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

09 June 2023 via correspondence

Present:

Name	Role	Items
Dr Murat Soncul	CAG Alternative Vice Chair	2a, 2b, 2c, 2d
Dr Martin Andrew	CAG Member	2b, 2d
Dr Sandra Duggan	CAG Member	2a, 2d
Professor Lorna Fraser	CAG Member	2a. 2c
Ms Diana Robbins	CAG Member	2b, 2c

Also in attendance:

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

1. Expressions of interest

There were no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0062- Exploring determinants of pregnancy intention and relationships between pregnancy intention and outcome using routine data

Context

Purpose of application

This application from Imperial College London set out the purpose of medical research to explore the relationships between pregnancy intention and adverse pregnancy outcomes.

There is evidence of linkage between unplanned pregnancies and poor pregnancy outcomes, such as pre-term birth or low birthweight and postnatal depression. This may be due to additional stress and anxiety that an unplanned pregnancy may cause or because women whose pregnancy is unplanned may be less likely to have prepared for pregnancy or accessed pregnancy related services later. The applicants seek to include questions in antenatal care to develop understanding of the relationships between unplanned pregnancy and pregnancy outcomes, with the aim of identifying those at increased risk of worse outcomes.

The applicants seek to use data already collected as part of routine antenatal care to investigate the links between pregnancy intention and adverse pregnancy outcomes. Information will be extracted from patient records by those with an existing legal basis to process the information and also by research midwives. A pseudonymised dataset will be extracted and transferred to the Data Safe Haven at University College London for analysis.

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

Confidential patient information requested

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

Cohort	All pregnant people who completed their booking appointment at UCLH, Homerton or Guy's and St Thomas' Hospital from October 2020 onwards (UCLH),

	May 2020 (Homerton) and November 2022 (GSTT) until mid 2025. Approximately 52500 patients.
Data sources	1. Patient records held at: a. University College London Hospitals NHS Foundation Trust b. Homerton Healthcare NHS Foundation Trust c. Guy's and St Thomas' NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS number 2. Postcode
Identifiers required for analysis purposes	1. Postcode 2. Occupation 3. 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. The CAG agreed that the application was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

The CAG noted that support was needed for the transfer of full postcodes to University College London. Members observed that a quick process, using an online lookup table, could be undertaken to convert postcode to Index of Multiple Deprivation prior to transfer of these data. The CAG requested that the postcode was converted to IMD prior to transfer using one of many online lookup tables.

- **Feasibility of consent**

The applicants advised that consent was not feasible due to the number of patients involved and the retrospective nature of the data collection. The applicants also noted that acquiring patient information in order to make contact and seek consent would require a larger breach in patient confidentiality than the proposed methodology. The Sub-Committee were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Research midwives need to access confidential patient information in order to identify eligible patients and extract their data, as it is not feasible for the direct care team to undertake the work.

Research midwives need to access confidential patient information in order to identify eligible patients and extract their data, as it is not feasible for the direct care team to undertake the work.

The Sub-Committee were content that using non identifiable data was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

No specific patient notification is planned. The National Data Opt-Out will be applied. The CAG agreed that patient notification needed to be developed. Patients also needed to be able to opt-out of use of their data for this study specifically. Information about the study and how patients can opt-out needed to be included on the websites of participating organisations and in relevant clinical areas.

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 advised that the application had been discussed with their patient and public involvement group, who were supportive of the application. The patient and public involvement group is comprised of 20 women from around the UK, aged 19-49 years and from a variety of ethnic backgrounds. The proposed data extraction was presented to the group and opinions sought. Overall, the group agreed that this was an acceptable use of routinely collected data.

The CAG commented that the patient and public involvement undertaken appears proportionate to the scale of the breach in confidentiality.

Exit strategy

The extraction of data from the maternity information system will occur within the Trust. The data extracted will contain full postcode and NHS number. The NHS number will be replaced with a reference number and the re-identification key held on the Trust servers and can only be accessed by the Trust research midwife or data processor. However, full postcode will still be in the dataset at this point. On receipt in the UCL Data Safe Haven the postcode will be mapped to index of multiple deprivation and then deleted. At this point the data can be considered anonymised.

