Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *01 March 2024* via correspondence.

Present:

Name	Capacity	Items
Dr Murat Soncul	Alternate Vice Chair	Items 2a, 2b, 2c and 2d
Professor Lorna Fraser	CAG Member (Expert)	Items 2a & 2c
Dr Harvey Marcovitch	CAG Member (Expert)	Items 2c & 2d
Ms Rose Payne	CAG Member (Lay)	Items 2b & 2d
Mr Umar Sabat	CAG Member (Expert)	Items 2a & 2c

Also in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.a	**24/CAG/0038**	**Maternity Survey 2024**
	Contact:	Jenny King
	Data controller:	CQC

	Application type:	Non-research

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

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 NHS Maternity Survey.

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

The 2024 Maternity Survey will be the eleventh carried out to date, and the fourth using a mixed method approach, following a successful pilot of the approach in 2020 and the first mainstage during 2021. The 2024 Maternity Survey will be managed and coordinated by the Survey Coordination Centre, for the NPSP, based at Picker Institute Europe. The survey will follow the same mixed method approach as the 2021- 2023 Maternity Surveys.

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 three approved contractors (Patient Perspective, Quality Health or Explain Market Research Ltd). For the first time for the Maternity Survey, approved contractors will have the option to run centralised DBS checks, rather than each NHS trust, prior to each mailing/ contact attempt. NHS Trusts will still be required to undertake an initial DBS check as part of sample preparation. The DBS enables contractors to submit and receive an electronic file containing relevant patient records, using dedicated software. The patient records in the file are matched against the NHS Spine Personal Demographics Service (PDSS).

The contractors will distribute questionnaires to patients using the same methodology as used in previous applications since 2021, following the successful pilot in 2020.

	Mode of contact
Contact 1	Postal letter inviting the mother to take part online
Contact 1.1	SMS reminder timed to arrive with the initial letter including a link to the survey
Contact 2	Postal reminder letter inviting the mother to take part online
Contact 2.2	SMS reminder timed to arrive with the second letter including a link to the survey
Contact 3	Postal reminder letter along with a paper questionnaire

Contact 4	Postal reminder letter inviting the mother to take part online
Contact 4.4	SMS reminder timed to arrive with the initial letter including a link to the survey

Confidential information requested

Cohort	Mothers aged 16 years or over at the time of delivery, who gave birth under the care of an NHS trust (including home births), in February 2024.All those who gave birth during that month for each trust will be invited.
Data sources	1. Electronic patient records within all eligible Trusts in England (120-130 trusts)
Identifiers required for contact purposes	1. Name 2. Date of birth 3. NHS Number of mother 4. NHS Number of infant 5. Address and unit level postcode
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. NHS Number of mother 4. NHS Number of infant 5. Address and unit level postcode
Identifiers required for analysis purposes	1. Unique identifier 2. Postcode
Additional information	The applicants anticipate that the sampling period will only span one month (February 2024) for the majority of trusts. However, where a trust had fewer than 300 eligible mothers give birth in that month, they may be asked to go back through January until a sample of 300 is achieved.

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 Precedent Set Review Sub Committee agreed that this was a well-presented application.

The CAG noted that as well as maternity service users, the applicants were also engaging with midwives. The members agreed that the public involvement was adequate for the purpose of this application. The CAG requested an ongoing plan of relevant continuous patient and public involvement. **(Condition 1)**

The CAG noted that the primary approach for informing patients of the study would be the display of posters within the participating trusts during the sampling period, which would give patients the opportunity to opt-out of the survey should they wish to. The applicant also mentioned that although the provision of posters was the primary method of informing the study population of the survey, trusts would also be informed that they can undertake their own additional promotional activities, where considered appropriate, for example through press releases and local social media. NHS Trusts would be provided with a Communications Toolkit to support their publicity and promotional activities. Therefore, the CAG suggested that the applicant consistently consult the Trusts to make sure that the notifications were disseminated effectively. **(Recommendation 1)**

Confidentiality Advisory Group advice: Conditionally supported

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.

Number	Condition	Response from the applicant
1.	Provide an ongoing patient and public involvement plan and ensure continuous engagement with the public involvement groups. This should be reported back to CAG at first annual review.	
Recommendation:		
1.	The CAG recommended consistent discussions with the Trusts to make sure that the notifications are disseminated effectively.	

