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

06 November 2020

Present:

Name	Capacity	Items
Dr Murat Soncul	CAG Alternative Vice-Chair	1a, 1b, 2a, 2b
Dr Malcolm Booth	CAG Member	1a, 2a, 2b
Prof Barry Evans	CAG Member	1a, 1b, 2a
Prof Jennifer Kurinczuk	CAG Member	1b, 2b

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Katy Cassidy	HRA Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 20/CAG/0123 - REadmission And Cardiovascular ouTcomes following Acute Myocardial Infarction in England and Wales (REACT-AMI)

Context

Purpose of application

This application from Keele University Clinical Trials Unit sets out the purpose of medical research that aims to determine the type, incidence, prevalence, secular trends and prognostic impact of post-discharge complications and unplanned readmission on long term clinical outcomes in patients admitted with a heart attack. Applicants also hope to develop risk scores to predict future events and risk stratify patients presenting with heart attacks, which would allow clinicians managing these patients to tailor treatment according to the patient baseline risk and risk of future events.

Acute myocardial infarction (heart attack) remains a leading cardiovascular cause of morbidity and mortality worldwide and is the commonest manifestation of coronary heart disease. It is estimated that almost half of the cardiovascular disease-related deaths are due to heart attacks in the UK. The acute survival of patients following a heart attack has improved significantly over the past decade. However, the UKs ageing population is resulting in an increasingly multimorbid population at greater risk of complications, readmissions and mortality. There is limited information around the incidence and type of post discharge complications of heart attacks, readmission and their association with long term outcomes.

The team plans to use data from a large observational cohort of all recorded heart attack cases in England and Wales, initially from 1st January 2005 to 31st March 2020; The Myocardial Ischaemia National Audit Project (MINAP) dataset. MINAP is a dataset within the national cardiac audit programme (NCAP) which contains information about the care provided to patients who are admitted to hospital with acute coronary syndromes (heart attack). This dataset is held at The National Institute for Cardiovascular Outcomes Research (NICOR) which is hosted at Barts Health NHS Trust. The legal basis for the NCAP datasets is support under Regulation 5, CAG ref: ECC 1-06(d)/2011 which was replaced by 17/CAG/0071.

Applicants plan to link the MINAP dataset with Hospital Episode Statistics (HES) data and Office of National Statistics (ONS) mortality data which are held by NHS Digital. They outline the process, of NICOR disclosing identifiers of patients in the MINAP dataset to NHS Digital for the purposes of linkage with HES and ONS data. This dataset is then sent back from NHS Digital to NICOR, for the purposes of linking the HES and ONS data to the MINAP clinical dataset. The dataset will be pseudonymised before being sent to researchers at The University of Keele Clinical Trials Unit, however it can be considered anonymous to the research team as they will not have access to any re-identification key. Analysis will be performed by Keele Cardiovascular Research Group.

This study is planned for four years from the date of data access from NICOR. During this time, annual updates of newly recorded patients will be requested from NICOR. The applicant expects that this will be approximately 90,000 patients per year, and will include any new patients recorded in the MINAP dataset.

A recommendation for class 4 & 6 support was requested to cover 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	Approximate Total UK sample size: 700,000 initially, with an additional 90,000 per yearly update (4 yearly updates in total) Patients admitted with a diagnosis of a heart attack from 1st January 2005 to 31st March 2020, presenting to one of the 235 acute NHS hospitals in England or Wales. Lower age limit: 18 Years Upper age limit: 105 Years

	(This is all patients in the Myocardial Ischaemia National Audit Project (MINAP) dataset).
Data sources	1. Myocardial Ischaemia National Audit Project (MINAP) dataset held at The National Institute for Cardiovascular Outcomes Research (NICOR), hosted by Barts health NHS Trust. 2. Hospital Episode Statistics (HES) & Office of National Statistics (ONS) Civil Registration and Death Register held at NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID 3. Date of Birth 4. Postcode 5. Gender 6. Date and time of admission
Identifiers required for analysis purposes	1. Date of death (not sent to applicant as full date of death, it is modified by NICOR to 'survival time to censored time' in number of days) 2. Postcode (not sent to applicant but modified to deprivation score by NICOR) 3. Gender 4. Ethnicity
Additional information	This study is planned for four years from the data of data access from NICOR. During this time, annual updates will be requested from NICOR. These annual updates will be requesting the same data for all additional patients added into MINAP each year.

