Minutes of the meeting of the Confidentiality Advisory Group

14 October 2021 – held via Zoom

Present:

Name	Position
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Ms Sophie Brannan	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Mr Andrew Melville	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Marc Taylor	CAG member
Dr Sandra Duggan	CAG member
Professor Sara Randall	CAG member
Dr Pauline Lyseight-Jones	CAG member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Mr Michael Pate	Confidentiality Advisor
Mr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **16 September 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **16 September 2021** meeting applications.

3. New applications – Research

a. 21/CAG/0144 – Risk of COVID-19 related hospital admission and death in cancer patients in Central Manchester

Context

Purpose of application

This application, from the Christie NHS Foundation Trust (with the controller for the activity confirmed to be the Christie NHS Foundation Trust) sets out the purpose of medical research which aims to use NHS number to link additional Christie data on systemic therapies and radiotherapy treatments, blood tests and diagnostics, as well as diagnosis and staging data, with data that is already included in the Greater Manchester Integrated Digital Care Record (GM-IDCR).

This study will provide a Greater Manchester-specific insight into how cancer diagnosis and treatment affect rates of COVID-19 diagnosis, hospitalisation, complications, and death. It will determine the extent of the evidence supporting shielding by cancer patients during the COVID-19 pandemic. The results of this study may ameliorate the fear felt by many cancer patients about attending regular follow-up appointments and the potential risk of contracting COVID-19 while attending hospital.

NHS number will be used to link additional Christie data points that are being added to the data already included in the Greater Manchester Integrated Digital Care Record (GM-IDCR) so that the data can be matched to the correct individual. After linkage, Graphnet (data processors) pseudonymises the data and makes it accessible to the research team in a dedicated research portal. At the point it can be accessed by the study team, the data can be considered anonymous to the study team because the study team do not hold the pseudonymisation key.

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

Confidential patient information requested

Cohort	1. All Christie patients diagnosed with cancer since 1st March 2015 that were still alive on 1st February 2020 – 65,000 records.
Data sources	1. The Greater Manchester Integrated Digital Care Record (GM-IDCR), which is sited within the Graphnet CareCentric record-sharing solution 2. Additional Christie patient data that have been uploaded to the research area of the Graphnet CareCentric record-sharing BI solution for the purpose of this study. The additional cancer data from The Christie are data on systemic therapies and radiotherapy treatments, blood tests, and diagnostics as well as

	diagnosis and staging data that had not already been uploaded to Graphnet.
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	None
Additional information	The research team are recruiting age and sex-matched controls in the ratio of 1:5 (325,000). The controls fall outside of the scope of support. With respect to the recruitment ratio of 1:5, the research team are aiming to detect differences in COVID outcomes between individuals with and without cancer. COVID incidence and deaths are relatively rare outcomes and they need a large enough sample size to provide sufficient statistical power to detect potentially small differences in COVID outcomes between the two groups. Because this is a retrospective study, it is possible to increase the sample size relatively easily with minimal cost. The cancer cohort is expected to include almost the entire GM cancer population. Therefore a cohort match of 1:5 of cancer to non-cancer individuals was deemed to be appropriate to provide the level of statistical power needed.

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 to transition the study to support under Regulation 5.

Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the

elements of the project that are expected to be continuing following expiry of the 'COPI notice', and which require support under regulation 5.

NHS number will be used to link additional Christie data on systemic therapies and radiotherapy treatments, blood tests and diagnostics, as well as diagnosis and staging data, with data that is already included in the Greater Manchester Integrated Digital Care Record (GM-IDCR). Linkage will ensure that the data is connected to the correct patient.

Graphnet Health Limited has an existing legal basis to hold confidential patient information for GM-IDCR to be used for patient care purposes, and this data flow does not fall under the scope of support.

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.

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 size of the cohort (390,000) makes taking consent prohibitive.

The CAG accepted the explanation as to why consent could not be taken.

- **Use of anonymised/pseudonymised data**

The NHS number will be used to link data collected as part of routine care with additional data points, as previously described. The data is being linked by the controller of the database in which the data resides. The research team are only receiving anonymised data, with no 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.

Whilst acting under the COPI notice, the national data opt-out does not apply. However, upon transitioning to regulation 5 support, the national data opt-out will apply. As part of the application, the research team requested for the national data opt-out to apply to this application under Regulation 5 support.

