Minutes of the meeting of the Confidentiality Advisory Group

17 October 2019 at HRA Manchester, Barlow House

Present:

Name	*Present*	*Position*
Dr Patrick Coyle	Yes	CAG Vice-Chair
Ms Clare Sanderson	Yes	CAG Alternate Vice-Chair
Dr Martin Andrew	Yes	CAG Member
Ms Sophie Brannan	Yes	CAG Member
Professor Barry Evans	Yes	CAG Member
Dr Liliane Field	Yes	CAG Member
Dr Katie Harron	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Ms Gillian Wells	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor

1. Introduction, apologies and declarations of interest

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 has not yet provided a response to the advice provided by the CAG in relation to the 19 September 2019 meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the 19 September 2019 meeting applications.

3. RESUBMITTED APPLICATIONS – RESEARCH

a. 19/CAG/0182 – National Joint Registry – Research Activity

Context

Purpose of application

This application from the Healthcare Quality Improvement Partnership set out the purpose of medical research through the secondary use of information collated for audit purpose by the National Joint Registry, under reference 18/CAG/0146, for research purposes.

The CAG's remit only extends to the secondary use of data for research purposes for those patients, within England and Wales, whose consent status is not known within the National Joint Registry. This currently extends to approximately 6% of records within the NJR. Those patients who have consented to the use of their information within the National Joint Registry have provided consent in relation to research purposes. The latest consent rate states 92.3% of patients have provided consent to their inclusion. Those patients who have declined consent would not be included in the research database.

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

Confidential patient information requested

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

Cohort	Patients who are included on the National Joint Registry following a hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards on the basis of section 251 support via application 18/CAG/0146.
Data sources	1. National Joint Registry dataset
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode (unit level)
Identifiers required for analysis purposes	1. Gender 2. Age 3. Ethnicity

Additional information	The application set out a consented arm; this is not within the scope of the proposed support.

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.

The Group acknowledged that this was a revised application submission which had been made in response to the previously deferred outcome issued under reference 19/CAG/0057.

Further information had been requested in four specific areas as follows: the inclusion of adults who lack capacity for themselves within the research database; clarification of the scope of support required under the Regulations for the research database, access and governance arrangements for researchers based outside the EEA and assurance that all releases from the research database would be GDPR compliant. These areas formed the scope of the CAG review of the revised application.

The applicant had provided a detailed covering letter which addressed the CAG's request for further information together with a revised application.

Public interest

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

Members maintained the view that there was public interest in the wider use of information collated for the purposes of audit under the National Joint Registry for research purposes, as this was an incredibly rich dataset which could be used to inform improvements in patient care and treatment.

Scope

As part of the revised submission, the applicant had set out the various pathways under which patients could be included within the National Joint Registry audit application and what legal basis was being relied upon, in relation to the common law duty of confidence, for the onward processing of their data for research purposes. The following assurance was provided, which also clarified the scope of support which was being requested under this application.

1. Patients who have consented – consent in place for research purposes; no support required,

2. Patients who have declined consent – no legal basis in place; patient excluded from the NJR and research database as no confidential patient information is collated on these individuals,

3. Patients lacking capacity where a consultee has agreed participation – included via provisions of the Mental Capacity Act 2005; no support required,

4. Patients lacking capacity where a consultee has not agreed participation – no legal basis in place; this sub-group of patients is excluded from the research database,

5. Patients where consent status is unknown – legal basis is section 251 support; support is sought under the Regulations to include information collected for non-research purposes under application reference 18/CAG/0146 within the research database. This will require processing and flow of confidential patient information for linkage purposes.

The CAG agreed that the additional clarification which had been provided clearly set out the scope of support which was required under the Regulations for this research application and provided assurance around the alternative legal basis for processing, in relation to the common law duty of confidence, for the wider sub-cohorts of patients included within the NJR.

Members noted a contradiction within the application and supporting documentation in relation to how the withdrawal of consent by a patient following regaining capacity would be handled. It was suggested that data collected to the point consent was

withdrawn would be retained; however, the Group agreed that any patient should be able to determine what data, if any is retained, should they choose to withdraw consent. The applicant would be asked to provide assurance to this point.

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.

- Mental Capacity Act 2005

The applicant had provided a revised approach to the inclusion of adults who lacked capacity to confident for themselves within the NJR and associated research database which addressed the requirements of the Mental Capacity Act 2005. The supporting documentation was provided for consideration.

The applicant explained that it was anticipated that the overall percentage of patients which were included in the NJR with section 251 support, due to an unknown consent basis, would decrease following the introduction of this revised methodology.

The CAG agreed that the revised information provided within this resubmission evidenced that appropriate steps had been taken to include adults who lack capacity to consent for themselves within the NJR research database, addressing the outstanding points raised in the previously deferred outcome. The Group acknowledged that within the annual review for the overarching audit application, the applicant provided a detailed overview of the basis under which patients were included within the database. It was agreed that the applicant would be asked to report specifically in relation to this category also, to provide evidence against the anticipated decline in requirement for section 251 support to be required.

- Feasibility of consent

The Group recognised that the majority of patients were included on the NJR and resulting research database on the basis of consent. The scope of section 251 support required for the research database had been clearly set out by the applicant, as referenced above. Members were assured that, for those patients who were included

with support under the Regulations, this was the appropriate means for these individuals.

