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

21 July 2022 – Via zoom

Present:

Name	Capacity	Items
Professor William Bernal	CAG Alternate Vice-Chair	2a, 2b, 2c, 3a
Dr Tony Calland, MBE	CAG Chair	2a, 2b, 2c, 3a
Mr David Evans	CAG Member	2a, 3a
Dr Pauline Lyseight-Jones	CAG Member	2a, 3a
Dr Harvey Marcovitch	CAG Member	2b
Mr Andrew Melville	CAG Member	2c
Professor Sara Randall	CAG Member	2b, 2c

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

Professor Richard Feltbower	Applicant - PICANet Co-Principal Investigator (item 2a only)
Professor Elizabeth Draper	Applicant - PICANet Co-Principal Investigator (item 2a only)
Hannah Lever	Applicant - PICANet Senior Project Manager (item 2a only)
Professor Louis Appleby	Applicant - Director, NCISH (item 2b only)
Professor Nav Kapur	Applicant - Head of Suicide Research, NCISH (item 2b) & MASH Principal investigator (item 2c)
Dr Pauline Turnbull	Applicant - Project Director, NCISH (item 2b only)
Dr Caroline Clements	Applicant - Project Manager/Research Fellow (item 2c only)

1. Introductions, apologies and declarations of interest

There were no apologies noted.

CAG Member Mr David Evans identified a potential conflict of interest, in that he is employed by NHS E/I who are a joint data controller for the English data in item 2a. However as NHSE/I are not directly involved in the management of this application, which is undertaken by Universities of Leeds & Leicester, it was agreed that this could be recorded for transparency, but that this would not constitute a conflict of interest, and Mr Evans did participate in the development of the recommendation developed by CAG.

Professor Will Bernal CAG Alternate-Vice Chair commented that as part of his clinical role he does review PICANet outputs in his Trust. This was not considered to be a conflict of interest for item 2a, and Professor Bernal did participate in the development of the recommendation developed by CAG.

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

a. 21/CAG/0090 - Paediatric Intensive Care Audit Network (PICANet)

This is a request to defer the national data opt out for 21/CAG/0090, non-research application. Healthcare Quality Improvement Partnership (HQIP) commissions University of Leeds (on behalf of Healthcare Quality Improvement Partnership (HQIP), NHS England & Improvement (NHSE&I) and University of Leicester, to undertake the Paediatric Intensive Care Audit Network (PICANet).

PICANet has been supported since 2002 with consistent submission of annual reviews since that time, and applicants refreshed their application last year to split out into a research and a non research application. The applicants have confirmed that the NDO will still apply to their research application (21/CAG/0098).

Support is in place for clinical teams to provide the audit team with confidential patient information.

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 PICANet.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to monitor individual PICU performance
2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data

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. PICANet is responsible, via Risk-adjusted resetting sequential probability ratio test (RSPRT) plots, for the identification and monitoring of PICUs which are 'outliers', regarding real time mortality. This can identify potential patient safety issues (and good practice) at an early stage. This process depends on the completeness of data from each hospital. This performance monitoring will be sensitive to incomplete data, and geographical variation in the impact of the NDO means that PICUs in some areas

will appear to perform better or less well, simply because of the extent of missing data that will arise with the application of the NDO. Some PICUs will therefore be falsely reassured of the quality of care they are providing, whereas patients and staff in other hospitals may be misidentified as a concern for the same reason. This has been modelled in the paper provided by the applicant. The application of the NDO would also therefore affect the ability to share best practice, to improve patient outcomes in a timely fashion.

The application of the NDO would also compromise the ability of PICANet to monitor population and public health risks, as was undertaken during the Covid-19 pandemic. Application of NDO would also compromise the ability of the audit to highlight important health inequalities in relation to key socio-demographic characteristics, in particular deprivation and ethnicity, by preventing comprehensive investigation of small sub-populations of children, or certain disease sub-types which may benefit disproportionately from clinical interventions to preserve health outcomes. Application of the NDO would also restrict local quality improvement for critically ill children, whether they have or have not opted out.