The Manchester Cancer Research Centre statement on patient data, "Personalised medicine for all: our patient and research data statement" had been included with the application. However, the CAG was of the opinion that the notification was not project-specific.

The CAG requested a project-specific notification on the Trust website, not only for the cancer patients involved but also for the controls. This should explain that the study will be extended past the COPI Notice.

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 protocol was reviewed by the patient advocate group, Independent Cancer Patients' Voice. A letter confirming this, dated 12 October 2020, was included in the application. The feedback was:

"As cancer patients we believe this is an extremely important study as it will provide significant understanding of our risks of severe COVID-19. In addition, there is an urgent need to understand which patients with cancer should shield so that the effect of COVID-19 on our lives is proportionate to our individual risk. We fully support the way in which the data is being obtained and used in this study and feel that the researchers have considered in depth measures to ensure good data governance."

With respect to the involvement of non-cancer participants in PPIE, the research team are working with members of their own Public Community Involvement and Engagement (PCIE) panel and GM PCIE forum - https://www.arc-

gm.nihr.ac.uk/public-community-involvement-engagement - who have provided input for shaping of information and communications to raise awareness on data sharing and the GMCR. They are working in partnership with a small number of community stakeholders to do some wider engagement and qualitative research to explore awareness and perspectives on data sharing (in context of GMCR) amongst marginalised and seldom heard communities (e.g. BAME communities, asylum seekers/ refugees, people experiencing homelessness).

There is also a sandpit event planned. It will focus on identifying new research questions to answer using the GMCR and is gathering ideas and attendees from the panel and forum mentioned above.

https://events.manchester.ac.uk/event/event:nc6-ks91t8cp-wb86c9/turinguom-sandpits-202122-greater-manchester-care-record

The CAG was content with the PPI that had been conducted and was planning to be conducted.

Exit strategy

Identifiable data will be destroyed by Graphnet once linkage and anonymisation is complete. The research team have no way of accessing the linkage key and thus, to the researchers, the data are fully anonymised.

The applicant expects processing to be complete by 30th June 2022 at the latest, thus is requesting supporting for 3 months following expiry of the COPI Notice.

The CAG accepted this explanation.

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

1. A project-specific notification should be placed on the Trust website, not only for the cancer patients involved but also for the controls. This should explain that the study will be extended past the expiry of the COPI Notice. The notification should be provided to the CAG before 31 March 2022.

2. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

3. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5.

4. Favourable opinion from REC **Received 09 August 2021**

5. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information (The Christie NHS Foundation Trust and Graphnet) is in place once support under Regulation 5 is active.**

b. 21/CAG/0149 – Legacies and Futures: Gestational Parents' Experiences with Vulnerability and Resilience as it Influences Parent and Neonatal Health

Context

Purpose of application

This application from University College London sets out the purpose of medical research that aims to research what roles resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational parents, as compared to their cis-heterosexual peers, during their antenatal care and their neonates.

There is an assumption that those using pregnancy-related health services are cisgender and heterosexual. The patient population also includes those of different genders and sexual orientations. Structural cis-genderism and hetero-sexism in reproductive healthcare may cause stressors of stigma and discrimination, including social and medical exclusion, during critical windows of foetal development. Stress and discrimination are linked to higher rates of miscarriage, preterm birth, macrosomia, and other undesirable birth outcomes. These stressors affect more than 525,000 lesbian, gay, bisexual, queer, and/or transgender (LGBTQ+) potential gestational parents in the UK, resulting in preventable higher risk for prenatal complications. The applicants intend to assess the impact of vulnerability as a measure of minority stress and systemic exclusion, alongside multi-level resilience factors.

