Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on *21 March 2024* via video conference.

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Murat Soncul	CAG Alternate Vice-Chair
Dr Martin Andrew	CAG Expert Member
Dr Sandra Duggan	CAG Lay Member
Professor Lorna Fraser	CAG Expert Member
Dr Harvey Marcovitch	CAG Expert Member
Mr Andrew Melville	CAG Lay Member
Mr Umar Sabat	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Mr Paul Mills	Confidentiality Advice Service Manager
Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor (item 4a only)
Byron Hyde	Observer - Academic from the University of Leeds. Interested in applying to be a CAG Member
Paula McGee	Observer - South Birmingham REC Chair (items 4a-4c only)
Dr Mary Murphy	Observer - Northern Ireland REC A Chair
Matt Foxwell	Applicant - Picker Survey Coordination Centre (item 4a)

Caroline Killpack	Applicant - Picker Survey Coordination Centre (item 4a)
Will Mayes	Applicant – CQC (item 4a)
Chester Howarth	Applicant – Researcher CQC (item 4a)
Paul Donnelly	Applicant - Strategic BI lead (item 4b)
Alex Bell	Applicant- Deputy Director of BI (item 4b)
Hayley Gillingwater	Applicant- IG lead (item 4b)
Michael Ball	Applicant - Senior Data Assurance Manager (NECS) supporting the ICB (item 4b)
Professor Claudia Estcourt	Applicant – CI (item 4c)
Dr Jo Gibbs	Applicant - Information Guardian and co-investigator (item 4c)
Dr Fiona Mapp	Applicant - Trial coordinator (item 4c)
Ms Kavitha Saravanakumar	Applicant - Director of Business Intelligence, NHS North West London, co-investigator for the PREPARE study (item 4d)
Mr Alastair Bearne	Applicant - patient contributor, co-investigator for the PREPARE study (item 4d)
Joanne Droney	Applicant – CI (item 4d)
Fiona Graham	Applicant - Senior Research Associate (item 4e)
Nick Cristofani-Wykes	Applicant - Project Manager iPLATO (will be receiving and processing patient data as part of the study) (item 4e)
Jenni Palmer	Applicant - NHS Partner Manager (South) iPLATO (item 4e)

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from Mr David Evans, Professor Sara Randall and Mrs Sarah Palmer-Edwards gave their apologies.

2. DECLARATIONS OF INTEREST

2.1	**24/CAG/00046 (item 4d)**	**PREPARE v1.0**

	Conflict:	CAG Member Professor Lorna Fraser declared an interest in this item, as she knows several members of the research team. The Committee agreed that Professor Lorna Fraser did not need to leave the meeting but should not participate in the discussion.

3. 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 agreed with the advice provided by the CAG in relation to the **15 February 2024** meeting applications

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **15 February 2024** meeting applications.

Minutes

The minutes of the following meetings have been ratified and published on the website:

- 09 February PS
- 15 Feb full
- February Sub-Committee

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4a	**24/CAG/0054**	**2024 Children and Young People's Patient Experience Survey**
	Contact:	Will Mayes
	Data controller:	Care Quality Commission
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present

Summary of application

This non-research application submitted by Picker Institute Europe on behalf of the Care Quality Commission, sets out the purpose of conducting the 2024 Children and Young People's Patient Experience Survey (CYP24).

The CYP 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 CYP24 will be the fifth carried out to date, and the first to be completed using a mixed method approach.

All eligible trusts (119) will be asked to conduct the survey, with preparations expected to begin in March 2024 and fieldwork expected to start from July 2024. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (Picker Institute Europe) and one of the approved contractors (Picker Institute Europe, Quality Health, Patient Perspective or Explain).

There are three questionnaire versions to cover age specific groups: 0-7-year-olds (completed by parent / carer only); 8-11-year-olds (completed by parent/ carer; and then questions for child themselves); and 12-15-year-olds (completed by parent / carer; and then questions for the young person themselves).

