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

23 June 2022 – Via zoom

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	2a, 2b, 2c
Mr David Evans	CAG member	2b, 2c
Dr Harvey Marcovitch	CAG member	2a
Professor Sara Randall	CAG member	2a, 2c
Ms Diana Robbins	CAG member	2b
Ms Clare Sanderson	CAG alternative vice-chair	2a, 2b, 2c

Also in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Kate Walker	Applicant NBOCA (item 2a only)

Dr Min Hae Park	Applicant NOGCA (item 2a only)
Christine Taylor	Applicant NELA project manager (item 2b only)
Dave Murray	Applicant (item 2b only)
Carolyn Johnston	Applicant (item 2b only)
Calvin Down	Applicant RCPCH Head Of Audits (item 2c only)
Dr Colin Dunkley	Applicant Epilepsy12 Clinical Lead (item 2c only)
Helen Stacey	Applicant Epilepsy12 Manager (item 2c only)

1. Introductions, apologies and declarations of interest

There were no apologies.

Dr Harvey Marcovitch declared a conflict of interest with 2c, but is not a reviewer. He was on the Council of RCPCH for many years and is an Honorary Fellow. He did not participate in the development of the advice given by CAG regarding item 2c.

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

a. ECC 1-03(d)/2012 National Gastrointestinal Cancer Audit Programme (National Bowel Cancer Audit – NBOCA) & ECC 1-06(c)/2011 & National Gastrointestinal Cancer Audit Programme (Oesophago-Gastric Cancer – NOGCA) considered together but 2 separate outcomes:

- ## ECC 1-03(d)/2012 National Gastrointestinal Cancer Audit Programme (National Bowel Cancer Audit – NBOCA

This is a request to defer the National Data Opt-Out for ECC 1-03(d)/2012, the National Bowel Cancer Audit (NBOCA). A request was also received to defer the National Data Opt-Out for ECC 1-06(c)/2011, the National Oeosphago-Gastric Cancer Audit (NOGCA). A separate outcome letter had been produced for NOGCA.

Both audits are part of the Gastrointestinal Cancer Audit Programme (GICAP). GICAP was commissioned by HQIP on behalf of NHS England and the Welsh Government as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The Programme aims to evaluate and improve the care of NHS patients with bowel or oeosphago-gastric cancer. The applicants have submitted annual reviews for each application, as required.

Confidentiality Advisory Group advice

The applicants have set out their rationale as to why the NDO will significantly impact the audit. The CAT requested further details on the communications strategy and the patient and public involvement and engagement that had been conducted or was planned. The applicants provided a supplementary response This provided the draft text to be included in the patient information leaflets for both audits. The applicants also advised that the application for the exemption from NDOO was circulated to NBOCA and NOGCA Patient Panels for consultation. Feedback from this activity was provided.

1. Deferral rationale: patient safety

Bowel and oeosphago-gastric cancer are two of the five most common cancers in the UK. The main curative treatment for both cancers is surgery, often combined with chemotherapy and/or radiotherapy. Both audits benchmark the performance of NHS providers and consultant surgeons against national performance.

Since NBOCA began this benchmarking, improvements in 90-day post-operative mortality following bowel cancer resections have been seen.

An important part of the audits' work is to identify potential outliers. A process is in place to notify HQIP and the Care Quality Commission/Welsh Government if organisations or surgeons have been identified as a potential outlier.

The applicants noted that the effects of application of the National Data Opt-Out may appear small, but bowel cancer surgery is not centralised and the loss of even a

small number of records at the organisation or surgeon level can impact on the ability to detect outliers.

The CAG noted that case ascertainment in England for NBOCA is approximately 90% and appropriate statistical adjustments were made to cater for this. Members queried why similar adjustments could not be made for a loss of data due to the National Data Opt-Out. When invited into the meeting, the applicants advised that a limited amount of information was available for patients who had not been included in the audit for reasons other than application of the National Data Opt-Out. If the National Data Opt-Out was applied, the applicants would not be able to access any information about those patients.

The CAG agreed that sufficient information had not been given 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. A National Data Opt-Out equivalent was not available in Wales and members suggested that the applicants conduct modelling work, comparing the audit data collected in England, with the National Data Opt-Out applied, to data collected in Wales.

2. Deferral rationale: Introduction of bias

Data from around 30,000 patients diagnosed with bowel cancer are processed by NBOCA each year. Data for 2019/20 suggested that the proportion of registrations with the National Data Opt-Out had doubled compared to 2018/19.