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 CAG agreed that the application was in the public interest and has a clear medical purpose.

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 reason that consent is not practicable or appropriate for a number of reasons, including the size of the cohort (at least 700,000), the difficulty in consenting people with an acute heart attack so as to not delay treatment, and wishing to study a complete national cohort to avoid selection bias.

The CAG agreed with the rationale given for not seeking consent.

- **Use of anonymised/pseudonymised data**

The applicants require confidential patient information for linkage from the MINAP dataset to HES and ONS data

The CAG noted that the applicants plan to use existing legal databases and their protocol follows a well-established model of using NICOR and NHS Digital to perform the linkages, and release pseudonymised data back to the researchers. Deprivation score is calculated from postcode by NICOR.

There was some uncertainty in the original application about full date of death being released to the researchers, but the applicant has confirmed that NICOR modify the date of death to ‘survival time to censored time’ in number of days, and researchers will only have access to

anonymised data. As such, the Members were content that this study could not be performed in any other way that would further reduce the use of identifiers.

‘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 applicant has provided a patient information leaflet developed with help from NICOR using their template for studies such as this. This is to be displayed on the NICOR website. There is a study specific opt out mechanism given on the patient notification leaflet, whereby patients can let NICOR know they don’t wish their data to be used for this project. The National Data Opt Out will be applied by NHS Digital.

The Sub-committee were content with the patient notification and opt out mechanism.

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 not undertaken any Patient and Public Involvement (PPI) to ask patients regarding the acceptability of using their confidential patient information for this study without prior consent. However he is in communication with a Patient and Public Involvement (PPI) group, and has responses from them indicating that given the high burden of myocardial infarctions on the patient community and NHS services, the relevance of the study to a patient population was presumed. The applicant also plans to set up a Patient and Public Involvement (PPI) group specifically for this study.

The Members felt that despite the lack of Patient and Public Involvement (PPI) performed, the applicant did have plans create a study specific Patient and Public Involvement (PPI) advisory

group to address this. They did not wish to hold up this study on this basis, but did feel a condition of support was required regarding further Patient and Public Involvement (PPI) undertaken to explore the acceptability of using confidential patient information without prior consent to perform linkages and provide anonymous data to the researchers.

Exit Strategy

This study is planned for four years from the data of data access from NICOR. During this time, annual updates of new MINAP patients will be requested from NICOR. The end date for the study is estimated at four years from date of data access, or 31 December 2025, whichever comes first. A 10 year maximum retention period for the data collected is requested in CAG form, however applicants will not have any identifiers as part of their dataset, so support will be given until the final linkage is completed.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support is given on the understanding that full date of death is not received by researchers at Keele University.

2. Further Patient and Public Involvement (PPI) is required to be undertaken to explore the views of patients regarding the use of confidential patient information to perform the proposed linkages without prior consent. Please provide evidence of the outcomes of the Patient and Public Involvement (PPI), at annual review.

3. Favourable opinion from REC
   Confirmed 25 November 2020

4. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.
   Confirmed:

- The NHS Digital **2019/20** DSPT equivalent review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (17 November 2020)
- The NHS Digital **2018/19** DSPT review for **Barts health NHS Trust (On behalf of NICOR)** was confirmed as **'Standards Not Fully Met (Plan Agreed)'** on the NHS Digital DSPT Tracker (checked 17 November 2020). Please note the updated specific condition of support below. The **2019/20** DSPT was published but not yet reviewed.
    - **Barts Health NHS Trust (On behalf of NICOR)** should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0143 - CTSU clinical trial follow-up service with NHS Digital to provide de-identified follow-up data for use in the EBCTCG breast cancer meta-analyses

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to use data collected by the CTSU clinical trial follow-up service for Early Breast Cancer Trialists' Collaborative Group (EBCTCG) to support the conduct of meta-analyses of the comparative effects of different treatments for women with early breast cancer on death from breast cancer.