The contractors will distribute questionnaires to patients using the approach detailed below:

	Mode of contact
Contact 1	Postal letter inviting the parent/carer/patient to take part online
Contact 2	3 days later an SMS reminder will be sent, including a direct link to the online survey
Contact 3	At the start of week 2, a reminder letter will be sent to non-responders
Contact 4	3 days after contact 3 an SMS reminder will be sent, including a direct link to the online survey
Contact 5	In week 4, a 3rd reminder letter will be sent to non-responders, including a paper questionnaire
Contact 6	In week 6 a final postal reminder is sent
Contact 7	3 days after contact 6 a final SMS reminder will be sent, including a direct link to the online survey

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.

Confidential information requested

Cohort	People aged between 15 days and 15 years who were admitted and discharged as inpatients or day cases to an acute hospital between 1st March and 31st May 2024. A list of reasons for exclusion, such as deceased patients and those over 16 years of age at the time of discharge, is included in the application. Maximum of 1,250 patients per Trust
Data sources	1. Each participating NHS trust in England providing hospital services (inpatient and day case) to children and young people (119).
Identifiers required for contact purposes	1. Name of patient 2. Address fields including postcode 3. Mobile phone number (attached to the patient's record so could be either the child / young person's or the parent / carer's) 4. Patient unique identifier
Identifiers required for deceased check purposes	1. NHS Number 2. Full date of birth
Identifiers required for analysis purposes	1. Trust Code 2. Unique identifier (a three digit Trust code and 4 digital serial number related to sampled patient) 3. Postcode – to map to LSOA 4. Month and Year of birth 5. Gender 6. Ethnicity 7. Date of admission 8. Date of discharge 9. Length of Stay 10. Main speciality of consultant on discharge 11. Treatment Function Code

	12. Treatment Centre Admission 13. Admission method 14. NHS Site code-Admitted 15. NHS Site code-Discharged
Additional information	Trusts may also choose to collect additional sample variables outside of those detailed in the Survey Handbook. This can be valuable to trusts in enabling them to make greater use of their survey locally to target quality improvements. *Sample and mailing data will be submitted by trusts to approved contractors in a single file. The file which contains both mailing and sample information will be split into separate files by the contractor before submitting only the sample information to the Coordination Centre for checking and approval.* Please note that the Survey Coordination Centre does **not** receive any names or full addresses

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The Group reviewed the patient and public involvement undertaken and were not content that what had been undertaken up until this point was with a sufficient representative cohort of young people, and felt that the applicant had not sufficiently discussed the increase in the number of contacts (both postal and SMS). As the increase in the number of contacts is the reason this application has come to the full CAG committee rather than the usual precedent set route, this should be thoroughly discussed before ‘s251’ support is provided. The CAG asked the applicant to talk through the patient involvement undertaken around the use of mobile phones, additional contacts to include 4 SMS and 3 letters, with relevant patient groups who represent the cohort. The applicant described the pilot, which included interviews about the use of mobile phones. The applicant has plans to discuss the number of contacts, and the materials that they will receive, as part of the ‘cognitive testing’ which is due to start soon. This will be with 45 patients and young people. The CAG would like to hear feedback from this work, to be assured there was support for the

additional contacts from a representative population. The CAG suggested that the applicant should also look at testing the communications toolkit materials with the patients. The CAG stated that they would like to see a breakdown of demographics of the patients, to be assured there was a diverse mix of people in the patient involvement cohort. The CAG recommend the applicant use the new guidance regarding patient involvement which is published here**. [Action 1]**

The CAG noted that the opt out poster for Trusts did not state anywhere on it that the survey processes identifiable data for the purpose of inviting patients to take part, with 's251' support. The applicant should update the Trust posters with this information and provide updated opt out posters to CAG. **[Action 2]**

The CAG noted that the following will be shared with trusts and third sector organisations a spart of a newly developed communications toolkit/impact strategy, and copies will be provided to CAG once finalised:

- Website banners
- Posters: publicity and dissemination
- Social media cards
- Infographics