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. Please develop a patient notification method that includes a study specific opt-out option. The notifications should be included on the websites of participating organisations and in relevant clinical areas. Please provide to CAG for review.

2. The postcodes are to be converted to Index of Multiple Deprivation prior to transfer using one of many online lookup tables, or please justify why this is not practicable.

3. Please provide the NHS England 2021/22 DSPT review for Homerton Healthcare NHS Foundation Trust, as per standard condition of support below.

Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 15 June 2023.**

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. See section below titled ‘security assurance requirements’ for further information. **Pending**

Confirmed: The NHS England 2021/22 DSPT reviews for **University College London, University College London Hospitals NHS Foundation Trust and Guy's and St Thomas' NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023).

Pending: The NHS England 2021/22 DSPT review for Homerton Healthcare NHS Foundation Trust is pending.

b. 23/CAG/0069 - A study examining the outcomes of blood transfusions where "least incompatible blood" has been issued due to the rarity of available red cell units

Context

Purpose of application

This application from NHS Blood and Transplant (NHSBT) set out the purpose of medical research that aims to follow up the transfusion outcomes of approximately 120 patients who have received "least incompatible" blood in England. The study will seek and examine hospital laboratory parameters to assess whether the transfusions, if given, led to an expected rise in haemoglobin (the oxygen carrying bit of the blood) and no reported reactions or rise in laboratory markers of haemolysis (destruction of red cells by antibodies).

Some patients have antibodies in their blood which makes finding perfectly matched, or compatible red blood cells for transfusion hard to find. These antibodies are often to red cell antigens that are found in the majority of the donor population, and therefore there is not compatible blood available. In these rare instances, the UK blood services select "least incompatible" (weakly reactive Vs the patient) blood for transfusion. As these instances are rare, very little is known about the outcomes of these transfusions, and whether the patient benefitted from the transfusion, if given. This study will help inform transfusion decision making when treating other patients with these rare antibodies in future, as it will provide additional information as to the clinical significance of the rare antibodies in question, and will inform future blood selection policies, which should improve patient care.

Patients who had an antibody to a high frequency antigen and whom NHSBT had issued red blood cells (RBC) for transfusion have been identified from the NHSBT clinical systems, retrospectively and dating back to around 10 years ago. The applicants currently do not know if these patients were actually transfused, and outcome data will only be collected for those that have received at least one unit of 'least incompatible' red cells issued by NHSBT as per inclusion criteria. However, the final fate of the units will be established for all patients, and 's251' support is therefore required for all 120, as their confidential patient information will be processed regardless of whether or no they end up fitting the inclusion criteria. An enquiry will be made by the NHSBT research team, via telephone or secure nhs.net

e-mail, to hospital transfusion departments, as to the outcomes of the transfusion of least incompatible units. Data returned will include clinical data surrounding the transfusion, which will be linked back to the NHSBT data. Analysis will be undertaken on a pseudonymous dataset.

A recommendation for class 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	120 patients who have been identified as having a rare antibody which led to the selection of 'least incompatible blood' issued by NHSBT
Data sources	1. NHSBT - laboratory Information Management System (LIMS) 2. Referring hospital transfusion departments where least incompatible units sent to, and patients were transfused – medical records
Identifiers required for linkage purposes	3. Name 4. Date of Birth 5. NHS number
Identifiers required for analysis purposes	4. Analysis undertaken on a pseudonymous dataset

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Sub-Committee noted that this interesting and important study has significant public interest, although the cohort that is directly affected is small as this is a rare situation.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants reason that the data is historical and patients would be hard to trace in order to gain consent for this specific purpose, as some patients are from more than 10 years ago.

The Sub-Committee agreed with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to identify the correct patient at the Trust and for linkage to outcome data.

