Minutes of the meeting of the Confidentiality Advisory Group

09 March 2023 via Zoom

Present:

Name	Role
Dr Tony Calland, MBE	CAG Chair
Dr Patrick Coyle	CAG-Vice Chair
Dr Murat Soncul	CAG Alternate-Vice Chair
Dr Martin Andrew	CAG Member
Professor Lorna Fraser	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Ms Rose Payne	CAG Member
Professor Sara Randall	CAG Member (Left after item 4a)
Mr Dan Roulstone	CAG Member
Mr Andrew Melville	CAG Member

Also, in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Mr William Lyse	HRA Approvals Administrator
Emma Marshall	HRA Confidentiality Specialist
Caroline Watchurst	HRA Confidentiality Advisor
Dr James Medcalf	Medical director, UK Renal Registry (Item 3a only)
Retha Steenkamp	Head of Operations, UK Renal Registry (Item 3a only)
Professor Sir Louis Appleby	Director of NCISH, Professor of Psychiatry (Item 4a only)
Dr Pauline Turnbull	NCISH project director (Item 4a only)
Su-Gwan Tham	NCISH research associate (Item 4a only)
Katie Doyle	Head of Research, Northern Care Alliance NHS Foundation Trust (Observer)
Helen Moffitt-Adams	Research and Innovation Manager, Northern Care Alliance NHS Foundation Trust (Observer)
Thomas Boby	CAG Member (Observer)
Sarah Palmer - Edwards	CAG Member (Observer)

1. Introduction, apologies, and declarations of interest

Apologies from:

- Dr Malcom Booth
- Professor Sara Randall (after item 4a)

Conflicts of interest - CAG Member Professor Lorna Fraser declared that she is employed by the same organisation as item 6b) – Kings College London. However, as she does not work on the application and does not know the applicant, this was not considered a conflict of interest, and she did participate in the development of the recommendation provided by the CAG.

2. Support decisions

Secretary of State for Health & Social Care Decisions

There were no non-research applications in relation to the **02 February 2023** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **02 February 2023** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- January Sub-Committee minutes published.
- Precedent Set Minutes 10 February 2023 published.
- 19th Jan and 2nd Feb Full CAG meeting minutes published.

3. Consideration Items - Requests for National Data Opt-Out exemption.

a. 16/CAG/0153 – UK Renal Registry (UKRR) (non-research)

Scope of NDO exemption request

This is a request to defer the national data opt out for 16/CAG/0153. The UK Renal Registry (UKRR) is operated by the UK Kidney Association (UKKA) (a trading name

of the Renal Association), and the UKKA is the sole data controller of the data collected.

UKRR has been supported since 2004 with consistent submission of annual reviews since that time, and applicants refreshed their application in 2016 to supersede PIAG 1- 07(c)/2004 and take into account various amendments.

Support is in place for clinical teams to provide the audit team with confidential patient information regarding patients with Chronic kidney disease (CKD), including those receiving renal/Kidney replacement therapy (KRT), and Acute kidney injury (AKI). It receives data from renal units and laboratories in the UK.

Support is also in place to receive linked outcome data from UKHSA (previously PHE), NHS Blood & Transplant, NHS England (previously Digital) (ONS & HES), and DHCW (previously NWIS) (PEDW).

The applicants submitted this request in relation to this non-research application, 16/CAG/0153. The UKRR also has a research application (16/CAG/0064), and the applicants are clear they only wish for this exemption to be applied to the non-research application, and not to the associated research application. This outcome letter relates only to the non-research activities undertaken under CAG reference 16/CAG/0153.

Confidentiality Advisory Group advice

As part of the request, the applicant provided three core reasons why application of the NDO would impact the running of the UKRR.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to monitor individual Trust performance.

2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data

3. Technical impacts – if applied, this will add workload to direct care teams to apply the National Data Opt Out.

1. <u>Deferral rationale: patient safety</u>

The paper set out a strong argument detailing the potential impacts on patient safety. This included how data is used to monitor performance. The UKRR is responsible for monitoring performance, and identification of kidney centres and hospitals which are 'outliers' for mortality (among other markers). This process depends on the completeness of data from each kidney centre and hospital. This process will be sensitive to incomplete data, and geographical variation in the impact of the NDO

(described in section below in bias), means that hospitals in some areas will appear to perform better or less well, simply because of the extent of missing data that will arise with the application of the NDO. Some hospitals will therefore be falsely reassured of the quality of care they are providing, whereas patients and staff in other hospitals may be misidentified as a concern for the same reason.

The paper also detailed that the UKRR is responsible for monitoring and dissemination of the incidence of AKI alerts to assist in the early intervention of patients with an acute kidney injury, and for the provision of data to Getting It Right First Time (GIRFT), the Renal Services Transformation Program (RSTP), Model Hospital, and commissioning services via a quarterly data flow to NHS England to support initiatives to improve and regularly monitor indicators of quality of care.

If the NDO were applied to this dataset, patient care is at risk for those who have opted out, but also for those who have not opted out, and require kidney treatment in the future.

Members were supportive of exempting the NDO regarding the non-research KRT and AKI elements of the audit, due to the patient safety impact.

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. The data opt out figures from the UKRR show that the opt out rate across kidney centres in England is on average (~6%), which is a higher rate than the national average (5.4%). There is also significant variance in the opt-out rate when looking at individual kidney centres, with the rate being as low as 2% in some centres and as high as 9% in others. New patients in 2020 specifically have even more variation in the opt-out rate, with the peak opt-out rate at 11% in one kidney centre.

The higher rates of opt-out are focused in metropolitan centres with London centres alone reporting four of the five highest opt-out rates amongst kidney centres in England. There is also a major disparity in NDO rates between different ethnic groups, with patients of White, Asian, or Other backgrounds showing rates around the national average, while patients of a Black or Mixed background have an opt-out rate of 10.8% and 7.6% respectively. This non-random opt-out variation introduces a high risk of bias in the data, skewing the registry's reporting on key measures, particularly around ethnicity, gender and deprivation. It is known that kidney disease has disproportionate impacts on different ethnic groups, and there are also different transplant rates between men and women. It is therefore essential that the UKRR is able to collect

accurate data on these demographics, to accurately measure any disparities in the quality of care and outcomes for each group and to ensure equity of access and treatment between ethnic, gender and deprivation groups.

The applicant was queried regarding actual case ascertainment prior to the meeting and provided figures regarding a 100% ascertainment rate for the KRT audit, bar one centre that is temporarily not submitting for technical reasons (they represented about 1.6% of the KRT patient population based on 2020 data). The applicant informed CAG that the lab AKI audit has approximately 98% of labs in England will submit data across the year.

The applicant was also queried regarding actual case ascertainment during the meeting, regarding confirmation of whether the case ascertainment rates provided relate to the percentages of eligible patients actually included in the audit, not just the percentage of sites submitting data. The applicant confirmed that this the 100% case ascertainment figure did represent all patients. Therefore, Members were convinced that the NDO would cause an additional significant amount of bias, with regards to the KRT and AKI elements of the audit.

Members were supportive of exempting the NDO regarding the non-research KRT and AKI elements of the audit, due to the impact of bias (on patient safety and health inequalities), as there is 100% for KRT and 98% for AKI case ascertainment currently.

However, the Members noted that no case ascertainment rates had been provided regarding patients diagnosed with Chronic Kidney Disease (CKD) of all stages (1-5). The Members also noted that these patients are not a homogonous group, and that data collection was likely to be more difficult for this group. The applicant confirmed that currently data was being provided from 19 units, but indicated that by December 2023 this should be expanding to 52 units. This would appear that currently case ascertainment for the CKD group is around 36%. The applicant stated in the meeting that the renal services transformation programme are more interested in this group, as there is lots of scope for quality improvement in this area. For example, it is important to measure whether or not people are given access to dialysis choices, in order to try to improve access, and therefore patient outcome. The CAG were sympathetic, however they considered that with such a low case ascertainment rate currently, it is not possible to make the same arguments surrounding bias and health inequalities, as the applicants are already missing data from more than 60% of patients. The Members were therefore not convinced that the NDO would cause an additional significant amount of bias, which was enough to justify overriding patient rights to disapply the NDO regarding CKD patients. The applicant is encouraged to resubmit a supporting paper regarding this subgroup, when the case ascertainment has risen to a number that would have an impact on patient safety and health inequalities.

3. <u>Deferral rationale: technical impacts</u>

The applicants indicated that applying the NDO would generate additional workload for hospital teams, which could lead to disengagement across the audits, either through delayed entry, reduced entry or complete disengagement from data entry due to the increased burden, or fear of being in breach. This would ultimately impact the ability of the registry to deliver its remit in effectively measuring and providing high quality data.

Whilst the CAG noted the potential technical challenges articulated in the paper, it was also noted there had been a long lead-in period for implementation of the NDO. CAG understood that the NHS had been under considerable pressure during the last years due to COVID-19 and there has been necessary focus on other matters. However, Members were clear that practical difficulties around the NDO implementation would have to be very clear with evidence and not just statements of potential negative impact. Requests for deferral from the NDO from the CAG should be exceptional and based primarily on reasons other than that of system process issues. Members were therefore not persuaded that this specific reason provided sufficient reasonable justification to disapply the NDO.