- Use of anonymised/pseudonymised data

Confidential patient information was required for the purposes of linkage which could not be otherwise achieved.

Data flows

Members commented that the data flow chart which had been provided in support of the application included details of data flows for both the overarching non-research audit and the subsequent research-based flow. Whilst the Group was clear, from the supporting narrative information which was provided, of the scope of support which was necessary for this research application, it would be helpful for the research-only data flows to be extracted into a specific flow chart. This would be requested at the time of annual review.

Access and governance arrangements

The applicant confirmed that all requests to access the research database would be reviewed by the Data Access Request Group within the Healthcare Quality Improvement Partnership (HQIP), as controller for the overarching audit programme. As part of the review, applicants would be required to evidence the appropriate security arrangements were in place, regardless of the geographical base of the applicant.

It was further explained that once a data access request had been approved, the researchers would access the necessary data via a web portal, rather than be provided with an extracted dataset. It was confirmed that data could not be downloaded or copied from the web portal. HQIP was responsible for overseeing the web portal, rather than the NJR. The CAG received the information and was assured by the established protocol, managed by HQIP, to manage data access and security.

The applicant recognised that, under current data protection legislation, pseudonymised data was considered personal data and clarified that all data sharing agreements were GDPR compliant.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Provide assurance that, should a patient subsequently withdraw consent for their inclusion in the NJR and/or research database, they would be provided with an opportunity to decide what data, if any is retained for use.

Specific conditions of support

The following sets out the specific conditions of support.

1. Provide a revised data flow chart at the time of annual review which sets out the data flows for research purposes only.

2. Figures should be reported back within future annual reviews around the number of patients which are included within the research database under the provisions of the Mental Capacity Act 2005, together with the number included on the basis of unknown consent.

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

4. 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. **Pending – Northgate, processor for the NJR and research database, remains pending.**

4. NEW APPLICATIONS –Research

a. 19/CAG/0161 - Early cryoprecipitate in major trauma haemorrhage: CRYOSTAT-2

Context

Purpose of application

This application from Queen Mary University of London and NHS Blood and Transplant set out the purpose of medical research which aims to undertake a randomised-controlled trial evaluating two treatment methods for patients who suffer uncontrolled bleeding following a major trauma incident.

Patients who have severe bleeding after injury develop a problem with their clotting system which means that they tend to bleed more. One of the main problems is due to low levels of fibrinogen, a clotting protein normally circulating in the bloodstream. Fibrinogen acts as the 'glue' which holds a blood clot together and at low levels, blood clots don't form properly, and bleeding can continue. Cryoprecipitate is a frozen blood component prepared from plasma and rich in fibrinogen. By transfusing cryoprecipitate early to replace fibrinogen levels in bleeding trauma patients, it is predicted that blood clots will be more stable and reduce bleeding. The study involves two patient cohorts – the first is treated with standard of care treatment involving blood transfusions, the second involves administration of cryoprecipitate and standard treatment with normal blood transfusions, to see if cryoprecipitate can improve survival in trauma patients with severe bleeding. The cryoprecipitate treatment will be administered to patients within 90 minutes of an eligible patient's admission to hospital.

The study commenced in August 2017 and aims to recruit 1142 patients from 24 major trauma centres across the UK. Due to the emergency situation, patients are recruited to the study on the basis of personal and/or professional consultee's advice, under the emergency provision of the Clinical Trial Regulations until the patient regains capacity and fully informed consent can be obtained direct from the patient. The applicants have subsequently found that there is a subset of patients (76 patients from the current recruited cohort of 273, 28% of overall cohort) from whom it was not possible to obtain fully informed consent. The application has been submitted to the CAG to seek support under the Regulations to enable linkage with wider administrative datasets held by

NHS Digital and the Trauma and Audit Research Network to enable follow-up of this cohort of patients.

A recommendation for class 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 aged 16 and over who suffered a major trauma haemorrhage from August 2017 onwards in England and Wales, who were recruited to the CRYOSTAT2 trial on the basis of personal/professional consultee from whom formal informed consent was not provided for the ongoing participation in the study. 28% of the recruited patient cohort do not have a recorded consent.
Data sources	1. CRYOSTAT2 study records held at participating Trusts 2. ONS Mortality data, NHS Digital 3. Patient reported outcome measures (PROMS) data, Trauma and Audit Research Network
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode (unit level) 5. Sex
Identifiers required for analysis purposes	1. Date of death 2. Cause of death 3. Sex

Additional information	The study also involves patients in Northern Ireland which are out of scope for the CAG application.

Confidentiality Advisory Group advice

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

Public interest

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

Members recognised that there was a clear public interest in the trial, which aimed to evidence the best treatment pathway for patients who have suffered uncontrolled bleeding following a major trauma. The outcomes of the trial have the potential to inform best practice treatment for this patient group.

Scope

Supported applications made under section 251 NHS Act 2006 and the Health Service (Control of Patient) Information Regulations 2002 set aside only the common law duty of confidence. Where an applicant is seeking to process confidential patient information without consent in relation to living patients, the proposed activity must have an established legal basis to prevent a breach of the common law duty of confidence and must also evidence compliance with current data protection legislation. This requirement is reinforced at section 251(7) of the NHS Act 2006, which states:

> '*Regulations under this section may not make provision for or in connection with the processing of prescribed patient information in a manner inconsistent with any provision of the data protection legislation*.'