The Clinical Trial Service Unit clinical trial follow-up service (CTSU-ctfs) undertakes linkages of the identities of participants in clinical trials for early breast cancer with NHS Digital, in order to provide follow-up information to the Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Since the 1940s, several hundred randomised trials of women with early breast

cancer have been conducted, involving hundreds of thousands of women. The need to identify effective treatments is ongoing and requires long-term follow-up of women recruited into trials. To aid in developing understanding of the results of these trials, every few years since 1985, the EBCTCG has brought together evidence on the major questions for central meta-analyses of the anonymised individual participant data. The CTSU-ctfs was set up in the 1980s to assist clinical researchers in designing, conducting and analysing clinical trials. One service offered by the CTSU-ctfs was assistance in obtaining long-term follow-up of patients in UK clinical trials via the Office of National Statistics (ONS). The CTSU-ctfs has been used by researchers for their own analyses and to contribute data to the EBCTCG meta-analyses of clinical trials.

In this application, the applicants are seeking support to follow-up 1385 patients who took part in seven trials conducted between 1948 and 1987. The applicants are also seeking support to continue to hold the confidential patient information already obtained for the 1385 patients. Confidential patient information will be transferred from CTSU-ctfs to NHS Digital, to be linked to the HES and MRIS (Medical Research Information Service) datasets at NHS Digital. A dataset containing confidential patient information will then be returned to CTSU-ctfs, who will create a copy of the dataset. This copy will be de-identified and provided to EBCTCG, who will use this dataset to conduct meta-analysis. A copy of the dataset created by NHS Digital, containing confidential patient information, will be retained by CTSU-ctfs until the project is complete. It will then be deleted according to procedures approved by NHS Digital.

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	1385 patients recruited to 7 UK clinical trials into treatment of early breast cancer between 1948 and 1987.
Data sources	1. HES and MRIS datasets held by NHS Digital

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. Date of birth 5. Date of death 6. Postcode – District Level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 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 CAG agreed that there was a medical purpose and that the activity was in the public interest.

Scope of support

The CAG raised a query on whether the applicants were also seeking support for EBCTCG/CTSU-ctfs to continue to hold the confidential patient information collected from trials conducted between 1948 and 1987. The applicants advised, under their data sharing agreement with NHS Digital, the historic datasets were held with legal bases under GDPR, namely Article 6 (1) (e) and Article 9 (2) (j). The data sharing agreement with NHS Digital provided an interim legal basis to hold the confidential patient information, but not to undertake processing. Support under Regulation 5 is sought for the applicants to both hold and process the existing datasets.

The CAG noted that support under Regulation 5 could not be granted retrospectively, but agreed that support would be given for the continued holding and processing of confidential patient information collected in the seven trials conducted between 1948 and 1987.

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 applicant noted that the cohort was patients recruited into breast cancer trials between 1948 and 1987. It was likely that many patients would now be deceased or difficult to trace. The CAG noted the information provided and raised no queries in this area.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for NHS Digital to undertake the required data linkage to the HES dataset. The CAG noted the information provided and raised no queries in this area.

'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.

Privacy notices for both EBCTCG and CTSU-ctfs had been placed on the EBCTCG website. The applicants advised that no other patient notification was planned, due to concerns that targeting for notification the participants of trials that took place many decades ago would be difficult to achieve, may be be ineffective and potentially distressing for patients or their relatives.

The applicants advised that a dissent process specific to CTSU-ctfs participants to record their dissent for the use of their records for research purposes, but that privacy notices for both EBCTCG and CTSU-ctfs had been placed on the EBCTCG website. Any requests to opt-out would be respected.

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 advised that the EBCTCG includes patients and patient representatives in the design and interpretation of the findings of the EBCTCG meta-analyses. Three patient representatives sat on the EBCTCG Steering Committee, which has a role in all of the above aspects of the research process.

