Minutes of the meeting of the Confidentiality Advisory Group

24 November 2022 via Zoom

Present:

Name	Role
Dr Tony Calland MBE	CAG Chair
Dr Murat Soncul (AVC)	CAG Alternate Vice Chair
Dr Martin Andrew	CAG Member
Professor Lorna Fraser	CAG Member
Dr Katie Harron	CAG Member (Left after discussion of 4d)
Mr Anthony Kane	CAG Member
Mr Andrew Melville	CAG Member
Professor Sara Randall	CAG Member
Ms Diana Robbins	CAG Member

Also, in attendance:

Name	Position (or reason for attending)
Mr Will Lyse	HRA Approvals Administrator
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dayheem Sedighi	HRA Approvals Administrator (Internal Observer)
Professor Patrick Doherty	Applicant (attended for discussion of item 3a only)
Nerina Onion	Applicant (attended for discussion of item 3a only)
Eve Cross	Applicant- Quality Assurance Coordinator (attended for discussion of item 3b only)
Laura White	Applicant - Operations Director (attended for discussion of item 3b only)

1. Introduction, apologies, and declarations of interest

CAG Members gave apologies – Professor William Bernal - CAG alternate Vice Chair & Dr Sandra Duggan, CAG member

The following conflicts of interest were declared.

- CAG Member Professor Lorna Fraser declared a conflict of interest with item 3a. The applicant is her recent head of department from University of York, and Lorna did not participate in the development of any recommendation by CAG

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the **27 October 2022** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **27 October 2022** meeting applications.

Minutes:

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

- 16 September & 30 September PS meeting minutes
- 22 September & 6 October 2022 full meeting minutes
- August & September sub-committee minutes

3. Consideration Items – National Data opt Out Exemption requests

a. ECC 3-04 (a) 2012 - National Audit of Cardiac Rehabilitation (NACR) -resubmission of NDO exemption

Scope of NDO exemption request

This national audit has had support since 2012 for clinical teams at Trusts to input data (including identifiers) to a system administered by NHS Digital. NHS Digital remove identifiers from the data and send a monthly pseudonymised dataset to the National Audit of Cardiac Rehabilitation (NACR) team at University of York for audit purposes.

Whilst University of York do not receive identifiers this request was to disapply the NDO for the primary data flows that have Regulation 5 support.

The applicant has previously requested an NDO exemption, which was considered by CAG and rejected. However, the applicant was invited by CAG to re-submit, to ensure fairness to all applicants as the CAG further developed the criteria for consideration.

Confidentiality Advisory Group advice

As part of the request, the applicant provided two core reasons why application of the NDO would impact the running of NACR

1. Health inequalities – there are indications that the application of the NDO is not random, and this missing data impacts the integrity of any reporting and subsequent recommendations made by NACR, that will increase health inequalities in services provided.
2. Patient safety – the loss of data will reduce the ability to detect signals of concern to patient safety.

1. Deferral rationale: Health inequalities

Members considered the paper provided by the applicants, which explained that one of the key delivery objectives of the NHS Long Term Plan is to increase uptake to cardiac rehabilitation (CR) services from 50% to 85% by 2028. The scaling up of CR services is estimated to prevent up to 23,000 premature deaths and 50,000 acute admissions over 10 years. In order to evaluate progress these targets, NHS England & Improvement (NHSEI) has commissioned the NACR to collect and provide routine practice data to help target NHSEI funding with an aim to tackle low uptake and address inequalities in service provision. Evidence shows there are currently significant service inequalities, in the context of low uptake for female patients, patients from minority ethnic populations and patients who live in areas with high social deprivation.

The applicant has been applying the NDO since August, and as such, was able to provide CAG specific figures on how the NDO is affecting the validity of the audit. In only two months of NDO application, patient representativeness has altered in terms of ethnicity and social deprivation. An average of 4.5% of records have been removed, with a monthly variation of 3.8%-5.3%. As NACR receives around 7,000 new records entered per month, this would lead to a minimum of 4,200 missing patients by August 2023. There are much larger proportional differences in minority ethnic groups, ranging between 1.39% to 9.17% proportional reductions. This highlights a higher rate of opt-out in these groups than in the white ethnic group, which hinders the ability of NACR to report accurately on trends of uptake by ethnic groups and in the context of social deprivation.

The applicant further explained in the meeting, regarding the effects of the loss of the data, if the NDO continued to be applied. In certain ethnic groups, there are opt out rates of up to 9%. This represents a small but significant proportion of NACR, and in addition, ethnic minority individuals and those who live in more deprived areas who are more likely to opt out via the NDO, are also the same group who are evidenced as also being the least likely to take up cardiac rehabilitation. Those who are less likely to take

up cardiac rehabilitation are evidenced as more at risk of mortality. Having cases missing impacts on the ability of NACR to effectively report on health inequalities in certain areas. It is important that any reports to NHS England are based on a fully representative sample, as these reports directly impact resourcing decisions, and are used to effectively target health inequalities. Application of the NDO would reduce the ability to be able to effectively target resources, which would have a direct impact on patient safety. NHS England would be unable to increase cardiac rehab attendance for those individuals who are more likely to opt out, which are the same group disproportionately affected by unequal service provision/uptake, and therefore these individuals (who may have opted out via the NDO or not), would be more at risk of acute cardiac admission to hospital, and premature death.

Application of NDO would therefore compromise the ability of the audit to highlight important health inequalities in relation to socio-demographic characteristics, in particular deprivation and ethnicity. It would prevent a comprehensive investigation of small sub-populations which may benefit disproportionately from clinical interventions to preserve health outcomes. Therefore, Members were supportive of exempting the NDO, due to the impact on health inequalities.

2.Deferral rationale: Patient safety

Members considered the paper provided by the applicants, which confirmed that the case ascertainment of the audit was 96.1%. It also described the elevated risk to patients between certain treatments, for example moving from hospital to home based therapies, and a correlation with increased death if the programmes are not completed. In the meeting, the applicant explained that with a loss of around 5% of data to the audit, this would reduce its ability to accurately report on various important patient safety aspects of different treatment programmes, such as cardiac events, or rates of mortality. If NACR is unable to effectively identify if certain cardiac rehabilitation programmes are safe or not, this is a risk to patient safety if programmes are seen as safe, when in fact they are not.

Monitoring performance depends on the completeness of data. This monitoring will be sensitive to incomplete data, and variation in the impact of the NDO means that some programmes 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. Incorrect reporting would mean that improvements will not be made and there is the potential for lives to be lost. Application of the NDO would restrict the potential benefits of local quality improvement initiatives for individuals who require cardiac rehabilitation in the future, whether they have or have not opted out.

Members were supportive of exempting the NDO, due to the patient safety impact.

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 draft edited patient notifications, regarding informing the population that the NDO would not be applied, and a communications strategy was also provided as part of the supporting paper. The applicant has plans to disseminate this information via stakeholder organisations, newsletters and their website.

Members were broadly content with the updated notifications provided.

However it was commented that although an NACR specific opt out option is available, it is not immediately obvious how a patient would opt out. There is an email contact for any questions or concerns, but there is no signposting for how a patient would opt out if they wished to. The applicant is to update the notification materials to make it clear who to contact to opt out of NACR, providing more than only an email address. A phone number and postal address should also be provided.

Patient and Public Involvement

The CAG noted that although the applicant has provided multiple supportive letters, and mentioned involvement of a charity - Coronary Care Partnership UK (CCP-UK), and stated in the supporting paper that patient representatives continue to be actively involved in NACR Steering Group including involvement in discussions regarding the impact of NDO, the specifics of any patient support are not clear, as no feedback or comments had been provided. It was not clear if the applicants had actually discussed the non-application of the NDO with any patient and public representatives directly. The applicant is therefore required to undertake some further patient and public involvement with lay individuals, perhaps as a focus group, to discuss the acceptability of the non-application of the NDO.

The CAG felt that the justifications provided surrounding patient safety were strong, and therefore the Members did not require to see evidence of further patient and public involvement discussions prior to supporting, as the public interest is clear. The applicant is asked to provide feedback after further patient and public involvement has been undertaken, as part of the resubmission of the entire application.

Refreshed application

Separately to this application for NDO deferral, and as per the last NDO deferral exemption outcome letter, the CAG considered that as the ECC 3-04 (a)/2012 application is now 10 years old, and the Information Governance landscape has changed greatly since the original application was supported, a refreshed application should be made to CAG to supersede ECC 3-04 (a)/2012**.** This should be provided to CAG at the time of next annual review, instead of the annual review form, and should include a new CAG application form and entire set of supporting documents. This would be prior to 11 June 2023, as this is when the next annual review is due.

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 justification and health inequalities rationale 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 three months.

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.

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 patients included in the activities specified in ECC 3-04 (a)/2012.

2. A local patient objection mechanism must continue to be used in relation to ECC 3-04 (a)/2012.

3. Please provide updated patient notification documents, with clarity on how a patient can opt out, as per advice in this letter, within 3 months from the date of this letter.

4. The applicant is requested to submit a refreshed new application to CAG in lieu of their next annual review, which is 11 June 2023. This new application will supersede ECC 3-04 (a)/2012.

5. Please provide feedback of further discussions with patients and the public, surrounding the non-application of the National Data Opt-Out. This can be provided as part of the refreshed application (condition 4).

b. 22/CAG/0014 - The Trauma Audit & Research Network (TARN)

Scope of NDO exemption request

This is a request to defer the National Data Opt-Out for 22/CAG/0014, the Trauma Audit & Research Network (TARN).

TARN was initially established in 1990, supported initially by PIAG (PIAG 3-04 (e)/2006), ECC (ECC 7- 05(g)/2011) and now by refreshed application 22/CAG/0014. The applicants have consistently submitted annual reviews. All the conditions in the outcome letter are met, except the further patient and public condition, which applicants have arranged to submit in January. This is noted by CAG.

Support is in place for clinical teams at Trusts and Health boards (England & Wales) to input data (including identifiers) to the Trauma Audit and Research Network (TARN), at The University of Manchester for the purposes of national clinical audit. Support is also in place for NHS Digital and Digital Health and Care Wales (DHCW) to disclose confidential patient information linked to outcome data for all English/Welsh patients with specified trauma ICD 10 codes to TARN, for the purposes of linking to TARN data, and for TARN to disclose this on to individual Trusts, for the purposes of validation. There are other specific elements to their support, which are detailed in the outcome letter, dated 21 February 2022.

Confidentiality Advisory Group advice

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

1. Patient safety – The NDO presents a significant risk to the future success of TARN and continuing improvements, as the NDO would introduce a risk of error in future service improvement and planning strategies which could cause negative effects on patient care.