Four sites, University College London Hospitals NHS Foundation Trust, Brighton and Sussex University Hospitals NHS Trust, Imperial College Healthcare NHS Trust and King's College Hospital NHS Foundation Trust, have been selected as recruitment sites, based on higher rates of LGBTQ+ residents in their catchment area. A monthly report will be run by the Principal Investigator or a supporting IT midwife at each site. This report will include active antenatal patients with a gestational age lower than 36 weeks. This list will be transferred to the Data Safe Haven at University College London, where the researcher will access the information. A selection of participants from this list will be emailed by the researchers and invited to take part in the study. LGBTQIA+ participants will be matched with cis-heterosexual parents accessing antenatal services at the same care site. Matching cases across the groups controls for potential confounders, including geographic and temporal differences that would otherwise not key to the overall analysis as individual variables. If interested, participants will follow a link in the email to a screener questionnaire that will be used to assess eligibility. If eligible, patients will be emailed with an invitation to participate in the study and sent a link to provide consent and complete the study surveys. Their participation will then proceed on a consented basis. Support is needed for the research team to receive the list of patients from the participating sites and to email eligible patients.

A recommendation for class 2, 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

Cohort	Patients aged 18-49 years who identify as lesbian, gay, bisexual, queer and/or transgender, or cisgender and heterosexual, and who are currently pregnant and receiving antenatal care at one of the 4 study sites. The applicants anticipate that 800 patients will be included.
Data sources	1. Electronic and paper records held at 4 participating sites: • University College London Hospitals NHS Foundation Trust • Brighton and Sussex University Hospitals NHS Trust • Imperial College Healthcare NHS Trust • King's College Hospital NHS Foundation Trust

Identifiers required for linkage purposes	1. Name 2. Hospital ID number 3. Date of birth 4. Date of death 5. Postcode – district level
Identifiers disclosed to the Data Safe Haven at UCL for contact purposes	1. Name 2. Email address 3. Gestational due date
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender 5. Ethnicity 6. Sexual orientation
Additional information	The scope of support only extends to the sharing of contact details with the researchers. Once consent has been given, patients will complete online surveys and an at-home journal.

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 had a clear public interest.

Scope

The CAG requested clarification on whether support was needed to allow research midwives and hospital staff to access confidential patient information in order to identify patients.

The sampling framework allowed for the potential that 40,000 patients would be contacted. In the previous deferred outcome, the CAG has suggested that a staged approach was implemented. The applicants had agreed to adopt this approach, which would reduce the number of records that would be accessed.

The CAG noted that the Chief Investigator and the student researcher had links to the USA. Members advised that confidential patient information could not be exported outside the UK, unless patients consented to this.

The CAG noted that it was not clear whether support was required for the research midwives in participating trusts to access patient records and asked that this was clarified.

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 Principle Investigators at participating sites had advised that it was not practicable for consent to be sought prior to recruitment, due to the staff time and costs that would be involved in recruiting in-clinic and via social media.

The study coordinator reaching out via email was deemed to be the most feasible recruitment method. As part of applying for CAG support, notification methods have been developed to serve the purpose of connecting with patients.

The CAG considered whether recruitment should only be by proactive means, e.g. promoting the study in relevant units and on social media, using the materials provided in the application, and inviting interested patients to contact the study team. The applicants had advised that the funding available was not sufficient to cover a recruitment drive and that recruitment targets needed to be met to avoid a funding penalty.

Members agreed that the need to meet recruitment targets and avoid financial penalties if trust research staff administer the invitations was not sufficient reason for not pursuing proactive consent. The CAG did agree that there were no practicable alternatives to the proposed method of identifying and contacting patients.

Members queried whether the applicants planned to re-think their recruitment methodology should they struggle to reach the recruitment targets. The CAG asked that the applicants provide a report on the progress of recruitment within 3 months of the Fully Supported Outcome being issued.

- Use of anonymised/pseudonymised data

The research team require access to confidential patient information to email potential participants to seek their consent to take part in the study. The applicants advised that no funding was available to cover the cost of having the direct care team contact potential participants. A potential issue over ensuring that participants care teams did not know whether the patient was taking part in the study or not was noted.

'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 will use multiple ways to inform patients of their rights to dissent from participation. This includes signposting them to how they can ensure that they are not contacted by the study team or any other research team. The study will be promoted via social media and the text of Facebook, Twitter and Instagram posts were provided. Leaflets and flyers were also provided.

Patients are able to contact the study coordinator to mark their email addresses for "no further contact" at any point (including enrolling in and then later withdrawing from

the study). Additionally, when patients are emailed the study screener questionnaire, they are auto-dissented after emailing twice with no response.