Informing the patient population

In order to ensure that the relevant patient population are informed that the NDO would not be applied, the CAG agreed that it would be critical, as a general principle, for clear communication methods around the deferral to be established. The applicant confirmed that a notification and local dissent mechanism is already in place for those patients whose data is processed under Regulation 5 support, and it is expected that this will continue.

The applicant provided a draft edited privacy notice, regarding informing the population that the NDO would not be applied, and a communications plan was also provided.

Members were content in general with the communications plan provided, and the leaflet in general, however the CAG were not content with the statement regarding why the UKRR was exempted from the NDO; '*Although the National Data Opt-out programme allows NHS patients to decline the use of their data beyond their immediate care, the work of the UKRR is deemed essential and is therefore not included.*'

This statement should be improved, as it does not explain why the work is deemed 'essential' or by whom. The applicant should explain why the UKRR is exempt from the NDO, by detailing the effects on patient safety and health inequalities, after consideration by the Secretary of State for health and Social care, following advice from CAG.

In addition, despite the applicant confirming a local opt out would continue to apply, the Members noted that it appeared that there was only an option to do so via the

patients clinical team. It was also not clear to the CAG from the UKRR website, how a patient could opt out. The applicant is therefore required to include an opt out option via the UKRR centrally (via name, email address, phone number and postal address), as the UKRR hold identifiers, and would be able to opt out individuals if they wished. The applicant is required to update the patient notification accordingly, and ensure this is made clear on the website. This is especially important with regards to ensuring that patients who wish to opt out of UKRR have this wish respected, as if the opt out is controlled centrally, then it will cover all sites, whereas if the patient attended various different hospitals, it is not clear how this persons opt out would follow them from unit to unit.

In addition, it was noted during the meeting that if a patient opted out of UKRR only via direct care team, or had an NDO opt out registered, the direct care team at kidney centres and hospitals would anonymise the data and disclose only anonymised data to the UKRR. It is noted that this is common procedure with regards to audits, however the CAG would like confirmation that the data will be anonymised in accordance with ICO guidelines before being released to the UKRR, in order to avoid any breach of confidentiality. The CAG would also like this made more clear in the patient notification documents. There are some statements regarding this, but Members felt this could be communicated to patients better.

It was also not clear of the opt out process if a patient contacted the UKRR to opt out, after their data was already collected, as the CAG noted a statement regarding if their data is already included in the UKRR, then it won't be taken out. The CAG noted that in line with other audits, it could be acceptable to retain anonymised data of opted out patients, for the purposes of clinical audit, but this should be explained clearly, and the CAG felt this was not well explained on the leaflet currently.

The CAG also noted that with regards to retention and use of anonymous data only of opted out patients, that for research purposes, these patients should have their opt outs upheld, and all data removed, rather than the identifiers only. The differences between opt outs with regards to the audit, and the research registry should also be made clear on the notification. The applicant confirmed in the meeting that where people opt out, the applicants do not continue to use that data for research, only for audit purposes. This is in line with other audits.

The updated version of the patient notification should be provided to CAG for review.

Patient and Public Involvement

The applicant appears to have undertaken patient and public involvement surrounding the non-application of the NDO. Letters of support from various groups have been provided, that are supportive of the non-application of the National Data Opt-Out. The CAG were content with the patient and public involvement undertaken.

Data collection of patients on holiday

The applicant stated in the meeting that they may write to centres to ask them not to include patients who are on holiday. The applicant is to confirm if this has been undertaken.

Reduction of identifiers

The CAG noted that a condition of support from the original outcome letter was to *"provide evidence of progression towards unnecessary use of identifiers, specifically in relation to data flows involving NHS Digital, and steps to investigate the provision of study ID instead of confidential patient information."* As part of the first annual review, The UKRR reported that they had implemented steps to reduce the number of identifiers that will be used for the linkage of the UKRR and Hospital Episodes Statistics (HES)/Office for National Statistics (ONS) data, and that the first linkage took place in August 2018 with NHS number, date of birth, gender, UKRR number and postcode. The linked UKRR-HES-ONS dataset was pseudonymised, and only the unique UKRR identifier ("UKRR number") returned to the UKRR together with the HES data.

However, as part of this NDO exemption application the CAG noted that name still appeared to be being collected, and were unclear why this was required. The applicant is to consider if they require to collect name. The applicant is also requested to consider if they can reduce the number of other identifiers, especially regarding those who have died, as no further linkages will be required for these patients.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, members agreed that the patient safety rationale and bias issues were strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

Whilst a patient notification strategy and draft notification materials were provided, the CAG felt that the applicant could improve the patient notification materials, and CAG should have oversight of these within one month.

Given that the applicants provided a notification strategy and draft documentation, CAG therefore recommended, in this specific instance, to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

This is only in relation to Acute Kidney Injury (AKI) and kidney replacement therapy (KRT). The request to defer applying the National Data Opt-Out in relation to Chronic Kidney Disease (CKD), is currently not supported, and a further application will be required if case ascertainment increases, and if a patient safety argument can be evidenced.

Specific conditions of support

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to Acute Kidney Injury (AKI) and kidney replacement therapy (KRT) patients included in the activities specified in 16/CAG/0153.

2. The National Data Opt-Out is to be applied to Chronic Kidney Disease (CKD) patients included in the activities specified in 16/CAG/0153, and the applicant is to resubmit a further paper regarding these patients, if required.

3. The National Data Opt-Out is to be applied to the research activities specified in 16/CAG/0064, the associated UK Renal Registry Research Database.

4. A local patient objection mechanism must continue to be used in relation to 16/CAG/0153.

5. Please provide updated patient notification documents within one month from the date of this letter, including;

    a. An updated statement detailing why the UKRR is exempted from the NDO,
    b. Updated opt out options (via the UKRR centrally, including website details),
    c. Further explanation regarding the use of anonymised data if a patient opts out, both prior to being included into UKRR, and after their data is already included.
    d. The use of anonymised data of opted out patients should not be used for research purposes, and this should be explained on the patient notification.

6. With regards to patients that registered an NDO, or a UKRR specific opt out, please provide confirmation, within one month from the date of this letter, that the data will be anonymised by the direct care team in accordance with ICO guidelines before being released to the UKRR. This would not require ‘s251’ support.

7. Please confirm if you are writing to centres to ask them not to include patients who are on holiday, within one month from the date of this letter.

8. Please consider if name is still required to be collected, and if so, please provide justification. Please also consider if you can reduce the number of other identifiers collected, especially with regards to deleting all data of deceased patients, within one month from the date of this letter.

4. New Application

a. 23/CAG/0024 - National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) - non research only

Context

Purpose of application

The National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) has existing support to collect confidential patient information for the NCISH core database on patients who died by suicide when under the recent care, or recently discharged from, specialist mental health services.

NCISH has collected in-depth information on all patient suicide deaths in the UK since 1996. The overall aim of the project is to improve patient safety in mental health settings and to reduce patient suicide rates. Recommendations from NCISH have been cited in national policies, clinical guidance, and regulation in all UK nations, and been used to support service and training improvements. The data collected is used to examine the circumstances leading up to and surrounding the deaths by suicide of patients under the care of, or recently discharged, from specialist mental health services. Factors in the management and care of patients which may be related to suicide are also identified. The applicants also report on the incidence of homicide by patients who have been in contact with mental health services.

There is a three-stage process to collecting suicide data. Firstly, the Office for National Statistics provides data for all deaths by suicide or undetermined intent registered in England and Wales. Through administrative contacts at relevant healthcare organisations, the contacts the individual patients had with mental health services in the 12 months prior to the incident, are collected. If it is determined that a patient had contact, NCISH then sent a questionnaire to the consultant psychiatrist or other senior professional who had cared for the patient, to obtain detailed clinical data. NCISH obtain information on all homicide convictions from the Home Office Homicide Index (England and Wales). The addresses and alias names and dates of birth for homicide

perpetrators in England and Wales is obtained from Greater Manchester Police (GMP). The applicants then identify any perpetrators who have had contact with mental health services in the 12 months prior to the incident through administrative contacts at healthcare organisations.

The pseudonymisation key is held on NCISH computers which can only be accessed in whilst in NCISH offices.

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

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 meeting all of the below criteria will be included in the programme: <u>Suicide data</u> • Death by intentional self-harm or death of undetermined intent where one of the following ICD-10 codes has been allocated to the individual: suicide (ICD-10 codes X60-X84) or undetermined conclusion (ICD-10 codes Y10-Y34 (excluding Y33.9), Y87 and Y87.2). • Had contact with mental health services (psychiatric, drug and alcohol, child and adolescent or learning disability services if they are within mental health services) in the 12 months prior to their death. Patients who were seen for a one-off assessment in a liaison setting with no follow-up arranged would not meet NCISH criteria for a patient suicide. <u>Homicide data</u> • Received a homicide conviction for murder, manslaughter (culpable homicide in Scotland), infanticide, or verdict of not guilty by insanity and unfit to plead. • Had contact with mental health services (psychiatric, drug and alcohol, child and

	adolescent or learning disability services if they are within mental health services) in the 12 months prior to the incident.
Data sources	1. Vital Statistics mortality data, Office for National Statistics 2. Patient information held at NHS trusts 3. Homicide Index, Home Office (England & Wales) 4. Police National Computer, PNC Information Access Panel
Identifiers required for linkage purposes	Suicide and homicide work programmes 1. Surname 2. First name 3. Address, including postcode / place of death (if different to address of residence) 4. Date of birth 5. Sex Suicide work programme only 1. NHS number 2. Date of death 3. Cause of death
Identifiers held in NCISH	Suicide and homicide work programmes 1. Surname 2. First name 3. Address, including postcode / place of death (if different to address of residence) 4. Date of birth 5. Sex Suicide work programme only 1. NHS number 2. Date of death 3. Cause of death
Identifiers required for analysis purposes	Anonymised information only will be used for analysis

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 application had a strong public interest.