2. Introduction of bias – the application of the National Data Opt Out will impact the integrity of the data, especially for specific patient groups, where only low numbers of cases are available to evaluate services.

<u>1. 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 in relation to standards of care, providing accurate patient outcome analysis, and facilitating improvements for the treatment of trauma patients. However, the CAG felt the applicant did not set out the specific link between the application of the NDO, and consequences for the negative impact on patient safety.

The first of these arguments is benchmarking comparisons. TARN reporting compares Trauma Units and Major Trauma Centres with their peer hospitals across England, Wales NI & Ireland. As the NDO is only applied to English hospitals, there will no longer be an accurate comparison between hospital performance in England and their peers in the rest of the UK. The applicant has also stated that NDO uptake is not uniform across regions of the country (with an opt out rate of 7% in London versus only 4% in the North East and Yorkshire), and stated that patients opting out in and patient demographics across these regions also differ, but not provided any specific example to show what effect this would have. It is clear that if there is a higher prevalence &/or differing case mix of NDO patients in some areas of the country, this could have a distorting effect on benchmarking comparisons (Major Trauma Dashboards & Clinical report) between Hospitals and Networks in England, with critically poor clinical practice or outcomes in some geographical locations potentially going unrecognised. Outlier reporting is also mentioned in the paper - Monitoring performance depends on the completeness of data. This monitoring will be sensitive to incomplete data, and geographical variation in the impact of the NDO means that 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 Trusts will therefore be falsely reassured of the quality of care they are providing, whereas patients and staff in other Trusts may be misidentified as a concern for the same reason. However no modelling or statistical evidence of how application of exactly how the NDO would affect these outlier reports and in turn patient safety, for example providing data on how many patients could potentially have experienced a poorer outcome/or any effect on mortality, if a poorly performing outlier hospital was identified later than it should have been, due to the NDO being applied.

A further reason is service evaluation/improvement planning, which also links in to the first, as application of the NDO will make it harder to identify potential areas of concern in patient care pathways which would impact on service improvement strategies – this will impact on the speed at which problems can be identified and less data could potentially mean interventions are less targeted. The applicant states that *'even a 5% data loss has the potential to bias conclusions, meaning that the resulting service changes might be harmful rather than helpful to patient outcomes'*, but did not provide examples, or explain specifically how application of the NDO would bias the outlier reports, or impact service improvement. Therefore, from the paper provided, it was difficult for CAG to make the link to the patient safety consequences for individual

patients in the future, and the applicant is asked to make this link specifically as a response to this outcome letter. The applicant has also separately mentioned the national impact on service development, which is a similar argument to service evaluation/improvement planning. The applicant reasons that losing a proportion of the trauma population due to NDO, would have the potential to weaken the evidence needed to influence change and in turn impact on the value that it could then bring to patients and the national trauma system. Again, the applicant did not provide examples, or explain specifically how application of the NDO would weaken the evidence, or impact national service development.

A third reason surrounding injury prevention was provided; for example there is '*Current work evaluating the impact of the introduction of e-Scooters*'. The applicant has stated that as information from these audits contributes to health and injury prevention policy, that loss of patient data due to NDO, could bias this process, resulting in injury prevention opportunities being missed or misinformed. However the link between NDO application and patient safety is again implied rather than specific, as the applicant has not made clear what the consequences would be of the lack of full case ascertainment in relation to work surrounding e-scooter accidents, and the onwards link to patient safety.

Major trauma excess survival rate (the Ws outcome statistic) was discussed. A probability of survival is calculated for each injured patient and retained on the TARN database. This allows comparative outcome analyses (Ws = Observed survival rate – expected survival rate= excess survival rate) for hospitals and Networks of patients to be performed. Comparison of providers takes account of differences in the mix of patients between providers by adjusting for known, measurable factors that are associated with the performance indicator. These include age, gender, injury severity and co-morbidity. The applicant has stated that the data published by NHS digital demonstrates that there are differences in both the rate and count of NDO patients by gender and by age. Any change in case mix due to NDO could impact on the Ws, by introducing population bias into this model therefore compromising its effectiveness as a tool to improve public health. However, the applicant has not modelled or explained the specific gender and age differences reported by NHS Digital that may have an effect on TARN data. In order to make the link between application of the NDO and patient safety, these specific differences should be explored. In addition, to compare hospitals performance using Ws, it is technically required from hospitals to have at least 50 cases, so if a hospital loses cases through opt-out and won't reach the 50 cases threshold, it would not be provided with a performance score (Ws) which would compromise the ability to improve the health of the local population. This statement has been provided on its own, rather than including any projections surrounding how many of the submitting hospitals might not be able to make the 50 case threshold due to application of the NDO, and therefore it does not provide any link to how application of the NDO would potentially affect patient safety with regard to survival rate performance scoring.

The applicants provided information on Major Trauma PROMs (Patient Reported Outcome Measures)**,** and explained that TARN generates reports highlighting to hospitals any patient who is experiencing severe to extreme problems at 6 months, to support follow up, and has developed a predictive model to support this process. Current trauma care systems are designed to maximise survival, however the PROMS work means that future changes in services will be designed to maximise positive long term outcomes as well as survival. Loss of patient data due to NDO could have a distorting effect on the PROMs conclusions and may lead to erroneous conclusions about service change (which could be causing harm rather than benefit). Again, the CAG felt this was good reasoning, but was too general, and the applicant needs to specify how the application of the NDO would affect the PROMS conclusions, and therefore affect patient safety.

The final argument provided surrounded financial restrictions on Major Trauma Centres through the loss of best Practice tariff (BPT), that could directly restrict the standard of care they are able to deliver to major trauma patients. In England, Major Trauma centres treating patients with moderate and major trauma are potentially eligible for a conditional Best Practice Tariff (BPT) payment if certain care criteria are met. The patient data entered onto the TARN system is assessed against these criteria and TARN sends compliance rates to commissioners who then pay the Trusts using a block payment system. Major Trauma BPT is worth between £60-80 million each year to NHS Trusts and facilitates a higher quality of care for trauma patients. The NDO could therefore equate to a financial loss of between £3.2 and £4.3 million for Major Trauma Centres across England, which could negatively impact the quality of patient care that can be delivered as a result and therefore, patient safety and outcomes. The CAG noted these arguments and felt although very important, that financial aspects are not a significant argument in relation to the CAG threshold regarding application of the NDO. If the applicant can further evidence exactly how the financial loss could impact patient safety, and provide specific examples, this will be further considered by CAG.

Although the CAG was convinced by the <u>potential</u> justifications provided in the paper, especially surrounding benchmarking and outlier reporting, the Members felt there was a lack of data for how application of the NDO would affect trauma care. CAG did not feel that the application gave sufficient detail of the potential effect that applying the NDO would have on patient safety, with regards to specific modelling and examples, as per the section below on bias.

<u>2.Deferral rationale: Introduction of bias</u>

The applicants state they are not able to model the impact of the NDO on TARN data, as despite applying the NDO to their dataset since 1st August 2022, the applicants explained to CAG that TARN is a retrospective data collection tool, and some Trusts are not yet up to August data entry.

A generic argument is therefore made surrounding incomplete data lessening the utility of TARN data for informing and monitoring improvement. If the data entered into the system is not representative of the whole cohort, these tools will have less utility. However, no statistical evidence or modelling was provided regarding the demographic characteristics of those included in TARN specifically, or any types of people at particular risk for traumatic events, who may or may not apply an NDO. The applicants reasoned that applying the percentage of the population registered with a GP who have opted out of having their data shared as of 1st April 2022 (5.4%) could potentially equate to a reduction in 5,400 patients over the course of a year. As the applicants have confirmed they have 100% case ascertainment when looking at data collected from major Trauma Centres, this loss of data through the NDO will inevitably introduce bias into the TARN dataset, which the applicant states could be detrimental to service evaluation and improvement planning which in turn, would directly negatively impact on patient care and outcome on a national scale. However as the applicant has not focussed on the non-random nature of the NDO, and has not undertaken any statistical modelling by using a breakdown of opted out patients by demographic characteristic or by Trust, it was difficult for CAG to see an indication of the actual impact of the NDO, for TARN.

The applicant is therefore asked to look at a breakdown of the data already collected by TARN and compare the demographic characteristics of their dataset to the demographic characteristics indicated by NHS Digital regarding those who are registering an NDO. In this way, the applicant should be able to model the potential effects of the NDO being applied to TARN, even without waiting until all Trusts have submitted the August data. In this way, the applicant should be able to provide evidence based on modelling of how application of the NDO would negatively impact health inequalities, patient safety, and provide specific examples of the consequences of NDO application, especially for smaller groups. The only mention of smaller groups is in the summary at the end of the paper, stating very generally – '*Bias in conclusions of evaluation of service provision for specific patient groups (especially where only low numbers of cases are available to evaluate services).*', and '*Bias in conclusions of evaluation of service provision for specific patient groups (especially where only low numbers of cases are available to evaluate services)*'. The evidence of the data from August onwards would also be helpful when available, as the data from the application of the NDO for those months since 1st August would provide greater legitimacy to the arguments provided.

Although the CAG were convinced by the potential justifications provided in the paper, it was felt that the applicant had not managed to make the connection between how application of the NDO to TARN specifically would bias the dataset, and negatively affect patient safety, and the reasoning was implied rather than specific. The Members agreed that as no evidence based on statistical modelling had been provided, sufficient information had not yet been given in the application to support denying patients their

right to opt-out. The applicants would be asked to provide further information to evidence that patient safety would be adversely affected by application of the National Data Opt-Out, evidenced with statistics and modelling.

Research

The applicants have confirmed that this application is only in relation to the non-research audit – 22/CAG/0014. However, as the word research is in the title of the application, as there appeared to be some research outputs in the paper provided, a discussion was had during the meeting with the applicant, regarding whether or not TARN required an associated research application with CAG.

The CAG asked the applicant if they were using the TARN dataset to undertake research. The applicant responded that yes they were using the TARN dataset to undertake research, however this comment was caveated with the phrase – 'we use anonymised data'. However, if the anonymised data was only able to be collected initially with 's251' support, as the TARN dataset is, then the data collected for non-research purposes cannot be used for research purposes, even if it is anonymised. The process of anonymising it for research purposes requires a 's251' research application and associated Favourable Opinion from a Research Ethics Committee.