The Members asked the applicant to briefly explain the difference between the communications toolkit and the notification posters in the Trusts. The applicant explained that the key differences the two are that the communications toolkit is more to increase awareness around the time of the survey is launched, so patients can find information about opting out, but also find information about how to request accessible communications if required. It is also hoped this might increase participation in the survey. The applicants will have an engagements webinar with Trusts when the communications toolkit is issued. The applicants will also provide a series of results outputs for Trusts to share with their population, to explain what improvements have been made to services based on the CQC survey results, in order to close the feedback loop for the public. The CAG requested that the applicant provide the additional full set of communication toolkit materials that are being developed, as soon as they are ready. **[Condition 1]**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Please provide feedback from the 'cognitive testing' with 45 people, to be assured there	

	is support for the additional number contacts from a representative population. Please also consider testing the communications toolkit materials with the patients. Please provide a breakdown of demographics of the participants, to be assured there was a diverse mix of people who represent the cohort.	
2.	Update the Trust posters to state that the survey processes identifiable data for the purpose of inviting patients, with 's251' support, and provide to CAG.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition
1.	Please provide the additional full set of communication toolkit materials that are being developed, as soon as they are ready.
2.	Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:** The NHS England **22/23** DSPT reviews for **Picker Institute Europe, Patient Perspective, Quality Health Limited & Explain** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 March 2024)

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

4b.	**24/CAG/0040**	**Humber and North Yorkshire Integrated Care Board Population Health Management**
	Contact:	Alan Pond
	Data controller:	Humber and North Yorkshire Integrated Care Board
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application

This is a non-research application from Humber and North Yorkshire Integrated Care Board (ICB) for the purpose of population health management.

Population Health Management involves using data to identify local 'at risk' populations to enable planning and targeting of interventions of the population to prevent ill-health and improve care for the local population. It allows commissioners to design appropriate care pathways for the population which can in turn reduce health inequalities and improve the health of the population.

Population Health Management necessitates the use of large scale, whole ICB population, use of national datasets combined with GP data. Support is requested for the flow of confidential patient information from GP suppliers to the risk stratification supplier and to link this information with national datasets through NHS number. Support is not being requested for the flow of national datasets as this is sent in a pseudonymised form. Population Health

Management analysis will be undertaken on anonymised or aggregated data and does not require support. The ICB also indicates that there should be the ability to reidentify patients to enable direct care provision, under this population health management application.

Confidential information requested

Cohort	All GP-registered patients in the Humber and North Yorkshire Integrated Care Board area.
Data sources	1. GP data 2. National commissioning datasets (outside scope of support)
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	1. None

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The Group queried whether the applicants were clear on what activities were considered risk stratification and what were population health management. There appeared to be some confusion in this application as it references the potential to reidentify patients for direct care purposes. For CAG, this type of activity seems more akin to risk stratification than population health management. The applicants confirmed that reidentification by GPs for direct purposes will happen under population health management activities. An example was cited, where cohorts of patients (for example suffering from hypertension) may be provided back to GPs to reidentify and provide care. It differs from risk stratification as in this case the patients are identified solely by the linked data, and not via outputs from the risk stratification tool.

Whilst members felt the approach described still appeared to be risk stratification via another route, they were content with the response. The CAG however agreed that this approach needs to be made explicit to patients. The applicants indicated that they are working with their Caldicott Guardian and communications team to make this clear.

Members noted that the public involvement evidence provided was excellent which included a diverse group with a wide variety of views. However, this work was undertaken in 2018 and views are likely to have changed in the past six years, and attitudes may have altered. The CAG queried what further plans for public involvement are in place. The applicants indicated that they are developing a communications plan which could include a press release, pages on GP websites, paid for social media, texts by practices, posters and leaflets, plus potentially a clinician lead video explainer.

Members noted the response was more reflective of how the population is informed of the activities. The CAG were particularly interested in plans to interact with patients and seeking views on the acceptability of using confidential patient information without consent. The applicants noted that they need to have more contact at a local level and need a better way to achieve this. Potential options were being considered and the ICB is working with other ICBs that are further ahead to learn of good practice.

The CAG also noted that the communication materials provided were not in plan English and do not provide clarity to patients on how their data is used and for what purposes. The applicants recognised that these are early drafts and that there is more work to do as it is important to get these communication materials correct.