The researcher undertaking the study will need to contact hospital transfusion departments within England in the hospitals where the patients were treated and make enquiries as to the outcomes of transfusion of the individual patients. This cannot be done in an anonymised or pseudonymised manner, as the researcher needs to be able to identify the patient to ensure that they are requesting the correct outcome information from the referring hospital.

The CAG agreed this could not be undertaken without identifiable information.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant reasons that as NHSBT is a provider of diagnostic services to hospital transfusion laboratories, they do not have direct contact with this cohort of patients via a direct channel of communication. The patients may be aware that they have one of the antibodies of interest and carry a card that states this. Therefore a communication via the NHSBT website may be the most appropriate means. A communication will be drafted to post in the most appropriate area of the website.

National Data Opt-Out will be respected. There is currently no study specific opt out option available, but the applicant has stated that one will be developed as part of a patient notification document.

The Sub-Committee noted that there was currently no patient notification or study specific opt out mechanism, and this these documents should be developed.

Patient and Public Involvement and Engagement

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

The applicant has stated that the patient cohort (n=120) is a very rare cohort, and patients and the presence of the antibodies of interest are not associated with a particular condition or diagnosis and therefore the cohort have no dedicated common forum/diagnosis or route of communication where many of them can be contacted. Therefore they reason that a patient and public involvement exercise for this specific cohort is extremely difficult to undertake.

The Members stated that they could not support the application without some patient and public involvement (PPI)being undertaken. The CAG note the reasons the applicant has provided, but commented that you do not need to find people who exactly match the cohort that they are studying. As this could potentially affect anyone suddenly needing transfusion, a more general PPI group would suffice, for example there are several patient groups for survivors of trauma or ITU patients that would be suitable. The use of confidential patient information without consent should be discussed.

The CAG also commented that although the study management group appears to have 'extensively discussed' the use of confidential patient information without consent, it does not appear there is any lay representation on this group, and the CAG suggest that the applicant could appoint some lay members to this, although this is not a requirement.

Exit strategy

The study will last approximately 6 months - the confidential patient information will be deleted from NHSBT servers approximately 6 – 12 months after the end of the study.

The Members noted that it was not completely clear at which time point this anonymisation will take place, and they would appreciate clarity on that.

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 would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, within one month.

Request for further information

1. Please develop a patient notification method that includes a study specific opt out mechanism, and provide to CAG for review.

2. Please discuss the use of confidential patient information without consent with a patient and public involvement group, and provide feedback to CAG.

3. Please provide clarity on when the data will be anonymised.

Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 02 May 2023**

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. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England **21/22** DSPT review for **NHS Blood and transplant** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023)

   Due to the number of participating organisations involved it is the responsibility of NHSBT, as controller, to ensure that organisations meet the minimum required

standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

c. 23/CAG/0072- Listen2Baby - Improving monitoring of the baby during uncomplicated labour: a study using experience-based co-design

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to improve the quality and safety of fetal monitoring in uncomplicated labours through an improved understanding of the organisational context and practice of intermittent auscultation (IA) during labour, and ultimately improve care for women and babies, by the development and initial evaluation of a 'toolkit' to improve IA practice.

For approximately 30,000 women annually experiencing an uncomplicated labour, UK guidance recommends that midwives monitor the baby's heart rate using a hand-held fetal stethoscope or ultrasound device, known as IA or 'listening at regular intervals'. Several national investigations have found issues with the way IA is carried out in practice that have contributed to death or severe injury in babies. Problems include IA not being carried out at the right time or often enough; the baby's heart rate not being recorded properly; and midwives not recognising or acting on concerns about the baby's heart rate. There is no research evidence about the best way to do IA in practice. This research will explore how midwives do IA in practice, and what IA is like for women and their partners. Applicants plan to use this information to design and test a practical 'toolkit' to help midwives do IA in the best way to ensure safety for babies.