The same question was put to the applicants earlier in 2022 as part of the refreshed non-research application; *'Noting that this is a non-research application. Also noting that your title is 'The Trauma Audit & Research Network (TARN)', however from previous discussions with you the TARN data is used only for non-research projects. If it is useful to you, and you wish to create a research database for researchers to use data in the form of anonymous extracts for the purposes of research, please do submit a CAG research application alongside an ethics application to the REC, to allow this activity. We can help you with this submission if you require.'* To which the applicants responded; '*Noted, Not required at this time.'.*

In the context of these conflicting statements, the applicant is instructed to urgently contact the Confidentiality Advice Team (CAT), to establish if a corresponding research database application with CAG, and an associated Favourable Opinion from a Research Ethics Committee, is required. In the meantime, the CAG would like to make it clear to the applicant that research is excluded from the NDO deferral decision. Research use of the data collected under 's251' support is also excluded from the TARN application. Even anonymous research outputs should not be being utilised, as the applicants would not have this data if it were not collected under 's251'. If it is required to be provided in anonymous format for research purposes, a research application with CAG is required in order for the data to be processed for research purposes. It may be that the applicant is using the word 'research' in a different manner to how the CAG would perceive the word 'research', however clarity is required on this point urgently.

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 applicants set out a communications strategy, including draft materials. It was noted that it appears the local opt out mechanism is available, but it is not immediately clear how a patient could opt out from the privacy notice, and on the notification document only an email address has been provided. The applicant is requested to update the privacy notice to make it clearer to patients how to opt out of TARN, including providing a telephone number and a postal address in addition to an email address to do so, on both notification documents. The applicant is advised to show these updated documents to a patient group for review.

It appears that no patient and public involvement had been undertaken, however this is planned for 25th November, with the Sheffield emergency care forum. The CAG strongly felt that they would like to see evidence of patient and public involvement and engagement that supported the non-application of the National Data Opt-Out. The CAG asked that feedback from this was provided, prior to supporting this NDO deferral request.

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.

The CAG agreed that insufficient justification had been provided to justify a deferral of application of the National Data Opt-Out in relation to the non-research activities contained within 22/CAG/0014. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be provisionally supported. This is because the CAG accepted that the applicants had presented relevant arguments, however no statistical modelling had been provided, and no patient and public involvement had been undertaken. Therefore, the CAG are giving the applicants an opportunity to add and expand to their contribution. The CAG would make a final recommendation on whether the deferral request should be supported once responses to the below queries had been provided and considered. The applicant is reminded that if insufficient evidence is provided in the responses, the CAG reserve the right to reject the application.

In order to complete the consideration of this request, please respond back to the request for further information within 3 months.

Request for further information

1. Further statistical modelling is required to evidence that application of the National Data Opt-Out would have an adverse effect on patient safety, and health inequalities. This should include more detail on the specifics of the examples provided in the paper, and ensure the link is made between NDO application, and patient safety, rather than a generic link about non-specific bias.

2. Please provide updated patient notifications, which make it clearer how an individual can opt out of TARN only, provide more than an email address only for opt out, and have this reviewed by a patient and public involvement group.

3. Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.

Once received, the information will be reviewed by the CAG and a recommendation and decision issued as soon as possible. If the response is satisfactory a final outcome will be issued. If the response is not satisfactory, the application will be rejected.

Specific conditions of support (provisional)

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the non-research activities specified in 22/CAG/0014.

2. A local patient objection mechanism must continue to be used in relation to 22/CAG/0014

3. The applicant is requested to urgently discuss with the Confidentiality Advice team (CAT) and submit a new research database application to CAG, if one is required. Deferral of the National Data Opt-Out is not in place for any research use of the data collected under ‘s251’ support.

4. New Applications

a. 22/CAG/0169 - Greater Manchester Care Record – system supplier processing of confidential patient information to create a de-identified data mart for NHS GM secondary uses (Non-Research)

Context

Purpose of application

This non-research application submitted by NHS Greater Manchester Integrated Care, sets out the purpose of creating a pseudonymised copy of the Greater Manchester Care Record (GMCR), to be used for non-research secondary purposes such as population health management, and commissioning intelligence for example;

- Risk stratification,
- designing and targeting interventions to prevent ill health and improve care,
- reducing unwarranted variation in outcomes,
- reviewing service provision to identify gaps,
- strategic planning,
- redesigning care pathways,
- monitoring patient outcomes,
- Audits,
- Checking data quality,
- evaluating policy,
- improving patient safety

In response to the COVID-19 pandemic, health and care organisations in Greater Manchester established the GMCR, a shared care record which amalgamates essential information for the city-region's 2.8m citizens from across health and care. This enables better informed direct care, digital transformation of care pathways, and was established for the purposes of direct care. This has been established since April 2020.

Under the Covid-19 COPI notice, the applicant’s data processor Graphnet created deidentified datasets for use for covid-19 related population health research and other non-research secondary uses, also related to covid-19. 15 university-led research studies have so far been approved looking at the impact of COVID-19 in Greater Manchester on cancer patients, mental health/self-harm, diabetes patients and the treatment of rheumatoid arthritis, amongst others. Some are still ongoing but

are not currently processing identifiable information and so do not require ‘s251’ support.

Applicants have confirmed that there has been no processing of the data for secondary uses between the expiry of the COPI notice (end of June 2022) and now. After the ‘s251’ support has been provided, the GMCR purposes are going to be wider than Covid purposes.

This application for ‘s251’ support is to allow the disclosure of confidential patient information to Graphnet Health Ltd during the processing of the GMCR, to create a pseudonymised dataset for non-research secondary purposes. There is a sister research application for research uses – 22/CAG/0170. The de-identified data mart provides de-identified, linked row level data and is designed to be used for aggregate anonymised outputs such as population health, public health, risk stratification and segmentation. Access to the de-identified data mart will be made available to NHS GM ICS partners under an application and GM governance approval process as set out in the DPIA.

A recommendation for class 1 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	Approximately 3 million patients of all ages; (a) registered with a GP in Greater Manchester, or (b) have interacted with NHS services in Greater Manchester. This includes people that may have deceased since the GMCR was established. Records are not removed from the research database as they are needed for longitudinal analysis.
Data sources	1. Graphnet Ltd shared care records already linked together for purposes of clinical care, created from 500+ organisations including Primary Care, Secondary Care, Mental Health Trusts, Community Trusts, Out-of-Hours Services, Specialist Trusts, Social Care & North-West Ambulance Service, and local authorities.

Identifiers required for linkage purposes	Graphnet will have access to the patient's entire medical record in the process of removing all items of confidential patient information
Identifiers required for analysis purposes	1. N/A – all analysis undertaken without the use of identifying information
Additional information	Source data is de-identified on a weekly basis – applicants have confirmed this has not happened since the expiry of the COPI notice.

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 was strongly in the public interest.

Scope

Members were aware that the scope of the application is to ultimately legitimise the deidentification and secondary use of shared care records in the Greater Manchester area for non-research purposes.

CAG noted that the application included references to non-research uses of 'population health' and 'risk stratification'. These are fairly broad terms that could mean a variety of uses and members CAG requested further details surrounding definitions and descriptions of what population health and risk stratification entail, and that these are medical purposes. Members asked for this to be carefully defined as this will impact the scope of support provided for non-research uses. Any further uses outside these definitions should be included via an amendment.

Members were also made aware that this application is a precursor to a wider Secure Data Environment (SDE) application that will be submitted in the future, which will include linkages to national datasets. This application will be expired once the SDE application is supported and this wider context was noted by members. To assure CAG that the non-research uses remain within scope members requested a report on non-

research use cases of the GMCR at the first annual review, or as a supplementary document to the future SDE application, whichever is earlier.

Data sources

The CAG requested further clarity on if the dataset contained social care data, and if so, exactly what data was included. If it is included, the applicant is to justify the need for it within this dataset.

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 reasoned that to consent three million people would be completely disproportionate in both administrative time, cost and effort and even place an unreasonable burden on the NHS. Additionally, a consented system would create bias in the data which would seriously affect attempts to reduce health inequalities for vulnerable populations.

The CAG was content that consent was not a feasible option.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to be processed in order to create a deidentified database for the purposes of non-research secondary uses.

The CAG was content that using anonymous information was not a practicable alternative, but also noted that those accessing the data for secondary purposes would not have access to any identifiable information.

'Patient Notification' and mechanism for managing dissent

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

No separate submitted patient notification documentation was provided; however, the applicant provided a link to their website; https://gmwearebettertogether.com/ with a specific link to information about secondary uses and research.

The National Data Opt-Out will be applied at the point Graphnet pseudonymises the care record. Every time updated de-identified data is loaded, dissent and dissent withdrawal codes will be checked and removed / added as applicable.

The CAG was impressed by the amount of information on the website, including the informative videos. The comprehensive notification was very good concerning the use of the shared care record for direct care purposes, and the Members also noted good options regarding translation and other languages. However, the Members noted that even though 's251' was mentioned on the website, it was not specific regarding what the breach of confidentiality actually is. The notification appears to only be about what has happened in the past, rather than what the applicant is proposing, and this needs updating to specifically describe the breach of confidentiality, and that 's251' is the legal basis for processing. The applicant is asked to provide to CAG an updated patient notification document in the format they expect it to take after 's251' support is in place.

As a DHSC policy position the National Data Opt-Out is expected to be applied to all activities under 's251' support. However, a principle of support is that there is additionally an application specific opt out option communicated to patient. This is so patients have the opportunity of opting out of this specific activity without wider impacts to other activities. Currently the only opt out options appears to be either the National Data Opt-out or the GM Shared Care record. There appeared to be no option for patients to opt out specifically of GMCR non-research or research uses. As such, Members requested that an application specific opt out mechanism for secondary uses is developed and communicated through the notification routes. References directing patients to the NDO should be removed.

It was also felt that the notifications developed should not be only information on the website, there should be physical leaflets and posters produced, to develop a layered approach to notifying the population, in a similar manner to the public campaign, for example including QR codes leading to further information on the website, and possibly posters developed to be displayed in GP surgeries or other healthcare areas.

Patient and Public Involvement and Engagement

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

The applicant has submitted a Communications & Engagement Campaign Report. The campaign was delivered between June 2021 and March 2022, and included extensive outdoor advertising and social media advertising, media and PR releases and communication materials delivered to via local partners. The engagement activity reached out to some of the diverse communities of Greater Manchester and selected based on previous insight around lack of trust in data sharing and those communities least likely to engage with the health and care system. This included older people, the South Asian and Black African/Caribbean communities and people living in deprived

areas. Six focus groups were run online and face to face with over 80 people taking part to understand their views towards the GMCR.

The CAG was impressed by the huge amount of engagement work that had been done with varying diverse communities. However, the Committee were agreed that this appeared to be mainly about the shared care record, rather than any discussions regarding the breach of confidence and secondary uses of data. Therefore, the Members requested for additional work to be undertaken with patients and the public, specifically focussing on the use of data without consent for the purposes of this non-research application. This is to provide assurance to CAG of the acceptability of processing confidential patient information to create a deidentified dataset for secondary uses.