The National Data Opt-out will be applied, as well as any local opt-out of access/contact related to research. The sites will be asked to exclude any patient records that have been flagged as not wanting their data used for research.

Members noted the importance of emails not being sent to patients after a miscarriage. The CAG asked that the applicant clarify how long the gap between the researchers receiving patient email addresses and the sending of the invitation email will be.

The Group noted that a number of recruitment materials were provided and it was not clear which were intended as patient notification, and which would be given to patients after email contact had been made. Patient notification materials, which explain how patients can dissent to contact prior to receiving the email invitation, should be created and provided to the CAG.

The CAG asked that the text of the invitation emails was revised to explain how patients contact details had been obtained by the researchers. The other participating sites should also be mentioned, as well as the inclusion of an NHS header and mention of NHS involvement. Email and telephone contacts for the researchers should also be provided. The email should be reviewed by relevant PPI group.

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.

A pre-study questionnaire was circulated within parenting forums and groups. Participants were asked to give their opinion about the study, including key aspects of the methodology, such as recruitment. The results of the survey showed 100% support for the study. 74.13% agreed with the proposed approach of emailing potential participants. PPI participants favoured emails being sent twice, before the patients were marked as “no further contact.” The recruitment materials also include directions on how patients can opt-out of contact and use of their email without consent.

Exit strategy

Patients identified as eligible will be contacted in order to seek consent. Support under Regulation 5 will then no longer be required.

The applicant advised that the identifiers used to link the accounts would retained for the minimum time necessary. This will vary based on the length of pregnancy and recovery period, but would be for a maximum of 10 months.

A record of patient email addresses will be retained, alongside information on when contact was made and whether patients dissented. This record is kept so that patients are not contacted again, either during their current or future pregnancies.

The applicants noted that the email addresses of patients who were not contacted before their due date may be retained. In this instance, all information related to these patients will be deleted from the Data Safe Haven as soon as possible.

The CAG asked that the applicant clarify that the data on all patients not consented by their due date will be deleted.

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.

Request for further information

1. Clarify how long the gap will be between the researchers receiving patient email addresses and the sending out of the invitation email.

2. Clarify whether support is required for the research midwives in participating trusts to access patient records.

3. Clarify that the data on all patients not consented by their due date will be deleted.

4. Confirm that no patient information will be disclosed to the USA.

5. Patient notification materials, which explain how patients can dissent to contact prior to receiving the email invitation, need to be created and provided to the CAG.

6. The following changes to the invitation email need to be made:

    a. The text of the invitation emails needs to be revised to explain how patients contact details had been obtained by the researchers.

    b. The other participating sites should also be mentioned

    c. An NHS header needs to be included on the email and NHS involvement explained.

    d. Email and telephone contacts for the researchers also need to be provided.

    e. The email needs to be reviewed by a relevant patient and public involvement group.

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. Provide a report on the progress of recruitment within 3 months of the Fully Supported Outcome being issued.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 10 September 2021.**

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

The NHS Digital **2020/21** DSPT review for **University College London, University College London Hospitals NHS Foundation Trust, Brighton and Sussex University Hospitals NHS Trust and King's College Hospital NHS Foundation trust** are confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked date 14 October 2021).

The NHS Digital **2020/21** DSPT review for Imperial College Healthcare NHS Trust is pending.

c. 21/CAG/0151 - Randomised trial of clinical and cost effectiveness of Administration of Prehospital fascia Iliaca compartment block for emergency hip fracture care Delivery

Context

Purpose of application

This application from Swansea University set out the purpose of medical research that seeks to test the safety, clinical effectiveness and cost-effectiveness of paramedics providing Fascia Iliaca Compartment Block (FICB) as pain relief to patients with suspected hip fracture in the pre-hospital environment.

Hip fractures are a common injury for elderly people. Pain relief given before the patient reaches hospital is often inadequate and causes side effects which may slow down recovery. The applicants have conducted a small study to test whether a local anaesthetic injection into the hip area, a treatment called Fascia Iliaca Compartment Block (FICB), given by paramedics at the scene of injury is safe and acceptable. The results concluded that a full trial is feasible.