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

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. Due to the relatively small number with respect to key PICANet variables such as deaths in critical care, 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 PICANet data is key for use in the planning, evaluation and development of services in the NHS.

Applicants reason that the data opt out figures from NHS digital show that individuals of child bearing age (6-7%%) opt out at a higher rate than the national average (5.4%), and these individuals are the group most likely to be registering an NDO on

behalf of their child, who may then be admitted to a PICU. Additionally, evidence from MBRRACE-UK work has shown that approximately 8% women giving birth (Jan 2022) were opted out, meaning that data for their baby will also have the opt out applied. The applicant confirmed that actual case ascertainment is at least 99%.

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 nearly 100% case ascertainment currently, and this bias would adversely affect patient safety 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. Members were broadly content with the updated notifications provided.

However it was commented that the content of the text could be clearer, and have shorter sentences in areas, to be more accessible for a lay audience. It was also noted that it was not clear who the target audience was, ie. whether these notifications were aimed at parents/carer, young children or older children. This is a general comment, and any changes regarding improvements to notifications should be provided at the next annual review for CAG to comment on.

Specifically regarding the application of the NDO, it was commented that because there is only 1 set of notifications regarding PICANet (encompassing the non-research activities, and the research elements), that it was important to be clear to anybody reading the notifications that the NDO would still apply to research activity.

Updated versions of each should be provided to CAG, ensuring that the wording regarding not applying the NDO was clear and appropriate, and a clear distinction was made between research and non-research.

Patient and public involvement

The CAG noted that although no patient and public involvement has as yet been undertaken, the applicant has clear plans to do so. The CAG felt that the justifications provided surrounding patient safety were very strong, and therefore the Members did not require to see evidence of Patient and public involvement discussions prior to supporting, as the public interest is clear. The applicant is asked to provide any feedback when they have received it, after the planned patient and public involvement has been undertaken.

Private providers/ devolved nations

During a discussion in the meeting, the applicant clarified how the NDO should be applied regarding private organisations, and across the UK. For avoidance of doubt, the applicant should read this information to ensure that scope of NDO application is clear for the organisations within PICANet. 4. Which organisations does the opt-out apply to? - NHS Digital.

The guidance states that all providers of health, public health or adult social care services outside of England are out of scope for application of the NDO. There is no equivalent in Wales, Scotland, or Northern Ireland. Additionally CAG support only covers England and Wales.

The advice surrounding private providers will depend on the specific providers involved in PICANet. Out of scope for application of the NDO includes;

- privately (non-NHS) funded patients within private providers unless the care is funded or arranged by a public body
- care which is not provided or arranged by a public body, that is privately arranged/privately funded care

However in scope is the following;

- private providers including Any Qualified Providers (AQPs) who provide health and adult social care services which are funded or under contract with a public body, for example NHS England, CCG or local authority)

Therefore the applicant is advised to read the section in the website provided and ensure that they understand the scope for each provider. The CAG also noted therefore that the applicant may wish to develop different patient notification methods for each of the devolved nations, and the applicant agreed that this would be of benefit.

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 21/CAG/0090.

2. A local patient objection mechanism must continue to be used in relation to 21/CAG/0090.
3. Please provide updated patient notification materials, which make a clear distinction between the application of the NDO for research and non-research. These should be provided within 3 months from the date of this letter.
4. Please provide any feedback of planned discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, when it is available.

b. PIAG 4-08 (d) 2003 - National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)

This is a request to defer the national data opt out for PIAG 4-08(d)/2003. The Healthcare Quality Improvement Partnership (HQIP) commissions University of Manchester, to undertake the National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH).

NCISH has been supported since 2003 with consistent submission of annual reviews since that time.