Scope

The CAG noted that data from all four UK nations will be collected in one database. Members asked for further details on how patients treated in more than one nation are handled, e.g. patients who live in Scotland but receive treatment in England, and vice versa. This included whether support was needed for any disclosures of confidential patient information generated in England and Wales to Scotland for the purpose of patient identification or data linkage.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The CAG queried whether all the identifiers listed in the application are needed to identify patients or whether NHS number only could be used. The applicants advised that it was sometimes difficult to identify patients by NHS number alone. Many of the most vulnerable patients may not have an NHS number. The CAG asked that further justification was provided on why each item of confidential patient information was required.

Members queried whether confidential patient information was required for victims of homicide. The applicants explained that information on victims was required to report on the number of victims as previous reports were criticised for reporting on the number of perpetrators only and not the victims. Also, homicide victims were likely to have mental health issues. The applicants agreed to investigate how quickly confidential patient information for homicide victims could be deleted after collection.

- **Feasibility of consent**

It is not possible to seek consent from patients in the suicide work programme, as all eligible patients will be deceased.

It is not practicable to obtain consent from perpetrators convicted of homicide due to the large cohort and the time and resources required.

The CAG considered whether consent should be sought from the perpetrators of homicide. Members agreed that consent was not feasible, not due to the numbers

involved, but due to the public interest in the collection of the data and that the homicide perpetrators were unlikely to respond to requests for consent.

- **Use of anonymised/pseudonymised data**

NCISH required access to confidential patient information to contact with the administrative staff and treating clinicians to verify that contact had been made with their services and to request detailed clinical information via the questionnaire. This was not possible in any other way.

The applicants noted that NCISH continued to review whether the project could be undertaken without confidential patient 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.

No participants will be directly approached about inclusion in NCISH. NCISH has a website, which contains information about the programme and the National Data Opt-Out. The applicants also use the NCISH twitter account to promote the programme.

The applicants provided a Privacy Notice. The applicants noted that they are currently undertaking review of the privacy notice to remove references to 'research', and instead will note e.g., 'the NCISH programme'.

The Privacy Notice contained text which suggested that patients needed to give a reason for opting-out. The CAG noted that this wording was potentially confusing but agreed that a project-specific opt-out did not need to be offered. This decision was made to the nature of this application specifically and that the patients in the suicide work programme will be deceased. This decision does not set a precedent for future applications.

The National Data Opt-Out does not apply to data collected by NCISH.

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 have worked with service users, their families, friends and carers when designing and developing NCISH studies.

A dedicated patient and public involvement group, the Mutual Support for Mental Health Research (MS4MH-R) PPI group, has been set up. They are regularly consulted for their advice and feedback on specific aspects of the programme, including methodology, data collection, and recruitment plans, reviewing, and contributing to programme, pro forma and survey design, and commenting on interpretation of findings, and overall tone.

Topic-specific steering groups have also been created. Each group is comprised of 10-12 members and includes people who work with the group of interest, academics in the field, and experts by experience (including from the dedicated PPI Group). These focussed groups provide advice on aspects of programme design, interpretation of key messages, including the language and tone of draft reports, and dissemination. The applicants provided a document, outlining their patient and public involvement approach.

The CAG agreed that the patient and public involvement carried out was good. However, more detail on the demographics of those involved and the outcome of discussions was requested.

Exit strategy

The NCISH keeps personal data in a form which the data subject can be identified only for as long as it is required for the purposes for which it was collected. Questionnaire items are not stored with patient identifiers. The programme must keep data for 6 years following the termination of contract with the programme's commissioners (HQIP).

The CAG noted that confidential patient information on individual patients was retained for 6 years. All patients in the suicide work programme would be deceased, therefore no new data linkages can be undertaken. Members requested that further justification on why confidential patient information needed to be retained for 6 years was provided.

Ongoing ‘s251’ support is required for NCISH overall, however support is provided for 5 years in the first instance, in line with other applications of this type that require ongoing support.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The support in place under PIAG 4-08(d)/2003 will be expired and replaced by this application.

2. Support is provided for five years, at which time point a duration amendment is required.

3. Provide further details on how patients treated in more than one nation are handled, including whether support is needed for any disclosures of confidential patient information generated in England and Wales to Scotland for the purpose of patient identification or data linkage.

4. Provide further justification was provided on why each item of confidential patient information is required for linkage.

5. Provide further justification on why confidential patient information needed to be retained for 6 years was provided.

6. Investigate how quickly confidential patient information for homicide victims can be deleted after collection.

7. The Privacy Notice needs to be revised to remove mention of a project-specific opt-out. The explanation that that National Data Opt-Out will not be applied needs to remain.

8. Provide more details on the demographics of those consulted during patient and public involvement and the responses received to questions around the use of confidential patient information without consent.

9. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

The NHS England **2021/22** DSPT review for **National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH), University of Manchester** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 March 2023).

5. Consideration Item – Amendment

a. 22/CAG/0051 - Our Future Health

Amendment request

This application from Our Future Health Ltd aims to create a research tissue bank for use in research into early detection of disease. The aim is to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early, with the hope that this will lead to better patient outcomes. The applicants have Regulation 5 support to allow the disclosure of confidential patient information from NHS England (previously NHS Digital) to APS Group, the contracted mailing supplier, to facilitate the sending of invitation letters to selected patients. This is through the NHS DigiTrials service. The initial CAG support provided support for approximately 3 million patients to be contacted. A recently supported amendment allowed for approximately 12 million patients to be contacted.

This amendment sought support to increase the number of people invited through NHS DigiTrials routes to approximately 45 million people. This is the result of increased capacity of both clinic availability, and invitation mailouts, which means the applicants can invite individuals at a higher rate, and greater scale to support achieving recruitment targets.

Our Future Health aim to recruit up to 5 million adults from across the UK to create a cohort of people who have consented to participate in the research. The applicant has confirmed that this is not changing. However, the proportion of people consented through the DigiTrials route is increasing from 150,000 to potentially over 2 million. Based on current conversion rates, inviting 45 million people will lead to recruitment of approximately 1 million people. However, as awareness of the activity increases, and further work is undertaken in this area, the applicants expect the recruitment rate to increase and lead to a higher number of people consenting.

Confidentiality Advisory Group advice

The amendment requested was considered at the Full CAG meeting on 09 March 2023.

With regards to the original application, the CAG were supportive in principle of this research application, and there remained a public interest in the research. However, significant concerns were raised by CAG regarding the rapid increase on reliance of regulation 5 support, from 3 million approximately 1 year ago, to 12 million in December 2022 and 45 million in this amendment. It was noted by Members that there was always an intention to increase the number of invites sent from the initial 3 million, and the scientific justification for consenting 5 million people is already accepted, as this is not increasing. However, Members are aware that the scale of breach proposed would be precedent setting and needs careful consideration.

CAG has a responsibility to justify that there is sufficient public interest in any recommendation of Regulation 5 support, which has to balance the benefits in undertaking the activity against the breach of confidence, including its scale. This needs to be further evidenced prior to providing support for this amendment.

To support this consideration, CAG requested some examples of tangible benefits of the end results of Our Future Health. These can be both short term benefits, and longer-term examples of the aims of the application and why it may be of benefit to the UK population.

Practicable alternatives

The CAG were aware that other methods of recruitment were described in the original application, which are outside of CAG remit. The initial CAG application planned for only 150,000 individuals out of 5 million to be consented via the DigitTrials recruitment method. This amendment appeared to increase the number consented via this method to around 2 million. It was therefore not clear from the amendment request if these alternative methods are still being utilised to their maximum potential, and if they remain a practicable alternative to Regulation 5 support. Whilst the amendment submission referred to the increased capacity in consent clinics available, it did not sufficiently justify why this capacity could not be met through the alternative methods. As such, CAG requested an appraisal of all recruitment routes being used, in order to evidence if these alternative methods could represent a practicable alternative to the requested amendment to Regulation 5 support, as Regulation 5 support is a method of last resort when there are no other alternative routes available.

Given that the requested increase is essentially to all adults in England, it was unclear to Members as to why the electoral roll could not be used to send invites as a practicable alternative. This would allow invitation letters to be sent to addresses only with no

associated name and without using medical records, therefore avoiding a breach in confidence. It was commented that if a breach of confidence of this size had been articulated as a possibility in the initial application, that CAG may have suggested this as a practicable alternative at this time point, to avoid an application at all. A future amendment request should clarify why the electoral roll is not a practicable alternative.

Patient and Public Involvement

The CAG commended the excellent work done on public engagement so far, and recognised the enthusiasm of the public involved, as explained in the documentation. The CAG also commented on the patient and public involvement undertaken in targeting "difficult to reach" groups and the importance of having these groups included. It was also helpful to the members to see some of the negative responses that had been provided as part of the feedback regarding complaints.