The applicants will conduct a randomised controlled trial to assess whether FICB is a safe, effective and cost-effective treatment. The research will take place at four research sites in England and Wales. Each site will be comprised of two NHS organisations; an ambulance service and a receiving hospital. Patients will be allocated to receive either FICB or a usual treatment (often morphine) at a ratio of 1:1. Patients in both arms of the trial will still receive Entonox, paracetamol and anti-sickness tablets, as needed. Patients will be initially recruited into the study under the emergency provisions of the Mental Capacity Act. An NHS researcher (paramedic or nurse) will approach the patient within ten days of their attendance by paramedics to discuss the trial. All patients will be included in anonymised follow up using routinely collected data, unless they dissent from this. Patients will be asked whether they would be willing to take part in questionnaires for the study. If so, they will complete a consent form and be sent two questionnaires - one at one month after the 999 call, and one at four months after the 999 call. Confidential patient information will be uploaded by the participating trusts to the researchers at Swansea University via REDCap. Confidential patient information will then be disclosed from the University of Swansea to NHS Digital and Digital Health and Care Wales for linkage to routine health datasets. A pseudonymised dataset will then be disclosed from NHS Digital to the SAIL Gateway. A pseudonymised dataset will be disclosed from Digital Health and Care Wales to the SAIL Databank for linkage to routine healthcare data and then to the SAIL Gateway.

Patients will be initially recruited into the study under the emergency provisions of the Mental Capacity Act. Support is sought as, while the applicants anticipate that the majority of patients will be consented, some may be discharged from hospital before consent can be obtained. Therefore, the applicants are seeking support to include these patients and to conduct the data linkages to NHS Digital and Digital Health and Care Wales.

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

Confidential patient information requested

Cohort	Patients aged 18 years and over who are treated for a suspected hip fracture in a pre-hospital setting.

	The applicants anticipate that 1404 patients will be recruited, 702 in the control arm and 702 in the intervention arm.
Data sources	2. Confidential patient information from patient records in the following trusts, health boards and ambulance services: a. East of England Ambulance Service, b. South East Coast Ambulance Service, c. South Western Ambulance Service, d. Welsh Ambulance Service NHS Trust, e. Princess Royal Hospital, University Hospitals Sussex NHS Foundation Trust, f. Royal Surrey NHS Foundation Trust, g. Ashford and St Peter's Hospitals NHS Foundation Trust, h. Royal Devon and Exeter NHS Foundation Trust i. Swansea Bay University Health Boards, j. James Paget University Hospitals NHS Foundation Trust 3. Patient-reported data: a. pain scores (taken by paramedic before randomisation and at by nurse at arrival at ED); b. One month questionnaire, c. Four month questionnaire. 4. Linked routine data provided by NHS Digital from the following datasets: a. Civil Registrations – Deaths b. Emergency Care Dataset c. HES: Civil Registration (Deaths) Bridge d. Hospital Episode Statistics Admitted Patient Care ~~e.~~ Hospital Episode Statistics Critical Care 5. Linked routine data provided by the SAIL Databank from the following datasets: a. Annual District Death Extract b. Critical Care Dataset c. Emergency Department Dataset d. Patient Episode Database for Wales e. Welsh Demographics Service

Identifiers required for linkage purposes	6. Name 7. NHS number 8. Date of birth 9. Postcode – unit level
Identifiers required for analysis purposes	7. Date of birth 8. Date of death 9. Deprivation scoring 10. Gender 11. 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 had a medical purpose and was in the public interest. However, members agreed that a practicable alternative could be implemented, which would remove the need for support under section 251. The practicable alternative is detailed below.

If this alternative cannot be implemented, there are other queries that will need to be addressed before support can be recommended.

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 it is not appropriate to seek consent from patients who are in pain or shock. Consent will be sought from patients by a trained NHS researcher

within approximately 10 working days of the patient's injury. This is most likely to occur in hospital, but will be taken in the community for patients recruited to the trial but then either discharged relatively quickly from or not admitted to hospital. The applicants had conducted a feasibility trial, RAPID 1, in which it was found that it was not possible to seek consent from a small but significant proportion of patients, especially those discharged early or not admitted to hospital.

Members noted that patients would initially receive treatment in line with standard care, including paramedics seeking consent to treatment. Although some patients recruited into the trial will be cognitively impaired, recruitment under the Mental Capacity Act will only take place should patients lack capacity to consent when approached later.

