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

August 2020

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1.a, 2.a, 2.b, 2.c
Dr Rachel Knowles	CAG member	2.a, 2.b
Mr Andrew Melville	CAG member	2.b, 2.c
Ms Sophie Brannan	CAG member	1.a, 2.c
Prof Barry Evans	CAG member	1.a, 2.a

Also in attendance:

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

1. New Precedent Set Review Applications – Non-Research

a. 20/CAG/0093 – 2020 Urgent and Emergency Care Survey

Context

Purpose of application

This application from the Care Quality Commission set out the purpose of conducting a national survey of patients aged 16 years and over who attended a Type 1 emergency department in September 2020 or a Type 3 urgent care department in September 2020.

The NHS Patient Survey Programme (NPSP) was initiated in 2002 by the Department of Health and Social Care and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The CQC have commissioned the Survey Coordination Centre for Existing Methods (SCCEM) at Picker to manage and coordinate the survey programme under the title of the SCCEM. The 2020 Urgent and Emergency Care Survey will be the eighth carried out to date. All eligible trusts will be asked to conduct the survey with preparations expected to begin in September 2020 and fieldwork expected to start from November 2020. All trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey. An overview of the survey methodology, and a copy of the Survey Handbook and Sampling Instructions from 2018, were provided with the application.

The methodology for the 2020 survey is unchanged from the 2018 survey. Two separate questionnaires will be created; one for patients attending a Type 1 department and another for patients attending Type 3. For trusts with only Type 1 departments, the sample size will remain at 1250. Trusts who have both departments will have a sample size of 950 for Type 1 and 420 for Type 3. In administering the survey, NHS Trusts will be advised to employ the service of one of the approved contractors to reduce the cost, burden and risk in the provision of survey data. As in 2018, and across all surveys in the NPSP, NHS Trusts will submit a sampling checklist and declaration for trust Caldicott Guardians to sign, to minimise the likelihood of complete mailing details being sent to the SCCEM in error. The sampling checklist and declaration should be completed by the trust prior to sending the combined mailing and sample file to the approved contractor, and then by the approved contractor when sending the sample data only. The complete mailing data will be removed, except for the full postcode, which will be sent to the SCCEM as part of the sample file. Both the approved contractors and the SCCEM will not open a sample file until a satisfactory sample declaration form has been received. The end product from this survey will be a set of aggregate statistical data that does not contain patient identifiable information. The statistical data outputs will be provided at both national and at trust level. This statistical dataset is used for a wide variety of purposes, with the ultimate aim of supporting the improvement of patient experience in England.

A recommendation for class 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	People aged 16 and over who attended a Type 1 emergency department in September 2020 or a Type 3 urgent care department in September 2020. The applicants anticipate that 127 trusts will be involved. Trusts will be instructed to contact the SCCEM if they are unable to draw the required sample size from their Type 3 department in which case they will be instructed to also sample back to August 2020. The Sampling Instructions will ask trusts to exclude: - deceased patients - children or young persons aged under 16 years at the date of their attendance at the emergency department - any patients who are known to be current inpatients - planned attendances at outpatient clinics which are run within the Emergency Department (such as fracture clinics) - patients without a UK postal address - patients attending primarily to obtain contraception (e.g. the morning after pill), patients who suffered a miscarriage or another form of abortive pregnancy outcome whilst at the hospital, and patients with a concealed pregnancy* - any patient known to have requested their details are not used for any purpose other than their clinical care - any patients who were admitted to hospital via Medical or Surgical Admissions Units and therefore have not visited the emergency department