Exit strategy

It is understood that the deidentification process for individual patients will be ongoing in order to maintain the dataset. With regards to this application, a future Secure Data Environment (SDE) application is expected to be submitted in approximately April, which will supersede this application.

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 Secretary of State for Health and Social Care 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. Define what the applicants consider to be risk stratification and population health activities, with examples of each, noting this will be used to define the scope of the application.

2. Provide clarity whether the dataset contains social care data, and if so, what type of social care data is included, and justify why it is needed.

3. Please provide updated patient notification, which describes the breach of confidentiality for which ‘s251’ support is requested, with a GMCR specific opt out option, split out into non-research and research.

4. Please detail the notification strategies that will be used to inform the patient population regarding this activity. This should include wider notification methods than only the website.

5. Undertake additional work with patients and the public to establish acceptability of the use of data without consent, for the purposes of this application to CAG. A report of this work should be provided to CAG.

Specific conditions of support (Provisional)

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

1. Please provide a detailed report at annual review (or with a future SDE application if earlier), to provide data on non-research activities undertaken, which will be reviewed at a full CAG meeting.

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 review for **Graphnet Health ltd** (8GX89) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 29 November 2022).

a.(reviewed together with 22/CAG/0169). 22/CAG/0170 - Greater Manchester Care Record Research Database (Research)

Purpose of application

This research application submitted by NHS Greater Manchester Integrated Care, sets out the medical research purpose of creating a pseudonymised copy of the Greater Manchester Care Record (GMCR), to create an effectively anonymised research database, to facilitate research projects seeking to use routine data to address important research questions about the health of the Greater Manchester population. Research undertaken using this database will include epidemiological (including Covid-19) studies, population health, and operational studies. Examples of previous research undertaken before the COPI notice expired includes trends in primary care-recorded self-harm during and beyond the Covid-19 pandemic, and ethnic inequalities in Covid-19 vaccination uptake. Examples of non Covid-19 related research questions include investigating mental health outcomes for women and partners who have experienced

pregnancy not ending in live births and looking at 5 year survival after a diagnosis of dementia, and how it is affected by socioeconomic group.

In response to the Covid-19 pandemic, health and care organisations in Greater Manchester established the GMCR, a shared care record which amalgamates essential information for the city-region's 2.8m citizens from across health and care. This enables better informed direct care, digital transformation of care pathways, and was established for the purposes of direct care. This has been established since April 2020.

Under the Covid-19 COPI notice, the applicant's data processor Graphnet created deidentified datasets for use for Covid-19 related population health research and other non-research secondary uses, also related to Covid-19. 15 university-led research studies have so far been approved looking at the impact of Covid-19 in Greater Manchester on cancer patients, mental health/self-harm, diabetes patients and the treatment of rheumatoid arthritis, amongst others. Some are still ongoing but are not currently processing identifiable information and so do not require 's251' support.

Applicants have confirmed that there has been no processing of the data for secondary uses between the expiry of the COPI notice (end of June 2022) and now. After the 's251' support has been provided, the GMCR purposes are going to be wider than Covid-19 purposes.

This application for 's251' support is to allow the disclosure of confidential patient information to Graphnet Health Ltd during the processing of the Greater Manchester Care Record, to create a pseudonymised dataset for research purposes. There is a sister non-research application for non-research secondary uses – 22/CAG/0169. The De-identified data mart provides de-identified, linked row level data and is designed to be used for aggregate anonymised outputs for research purposes.

University of Manchester Research Data Engineers (RDEs) access the data mart via secure login and, for each research project, create a bespoke data extract that goes through several further rounds of de-identification. This data extract can be accessed via the data portal by named members of the group proposing the project. Data can only be downloaded from the portal in aggregate form once checked for disclosure control by a second project team member, and all downloads are monitored by Graphnet. RDEs and project team members cannot access the linkage key between the pseudonymised GMCR ID and confidential patient information.

Data access applications are restricted to research teams from UK HEIs only. The following restrictions will be applied for operations and capacity reasons:

- Undergraduate and master's students are not permitted to apply for data access
- PhD students registered at a Greater Manchester HEI may apply for data access
- PhD students from other UK HEIs may only apply for data access if the study is led by a Greater Manchester researcher who takes responsibility for the student's involvement

Study proposals must be approved by the GMCR Secondary Uses and Research Groups (SURG) before researchers are granted data access. The Research Operations Group (ROG) provides advice to the study team and assists them in progressing their proposal through the approvals process. Both groups will consider the following in their approval decision:

- Scientific robustness and relevance
- Data quality of the requested data
- Data minimisation principle
- Re-identification risks
- Completion of relevant data protection training by the applicants
- Relevant analysis expertise in the study team

GMCR Secondary Uses and Research Groups (SURG) contains lay representation, and CAG have been provided with their terms of reference. A list of all approved projects and any research outputs arising from the project is maintained, and more information on completed studies can be found at https://gmwearebettertogether.com/research-and-planning/

A recommendation for class 1 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	Approximately 3 million patients of all ages; (a) registered with a GP in Greater Manchester, or (b) have interacted with NHS services in Greater Manchester. This includes people that may have deceased since the GMCR was established. Records are not removed from the research database as they are needed for longitudinal research.
Data sources	1. Graphnet Ltd shared care records already linked together for purposes of clinical care, created from 500+ organisations including Primary Care, Secondary Care, Mental Health Trusts, Community Trusts, Out-of-Hours Services, Specialist Trusts, Social Care & North-West Ambulance Service, and local authorities

Identifiers required for linkage purposes	Graphnet will have access to the patient's entire medical record in the process of removing all items of confidential patient information
Identifiers required for analysis purposes	1. N/A – all analysis undertaken without the use of identifying information
Additional information	Approved researchers can access the data via a secure virtual environment provided by Graphnet. Source data is de-identified on a weekly basis – applicants have confirmed this has not happened since the expiry of the COPI notice.

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

Members were aware that the scope of the application is to ultimately legitimise the deidentification and secondary use of shared care records in the Greater Manchester area for research purposes.

The Members were unclear on the applicant's policy with commercial partners. Although the application clearly stated that the research team would not 'sell' any data, the CAG noted mention of 'going into partnership' with pharmaceutical companies within the application and therefore requested clarity on this relationship, as it was noted that the application states that research applications are restricted to Higher Education Institutions (HEIs) only. If any data is to be shared with pharmaceutical companies, even in anonymised format, this should be made clear as part of the application.

Members were also made aware that this application is a precursor to a wider Secure Data Environment (SDE) application that will be submitted in the future, which will

include linkages to national datasets. This application will be expired once the SDE application is supported and this wider context was noted by members. To assure CAG that the research uses remain within scope members requested a report on research use cases of the GMCR at the first annual review, or as a supplementary document to the future SDE application, whichever is earlier.

Data sources

The CAG requested further clarity on if the dataset contained social care data, and if so, exactly what data was included. If it is included, the applicant is to justify the need for it within this dataset.

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 reasoned that to consent three million people would be completely disproportionate in both administrative time, cost and effort and even place an unreasonable burden on the NHS. Additionally, a consented system would create bias in the data which would seriously affect attempts to reduce health inequalities for vulnerable populations.

The CAG was content that consent was not a feasible option.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to be processed in order to create a pseudonymised database for the purposes of creating a research database.

The CAG was content that using anonymous information was not a practicable alternative.

- **Data Access Committee**

The CAG noted the description provided in reference to the data access committee – the GMCR Secondary Uses and Research Groups (SURG). The CAG requested for the applicant to provide further clarifications on the makeup of this group regarding lay representation, as it is noted there are lay members, but it is not clear how many in comparison to other member types. It is noted that the committee will check if patient and public involvement has been undertaken and that a list of studies will be maintained. It is noted that terms of reference have been provided, and that access is restricted to HEIs as described in the application.

The applicant has stated that the SURG will use the following criteria before providing any data to researchers.

- Scientific robustness and relevance
- Data quality of the requested data
- Data minimisation principle
- Re-identification risks
- Completion of relevant data protection training by the applicants
- Relevant analysis expertise in the study team

However as the data will only be made available using 's251' support, which requires an appropriate medical purpose for processing, alongside a public interest in the activity being undertaken, the applicant is requested to ensure that both medical purpose and public interest are included in the criteria used to decide which studies can access the data. This should be updated in the terms of reference document, and an updated version provided.

'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 separate submitted patient notification documentation was provided; however, the applicant provided a link to their website; https://gmwearebettertogether.com/ with a specific link to information about secondary uses and research.

The National Data Opt-Out will be applied at the point Graphnet pseudonymises the care record. Every time updated de-identified data is loaded, dissent and dissent withdrawal codes will be checked and removed / added as applicable.

The CAG was impressed by the amount of information on the website, including the informative videos. The comprehensive notification was very good concerning the use of the shared care record for direct care purposes, and the Members also noted good options regarding translation and other languages. However, the Members noted that even though 's251' was mentioned on the website, it was not specific regarding what the breach of confidentiality actually is. The notification appears to only be about what has happened in the past, rather than what the applicant is proposing, and this needs updating to specifically describe the breach of confidentiality, and that 's251' is the legal basis for processing. The applicant is asked to provide to CAG an updated patient notification document in the format they expect it to take after 's251' support is in place.

As a DHSC policy position the National Data Opt Out is expected to be applied to all activities under 's251' support. However, a principle of support is that there is additionally an application specific opt out option communicated to patient. This is so patients have the opportunity of opting out of this specific activity without wider impacts to other activities. Currently the only opt out options appears to be either the National Data Opt, or the GM Shared Care record. There appeared to be no option for patients to opt out specifically of GMCR non-research or research uses. As such, Members requested that an application specific opt out mechanism for research is developed and communicated through the notification routes. References directing patients to the NDO should be removed.

It will also be important for the applicant to clarify the role of pharmaceutical companies, if any, in the information provided to patients, as there seems to be an inconsistency currently in the notification as compared to the application, as described above.

It was also felt that the notifications developed should not be only information on the website, there should be physical leaflets and posters produced, to develop a layered approach to notifying the population, in a similar manner to the public campaign, for example, including QR codes leading to further information on the website, and possibly posters developed to be displayed in GP surgeries or other healthcare areas.

Patient and Public Involvement and Engagement

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

The applicant has submitted a Communications & Engagement Campaign Report. The campaign was delivered between June 2021 and March 2022, and included extensive outdoor advertising and social media advertising, media and PR releases and communication materials delivered to via local partners. The engagement activity reached out to some of the diverse communities of Greater Manchester and selected based on previous insight around lack of trust in data sharing and those communities least likely to engage with the health and care system. This included older people, the South Asian and Black African/Caribbean communities and people living in deprived areas. Six focus groups were run online and face to face with over 80 people taking part to understand their views towards the GMCR.