CAG agreed that there is a need for comprehensive ongoing public involvement to be undertaken with a diverse population from across the geographical ICB area. This should test the acceptability of the use of confidential patient information and members agreed that this would be a good route to support the development of communication materials. It is recommended that this is undertaken in a coordinated approach with risk stratification given the similarities. Members agreed that the application could be supported with initial public involvement that covers the key points above **(Action 1).** Given that this

will likely be coordinated with risk stratification this should be provide no later than 3 months. An action plan for continued extensive public involvement should also be provided. **(Action 2).** This plan should enable a further comprehensive report in public involvement to be provided within six months of support **(Condition 1)**.

Members were unclear on which communication routes will actually be used, as responses indicated that the routes stated were potential routes. The CAG agreed that a clear communication plans on the routes that will be used should be provided **(Action 3).** As well, the CAG requested sight of a final draft of the communication materials which should include give a clear explanation on what is risk stratification and population health management, how confidential patient information is used, how to opt out and that Section 251 support has been provided by the Secretary of State for Health and Social Care, on advice of the Confidentiality Advisory Group. CAG would encourage a coordinated notification to encompass risk stratification and population health management , and a layered approach to this communication. **(Action 4).**

Members reflected that the opt out system is complicated and not ideal given the potential impacts on direct care for patients, as well as other wider impacts for all research and planning operating under Section 251 Support. This is why CAG requests a project specific opt out. CAG understood the difficulties in this case with the project specific opt out, but asked what progress the ICB has made in delivering this. The applicants indicated that they had applied for a national Snomed code for this activity but this was turned down on the basis that the National Data Opt Out can be applied. The applicants have looked for an alternative Snomed Code to use but given the wide geography they have been unable to find a spare code.

CAG commented that they understand the specific issues and have had discussions nationally regarding this, but there is no immediate solution available. The applicants indicated that they want to fully engage with delivering this but also want to do this correctly before support is recommended. The CAG suggested to speak with other ICBs who have already implemented a system, such as Greater Manchester ICB, but did request further detail on a project specific opt out before supporting. **(Action 5)**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Undertake public involvement with a diverse population from across the geographical ICB	

	area. This should test the acceptability of the use of confidential patient information and also could be used to support the development of communication materials. A report should be provided to CAG summarising: • the demographics of who you have involved, how many and why their involvement is relevant • How you have involved people, such as focus groups or meetings • What questions or topics were used • The number and types of responses you received i.e. both positive and negative and what changed because of this feedback It is recommended that this is undertaken in a coordinated approach with risk stratification given the similarities. Please see CAG expectations on public involvement here for further information.	
2.	Provide a public involvement plan for continued engagement that would enable a further substantive report to be provided to CAG within 6 months from the support outcome.	
3.	Provide a clear communication strategy on the routes that will be used to inform the population. This should be routes that will be used, not may be used.	
4.	Provide final drafts of the communication materials to be used which should include: • a clear explanation on what is risk stratification and population health management • how confidential patient information is used • how to opt out • that Section 251 support has been provided by the Secretary of State for	

	Health and Social Care, on advice of the Confidentiality Advisory Group. between RS and PHM, and also explain about s251 etc, opt out options are clear. CAG would encourage a coordinated notification to encompass risk stratification and population health management , and a layered approach to this communication.	
5.	Provide detail on a project specific opt out route that can be used. CAG suggested learning from Greater Manchester ICB on their opt out approach.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition	Response from the applicant
1.	Within six months of a supported outcome provide a summary of further public involvement undertaken and the outputs.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

4c.	24/CAG/0048	SEQUENCE Digital: A multicentre trial of the eSexual Health Clinic-V1
	Chief Investigator:	Professor Claudia Estcourt
	Sponsor:	Noclor on behalf of Central and North West London NHS Foundation Trust
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present

Summary of application

This application from Central and North West London NHS Foundation Trust set out the purpose of medical research to investigate whether provision of usual care plus the eSexual Health Clinic (eSHC) provides safe and efficient care to patients with chlamydia and their sex partners.