The applicants had tested the acceptability of CTSU-ctfs for EBCTCG processing confidential patient information by without consent by canvassing three patient support groups, the PHE National Cancer Registration and Analysis Advisory Group for the Review of Informed Choice for Cancer Registrations, the Independent Cancer Patients' Voice and the UK National Cancer Research Institute Breast Group. Representatives from these groups provided letters of support. The CAG noted the information provided and raised no queries in this area.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support is not given for the retrospective holding of confidential patient information collected in the seven trials conducted between 1948 and 1987. Support is given for the continued holding and processing of confidential patient information collected in the seven trials conducted between 1948 and 1987.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 19 December 2019.**

3. 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 Oxford – Medical Sciences Division – Nuffield Department of Population Health (by check of the NHS Digital DSPT tracker on 17 November 2020) and NHS Digital (by check of the NHS Digital DSPT tracker on 17 November 2020) have confirmed 'Standards Met' grade on DSPT submission 2019/20.**

Declarations of Interest

There were no declarations of interest.

2. New Precedent Set Review Applications – Non-Research

a. 20/CAG/0139 - 2021 NHS Maternity Survey – Mixed Methods

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2021 NHS Maternity Survey.

The Maternity Survey started in 2007 and falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England.

The 2021 Maternity Survey will be the eighth carried out to date, although this will be the first time that the maternity survey will be completed using a mixed method approach, following a successful pilot of the approach during 2019/20.

Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI) and once of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe). The contractors will distribute questionnaires to patients using the approach detailed below, as successfully piloted:

Contact	Type	Content of contact	Days from first mailing
1	Postal	Invitation letter inviting the patient to take part online, Multi-language sheet	1
1.1	SMS	SMS reminder (if phone number available), including a link to the survey	4
2	Postal	Reminder letter, Multilanguage sheet	15
2.1	SMS	SMS reminder (if phone number available), including a link to the survey	18
3	Postal	Reminder letter, Paper questionnaire, Freepost return envelope, Multi-language sheet	29
4	Postal	Reminder letter, Multilanguage sheet	43
4.1	SMS	SMS reminder (if phone number available)	46

Ahead of each reminder mailing, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on the full sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

Please also note that whilst the survey remains similar to previous years, the applicants have added in COVID status to the data requested for analysis so they can distinguish between these for reporting purposes.

A recommendation for class 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** maternity service users **aged 16 and over** at the time of delivery who had a live birth between **1 February and 28 February 2021**. (and earlier for smaller trusts), Exclusions: • Mothers who were under 16 years of age at the time of delivery. • Mothers who had one or more stillbirths. • Mothers whose baby has died since delivery • Mothers who have died during, or since, delivery. • Mothers who were in hospital, or whose baby was in hospital, at the time of drawing the sample. • Where possible, mothers who had a concealed pregnancy. • Where possible, mothers whose baby was taken into care or adopted. • Mothers who delivered in a private maternity unit or wing. • Mothers who delivered in a maternity unit managed by another provider • Mothers without a UK postal address *(but do not exclude if addresses are incomplete but still useable, e.g. no postcode)*. • Mothers who have requested that their details are not used for any purpose other than their clinical care, including requests made following sight of survey pre-publicity; This does not include the National Data Opt-out Programme.
Data sources	1. Electronic patient records within all eligible Trusts in England (120-130 trusts)
Identifiers required for contact purposes	7. Title 8. Initials or first name 9. Surname 10. Address Fields including postcode 11. Mobile phone number

	12. Patient unique identifier
Identifiers required for analysis purposes	1. Patient unique identifier 2. Postcode 3. Mother's year of birth 4. Mother's gender 5. Time of delivery 6. Number of babies born at delivery 7. Day of delivery 8. Month of delivery 9. Year of delivery 10. Maternity Care Setting (Actual Place of Birth) 11. Actual delivery place 12. Mother's ethnic group 13. Trust code 14. NHS Site code (of birth) 15. CCG code 16. Mobile phone indicator 17. Whether or not mother received antenatal and/or postnatal care from the trust 18. Covid-19 diagnosis during labour and birth (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified) 19. Treated as a suspected or confirmed covid-19 case

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.

Members agreed that the activity has a medical purpose and was in the 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 agreed that consent is not feasible, given the potential to introduce bias, and the lack of capacity of Trust staff.