The CAG was impressed by the huge amount of engagement work that had been done with varying diverse communities. However, the Committee were agreed that tis appeared to be mainly about the shared care record, and Covid-19 related research rather than any discussions regarding the breach of confidence and other research uses of data. Therefore, the Members requested for additional work to be undertaken with patients and the public, specifically focussing on the use of data without consent for the purposes of this research application. This is to provide assurance to CAG of

the acceptability of processing confidential patient information to create a deidentified dataset for research uses.

Exit strategy

It is understood that the deidentification process for individual patients will be ongoing in order to maintain the dataset. With regards to this application, a future SDE application is expected to be submitted which will supersede this application.

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. Please clarify the proposed relationship with pharmaceutical companies, including whether any data is proposed to be shared under the ‘s251’ support for this research database.

2. Please provide further examples of research questions that you wish to answer using this research database.

3. Please provide clarity on if the dataset contains social care data, and if so, exactly what data is included. If it is included, please justify the need for it within this dataset.

4. Please provide further information about how many lay individuals are in the GMCR Secondary Uses and Research Group (SURG), compared to other members.

5. Please provide an update terms of reference document for the SURG to include the assessment of medical purpose and public interest prior to agreeing any data release.

6. Please provide updated patient notification, which describes the breach of confidentiality for which ‘s251’ support is requested, with a GMCR specific opt out option, split out into non-research and research.

7. Please detail the notification strategies that will be used to inform the patient population regarding this activity. This should include wider notification methods than only the website.

8. Undertake additional work with patients and the public to establish acceptability of the uses of data without consent, for the purposes of this application to CAG.

9. Please provide a Favourable Opinion from the Research Ethics Committee as per standard condition of support.

Specific conditions of support (provisional)

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

1. Please provide a detailed report at annual review, (or SDE application if before), to provide data on activities undertaken, which will be reviewed at a full CAG meeting.

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

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

The NHS Digital **21/22** DSPT review for **Graphnet Health ltd** (8GX89) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 29 November 2022)

b. 22/CAG/0162 - Public health Wales: Adult rare disease register

Purpose of application

This non-research application submitted by Public Health Wales, sets out the purpose of establishing the Welsh Adult rare disease register – a systematic and comprehensive collection, registration and publication of population level data on rare diseases occurring in the adult population in Wales. Anonymous data collected under 's251' support may be used for collaborations with the EU rare disease platform in due course.

Applicants begun data collection in July 2020 on shielding conditions in adults, using the Covid-19 COPI notice as a legal basis for processing. The data collection began as a result of the pandemic, to identify patients with shielding conditions that had not already been included in the Health Protection response. The Welsh COPI notice Eich cyf (NHS Wales) expired 30 September 2022. Since 30 September 2022, the data

collection and processing has continued under the statutory authority provided by the Public Health Wales NHS Trust (Establishment) Order 2009, and therefore the current purpose of the registry is limited to health protection until ‘s251’ support is in place for further purposes.

This application for ‘s251’ support is therefore to establish the Adult rare disease register as a long-term surveillance registry and move beyond only pandemic related health protection functions to ‘health intelligence’ functions. This is in keeping with the established registry in England thereby providing equitable data collection in Wales, to that already collected in England, to support Welsh patients with rare diseases and Welsh clinicians and decision makers who need to provide services for these patients. This is currently on the National agenda with a National rare disease implementation plan and strategy.

Rare diseases are defined as having an incidence of < 1 in 2000 and also having a unique Orpha code assigned by Orphanet (European rare disease network) (https://www.orpha.net/consor/cgi-bin/index.php). The data collected will be used to assess:

1) The incidence of rare diseases

2) Time taken to diagnose a rare disease

3) Enable planning of Health Service provision for affected adults

4) Mortality / Life expectancy

Detailed epidemiological information about rare diseases is currently inadequate. The register aims to fill this gap in knowledge in Wales for both health professionals and patients; particularly for non-genetic rare diseases that currently have no screening programme or genomic testing. Accurate information on population incidence can act as a lever to ensure that services (NHS, third sector etc) are properly funded. An aim of the registry is for clinicians to use register data as a starting point for audit and evaluation of treatments and care. Patients and families will benefit from knowing about the incidence of disease and about improvements in diagnosis and life expectancy.

‘s251’ support is requested for the disclosure of confidential patient information from participating Welsh data sources to Public Health Wales NHS Trust in order for these to be linked to each other to create a Welsh adult rare disease register. Alongside the identifiers applicants will collect a description of the disease (from clinical portal), the ICD10 code for the disease, the Orphanet code for the disease, time of first diagnosis, date of any surgery, date of death, and any relevant co-morbidities. The prime data source to date has been through inpatient data. A request is made for data on a particular disease or group of diseases to DHCW. The data is transmitted as an excel spreadsheet from DHCW to PHW through a secure data portal and downloaded. Updates on existing registered diseases are requested annually. The number of new

inpatients is likely to be small over 1 year as these are rare diseases. Named patient data may be released to treating consultants for audit purposes.

A recommendation for class 3, 4, 5 and 6 support were 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	Applicants calculate around 186,000 people in the Welsh population to potentially have a rare disease during the course of their life
Data sources	1.Public Health Wales: a. CARIS 6-06 (b)/2014 – Congenital Anomaly Register and Information Service for Wales - transfer of cases to the Adult rare disease register for those cases diagnosed as children and previously registered with the Congenital Anomaly & Rare disease Register upon reaching their 18th birthday. 2. Cardiff & Vale University Health Board a. SHIRE – Medical Genetics database 3. Clinical Portal Systems (Electronic medical records) – from all Welsh Health boards. a. Betsi Cadwaladr University Health Board b. Hywel Dda Health Board c. Swansea Bay University Health Board d. Cwm Taff Morgannwg Health Board e. Cardiff & Vale University Health Board f. Aneurin Bevin Health Board g. Powys Teaching Health Board. 4. Digital Health & Care Wales (DHCW) – a. Inpatient data (Patient Episode Database Wales) b. Welsh Demographic Service

	5. Speciality data sets maintained by interested consultants (e.g. endocrine & metabolic, rheumatology, immunology etc) – Some consultants / departments keep their own records / databases on their patients. Mostly this will be at a centre of expertise such as Cardiff & Vale in Wales but other centres across England where Welsh patients might be referred. E.G. the endocrinology team at University Hospital of Wales, Cardiff keep a database on patients referred to them and require their expert treatment. Therefore, these data sources could be from all Welsh Health boards/potentially English centres. 6. Patient led disease specific registers -– These are third sector sources, where charities, and other patient groups collect data on their members to highlight that particular disease and its challenges.
Identifiers required for linkage purposes	1. Patients full name 2. Address at time of registration including postcode 3. NHS number 4. Date of birth 5. Gender 6. Ethnic origin 7. Hospital number 8. Date of death 9. Date of diagnosis
Identifiers required for analysis purposes	1. Address at time of registration including postcode – applicant has stated required for analysis, but has also stated '*The postcode will be used to link to the Welsh Index of Multiple Deprivation (WIMB)*' 2. Date of birth 3. Gender 4. Ethnic origin 5. Date of death 6. Date of diagnosis

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 assured of the public interest in this activity.

The CAG requested the applicant to clearly restate their medical purpose, by articulating better the purposes aside from shielding, as much of the information provided in the application concerned Covid-19 and shielding, which are no longer relevant. It was clear that the purposes now will cover the evaluation of treatments and care of those individuals with rare diseases, however the Members considered this was inadequately expressed. The committee therefore requested the applicant to provide a restated medical purpose, putting more emphasis on how this application would be beneficial to rare disease groups.

Scope

The CAG was unclear on the scope of 's251' support required in terms of data flows and data sources. This was particularly with regard to '*speciality data sets'* from interested consultants. It was not clear who these consultants are, what the data sources are, or how the applicant would become aware of these data sources, how the process would work or how the data would flow. As 's251' support is given for specific flows from specific sources, further detail is required about these sources in order to be able to recommend support for this application.

The Members also required clarity around; '*Patient led disease specific registers - third sector sources, charities, and other patient groups.'* It is currently unclear what these sources are, although there are comments in the application about '*Behcet's Disease Society'* and the data flow diagram states the '*CF registry'*. The applicant is asked to identify these sources, describe what data is being provided, how the data is being transferred to the applicant, and confirmation whether 's251' support is required for these flows, or if this is undertaken with consent.

The Committee were also unclear regarding the scope of 's251' support required regarding self-referrals. How would people know to refer themselves? Does this require 's251' support or is this a consented flow?

The Members stated that for any resubmission, an updated comprehensive list is required of all the data sources that will contribute to this register, being especially clear on the role of individual consultants, charities, and self-referrals.

The resubmission should also provide an amended data flow diagram, which clearly displays all the specific data sources which make up the registry, and outlines all the links and flows between data sources, clearly stating the common law legal basis for each flow.

Research

As part of the application, the applicants mentioned sharing anonymous data collected under ‘s251’ support with external researchers for research purposes. However it is noted by CAG that this non-research application is not sufficient for that purpose, and the applicant is advised to submit a corresponding research database application to CAG and a Research Ethics Committee if they wish to use the data for research purposes.

Practicable alternatives

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

- **Feasibility of consent**

The applicant reasons that epidemiological surveillance and monitoring of rare diseases is dependent upon high quality data usually held by a register. A register can only achieve adequate levels of completeness if it collects data from multiple sources. Many reliable and valuable notification sources involve little or no direct contact with patients, which makes obtaining explicit consent impracticable. The CAG was content that consent was not a feasible option.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to avoid double counting and for validation, which is particularly important for diseases with low incidence. Identifiers are also needed so that the register can link to other datasets.

CAG were content that using anonymous information was not a practicable alternative.

Justification of Identifiers

The CAG queried the amount of confidential patient information proposed to be collected for this register. The Committee wished to remind the applicant that by law, CAG must support the minimum set of identifiers required. This amount of data items did not seem to be the minimum for the required purpose, and therefore in any resubmission, the CAG would require clear justification as to why each identifiable data item is required.

‘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 did not provide patient notification for this application. However, when queried, the applicant confirmed the intention to update their website once all permissions were in place, as well as an opt out option, but did not provide any further materials. CAG recognised that the National Data opt Out does not apply to Welsh patients.