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

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 NCISH.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and damage care for all individuals under the care of a mental health service
2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data, and will further exacerbate health inequalities, as the cohort is often a marginalised group
3. Technical impacts – application of the NDO would generate additional workload for hospital teams, which may delay return of the data to NCISH, and potentially harm good relationships with Trusts

1. Deferral rationale: patient safety

The paper set out a strong argument detailing the potential impacts of a substantial overall loss of information on patient safety. NCISH was set up to ensure that all patient deaths are investigated, and that learning feeds into improvements in the quality and safety of care. Applicants rely on complete national case ascertainment in order to make recommendations to improve mental health safety that apply

across mental health settings. NCISH analysis of suicide deaths in particular clinical settings and within particular groups of people, provides evidence and recommendations that directly shape national policy and inform guidelines for effective methods of preventing patient suicides. Applicants are concerned that applying the NDO to the NCISH data collection will introduce bias that could potentially damage the safety of all people under the care of mental health services, with a disproportionate bias in relation to particularly vulnerable groups.

NHS England and NHS Improvement has an aim to reduce health inequalities, with a focus on: people with severe mental illness, people in deprived areas, ethnic minority communities, people with multi-morbidities, protected characteristic groups, people experiencing homelessness, drug and alcohol dependence, vulnerable migrants, and other socially excluded groups. Whilst there is little information about opt-out rates in specific vulnerable communities, the applicants reason that it is feasible that many of these groups would have high opt-out rates. For example, the National data opt-out equality impact assessment identified that rates were likely to be high among ethnic minorities and people with lower incomes – both groups where suicide prevention is a particular concern. The National Data Opt-Out Equality Impact Assessment also cites the transgender community as historically having a distrust of health services (e.g. due to perceived barriers being placed in the way of accessing health care), and suggest that this may lead to higher opt-out rates. Suicide prevention is also a concern within this community, and a high opt-out rate would remove the potential for learning from suicide deaths, to prevent more in the future. These effects would be compounded by low numbers of people identifying as transgender, and suicide being a rare outcome. Data being skewed in this way has the potential to harm public health rather than improve it, by worsening existing inequalities.

Being part of one of these vulnerable groups, may indicate an increased suicide risk. If those individuals with an increased suicide risk are also more likely to apply an NDO, variation in the impact of the NDO means that NCISH are not collecting data about those individuals who will be most affected, and this would undermine the safety of current patient care, for those who have or have not opted out. Signal changes are not large, and if any information was missed, this could prevent the ability of NCISH to provide effective outputs.

Applicants also investigated the impacts of implementing NCISH recommendations using a before-and-after design, and found that implementing NCISH safety recommendations in mental health trusts was associated with significant reductions in suicide rates. Suicides were particularly decreased in specific high-risk settings that the recommendations targeted, including ward safety, improved community

services, and crisis teams. If the recent rates were reduced by applying the NDO by 5-10%, this would potentially overestimate the effectiveness of some service changes, and possibly even suggest that some service changes were effective when they were not.

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

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. As is explained in detail above, there may be a differential loss of information about vulnerable groups of people whose safety NCISH are most concerned about. Additionally application of the NDO would undermine any detection of trends – applicants may miss a rise in a small group that NCISH would otherwise have taken action on. Applying the National Data Opt-Outs to NCISH data collection would therefore mean inaccurate reports of any trends in patient suicide numbers and rates over time, either overall or in specific clinical settings.

For example, in the 2022 annual report, applicants noted an increase in suicide in various patients: under 18s, people with serious financial difficulties, and people with a history of domestic violence. NCISH also noted an increase in patients dying by hanging or strangulation. These increases could have been masked by applying the NDO. Missing data therefore has the potential to skew analysis and recommendations for clinical improvements, and to worsen existing health inequalities. Members were convinced that the NDO would cause an additional significant amount of bias.

Members were supportive of exempting the NDO, due to the impact of bias, as there is high case ascertainment currently, and this would worsen health inequalities.

3. Deferral rationale: technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, which could lead to delayed return of the data to NCISH, and potentially harm good relationships with Trusts.

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

Informing the patient population

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

The applicant provided a draft wording to include in notifications, regarding informing the population that the NDO would not be applied, and a communications plan. It is of note that in this cohort there is no local opt out available, or notification which the cohort will see, as they are deceased. This is accepted by CAG. The notification is therefore for transparency, and for the general public.

Members were broadly content with the notification wording, although the CAG commented that the phrasing ‘granting exemption’ should be altered to state ‘recommended’.