As described above, even small losses of data have implications for the Audits' ability to monitor outcomes relating to patient safety. Furthermore, there is considerable concern about the risk of bias because the application of the National Data Opt-Out is not similar across the country. Figures from NHS Digital show that rates of opt-out vary considerably, exceeding 10% in one in twenty GP practices. A small number of practices have opt-out rates of over 50%. Such regional differences suggest the pattern of data loss would not be random.

Precise information about the pattern of opt-outs across different population groups within geographical areas is not available. Consequently, it is not possible to model the impact of non-random objections or to apply methods to correct estimates for this data loss. The introduction of such biases will limit the ability of the Audits to accurately describe practice and outcomes, and thereby support the robust benchmarking of performance at an organisational and surgeon level. This will bring into question the reliability of comparisons across regions or organisations.

As noted above, sufficient information had not been provided to evidence the impact that application of the National Data Opt-Out would have.

3. Deferral rationale: technical Impacts

The applicants did not provide any arguments around why the National Data Opt-Out could not be applied due to technical issues.

Informing the patient population

In the supporting paper, the applicants set out a communications strategy. This strategy included publication of the National Data Opt-Out deferral via the audit websites. Website links to information had been provided, but the draft documents had not been supplied.

A study specific opt-out will be available. This will be publicised via the audit privacy notices, patient information sheets and other materials. The text of the information to be included in the patient information sheets was provided.

The patient notification documents, including an explanation of deferral the National Data Opt-Out, needed to be provided for review. The patient information materials currently advised patients that only their NHS number was collected, and the materials needed to explain that other items of confidential patient information would be collected.

The CAG also requested that a layered approach to patient notification was adopted. This needed to include posters and leaflets, in addition to the information available online.

Patient and public involvement needed to be undertaken specifically around the deferral of the National Data Opt-Out. Feedback from this activity needed to be provided to the CAG.

Confidentiality Advisory Group advice conclusion

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 1-03(d)/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 approved. 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.

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.
2. The patient notification documents need to be provided. A layered approach to patient notification also needed to be adopted, including posters and leaflets as well as online information. The patient notification documents need to include:
    a. An explanation of deferral the National Data Opt-Out.
    b. An explanation that other items of confidential patient information, in addition to their NHS Number, would be collected.
3. Patient and public involvement needs to be undertaken specifically around the deferral of the National Data Opt-Out. Feedback from this activity needs to be provided to the 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. The National Data Opt-Out is to be applied to the non-research activities specified in ECC 1-03(d)/2012.

ECC 1-06(c)/2011 & National Gastrointestinal Cancer Audit Programme (Oesophago-Gastric Cancer – NOGCA)

This is a request to defer the National Data Opt-Out for ECC 1-06(c)/2011, the National Oeosphago-Gastric Cancer Audit (NOGCA. A request was also received to defer the National Data Opt-Out for ECC 1-03(d)/2012, the National Bowel Cancer Audit (NBOCA). A separate outcome letter had been produced for NBOCA.

Both audits are part of the Gastrointestinal Cancer Audit Programme (GICAP). GICAP was commissioned by HQIP on behalf of NHS England and the Welsh Government as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The Programme aims to evaluate and improve the care of NHS patients with bowel or oeosphago-gastric cancer. The applicants have submitted annual reviews for each application, as required.

Confidentiality Advisory Group advice

The applicants have set out their rationale as to why the NDO will significantly impact the audit. The CAT requested further details on the communications strategy and the patient and public involvement and engagement that had been conducted or was planned. The applicants provided a supplementary response This provided the draft text to be included in the patient information leaflets for both audits. The applicants also advised that the application for the exemption from NDOO was circulated to NBOCA and NOGCA Patient Panels for consultation. Feedback from this activity was provided.

1. Deferral rationale: patient safety

Bowel and oeosphago-gastric cancer are two of the five most common cancers in the UK. The main curative treatment for both cancers is surgery, often combined with chemotherapy and/or radiotherapy. Both audits benchmark the performance of NHS providers and consultant surgeons against national performance.

Since NBOCA began this benchmarking, improvements in 90-day post-operative mortality following bowel cancer resections have been seen.

An important part of the audits' work is to identify potential outliers. A process is in place to notify HQIP and the Care Quality Commission/Welsh Government if organisations or surgeons have been identified as a potential outlier.

For NOGCA the number of patients who undergo surgical resections annually is small, with around 2,100 operations performed in England and Wales. The loss of 5% of patient records as a result of application of the National Data Opt-Out would impact on the ability to identify outliers.

