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

28 July 2022 – Via zoom

Present:

Name	Capacity	Items
Dr Tony Calland, MBE	CAG Chair	2a, 2b
Dr Patrick Coyle	CAG Vice Chair	2a, 2b
Dr Malcolm Booth	CAG Member	2a
Professor Lorna Fraser	CAG Member	2b
Mr Dan Roulstone	CAG Member	2a, 2b

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Professor Gavin Perkins	Applicant - Chief Investigator (item 2a only)
Jill Woods	Applicant - Quality Assurance Manager (item 2a only)

Adam de Paeztron	Applicant - OHCAO Manager (item 2a only)
Holly Robinson	Applicant - NPDA Manager (item 2b only)
Professor Justin Warner	Applicant - NPDA clinical Lead (item 2b only)

1. Introductions, apologies and declarations of interest

Dr Sandra Duggan, Ms Diana Robbins, and Mr Umar Sabat , CAG members, gave their apologies.

Regarding item 2b, Calvin Down, applicant (Head of Audits, RCPCH) sends his apologies.

Professor Lorna Fraser, CAG Member, notes that she sits on the RCPCH Health Informatics Committee with Calvin Down, an applicant for item 2b. she does not work with him or use the diabetes audit data so this was not considered a conflict of interest.

2. Consideration items - requests for National Data Opt-Out exemption

a. 22/CAG/0087 - Epidemiology and Outcome from Out of Hospital Cardiac Arrest. (OHCAO)

This is a request to defer the national data opt out for 22/CAG/0087, non-research application. University of Warwick undertakes Epidemiology and Outcome from Out of Hospital Cardiac Arrest Audit (OHCAO), with long term funding from the British Heart Foundation and Resuscitation Council UK.

The OHCAO application has been supported since 2013 as a research database (ECC 8-04 (c)/2013). The applicant has recently re-submitted to separate the application out to include a non-research application – 22/CAG/0087**.** The applicants have confirmed that the NDO will still apply to their research application (22/CAG/0072).

The applicant has previously requested an NDO exemption, from both the research and non-research applications, which was considered by CAG and rejected. However, the applicant was invited by CAG to re-submit regarding the non research

application only, to ensure fairness to all applicants as the CAG further developed the criteria for consideration.

Support is in place for disclosure of confidential patient information from participating NHS ambulance trusts to the University of Warwick for inclusion in the OHCAO database, and the disclosure of confidential patient information to NHS Digital for linkage to outcome data and the return of the linked dataset to the University of Warwick.

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 OHCAO.

1. Patient safety – the loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to track survival rates and target unwarranted variation, both before the ambulance arriving, and during hospital admission.
2. Introduction of bias – there are indications that the application of the NDO is not random so impacts the integrity of the data with the risk of insights being drawn, and subsequent recommendations made, that increase health inequalities.

1. Deferral rationale: patient safety

The paper set out a strong argument detailing the potential impacts on patient safety. This included how data is used to monitor performance. OHCAO is responsible for providing data to NHS England for the purposes of monitoring performance of NHS organisations and informing health improvement work and for commissioning purposes. Currently 30,000 lives are lost each year due to cardiac arrest and the registry has been able to benchmark that UK outcomes are much poorer than some other European countries, showing that there are still many improvements to be made. NHS England's Long Term Plan aims to save an additional 4000 lives each year by 2028, which will be informed by OHCOA outputs. Survival depends on three things; immediate CPR, early defibrillation, and post-arrest care in hospital.

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, and ambulance services 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. For example, the audit monitors the overall safety and effectiveness of ambulance services using outlier statistics of 4-6%. This is lower than the NDO rate of 7% in London, and therefore application of the NDO could mask any outlier findings with regards to key performance metrics such as how quickly ambulance services are recognising cardiac arrest and providing instructions to start CPR, and how effective ambulance services are at restarting the heart. Incorrect reporting of these key performance indicators mean that outliers will be missed, and improvements will not be made and there is the potential for lives to be lost.

Additionally, this non uniform variation of NDO application may mean that pre-hospital interventions are targeted incorrectly on certain geographical areas. For example, the placement of defibrillators may be skewed by not being able to correctly identify cardiac arrest hotspots to ensure that defibrillators are positioned in areas of greatest need. Similarly, resuscitation training may not be guided to the highest priority communities. These interventions have directly been shown to save lives. Therefore, application of the NDO may mask this ability to improve patient outcomes by reducing deaths due to Out of Hospital Cardiac Arrest (OHCA) that could otherwise have been prevented, if the correct geographical hotspots and areas of need could be identified. Application of the NDO would restrict the potential benefits of local quality improvement initiatives for individuals who have an OHCA in the future, whether they have or have not opted out.