The eSHC is an online service enabling patients with chlamydia to answer health questions online and to receive antibiotic treatment. Using the patient's information, a validated clinical decision-making algorithm within the eSHC predicts whether prescribing standard antibiotic treatment is safe. A research nurse or doctor will review the patient information and, if clinically safe, authorises an electronic prescription to be sent to the patient's community pharmacy. The eSHC also helps patients notify their sex partners, either directly or anonymously. Notified sex partners can access the eSHC or other services for testing and treatment.

The applicants seek to conduct a randomised controller cluster crossover study, to determine the effectiveness of the eSHC compared with usual care. 12 sexual health services will either use the eSHC alongside usual care or usual care only. All trial sites will take part in the control and the intervention phases. Half the services will do the intervention phase first, and half will do the control phase first. Before the start of the trial, services will be randomised to the control or intervention during phase 1. The trial sites will be randomised to one of the following options; patients will be offered up to 6 months of the intervention (offer of the eSHC + usual care for all eligible patients) followed by up to 6 months of control (usual care only) or given 6 months of control (usual care only) and then offered up to 6 months of the intervention (offer of the eSHC + usual care for all eligible patients).

Confidential information requested

Cohort	2400 patients diagnosed with chlamydia. The number of sex partners will depend on how many partners those index patients report and notify, and how many among them choose to use the eSHC. The applicants estimate that around 350 sex partners will use the eSHC from a sample size of 2400 index patients.
Data sources	1. Electronic patient records at participating sites
Identifiers required for	1. Name 2. Date of birth

linkage purposes	3. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender 3. Ethnicity

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG agreed that the scope of support was unclear and asked the applicant to clarify why s251 support was being sought. There was some confusion in the application over which activities are undertaken for research and which for direct care. The applicants advised that the Information Governance team at Central and North-West London NHS Foundation Trust had advised that s251 support was needed as not all the participating organisations would consider the research nurses to be part of the direct care team. The applicants confirmed that two aspects of the study required support; the identification of patients and de-identification of patient records, which are undertaken by research nurses.

Members noted that patients in the intervention arm would need to actively engage with the eSHC online service. This presented several opportunities for patients to consent to use of their data in research. The applicants explained that patients needed to start treatment as soon as possible after starting treatment and it would not be practicable to seek consent at that time. The applicants also noted that the amount of information patients would need to be given may potentially discourage patients from using the intervention or pursuing treatment. The applicants also noted that the test result messages were sent via text and patients would not be interacting with Health Care Professionals at that point.

Members queried whether patients could consent to use of their data in research when signing up to the eSHC. The applicants noted that the amount of information that would need to be provided to patients may be off-putting, particularly to those in socially marginalised groups, who the applicants hoped to include.

The CAG continued discussion of this issue after the applicants left the meeting. Members agreed that they were not convinced that consent could not be sought. The CAG noted that the applicants had potentially confused the

issues of consent to use the eSHC and consent to the research. While noting the applicants concerns over providing too much information to patients, the CAG advised that a layered approach to consent was adopted. This would mean that, for example, patients could indicate when signing up to the eSHC whether or not they were happy for their data to be included in research. A link to further information could be included, should patients wish to know more before deciding. Guidance from the Health Research Authority on consent can be found here Informing participants and seeking consent - Health Research Authority (hra.nhs.uk)

The feasibility of seeking consent to the research when patients signed up to the eSHC online service needs to be explored. Should consent still be deemed unfeasible, stronger justification on why consent is not possible needs to be provided. Members agreed that support could not be recommended until it was evident that the feasibility of seeking consent had been fully explored. **[Issue 1]**.

The poster explained that only pseudonymised data, information which does not identify patients, will be used in the study. Members noted that this was not accurate, as research staff would have access to confidential patient information. The posters needed revision to ensure that the processing of patient information was accurately described. **[Issue 2]**.

The applicants had advised that the National Data Opt-Out (NDOO) could not be applied as sexual health services did not collect patients NHS numbers. Members agreed that obtaining NHS numbers to apply the NDOO would necessitate a larger disclosure of confidential patient information and would undermine the confidentiality expectations of patients using the service.

The CAG asked the applicant whether the participating services had been identified. The applicants explained that 10-12 services would be participating and the list of services can be provided. **[Issue 3]**.