	- Any attendances at Walk-in Centre's - Any attendances at Type 3 departments not wholly managed by the sampling trust.
Data sources	1. Electronic patient records held at the 127 participating trusts
Identifiers required for linkage purposes	Administration of the 2020 Urgent and Emergency Care Survey requires NHS trusts to share two distinct sets of information with their approved contractor: 1. The **mailing file** is used to address questionnaires to the appropriate person. It contains: ▪ A standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of patients from each trust), e.g. UEC20XXXNNNN where XXX is the trusts 3 digit trust code and NNNN is the 4 digit serial number relating to sampled patients. ▪ Title (Mr, Mrs, Ms, etc.) ▪ First name ▪ Surname ▪ Address Fields ▪ Full Postcode
Identifiers required for analysis purposes	1. The **sample file** is used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. This file contains: ▪ The unique identifier code (as above) ▪ NHS Trust code ▪ Date and time of attendance ▪ NHS Site code ▪ Department type (Type 1 or Type 3) ▪ Ethnicity ▪ Gender ▪ Year of birth ▪ CCG code ▪ Patients full postcode ▪ Mobile phone indicator

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the proposed activity had a medical purpose and was within 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**

The applicant explained that there are three central arguments why seeking consent for this survey would not be practicable. Firstly, it would remove the benefits of the trust employing a specialist contractor as it would first require them to arrange their own mailing to patients. Second, there was a risk of introducing a systematic and damaging bias in response rates by changing the nature of the survey from an opt-out system to an opt-in system. Trusts, CQC, the Department of Health and Social Care and NHS England and Improvement, need accurate measurements in order to assess the quality and impact of their services and policies, and act upon the results to improve the experience of patients. Changing the nature of the survey would invalidate the main published statistical series arising from these surveys and impact on the reliability of the baseline used to monitor the NHS Outcomes Framework indicator for the survey. Whilst analysing the survey, unreliable data would lead people to conclude that they could not say whether a policy or initiative was working; or worse, to stop those which were working because the data were inaccurate and did not demonstrate the improvement. Thirdly, given the often extremely busy nature of hospitals and the volume of patients it could be viewed as an unrealistic burden on staff to seek prior consent for this survey. The CAG noted the information given and raised no queries.

- **Use of anonymised/pseudonymised data**

The applicants advised that the approved survey contractors required confidential patient information in order to send questionnaires to selected patients. The CAG noted the information given and raised no queries.

'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.

Trusts will be required to display dissent posters in their site locations to inform service users that they may be sent a questionnaire. Contact details for the trust will be included on the posters so service users can indicate dissent. The trust is required to keep a record of this so these service users can be removed from the eligible population of patients attending A&E or Urgent Treatment Centre in September 2020 (including August for some trusts). The dissent posters are to be displayed for the full sample period (August and September 2020) and have been made available in English and 9 other languages (most commonly spoken in England). Trusts will be informed in July 2020 to display these posters and will be made publicly available on the NHS Surveys website.

Trusts will be required to keep a record of objections and dissent. However, the method in which they do this is at the discretion of the trust. The applicants noted that the majority of trusts use a flag on the electronic records systems and have a data field specifically about whether the service user is happy for their contact details to be used for any other purpose than clinical care. Other trusts will keep a separate record which is cross referenced against the eligible population before the final sample file is drawn. This method is a long-standing approach adopted for the Urgent and Emergency Care Survey and this process has previously been successfully managed by trusts. The CAG accepted the information given.

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 the methodology used in the 2020 survey is broadly similar to that used since the NHS Patient Survey Programme was established in 2002. The first Emergency Department survey was developed in 2003. Consultations with relevant policy stakeholders and patient involvement was undertaken when designing the questionnaire. Where possible, questions are kept the same to facilitate year-on-year comparisons. However, the questionnaire content is reviewed before each survey to consider if any questions are not working and if new questions are needed to ensure the questionnaire is up to date and in line with current policy and practice. Questionnaire development work began in March 2020 to determine what changes were needed to questionnaire content, across both Type 1 and Type 3 questionnaires. The finalised questionnaire was expected to be ready in August 2020. The CAG accepted the information given.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. 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: Patient Perspective Ltd (by check of the NHS Digital DSPT tracker on 25 August 2020), Picker Institute Europe (by NHS Digital email dated 17 July 2019) and Quality Health Ltd (by NHS Digital email dated 23 July 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

2. New Precedent Set Review Applications – Research

a. 20/CAG/0094 - DAVINCI: How visual identification systems for people with cognitive impairment are used in hospital and their acceptability to patients and carers

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research that seeks to explore whether and how the use of visual symbols and other support can improve the quality of care for patients with dementia in hospital.