- **Use of anonymised/pseudonymised data**

Members were content that the use of anonymised or pseudonymised information was not practicable, given the need to distribute information to patients. The Sub-Committee also were content with the postcode being used for analysis; postcode is deleted after mapping to LSOA and local authority, as per previous surveys. Covid-19 status is the only additional sensitive information required compared to previous maternity surveys, and members were content with this flow of data, as it was comparable to the recently supported survey CAG reference 20/CAG/0085.

'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 applicants provided an overview of the patient notification and awareness raising mechanisms offered to Trusts. Posters will be displayed in participating Trusts throughout the sampling period to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised. These have been produced in English and translated into 9 other languages to improve accessibility. Trusts will be asked to consider the impact of Covid-19 on the visibility of posters, and to think carefully about where to place them appropriately.

Although the provision of posters is the primary method of informing the study population of the survey, trusts will also be informed that they can undertake their own additional promotional activities, where considered appropriate, for example through press releases and local social media.

16-17 year olds additionally have a specific notification leaflet, and will be informed directly by hospital staff about the survey. This is a recommendation from CAG regarding 16-17 year olds in a previous survey.

Members also were content that the applicants had adequately explored the use of an SMS opt out mechanism and were in agreement with the decision and reasoning not to use an SMS opt out mechanism. There is a helpline number included in the SMS which applicants can call to opt-out if required.

The members did question the amount of contacts by letter and SMS that a patient would receive, however the same methodology has been previously supported by CAG, and the applicants have performed PPI regarding the amount and type of contacts which appears to be supportive.

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 application form provides a detailed overview of the patient and public involvement in the development of this survey, including how this 2021 survey was shaped by involvement of patients. As part of these discussions applicants checked patients' views on their information being used for these purposes without consent. The majority of patients were comfortable with this approach.

Further to this, a response to provisional outcome for the 2020 NHS Adult Inpatient Main Stage Survey – Mixed Methods (20/CAG/0085) provided an update on PPI undertaken to date, which was accepted by the CAG in a fully supported outcome letter dated 22 September 2020.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.

   Confirmed: The NHS Digital **2018/19** DSPT submission for **Ipsos MORI, Patient Perspective, Quality Health and Picker Institute Europe** were confirmed as '**Standards Met'** by NHS Digital by check of DSPT tracker (17 November 2020). The **2019/20** DSPT submissions have not yet been reviewed by NHS Digital, but the applicant has requested that these be reviewed.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0145 - 2020 Children and Young People's Patient Experience Survey

Context

Purpose of application

This application submitted by Picker Institute Europe and commissioned by the Care Quality Commission, set out the non-research purpose of facilitation of the 2020 Children and Young People's Patient Experience Survey. The survey, which will be fifth carried out to date, forms part of the NHS National Patient Surveys Programme and was last run in 2018 (CAG reference 18/CAG/0150).

The applicants are seeking support for the transfer of patient identifiable data from acute trusts, to an approved survey contractor for the purpose of mailing out questionnaires for the 2020 Children and Young People's Survey. The applicants expect that the vast majority of the trusts involved will opt to use an approved survey contractor, either: Picker, Quality Health or Patient Perspective. In 2018, 125 of 129 trusts chose to use a contactor.

The methodology for the 2020 survey is largely unchanged from the 2018 survey. In 2018, the applicants received support to send three separate, age-dependent, self-completion questionnaires to patient's home addresses. One questionnaire is for the parents/carers of children aged 0-7 year's old, one for children and young people aged 8-11 years old and their parents/carers, and one for young people aged 12-15 years old and their parents/ carers. The sampling methodology is also unchanged from the 2018 survey. The sample for the survey is a disproportionate stratification model with a total sample size per participating NHS Trust in England of 1250 patients. The total sample size is comprised of a target sample size for each age group: 450 patients within the 0-7 year-old category, 400 patients within the 8-11 year-old category and 400 patients within the 12-15 year-old category. All eligible trusts will be asked to conduct the survey with preparations expected to begin in October 2020 and fieldwork expected to start from February 2021. All trusts will draw a sample of patients according to set criteria and will follow standardised materials and procedures for all stages of the survey. An overview of the survey methodology, the Survey Handbook and Sampling Instructions were provided with the application.