In practice, this means that an activity must demonstrate that it would not be acting inconsistently with the provisions of data protection legislation (the General Data Protection Regulation and Data Protection Act 2018), before support can be considered.

A document had been shared titled '*Managing non-response: establishing the ICO and CAG position*', with the applicant. The document set out the established position of the Information Commissioner's Office (ICO) around the management of non-response to a formal request to consent in relation to data protection legislation, and the implication of non-response when considering making an application via the CAG. The ICO is responsible for guidance and enforcement measures in relation to data protection legislation.

Accepting that the document itself referred to the Data Protection Act 1998 due to the time of original development, the core issue and guidance set out within this document remain the same under previous and current data protection legislation. In summary, this guidance clarified that if a patient had been asked for consent, using consent as the condition for processing under data protection legislation, and if there was no-response then this is taken to be dissent. Non-response is not considered consent under data protection legislation. Any further processing of relevant information may therefore be non-compliant with data protection requirements if valid consent from the participant is not in place.

The applicant had explained that it was the intention that all patients would be consented into the trial once the initial emergency situation had passed. However, this methodology had not accounted for the potential for consent not to be achieved.

A detailed overview had been provided around the circumstances which had led to consent not being obtained from recruited patients. The CAG recognised that within this, there was certainly a sub-cohort of patients who would not have been approached for consent for their onward participation in the trial. These included patients who were abusive or violent and the research team had been advised not to approach, those who never regained capacity due to the nature of their injuries and those who were not approached due to the potential for distress due to the nature of their trauma, for example a car accident involving fatalities. On this basis, Members were assured that there was a sub-group of patients within the overarching unconsented cohort for which support under the Regulations could be recommended.

The application did not clearly state the number of enrolled patients from whom consent had failed to be obtained. It was cited that around 28% of enrolled patients did not have informed consent in place; however, at one place in the application it was stated that 273 patients had been recruited to date, but in the response to queries the applicant had specified that approximately 800 patients had been recruited to the trial.

In advance of the CAG meeting, clarification had been sought around the number of patients within the unconsented group which had been approached for consent as these individuals would need to be excluded from the scope of support under the

Regulations. The applicant had explained that, due to the number of sites involved and the checks which would need to be undertaken to ascertain this information, it was not possible to clarify this detail. Members queried this point, as it was understood that this information would be recorded locally within site records, in compliance with good clinical practice guidance.

The Group recognised the public interest in the trial and accepted the importance of collating follow-up information from all enrolled patients to inform the study analysis. However, the CAG cannot provide a recommendation of support to an activity if the proposed processing may be inconsistent with the provisions of current data protection legislation, as detailed in the above referenced guidance document.

Members agreed that the applicant would be required to confirm with the participating sites which enrolled patients had not been approached for consent for their ongoing participation in the trial in order to establish the cohort of patients which would be included within the scope of the support recommended under the Regulations.

It was recognised that this was a complex area of law for which the CAG had no remit to amend in terms of the implications for those patients which had been approached for consent. The applicant was advised to approach the ICO in connection to those patients which had been approached for consent in order to seek a formal opinion around whether section 251 support can be extended to this group without being in breach of current data protection legislation. If the ICO determined that the proposed processing for this sub-group of patients would not be inconsistent with current data protection legislation and section 251 support could be sought to prevent a breach of the common law duty of confidence, the CAG would reconsider the scope of support under the Regulations for the project.

For prospectively recruited patients, the study information materials had been revised to inform patients that, in the event their consent was not obtained, follow-up data would be collated with section 251 support. The CAG was assured that moving forward, patients would be sufficiently informed of how their data would be utilised in the event that consent was not obtained and agreed that support could be extended in these future circumstances.

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 trial had been approved under the emergency provisions of the Clinical Trial Regulations which enabled the enrolment of patients within the trial, without the need for consent to be taken. A declaration from a personal or professional consultee was subsequently sought around the patient's continued participation in the trial, until such time as the patient regained capacity to provide consent for themselves.

Members accepted the study methodology and agreed that there did not appear to be an alternative consenting mechanism. It was recognised that the initial trial design did not account for the possibility that consent may not be obtained from all patients; however, the Group was assured that the applicant had now taken steps to mitigate against this risk moving forward.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage with the wider data sources which could not be otherwise achieved.

'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 trial has a dedicated website which included a specific section intended for a patient audience. The privacy notice for the trial had been updated to provide information around how a patient's information would continue to be processed in the event that informed consent was not obtained. Provision for patient dissent was also promoted within the document. Members agreed that this document appropriately described how information would be processed within the trial and supported the information materials which would be provided to patients at the consent approach.

The Group agreed that it would be helpful to promote the study within the participating sites, in the interests of informing patients who may never be approached for consent, about how their data would be used. It was suggested that this could be achieved by displaying a poster within the relevant clinical areas at sites. The applicant would be asked to provide this document, prior to any final recommendation of support coming into effect.