Support under s251 was sought as some patients may be discharged before they can be approached for consent. Members noted that the average length of stay following a hip fracture, or a suspected hip fracture, was seven days, and queried why patients could not be approached at day 3 or 4 of admission, rather than waiting 7-10 days.

The CAG asked that approaching patients earlier was implemented as a practicable alternative. If this was not possible, then justification would need to be provided as to why not.

- Use of anonymised/pseudonymised data

The applicants require access to confidential patient information in order to conduct the linkage to NHS Digital and the SAIL Databank and/or Digital Health and Care Wales. The CAG agreed that this could not be undertaken in any other way.

Identifiers required for analysis

The CAG noted that patients' date of birth and date of death would be retained for analysis. Members queried why these identifiers were needed and whether an alternative, such as month and year of birth or death or time from injury to death, could be used instead.

'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 noted that the participant information pack will explain how patients can dissent from use of their data. However, this applies to the patients approached for consent, who are outside the scope of support. The Patient Information and Consent Forms that would be given to the consented patients and the consultee materials needed to be provided to the CAG for review.

The applicants provided a combined Patient Privacy Notice and Notification.

The applicants were asked to provide a separate Patient Notification document and a project specific dissent mechanism. The applicants advised that they were collaborating with their PPI and communications sub-group members to create these documents. If a resubmission to the CAG was made, these documents would need to be provided. The CAG noted that the current, combined Patient Privacy Notice and Notification was very complex and read as if given to patients before any processing of confidential patient information has taken place. The CAG needed to see the documents given to patients before their data was processed, which explained how patients can dissent to use of their data.

The National Data Opt-Out would be applied. The CAG agreed that the patient notification documents would need to explain that if patients registered with the National Data Opt-Out they would be opting out of use of their data in all research.

The Patient Information and Consent Forms that would be given to the consented patients and the consultee materials needed to be provided to the CAG for review.

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.

A member of the Service Users for Primary and Emergency Care Research (SUPER) Group was active in all aspects of bid development, attended Research Development Group meetings, and had the opportunity to comment on all aspects of study design. The members was named as a co-applicant and remains a member of RAPID2’s Trial Management Group (TMG). A second PPI member joined the TMG. Both PPI members have participated in discussions on the study’s methodological approach, and support the principles outlined in this application. PPI members have helped to shape patient facing materials including information sheets and notifications.

Patient and Public Involvement (PPI) contributors will continue their roles on the quarterly Trial Management Group, and the six-monthly Trial Steering Group. The PPI members will also report back to the SUPER group (meeting quarterly), as the study is an adopted study for the group. PPI members are and will continue to be involved in the study communications sub-group which plans and reviews study communications across stakeholder groups.

The PPI members of the Trial Management Group and the qualitative analysis sub-group will be offered the opportunity to contribute to future papers and be named as authors if they do so.

The CAG agreed that it was unclear whether the issue of use of confidential patient information without consent. If a re-application to the CAG was made, patient and public involvement needed to be conducted around this issue and feedback given to the CAG.

Exit strategy

The applicants advised that confidential patient data will only be held at sites, and deleted within 1 year after data collection concludes.

All data transferred to Swansea University will be pseudonymised, with patients known only by a study ID. Only participating NHS sites will be able to link these study IDs to named individuals. These lists will be deleted as soon as possible in line with Good Clinical Practice and the GDPR.

NHS Digital and Digital Health and Care Wales will follow their standard operating procedures for retention of data.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Patients should be approached for consent within 3 or 4 days of admission to hospital, rather than 7-10 days.

2. If this approach cannot be implemented, then justification needs to be provided as to why not.

If the above practicable alternative cannot be implemented, then the following queries will also need to be addressed.

1. A project-specific dissent mechanism need to be created and the materials provided to the CAG. These materials would need to explain the National Data Opt-Out and that by registering with the National Data Opt-Out they would be opting out of use of their data in all research.

2. The Patient Information and Consent Forms that would be given to the consented patients and the consultee materials need to be provided to the CAG for review.

3. Patient and public involvement needs to be carried out around the specific issue of use of confidential patient information without consent and feedback from this activity provided to the CAG.