Research

It was noted that this is a research application, however it appears there are both research and non-research purposes. This is an historic national confidential inquiry, receiving section 60 support prior to any distinction made between research and non-research applications. The CAG were of the agreement there are clear non-research elements to this application, which had an impact on clinical services, although accepting that the applicants did also require a research application, as they publish in research journals, and allow external researchers access to NCISH

data as part of a research database. The Members were clear that they did not wish to request the applicant make a new non-research application prior to the application of the NDO, as this could have an impact on patient safety. However the applicant is provided conditional support for a time limited period of 6 months, to allow for the applicant to make a clear distinction between research purposes and non-research purposes, make a new non-research application to CAG, and a new refreshed research application to CAG. The applicants are advised to talk to the Confidentiality Advice Team (CAT) for advice if required. The HRA has a tool to help define if your application is research or non-research; Is my study research? (hra-decisiontools.org.uk). 's251' support can be provided for research purposes (usually medical research), or non-research purposes, relating to the management of Health and Social Care, however the latter does not require review by a Research Ethics Committee. The CAG were clear they did not support the non-application of the NDO for research purposes, but this will be clearly demarked at the point of refreshed applications.

Patient and public involvement

The applicant noted that with regards to patient and public involvement, there were plans in place to discuss the non application of the NDO with an engaged and representative group. The CAG were encouraged that the applicant had plans to involve people who have had contact with mental health services, were relatives of those who died by suicide, and represented various vulnerable groups. The CAG felt that they would like to see evidence of the outcomes of the planned 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 within six months of this letter, to align with the refreshed applications requested.

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 health inequalities explanations were strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

CAG therefore recommended, in this specific instance, to the Health Research Authority that the National Data Opt-Out deferral request be conditionally approved, for a time limited period of 6 months, to enable the applicant to develop a distinction

between the research and non-research purposes of NCISH, as the Members accepted that application of the NDO to this application would result in patient safety consequences and disadvantage vulnerable groups.

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 PIAG 4-08(d)/2003.

2. This support is in place for a time limited period of 6 months, within which time, the applicant is requested to submit a new refreshed research application to CAG, and a new non-research application to CAG, both of which will supersede PIAG 4-08(d)/2003, within 6 months from the date of this letter.

3. Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, within 6 months from the date of this letter.

4. Please provide the updated draft patient notification documents, with the wording changed from granted to recommended, within 6 months from the date of this letter.

c. PIAG 2-07 (c) 2004 - The Manchester Self Harm Project - MASH

This is a request to defer the national data opt out for PIAG 2-07 (c)/2004. The Department of Health and Social Care fund the University of Manchester, to undertake the Manchester Self-Harm Project.

MASH has been collecting data since 1997, and supported under section 60 in 2004, with consistent submission of annual reviews since that time.

MASH has existing support to collect confidential patient information on patients who deliberately self-harmed and presented to any of the three hospital A&E departments in Manchester from 1997 onwards. It appears support is also in place to link to NHS Digital data to receive mortality outcomes.

Refreshed application

The exact scope of support is difficult to gather, due to the age of the application. In an amendment supported 22 June 2022, the Vice Chair advised '*because of the length of time since the study first received support, no further amendments will be considered without an entire refreshed application. This will ensure that the CAG and the applicant are clear on the scope of 's251' support required for the application, and that all processes are up to date with regards to any changes in information governance since the application was first supported.'*

The Members were clear however, that they did not wish to request the applicant make a refreshed non-research application prior to the NDO implementation deadline, as this delay could have an impact on patient safety. The applicant is therefore requested to make a new refreshed non-research application to CAG, in lieu of the next annual review. This will be considered at a full CAG meeting at that time. The next annual review is due 07 June 2023. The applicant is to determine if a research application to CAG is also required, if data collected under 's251' support is used for research purposes also. The CAG were however clear that the application presented to the Group regarding this NDO deferral request, had non-research purposes.

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 MASH.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and damage care for all individuals who present to hospital emergency departments for self-harm.
2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data, and will further exacerbate health inequalities, as the cohort is often a marginalised group.
3. Technical impacts – application of the NDO would generate additional workload for hospital teams, which may potentially harm good relationships with Trusts.