Application of NDO would also 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. For example, the audit has shown that the incidence of cardiac arrest is higher in deprived communities and those with a higher proportion of residents in minority groups. These communities also experience lower rates of bystander CPR and have less access to public access defibrillators. There also appears to be systematic bias in relation to where national community CPR initiatives are targeted – with those with the greatest need having lower access than white, affluent communities. This is explained further in the bias section below.

Members were supportive of exempting the NDO regarding the non-research elements of the audit, due to the strong patient safety impact, which is strongly linked to arguments surrounding bias, which is expanded on below.

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. The applicant specifically cites working age population, females, and non-white populations with a higher NDO uptake. The applicants note that opt-out rates range from 0% in some GP practices through to 87% in other practices, and variation is also present at a regional level with the rate in London being nearly double the rate observed in Yorkshire (7% versus 4%).

Any omission by NDO would introduce bias to the findings and impair efforts to monitor and improve outcomes in critical healthcare settings. 100% case ascertainment is critical so that quality improvement plans can be implemented and informed by robust data. The completeness and accuracy of OHCAO data is key for use in the planning, evaluation and development of services in the NHS. The applicant confirmed that actual case ascertainment is 100%.

Applicants model the effect of the NDO using data opt out figures from NHS digital regarding individual GP practices with high opt out rates. This shows huge variation in the number of cardiac arrests in the respective practice area if the NDO was applied in these cases, showing that only 12 out of a possible 52 patients would have been included in OHCAO. This is a loss of around 75% of data. The Members noted this is clearly very damaging to the audit, but also commented that the number of GP surgeries affected in this way would probably number 1-2% of the data across the whole audit, and therefore also required evidence of bias at a wider geographical level. The applicants presented evidence to CAG regarding the effect of wider regional variation, for example the higher than average 7% London NDO rate being greater than the key performance indicator rates to identify outliers, and also an argument presented in the previous paper which was not presented during the meeting; applicants previously provided evidence from Blackpool Clinical Commissioning Group (CCG) area. The 10.3% rate of opt out in Blackpool is double the national average. Data from the OHCAO registry have highlighted that Blackpool is a cardiac arrest hot spot, characterised by a high incidence of cardiac arrest, with low bystander CPR rates and poor access to community defibrillators. The

proportion of people in the North West region who have never received training in CPR is high (44% versus national average 39%). If the NDO was applied, it is possible that these effects would not have been identified nor proposed improvements made.

Regarding health inequalities, NHS Digital's equality and impact assessment for the National Data Opt-Out highlights that that people from ethnic minorities are more likely to opt-out. The applicants' analysis also shows that a higher proportion of GP practices from deprived areas opt-out. Deprivation and ethnicity are risk factors for cardiac arrest, and it is therefore a concern groups with existing health inequalities relating to risk of cardiac arrest will be disproportionately affected due to higher opt-out rates. Information regarding those who are most at risk will disproportionately not be recorded, and therefore this will reduce the ability of OHCAO to quantify their existence and put in place interventions to mitigate those risks. Therefore health improvements will not be targeted where they are most required, which risks worsening already existing health inequalities for those groups who are most at risk of cardiac arrest.

Therefore, Members were convinced that application of the NDO would cause an additional significant amount of bias.

Members were supportive of exempting the NDO regarding the non-research elements of the audit, due to the impact of bias, as there is 100% case ascertainment currently, and this bias would adversely affect patient safety, and health inequalities, as described above.

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 plan was also provided. The applicant has plans to disseminate this informaiton to ambulance

services, charities, and the public as far as possible. Plans include an annual press release. The applicants do not wish to undertake a media campaign, as this was previously shown to be expensive and ineffective in this cohort, noting that over 90% of the cohort will be deceased.

Members were broadly content with the updated notifications provided.

However it was commented that although the notifications did a good job at explaining what was happening, more could be done to bring out the key messages from the text for individuals who may not wish to read lengthy sections of text. The CAG therefore recommended developing a poster, which should have input from patients and the public.

Patient and public involvement

The CAG noted that although the applicant has provided extensive supportive letters from relevant charities, it was not clear if the applicants had actually discussed the non-application of the NDO with any patient and public representatives directly. The CAG commented that although the charities may include patients, it was in the best interest of the charities that the registry was as complete as possible, and the supportive letters may form a slightly biased view. The applicant is therefore required to undertake some patient and public involvement with 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 very 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.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, members agreed that the patient safety rationale and bias issues were very 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 22/CAG/0087.