The CAG noted that case ascertainment in England for NBOCA is approximately 90% and appropriate statistical adjustments were made to cater for this. Members queried why similar adjustments could not be made for a loss of data due to the National Data Opt-Out. When invited into the meeting, the applicants advised that a limited amount of information was available for patients who had not been included in the audit for reasons other than application of the National Data Opt-Out. If the National Data Opt-Out was applied, the applicants would not be able to access any information about those patients.

The CAG agreed that sufficient information had not been given 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. A National Data Opt-Out equivalent was not available in Wales and members suggested that the applicants conduct modelling work, comparing the audit data collected in England, with the National Data Opt-Out applied, to data collected in Wales.

2. Deferral rationale: Introduction of bias

Data from around 10,500 patients with OG cancer are included in NOGCA. The proportion of opt-outs for patients diagnosed in 2017/18 was estimated to be 3.5% when data extracts taken in 2019 and 2021 were compared.

As described above, even small losses of data have implications for the Audits' ability to monitor outcomes relating to patient safety. Furthermore, there is considerable concern about the risk of bias because the application of the National Data Opt-Out is not similar across the country. Figures from NHS Digital show that rates of opt-out vary considerably, exceeding 10% in one in twenty GP practices. A small number of practices have opt-out rates of over 50%. Such regional differences suggest the pattern of data loss would not be random.

Precise information about the pattern of opt-outs across different population groups within geographical areas is not available. Consequently, it is not possible to model the impact of non-random objections or to apply methods to correct estimates for this data loss. The introduction of such biases will limit the ability of the Audits to accurately describe practice and outcomes, and thereby support the robust benchmarking of performance at an organisational and surgeon level. This will bring into question the reliability of comparisons across regions or organisations.

As noted above, sufficient information had not been provided to evidence the impact that application of the National Data Opt-Out would have.

3. Deferral rationale: technical impacts

The applicants did not provide any arguments around why the National Data Opt-Out could not be applied due to technical issues.

Informing the patient population

In the supporting paper, the applicants set out a communications strategy. This strategy included publication of the National Data Opt-Out deferral via the audit websites. Website links to information had been provided, but the draft documents had not been supplied.

A study specific opt-out will be available. This will be publicised via the audit privacy notices, patient information sheets and other materials. The text of the information to be included in the patient information sheets was provided.

The patient notification documents, including an explanation of deferral the National Data Opt-Out, needed to be provided for review. The patient information materials currently advised patients that only their NHS number was collected, and the

materials needed to explain that other items of confidential patient information would be collected.

The CAG also requested that a layered approach to patient notification was adopted. This needed to include posters and leaflets, in addition to the information available online.

Patient and public involvement needed to be undertaken specifically around the deferral of the National Data Opt-Out. Feedback from this activity needed to be provided to the CAG.

Confidentiality Advisory Group advice conclusion

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 1-03(d)/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 approved. 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.

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.
2. The patient notification documents need to be provided. A layered approach to patient notification also needed to be adopted, including posters and leaflets as well as online information. The patient notification documents need to include:
    a. An explanation of deferral the National Data Opt-Out.
    b. An explanation that other items of confidential patient information, in addition to their NHS Number, would be collected.
3. Patient and public involvement needs to be undertaken specifically around the deferral of the National Data Opt-Out. Feedback from this activity needs to be provided to the 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. The National Data Opt-Out is to be applied to the non-research activities specified in ECC 1-03(d)/2012.

b. CAG 5-07(d)/2013 - National Emergency Laparotomy Audit (NELA)

This is a request to defer the national data opt out for CAG 5-07(d)/2013, the National Emergency Laparotomy Audit (NELA).

The National Emergency Laparotomy Audit (NELA) was set up in 2012 in response to a high incidence of death and wide variation in the provision of care and mortality for patients who receive emergency laparotomy (abdominal surgery) in England and Wales. NELA is delivered under contract to the Healthcare Quality Improvement Partnership (HQIP) by the Royal College of Anaesthetists and the Clinical Effectiveness Unit of the Royal College of Surgeons of England. From December 2022, the scope of the audit will also include patients who could undergo surgery, but do not, due to extreme illness or surgery not being in the patients' best interest.

The applicants have set out their rationale as to why the NDO will significantly impact the audit. The CAT requested further details on the proposed communications strategy and whether any PPI had been conducted.