Confidentiality Advisory Group advice: Deferred

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received. The CAG noted that the following points should be taken into consideration and addressed prior to resubmitting this application in future.

Number	Issue:
1.	The feasibility of seeking consent to the research when patients signed up to the eSHC online service needs to be explored. Should consent still be deemed unfeasible, stronger justification on why consent is not possible needs to be provided.

2.	The posters need revision to ensure that the processing of patient information is accurately described.
3.	The names of the 10-12 services that would be participating needs to be provided.

4d.	**24/CAG/0046**	**PREPARE v1.0**
	Chief Investigator:	Dr Joanne Droney
	Sponsor:	Royal Marsden Hospital NHS Foundation Trust
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present

Summary of application

This application from Royal Marsden Hospital NHS Foundation Trust set out the purpose of medical research to understand the patients involved in the creation of EPaCCS records and the type of information contained within EPsCCS records in different regions across England, and evaluate whether EPsCCS are associated with differences in where people are cared for and die.

There is a need to develop new systems to provide improved experience, quality, outcomes and value of care, particularly in end-of-life care where costs are high. Electronic Palliative Care Coordination System (EPaCCS) may provide a solution and the Department of Health has recommended continued roll out of EPaCCS nationally however there is a lack of high quality evidence to support their use. The applicants seek to explore how EPaCCs are used in routine care across England with the aim of helping to refine a national Theory of Change relevant to EPaCCS.

The evaluation of EPaCCS will include two work packages which will be analysed separately. In Work Package 1, the applicants processed anonymised data from three EPaCCS in London, Leeds and Bradford. Support is sought for Work Package 2. The Royal Marsden Hospital NHS Foundation Trust will disclose confidential patient information from the Coordinate My Care (CMC) dataset to Whole Systems Integrated Care (WSIC) at the North West London Integrated Care Board for linkage to a dataset of deceased people in London

2010-22. Two cohorts of patients will be created within the WSIC dataset for comparison: those with EPaCCS and those without EPaCCS. The linked datasets will then be de-identified and the patient identifiers separated from analysis variables. Anonymised linked datasets will be stored and analysed in the Trusted Research environment at Imperial College Health Partners.

Confidential information requested

Cohort	Deceased patients in North West London who had Coordinate My Care records created between 2010 and 31/03/2022. 172700 will be included.
Data sources	1. EPaCCS records - Co-ordinate My Care data from 2010-2022 in North-West London 2. WSIC data set - dataset of deceased people in London 2010-22 containing linked mortality data, coded primary, secondary, acute, mental health, community health and social care data
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – sector level 3. Gender 4. Ethnicity
Additional information	The applicants noted that they will not know the exact dates of inclusion until the CMC data is accessed.

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that all patients would be deceased. However, members noted the importance of transparency in research, not just for the patients who may be included, but to the wider public. The applicants agreed that information about the study would be included on the Royal Marsden Hospital NHS Foundation Trust. The CAG asked that the wording was provided **[Condition 1]**.

The CAG queried whether any free text data could potentially be included. The applicants provided reassurance that only coded data would be processed. The CAG accepted this clarification.

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Security assurances for 2022/23 are outstanding for the following organisations. • *North-West London ICB* Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition	Response from the applicant
1.	The applicants agreed that information about the study would be included on the Royal Marsden Hospital NHS Foundation Trust. The CAG asked that the wording is provided	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

4e.	24/CAG/0051	Improving uptake of cervical screening in women with SMI
	Chief Investigator:	Dr Fiona Graham
	Sponsor:	Newcastle University
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present

Summary of application

This application from Newcastle University set out the purpose of medical research that seeks to determine whether it is possible to undertake a trial of an enhanced text message reminder involving people with severe mental illness.

People with severe mental illness (SMI) have a higher mortality rate than those without SMI. Since the inception of the Cervical Screening programme, rates of screening have increased but those with SMI are less likely to attend. An information tool has been developed by mental health service users and health professionals for those who are anxious about the screening test. This is publicly available on the government's cervical screening website yet the link is not provided in the text reminders to invitees. The applicants seek to determine whether including a link to this resource has any impact on the screening uptake in patients with SMI who are overdue for screening.