The CAG members requested the patient notification materials that will be displayed on the website are provided in a resubmission. This should clearly state how participants can specifically opt-out of the register. Members noted this opt out option would be particularly important, as there is no national data opt out option available in Wales. Furthermore, the CAG requested for the notification to be discussed with patient and public involvement representatives.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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.

Prior to the meeting the applicant confirmed that no patient and public involvement has so far been undertaken. Reference to the Rare Disease Implementation Group (RDIG) was made and that patient representatives are also members of this group, but there was no further information regarding this group.

It was therefore not clear to the CAG what patient and public involvement had been undertaken, as it appears that some organisations may have been spoken to, but it was not clear if actual patients were included in any discussions. It was not clear if the use of confidential patient information without consent had been discussed and CAG members stated the current level of detail was inadequate.

In any resubmission, the CAG requested public and patient involvement should be undertaken, with a proportionate amount of patients (representing different rare diseases), specifically to discuss the use of identifiable information without consent for the purposes of this register, and additionally aid the applicant with reviewing the patient notification documents as stated above.

Exit strategy

There is no exit strategy, as the applicant states this is required in an ongoing fashion. The CAG would therefore provide 's251' support for 5 years in the first instance, and a duration amendment would be required at that time if continued support was required, as per other similar registries.

Confidentiality Advisory Group advice conclusion

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

Following advice from the CAG, the Secretary of State for Health and Social Care recommended that the application was **deferred**.

Further information required

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

1. Restate the medical purpose, ensuring that this is expanded outside of shielding purposes, and putting more emphasis on how this activity would be beneficial to rare disease groups.

2. Please note that if the applicant wishes to use any data collected under 's251' support as part of this application, for research purposes, the applicant will require a separate research database application, which would also require a Favourable Opinion from a Research Ethics Committee.

3. Provide clarity on who the charities, self-referrals and interested consultants are, and explain how the process would work. As part of this explanation, a comprehensive list of all data sources that make up the registry should be provided.

4. Amend the data flow diagram to clearly show all the data sources, organisations involved, and which data flows require 's251' support.

5. In any resubmission, please provide revised justification as to why each identifier is necessary.

6. Please develop patient notification documents, that provide an opt out for the register. These documents should be reviewed by patient and public involvement representatives.

7. Please undertake public and patient involvement, specifically surrounding the use of confidential patient information without consent.

Once a new application 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 application onto the next available meeting.

c.22/CAG/0163 - Real Time Suicide Surveillance System (Wales)

Purpose of application

This non-research application submitted by Public Health Wales, sets out the purpose of continuing to develop a Real Time Suicide Surveillance System (RTSSS) for Wales, in order to inform suicide prevention across Wales, and for ongoing monitoring of the impact of the pandemic on suspected suicide deaths. Reports will be provided to partners including the Welsh Government, police lead and public health teams, and an annual surveillance report will be published on the website. The RTSSS can also be used in instances where a public health concern has arisen, or to answer specific ad hoc requests.

The Welsh Government (Mental Health and Vulnerable Groups policy team) commissioned a national repository for (suspected) suicides within the Public Health Data, Knowledge and Research directorate in Public Health Wales, and the RTSSS for Wales was established in Public Health Wales from 1st April 2022, without the use of confidential patient information. However the applicants are applying for 's251' support to undertake the RTSSS because it has become clear that confidential patient information was required to ensure duplicates are not created, to link new information to existing records, and to request further information from other sources.

's251' support is requested to allow identifiable information to be disclosed from Health boards to Public Health Wales about patients who die where the event that led to their death was a suspected suicide attempt. Information from the NCCU will be provided about deaths from suspected suicide of Welsh residents who die in commissioned services outside of Wales. Information from mental health services and other health services about patients who have died by suspected suicide with information on their medical and mental health history, and use of medical, mental health and substance misuse services at the time of death and 12 months prior will be provided. Confidential patient information may be provided from prison services, and from ONS. Data from the police and the media will be provided, but this is not in scope for 's251' support as it is not confidential patient information. HM Coroner will also provide data which is out of scope for 's251', as it is in the public domain. Data will be de-duplicated and linked together. English RTSSS systems are also planned to be data sources for the RTSSS however details are not yet known and will be included as an amendment later.

PHW may request additional data from other data sources. To undertake the 2-way flow, name and DOB will be inputted to Welsh Demographic Service Dataset (WDSD) controlled by DHCW, via secure login to obtain NHS number. NHS number is inputted to Welsh Clinical Portal (WCP) controlled by DHCW, via secure login to obtain clinical information. Name/DOB/NHS number is disclosed to Welsh health board/GP via password protected file via email to obtain further clinical information, or to English Trusts. Name/DOB is disclosed to HMPPS via password protected file via email to obtain information on sentence length/ probation status. 's251' support is

required for this flow, but not the flow back, as that would not constitute patient information. Name/DOB disclosed to HM Coroner via password protected file via email to obtain information on inquest conclusion. ‘s251’ support is required for this flow, and the flow back, as the information flowing back would not be publicly available and would constitute confidential patient information.

PHW require further support for flows relating to data validation, which are not mentioned in the application, only in the data flow diagram, submitted as a result of CAT queries. PHW will disclose date of death, age, health board of residence and health board of location of death to NHS Wales Delivery Unit where an individual was known to mental health services in order to validate against Nationally Reported Incident held by the DU. If missing cases are held by the DU, further information is sought from the Police. ‘s251’ support is required for the flow of confidential patient information to the NHS Wales Delivery Unit, and the police, but not for any flow back. PHW will disclose date of death, age and location of death to the British Transport Police in order to validate against BTP data. If missing cases are held by the BTP, further information is sought from the local Police force. ‘s251’ support is required for the flow of confidential patient information to the BTP, and the police, but not for any flow back. PHW RTSSS will disclose name and date of birth Child Death Review Programme, also held by Public Health Wales, to validate against CDRP data. If missing cases are held by the CDRP, information is saved in secure file location on the PHW network and information is uploaded to the RTSSS database. ‘s251’ support would be required for this disclosure and any corresponding inclusion into RTSSS.

A recommendation for class 4, 5 and 6 support were 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	Suspected suicide deaths of individuals who die in Wales (Welsh residents and non-Welsh residents) & Suspected suicide deaths of Welsh residents who die elsewhere It is anticipated that around 300-350 deaths will be reported to RTSSS per year. Electronic data on suspected suicides from 1st April 2022 are stored in the RTSSS database However support is only relevant for data collected after ‘s251’ is in place.

Data sources	Initial disclosure:
	
	• Primary care or health boards in Wales or Trusts in England if death occurred there (including Critical Care Units, Mental Health Services, Substance Misuse Services)
	• National Collaborative Commissioning Unit hosted by Cwm Taf Morgannwg University Local Health Board
	• HM Prison and Probation Service in Wales
	• Office for National Statistics
	
	Follow up information:
	
	• General practitioners · Welsh health boards/English Trusts/ mental health services /substance misuse services
	• Digital Health & Care Wales (DHCW)
	  ○ Welsh Clinical Portal
	  ○ Welsh Demographic Service Dataset
	• HMPPS
	• HM coroner
	
	Data validation:
	
	• NHS Wales Delivery Unit (Nationally Reported Incident data)
	• British Transport Police
	• Public Health Wales (PHW) - Child Death Review Programme
	
	Processors not in scope:
	
	• 4 Welsh Police forces (not in scope for ‘s251’)
	• Senior coroners in Wales or England (not in scope for ‘s251’)
	• Media

Identifiers required for linkage purposes	1. Forename 2. Surname 3. Date of birth 4. Date of death 5. Address 6. Postcode 7. NHS number

Identifiers required for analysis purposes	No identifiers required for analysis, except occasionally, Full date of death (Only month and year of death for the majority of analyses. However, for any potential suspected suicide cluster investigation, it may be possible that applicants would need to produce a chart showing dates of death, for a very limited audience (i.e. Directors of Public Health and multiagency professional members of a cluster response group).

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 was strongly in the public interest.

Scope

The applicant confirmed that RTSSS English sources are currently not in scope for 's251' support and will be included as amendments if required.

The CAG requested confirmation from the applicant that the activities in this application are all 'non-research' purposes, and not 'research'.

The CAG accepted the confirmation of the scope of 's251' support required from the applicant, however Members noted that the submitted data flow diagram does not exactly match the scope of support requested. Members requested this is updated to match the description and that the legal basis under common law for each flow is labelled, so it is clear which flows are being undertaken with 's251' support.

Data sources

The Members wished the applicant to clarify what the legal basis under common law is for the Child death review Programme, controlled by Public Health Wales.

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 some of the two-way flows appear to be sending confidential patient information both ways, however it should be possible for the applicant to send

a pseudonymised ID of the suicide register number to each organisation alongside the identifiers, and for the organisations to remove the direct identifiers prior to sending it back to the applicant, with only the pseudonymised ID in place. The CAG requested if this could be undertaken, or clarification as to why this could not be done.

- **Feasibility of consent**

The cohort are deceased. The applicant has stated that for health professionals seeking consent from family members for data to be shared with the RTSSS at such a traumatic time is inappropriate. However, it is not possible to gain consent from family members under common law, unless the particular family members are also the legal representative. The applicants have confirmed they understand this.

The CAG was content that consent was not a feasible option, as the cohort are deceased.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to ensure duplicates are not created, to link new information to existing records, and to request further information from other sources. CAG was content that using anonymous information was not a practicable alternative.

Justification of identifiers

Full date of death will enable RTSSS to identify patterns and trends of characteristics and modifiable factors in order to inform suicide prevention activities. Only month and year of death will be required for the majority of analyses. However, for any potential suspected suicide cluster investigation, it may be possible that applicants would need to produce a chart showing full dates of death, for a very limited audience (i.e. Directors of Public Health and multiagency professional members of a cluster response group).

The CAG queried whether the applicant planned to retain full date of death for all participants in the RTSSS (despite not requiring it for all analyses). If so, the CAG noted they would be supportive of this. The applicant is to confirm if there is a time point at which full date of death could be deleted.

However, the Members noted that as the participants are deceased, all identifiers (aside from date of death) should be anonymised and removed after de-duplication and linkage, as there would be no further linkages required. If this is acceptable to the applicant, the applicant should confirm a timeframe for deletion. If the applicant wishes to retain identifiable information, justification as to why, should be provided.

'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 did not provide CAG with any patient notification due to the cohort being deceased. Application specific opt out is also therefore not possible.

The National Data Opt-Out would apply to English residents. If applicants sought information from a health service body regarding an English patient and the Data Opt Out was stated on their record, the individuals informaiton would be removed.