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

2.b	**24/CAG/0043**	**Geriatric Medicine, Care and the End of Life:**

		Appreciating Clinical Uncertainty in the Acute Care of Older Adults
	Chief Investigator:	Mr Luke Stalley
	Sponsor:	University of St. Gallen
	Application type:	Research

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

Summary of application

This application from University of St. Gallen set out the purpose of medical research that seeks to understand the nature and extent of palliative care within geriatric medicine amid the clinical uncertainty that defines the health status of the populations geriatricians care for.

A researcher is undertaking a number of different methodologies at 3 participating Trusts, including consented staff observations and interviews and consented interviews with patients. These elements do not require 's251' support. Fieldwork will take place over six 1 month-long periods.

However the researcher, who is not considered direct care team, is also undertaking ethnographic observations, including shadowing geriatricians, and observing clinical settings where geriatricians work – such as Multi-Disciplinary Team (MDT) meetings and staff handovers. Support under Regulation 5 is required for this aspect of the study, as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded without consent.

Confidential information requested

Cohort	Approximately 30 patients in each site, under the care of geriatricians, who may, or may not be approaching the end of life, from participating Trusts who were discussed during clinical observations/MDT meetings, and have not provided consent.
Data sources	1. Clinical meetings/observations of geriatricians in Nottingham University Hospitals NHS Trust, Barnet Hospital (part of Royal Free London NHS Foundation Trust) & Cambridge University Hospitals NHS Foundation Trust, recorded via written field notes.
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes

Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

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 Precedent Set Review Sub Committee agreed that this was a well-presented application with no issues.

Confidentiality Advisory Group advice: Fully supported

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

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 20 February 2024**

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 review for **Nottingham University Hospitals NHS Trust, Barnet Hospital (part of Royal Free London NHS Foundation Trust) and Cambridge University Hospitals NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 12 March 2024).

2.c	**24/CAG/0044**	**Getting the bloods to the laboratory: developing interventions to improve the blood culture pathway for patient safety and antimicrobial stewardship (Parts 1c & 2)**
	Chief Investigator:	Professor Carolyn Tarrant
	Sponsor:	University of Leicester
	Application type:	Research

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

Summary of application

This application from the University of Leicester set out the purpose of medical research that seeks to develop understanding of the organisational, social, and behavioural factors that impact on practices along the pre-analytic blood culture pathway in acute care.

Antimicrobial resistance is a global threat and overuse of antibiotics in healthcare settings contributes to the problem. Patients in acute hospital settings often present as acutely unwell with symptoms suggestive of infection and timely administration of antibiotics is critical to avoid mortality from sepsis. Being able to deploy antibiotics quickly in emergency and acute cases is vital, but can result in antibiotic overuse. Guidelines indicate that initial prescribing decisions should be reviewed within 48 -72 hours, to identify whether antibiotics can be stopped or switched to a more targeted option, to avoid inappropriate antibiotic use. Decision-making about continuing or stopping antibiotics is highly contingent on microbiology results, for example negative culture results provide a basis for decisions to stop antibiotics, and results identifying the infective organism are required to inform decision-making about switching to a narrow spectrum alternative. If microbiological results are not available at review, clinicians are dependent solely on clinical assessment as the basis for decisions about continued antibiotic use. Evidence suggests that 40-60% of hospital patients do not have cultures taken when antibiotics are started. Interventions have been developed to address clinical and technical issues in the blood sampling pathway, but social, behavioural and other factors have not been explored. The applicants seek to undertake mixed-methodology research into other factors that may impact on the blood sampling pathway.

A component of the research is an ethnographic study involving observations and interviews with healthcare staff in three participating trusts. Around 150 hours of observations in total across the three sites in emergency departments and admissions units, other hospital wards, and microbiology laboratories. Initial observations will focus on documenting which staff members are responsible for requesting and taking blood samples, and researcher familiarisation with how the blood sampling pathway operates within the site. Subsequent observations will include in-depth observations of practice related to antibiotic prescribing and decision-making about blood sampling and blood sample collection. Antibiotic reviews will be conducted to capture the impact of blood results on antibiotic review decisions. Observational data will be captured through fieldnotes and audio-recorded data summaries. Photographs will be taken of key activities and artefacts, e.g. of blood sampling equipment, blank sample order form forms; no individuals or identifying patient details will be included in photographs. Local documents relevant to the blood sampling pathway will be collected and added to the data set. As patient care and sample testing will be observed, the applicants seek support for any inadvertent disclosures of confidential patient information made.