It appears that the patient and public involvement has been continuous, including those who had consented to Our Future Health in order to gain feedback around the consenting process. However it appeared from the information provided to CAG that no further patient and public involvement had been undertaken since 2021 surrounding specifically the sharing of confidential patient information without consent, in order to send out invitation letters, and it did not appear that any patient and public involvement had been undertaken specifically surrounding the increasing of invitations via NHS DigiTrials to 45 million people. The applicant is asked to further explain what patient and public involvement activities have been undertaken recently surrounding the specific breach, and the increase from 12 to 45 million invites being sent. The applicant is advised to include detail on sceptics, and varied demographic characteristics. If none has been undertaken on these specific points, the applicant is advised to undertake further patient and public involvement prior to the resubmission of this amendment.

Feedback and improvements

The CAG noted that some of the complaints and comments provided were surrounding letters being sent to individuals who were deceased, and also to a few individuals who had moved abroad. Whilst the proportion of complaints was low compared to the number of invites sent, it was noted that these will increase when numbers of invites increase. Whilst the detail of complaints was provided, there was little information on how the complaints are monitored for trends, and what actions are taken to minimise this. Given that Our Future Health are not responsible for identifying and sending the invites it was understood that this work would need to be in partnership with DigiTrials, but Members requested further information on how complaints are monitored and actions undertaken to prevent recurrence, with examples.

Patient notification and media campaigns

The CAG commended the Our Future Health website, and its ease of use and interoperability. The notification documentation was also commendable, as was the agreed plan regarding media coverage in specified areas prior to sending letters out. However, CAG were unclear on the efficacy of these campaigns. CAG need to be assured that the population has an awareness and is able to register an objection prior to invites being sent. The applicant is therefore requested to provide any evidence they have of how the media campaigns are working, and if they have been filtering into communities. The CAG requested a detailed example of a previous area, explaining what patient notification has been undertaken, and to consider whether this is sufficient moving forwards, and to re-appraise whether any additional notification is necessary.

Detailed plans for future increase

Whilst CAG understands that momentum is important, the timescale and scope of recruitment requested in the amendment are substantial. More detailed plans of the roll-out and confirmation of continued patient awareness about the project should be evidenced for a future submission.

The applicant is to provide a coherent plan for the roll-out, which provides detail of certain numbers of patients in certain areas, at certain timescales. It is noted that a plan has already been provided, but this detailed only the number of invites per month rather than targeted information regarding number of invites in each area. This should include an example of the detailed process of opening clinics in an example area, to align with the specific media notifications, prior to sending out the invitations.

The amendment has requested a very substantial increase in the confidential patient data made available to APC mailing via Digitrials. The CAG is required to justify that the public interest continues to be of such magnitude that it meets the increasing requirement for the data use. Therefore, it is suggested as part of the resubmitted amendment, that CAG will require a report at three monthly intervals to show the justification of any further increase of data requirement, balanced against the increase in consents obtained towards the stated target. In this way the CAG can be reassured that continuing support for this data use is in the public interest. Information about public attitudes to the project will also be required as stated elsewhere in this letter. CAG will then have information to support the further consideration of future amendments, should more confidential data be required to enable an appropriate number of consented individuals to be achieved.

Future amendments

The CAG is not prepared to advise support for any amendment request that extends support immediately to 45 million. Given the precedent setting nature of this request, certain checks and balances need to be in place to assure CAG that it remains in the public interest.

As such, any further amendment to be considered by CAG, following the actions detailed in this letter, should be for an interim number of invites for a further three months. With each amendment request, the applicant should consider the necessity of the increase using similar considerations as above.

However, CAG are acutely aware that the activity is ongoing, and the actions above may not be in place prior to reaching the current 12 million capacity, and that this may cause significant operational issues to Our Future Health. Given this, CAG would support an initial interim amendment for an increase of an additional 4 million patients without having to respond to the queries raised in this letter. Based on the applicant's timescale this would cover activities until June 2023, which should provide time for a further amendment to further increase in the number of invites. It is this further resubmitted amendment that will be considered at a Full CAG meeting, and should contain responses to the concerns raised in this letter.

Confidentiality Advisory Group 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 amendment was deferred.

Further information required

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

1. 1. Please provide examples of tangible benefits of the end results of Our Future Health.

2. Please fully justify why other recruitment methods that do not require Regulation 5 support, are not practicable alternatives to the DigiTrials recruitment method.

3. Please explain why using the electoral roll was not thought to be a practicable alternative to Regulation 5 support for both the initial application, and also regarding this amendment request.

4. Please clarify what patient and public involvement has been undertaken recently specifically surrounding the sharing of confidential patient information without consent, in order to send out invitation letters, and the increase from 12 to 45 million invites being sent. If none has been undertaken recently, please undertake some before resubmitting.

5. Please provide an explanation of what has been done, or what is planned, in response to previous and future complaints and feedback, in order to assure CAG of the process for reviewing feedback, complaints and making improvements.

6. Please provide evidence regarding the effectiveness of the media campaigns at filtering into communities, and provide an indication of how many people are viewing these notifications.

7. Please provide a detailed example of a previous area, explaining what patient notification has been undertaken, and to consider whether this is sufficient moving forwards, and to re-appraise whether any additional notification is necessary.

8. Please provide a coherent plan for the roll-out, which provides detail of certain numbers of patients in certain areas, at certain timescales. This should include an example of the detailed process of opening clinics in an example area, to align with the specific media notifications, prior to sending out the invitations, to provide a detailed example for Members.

9. Any future amendment should be for approximately three months' worth of invitations, or a similar rolled back request, in order to be able to provide updates after that time regarding the consent rate, the success of other recruitment routes, and attitudes of patients and the public.

Once a new amendment is received, the information will be reviewed at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the amendment onto the next available meeting.

6. New Applications - Continued

a. 23/CAG/0029– A urine test for cervical screening.

Context

Purpose of application

This application from the London School of Hygiene & Tropical Medicine set out the purpose of medical research that seeks to measure patient response rates, HPV prevalence and histological outcomes among older women to estimate the likely impact on cervical cancer incidence and mortality of introducing a nationwide catch-up screening programme.

The NHS Cervical Screening Programme (CSP) prevents an estimated 5000 deaths per year by offering regular cytology screening. HPV screening has replaced cytology in many countries, including in the UK. Currently, screening in the UK is stopped at 65 years of age, which is unchanged since the introduction of the screening programme in 1988. Australia offer HPV screening up until the age of 74 and Denmark offer screening to all women born before 1948. Most cervical cancers in young women are diagnosed at stage 1 but the proportion diagnosed at stage 2 or worse increases with time since last screening test, and the ratio of mortality to incidence increases after age 65 when cytology screening stops. The justification for ceasing screening at 65 is that it is unlikely that women aged over 64 years who have been regularly screened will go on to develop the disease. However, around 1 in 1200 women who were regularly screened after 50 years of age and 1 in 230 women who were unscreened after age 50 to develop cervical cancer after the age of 65. Around half the relevant population were either unscreened or inadequately screened after age 50. The applicants seek to offer a catch-up HPV test, via a urine test that patients can do at home and use the results to measure response rates, HPV prevalence and histological outcomes to estimate the likely impact on cervical cancer incidence and mortality of nationwide introduction.

Support is sought to enable researchers, who are not part of the direct care team, to access patient records at participating GP practices in order to identify and make contact with eligible patients. Support is also required to allow the extraction of confidential patient information from GP practices and transferred to NHS England for linkage to cervical screening record, current status, and registrations of cancer and death. Patients NHS number and date of birth will be removed before the linked dataset is transferred to the London School of Hygiene & Tropical Medicine. GP practice data and the linked dataset will be linked via the study ID.

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

Confidential patient information requested

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

Cohort	Women aged 60 – 79 years of age who ceased from the NHS CSP without an exit primary HPV test. 18000 women will be included.
Data sources	1. Patient records at participating GP practices 2. NHS England DARS for current patient status, cancer registration and mortality from national registers and the NHS Cervical Screening Programme (Open Exeter).
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG asked that the names of the GP practices involved were provided.

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 was not feasible to seek consent for the collection of demographic data from GP practices, or cervical cancer screening records and follow-up data from NHS England. Data for patients who took up the offer and patients who did not respond is required to undertake valid statistical analysis. The applicants advised that patients who did not respond to a request for consent are likely to engage less with the screening programme. The applicants also seek to demonstrate whether the catch-up screening reaches under-screened women.

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

- **Use of anonymised/pseudonymised data**

Research staff will need to access confidential patient information at participating sites in order to identify and contact eligible patients. Confidential patient information will be transferred to NHS England for linkage to datasets they hold, so that current patient status, cancer registration and mortality from national registers and the NHS Cervical Screening Programme (Open Exeter).

The applicants require access to confidential patient information to identify eligible patients and make contact to seek consent.

The CAG was content that consent could not be sought prior to processing confidential patient information for the purpose of contacting suitable patients.

'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 poster and Patient Information Booklet advise that patients can dissent to the inclusion of their data. Patients who have dissented before invitation will not be contacted or invited to participate in the screening initiative. Data from those dissenting (at any point) will not be included.

The National Data Opt-Out will be applied.

Patients who expressly dissent before invitation will not be written toand their data will not be collected. This includes those who are Type 1 and Type 2 Opt-outs and those who expressly dissent in response to local media or posters displayed in their

GP practice. Patients who expressly dissent to the use of their data after receiving their invitation will also not be included.