1. Deferral rationale: Patient safety

The paper set out a strong argument detailing the potential impacts of a substantial overall loss of information on patient safety. MASH provides evidence and

recommendations that help shape policy and inform national guidelines for the treatment and care of people who self-harm. Study outputs, are a key evidence base for work in self-harm and suicide prevention. Applicants rely on complete case ascertainment in order to provide this evidence and make recommendations. Applicants are concerned that applying the NDO to the MASH data collection will introduce bias that could potentially damage the future care and safety of people who self-harm, with a disproportionate bias in relation to particularly vulnerable groups.

NHS England and NHS Improvement has an aim to reduce health inequalities, with a focus on: people with severe mental illness, people in deprived areas, ethnic minority communities, people with multi-morbidities, protected characteristic groups, people experiencing homelessness, drug and alcohol dependence, vulnerable migrants, and other socially excluded groups. Whilst there is little information about opt-out rates in specific vulnerable communities, the applicants reason that it is feasible that many of these groups would have high opt-out rates. For example, the National data opt-out equality impact assessment identified that rates were likely to be high among ethnic minorities and people with lower incomes – both groups where suicide prevention is a particular concern. The National Data Opt-Out Equality Impact Assessment also cites the transgender community as historically having a distrust of health services (e.g. due to perceived barriers being placed in the way of accessing health care), and suggest that this may lead to higher opt-out rates. Data being skewed in this way has the potential to harm public health rather than improve it, by worsening existing inequalities.

Higher NDO rates will reduce the potential for identifying and learning from self-harm presentations from members of these groups. Being part of one of these vulnerable groups, may indicate an increased risk of self-harm. If those individuals with an increased risk of self-harm are also more likely to apply an NDO, variation in the impact of the NDO means that MASH are not collecting data about those individuals who will be most affected, and this would undermine the safety of current patient care, for those who have or have not opted out.

Signal changes are not large, and if any information was missed, this could prevent the ability of MASH to provide effective outputs. For example, any changes over time in self-harm in smaller sub-groups (e.g., ethnic minority groups, LGBTQ+) may be hidden, and inhibit the ability of MASH to identify new factors and emerging trends (e.g., new methods of self-harm), which applicants would otherwise seek to make clinicians, health services, and policy makers aware of. In the paper provided,

applicants provided evidence from a 2021 paper looking at self-harm in children and young people from ethnic minority backgrounds. A more rapid increase in self-harm was detected over time in people from ethnic minority groups than in age-equivalent white people. The numbers included in these analyses were small for the ethnic minority groups. These increases could have been masked by applying the NDO. Even minimal amounts of lost data due to NDO may impact the outcome of such analyses, leading to incorrect conclusions and recommendations, and worsening existing health inequalities.

During a discussion in the meeting, the applicants further explained that self-harm is very strongly associated with suicide risk, with the risk of suicide 200 times that of the general population in the first month post presenting with self-harm. Therefore it is very important that individuals are provided with the recommended care and interventions to prevent suicide. However a further patient safety example provided in the meeting discussion by the applicants, is that due to evidence provided by MASH, it has been found that people from ethnic minority groups are less likely to be given the appropriate assessments as recommended by NICE, following self-harm. If a few individuals were not in this analysis due to the application of the NDO, it is possible that this would not have been identified. If the rates were reduced by applying the NDO by 5-10%, this would potentially overestimate the effectiveness of some service changes, and possibly even suggest that some service changes were effective when they were not, and could impair the ability of MASH to identify if interventions are working, leading to possible preventable suicides in individuals treated in the future, both those who have opted out or those who have not opted out.

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

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns. As is explained in detail above, there may be a differential loss of information about vulnerable groups of people whose safety MASH are most concerned about. Additionally, application of the NDO would undermine any detection of trends – applicants may miss a rise in a small group that MASH would otherwise have taken

action on. Applying the National Data Opt-Outs to MASH data collection would therefore mean inaccurate reports of any trends in self-harm numbers and rates over time. Missing data from vulnerable groups therefore has the potential to skew analysis and recommendations for clinical improvements, and to worsen existing health inequalities.