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 trial has had a dedicated user involvement group in place since its inception. It was also explained that a patient and public advisor for injury research group had been involved with the study. Two members of this group were represented on the Trial Steering Committee, which had been involved with the decision to make an application for support under the Regulations. A clear overview had been provided around the user involvement throughout the application history and evidenced support for processing confidential patient information without consent. The CAG was assured that the activity undertaken in this area was appropriate and proportionate to the application activity.

Data Protection Compliance

Members noted a reference within the application to the disclosure of information to the USA. Assurance was sought from the applicant that any disclosure would be compliant with the provisions of the General Data Protection Regulation and Data Protection Act 2018.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Confirm the overall number of enrolled patients from whom consent had not been obtained.

2. From this cohort, confirm the number of enrolled patients who had not previously been approached for consent, in order to establish the cohort for which support can currently be recommended.

3. Contact the ICO to seek a formal opinion around the onward processing of data for patients who were approached for consent but did not provide response. If the ICO confirm that the processing would be lawful under current data protection legislation, provide a copy of this evidence for review to support the inclusion of the wider patient group.

4. Posters should be displayed at study sites to inform patients and the public about the study and how information would be used in the event that consent was not obtained. Provide a copy of this document for review.

5. Provide assurance that disclosures of information to the USA would compliant with current data protection legislation.

Specific conditions of support

The following sets out the specific conditions of support.

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

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

    - **Trauma and Audit Research Network has a confirmed 'Standards Met' grade on DSPT 2018/19 (Checked via tracker on 30/09/2019),**
    - **NHS Digital has a confirmed 'Standards Met' grade on DSPT 2018/19,**
    - **NHS Blood and Transplant Service – DSPT pending review by NHS Digital.**

b. 19/CAG/0169 – Accessing Urgent Care with Dementia

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research that seeks to examine how patients with dementia and their companions or professional carers access out of hours primary care, and how decisions about care for patients with dementia can be facilitated in an intervention.

This is an observational feasibility study, and patients' healthcare and treatment will not be affected. The study will analyse out of hours GP telephone calls, through 111 and out of hours services, and face-to-face GP consultations run by out of hours services. Patients will be consented into the majority of the activities undertaken during the study.

This application to CAG has been submitted to seek support for the research team to access confidential patient information held in patients' medical records onsite in GP practices and out of hours GP services within BrisDoc Healthcare Services, in order to extract anonymised data. The GP services will identify patients diagnosed with dementia who have accessed urgent care within the relevant time frame. The BrisDoc staff will anonymise the records to remove confidential patient information. The anonymised records will be transferred to a University of Bristol encrypted laptop using an encrypted hard drive. The researcher will access the records using this laptop when onsite at the locations where the data was extracted. The records will contain documents that contain free text, such as letters and attachments, as this is where the complexity of the decision making around urgent care in dementia would be captured. The researcher will extract the relevant data from letters and free text while on site and anonymise the data. Only fully anonymised data will be removed from the GP services, and staff within the service will check the data before it is transferred to the University of Bristol. This data will be used to undertake a mapping study, identifying how patients with dementia access services and providing the researchers with an overview of differences when accessing the services.

A recommendation for class 1, 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	Male and female patients aged 18 years and above, who have a diagnosis of dementia and accessed urgent care via BrisDoc Healthcare Services and two recruited GP practices between 01 June and 31 July 2019 and 1 November and 31 December 2019.
Data sources	1. Electronic and paper records within GP surgeries and GP out of hours calls.
Identifiers required for linkage purposes	Not applicable – relevant patient notes will be provided to the applicant on site by members of the clinical care team.
Identifiers required for analysis purposes	4. Date of birth 5. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Members recognised that dementia care was an important health topic and the findings of the study had the potential to improve the care pathway for patients with dementia, which was within the public interest.

Scope

The Group recognised that the application included a number of workstreams; however, the application for section 251 support related only to the patient care mapping exercise within primary care which involved the review of patient records within GP practices and out of hours care providers. Members were clear around this element of the overall protocol and assured that this activity required a recommendation of support under the Regulations.

The application form contained information around the wider elements of the research programme, which would be operated with patient consent. Whilst it appeared from the information provided that the initial approach would be made by members of the patient's clinical care team, the Group had some concerns around patients which were identified and approached for consent from records at the out of hours service.

At Q27 and Q28 of the application form, it was suggested that the researcher would be working under an honorary contract within the out of hours service and be required to sign a confidentiality agreement prior to reviewing records for eligible patients. Members were unclear whether this statement referred to the patient mapping exercise or the recruitment methods for the wider elements of the study. The CAG noted that an honorary contract did not in itself provide a legal basis, in relation to the common law duty of confidence, to legitimise access to confidential patient information. It was agreed that assurance would be sought from the applicant that the wider elements of the study, which would operate under patient consent, did not require access to confidential patient information without consent by members of the research team.

The CAG was unclear how many patient records would need to be accessed within the participating GP practices and out of hours services in order to identify the eligible cohort for inclusion. It was agreed clarification would be sought from the applicant in order to define the overarching scope of support required for the application activity.

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 applicant would be accessing patient records on site at the GP practices and out of hours service providers to extract anonymised information only. Nominated contacts within the GP practices would be undertaking an assurance check of extracted data to ensure this was fully anonymised, prior to removal from the sites. The CAG acknowledged that steps had been implemented to minimise the access and flow of confidential patient information with support under the Regulations.