The poster, pre-invitation letter and information booklet advise that patients can dissent to use of their data by contacting the study team but is not explicit that patient data will still be processed if they do not inform the researchers that they wish to dissent. Also, patients are asked to contact the study team to opt-out, meaning that confidential patient information will need to be disclosed to the researchers before any dissenting patients can be removed.

The CAG published specific guidance, managing-non-response-guidance-v1-2_Aplc9nj.pdf

after discussion with the ICO, on their position regarding patients who are approached to consent, who then do not reply. The position from CAG is that if a patient is specifically approached to consent, and they do not respond to that approach, then non-response to consent must be accepted as dissent. The CAG asked that the materials sent to patients were revised, with input from patient and public involvement, to make it clear that patients confidential patient information will be processed unless they specifically dissent.

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 GP practice nurse invited a group of six women aged over 60 to form a PPI group to review the draft invitation letters, information leaflet and patient information booklet. The project manager explained to the PPI group why it was necessary to collect patient information without explicit consent on cancer registration, mortality, and past screening history. The PPI group were presented with different scenarios and asked to say which were acceptable.

All six women found it acceptable for researchers to have access to the cervical screening records, national records concerning cancer diagnoses or death, full date of birth and postcode. Two women also found it acceptable for researchers to have access to NHS number, name, full address, and telephone number without consent.

Everyone invited to participate in the study will receive the information booklet which describes the data that will be collected without explicit consent.

The CAG highlighted the value of work done by those within the patient and public involvement group. However, members agreed that 6 people was not proportionate to the size of the intended 18,000-person cohort. The CAG queried whether the research team planned to undertake further patient and public involvement with a larger group.

Lastly, the Committee encouraged the continuation of the patient and public involvement group and urged further contribution on the upcoming changes to notification, specifically around opt-out and non-responders.

Exit strategy

The exit strategy for patients who agree to take part in screening is consent. NHS England will need access to confidential patient information to access link GP patient records to cancer screening, cancer registration and mortality data. The patient NHS numbers and dates of birth will be deleted from the dataset prior to transfer to the London School of Hygiene & Tropical Medicine.

The CAG was content with the exit strategy proposed.

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. Provide the names of the GP practices participating in the study.
2. The patient notification materials need to be updated to state that patients confidential patient information will be processed without consent unless a patient specifically objects
3. Clarify if further patient and public involvement, with a larger group, is planned.

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. **Favourable issued 16 January 2023**
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:

The NHS Digital **21/22** DSPT reviews for **London School of Hygiene & Tropical Medicine** and **NHS England** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 14 March 2023)

Due to the number of participating GP sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

b. 23/CAG/0030– Sentinel Stroke National Audit Programme (SSNAP) – Research (reviewed alongside 23/CAG/0031)

Context

Purpose of application

This application from King’s College London (on behalf of Healthcare Quality Improvement Partnership (HQIP), NHS England & the Welsh government) set out the purpose of medical research, of creating a research database collecting data on all patients with a new episode of stroke or TIA (transient ischaemic attack), or those suspected of having a stroke, admitted to hospital in England and Wales.

Healthcare Quality Improvement Partnership (HQIP) and NHS England are joint data controllers for English data for this research application, and HQIP and the Welsh government are joint data controllers for Welsh data for this research application. The database is managed by King’s College London, who have been commissioned by HQIP, and Net Solving Ltd & Rackspace host the dataset. These are considered data processors for this application.

Sentinel Stroke National Audit Programme (SSNAP) currently has ‘s251’ support under non-research application reference ECC 6-02 (FT3)/2012, and prior to that, under ECC 5-06 (g)/2010 (Stroke Improvement National Audit Programme – SINAP). This research application (23/CAG/0030) has been submitted alongside a non-research application (23/CAG/0031), in order to split out the research and non-research functions of SSNAP into separate CAG applications, and to refresh the support required, as requested by conditions 3 & 4 of support regarding the recent non-research National Data Opt Out Exemption application. ECC 6-02 (FT3)/2012, will be expired and replaced with 23/CAG/0030 and 23/CAG/0031. The National

Data Opt Out exemption will continue for the new non-research application only (23/CAG/0031), and does not apply to this research database application (23/CAG/0030).

The aim of the research database is to support high quality research into the provision of stroke care and current standards of clinical practice, the impact of the organisation of stroke services on care provision, the impact of specific stroke interventions on outcomes, the development and impact of new technologies, and other areas of research into stroke. Data collection started in 2012 and is ongoing under ECC 6-02 (FT3)/2012. Data is

collected from English Trusts (including ambulance services) and Welsh Health Boards, via a secure web based application. Confidential patient information is collected to allow identification of multiple admissions for the same individual, and also to enable linkage between Hospital Episode Statistics and Civil registrations – mortality data from NHS England, and with Patient Episode Database for Wales (PEDW) from DHCW. Data is collected from onset of symptoms up to 6 months post-discharge from hospital.

Identifiable patient data collected as part of SSNAP dataset is stored at King's College London on a platform hosted by Net Solving Ltd/Rackspace. When a new patient record is created on SSNAP which contains patient identifiable information, this record is pseudonymised to all users except the teams/services where the patient is being treated. The other exceptions are the global administrator of the web tool and authorised personnel at King's College London will have access to confidential patient information, which will be viewed and processed only for the purposes described in the application. Patients are consented if possible at their 6 month follow up. The applicant has confirmed that currently this is 35% of patients. There are challenges surrounding the 6 month follow ups being undertaken at all, and therefore it is not practicable for consent to be undertaken in cases where there is no follow up.

The REC favourable opinion will allow research to be carried out by the SSNAP Research Team or by sharing de-identified data with other researchers. Data may also be shared for the purposes of research if the recipient has their own project specific-research ethics approval in place and an appropriate legal basis for data sharing. Requests are reviewed by the SSNAP team and will be subject to approval by the HQIP Data Access Review Group (DARG). An HQIP data access form has been provided, as have terms of reference for SSNAP Scientific Advisory Group. Applicants have also planned to create a small Scientific Committee to advise on data use applications to SSNAP, and to report to the ICSWP and to SSNAP's commissioners, HQIP, on data uses and research-related issues. This committee will have representation from the public, patients and carers. Only anonymous data is released to external third parties, or pseudonymous data which cannot be re-identified by the third party.

A recommendation for class 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients with a new episode of stroke or TIA or those suspected of having a stroke, admitted to hospital in England and Wales. The minimum age requirement is 16. Approximately 85,000 people per year
Data sources	1. English Trusts including Ambulance Trusts – clinical records 2. Welsh Health boards – clinical records 3. NHS England (previously NHS Digital); · Hospital Episode Statistics (HES) · Civil Registration – Deaths 4.DHCW; · Patient Episode Database for Wales (PEDW)
Identifiers required for linkage purposes (and therefore required to be retained in the SSNAP database)	1. Name 2. NHS number 3. Hospital number 4. date of birth, 5. Date of death 6. postcode 7. gender 8. ethnicity 9. Computer Aided Despatch number (CAD) 10. postcode of ambulance pickup
Identifiers required for analysis Purposes	1. Full date of death required for SSNAP internal analysis, however this is modified for disclosure to external researchers. 2. Gender 3. ethnicity All external disclosures are therefore effectively anonymous to the recipients.
Additional information	linkage undertaken quarterly with NHS E (prev D), & DHCW. All individuals in SSNAP are requested for each data request.

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 were agreed there was a public interest in this activity, however unlike the audit application, this is a provisional outcome, as the CAG felt there was further work to be done before recommending support for the research application.

Practicable alternatives

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

· Minimising flows of identifiable information

The CAG noted that the applicant collected name. the CAG were unclear why name was required for linkage, if the NHS number and other details were available. The applicant is to justify why name is required for linkage, and therefore why name is required to be collected at all.

The Committee also noted that it appears that each time linkage is undertaken with outcome data, which is undertaken quarterly, the entire SSNAP cohort appears to be being sent to NSH England. The CAG were unclear why this was necessary, and requested the applicant to confirm if SSNAP patients could be flagged at NHS England/DHCW, to avoid having to re-send the entire cohort each quarter. In this way, the applicant should be able to send only new patients from the last quarter, and still receive linked outcome data for the entire SSNAP cohort.

· Feasibility of consent

The applicant states that consent will not be sought for use of data in research, for the following reasons;

· Many patients cannot communicate after stroke either because of reduced level of consciousness, specific language or cognitive difficulties or because they die in the hours or days following a stroke meaning informed consent is not possible.

· It is necessary for full representation and complete coverage which is required in order to produce valid and comprehensive conclusions on care quality and outcomes. If informed consent were required as a prerequisite to be able to collect and analyse this data, the experience of many patients, particularly the most vulnerable, would be excluded.

· The cohort size makes it unrealistic to gain consent for every patient. There are more than 85,000 cases per year for analysis, over 40% of whom will have communication difficulties.

Consent will still be sought at the 6 month follow up clinical appointment, in cases where this is undertaken. This is currently 35% of patients in SSNAP. It is not practicable for consent to be sought by clinicians at 6 months in cases where no 6 month follow up is undertaken clinically. The applicant has provided a pre 6-month consent form for occasions where it is possible for the direct care team to consent earlier.

The Members agreed that consent was not a practicable alternative regarding the initial data collection. However CAG agreed to retain the condition regarding consenting at the 6 month follow up visit where possible, and this extends to any contact the direct care team may have with the patient. The applicant is encouraged to consent patients earlier during admission wherever it is possible to do so.