The applicants seek to collect additional sample variables as part of the data submitted by NHS trusts to the Survey Coordination Centre for Existing Methods (SCCEM). These variables are:

- Full postcode information for each patient in the sample from a trust – to enable the SCCEM to map case level postcodes to the Lower Layer Super Output Areas (LSOA) deprivation indices in order to examine links between deprivation and patients' experience of hospital care.
- A flag to indicate whether there is a mobile phone number recorded for the patient's parent or carer – to assist in the planned transition from a purely paper-based approach to a mixed mode design where respondents will have the option of providing their feedback through a paper questionnaire or online.
- Covid-19 diagnosis – to aid in assessing the impact that Covid-19 has had on services.
- Treated as a suspected or confirmed covid-19 case - to aid in assessing the impact that Covid-19 has had on services.

A recommendation for class 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	Children and young people aged between 14 days and 15 years who were admitted as inpatients, day-cases and emergencies to an acute hospital between 01 November and 31 December 2020. Trusts will be required to draw a disproportionate stratified sample of patients who were admitted and discharged during this time period. The maximum sample size for the survey is 1250 patients. If a trust is unable to draw a minimum sample size of 400 patients they must contact the SCCEM directly and will be instructed to also sample back to 01 October 2020.
Data sources	1. Each participating NHS trust in England providing hospital services (inpatient and day case) to children and young people
Identifiers required for linkage purposes	1. The **mailing file** is used to address questionnaires to the appropriate person. It contains: ▪ A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of patients from each trust), e.g. CYP20XXXNNNN where XXX is the trusts 3 digit trust code and NNNN is the 4 digit serial number relating to sampled patients. ▪ Child/ young person's first name ▪ Child/ young person's surname ▪ Address Fields ▪ Full Postcode
Identifiers required for analysis purposes	1. The **sample file** is used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. This file contains: ▪ Trustcode ▪ The unique identifier code (as above) ▪ Year of birth ▪ Gender ▪ Ethnicity ▪ Date of admission ▪ Date of discharge ▪ Length of stay ▪ Main speciality on discharge ▪ Treatment function code ▪ CCG code

	▪ Treatment centre admission ▪ Admission method ▪ NHS site code of admission ▪ NHS site code of discharge ▪ Patients full postcode ▪ Parents or carers mobile phone indicator ▪ Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified. Note: some trusts may have upgraded to using ICD-11 codes. If that is the case, those trusts would create this variable from using ICD-11 RA01.0 COVID-19, virus identified and RA01.1 COVID-19, virus not identified) ▪ Treated as a suspected or confirmed covid-19 case The two sets of information listed above will be submitted by trusts to approved contractors as one file. Approved contractors will split the data out and only the sample data will be provided to the SCCEM to enable centralised checks on the appropriateness of samples drawn. Some trusts may experience delays in clinical coding needed for the COVID-19 specific sample variables. Consequently, if a trust is not able to provide the COVD-19 specific variables as part of their sample file submission, the applicants will request that these trusts submit the COVD-19 related variables as part of a separate attribution file to be sent directly to the SCCEM during fieldwork. This file would contain: ▪ NHS Trust code ▪ Patient Record Number (PRN)- the unique identifier code for each sampled patient ▪ Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified. Note: some trusts may have upgraded to using ICD-11 codes. If that is the case, those trusts would create this variable from using ICD-11 RA01.0 COVID-19, virus identified and RA01.1 COVID-19, virus not identified) ▪ Treated as a suspected or confirmed covid-19 case The file would be transferred to the SCCEM directly using the file transfer secure site. It would be matched into the final survey response file to aid analysis

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 noted that additional questions had been included to collect information on confirmed COVID-19 or probable COVID-19 diagnosis, and impact on patients' experience of care. The CAG raised no issues in relation to these additional questions.

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. The CAG agreed that the application had a medical purpose and was in the public interest.