- Feasibility of consent

The applicants explained that information would need to be sent to patients by post in order to seek consent. It was explained that this method of seeking consent had a low response rate and those who did not respond would need to be excluded from the study, which would impact on the validity of the results.

The patient and public involvement steering group had been consulted around the issue of seeking consent for the care mapping exercise. The feedback provided was that many of the patient group would live in care home or other institutions which may present a particular challenge when seeking consent, as patients in care homes may have difficulty with short term memory difficulties and changes in executive functioning. There may also be limited capacity for relatives or care home staff to support the patient in the consenting mechanism.

The CAG recognised that the applicant had taken steps to minimise the disclosure of confidential patient information within the described methodology for the mapping exercise. Members accepted the rationale provided by the applicant and support of the patient group and agreed that it was not feasible to seek consent for this element of the project.

- Use of anonymised/pseudonymised data

It was explained that the service providers would be anonymising the patient records prior to sharing information with the researcher. However, the services did not have capacity to anonymise all free text information prior to this disclosure. The applicant required access to the free text documentation as it was likely that this would include the rich and detailed information around the provision of care to the patient. The CAG acknowledged the steps which had been taken to minimise access to confidential patient information; however, it was assured that the detail to be extracted from free text documentation was key to the study analysis.

Data flows

Members were unclear from the information provided when the anonymised information would be transferred on to the encrypted laptop. The CAG specified that it would be preferable if the transfer took place after the free text had been anonymised. Clarification would be sought from the applicant around this point as it was unclear whether any free text information would be transferred on to the laptop prior to the applicant-led anonymisation process.

The Group queried whether transfer via an encrypted laptop was the most appropriate mechanism. Whilst the information held on the laptop would be anonymised, so there was no risk of patients being identified, if the laptop was lost or stolen, the applicant would have lost all gathered data. It was agreed that the applicant would be asked to consider this data integrity query and confirm whether there was an alternative means of data transfer or back-up.

<u>'Patient Notification' and mechanism for managing dissent</u>

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 <u>inform</u> the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local

obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A document had been drafted which would be displayed in GP practices, either as a poster or distributed as a flyer, to promote the study and provide means for patients to raise a dissent. Members agreed that whilst the wording was clear within the document, it would be helpful if wider study contacts could be provided for patients or carers who wished to find out further information. It was agreed that a revised document would be requested.

Whilst a project-specific dissenting mechanism had been described, which involved informing the GP reception to enable a dissent form to be completed. Members commented that the dissenting form itself was too generic and would need to capture project-specific details to prevent the patient from being opted out of all secondary uses of their data. A revised document would be required prior to any final recommendation of support coming into effect.

It was unclear whether some of the patients which would be included in the mapping exercise element of the project, on the basis of section 251 support, may also be included or approached to participate in the wider consented elements of the study. The Group queried whether any known objections received from patients to the consented elements could be applied to the data mapping exercise. The applicant would be asked to clarify on this point.

Patient and Public Involvement and Engagement

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

The applicants had consulted with a group of seven people with experience of dementia when designing the study and developing the participant information sheets and consent forms. A detailed overview was provided around the changes which had been implemented as a result of these changes within the application.

The applicants also planned to form a group of people with lived experience of dementia to help with the management of the project, and the analysis and dissemination of findings. It was explained that six patients with dementia and their companions would be recruited into this group, and that the group will meet at six, ten, fourteen and eighteen months. The applicant also explained that two different Alzheimer's Society Living Well with Dementia groups which involved an additional nine patients living with dementia and two carers had also been engaged with around the project.

The only aspect of the study that used confidential patient information without consent was the mapping study of primary care records, which had been included in the study as the suggestion of the patient and public involvement steering group. The group had explained that people with dementia and their carers often accessed unplanned care in a different way to professional carers. For example, the patient group explained that care home staff were more likely to use out of hours primary care services, but with people with dementia and their informal carers were more likely to access A&E or their in-hours GP. The mapping study was designed to provide an overview of these differences. The PPI steering group had noted the difficulty of gaining consent from the patient group via postal contact. The CAG commended the detailed and appropriate activity which had been carried out in this area, noting that the views of patients and carers were at the heart of this research programme.

Confidentiality Advisory Group advice conclusion

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

1. Request for further information
   Provide assurance that the wider elements of the study, which will operate under patient consent, will not involve access to confidential patient information without consent outside the direct clinical care team.

2. Confirm how many patient records would need to be accessed within the scope of the mapping exercise in order to achieve the target cohort.

3. Clarify when data would be transferred from GP practices and out of hours service providers to the University encrypted laptop.

4. Consider an alternative mechanism to transfer data or inclusion of a data back-up mechanism in addition to storage on the encrypted laptop.

5. Revise the patient-facing poster/flyer document to include additional information around study contacts, should patients or their carers wish to find out more about the study. Telephone, email and postal contacts should be included to facilitate follow-up. Provide the revised document for review.

6. Revise the patient dissent form to make the document project-specific – provide a revised copy for review.

7. Clarify whether patients who had been approached around the consented elements of the project but declined participation would be excluded from the data mapping exercise.

Specific conditions of support

The following sets out the specific conditions of support.