Although, the relevant population is deceased, there is information for the general public on the Real Time Suicide Surveillance System on the Public Health Wales website. Real Time Suicide Surveillance System - Public Health Wales (NHS Wales)

The CAG were content that there was no notification for patients, however as the applicant is notifying the general public about the application, the CAG requested that the website have some more detailed information about the data sources and flows which are happening under ‘s251’ support, and the legal basis under common law for the creation of the RTSSS should be explained.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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.

No patient and public involvement and engagement activities have been undertaken to discuss the use of confidential patient information without consent. The National Advisory Group on Suicide and Self harm prevention includes members of third sector organisations as well as members with a personal history of bereavement by suicide, so this group could be approached to gather views on the use of confidential patient information without consent, as suggested by the applicant.

The CAG requested that the applicant engage with families managing bereavement, to discuss the acceptability of this use of confidential patient information without consent.

Exit strategy

‘s251’ support is required in an ongoing fashion, as the RTSSS will be continually collecting data on new cases. The CAG would provide 's251' support for 5 years in the first instance, and a duration amendment would be required at that time if continued support was required.

However, the CAG felt that an exit strategy from ‘s251’ support for individual’s data should be possible, as is explained in the section above regarding justification of identifiers.

Home working

The CAG requested confirmation that staff who access confidential patient data from their homes are accessing data via a VPN (Virtual Private Network).

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 Secretary of State for Health and Social Care 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. Please confirm that this application is for non-research purposes, and that no corresponding research application is required.

2. Please submit an updated data flow diagram, with the common law legal basis for each flow of data clearly labelled so it is clear what ‘s251’ support is requested for

3. Please clarify what the legal basis under common law is for the Child death review Programme, controlled by public Health Wales

4. Please consider minimisation with regards to the two-way data flows, and confirm if the flow can be undertaken with only a pseudonymous ID, or provide justification as to why not.

5. Please confirm if you plan to retain full date of death for all participants in the RTSSS. Please confirm if there is a time point at which full date of death could be deleted.

6. Please confirm if all identifiable information (aside from date of death) can be deleted from an individual’s RTSSS record after de-duplication and linkage. If so, please confirm a timeframe. If not, please provide justification.

7. Please update the website with more detailed information about the data sources and flows which are happening under ‘s251’ support, and the legal basis under common law for the creation of the RTSSS should be explained.

8. The applicant should engage with families managing bereavement, to undertake patient and public involvement to discuss the acceptability of this use of confidential patient information without consent.

9. Please confirm that staff who access confidential patient data from their homes are accessing data via a VPN (Virtual Private Network).

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. ‘s251’ support will be provided for five years in the first instance. A duration amendment will be required at that time in order to extend support.

2. RTSSS English sources are currently not in scope for ‘s251’ support and will be included as amendments if required.

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

Public Health Wales is confirmed as meeting the standards required by the Welsh information governance team.

Due to the number of participating organisations involved it is the responsibility of Public Health Wales, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, or the Welsh equivalent, and take remedial action if they become aware of any that fall below this, or where any concerns are raised

5.Re-submitted Applications

a.22/CAG/0171 - Ambulance Data Set – Returning linked patient outcome data to Ambulance Services (non-research)

Purpose of application

This non-research application from NHS England, sets out the purpose of providing a flow of linked Emergency Care Dataset (ECDS) and Ambulance Data Set (ADS) data back to the to the eleven English Ambulance NHS Trusts to inform individual clinical development plans and wider Ambulance Service operational and clinical improvement strategies.

There is a legal direction in place to flow data collected by Ambulance Trusts to NHS England (previously Digital), to create the ADS. Additionally, this legal direction covers linkage between ECDS and ADS, which is already undertaken and does not require 's251' support. Separately to the flow of data to Ambulance Services, under the joint NHSE/NHSD commissioning arrangements, the NHS England and NHS Arden & Gem CSU (DSCRO) is also able to receive and link identifiable patient information (ADS data) with other datasets, (e.g. ECDS) and apply its own pseudonymisation key before flowing the data to the National Commissioning Data Repository (NCDR) (a web based application developed by Arden & GEM CSU on behalf of NHS England). This is out of scope for this application. The only element of the application that requires 's251' support is an identifiable flow of linked data from the DSCRO to the 11 ambulance Trusts. The only identifiers used are CAD ID and call sign, so that the patient outcome can be linked to the initial treatment episode. NHS Digital have confirmed 's251' support is required for this flow, as the ambulance Trusts will be able to re-identify the patient using the CAD ID and call sign.

The ambulance services provide care to 25,000-40,000 patients per day. These organisations are publicly funded and there is a moral and fiscal responsibility to ensure that these services are allocating their resources appropriately. A major barrier to this is that resources are allocated based upon predictions of what type of care a given patient will need, however there are no reliable means by which this prediction can be correlated with the actuality of the care needed. It is therefore important to be able to review resource allocation and care provided in the context of further care provided once a patient is admitted to hospital. This application will use linked outcome data to analyse patterns, which will aim to inform development needs and best practice identification.

Once received into each of the 11 Ambulance Services, the ECDS data will be kept in a separate table within data warehouses so won't form part of the main patient record, but by holding the data CAD ID and Call Sign this will enable linkage to the existing

patient record. The CAD ID and Call Sign will be retained in this separate table to ensure that the correct episode of care is linked in cases where there are multiple patient contacts over a short period of time. These records will be managed in line with the national NHS data retention policies.

Regarding informing individual clinical development, the provision of linked data will allow ambulance service clinicians to continue to build on their confidence, competence and knowledge to improve the delivery of care to patients through the understanding of the impact of their own clinical practice on the patient outcomes through the clinical supervision process. Benchmarking clinician activity will also allow understanding of where additional skills development and mentorship is available; whilst reflective practices are helpful for clinicians, understanding of their performance on an aggregated level against their peers will support targeted training interventions. Benchmarking clinician activity and involvement in point of care delivery will allow understanding of the following examples:

- Where clinical skills have been delivered for patient benefit and where opportunities may exist to improve (e.g. gaps in skill set offered, gaps in individual practice and where mentorship, clinical supervision or additional practice support would be beneficial)
- indicators, aggregated peer or team data and other KPI or regulatory requirements.
- Monitoring of clinical care given to patient cohorts and the development of evidence-based practice/interventions for patient benefit
- Inform wider work on service delivery model evolution
- Inform the management of complaints, potential serious incidents or other enquiries that relate to clinical care delivery by clinicians

Regarding wider Ambulance Service operational and clinical improvement strategies, Business Intelligence Teams will be able to undertake pattern analysis to understand if clinical behaviours are consistent for patient cohorts and across treating clinicians, as well as treatments administered by the Ambulance Service. This will allow organisational planning and ensure that patient presenting with similar conditions and requirements are receiving interventions and treatments that consistently best meet the needs of patients. The application will support the identification of gaps in provision at a local level, and will provide a stronger evidence base to work collaboratively with commissioners understand where changes to patient pathways within particular areas would benefit patients and reduce pressure on busy Emergency Departments (ED), one of the key areas of interest from Health Ministers and the Secretary of State.

For example, by linking the diagnosis to the presenting symptoms, the ambulance Trusts will be able to identify better systems for identifying those conditions which require urgent medical attention and refer future patients to the correct care pathway, e.g. stroke and cardiac arrest. Likewise, if Ambulance Trusts are able to identify that certain subsets of patients with the same patterns of presenting symptoms are often not admitted to hospital or discharged very quickly, then A+E attendance could

potentially be avoided for future patients presenting with those symptoms, which would benefit all parties, including the patient.

The pattern analysis will support senior leadership to understand if operational practices and systems are consistent for patient cohorts and clinicians. Some examples are below:

- Understanding patient destination following conveyance, and if it differs from the ED to inform service and pathway development (e.g. where a patient is conveyed to ED but then direct streamed at ED triage to another co-located service or department).
- Patients conveyed by Ambulance Services with time critical and time sensitive illness are prioritised for care and handover accordingly
- Treatments or therapies that may be administered by ambulance service that could be improved or changed
- Understanding of any simple assessments, treatments and other investigations that can be 'front loaded' to optimise subsequent assessment and treatment of Ambulance patients e.g. where there are Ambulance handover delays.
- Identify opportunities for service improvement, operational efficiencies, and shared governance to inform better working for patient benefit

There is no intention to share individual level data outside of the ambulance services e.g. with commissioners, although summary outcomes of the data analysis may be shared to inform commissioning of care pathways and service improvements. The outputs will be made available in aggregated form through internally developed dashboards and data insights platforms for senior leadership teams within Ambulance Services to understand the current position and commission policy development to improve patient care. These dashboards will not disclose any personalised patient information.

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	All patients in contact with any of the 11 English Ambulance Services listed below, who go on to receive care through an NHS Provider that completes an Emergency Care Record through the Emergency Care Data Set (ECDS) and flows to NHS Digital.

	Approximately 5 million patients per year
Data sources	1. NHS England (previously NHS Digital) – a. Ambulance Data Set (ADS) collected from the following 11 Ambulance Services: i. East Midlands Ambulance Service ii. East of England Ambulance Service iii. Isle of Wight Ambulance Service iv. London Ambulance Service v. North East Ambulance Service vi. North West Ambulance Service vii. South Central Ambulance Service viii. South East Coast Ambulance Service ix. South Western Ambulance Service x. West Midlands Ambulance Service xi. Yorkshire Ambulance Service b. The Emergency Care Dataset (ECDS) collected from acute NHS hospitals.
Identifiers required for linkage purposes	• linkage between ADS & ECDS is undertaken with alternative legal basis • Linkage between ECDS and ambulance Trust clinical record; 1. ADS 3 Call Identifier –CAD ID (Unique number generated within the Ambulance Service 999 Operations Centre) - (direct identifier) 2. ADS 36 Call Sign - (Unique vehicle reference of ambulance service) (direct identifier)
Identifiers required to be returned to individual ambulance Trusts for analysis purposes	1. ADS 3 Call Identifier –CAD ID (Unique number generated within the Ambulance Service 999 Operations Centre) - (direct identifier) 2. ADS 36 Call Sign - (Unique vehicle reference of ambulance service) (direct identifier) 3. ECDS 20.1 Diagnosis 4. ECDS 21.1 Investigations 5. ECDS 22.1 Treatments 6. ECDS 23.1 Referred to Services 7. ECDS 24.2 Discharge Status 8. ECDS 24.4 Discharge Destination 9. ECDS 24.5 Discharge Info Given 10. ECDS Emergency Care Departure Time
Additional information	Ambulance Services will only receive data that pertains to records that were initially generated within their service It is proposed that this data will flow to Ambulance Services on no more than daily basis using linked data in arrears (e.g. Monday will flow the previous Monday)

	However, due to resource capacity and funding, delivery of the technical requirements can only be scoped and formally started following confirmation of 's251' support to the application. It is anticipated that the technical requirements could allow for scheduling of data sharing to able to be shared on a daily basis with a rolling 7-day time delay, so each day, data would flow for the same day of the previous week. However, if through development there is a technical/resource issue identified applicants may look to reduce the frequency of data flows to mitigate any technical challenges.

