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

09 June 2022 – Via zoom

Present:

Name	Capacity	Items
Professor William Bernal	CAG Alternate Vice-Chair	2a, 2b
Mr Anthony Kane	CAG Member	2a
Dr Harvey Marcovitch	CAG Member	2a, 2b
Mr Andrew Melville	CAG Member	2b
Professor Sara Randall	CAG Member	2a
Dr Sandra Duggan	CAG Member	2b

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr Sam Waton,	NVR Manager (Royal College of Surgeons of England) (item 2a only)

Professor David Cromwell	CEU Director (item 2a only)
Mr James Chal	NICOR Chief Operating Officer – Barts Health NHS Trust (item 2b only)
Professor Mark de Belder	Chair, National Cardiac Audit Programme Operational and Methodology Group, (NICOR) – Barts Health NHS Trust (item 2b only)
Mr Richard Arnold	NHS England/Improvement (item 2b only)

1. Introductions, apologies and declarations of interest

There were no apologies or declarations of interest noted.

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

a. CAG 5-07(f)2013 - National Vascular Registry (NVR)

The National Vascular Registry (NVR) that has been supported since 2013. Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with NHSD data. Support under the Regulations is in place for emergency procedures only, as consent is sought from patients who undergo elective procedures.

The applicants have set out their rationale as to why the NDO will significantly impact the audit, and CAT have not requested any further detail on these aspects given that have had sight of the paper outlining CAG principles when considering these requests.

Confidentiality Advisory Group advice

1. Deferral rationale: Introduction of bias

Application of the National Data Opt-Out is likely to result in around 5% of patient records being lost from the NVR every year. This estimate is based on data provided by NHS Digital on current levels of opt-out. The NVR collects data for patients who undergo repair procedures

for abdominal aortic aneurysm (AAA), patients who undergo lower limb angioplasty or stent, lower limb bypass surgery or lower limb amputation to treat peripheral arterial disease (PAD), and patients who undergo carotid endarterectomy or carotid stenting. Some of these conditions, particularly AAA, are relatively rare. The loss of data, even a small amount, relating to treatment of these conditions may adversely affect the ability to detect outliers.

The registering of National Data Opt-Outs is not uniform across geographical regions. The characteristics of those who register an opt-out are also not the same. This introduces the risk of selection bias.

2. Deferral rationale: patient safety

An important role of the NVR is to monitor the performance of hospital vascular services to assure patient safety and the quality of clinical services. The performance of surgeons is also monitored, and the data used to support clinical revalidation. The data collected is also used to support quality improvement initiatives, provides performance information to the Care Quality Commission (CQC), Care Inspectorate Wales, Get-it-right-first time (GIRFT), NHS model hospital and other organisations involved in hospital regulation and inspection.

The NVR has been providing data since 2013. During this period, steady improvement in outcomes, particularly for patients who receive elective AAA repair or carotid surgery. The NVR has also been highlighted variation between NHS vascular units in waiting times for vascular surgery and the treatments given. The NVR has also implemented the collection of data on implanted medical devices for patients who underwent AAA repair.

The applicants, in collaboration with the Vascular Society of Great Britain and Ireland, British Society of Interventional Radiologists (BSIR), and Medical and Healthcare products Regulatory Agency, have established a system to support tracking of devices, which is used to highlight when a device may be associated with an excessive number of revisions and to facilitate the recall of patients. This reporting is currently limited to AAA repairs, expanding the reporting to the NVR of other procedures is planned. Application of the National Data Opt-Out would mean that patients who opted-out would not benefit from the device recall facility.

As noted above, loss of patient data will adversely impact the ability to monitor patient safety and to evaluate the quality of care. The number of procedures undertaken each year within organisations may be small, therefore loss of data for a small number of patients may have a disproportionate impact on the ability to detect poor performance or may lead to the incorrect identification of poor performance.

When addressing questions from the CAG, the applicant noted that, without the NVR, complete case ascertainment was difficult due to problems with diagnostic or therapeutic coding, such as when more than one code exists or is used for the same condition or procedure. If patients who registered a National Data Opt-Out were excluded from the NVR, it would not be possible to know if any numbers or outcomes produced for hospitals are accurate.

3. Deferral rationale: public interest

The CAG agreed that there was a strong public interest in granting the deferral, due to the patient safety concerns set out above.

Informing the patient population

The CAG reviewed the patient notification materials provided. Members agreed that clearer information on how patients can register project-specific dissent needed to be provided.

Members noted that the Privacy Notice contained the following passage, *"If you give consent and then change your mind, please send [an email to] nvr@rcseng.ac.uk and put "Request to opt-out" in the subject line."* The word "*email*" needed to be added before the email address.

Confidentiality Advisory Group advice conclusion

Following thorough review of the deferral request, members agreed that the rationale on patient safety and public interest had been sufficiently set out to enable deferral of the National Data Opt-Out.