- **Feasibility of consent**

The applicants cited three central arguments support why consent is not feasible for the survey process, which have been accepted in relation to other applications submitted for the NHS National Patient Survey Programme. These are; that it would remove the benefits of the Trusts being able to employ a specialist contractor to facilitate the survey process as it would require them to arrange their own mailing to patients, it would introduce a systematic bias in response rates by changing the nature of the survey from an opt-out system to an opt-in system, and that the introduction of a prior consent process for the survey would put an unrealistic burden on busy staff. The CAG noted this information and raised no queries.

- **Use of anonymised/pseudonymised data**

Processing of confidential patient information is required to enable the surveys to be sent to the correct patients. The CAG noted this information and raised no queries.

'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.

Trusts will be required to display Dissent posters in prominent locations at their site locations to inform possible service users about the potential for them to be sent a questionnaire. On these posters, there is a requirement for contact details at a trust to be provided (email address, telephone number and postal address) so patients can indicate dissent. The trust is required to keep a record of this so these patients can be removed from the eligible population of patients admitted to and discharged from hospital during November and December 2020. The dissent posters are to be displayed for the full sample period (November and December 2020) and have been made available in English and 11 other languages (most commonly spoken in England). Trusts will be informed in early October 2020 to display these posters and will be made publicly available on the NHS Surveys website.

Although the provision of posters is the primary method of informing the study population of the survey, trusts will also be advised and encouraged to undertake their own supplementary activities to inform patients of the upcoming survey, where considered appropriate, for example through press releases and local social media. The survey handbook will be updated with suggestions on how trusts can do this.

Posters will be used to promote the survey and will supply a telephone, email and postal contact to enable patients to raise an objection to their involvement in the survey process. Trusts will be required to keep a record of objections and dissent. However, the method in which they do this is at the discretion of the trust. The applicants anticipate that the majority of trusts will use a flag on the electronic records systems and have a data field specifically about whether the service user is happy for their contact details to be used for any other purpose than clinical care. Other trusts will keep a separate record which is cross referenced against the eligible population before the final sample file is drawn. This method is a long-standing approach adopted for the Children and Young People's Patient Experience Survey and has been successfully managed by trusts in previous surveys.

The CAG noted that the questionnaire and other patient facing materials were still in development. Members asked that the final versions were provided for review prior to being sent to participants.

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 overall methodological approach for the survey is broadly similar to that which has been used since the national NHS Patient Survey Programme (NPSP) was established by the Department of Health and Social Care in 2002. The applicants note that methodology is based on best research practice and evidence accrued during the course of the programme to date and learnings adopted from previous iterations of the survey being implemented. It involves a postal paper self-completion questionnaire being mailed directly to a patient's home address.

The first Children and Young People's Patient Experience Survey, run as part of the NPSP, occurred in 2004 on behalf of the Healthcare Commission. Since then the national survey has been run another three times: in 2014, 2016 and 2018 on behalf of CQC. The 2020 Children and Young People's Patient Experience Survey will be the fifth time it has been carried out and over time patients have been involved in the following ways in developing, reviewing and refining the survey questionnaire. The applicants provided details on the patient and public involvement conducted in preparation for the 2004, 2014, 2016 and 2018 surveys.

In preparation for the 2020 survey, the applicants had begun questionnaire development work in August 2020, to determine the changes needed to the questionnaire content. The finalised questionnaire is anticipated to be ready in November 2020. The applicant provided details on the preparation work that had been undertaken.

The CAG noted that the patient and public involvement had been hindered by the coronavirus pandemic. Extensive patient and public involvement had been carried out when developing the 2018 survey, which remained relevant. Members accepted that additional patient and public involvement need not be carried out for the 2020 survey but agreed that further patient and public would need to be undertaken prior to any further applications for future Children and Young People surveys.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Provide the final versions of the questionnaires and patient-facing documents for review before they are sent to patients.

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: Patient Perspective, Picker Institute Europe and Quality Health (by check of the NHS Digital DSPT tracker on 19 November 2020) have confirmed 'Standards Met' grade on DSPT 2018/19).**

Declarations of Interest

There were no declarations of interest.

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date