The Members also requested absolute clarity on the proportion of patients consented currently, as the applicant has implied that 35% of patients have a 6 month follow up, and that 100% of these patients are consented, which seems unlikely. The applicants response equally means that 0% of the consented patients have been consented at any other time in the patient pathway, which also seems unlikely, as the applicant has provided a pre 6-month consent form.

The CAG would also like to make clear to the applicant that when seeking consent from patients for research purposes, this should be appropriately detailed in the consent forms, which will be reviewed as part of the REC review. This is further discussed below in the section on patient notification.

In addition the CAG would like to note to the applicant, that if patients have consented to the use of their data for SSNAP research purposes, consent overrides the National Data Opt Out, and therefore any NDO opted out patients who consent into SSNAP do not have to be excluded from research purposes. This should incentivise the applicant to seek consent wherever possible.

· Use of anonymised/pseudonymised data

Confidential patient information is required to identify duplications of the same patient, and to ensure it is possible for SSNAP to link between records of the same patient treated at different hospitals. Confidential patient information is also required for linkage to outcome data. It is not possible to undertake this process without identifiable data. The CAG were content that the use of anonymous data was not a practicable alternative for these processes.

Justification of identifiers

Members noted that it appeared that the Chief investigator and a student (internal researchers) had access to confidential patient information for analysis, however the CAG were unclear why this would be required. The applicant is to confirm if internal

analysis undertaken by the SSNAP research team can be on a pseudonymous dataset. If it cannot, please justify why confidential patient information is required for this.

Data Access Committee

The CAG noted that the applicant has described a process whereby external data requests are reviewed by the SSNAP team and will be subject to approval by the HQIP Data Access Review Group (DARG). An HQIP data access form has been provided, as have terms of reference for SSNAP Scientific Advisory Group, which is not yet in existence - applicants plan to create a small Scientific Committee to advise on data use applications to SSNAP, and to report to the ICSWP and to SSNAP's commissioners, HQIP, on data uses and research-related issues. The applicant states that this committee will have representation from the public, patients and carers. The CAG noted that the HQIP website states that although the HQIP DARG is responsible for the final approval for data release, HQIP would depend on advice from the local audit (SSNAP) regarding the scientific validity and the public benefit of the data release.

As there is currently no SSNAP Scientific Advisory Group in existence, the CAG were unclear how this function would be fulfilled by SSNAP. Additionally, if created as described in the terms of reference, ie. potentially with only 1 lay member, and only meeting twice a year, the CAG did not feel that this would be sufficient for the purpose. The terms of reference also only described assessing the scientific validity of any external data request, however, the Committee were not clear if the SSNAP Scientific Advisory Group are also assessing whether these requests are in the public interest, and had a medical purpose, and were also unclear on the detail of any decision making process. The Group would therefore like more information on how research proposals will be reviewed and approved, in the form of an updated ‘terms of reference’ document for the SSNAP Scientific Advisory Group. This should include details of how the applicant is assured that the data released to external parties is not identifiable, potentially increase the amount of lay membership, number of meetings, and include detail on how public interest and medical purpose are assessed.

‘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 has described a layered approach. A poster has been provided as patient notification designed for the initial stroke admission – this leads on to further information via QR code to the patients, public and carer area of a website, from

where the research area can be found. This has a breadth of information for patients including a fair processing statement.

A patient can also ask for a leaflet on the ward. These have been provided for review – one for community stroke teams and one for Trusts. Clinicians will seek consent if possible at any time point. A Patient Information Sheet for England and Wales document can be provided at any time in the patient pathway, and used to consent an individual.

A patient information sheet, consent form, and easy access version have been provided for the 6 month follow up, aimed towards consenting patients at this timepoint.

SSNAP also has an active Twitter account to promote general audit activity, and part of this is to promote research papers and conference research submitted and published using SSNAP data. SSNAP also produces a quarterly publicly available newsletter. Whilst this is mainly aimed at the stroke care providers submitting data to SSNAP, this is public and promoted via Twitter. This contains information about recent research using SSNAP data.

A study specific opt out is offered. The applicant has confirmed as part of query responses that the National data Opt Out (NDO) will be applied to the research data, but this is not clear on any of the patient notification documents provided. There is no mention that the NDO is respected for research. The CAG consider this needed to be added.

The CAG considered that the applicant had not updated the documentation provided to include clear references to research use of the data. For example, the documentation provided mentions that SSNAP is exempt from the NDO, but does not clarify that this is only relevant with regards to the audit. There seemed a general lack of distinction between research use and audit purposes, including a lack of options with regards to opting out of just the audit, just research, or both. Members commented that the quality of some of the information on the website was good, but is aimed more at clinicians. The CAG felt that it could be improved with regards to directing patients more clearly to the relevant areas of the website. The CAG also mentioned that as 35% of patients are asked for consent at 6 months, this should be reflected in the earlier notification, regarding the likelihood of being asked for consent at a clinical follow up.

In general, a phone number and email to opt out of SSNAP are offered in some notifications, but some point only to the direct care team – for example; ‘What if I do not want my confidential information included in SSNAP? Please tell the person who gave you this leaflet’. The CAG considered that a named person or position, a phone number, email, and postal address should be provided in a uniform manner across all notification, in order for patients to opt out if they wish.

With regards to the poster, the CAG commented that they felt this was too sparse, and did not clearly explain what SSNAP was. They also commented that a web address was also required in addition to a QR code.

The other various patient notification materials also need updating. There are references to NWIS, however this organisation is now DHCW. There are references to NHS Digital, however this organisation is now NHS England. Where notifications state ‘granted by HRA CAG, the terminology should be corrected to HRA on advice from CAG (for research), and Secretary of State for Health and social care on advice from CAG (for non research). The ‘Patient information sheet – england and wales’ states that the NDO is exempt, but

again this does not refer to research, as SSNAP is only exempt from applying the NDO for non-research activities. There is also no mention of CAG or ’s251’ on this document.

The applicant is therefore required to update all notification documents in line with advice in this letter. The breach of confidentiality that requires ‘s251’/CAG should be clearly explained. There should be simple wording to explain the difference between the audit, and the research purposes. The application of the NDO needs to be clear between non-research and research. Some documents only say to speak to a clinician if patients want to opt out, and this should be updated to include contact details for SSNAP. The distinction between opting out of research and/or non research should be clarified on the documentation. The errors with regards to NWIS and NHS Digital, and the CAG decision makers should be rectified. Where the consent forms and information sheets seek to consent for research, this should be clearly described. The CAG also wish for the applicant to ask a patient and public involvement group to review the updated documentation.

Please clarify for the CAG how the NDO will be applied to research activities, as this is confirmed in query responses that it will be applied, but the process is not detailed in any of the application documents.

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 states that Patient Public Voice representation is embedded, and will remain embedded, in SSNAP governance through many channels, and through these channels patients and carers play a central role in developing, agreeing and finalising improvement goals and measures, and including consultation on information governance and fair use of patient data. Two stroke survivors and two Stroke Association representatives sit on the Intercollegiate Stroke Working Party (ICSWP), SSNAP's steering group, which meet three times a year frequently covering the use of SSNAP data in research including updates on recent data requests from external third parties who have applied to use SSNAP data via the Data Access Request Group (DARG) at HQIP, as well as research conducted by the SSNAP team at King's College London.

SSNAP has recently held a consultation with PPV representatives, including stroke survivors, carers and Stroke Association Support Coordinators, to discuss SSNAP's

application to the CAG for exemption from the National Data Opt-Out and better understand the views of patients and the public on the impact of the opt-out on patient care and safety. SSNAP will continue to hold these discussions, including around the use of SSNAP data in research, through the groups and channels listed above. SSNAP will also collaborate and seek advice from PPV experts in the Department of Population Health Sciences at King's College London, including the stroke research patients and family group and the 'Improving Lives of Stroke Survivors with data' programme grant team to inform future SSNAP PPV activities specifically those related to data use applications of SSNAP data.

The CAG commented that it doesn't seem as if there is any evidence of the use of confidential patient information without consent being discussed with patients and the public, as the applicants state that a PPV focus group will be developed, including stroke charities, stroke research participants, and patient and carer representatives. Although some has recently been undertaken regarding the deferral of the NDO, it does not appear that any patient and public involvement has been undertaken specifically on the use of

confidential patient information without consent, and particularly for the purposes of research.

Exit strategy

Consent is sought at the 6 month clinical visit where possible. The exit strategy from support for individual patients is therefore consent for approximately 35% of patients.

For those that are not consented, there is currently no exit strategy, however, as a response to queries, applicants propose that for those patients who have not provided consent, they will remove all identifiers from their records after 5 years of admission. The process for this will need to be discussed further with the webtool developer.

The Members considered that it would not appear necessary to retain identifiers for this long, regarding deceased patients, as this should be able to be removed soon after they are deceased. The applicant is to confirm if the exit strategy for those who do not consent is to be removal of identifiers after 5 years, and also to confirm if confidential patient information can be deleted earlier for those who are deceased.

Ongoing 's251' support required for SSNAP overall, as despite an expected end date of current commissioning being 31 March 2026, it is envisaged that SSNAP will continue after that. Therefore support for 5 years in the first instance, in line with other applications of this type that require ongoing support.

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. 1 The applicant is to justify why name is required for linkage, and therefore why name is required to be collected at all.

2. Please confirm if SSNAP patients could be flagged at NHS England/DHCW, to avoid having to re-send the entire cohort each quarter.