General practices in the borough of Lambeth will be approached to take part. Practices will be provided with a script to run on their data systems that will

enable them to easily identify eligible participants. A GP will screen the list to confirm eligibility. The list (date of birth and NHS numbers) will be passed to iPLATO, the provider commissioned by the NHS to conduct research and deliver cervical screening text message reminders. iPlato will randomise patients with SMI and overdue cervical screening to either an intervention group, who will receive an enhanced text message reminder with a link to the tool, or a control group who will receive the standard text message. iPlato will also assign participant ID numbers and collect feasibility measures e.g. numbers of missing mobile phone numbers, numbers of texts delivered. After the end of the intervention period, GP practice staff will collect demographic data (to explain any variation in findings), whether participants booked a cervical screening appointment and proceeded to attend. Pseudonymised data will be shared with the research team, including the PID number which will include the group randomised to, and excluding DOB, NHS numbers or mobile numbers. After the end of the intervention period, iPLATO will send a short online survey, via SMS, to participants to collect brief data on whether they accessed the information, to what level and if it influenced their attendance at cervical screening. iPLATO will share the pseudonymised survey responses with the research team.

s251 support is being sought as GP practices will be sharing with iPLATO confidential patient information of eligible patients without patient consent. iPLATO are aware that all patients in this study have an SMI diagnosis and the disclosure of the NHS number, mobile number, and DOB includes conveying something about the health of these individuals. As GP practices are disclosing health information (a diagnosis of SMI) to iPLATO about these individuals without their consent this could be considered breaching the common law duty of confidentiality. Whilst iPLATO are willing to process the data without s251 support in place, they have expressed concern that practices won't release data unless there is a s251 in place. The applicants noted that the process by which the confidential patient information would be received by iPLATO in this research study is different to how it is received for direct care purposes. The pathway for sending text message reminders for the purposes of direct care, iPLATO receive a list of patients from CSAS and extract the contact details through Personal Demographic Service. For this research project, they will receive the list of eligible patients from the practice directly via secure NHS email and extract the contact details through their connection to the GP's clinical system.

Confidential information requested

Cohort	Women aged 25-65 years, with severe mental illness who are eligible for cervical screening
Data sources	1. Medical records at participating GP practices

Identifiers required for linkage purposes	1. NHS Number 2. Date of Birth 3. Postcode – district level
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender 3. Ethnicity

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The applicants don't intend to display posters in the GP waiting rooms, as they do not think the target population will necessarily see the posters and may lead ineligible patients to contact iPLATO to opt-out of a study. Members also noted that patients were only able to object once they received the text message and that they should be given the opportunity to dissent before their data left the GP practice. The CAG noted that queries or requests to opt-out should not be made to iPLATO, but to the GP practices. Members also noted the importance of transparency in research, not just for the patients who may be included, but to the public, and that notification had a wider purpose than just making patients who may be included aware of the project.

The applicants advised that they would explore including information about the study on the websites of relevant charities. The CAG observed that the pilot study was taking place in Lambeth and most patients would be under the care of NHS South-East London - Integrated Care Board (ICB), and suggested that the applicants seek assistance in promoting the study from the ICB. The patient notification should direct patients to contact their local GP practice to dissent to use of their data.

The link in the text message directed patients to an outdated Public Health England website. Members asked that the link was updated.

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Ways of informing the public about the study need to be explored, including promoting the study via relevant charities and participating GP practices, as well as via NHS South-East London - Integrated Care Board (ICB). The patient notification should direct patients to contact their local GP practice to dissent to use of their data. The patient notification strategy and materials, such as posters and website text, need to be provided to the CAG for review.	
2.	The link in the text message directed patients to an outdated Public Health England website. Members asked that the link is updated.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5. ANY OTHER BUSINESS

There was no other business for discussion.

Dr Tony Calland, MBE	27 March 2024
…….	……..
Signed - CAG Chair	*Date*
Katy Cassidy	25 March 2024
…….	……..
Signed – HRA Confidentiality Advisor	*Date*