2. A local patient objection mechanism must continue to be used in relation to 22/CAG/0087.
3. Please provide a poster to inform the relevant cohort about OHCAO and that the NDO will not be applied. This should be developed with PPI input, and should be provided within 3 months from the date of this letter.
4. Please provide feedback of further discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, within 3 months from the date of this letter.

b. ECC 2-03(c)/2012 - National Paediatric Diabetes Audit (NPDA)

This is a request to defer the National Data Opt-Out for ECC 2-03(c)/2012. Healthcare Quality Improvement Partnership (HQIP) commission the Royal College of Paediatrics & Child Health, to undertake the National Paediatric Diabetes Audit (NPDA).

NPDA has been collecting data since 2003, and was originally undertaken by the NHS Information centre. Since 2012, RCPCH have undertaken the audit, under ‘s251’ support, with consistent submission of annual reviews since that time.

NPDA has existing support to collect confidential patient information on children and young people treated for diabetes. Support is also in place to link to NHS Digital outcome data.

Confidentiality Advisory Group advice

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

3. Patient safety – The NDO presents a significant risk to the future success of the NPDA and continuing improvements to patient care, and would fail to identify when patients miss key health checks.

4. Introduction of bias – the applicant assumes that the application of the National Data Opt Out will be evidenced in the future as not being random, and will impact the integrity of the data.

5. Technical impacts – the increased workload on front-line NHS staff would cause staff to stop uploading cases in real time.

1. Deferral rationale: patient safety

The applicant provided some examples of how the NPDA improves patient safety overall, including monitoring of Trust service performance to assure safety and standards of clinical services, for example supporting national improvements in HbA1c levels amongst children and young people, and facilitating improvements in health check completion rates. The applicant also commented that they report to CQC on outlier status for key audit measures, but did not explain how application of the NDO would bias these outlier reports.

The main patient safety argument put forward by the applicant was that for some trusts, the NPDA data capture system is the only electronic patient record (EPR) system available for them to record diabetes-specific care and outcomes, and to track outcomes and care delivered. Patients in these services opting out of this system will be at increased risk of missing key health checks, as they will not be entered into the data capture system.

However, the Members did not feel that the application gave sufficient detail of the potential effect that applying the NDO would have on patient safety. Questions to the applicant at the meeting elicited further information on this.

Members clarified with the applicant that the majority of Trusts use the NPDA data capture system as their main method of assuring that key health checks were made. The applicants answered that they assumed that it would be 90% or more of Trusts,

commenting that it was only Leeds that had an appropriate equivalent. The applicants commented that the NPDA database would inform clinicians which individual patients require which health checks, but if the NDO was applied, those patients would not benefit from the correct tests. CAG request further clarification/confirmation surrounding the number of Trusts which use this database for this purpose. The Sub-Committee also asked specifically how patients who opt out of the NPDA locally are clinically followed up, as this would be the same mechanism for those who applied the NDO. The applicant was not sure how their care is managed currently, and how it is affected by not being in the NPDA database.

2. Deferral rationale: Introduction of bias

The applicants are not able to model the impact of the NDO on NPDA data as there is not a comparable routine dataset available. They also state that they have not seen any data on breakdown of opted out patients by demographic or by Trust, but assume an unequal take up will ultimately be evidenced. A generic argument is therefore made surrounding incomplete data lessening the utility of NPDA 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 paediatric diabetes specifically, or any types of people at particular risk who may or may not apply an NDO. The applicants have not detailed in the paper why a loss of a small amount of data will make a large difference, specifically to patient safety or health inequalities. They have stated that case ascertainment is difficult to estimate, but likely to be within 3% of GP record data.

In the meeting, the applicant clarified that any non-random trends in geography or patient demographics of those who apply an NDO would affect the NPDA data. The applicants reasoned that any variability or inconsistency in the application of the NDO across the country would render the last 12 years of longitudinal data unusable, as applicants would not be able to compare the datasets to each other. The CAG asked for more information about how this variability might be skewed to particular groups, which may cause a particular problem for the NPDA. The applicant commented that children from more deprived areas, or from ethnic minorities may have higher risk of developing diabetes, specifically noting that NHS England aims to improve access to modern diabetic monitoring technology specifically for ethnic minority individuals. If these individuals disproportionately opted out, then monitoring this may be skewed, and improvements would not be able to be made, which would further increase health inequalities.

