience survey, has been developed to support initial prototyping, proof of concept testing and eventual national rollout. Communications and engagement will be tested alongside technical delivery during the first two stages of the development process and results of this testing will inform the approach prior to national rollout to ensure patients are clear about the aims of the survey, how their data is being used, how they can opt out, what will happen as a result of their feedback etc.

The CAG agreed that further work would need to be undertaken. Although some consultation had been undertaken regarding the project this had only included a small number of patients and the group did not feel it was commensurate with the extent to which confidential patient information would be accessed without consent and the amount of personal data to be shared in order that the sampling group could be identified. The patient and public involvement needed to include discussion of the specific issue of processing confidential patient information in the proposed way, without consent. The intentions of the study, including all purposes that the survey responses will be used for, also needs to be explored.

Exit strategy

The application did not outline an exit strategy or provide a proposed end date for support. Members agreed that any resubmitted application would need to provide these details.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Secretary of State for Health and Social Care recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which

addresses the below points and sets out where revisions have been made to the revised CAG application.

1. If NHS Digital can convert patients' dates of birth to age then, as long as no other items of confidential patient information will be transferred, then CAG will consider the data to be pseudonymised and support under Regulation 5 may not be needed.

We would be grateful for confirmation of whether this is possible If it isn't then the following points will need to be addressed in the resubmitted application:

1. Justification needs to be given as to why NHS Digital cannot apply the sampling methodology.

2. The reference to potential linkages to further details about the appointment in NFR12, on page 12 of the GP appointment questionnaire - final report, needs to be clarified.

3. Clarification needs to be provided on the flow of information back to GPs, including whether this will be aggregated data and that there will be no risk of re-identification by GPs.

4. Clarification on whether NHS Digital will apply the National Data Opt-Out, prior to sending patient details to NHS BSA.

5. The notification materials, such as posters and leaflets, will need to be provided.

6. Further patient and public involvement needs to be undertaken, including discussion of the specific issue of processing confidential patient information without consent on the proposed scale. The intentions of the study, including all purposes that the survey responses will be used for, also needs to be explored.

7. An exit strategy, including the proposed end date of support, needs to be provided.

Once a new application is received the information will be reviewed at the next available CAG meeting.

Declarations of Interest

Mr David Evans declared a conflict of interest and left the meeting before this application was discussed.

5. Any other business

The volunteer satisfaction and demographic survey was brought to Members' attention.

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

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date