The number of patients in English hospitals with dementia is growing. Previous research has shown that these patients may experience poor care, such as not eating and drinking well, poor mobility and falls. Patients with dementia also struggle in these noisy and busy environments. Some hospitals use symbols such as a butterfly or flower to identify patients with dementia, so that staff are aware of their additional needs. Little is known about how these symbols are used in practice and the consequences of their use.

The applicants will conduct observations in four acute hospitals to explore how these symbols are used in practice and whether they are combined with other types of staff support. One patient with dementia from each participating hospital will be identified and followed, so that the applicants can describe how care is delivered and build a picture of how use of the symbols affects the care given by staff on a daily basis. Up to 20 patients, relatives or carers, who use support groups such as dementia cafes, will be interviewed to explore their experiences of these symbols and hospital care. Written consent will be sought from those participating in the interviews and case studies. Support under s251 is being sought for the observational aspect of the research. The applicants will undertake up to 6 days of observations in four different acute hospitals. One researcher will be working in two hospitals, and the other in the remaining two. These hospitals will be selected on their size, location and type of symbol used.

A recommendation for class 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	Patients aged 18 years and over with a diagnosis of dementia, who are inpatients at acute hospitals using different visual identification systems for people with memory problems
Data sources	1. University Hospitals Leicester NHS Trust 2. Cambridge University Hospitals NHS Foundation Trust 3. Northampton General Hospital NHS Trust 4. Surrey and Sussex Healthcare NHS Trust
Identifiers required for linkage purposes	The applicant advised that no items of confidential patient information were required for linkage purposes
Identifiers required for analysis purposes	The applicant advised that no items of confidential patient information were required for analysis purposes

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 had a medical purpose.

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 applicant advised that it was not feasible for researchers to ask all those present on the ward to consent to the observations. The researcher will be focusing on how decisions are made about which patients are given an identifier, where the identifier is placed, and how staff react to the identifier. The researcher will be spending time on the ward, for example, sitting at the nursing station and observing the layout and design of the ward, as well as following the routines of the day. No personal information will be collected from those observed and patients and staff will be notified that researchers are present. The CAG agreed with the rationale given for not seeking consent.

- **Use of anonymised/pseudonymised data**

The applicants will not record any items of confidential patient information during the observations. The CAG noted this and raised no queries.

'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 applicants provided a poster, which will be displayed in public areas. This will advise patients who do not wish to be observed to inform their care team. Staff will also be asked to check that patients are happy for the researchers to observe their care, if observations will happen in the patient's bed space. If a patient wishes to know more about the study, they can contact the research team, who will provide them with reassurance that they will not be identified in any way. As the research is focused on the general ward's routines it will not be

possible to remove participant's data without undermining the whole observation which the research team will make clear to participants at that point.

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 advised that the funder had worked closely with their core patient and public involvement group to commission the project. The project team also had their own patient and public involvement members, who had advised on the acceptability and feasibility of the protocol, and also provided comments on the information sheets and other documentation as necessary.

The applicant advised that the research team had discussed the topic of observing in hospital wards with patient and public involvement representatives at a project meeting. They were provided with copies of the posters to be displayed on wards and gave the researchers verbal feedback about their views. They were clear that the applicants would need to ensure that everyone knew of the observer's presence on the ward. As no personal identifiable data will be collected from the participants in the general observations, they were happy with this process.

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.