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 was agreed that this was in the public interest.

Scope

The CAG were clear on the general scope of the application, in that linked data would be used for the purposes of improving the quality of clinical care by allowing individual clinicians to use the data as an educational tool to enhance their clinical knowledge, and to allow Trust wide reviews to identify shortfalls in provisions.

However there were some purposes that required clarification. For example, the monitoring of individual clinical performance could be controversial to clinicians. It was stated that the combined dataset would be used in the '*management of complaints'.* However the Members were not clear what this meant, commenting that if this was to monitor trends, then that would fit within the stated purpose, however if this was actually using the linked outcome data to answer complaints, that would not fit within the CAG understanding of the purpose.

The CAG noted the applicants response to CAT queries regarding what happens to the linked data when it is returned to the Ambulance Trusts. However, as there appears to be contradicting information throughout the application, the applicant is asked to clarify this as part of the provisional response. The CAG would like absolute clarity on whether

the returned data is being linked and included into the main clinical record. The Members assume that it is not, based on the responses to CAT queries, however clarity is needed.

If the data is not being included into the clinical record, and a separate database is retained by each of the 11 Ambulance Trusts, for audit and clinician supervision purposes, then the format and access to this separate database needs to be clarified. Will this separate database include linked baseline ambulance data, including the free text notes made by the paramedic? Or will it contain only the ECDS data. It is also not clear who will be able to access this separate database. If the data is to be used for individual clinician performance and supervision, will access to the database be restricted to only when that clinician is in supervision? Or can the clinician look up a patient in the separate database whenever they wish. Is it only the treating clinician that will have access to the patient, or is it other paramedics who may not have been involved in the care of that individual patient. No information on any governance surrounding the 11 databases has been provided, for example, and access controls, restrictions, or if access logs will be used to state who has accessed the database and for what purpose. The applicant is to expand on these points as part of a provisional response.

The CAG did accept that these responses would be difficult for the applicant, due to Trusts only agreeing to work on the application if ‘s251’ support was in place, however a certain level of detail is required prior to any recommendation of ‘s251’ support, because ‘s251’ support is specific.

To assure CAG that the non-research uses remain within scope of purposes described in the application, Members requested a report regarding the uses of the data at each Trust at each annual review.

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 noted the need for complete case ascertainment, particularly for those who are acutely unwell. Ambulance services take approximately 12,500-24,000 cases to hospital per day across England, and therefore consenting (for the ‘s251’ supported element) at this time of emergency is impractical. The applicant has confirmed that consent will not be sought, as a response to the original deferred outcome. The CAG members were content with this response, and agreed that consenting was not a practicable alternative, as it would not be possible to undertake an informed consent process regarding the ‘s251’ supported element, at the time of the emergency call.

- Use of anonymised/pseudonymised data

Confidential patient information is required to enable the 11 ambulance Trusts to link the ECDS outcome information back to the initial treatment data. The Members agreed this could not be undertaken with anonymous data as an alternative.

'Patient Notification' and mechanism for managing dissent

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

The applicant has proposed a set wording which is planned to be included into each Ambulance Trust privacy notices, but has stated that this wording would be provided to Trusts who could then amend it. Whilst CAG recognise that individual Trusts have autonomy over what they put on their website, the CAG strongly recommend harmony between each Trust, and that the wording is recommended by NHS England as not to be altered. The wording of the statement is included as a response to CAT queries.

The CAG noted that the terminology of this privacy notice was not clear, for example; '*If you do not want any details of your onward care sharing with us'.* This should be specific with regards to what details of the persons onwards care entails. The Members stated the privacy notice did not make clear what the 's251' support is for, as it was not clear what legal basis covers which flow. The applicant is to re-write the privacy notice insert with more clarity and specificity regarding data items, data flows, and legal bases for each.

The CAG also felt that an excerpt in a privacy notice is not sufficient patient notification regardless of content. This view appears to be supported by patients, after discussion with Healthwatch Birmingham, who noted the issue that current Privacy Notices are often not widely accessed or understood by patients. The CAG recommend a layered approach, so having a link to further information within the privacy notices, which leads on to a separate more detailed account of the activity, maybe on a central NHS England website. Members also suggested posters in A+E or even inside ambulances could be a way to inform patients of the use of their data. As the cohort are only people who end up in A+E, it could be possible to display something in these areas which states 'if you have arrived by ambulance'.. and then describes the application, and how to opt out.

Alongside a layered notification approach, the Committee noted that as the cohort was so large, a national communications strategy should be undertaken, in addition to local communication routes, which the applicant has stated will include local stakeholder

briefings, updates to websites, bulletins, patient forums and engagement events. This could include social media, advertising campaigns, media articles, etc. The applicant is to provide a local and national communications plan for disseminating information about this application.

The applicant has confirmed that the National Data opt out (NDO) and an application specific opt out will apply, however as some of the flows are covered by legal directions, The NDO or specific opt out should not apply to ambulance data flowing into NHS Digital, or from NHS Digital to the DSCRO, as this is undertaken with Directions as the legal basis. The applicant has stated '*Ambulance Services are able to flag records where consent has been withdrawn to share details; this will prevent onward sharing of records to NHS Digital at the beginning of the process.'* However, the opt outs should not be applied at that point, but should be applied at the point of disclosure from DSCRO to the 11 Trusts only. This should be made clear on the patient notification documents, and the applicant is to confirm if it is possible for the DSCRO to apply opt outs centrally, prior to disclosure, both NDO and study specific.

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.

Following a consultation with the Association of Ambulance Services Chief Executives (AACE), it was agreed that a survey approach for each Ambulance Service to cascade through their established communication routes would be the most appropriate method of engagement on this subject; with a further offer of face to face/additional correspondence with the ADS Programme Team should it be required. A patient survey was therefore undertaken by each Trust, and further details are in the application. Responses from each ambulance Trust were received, reaching a total of 196 responses.

The applicant has stated that there was 90% positive feedback surrounding the use of confidential patient information without consent, however the CAG felt that most of the queries asked in the patient survey seemed to be surrounding the Ambulance Data set (covered by directions), direct care, and the benefits of linking data generally, but not necessarily clarity surrounding the specific breach of confidentiality, and if patients supported this specific use of data. The CAG also considered that the amount of patient and public involvement undertaken was quite minimal considering the volume of patients who would be included in the cohort. The application is requesting support regarding the breach of confidentiality for 5 million patients per year, and the patient and public involvement undertaken was with less than 200 people. The CAG felt this was not proportionate. It was felt that NHS England could undertake further patient and public involvement, with more individuals who represent the cohort, maybe as focus groups rather than a survey, that specifically discussed the breach of confidentiality in this application. Noting that the applicant has identified difficulties with identifying the cohort, and spoken to the entire population, however, the cohort is actually only individuals who have attended A+E via ambulance, and if defining the cohort in this way, it may be easier to source a more targeted patient and public involvement group.

Exit strategy

's251' support is requested in an ongoing fashion for the flow to the 11 Ambulance Trusts. Data is already very minimised as only CAD ID and call sign being disclosed back to ambulance Trusts, so the CAG understood that the only exit strategy from support for this continuous flow would either be stopping the flow, or using a different common law legal basis. Support is therefore recommended for 5 years in the first instance, with a duration amendment required at the time to extend if required. The applicant will continue to explore alternatives to 's251' surrounding potential changes to legislation around data sharing in line the NHSX Data Strategy, and through the legal merger of NHS England with NHS Improvement, NHS Digital, NHSX and Health Education England.

Regarding an exit strategy for 's251' support for each individual patient, the CAG were keen to explore if the applicant would be able to anonymise the received data after a certain length of time, for example a year? If the linkage between baseline data and received data had been undertaken, the Members did not see a reason for the CAD ID and call sign or any other identifiers to remain in the dataset.

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 Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

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

Request for further information

1. Clarify how the data will be used in the 'management of complaints', noting that CAG would not expect the data to be used in the investigation of individual complaints.

2. Provide absolute clarity on whether the returned data is being linked and included into the main clinical record.

3. Confirm what format the databases will take at each Ambulance Trust. Will these contain linked baseline data, and if so, what data?

4. Confirm who will be able to access the separate databases. i.e. is access restricted to only when a clinician is in supervision? Is it only the treating clinician that will have access to the patient, or is it other paramedics who may not have been involved in the care of that individual patient?

5. Provide any information you have on governance surrounding the 11 databases, including access controls and restrictions. The CAG recommend access logs to state who has accessed the database and for what purpose.

6. Regarding the proposed wording to be inserted into the 11 Ambulance Trust privacy notices, CAG strongly recommend harmony between each Trust, and that the wording as recommended by NHS England is not to be altered. Please can you confirm if this is possible.

7. Develop a layered approach to patient notification, including improving the proposed privacy notice text, and developing a more detailed patient notification document that can also be displayed on websites, which is specific to this CAG application, and provide all relevant documents to CAG for review.

8. Consider if developing posters for A+E is an option, and if so, please provide to CAG for review.

9. Please provide a communications plan that is both national and local.

10. Regarding application specific opt out and National Data Opt Out, please confirm if it is possible for the DSCRO to apply opt outs centrally, prior to disclosure. Please ensure the opt out options are clearly stated on all patient notification documents.

11. Undertake further patient and public involvement, with more individuals, maybe as focus groups rather than a survey, that specifically discusses the breach of confidentiality in this application.

12. Confirm if the separated databases can be anonymised after a year, once linkage between ambulance data and outcome data has been completed, to represent an exit strategy from ‘s251’ support regarding individual patients.

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, 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.Support provided for 5 years in the first instance, and a duration amendment will be required at that time to extend ‘s251’ support.

2.Please provide an update at each annual review, regarding the uses of the data at each Trust, to ensure NHS England oversight regarding the data being used at each Ambulance Trust only for the purposes described in the application.

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

The NHS Digital **21/22** DSPT review for **NHS Arden & Greater East Midlands Commissioning Support Unit (Arden & GEM CSU)** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 16 December 2022)

Due to the number of Ambulance Trusts involved, it is the responsibility of NHS England, as controller, to ensure that Ambulance Trusts meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a Trust.

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 Murat Soncul, CAG Alternate Vice-Chair	*12 December 2022*

Signed – Confidentiality Advice Team	Date
Mr William Lyse, HRA Approvals Administrator	*05 December 2022*