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

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending: BrisDoc and participating GP practices require confirmation of appropriate DSPT review.**

NEW APPLICATIONS – Non-Research

c. 19/CAG/0180 - CQC 2019/20 Children and Young People's Patient Experience Survey – Mixed Method Standalone Pilot

Context

Purpose of application

This application submitted by Ipsos MORI on behalf of the Care Quality Commission, set out the purpose of carrying out a pilot study to test mixed methods of distribution of the 2019/20 Children and Young People's Patient Experience Survey (CYP).

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 CYP survey was first commissioned in 2014. The CQC have commissioned Ipsos MORI to manage and coordinate surveys within the NPSP under the title of the Survey Coordination Centre for mixed survey methods. 39 Trusts will be approached with the aim to recruit between 20-25 Trusts to take part in the survey.

The pilot will be conducted at a different fieldwork period to the mainstage survey, and will involve a different survey method (mixed method and SMS invitations) and revised survey materials (covering letters and reminders). Due to the differences in approach, timings, materials and Co-ordination Centre a separate application has been submitted for this pilot. The CYP pilot study will also include a control sample, as due to the difference in fieldwork timings it will not be possible to use the 2018/19 CYP mainstage fieldwork as a control. The pilot differs to the main survey as it will collect mobile phone numbers for contact and the postcode information will be used for the analysis (e.g. as a deprivation indicator). This follows the precedent set by the 2019 Maternity Survey, which recently received support to use full postcode for deprivation analysis (19/CAG/0021). A similar approach received support under the Regulations for the 2019 Adult Inpatient Pilot (19/CAG/0102).

The following approaches will be made to patients within the pilot:

Pilot Group

Contact	Details
1	Letter with URL link for online questionnaire
1.1	SMS despatched 3 days later with URL link for online questionnaire

2	1 week after 1, letter with URL
2.2	SMS with URL link for online questionnaire despatched 3 days later
3	2 weeks after 2, letter with URL and mail questionnaire
4	2 weeks after 3, letter with URL (50% of the pilot sample will also receive a paper questionnaire as part of this communication while the other 50% will not)
4.1	SMS with URL link for online questionnaire 3 days later

The control group will receive the same number and style of contacts as the current 2019 survey approach:

Contact	**Details**
1	Letter with paper questionnaire
2	Reminder with paper questionnaire
3	Reminder with paper questionnaire

In line with the mainstage survey methodology, the CYP pilot will use three separate questionnaires, with each developed to meet the needs of the target age group. Questionnaires sent to those aged 8-11 and 12-15 will have a short section for the child or young person to complete themselves, and a separate section for their parent or carer to complete. Where a child is aged 0-7, the questionnaire will be completed entirely by their parent or carer.

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	Patients aged between 15 days and 15 years (inclusive) who were discharged from hospital between September-November 2019, across 39 Trusts in England. 25,000 patients will be recruited across the full survey pilot. Exclusions: • Patients who were not admitted (e.g. ward attendees or patients who attended an outpatient appointment, but were not admitted) • Deceased patients • Persons aged over 16 years at the time of their discharge • Babies aged between 0 and 14 days at the time of their discharge • New-born babies where the mother was the primary patient (i.e. well babies, treatment function code 424) • Patients who were **only** admitted to a Neonatal Intensive Care Unit (NICU) or a Special Care Baby Unit (SCBU) • Obstetrics/maternity service users, including spontaneous miscarriages • Patients admitted for planned termination of pregnancy • Psychiatry patients, including CAMHS • Private patients (non-NHS) • NHS patients treated at private hospitals • Any patients who are known to be current inpatients • Patients without a UK postal address • Any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey instructions request that all responses to posters are logged and used for this purpose, and that trusts also consult dissent logs from previous CYP surveys and exclude patients who asked to be removed from those surveys as well).

Data sources	1. Electronic patient records within acute and specialist Trusts in England
Identifiers required for linkage purposes	6. Trust code 7. A standardised unique identifier code, 8. Title (Mr, Mrs, Ms, etc.) 9. First name or initial 10. Surname 11. Address Fields 12. Postcode (where available) 13. Mobile telephone number
Identifiers required for analysis purposes	6. The unique identifier code (as above) 7. Admission/discharge dates 8. Length of stay (this is calculated from the admission and discharge dates). 9. Main specialty code on discharge 10. Treatment function code 11. IC10 or IC11 codes 12. CCG code 13. Whether admission from Treatment Centre 14. Route of admission 15. NHS Site code on admission and discharge 16. Ethnicity 17. Gender 18. Year and month of birth 19. Postcode (this will be used to calculate deprivation and then securely deleted)

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 recognised that the ongoing evaluation of patient care via the NHS Patient Survey Programme was within the public interest. The purpose of this application was to test mixed methods of survey distribution as a means to improve the efficiency and response rates of the patient surveys. The Group was assured that this wider testing of methodology was also within 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.

- Minimising flows of identifiable information

The CQC had commissioned Ipsos Mori to undertake all activities in relation to the mixed methods piloting for the patient survey programme. Within this workstream, Ipsos Mori was the only contractor which would be processing confidential patient information for the purposes of survey administration, which was a departure from the mainstage survey programme under which a number of contractors were able to facilitate the survey. The CAG recognised that, in the interests of the pilot methodology, processing had been limited to a single contractor to standardise the subsequent analysis.