The applicants provided a draft patient information leaflet. This leaflet had been reviewed by the patient and carer group. The patient and carer group were also asked for their views on NDOO exemption, however the applicants noted that a small volume of responses was received. One patient expressed concern about exemption from the opt-out on the whole (not NELA-specific) as she thought patients ought to be able to opt-in rather than opt-out. One patient was in favour of exemption as it will increase the amount of data available for the audit.

The applicants plan to hold a meeting with the patient and carer group in July, where deferral of the NDOO can be discussed.

Confidentiality Advisory Group advice

1. Deferral rationale: patient safety

The main argument presented around patient safety is clinical staff access to the NELA webtool, which is used to carry out risk assessments for patients.

Risk assessments support shared decision making and help patients make the best decisions over this care. Risk assessments are carried out by entering patient data into the NELA webtool. The same data points used to provide the risk score are also used to produce risk adjusted outcomes for each hospital as part of NELA's outlier analysis. Since NELA was commissioned, the proportion of patients who receive a formal risk assessment has risen from around 55% to over 90%. Proportion of patients who receive consultant delivered care has risen from around 60% to over 90%.

The NELA webtool reduces the burden of data collection be clinical teams as it negates the need for duplicate entry into two different systems. If the National Data Opt-Out is implemented, clinicians may be unable to use the NELA webtool to obtain patient risk scores. There is also round the clock need to calculate risk scores, as the surgery decision is often made out of hours. If the NELA webtool was not available, it is likely that a bespoke tool would need to be created. The applicants have communications from several clinical teams who have flagged the risk to NELA data entry, due to the increased workload related to checking for the National Data Opt-Out prior to data entry in real-time, or fear of data breaches leading to diminished engagement with the audit.

The CAG agreed that there was a strong patient safety rationale for not applying the National Data Opt-Out, due to the emergency nature of the surgery and the use of the Risk Assessment Tool by clinicians.

2. Deferral rationale: Introduction of bias

Case ascertainment to NELA is over 85%. Figures from NHS Digital show that rates of registration with the National Data Opt-Out vary. Rate of opt-out exceeds 10% in one in twenty GP practices. The CQC uses information from NELA to inform their surveillance approach and to plan and support inspections. Missing information may bias the results.

The CAG queries why case ascertainment for NELA was 85%. The applicants advised that the data was entered in real time by clinicians and then compared with the data available in HES as the denominator, pulled by an algorithm from a variety of codes. The data set may not be complete or sites may not be able to complete data fields due to difficulty in accessing some of the information needed from their local data.

Trusts are RAG rated on their case ascertainment, and this forms part of the annual report and local quality reports. It is reviewed by the CQC as an indicator in the 'well led' domain, indicating that sites are engaged in engaging with the audit and capturing the correct data set. The case ascertainment has risen every year since

the audit has been running, and indicates good engagement with the clinical and audit communities in measuring and reporting for this high risk surgery.

Informing the patient population

NELA patients are offered a number of ways to dissent to use of their data by NELA. Patients can either inform their local care team that they do not wish for their data to be submitted or they can contact the applicants.

The patient information leaflet was provided. The CAG agreed that this document required revision for simplicity and clarity. A layered approach also needed to be adopted. Posters and leaflets were to be produced, to be used in addition to the website information.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within CAG 5-07(d)/2013. The CAG therefore recommended 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. Patient and public involvement needs to be undertaken specifically around the non-application of the National Data Opt-Out. Feedback from this activity needs to be provided to the CAG.

2. The patient notification materials need to be revised and a layered approach adopted, including posters and leaflets, as well as online information.

3. The National Data Opt-Out is not to be applied to patients included in the activities specified in ref. CAG 5-07(d)/2013.

4. A local patient objection mechanism must continue to be used in relation to CAG 5-07(d)/2013.

c. 17/CAG/0184 - UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)

This is a request to defer the National Data Opt-Out for 17/CAG/0184, Epilepsy12 - the National Clinical Audit of Seizures and Epilepsies for Children and Young People.

Healthcare Quality Improvement Partnership (HQIP) commissions The Royal College of Paediatrics and Child Health (RCPCH) to undertake the Epilepsy audit of children and young people, within the wider National clinical audit and patient outcomes programme (NCAPOP).

Epilepsy12 has been supported since 2017 with consistent submission of annual reviews since that time. The Royal College of Paediatrics and Child Health delivered the audit between 2009 and 2014, however, the previous rounds of the audit had been delivered without the requirement for support under the Regulations.

Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with 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 Epilepsy12.

1. Patient safety – loss of data will reduce the ability to monitor care safety and quality at Trust-level at risk. Loss of a small number of records can make a considerable difference, especially for elements such as epilepsy surgery services or medications safety.