This study has many elements which do not require 's251' support, as they are consented, or do not use confidential patient information without consent. The applicants do require 's251' support for a researcher to extract an effectively anonymous dataset for analysis from 8 participating Trusts. The extraction will happen twice, once during the initial study work package (ii), and then again during work package (v), which will be after the implementation of the developed toolkit to improve IA practice. Anonymised data about IA quality and compliance with guidance will be extracted from case notes, which are screened for eligibility and provided to the researcher by the direct care team. The applicants also require 's251' support for potential incidental disclosure of confidential patient information,

during observations of closed space clinical meetings, where it will not be possible to verbally consent the patients, as the patients will not be present.

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	240 case notes in total: up to 20 consecutive women from each site, (total of 160 in work package (ii)) and up to 10 consecutive women from each site, (total of 80 in work package (v)) who were monitored during labour with a hand-held monitor before the observation period. And any patients discussed in relevant meetings.
Data sources	1. Maternity notes from participating hospitals
Identifiers required for the purposes of extracting a dataset for analysis	1. Name 2. Date of birth 3. Maternity clinical records
Identifiers required for analysis purposes	1. N/A data is effectively anonymous for analysis

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

For clinical staff to obtain consent from the women whose notes are being reviewed would introduce significant administrative burden to the organisation and, depending on responses, could introduce bias into the results. It is also important that the notes reviewed are those of women who received care before the period of observation, because the observation taking place in the unit might have an impact on the quality of IA monitoring and recording. It is not possible therefore, to select for audit the notes of women who are in the unit during the period of observation and ask them for consent to access their case notes. It would therefore introduce significant administrative burden to NHS clinical staff to obtain consent from the women whose notes are being reviewed, all of whom will have left the maternity unit. This could also cause anxiety to women and partners as to the reason for the inclusion of their notes in the audit and, depending on responses, could introduce bias into the results.

It is also not practicable for the applicant to gain consent from women who may be discussed in clinical meetings, as the applicant may not know who these patients will be, and the patients will not be present to verbally consent.

The CAG accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to be viewed during the extraction of a dataset for analysis, and during incidental observations of meetings.

The applicant has reasoned in their cover letter as to why it is not practicable for the direct care team to anonymise the medical records prior to providing them to the researcher, ie. this would be too burdensome for clinicians, and often is not effectively undertaken. No confidential patient information will be recorded.

The CAG accepted this justification.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local

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

The applicants propose that they will inform women of the case note audit, and meeting observations taking place through posters in antenatal clinics and maternity units, and information on the maternity service website and social media channels. This information confirms that no confidential patient information will be recorded, and inform women that they can opt out by contacting the local Principal Investigator for the study.

The poster has been provided for review, and has an opt out option, and has a QR code link to more information. The QR code will take the patient to the study website. Applicants have included a transcript of the website text. This includes a draft privacy notice.

The social media text for NHS maternity service website / Facebook / other social media and mailing lists has been provided.

The National Data Opt-Out will be respected, and there is also a study specific opt out option.

The CAG were content with the patient notification and opt out methodology.

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 study has been designed by a multi-disciplinary co-investigator group, including two lay members, and has been informed by patient and public involvement throughout. The 2 lay members both have personal experience of being monitored using IA during labour and have wider experience of providing peer support to pregnant women and new mothers in their communities. Four representatives of service user organisations, including the Birth Trauma Association, Sands, the stillbirth and neonatal death charity, and The Motherhood Group, form a Lived-experience User Group, and were involved in commenting on the research aims and design of the research. A further five women have so far expressed an interest in joining this group, and applicants plan to recruit up to 30 people to this group, to aid in the toolkit design.

The two lay co-investigators, and the four Lived-experience User Group members did not have any concerns with confidential patient information being viewed, without their consent for the purposes of this study. They advised that the possible alternatives were impractical and overly burdensome, given that no patient identifiable data are being used for this study. They suggested that women should

be given the opportunity to opt out of their case notes being accessed for this audit, but did not think that individual women should be contacted as this would be overly burdensome for the NHS organisation, potentially anxiety-inducing for the woman, and might damage the integrity and value of the research by introducing bias.