4. Clarify why patients' date of birth and date of death are needed and whether alternatives, such as month and year of birth or death, or time from injury to death, could be used instead.

d. 21/CAG/0152 - Cardiovascular morbidity and mortality in Liothyronine-treated patients: a linked record cohort study (T3 Safety Study)

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research that seeks to determine whether patients treated with T3 (liothyronine) have a higher risk of death than those treated with T4 (levothyroxine).

Hypothyroidism or thyroid hormone deficiency affects 1-2 million people in the UK and untreated patients suffer significant ill-health. Levothyroxine (T4) is the conventional treatment for hypothyroidism and most patients who are treated with T4 respond well to treatment and enjoy a good quality of life. However, a small proportion of patients remain unwell with T4 and therefore some practitioners treat such patients with an alternative form of treatment called T3. Although many patients who receive T3 report significant improvement in well-being, the long-term safety of the drug has not been established and current UK and international guidelines do not recommend its routine use in practice.

The applicants seek support to use data collected for patients treated with T3 in an independent medical clinic between 1996 to 2013 in order to evaluate the long-term risk of death, heart disease and strokes. This data is held by the Vaccine Research Trust. The clinic dataset contains data for over 4000 patients. This data will be compared with data for patients treated conventionally for hypothyroidism with T4 and a control group of patients without hypothyroidism. The clinic data will be linked to NHS hospital admission and mortality records via NHS Digital and the Wales Secure Anonymised Information Linkage (SAIL) Databank. Administrators of the Vaccine Research Trust will identify eligible patients through a review of electronic clinic records held by the Trust. Patients treated with T3 will be identified and their demographic clinical and treatment details will be forwarded to NHS Digital and SAIL using a split-file approach in which patient identifiable data (NHS number, gender, date of birth) is sent to NHS Digital and clinical and treatment data is sent to SAIL. A final file comprising pseudonymised linked data with a new encrypted ID for the data groups (T3, T4 and controls) will be made available to Cardiff University researchers via the SAIL portal.

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

Confidential patient information requested

Cohort	Patients aged 18 years and over who were treated with T3 for at least 3 months at an independent medical clinic between 01 January 1996 to 31 December 2013 3100 - patients treated with T3.

	3100 - patients treated with T4. 24800 – control subjects, with no thyroid disease Patients in the control group will also have received treatment between 01 January 1996 to 31 December 2013, and will be age and sex matched to the T3 and T4 cohorts.
Data sources	6. Electronic patient records held by the Vaccine Research Trust 7. HES and ONS data, held by NHS Digital 8. Patient Episode Database for Wales (PEDW), ONS, and the Primary Care GP dataset, held by SAIL
Identifiers required for linkage purposes	10. NHS Number 11. Date of birth
Identifiers required for analysis purposes	12. Gender
Additional information	The applicants advised that they would request the week of birth and week of death from SAIL. These will then be truncated to age of death once the survival calculation was completed.

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 had a strong public interest and that the data flows involved were straightforward. Members noted that NICE has recommended further research into this area and that this particularly dataset is uniquely valuable because of the low level of T3 prescribing by the NHS.

Legal basis for the holding of confidential patient information by the Vaccine Research Trust

The application had been discussed by the CAG previously and given a deferred outcome. Members agreed that the main reason for the previous deferral, which was a lack of clarity over the legal basis under which the Vaccine Research Trust continued to hold and process the data transferred from Dr Skinner's independent clinic, had not been resolved.

The CAG agreed that further details were needed on the process followed after Dr Skinner's death and the transfer of ownership of the patient records to the Vaccine Research Trust.

Members queried whether patients were transferred to the care of a different provider following Dr Skinner's death and if patient data was transferred with them. If patients' records were transferred to a new care provider, then clarification needed to be given on the legal basis for retaining copies of the patient data after Dr Skinner's practice was closed.

The CAG suggested that, should the applicant be unable to provide a legal basis for the continued holding of confidential patient information under the common law duty of confidentiality, then an application to the CAG is to be submitted seeking support for the continued holding.

The CAG asked to be provided with a copy of the letter sent to Dr Skinner's patients after his death. Members also queried whether any patients responded with queries or objections

The CAG noted that the patients treated by Dr Skinner were private patients and queried whether the care of any patients was partially funded by the NHS.