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 28 July 2020.**

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. See section below titled 'security assurance requirements' for further information. **(Confirmed: University Hospitals Leicester NHS Trust and Cambridge University Hospitals NHS Foundation Trust (by check of the NHS Digital DSPT tracker on 25 August 2020) have confirmed 'Standards Met' grade on DSPT 2018/19).**

Pending: assurance remains outstanding for Northampton General Hospital NHS Trust and Surrey and Sussex Healthcare NHS Trust

b. 20/CAG/0095 - Gender-specific outcomes post transcatheter aortic valve implantation

Context

Purpose of application

This application from Imperial College Healthcare NHS Trust set out the purpose of medical research that seeks to compare the mid-long-term survival of men versus women in patients with aortic stenosis treated with current versus older transcatheter aortic valve implantation (TAVI) technologies.

Severe AS is the commonest form of valvular abnormality in the developed world and accounts for more than 40% of patients with native valvular disease with an approximately equal prevalence in men and women. TAVI is now widely practiced with treatment of over 300,000 patients worldwide. Many centres now regularly implant devices in patients for whom conventional aortic valve replacement (AVR) is deemed high or intermediate risk. Several studies have shown that women have an apparent better outcome with TAVI than men. There are many potential reasons why there may be an apparent favourable benefit of TAVI in women. Newer devices had reduced the introducer French size and have been associated

with reduced rates of vascular and bleeding complications. This may lead to a higher survival benefit in women.

The applicants will investigate gender temporal survival trends and complications, such as stroke and heart attack, in patients with AS treated with current transcatheter valves versus older generation transcatheter valves. The applicants have already successfully obtained the required periprocedural data from the National Institute for Cardiovascular Outcomes Research (NICOR), which is pseudonymised. In this application, the applicants are seeking support for the disclosure of confidential patient information from NICOR to NHS Digital for linkage to ONS mortality data before returning the data to NICOR. NICOR will then link this information to the applicants' NICOR data and will then return a pseudonymised dataset to the applicants.

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	14086 patients who underwent transfemoral TAVI for the treatment of severe aortic stenosis in the UK (between 2007 and 2017) will be included.
Data sources	1. NICOR national dataset 2. ONS mortality data held by NHS Digital
Identifiers required for linkage purposes	2. NHS Number 3. Name 4. Date of birth 5. Post code

Identifiers required for analysis purposes	1. Date of birth 2. Gender

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 applicant had a medical purpose and 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**

The applicant advised that the project was a retrospective observational study. The applicants will not hold confidential patient information. The CAG agreed that it was not feasible to seek consent.

- **Use of anonymised/pseudonymised data**

The applicants had stated that they would receive a pseudonymised dataset. The CAG noted that the terms ‘anonymised’, ‘pseudonymised’ and ‘pseudoanonymised’ were used

interchangeably in the application and, as a result, the required data flows were not clear. The CAG asked that further clarification was provided on the flows of identifiable data, anonymised data and pseudonymised data.

Justification of identifiers

The CAG noted that a number of identifiers would be used to undertake the linkage but noted that it was not unusual for NHS Digital to require this where a high-level of ascertainment is needed.

'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 applicants had not described a patient notification and dissent mechanism and it appeared that they intended to rely on the patient notification and dissent mechanism operated by NICOR. NICOR have existing support under s251 for their database activities. The applicants would only have access to data that, in this context, is effectively anonymised, as the 'look up' tables are held by NICOR and the applicants will not have access to these tables. The CAG recognised the difficulty this presented in the applicant providing a dissent mechanism, as they would not have access to identifiable data in order to remove individual patients on request.

The NICOR opt-out mechanism was clearly described in the privacy notice on their website and the CAG was satisfied that it was compliant with the usual standards. The CAG requested assurance from the applicant that this application will be included on the list of studies on the NICOR website.

Patient notification also needed to be included on the Imperial College Healthcare Trust. The notification needs to include a link to the NICOR website.

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 had advised that no patient and public involvement and engagement was planned. The CAG advised that patient and public involvement and engagement needed to be carried out with a suitable patient group, such as a cardiac disease support group or charity.