The applicant has indicated that case ascertainment is as close to 100% as possible. The applicant has also confirmed that there are no comparable sources of data on self-harm available. MASH is held up as the 'gold standard' for data surrounding self-harm presentations to hospital, as routinely collected hospital data such as from Hospital Episode Statistics or the Emergency Care Dataset (ECDS) only capture around half of all self-harm cases that present to the emergency department. These central datasets are therefore missing approximately 50% of individuals. It would therefore not be possible for applicants to compare to anything to see which demographics were missing from their dataset, should the NDO be applied.

Another project within the Multicentre Study of Self-harm in England, the Derby Monitoring Study of Self-Harm (CAG reference 19/CAG/0135), sits within Derbyshire Healthcare NHS Foundation Trust, and was an early adopter of NDO. Derby researchers were able to run a one-year cohort of self-harm data to check for NDO rates. Comparing the numbers before and after the check was completed, there was an overall loss of 10% of self-harm cases due to NDO. The CAG Members agreed that this was convincing evidence to show that this cohort may be opting out at disproportionate rates, and therefore MASH which currently has 100% case ascertainment would be disproportionately affected by such a high NDO rate. Members were convinced that the NDO would cause an additional significant amount of bias.

Members were supportive of exempting the NDO, due to the impact of bias, as there is high case ascertainment currently, and a disproportionately high NDO rate suggested, and this would worsen health inequalities and impact patient safety.

3. Deferral rationale: Technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, which could potentially harm good relationships with Trusts. An argument was also provided around it not being clear how Trusts or clinical teams would technically be able to apply the NDO.

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

Informing the patient population

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

The applicant provided a draft wording to include in notifications, regarding informing the population that the NDO would not be applied, and a communications plan.

Members were broadly content with the notification wording, although the CAG commented that the phrasing ‘granting exemption’ should be altered to state ‘recommended’. The CAG also noted that the communications are currently primarily via a privacy notice, and this is the only place that a local opt out method can currently be found. The CAG note and understand the justifications provided surrounding that fact that emergency situations are not the place to discuss how an individuals confidential patient informaiton is processed for the purposes of this project, but agreed that further notification methods should be developed. Perhaps a shorter notification statement on a website, which leads on to a longer privacy notice, in tandem with the suggested infographics, twitter and newsletter information.

The CAG also noted surrounding the local opt out option that it appeared to be titled objection rather than opt out, which appeared odd phrasing. The opt out contact options also appeared to be only a postal address and an email address, and the CAG suggested additional means of contact for opting out should be provided. The applicant plans to develop the notifications with the patient and public involvement group, which the CAG welcomed. It is a condition of support that the applicant provides the draft versions of the notifications that will be used, which have a clear explanation of why the NDO is not applied, and a clear explanation of how an individual could opt out of this project if they wish. The CAG wish to see the actual completed notification documents rather than just the wording to be inserted.

Patient and public involvement

The applicant noted that with regards to patient and public involvement, there were plans in place to discuss the non application of the NDO with an engaged and representative group. Mutual Support for Mental Health-Research (MS4MH-R), is a PPIE group set up to support and provide input on a range of work on self-harm and mental health. The patient and public group involved are representative of the cohort in this project, and this included representation from various vulnerable groups. The CAG were encouraged that the applicant had plans to involve representative individuals. The CAG felt that they would like to see evidence of the outcomes of the planned 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 within three months of this letter.

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 health inequalities explanations were strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

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, as the Members accepted that application of the NDO to this application would result in patient safety consequences and disadvantage vulnerable groups.

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 PIAG 2-07 (c)/2004.

2. A local patient objection mechanism must continue to be used in relation to PIAG 2-07 (c)/2004.

3. The applicant is requested to submit a new refreshed non-research application to CAG, which will supersede PIAG 2-07 (c)/2004, in lieu of the next annual review (by 07 June 2023).

4. Please provide evidence of 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.

5. Please provide the updated draft patient notification documents, written using the informaiton provided above, and with advice from a patient and public involvement group, within 3 months from the date of this letter.

