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

July 2020

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	1.a
Mr Anthony Kane	CAG member	1.a
Prof Jennifer Kurinczuk	CAG member	1.a

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 20/CAG/0088 - Antihypertensive Treatment in Elderly Multimorbid Patients: a pilot study

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to address a gap in understanding of the treatment effects of blood pressure lowering treatment in older patients with many underlying health conditions, and in particular when their blood pressure is not very high.

The beneficial effects of blood pressure (BP) lowering treatment are well understood. However, the importance of BP lowering treatment in certain patient groups remains uncertain. One such group includes older patients with many underlying health problems, in particular when their blood pressure is not very high. Little research has been conducted with this group, due to the difficulty of recruiting sufficiently large numbers of older and co-morbid patients into clinical trials. The applicants are seeking to recruit 200 patients aged 65 years and over, and who have a least 3 long-term health conditions or are taking at least 5 medications in addition to being taken to manage blood pressure, into a pilot study. Participants will be randomised to receive up to 2 additional or 2 fewer classes of BP lowering medication over the course of the study with their treatment assess every 4 weeks with the aim of testing whether the intervention can lead to important changes in blood pressure. The findings from the study will be used to establish the feasibility of a larger home-based study to assess the effect of treatment changes on patient-important outcomes.

The applicants are seeking support for the disclosure of confidential patient information from NHS Digital to the research team at the University of Oxford. The study team will provide NHS Digital with a search query to select individuals aged 65 years or more with three or more chronic conditions diagnosed within a 5-year time window prior to the latest assessment date. The selection of chronic conditions of interest will be based on 3-character ICD codes and individuals with a recorded diagnosis of heart failure will be excluded. The search query will be provided on a number of occasions, each time restricted to individuals who live within different regions in the Thames Valley area and are alive at the time of data sharing with the research team. Patients will then be contacted by post by the research team and their involvement will then proceed on a consented basis.

Patients who are registered with online pharmacy, Pharmacy 2U, and who reside in the Thames Valley area, will also be included. This recruitment pathway was outside the scope

of the s251 support sought, as patients will be contacted by Pharmacy 2U in order to seek consent for the sharing of their contact details with the study team. A website would also be made available for patients to register their interest in taking part. This was also outside the scope of support.

A recommendation for class 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Male and female patients aged 65 years and over, and who have a least 3 long-term health conditions or are taking at least 5 medications in addition to being taken to manage blood pressure. Confidential patient information for over 10,000 patients will be disclosed from NHS Digital, from which the applicants anticipate that 200 will consent to take part.
Data sources	1. NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode – unit level 5. Address 6. Gender
Identifiers required for analysis purposes	1. Postcode – unit level

Confidentiality Advisory Group advice

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

Public interest

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

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 advised that one of the aims of the study was to investigate the use of technological solutions to overcome challenges in recruitment to research studies and to look at ways that technology can be used to streamline the trial process. A bespoke, IT enabled system will be used to recruit and monitor participants with little direct physical contact between participants and the study team and without having to ask participants to travel away from their homes to attend any study-related appointments. The applicants noted that this was particularly relevant to the older cohort recruited to this study and due to the effects of the Covid-19 pandemic on recruitment to studies.

A key aspect being tested is a system to allow studies to recruit patients centrally and remotely, using details provided by NHS Digital, rather than working with a number of research sites to identify potential participants. These details will then be used to contact patients to seek consent and their participation in the study will proceed on a consented basis.

The Group accepted the rationale given for not seeking consent and raised no queries in this area.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for the research team to make contact with patients identified as potentially suitable in order to seek consent. The CAG raised no queries in this area.

'Patient Notification' and mechanism for managing dissent

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

The study will have two databases, a pre-screening database, holding the details of potential participants obtained from NHS Digital and Pharmacy 2U, and the ATEMPT database that will hold all the research data. When a potential participant registers their interest to take part in the study their details will be transferred from the pre-screening database to the ATEMPT database. When enrolment is complete the pre-screening database with details of those who did not register their interest in the study will be deleted.

The invitation letter sent to patients identified as potentially suitable will include contact details for the research team. If an individual contacted the research team to indicate that they did not want to take part, then their details were deleted from the pre-screening database. The trial IT system has a functionality to change the status of invited participants to 'mark as to not be contacted again' with the date of the decision made. This flags the participants in database to prevent their records to be used for research purposes.

Potential patient who register their interest but do not go on to give consent or are excluded under the exclusion criteria will be classified as screen failures. Their contact details and any other identifying information will be removed from the ATEMPT database and their screening data anonymised.

The applicant advised that the National Data Opt-Out will be applied to data requested from NHS Digital.

The CAG noted that patients may be surprised to receive the invitation letter. The letter advised patients that NHS Digital supplied the researchers with their contact details after going through their medical records. The letter needed to provide a fuller explanation on how the researchers had obtained the patients' contact details, including an explanation of the s251 process and that the researchers have had permission to obtain a randomised selection of patients fitting the criteria to ask for help with the research. The letter could also advise that the decision to recommend support under s251 was supported by patient and public involvement.

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 explained that five patient research ambassadors attended a face to face meeting with the study team in March 2020. Four out of five of those attending were aged 65 or over and at least two were receiving treatment for high blood pressure. One was also a carer for an elderly relative with multiple chronic conditions and was therefore able to provide a carer's viewpoint. Feedback was sought on the design of the study and the IT systems the applicants propose to use for the remote management of the study. The Chief Investigator also explained the use of confidential patient information without consent. Two of the five ambassadors have also agreed to be part of the Trial Steering Committee, providing patient representation throughout the trial. The CAG noted this information and raised no queries.

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.

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

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – University of Oxford Medical Sciences Division and NHS Digital (by check of the NHS Digital DSPT tracker on 17 July 2020) have confirmed 'Standards Met' grade on DSPT submission 2018/19).**

3. The invitation letter needs to be revised to include a clear explanation of how the researchers had obtained patients' contact details, including an explanation of the s251 support in place.

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