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. Further clarification needs to be provided on the flows of identifiable data, anonymised data and pseudonymised data.
2. Provide assurance that this application will be included on the list of studies on the NICOR website.

3. Patient notification needs to be included on the Imperial College Healthcare Trust. The notification needs to include a link to the NICOR website. The text of this notification is to be provided to the CAG for review.

4. Patient and public involvement and engagement needed to be carried out with a suitable patient group, such as a cardiac disease support group or charity, and feedback from this provided to the CAG. This needs to include discussion of the specific issue of the processing of confidential patient information without consent.

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. See section below titled 'security assurance requirements' for further information. **(Confirmed: Imperial College Healthcare NHS Trust, Barts Health NHS Trust and NHS Digital have confirmed 'Standards Met' grade on DSPT 2018/19, by check of the NHS Digital DSPT tracker on 26 August 2020).**

c. 20/CAG/0098 - Cardiovascular morbidity and mortality in Liothyronine-treated patients: a linked record cohort 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, run by the late Dr Gordon Skinner, 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

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	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	1. Electronic patient records held by the Vaccine Research Trust 2. HES and ONS data, held by NHS Digital 3. Patient Episode Database for Wales (PEDW), ONS, and the Primary Care GP dataset, held by SAIL
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Date of death 2. Gender

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.

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

The CAG noted that the applications were seeking support for the disclosure of confidential patient information from the Vaccine Research Trust to NHS Digital and SAIL. The dataset held by the Vaccine Research Trust was originally obtained from an independent clinic, which was now closed, and over 4000 patient records transferred to the Vaccine Research Trust. The register was effectively closed and the CAG was unclear whether the patients were aware that their data had been transferred and would be retained and used in other research.

The CAG asked for further clarification on the relationship between Dr Gordon Skinner and the Vaccine Research Trust. The legal basis under which the Vaccine Research Trust continues to hold and process the dataset transferred from the records of Dr Skinner's independent clinic to the Vaccine Research Trust needs to be clarified. The CAG agreed that the decision on whether support is recommended is to be deferred until this clarification has been received.

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.

- **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.

Justification of identifiers

The CAG noted that patients date of death would be retained, although this was not made clear on the data flow diagram. Members asked whether SAIL would return the date of death to the applicants and, if so, whether this could be truncated to age at death once the survival calculation was completed.

'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 applicant advised that the study will be publicised on the British Thyroid Foundation website. The text of the website notification was provided with the application. This included details on how patients can dissent from this specific project, by contacting the Vaccine Research Trust, and directed patients to the National Data Opt-Out.

The study opt-out information will be published on the website of the British Thyroid Foundation, the Vaccine Research Trust (VRT) and Thyroid UK (TUK).

The CAG noted that the wording of the website information was unclear. It stated that "Via the Vaccine Research Trust anonymised data containing NHS number and date of birth will be transferred securely to the NHS data centre." The application required the transfer of identifiable confidential patient information from the Vaccine Research Trust to NHS Digital and SAIL, and this needed to be reflected in the website notification.

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.

The Group advised that feedback from the patients who took part in patient and public involvement would be required. This would need to contain evidence that they had considered the specific issue of the processing of confidential patient information as required in the application and were supportive.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, whilst supportive in principle of the proposal, further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. The legal basis under which the Vaccine Research Trust continues to hold and process the dataset transferred from the records of Dr Skinner's independent clinic to the Vaccine Research Trust needs to be clarified.

The following additional points would also need to be addressed in the revised application:

1. Clarify if SAIL will return the date of death to the applicants and, if so, whether this could be truncated to age at death once the survival calculation was completed.

2. The text of the patient notification to be used on the website needs to be revised to make it clear that identifiable confidential patient information will be disclosed from the Vaccine Research Trust to NHS Digital and SAIL.

3. Feedback from the patients who took part in patient and public involvement needs to be provided. This will need to contain evidence that they had considered the specific issue of the processing of confidential patient information as required in the application and were supportive.

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