The Group requested clarification on how the records are stored, e.g. in paper or digital format, and whether records have undergone any digitisation process since Dr Skinner's death.

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 explained that it was not feasible to seek consent as the study involved a historic patient cohort, treated between 1996 and 2013. A number of patients may be deceased or lost to contact and the applicants noted that seeking consent from only those living and contactable may mean that only those in good health were included, potentially biasing the results. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is required to undertake linkage of patient data from the Vaccine Research Trust to datasets held by NHS Digital and SAIL. This cannot be undertaken in any other way.

'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 advised that the study will be publicised on the British Thyroid Foundation and Thyroid UK websites. The text of this notification was provided. This explained that identifiable patient information will be disclosed from the Vaccine Research Trust to NHS Digital and SAIL and that the research team cannot access confidential patient information in order to remove dissenting patients and directed patients to the National Data Opt-Out. The notification also included an email address for the data protection officer at the Vaccine Research Trust.

The CAG noted this information. The notification explained that records from Dr Skinner's clinic would be used. Members asked that further details on Dr Skinner's

clinic, including that it was located in Birmingham, were included, as patients may not remember the clinicians name after such an extended time period.

The CAG also noted that the opt-out information was difficult to find on the website for the Vaccine Research Trust.

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 explained that the study protocol had been reviewed by executives from the British Thyroid Foundation who had expressed support, including for the proposed method of data linkage.

During the early protocol development stage, the study was discussed with individual patients. The study was discussed with T3 and T4 users, both within and outside of the NHS in informal group discussions held during annual meetings of the British Thyroid Foundation. More formal discussions were held with executives of the BTF, who reviewed the study protocol in detail. The response from the BTF and patients was positive regarding undertaking the study and the use of confidential patient information without consent. A letter of support from the BTF executives was provided.

In the applicant's response to the deferred outcome, the applicant advised that the original discussions with patient groups were done informally and written feedback was not obtained at the time. The Vaccine Research trust have since approached a mix of former patients of Dr Skinner's clinic and sent them information on the proposed study along with a questionnaire survey which was e-mailed out in September 2020. The survey included questions on participants' opinions of the study relevance, the study data approach, the transfer of confidential patient information from the Vaccine Research Trust, and whether they would be happy for their data to be used as part of the research study. Out of 10 patients surveyed, 6 responded, with an overwhelmingly positive response. These responses were provided in "Thyroid Patients Questionnaire Response." The CAG asked that details were provided on the response from the 4 patients who were not positive, including whether they provided any comments or did not respond to the survey.

In addition, an announcement has been placed on the website of the Vaccine Research Trust to say that the data will be used for research and that confidential patient information will be transferred from the trust to NHS Digital for linkage, anonymisation, and forwarding to SAIL. This will clarify that confidential information will be transferred to NHS Digital (date of birth, gender, NHS number) and SAIL (date of death) but that

none of this confidential information will be made available to researchers since the data will be anonymised before being made available to patients.

The patient and public involvement carried out appears to be proportionate to the scale of the study.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Further details are needed to clarify the legal basis under which patient records were retained following Dr Skinner's death;

    a. Please advise whether patients were transferred to the care of a different provider following Dr Skinner's death and if patient data was transferred with them.

    b. If patients' records were transferred to a new care provider, then clarification needs to be given on the legal basis for retaining copies of the patient data after Dr Skinner's practice was closed.

    c. Provide a copy of the letter which was sent to Dr Skinner's patients after his death. Advise whether any patients responded to this letter with queries or objections and, if so, the action taken.

2. Advise whether the care of any patients was partially funded by the NHS.

3. Provide clarification on how the records are stored, e.g. in paper or digital format, and whether records have undergone any digitisation process.

4. The notification needs to contain further details about Dr Skinner's clinic, such as that it was located in Birmingham.

5. Clearer signposting to the opt-out information on the Vaccine Research Trust website.

6. Explain the responses of the other 4 people to whom the questionnaire was sent, including details on the responses received or if no reply was received.

4. Minutes of the meeting held on 16 September 2021

The minutes of the meeting held on 16 September 2021 were not reviewed as an outcome is pending.

5. Any other business

No other business was raised.

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

Signed – Chair Date

Signed – Confidentiality Advice Team Date