Although the CAG were interested in the justifications provided in the meeting, the CAG agreed that sufficient information had not 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, and health inequalities, would be adversely affected by application of the National Data Opt-Out, and this should include the verbal arguments already stated in the meeting, but evidenced with statistics and modelling.

3. Deferral rationale: technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, in the form of additional administrative burden. The applicant reasons that the clinical teams are uncertain how, or if, they will be able to implement the NDO. The applicant is concerned that this may cause many clinicians to revert to doing one, annual submission of data at the end of the audit year, which would be a regressive step, and at odds with NHSE's request to provide real time data on key metrics.

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

Research

The applicants have confirmed that this application is only in relation to the non-research audit - ECC 2-03(c)/2012. However, it was noted as part of the query responses that there is a separate research CAG application with a different applicant that uses the NPDA data as a data source – 18/CAG/0002. The CAG would like to make it clear that if the NPDA application did receive an NDO exemption, this would not apply to 18/CAG/0002. The research application, 18/CAG/0002 would be expected to have the NDO applied to the NPDA data prior to receipt, or apply to CAG separately to request exemption from the NDO.

Refreshed application

As part of the NDO exemption application, Members examined the current patient notification materials, and current local opt out. It was not clear to Members if a local opt out option was clearly displayed to the cohort. The materials state that if the patient or parent has any questions or concerns, they can contact the clinical team, but this is not clearly describing an opt out option. The CAG therefore felt that due to the age of the application, a refreshed application would be necessary to ensure that up to date methodology was in place regarding clearly displaying a local opt out mechanism.

The CAG also wondered if it was possible to build in consent into the audit, for example if the paediatrician notices that a child is opted out via the NDO, could the clinician consent into NPDA, which would override the NDO? The CAG queried the applicants regarding if some of the cohort could consent, especially due to the number of times the clinician sees the families. The answer was that it is virtually impossible to consent everybody, which is accepted by CAG, however it would be possible to have 's251' support for the initial data collection, and then go on to consent those who it is possible to consent, as an exit strategy from 's251' support for those patients. The Members felt very strongly that this was another reason that a refreshed application to CAG was needed, to ensure that these practicable alternatives to 's251' support were explored in more detail, as the CAG is not able to recommend 's251' support if there are reasonable practicable alternatives in place that would avoid a breach in the common law duty of confidentiality. It is also noted that in the initial supportive outcome letter in 2012, the applicants stated an intention to move towards a consent model in the future, aiming to reach a level of consent of 75% of patients by 2014.

The applicant is therefore requested to submit a refreshed new application to CAG in lieu of their next annual review, which is 15th November 2022.

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 not clear on these communications,

making references to multiple rights requests rather than clearly stating how an individual could opt out. The applicant is requested to update the privacy notice to make this clearer. The applicant is requested to look into developing age appropriate materials for the cohort, who are aged 19 and under.

It appears that some patient and public involvement had been undertaken, however this appeared to be with a few parents, and no children had yet been consulted.

Patient and public involvement needed to be undertaken specifically around the deferral of the National Data Opt-Out, with an age appropriate cohort. The CAG noted that as children aged 13 and over can apply their own NDO, these individuals should be consulted. Feedback from this activity needed to be provided to the CAG.

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 ECC 2-03(c)/2012. 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 a relevant point during the meeting, which was not presented in the paper, however the argument provided had not yet reached the critical threshold. 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 response to point 1 below, 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 information 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 examples provided in the meeting, and further examples.

2. Please provide further clarification/confirmation surrounding the number of Trusts which use the NPDA database as a clinical follow up tool, in place of their own EPR, so CAG can be clear to what extent the NPDA is used as a tool for ensuring key health checks are made, and if application of the NDO would affect individual patient care. Please also describe how patients who opt out locally are clinically managed, and how their care is affected by not being on the NPDA database.

3. Please consider if it is possible for a consent option to be built in to the audit, which would override the NDO. This can be addressed further as part of the resubmission.

4. Please provide updated patient notification methods, which make it clearer how an individuals can opt out of NPDA only. Please also develop child and young person friendly materials.

5. Please provide evidence of discussions with patients and the public, including children, 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.

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. 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 2-03(c)/2012.

2. A local patient objection mechanism must continue to be used in relation to ECC 2-03(c)/2012.

3. This NDO exemption does not apply to research application 18/CAG/0002.

4. The applicant is requested to submit a refreshed new application to CAG in lieu of their next annual review, which is 15th November 2022. This new application will supersede ECC 2-03(c)/2012.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Patrick Coyle, CAG Vice Chair		*09 August 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*09 August 2022*