8 service users in the local areas of the 2 lay co-investigators have also been approached for feedback on study materials.

The CAG were content with the patient and public involvement undertaken.

Exit strategy

The case note audit alongside observations, is being carried out in two time periods between 1st February 2024 (WP ii) and August 2025 (WP v). In each NHS organisation patient identifiable data will be processed without consent for the purposes of this research for two separate periods of 3 weeks during this time. 's251' support required until the 2nd data extraction of the datasets for analysis (WP v), and once the observations of meetings have finished, so until August 2025. The CAG were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 16 May 2023**

4. 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:**

   Due to the number of participating organisations involved it is the responsibility of University of Oxford, as controller, to ensure that organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

d. 23/CAG/0073- CompreHensive GeriAtRician led MEdication Review (CHARMER) - Work Package 4 Definitive Trial

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research that aims to test the effectiveness of the refined CHARMER intervention developed in the feasibility study, which is an intervention to support geriatricians and hospital pharmacists to proactively deprescribe for older people whilst they are in hospital, by measuring the impact proactive deprescribing has on readmission rates to hospital.

Research shows that almost half of older people in hospital are prescribed a medication with a risk of harm, but these medicines are rarely stopped. The reasons why geriatricians and hospital pharmacists do not proactively deprescribe for older people have been ascertained in a previous study. The research team has used this work to develop an intervention to support and encourage proactive deprescribing. This study has the potential to benefit patients in hospital by supporting clinicians caring for them to stop medicines that may cause harm. Stopping medicines should also reduce medicines administration burden and potentially improve medication adherence.

The deprescribing intervention developed and refined in earlier CHARMER studies will be compared to usual care on older people's medicine wards at twenty hospital sites in England. Twenty four hospitals will take part, in case hospital sites drop out during the study. Hospitals will begin as control sites and advance to receive the intervention at different stages in a stepped wedge design. Geriatricians and pharmacists at participating hospitals will receive the intervention, which will be tested for 4 weeks. All patients receiving care from clinicians on the study ward for the duration of the study will be enrolled. Routine data collection from site medical records will be collected for all patients. Consent will be taken where possible. ‘s251’ support will be required where consent is not possible. NHS number, Date of birth, and postcode, alongside a pseudo-ID will be disclosed to Norfolk and Norwich University Hospital NHS Foundation Trust, who will then disclose onwards to NHS England for the purposes of linkage to Hospital Episode Statistics (HES) (to identify readmissions), ONS data (to identify mortality) and prescribing datasets (to assess medication changes in primary care post discharge i.e. whether deprescribing was sustained). Most patient identifiers will be removed once data linkage is complete, however full date of death alongside other data is returned to Norwich Clinical Trials unit for analysis, therefore this flow also requires ‘s251’ support. This approach was tested in a recent feasibility study of CHARMER (22/CAG/0071).

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	All patients under the care of a participating geriatrician on a study ward during the active study window who do not consent to the study. Total of 24,000 participants. Applicant estimates that a maximum of 3000 patients will provide consent to take part, therefore a minimum of 21,000 will require 's251' support
Data sources	1. 24 Participating NHS sites a) Medical records 2. NHS England: a) Hospital Episode Statistics b) ONS Mortality Data c) NHS Prescription Dataset
Identifiers required for linkage purposes	4. NHS number 5. Date of birth 6. Postcode
Identifiers required for analysis purposes	1. Date of death

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Sub-Committee agreed that there is a clear public interest that will benefit the elderly population.

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 research team need to collect relevant data regarding the care that participating geriatricians and pharmacists deliver to all patients under their care. Consensus amongst the research team of geriatricians and pharmacists is that it will not be possible to seek consent from all patients for this required data; for example some patients may be discharged before they can be approached by a member of the hospital research team. This is supported by the research team's previous research in a comparable patient population, which demonstrated that 29% of patients could not be approached for consent prior to their discharge from hospital. Rates of approach for consent in the recent CHARMER feasibility study reinforced this finding (Sites rates of approach varied from 14% to 28%). Data collection from such a limited proportion of patients exposed to the effects of the intervention would prevent satisfactory evaluation of the safety and effectiveness of the intervention. CAG has previously supported the same model as part of the feasibility study.