3. Please provide absolute clarity on the proportion of patients consented currently, and indicate the proportion of these that are consented at each time point in the clinical pathway.

4. Please confirm if internal analysis undertaken by the SSNAP research team can be on a pseudonymous dataset. If it cannot, please justify why confidential patient information is required for this.

5. Please provide evidence of how SSNAP reach conclusions about the appropriateness of research which is undertaken externally. The Group would like clarity on what the process is in deciding which research projects will be undertaken, and this should be evidenced by an updated 'terms of reference' document for a data access committee, and any other relevant evidence. This should include more than 1 lay member, meet more than twice a year, assess public interest and medical purpose, and the applicant should also confirm that this committee has been created prior to 's251' support being provided.

6. Please consider if the website can be improved to better signpost patients to where the relevant informaiton is.

7. Please update all notification documents in line with advice in this letter. The breach of confidentiality that requires 's251'/CAG should be clearly explained. There should be simple wording to explain the difference between the audit, and the research purposes. The application of the NDO needs to be clear between non-research and research. Some documents only say to speak to a clinician if patients want to opt out, and this should be updated to include contact details for SSNAP. The distinction between opting out of research and/or non-research should be clarified on the documentation. The errors with regards to NWIS and

NHS Digital, and the CAG decision makers should be rectified. Where the consent forms and information sheets seek to consent for research, this should be clearly described. The CAG also wish for the applicant to ask a patient and public involvement group to review the updated documentation.

8. Please clarify for the CAG how the NDO will be applied to research activities.

9. Please undertake further patient and public involvement specifically on the use of confidential patient information without consent, and particularly for this research application.

10. Please confirm if the exit strategy for those who do not consent is to be removal of identifiers after 5 years.

11. Please confirm if confidential patient information can be deleted earlier than 5 years for those who are deceased.

12. Favourable Opinion from a Research Ethics Committee is pending, as per standard condition of support, listed below.

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. 1 Support for ECC 6-02 (FT3)/2012 is expired from the date of the supported non-research outcome.

2. Support is provided for five years, at which time point a duration amendment is required.

3. Consent remains necessary at the six month clinical follow up, where possible, and consent should also be sought at all possible clinical contacts prior to the 6 month visit.

4. The National Data Opt-Out **is** to be applied to patients included in the research activities specified in 23/CAG/0030.

5. Please ensure the updated CAG form including Professor Wolfes signature is provided to CAG, as soon as possible.

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

7. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

   The NHS England **21/22** DSPT reviews for **Kings College London (SSNAP team) – (EE133874-SSNAP), Net solving Ltd (8JA87), Rackspace (8HL77), & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 March 2023)

   The Welsh IG team have confirmed that security assurances are in place for Digital Health and Care Wales (DHCW)

   Due to the number of participating organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs (or CPiPs for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

c. 23/CAG/0031– Sentinel Stroke National Audit Programme (SSNAP) – (non- research application) (reviewed alongside 23/CAG/0030)

Context

Purpose of application

This non-research application from King's College London (on behalf of Healthcare Quality Improvement Partnership (HQIP), NHS England & the Welsh government) set out the purpose of collecting data on all patients with a new episode of stroke or TIA (transient ischaemic attack), or those suspected of having a stroke, admitted to hospital in England and Wales, to establish Sentinel Stroke National Audit Programme (SSNAP) - the national clinical audit of stroke services. SSNAP is part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

Healthcare Quality Improvement Partnership (HQIP) and NHS England are joint data controllers for English data for this audit application, and HQIP and the Welsh government are joint data controllers for Welsh data. The database is managed by King's College London, who have been commissioned by HQIP, and Net Solving Ltd/Rackspace host the dataset. They are considered data processors for this application.

Sentinel Stroke National Audit Programme (SSNAP) currently has 's251' support under non-research application reference ECC 6-02 (FT3)/2012, and prior to that, under ECC 5-06 (g)/2010 (Stroke Improvement National Audit Programme – SINAP). This non-research application (23/CAG/0031) has been submitted alongside a research application (23/CAG/0030), in order to split out the research and non-research functions of SSNAP into separate CAG applications, and to refresh the support required, as requested by conditions 3 & 4 of support regarding the recent non-research National Data Opt Out Exemption application. ECC 6-02 (FT3)/2012, will be expired and replaced with 23/CAG/0030 and 23/CAG/0031. The National Data Opt Out exemption will continue for this new non-research application only (23/CAG/0031), and does not apply to the research database application (23/CAG/0030).

The aim of SSNAP is to audit the processes of care for stroke patients who are admitted to hospital, from onset of symptoms up to 6 months post discharge from hospital, against the nationally agreed, evidence-based standards (NICE guidelines). It also sets out to assess outcomes for all stroke patients, including mortality at various intervals, change in modified Rankin score and institutionalisation rates. Anonymised analyses will be produced to allow stakeholders (commissioners, stroke clinicians, managers and patient advocates) to compare performance and practice for the non-research purposes described in the application.

Data collection started in 2012 and is currently ongoing under ECC 6-02 (FT3)/2012. Data is collected from English Trusts (including ambulance services) and Welsh Health Boards via a secure web based application. Confidential patient information is collected to allow identification of multiple admissions for the same individual, and also to enable linkage between Hospital Episode Statistics and Civil registrations – mortality data from NHS England, and with Patient Episode Database for Wales (PEDW) from DHCW. Data is collected from onset of symptoms up to 6 months post-discharge from hospital.

Identifiable patient data collected as part of SSNAP dataset is stored at King's College London on a platform hosted by Net Solving Ltd. When a new patient record is created on SSNAP which contains patient identifiable information, this record is pseudonymised to all users except the teams/services where the patient is being treated. The other exceptions are the global administrator of the web tool and authorised personnel at King's College London will have access to confidential patient information, which will be viewed and processed only for the purposes described in the application. Patients are consented if possible at their 6 month follow up. The applicant has confirmed that currently this is 35% of patients. There are challenges surrounding the 6 month follow ups being undertaken at all, and therefore it is not practicable for consent to be undertaken in cases where there is no follow up.

A recommendation for class 3, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients with a new episode of stroke or TIA or those suspected of having a stroke, admitted to hospital in England and Wales. The minimum age requirement is 16. Approximately 85,000 people per year
Data sources	1. English Trusts including Ambulance Trusts – clinical records 2. Welsh Health boards – clinical records 3. NHS England (previously NHS Digital); • Hospital Episode Statistics (HES) • Civil Registration – Deaths 4. DHCW; • Patient Episode Database for Wales (PEDW)
Identifiers required for linkage purposes (and therefore required to be retained in the SSNAP database)	1. Name 2. NHS number 3. Hospital number 4. date of birth, 5. Date of death 6. postcode 7. gender 8. ethnicity 9. Computer Aided Despatch number (CAD)

	10. postcode of ambulance pickup
Identifiers required for analysis purposes	1. Full date of death required for SSNAP internal non-research analysis 2. Gender 3. ethnicity
Additional information	linkage undertaken quarterly with NHS E (prev D), & DHCW. All individuals in SSNAP are requested for each data request.

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 were agreed this was in the public interest. A conditional outcome has been recommended, as the Committee agreed there was a public interest in the important work of the SSNAP audit continuing.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The CAG noted that the applicant collected name. the CAG were unclear why name was required for linkage, if the NHS number and other details were available. The applicant is to justify why name is required for linkage, and therefore why name is required to be collected at all.

The Committee also noted that it appears that each time linkage is undertaken with outcome data, which is undertaken quarterly, the entire SSNAP cohort appears to be being sent to NHS England. The CAG were unclear why this was necessary, and requested the applicant to confirm if SSNAP patients could be flagged at NHS England/DHCW, to avoid having to re-send the entire cohort each quarter. In this way, the applicant should be able to send only new patients from the last quarter, and still receive linked outcome data for the entire SSNAP cohort.

- **Feasibility of consent**

The applicant states that consent will not be sought for use of data in audit, for the following reasons;

- Many patients cannot communicate after stroke either because of reduced level of consciousness, specific language or cognitive difficulties or because they die in the hours or days following a stroke meaning informed consent is not possible.
- It is necessary for full representation and complete coverage which is required in order to produce valid and comprehensive conclusions on care quality and outcomes. If informed consent were required as a prerequisite to be able to collect and analyse this data, the experience of many patients, particularly the most vulnerable, would be excluded.
- The cohort size makes it unrealistic to gain consent for every patient. There are more than 85,000 cases per year for analysis, over 40% of whom will have communication difficulties.

Consent will still be sought at the 6 month follow up clinical appointment, in cases where this is undertaken. This is currently 35% of patients in SSNAP. It is not practicable for consent to be sought by clinicians at 6 months in cases where no 6 month follow up is undertaken clinically. The applicant has provided a pre 6-month consent form for occasions where it is possible for the direct care team to consent earlier.

The Members agreed that consent was not a practicable alternative regarding the initial data collection. However CAG agreed to retain the condition regarding consenting at the 6 month follow up visit where possible, and this extends to any contact the direct care team may have with the patient. The applicant is encouraged to consent patients earlier during admission wherever it is possible to do so.