3. Consideration items - Amendments

a. 20/CAG/0069 - C&I CRIS Linkage with HES and Mortality

Context

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

- The amendment, to;

1. Include Microsoft as a data processor - Microsoft Azure is a sub-processor of SLaM,

2. Change the data flow to minimise SLaM's role as a third-party Data Processor for the purpose of data linkage, limited to now only hosting data. Camden and Islington NHS Foundation Trust will now undertake the linkage.

3. Expand the patient/case cohort to be patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 - April 30 2022,

4. Extend the linked outcome data regarding HES and ONS data received from NHS Digital – up to and including the day the data is extracted,

   is **supported**, subject to compliance with the standard conditions of support.

- The amendment, to;

5. Receive HES/ONS linked data from NHS Digital regarding a matched cohort of non-patients resident in the London boroughs of Camden & Islington during the time period 1 January 2012 - April 30 2022,

   is **not supported**, on the basis that the CAG were not clear on the scope of support requested, and were not convinced there was no practicable alternative to 's251' support.

Amendment request

This application was originally supported 14th September 2020. The outcome letter states support is in place to establish a research database linking the mental health records of patients treated within the Camden and Islington NHS Foundation Trust area with Hospital Episodes Statistics (HES) and ONS Mortality Data held by NHS Digital, and that the cohort is; '*patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 to 31 December 2018.*' It is estimated that 140,000 patients were included in the Camden and Islington NHS Foundation Trust CRIS database.

The original outcome letter does mention the creation of a control group, but the clarity surrounding if 's251' support was required for this is not clear.

No linkage has as yet been undertaken.

This amendment sought support for five changes and clarifications to the application. These are listed below.

Change 1: SLaM have migrated to a cloud-based server and storage solution through Microsoft Azure and, consequently, the C&I Research Database is now securely hosted on Microsoft Azure as well through SLaM. The C&I Research Database remains wholly separated from the rest of SLaM's network on Microsoft Azure. Therefore this amendment sought support to include Microsoft as a new data processor, although it is understood that Microsoft Azure is a sub-processor of SLaM. The applicant has also updated associated documentation to make this clear.

Change 2: Minimisation of SLaM's role as a third-party Data Processor for the purpose of data linkage, limited to only hosting data. This change is represented by a corresponding change of the data flow, as C&I will now undertake the linkage. An updated data flow diagram and other associated documents have been provided alongside this change.

Change 3: expansion of the case cohort – requested upon recommendation from NHS Digital. i.e, extending the cohort from the original 2012 -2018. Applicants confirm they now wish the patient cohort to be patients of Camden and Islington NHS Foundation Trust with active records during the period from 1 January 2012 - April 30 2022. The applicant confirmed this to be approximately 20,000 additional individuals.

Change 4: extension of linked outcome data received (regarding linkages with HES/ONS). Although in the original CAG outcome no end date was set for these linkages, NHS Digital have requested that this is clarified. The period of data the applicant is looking to link to continues to be a somewhat moving target – they wish to ask for as much "current" data as possible, up to the point when the data are actually extracted. This is because this is a one-off linkage, rather than an ongoing agreement. NHS Digital have previously requested no end date is set for these types of linkages, as they do not have a mechanism to set an end date, and must extract the outcome data until the present date/day the data is linked.

Change 5: **clarification of control cohort**

The applicants wish to clarify that the data linkage not only includes individuals identified as patients of Camden & Islington NHS Foundation Trust from 2012-2022, but also a matched cohort of non-patients resident in the London boroughs of Camden & Islington during this same time to serve as a control group.

This control group was mentioned in the original application and is referred to in the final outcome letter, but not in the sections surrounding what support is provided for, and who the cohort is. This amendment would therefore represent a large increase in the numbers of case controls whose confidential patient information is processed without consent.

The applicants requests HES/ONS linked mortality data for **all** individuals resident in the London boroughs of Camden & Islington from 2012-2022 to serve as a control group, but if this is not practicable, applicants wish to apply for at least 2 controls per case. They estimate that this would mean ~300,000 matched controls (i.e. individuals resident in the London boroughs of Camden & Islington who were not patients of Camden & Islington NHS Foundation Trust during the study period).