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

3. Technical impacts – the increased workload on front-line NHS staff would cause staff to stop uploading cases or withdraw from the audit entirely.

1. Deferral rationale: patient safety

The applicant provided some examples of how epilepsy12 improves patient safety overall, including monitoring of Trust paediatric epilepsy service performance to assure safety and standards of clinical services, reporting of data to regulators (CQC) to

support inspection, reporting data to NHS England to underpin their policy and initiatives (particularly through the NHS England Epilepsy Oversight Group, and the Best Practice Tariff) to improve quality and reduce unwarranted variation, and reporting data to services and commissioners to support improvement activity at local and regional levels. However the Members did not feel that the paper provided sufficiently justified the effect that applying the NDO to the audit would have on patient safety. As such, this was asked of the applicant in the meeting.

The applicant explained that the audit is prospective and collects real time data. As such, it can be used as a treatment tool for each child currently treated, regarding decision assuring, sense checking and safety elements. If the NDO must be applied, and data was left out of the system, this platform would have less usefulness as a treatment tool, and may reduce the quality of care for individual children, whether or not they have opted out. If the treated child has opted out, the tool would not be able to be used at all to provide information about their treatment. The applicants also explained that as well as patient level uses such as the tool, some sub-groups of complex seizures have very small numbers, and some key information about these subgroups includes information about medical treatments, such as the risks of sodium valproate, and access to MRI scanning. If this information was not collected on a few individuals due to the NDO being applied, this would cause bias, which would in turn affect patient care.

Although the CAG were interested in the justifications provided in the meeting, the CAG agreed that sufficient information had not been given 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, and this should also include the verbal arguments already stated in the meeting.

The discussion about the use of the tool as a part of clinical care caused the CAG to further query some of the data flows. The CAG requested a data flow diagram to better understand the clinical care aspect, and see at what point the NDO is currently being applied, and to see if it was possible to separate the patient care element from the audit element.

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 explain to the family that this prevents them from using the treatment tool, but that they could consent into Epilepsy12, which would override the NDO?

2. Deferral rationale: Introduction of bias

The applicants reasoned that while on average 9,867 patients per year in England were registered into Epilepsy12 following a first suspected seizure, only a minority go on to be diagnosed with epilepsy. These small numbers mean that even a small increase in opt outs risks losing key sub-groups from audit reporting, if they became too small to risk publishing treatment details without compromising patient confidentiality. These sub-groups are key to using the data for monitoring national standards, variation, outlier management, assessing health inequalities, service planning, directing improvement and targeting commissioning. The CAG were convinced by the bias arguments provided, however on their own, without the additional justifications surrounding why the application of the NDO would affect patient safety, this is not sufficient to support the exemption. However the bias arguments provided are contributory, and if a sufficient justification is provided regarding patient safety, the CAG would be content to support an exemption on both bases.

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 this will cause data submissions for the majority of patients to cease, or trusts to withdraw from the audit altogether, and will reduce time available for direct patient care.

The applicant has also provided an argument surrounding the possibility of accidental data deletion, if the NDO ws required to be applied, due to an internal electronic safeguard that the applicant argues would have to be lifted.

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. The noted that regarding the accidental data deletion, this was much better addressed by other means, for example data entry training, and this was not an appropriate reason to defer 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.

In the supporting paper, and further query responses, the applicants set out a communications strategy, including draft materials. The main communication route appears to be the website, although applicants are planning to discuss the NDO at the national conference attracting 150 attendees, in September. Other communication routes appear slightly vague, for example; '*This could include the use of social media, website and internal newsletters.'* The applicant is requested to provide further detail regarding the planned communication routes.

It appears that some patient and public involvement had been undertaken, as some patient groups/charities are mentioned, however the type of input they had is unclear, and the outcome of any discussions are not mentioned.

Patient and public involvement needed to be undertaken specifically around the deferral of the National Data Opt-Out. 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 17/CAG/0184. 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. This should include more detail on the examples provided in the meeting, and further examples.

2. Please provide a data flow diagram to show clearly where the NDO is currently being applied, in relation to which elements are pertinent to patient care.

3. Please consider if it is possible for a consent option to be built in to the audit, which would override the NDO.

4. Please provide further detail on planned communication strategy.

5. 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.

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 17/CAG/0184.

2. A local patient objection mechanism must continue to be used in relation to 17/CAG/0184

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Ms Clare Sanderson, CAG Alternate-Vice Chair		*09 August 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*05 August 2022*