Consent will be sought where possible, however it is important that as many consecutive patients are included as possible to study the intervention without bias.

The CAG were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage to outcome measures.

NHS sites could provide identifiers to NHS England directly, rather than having to send them to NNUH prior to transfer. However, NHS England agreed that NNUH should be used as a central site.

The CAG were content that the use of non identifiable information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster and leaflet will be clearly displayed in participating study wards throughout the study window period to publicise the study to patients whose data will be included. The poster signposts the reader to the leaflet which provides more detailed notification information on the proposals and clear opt out guidance.

In addition, the leaflet will be included in hospital discharge documentation for all patients who have received care on one of the study wards during the study window, so patients have a copy of study information and opt out guidance after their hospital stay should they wish to opt out at a later date.

It appears other diverse communication strategies have been utilised, for example Twitter, blogs, video animation, social media publicity of infographics and plain English summaries.

The poster offers a study specific opt out and states National Data Opt-out respected.

The Sub-Committee commented that the posters and leaflet were well designed and the opt out was clear. They noted that the use of 'section 251 support' was not mentioned on the poster, but were content with this, as people can then access a leaflet or website for more information. The Members noted that the twitter feed does seem to be being used effectively.

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.

Charmer has a Patient and public involvement (PPI) team, which has five members with a diverse range of experiences, representing the voice of older patients and carers. They have been active in the design of the study and materials.

Use of identifiable patient data for the purposes of accurate linkage has been reviewed by various people, including patient representatives. It was deemed absolutely essential by these groups of people that applicants capture a minimum dataset for all patients exposed to the intervention and those receiving standard care. The use of patient identifiable data for the purposes of accurate data linkage has also been co-designed with three PPI representatives within the CHARMER definitive study team at study management group meetings; more widely with the whole programme PPI team (5 members), via CHARMER social media channels using diverse communication methods e.g. video animation, and with the NIHR CRN and prospective hospitals.

This approach has also been tested in the recent CHARMER feasibility study with no concerns or complaints from patients or family members. Moving forward, applicants plan an ongoing consultation process with patients and public. The CHARMER PPI team are building a wider CHARMER community by sharing a

tailored flyer on social media and with groups including U3A, charities, religious and community groups. The flyer invites people to provide their contact details to facilitate two-way communication with a large, diverse group of patients and members of the public with an interest in CHARMER. The CHARMER PPI team will prepare messages about the learnings from CHARMER as they emerge and will seek feedback from the community.

The Sub-Committee felt that the patient and public involvement was excellent. Although there are only 5 members at present, the use of confidential patient information without consent had been thoroughly discussed. The applicants have plans to expand and widen the team. The website also supports the assertion that the PPI members are active and involved in the study design. It was noted that moving forward, applicants plan an ongoing consultation process with patients and public. The CAG would therefore like to know more about the ongoing activities and further feedback from patients and the public, at annual review.

Exit strategy

Once date of death has been modified and deleted by Norwich Clinical Trials Unit, 's251' support no longer required. This will be removed by the end of the study analysis period – February 2026. The CAG were content with this.

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 actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide the Favourable Opinion of the REC, as per standard condition of support.

Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Please provide an update about the ongoing activities and further feedback from patient and public involvement, at annual review.

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

3. 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. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England **21/22** DSPT reviews for Norfolk and Norwich University Hospital NHS Foundation Trust, NHS England, & Norwich Clinical Trials Unit (EE133853-NMS-CTU) were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023)

   Due to the number of participating organisations involved it is the responsibility of University of Leicester, as controller, to ensure that organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Murat Soncul, Alternate Vice-Chair		*21 June 2023*
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst, HRA Confidentiality Advisor		*20 June 2023*