Confidential information requested

Cohort	The cohort in this component of the application are NHS staff. However, patients may be observed when staff observations are undertaken.
Data sources	No confidential patient information will be collected
Identifiers required for linkage purposes	No items of confidential patient information are required for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information are required for analysis purposes
Additional information	

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 the applicants have sought feedback from their public involvement representative on the specific question of the researcher overhearing confidential patient information and would forward the feedback on, once received. The CAG requested detailed feedback on the outcomes of the recommendations that were discussed by representatives on the specific question of the researcher overhearing confidential patient information. **(Action 2)**

The CAG agreed that the poster needed to be improved to inform patients of the specific breach of confidentiality. (i.e., observer incidentally overhearing identifiable data, which is not the focus of the study and will not be recorded). **(Action 3a)**

The CAG requested that updated poster should be reviewed by a group of patients and the public for accessibility and be provided to CAG for review. **(Action 3b)**

<u>Confidentiality Advisory Group advice:</u> 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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Provide detailed feedback on the outcomes of the recommendations that were discussed by representatives on the specific question of the researcher overhearing confidential patient information.	
3.	Please update the patient notification material as follows and provide to CAG for review: a. Update the poster to inform patients of the specific breach of confidentiality. (i.e., observer incidentally overhearing identifiable data, which is not the focus of the study and will not be recorded). b. The updated poster should be reviewed by a group of patients and the public for accessibility.	

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

2.d	24/CAG/0045	**Evaluating the impact of artificial intelligence triage in online consultations to reduce delays in urgent and emergency primary care: a qualitative process evaluation**
	Chief Investigator:	Dr Benjamin Brown
	Sponsor:	The University of Manchester
	Application type:	Research

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

Summary of application

This application from The University of Manchester set out the purpose of

medical research that seeks to explore how different GP practices implement AI triage and its impact on the service they provide. This will include identifying how well an AI triage system called PATCHS is working in GP practices. PATCHS is an online consultation system that enables patients to request help from their GP practice online. Outcomes will be used to help NHS England and online consultation companies to decide whether, and how best to use AI triage, and also to help patients and GP practice staff from diverse communities to understand what AI triage is and how it can best be used for patient care/ improved patient outcomes.

A researcher is undertaking a number of different methodologies at 7 participating GP practices, including consented staff observations and interviews and consented interviews with patients. These elements do not require 's251' support. Fieldwork will take place over a 12 month period. The time taken for observations will be up to 25 days in each practice with a maximum of 4-6 hours per day.

However the researcher, who is not considered direct care team, is also undertaking ethnographic observations, including shadowing clinicians who use the AI triage system, and observing clinical settings. Support under Regulation 5 is required for this aspect of the study, as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded without consent.

Confidential information requested

Cohort	Patients who submit online consultation requests during the observation periods, from participating GP practices and have not provided consent. Applicant estimates this might be 5-10 patients per day (25 days per site, x 7 sites = 875-1750 patients records)
Data sources	1. Clinical meetings/observations of clinicians who use the AI triage system in 7 participating GP practices
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

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 notification material was inadequate as it did not refer to incidental exposure to confidential patient information when a researcher was observing practices and procedures within a healthcare setting. The notification did not mention that no identifiers will be recorded. The notification should also state that 'section 251 support' was recommended by the Health Research Authority, on advice from the Confidentiality Advisory Group (CAG). **(Action 2)**

<u>Confidentiality Advisory Group advice:</u> 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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Please update the patient notification material as follows and provide to CAG for review. a. Add a statement to clearly explain the specific breach of confidentiality. (i.e., observer incidentally overhearing identifiable data, which is not the focus of the study and will not be recorded). b. The notification should state that 'section 251 support' was recommended by the Health Research Authority, on advice from the Confidentiality Advisory Group (CAG).	

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

Dr Murat Soncul	15 March 2024
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Signed – Chair	*Date*
William Lyse	19 March 2024
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Signed – Administrator	*Date*