- Feasibility of consent

The applicant provided three central arguments to support why is was not feasible to seek prior consent from patients for the survey invitation process. Trusts would not benefit from the expertise of the specialist survey contractor. There was also the potential for bias to be introduced into the survey through the requirement for clinicians to approach patients for consent to be invited. This requirement would also add an additional burden to clinical staff. The CAG acknowledged that there was past precedent in the justifications provided and accepted that these remained valid for the proposed survey activity.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the distribution of the patient surveys which could not be otherwise achieved.

'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.

Posters would 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. A template press release had also been drafted which can be issued by Trusts to raise the profile of the survey. Trusts were instructed to respect all known dissents as well as those which are raised specifically in relation to the survey within the patient sample extracted.

It was also noted patients could choose not to respond to the survey once received or actively decline participation by returning an uncompleted questionnaire.

Members were assured that the mechanism to inform patients about the survey and extend a means to dissent to their inclusion was clear and proportionate. The Group did note that the text message reminders did not include the provision of patient opt-out. It was suggested that the applicant explored the feasibility of including this provision for the next iteration of the survey.

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 provided a detailed overview of the user involvement in the patient survey programme to date and also the specific interaction which had been undertaken with the children and young people's panel about the pilot methodology. Members noted from the overview provided that those consulted were largely supportive of the trial methodology.

As part of the pilot programme, the applicant would also be carrying out 28 in-depth interviews with a range a patients and parents to understand the views on the use of data within the mixed methods survey programme. The Group agreed that the feedback from this wider user involvement activity which would be carried out alongside the survey would need to be provided within the submission of the next iteration of the survey, together with a detailed overview of how this had been incorporated into the methodology. Members suggested that the incorporation of an opt-out mechanism into the text messages be explored as part of the interview process, also to be fed back within the next submission of the survey.

Publication of findings

The CAG agreed that the publication of survey findings should also include details around the findings of the mixed methods pilot itself, alongside the reported survey results to inform the clinical and public audiences about the success of the electronic means of survey distribution. It was agreed that this would be added as a condition of support.

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. The feasibility of including an opt-out mechanism within the text message reminders should be explored during this iteration of the survey and used to inform the next submission.

2. Detailed feedback from the interviews being undertaken as part of the wider user involvement plan for the pilot survey should be provided as part of the next survey iteration. This should include details of how the views expressed had been incorporated into the survey methodology. It is recommended that views are sought as part of this activity around the necessity to include an opt-out mechanism within text message reminders.

3. Publication of the survey findings should also include feedback on the findings of the piloting of the mixed methods, together with the survey results.

4. 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. **Confirmed: Ipsos MORI 'Standards Met' confirmed on DSPT 2018/19 by NHS Digital email 13 July 2019.**

19/CAG/0181 - CQC 2019/20 Maternity Survey – Mixed Methods Standalone Pilot

Context

Purpose of application

This application submitted by Ipsos MORI on behalf of the Care Quality Commission, set out the purpose of carrying out a pilot study to test mixed methods of distribution of the 2019/20 Maternity Survey – Mixed Methods Standalone Pilot.

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 Maternity survey was first commissioned in 2007. The CQC have commissioned Ipsos MORI to manage and coordinate surveys within the NPSP under the title of the Survey Coordination Centre for mixed survey methods. 35 Trusts will be approached with the aim to recruit between 20-25 Trusts to take part in the survey.

The pilot will be conducted at a different fieldwork period to the mainstage survey, and will involve a different survey method (mixed method and SMS invitations) and revised survey materials (covering letters and reminders). Due to the differences in approach, timings, materials and Co-ordination Centre a separate application has been submitted for this pilot. The maternity pilot study will also include a control sample, as due to the difference in fieldwork timings it will not be possible to use the 2019 or 2020 Maternity mainstage fieldwork as a control. The pilot differs to the main survey as it will collect mobile phone numbers for contact and the postcode information will be used for the analysis (e.g. as a deprivation indicator). This follows the precedent set by the 2019 Maternity Survey, which recently received support to use full postcode for deprivation analysis (19/CAG/0021). A similar approach received support under the Regulations for the 2019 Adult Inpatient Pilot (19/CAG/0102).

The following approaches will be made to patients within the pilot:

Pilot Group

Contact	**Details**
1	Letter with URL link for online questionnaire
1.1	SMS despatched 3 days later with URL link for online questionnaire
2	1 week after 1, letter with URL
2.2	SMS with URL link for online questionnaire despatched 3 days later
3	2 weeks after 2, letter with URL and mail questionnaire
4	2 weeks after 3, letter with URL (50% of the pilot sample will also receive a paper questionnaire as part of this communication while the other 50% will not)
4.1	SMS with URL link for online questionnaire 3 days later

The control group will receive the same number and style of contacts as the current 2019 survey approach:

Contact	Details
1	Letter with paper questionnaire
2	Reminder with paper questionnaire
3	Reminder with paper questionnaire

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	Women aged 16 years or over at the time of delivery, who gave birth under the care of an NHS trust (including home births), in October and November 2019. Exclusions: • Women whose baby had died during or since delivery • Women who had a stillbirth (including where it occurred during a multiple delivery) • Women who were in hospital or whose baby was in hospital at the time the sample was drawn • Women who had a concealed pregnancy • Women whose baby was taken into care (foster care or adopted) • Women who gave birth in a maternity unit managed by another provider or in a private maternity unit or wing