The Members also requested absolute clarity on the proportion of patients consented currently, as the applicant has implied that 35% of patients have a 6 month follow up, and that 100% of these patients are consented, which seems unlikely. The applicants response equally means that 0% of the consented patients have been consented at any other time in the patient pathway, which also seems unlikely, as the applicant has provided a pre 6-month consent form.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to identify duplications of the same patient, and to ensure it is possible for SSNAP to link between records of the same patient treated at different hospitals. Confidential patient information is also required for linkage to outcome data. It is not possible to undertake this process without identifiable data. The CAG were content that the use of anonymous data was not a practicable alternative for these processes.

‘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 has described a layered approach. A poster has been provided as patient notification designed for the initial stroke admission – this leads on to further information via QR code to the patients, public and carer area of a website, from where the research area can be found. This has a breadth of information for patients including a fair processing statement.

A patient can also ask for a leaflet on the ward. These have been provided for review – one for community stroke teams and one for Trusts. Clinicians will seek consent if possible at any time point. A Patient Information Sheet for England and Wales document can be provided at any time in the patient pathway, and used to consent an individual.

A patient information sheet, consent form, and easy access version have been provided for the 6 month follow up, aimed towards consenting patients at this timepoint.

SSNAP also has an active Twitter account to promote general audit activity, and part of this is to promote research papers and conference research submitted and published using SSNAP data. SSNAP also produces a quarterly publicly available newsletter. Whilst this is mainly aimed at the stroke care providers submitting data to SSNAP, this is public and promoted via Twitter. This contains information about recent research using SSNAP data.

A study specific opt out is offered. The applicant has confirmed as part of query responses that the National data Opt Out (NDO) will be applied to the research data, but this is not clear on any of the patient notification documents provided. There is no mention that the NDO is respected for research. The CAG consider this needed to be added. This non-research application is exempt from the NDO, but it is not clear from the documentation that there is any distinction.

The CAG considered that the applicant had not updated the documentation provided to include clear references to the differences between audit and research use of the data. For example, the documentation provided mentions that SSNAP is exempt from the NDO, but does not clarify that this is only relevant with regards to the audit. There seemed a general lack of distinction between research use and audit purposes, including a lack of options with regards to opting out of just the audit, just research, or both. Members commented that the quality of some of the information on the website

was good, but is aimed more at clinicians. The CAG felt that it could be improved with regards to directing patients more clearly to the relevant areas of the website. The CAG also mentioned that as 35% of patients are asked for consent at 6 months, this should be reflected in the earlier notification, regarding the likelihood of being asked for consent at a clinical follow up.

In general, a phone number and email to opt out of SSNAP are offered in some notifications, but some point only to the direct care team – for example; '*What if I do not want my confidential information included in SSNAP? Please tell the person who gave you this leaflet'.* The CAG considered that a named person or position, a phone number, email, and postal address should be provided in a uniform manner across all notification, in order for patients to opt out if they wish.

With regards to the poster, the CAG commented that they felt this was too sparse, and did not clearly explain what SSNAP was. They also commented that a web address was also required in addition to a QR code.

The other various patient notification materials also need updating. There are references to NWIS, however this organisation is now DHCW. There are references to NHS Digital, however this organisation is now NHS England. Where notifications state 'granted by HRA CAG, the terminology should be corrected to HRA on advice from CAG (for research), and Secretary of State for Health and social care on advice from CAG (for non research). The 'Patient information sheet – england and wales' states that the NDO is exempt, but again this does not refer to research, as SSNAP is only exempt from applying the NDO for non-research activities. There is also no mention of CAG or 's251' on this document.

The applicant is therefore required to update all notification documents in line with advice in this letter. The breach of confidentiality that requires 's251'/CAG should be clearly explained. There should be simple wording to explain the difference between the audit, and the research purposes. The application of the NDO needs to be clear between non-research and research. Some documents only say to speak to a clinician if patients want to opt out, and this should be updated to include contact details for SSNAP. The distinction between opting out of research and/or non research should be clarified on the documentation. The errors with regards to NWIS and NHS Digital, and the CAG decision makers should be rectified. Where the consent forms and information sheets seek to consent for research, this should be clearly described. The CAG also wish for the applicant to ask a patient and public involvement group to review the updated documentation.

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 states that Patient Public Voice representation is embedded, and will remain embedded, in SSNAP governance through many channels, and through these channels patients and carers play a central role in developing, agreeing and finalising improvement goals and measures, and including consultation on information governance and fair use of patient data. Two stroke survivors and two Stroke Association representatives sit on the Intercollegiate Stroke Working Party (ICSWP), SSNAP's steering group, which meet three times a year frequently covering the use of SSNAP data in research including updates on recent data requests from external third parties who have applied to use SSNAP data via the Data Access Request Group (DARG) at HQIP, as well as research conducted by the SSNAP team at King's College London.

SSNAP has recently held a consultation with PPV representatives, including stroke survivors, carers and Stroke Association Support Coordinators, to discuss SSNAP's application to the CAG for exemption from the National Data Opt-Out and better understand the views of patients and the public on the impact of the opt-out on patient care and safety. SSNAP will continue to hold these discussions, including around the use of SSNAP data in research, through the groups and channels listed above. SSNAP will also collaborate and seek advice from PPV experts in the Department of Population Health Sciences at King's College London, including the stroke research patients and family group and the 'Improving Lives of Stroke Survivors with data' programme grant team to inform future SSNAP PPV activities specifically those related to data use applications of SSNAP data.

The CAG commented that it doesn't seem as if there is any evidence of the use of confidential patient information without consent being discussed with patients and the public, as the applicants state that a PPV focus group will be developed, including stroke charities, stroke research participants, and patient and carer representatives. Although some has recently been undertaken regarding the deferral of the NDO, it does not appear that any patient and public involvement has been undertaken specifically on the use of confidential patient information without consent, and particularly for this refreshed application.

Exit strategy

Consent is sought at the 6 month clinical visit where possible. The exit strategy from support for individual patients is therefore consent for approximately 35% of patients.

For those that are not consented, there is currently no exit strategy, however, as a response to queries, applicants propose that for those patients who have not provided consent, they will remove all identifiers from their records after 5 years of admission. The process for this will need to be discussed further with the webtool developer.

The Members considered that it would not appear necessary to retain identifiers for this long, regarding deceased patients, as this should be able to be removed soon after they

are deceased. The applicant is to confirm if the exit strategy for those who do not consent is to be removal of identifiers after 5 years, and also to confirm if confidential patient information can be deleted earlier for those who are deceased.

Ongoing ‘s251’ support required for SSNAP overall, as despite an expected end date of current commissioning being 31 March 2026, it is envisaged that SSNAP will continue after that. Therefore support for 5 years in the first instance, in line with other applications of this type that require ongoing support.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support for ECC 6-02 (FT3)/2012 is expired from the date of this letter.

2. Support is provided for five years, at which time point a duration amendment is required.

3. Consent remains necessary at the six month clinical follow up, where possible, and consent should also be sought at all possible clinical contacts prior to the 6 month visit.

4. The National Data Opt-Out is **not** to be applied to patients included in the non-research activities specified in 23/CAG/0031.

5. Please ensure the updated CAG form including Professor Wolfes signature is provided to CAG, as soon as possible.

6. Please ensure the supportive letter from the Caldicott Guardian of the submitting organisation is provided to CAG, as soon as possible, as this only appears to have been provided regarding the corresponding research application.

7. The applicant is to justify why name is required for linkage, and therefore why name is required to be collected at all, within one month.

8. Please confirm if SSNAP patients could be flagged at NHS England/DHCW, to avoid having to re-send the entire cohort each quarter, within one month.

9. Please provide absolute clarity on the proportion of patients consented currently, and indicate the proportion of these that are consented at each time point in the clinical pathway, within one month.

10. Please consider if the website can be improved to better signpost patients to where the relevant information is, within one month.

11. Please update all notification documents in line with advice in this letter. The breach of confidentiality that requires 's251'/CAG should be clearly explained. There should be simple wording to explain the difference between the audit, and the research purposes. The application of the NDO needs to be clear between non-research and research. Some documents only say to speak to a clinician if patients want to opt out, and this should be updated to include contact details for SSNAP. The distinction between opting out of research and/or non-research should be clarified on the documentation. The errors with regards to NWIS and NHS Digital, and the CAG decision makers should be rectified. Where the consent forms and information sheets seek to consent for research, this should be clearly described. The CAG also wish for the applicant to ask a patient and public involvement group to review the updated documentation, within three months.

12. Please undertake further patient and public involvement specifically on the use of confidential patient information without consent, and particularly for this refreshed non-research application, and provide feedback to CAG within three months.

13. Please confirm if the exit strategy for those who do not consent is to be removal of identifiers after 5 years, within one month.

14. Please confirm if confidential patient information can be deleted earlier than 5 years for those who are deceased, within one month.

15. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

    The NHS England **21/22** DSPT reviews for **Kings College London (SSNAP team) – (EE133874-SSNAP), Net solving Ltd (8JA87), Rackspace (8HL77), & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 21 March 2023)

    The Welsh IG team have confirmed that security assurances are in place for Digital Health and Care Wales (DHCW)

Due to the number of participating organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs (or CPiPs for Wales), and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

6. Any other business

No other business was raised.

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

Signed – Chair	Date
Dr Tony Calland, MBE (CAG Chair), Dr Patrick Coyle (CAG Vice Chair) & Dr Murat Soncul (CAG Alternate Vice-Chair)	*27 March 2023*

Signed – Confidentiality Advice Team	Date
Caroline Watchurst HRA Confidentiality Advisor	*21 March 2023*