As part of queries prior to the meeting, the applicant confirmed that data coming back from NHS Digital for cases is planned to be; sex, ethnicity, full date of death, alongside BRCID. NHS number, name, and full date of birth will be removed by NHS Digital. The applicants already hold censored date of birth, (to 1st of the month as pre SLaM CRIS data rules), and LSOA. Support is required for this flow as full date of death is included, and the applicant is also able to reidentify as they already hold identifiable information in the database, and this can be linked back with BRCID. This support is already in place.

The applicant confirmed that data coming back from NHS Digital for controls is planned to be; sex, ethnicity, full date of death, LSOA and censored DOB to 1st of month, alongside encrypted HESID. Support is therefore required for this flow, due to the full date of death being included, and this is dependent on NHS Digital modifying the postcode to LSOA, and the Date of birth to the 1st of month, however the applicant has not had this confirmed from NHS Digital.

The applicant has also provided updated documentation to reflect the changes, including updated terms of reference, updated protocol, data flow diagram, leaflet, poster, which the CAG accepted.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the CAG in a meeting on 21st July 2022. This was because the amendment submitted contains substantial changes to the application. The CAG were content to recommend support for change 1, and change 2, noting that change 2 was less disclosive than the original design. The CAG were content to recommend support for change 3, as this is a reasonable request due to the length of time since support was originally provided. The CAG were content to recommend support for change 4.

Regarding Change 5, the receipt of linked HES/ONS outcome data from NHS Digital of a control group of residents of Camden and Islington. The CAG were not content to recommend support for this element. The CAG noted this is because they were not clear on the scope of support requested regarding the control group. It was not clear why the applicant required individual patient level data, as this had not been justified as part of the amendment application. If the applicant resubmits, they are to provide justification as to the added value of individual level data. The members also noted that the rationale for a control group in general had not been clearly provided, This should be provided as part of any resubmission.

Could the applicant receive aggregated data from NHS Digital, without any identifying information, and remove the requirement for CAG support? If the applicant received a modified date of death rather than full date of death, does NHS Digital consider that this would require 's251' support? The applicant is asked to discuss this with NHS Digital and confirm if there are any methods of receiving this data that would not require CAG support.

The Members noted that little information has been provided about how exactly the control group is identified, this should be further explained in a resubmission, if one is required after discussions with NHS Digital.

The CAG were not clear on the size of the control group, as the applicant has provided 2 options, one which was all individuals resident in the London boroughs of Camden & Islington from 2012-2022, and one of at least 2 controls per case. They estimate that this would mean ~300,000 matched controls. Noting that Camden has a population of around 240,000 and Islington around 230,000, and therefore even the 300,000 people is nearly the entire population of both boroughs. For any resubmission, the applicant should pick one option for the number of controls, and justify why this many is required.

The CAG noted that the patient notification was not aimed at any controls, and if 's251' support is required for this, then notification should also be developed to explain to controls what is happening with their data, and provide an opt out option.

The CAG also noted that as part of any resubmission, extensive patient and public involvement should be undertaken who are representative of the control cohort, to establish the acceptability of this use of confidential patient information without consent.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for part of this amendment, and therefore advised recommending support to the Health Research Authority.

However, the receipt of HES/ONS linked data from NHS Digital regarding a matched cohort of non-patients resident in the London boroughs of Camden & Islington during the time period 1 January 2012 - April 30 2022is not supported, and the applicant is advised to re-submit an amendment for elements relating to the creation of the control group if required, to be considered at a full CAG meeting.

Specific conditions of support

The following sets out the specific conditions of support.

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

   The NHS Digital **20/21** DSPT reviews for **Camden and Islington NHS Foundation Trust, South London and Maudsley NHS Foundation Trust & MHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 August 2022)

   The NHS Digital **21/22** DSPT reviews for **Microsoft UK** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 02 August 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **6 May 2022**

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Professor William Bernal, CAG Alternate-Vice Chair		*15 August 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*09 August 2022*