	• Women who died during the birth, or who have died since the birth • Women aged under 16 years at the time of their delivery • Patients admitted for planned termination of pregnancy • Psychiatry patients, including CAMHS • Private patients (non-NHS) • Any patients who are known to be current inpatients • Patients without a UK postal address • Any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey instructions request that all responses to posters are logged and used for this purpose, and that trusts also consult dissent logs from previous Maternity Service surveys and exclude patients who asked to be removed from those surveys as well).
Data sources	1. Electronic patient records within Trusts in England
Identifiers required for linkage purposes	1. Trust code 2. A standardised unique identifier code, 3. Title (Mrs, Ms, etc.) 4. First name 5. Surname 6. Address Fields 7. Postcode (where available) 8. Mobile telephone number
Identifiers required for analysis purposes	1. The unique identifier code (as above) 2. Ethnicity 3. Day of delivery 4. Month of delivery 5. Year of delivery 6. Actual delivery place 7. NHS Site code 8. CCG Code 9. Postcode (used to calculate deprivation and then securely deleted)

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 recognised that the ongoing evaluation of patient care via the NHS Patient Survey Programme was within the public interest. The purpose of this application was to test mixed methods of survey distribution as a means to improve the efficiency and response rates of the patient surveys. The Group was assured that this wider testing of methodology was also within 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.

- Minimising flows of identifiable information

The CQC had commissioned Ipsos Mori to undertake all activities in relation to the mixed methods piloting for the patient survey programme. Within this workstream, Ipsos Mori was the only contractor which would be processing confidential patient information for the purposes of survey administration, which was a departure from the mainstage survey programme under which a number of contractors were able to facilitate the survey. The CAG recognised that, in the interests of the pilot methodology, processing had been limited to a single contractor to standardise the subsequent analysis.

- Feasibility of consent

The applicant provided three central arguments to support why is was not feasible to seek prior consent from patients for the survey invitation process. Trusts would not benefit from the expertise of the specialist survey contractor. There was also the potential for bias to be introduced into the survey through the requirement for clinicians to approach patients for consent to be invited. This requirement would also add an additional burden to clinical staff. The CAG acknowledged that there was past precedent in the justifications provided and accepted that these remained valid for the proposed survey activity.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the distribution of the patient surveys which could not be otherwise achieved.

'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.

Posters would 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. A template press release had also been drafted which can be issued by Trusts to raise the profile of the survey. Trusts were instructed to respect all known dissents as well as those which are raised specifically in relation to the survey within the patient sample extracted.

It was also noted patients could choose not to respond to the survey once received or actively decline participation by returning an uncompleted questionnaire.

The Group considered the wording of the text messages which would be sent in the pilot group. Whilst the message itself would be received from 'NHS Survey' the content would detail that this was related to the maternity survey, which was potentially disclosive if the message was received or opened by a third party. Whilst Members appreciated that, at the point the survey invitation was circulated, it was likely that this would be disclosive, this may have implications in the wider survey programme which involved more sensitive health conditions. The CAG agreed that no direct action was required from this point, but it was raised for consideration by the survey providers as they planned further pilots.

Members were assured that the mechanism to inform patients about the survey and extend a means to dissent to their inclusion was clear and proportionate. The Group did note that the text message reminders did not include the provision of patient opt-out. It was suggested that the applicant explored the feasibility of including this provision for the next iteration of the survey.

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 provided a detailed overview of the user involvement in the patient survey programme to date and also the specific interaction which had been undertaken for the Maternity Survey Pilot. This included cognitive interviews which were conducted to test the approach and the patient-facing materials, along with testing the acceptability with patients about being contacted by SMS. The response from the interviews was positive with new mothers being accepting of the survey approach. The findings were used to further refine the invitation letters as some respondents felt that the log in details could be more clearly displayed in the letters, and some of the messaging more engaging.

It was also explained that, running in parallel to the survey pilot, was a fuller consultation with stakeholders which would involve meetings, interviews and email consultations to explore the implications of the move to a mixed methods approach for

the patient survey programme. The Group agreed that feedback from this wider user involvement activity would need to be fed back as part of the next iteration of the survey.

Publication of findings

The CAG agreed that the publication of survey findings should also include details around the findings of the mixed methods pilot itself, alongside the reported survey results to inform the clinical and public audiences about the success of the electronic means of survey distribution. It was agreed that this would be added as a condition of support.

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. The feasibility of including an opt-out mechanism within the text message reminders should be explored during this iteration of the survey and used to inform the next submission.

2. Detailed feedback from stakeholder consultation undertaken as part of the wider user involvement plan for the pilot survey should be provided as part of the next survey iteration. This should include details of how the views expressed had been incorporated into the survey methodology.

3. Publication of the survey findings should also include feedback on the findings of the piloting of the mixed methods, together with the survey results.

4. 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. **Confirmed: Ipsos MORI 'Standards Met' confirmed on DSPT 2018/19 by NHS Digital email 13 July 2019.**

Minutes of the meeting held on 17 October 2019

The minutes of the meeting held on 19 September 2019 were received and accepted as a true record of events.

5. Any other business

No other business was raised.

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