One of the arguments for deferring application of the National Data Opt-Out was difficulty in undertaking the administration processes involved within the NHS trusts participating in the NVR. The CAG agreed administration difficulties should not be a deciding factor in whether a deferral was granted but agreed that it should be taken into consideration for this application due to the specific direct-entry upload processes undertaken within participating NHS trusts, to which no solution was available.

Patient and public involvement and engagement needed to be undertaken, specifically around the non-application of the National Data Opt-Out. The CAG asked that feedback from this was provided within 3 months of the issue of this outcome letter.

Specific conditions of support

1. The patient notification materials needed to be revised to provide clearer information on how patients can register project-specific dissent.

2. Members noted that the Privacy Notice contained the following passage, *"If you give consent and then change your mind, please send an nvr@rcseng.ac.uk and put "Request to opt-out" in the subject line."* The word "*email*" needs to be added before the email address.

3. Patient and public involvement and engagement need to be undertaken, specifically around the non-application of the National Data Opt-Out. Feedback from this is to be provided within 3 months of the issue of this outcome letter.

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

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

b. 17/CAG/0071 - Barts Health (NICOR) National Cardiac Audit Programme (NCAP) & 17/CAG/0152 - Barts Health (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI) – considered together but 2 separate outcomes:

○ 17/CAG/0071 - Barts Health (NICOR) National Cardiac Audit Programme (NCAP)

This is a request to defer the national data opt out for 17/CAG/0071, a non-research application. The Healthcare Quality Improvement Partnership (HQIP) commissions the cardiac audits on behalf of the Department of Health and Social Care (DHSC).

17/CAG/0071 superseded ECC 1-06(d)/2011 due to a change of data controller from University College London (UCL) to Barts Health NHS Trust. ECC 1-06(d)/2011 superseded ECC 1-06 (c)/2009 when responsibility for managing six national cardiac audits transferred from the NHS Information Centre (NHS IC) to NICOR/UCL in early 2011. The National Cardiac Audit programme (NCAP) has been supported since 2009 (through various data controller changes), with consistent submission of annual reviews since that time.

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

The applicants submitted this request in relation to 2 non-research applications, 17/CAG/0071 and 17/CAG/0152 (which is provided as a separate outcome letter). The ensuing paper provided by the applicants mentioned research. This outcome letter relates only to the non-research activities undertaken under CAG reference 17/CAG/0071.

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 NICOR.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to monitor individual Trust performance
2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data
3. Technical impacts – the systems are not designed to apply the national data opt out on a direct entry system which will add workload to direct care teams to apply the national data opt out, and increase associated costs to the NHS

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 at both individual cardiac consultant level, and at Trust level. The data is also used as a surveillance tool for cardiac medical devices such as stents, heart valves, defibrillators, and pacemakers, to ensure that treatment decisions are safe, effective and evidence based. As such the audit can be used to notify hospitals of relevant patients should a medical device be recalled, or a safety notice issued, which has direct impacts on patient safety, and would require all individuals to be included.

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

1a. Research

A discussion was had during the meeting with the applicant, who also stated they were requesting an exemption of the NDO regarding research activity also. The CAG felt that the patient safety justification does not extend to research activity. However, it was felt that the applicant was unclear what constituted research activity, and what did not. The CAG noted that the applicant has a separate research database application with CAG, 17/CAG/0078. The CAG felt that any activity related to 17/CAG/0078 could be constituted as research, alongside other aids, such as whether or not the activity had a Favourable Opinion from a Research Ethics Committee, and if the activity was judged to be research using the HRA

tool - Is my study research? (hra-decisiontools.org.uk). However, in this specific case, the CAG were in agreement with the applicant regarding the difficulty in splitting out the activities currently happening under the NICOR non-research reference 17/CAG/0071, and the NICOR research reference 17/CAG/0078. This is because although the applications were given support in 2017, this support was merely an administrative change in data controller, and the applications were not re-reviewed at a full CAG meeting, to be considered alongside updated information governance advice.

The Members were in agreement that they were content to recommend support for all NICOR non-research activity under CAG reference 17/CAG/0071 to be exempted from the NDO, however they were not content for this to extend to the research database activity of 17/CAG/0078. Because of the difficulties both the applicant and the CAG had in splitting out the activities, a refreshed application is required from the applicant for both CAG applications, to ensure the scope of support is clear. The CAG are aware that NICOR are currently submitting 4 administrative amendments for a change in data controller, and these will be processed as discussed. However, the applicant is additionally requested to submit two entire new refreshed applications to CAG regarding 17/CAG/0071 and 17/CAG/0078, to align with the next annual review, to ensure the scope of each is clear. At this time, if the applicant wishes to also submit a separate NDO exemption request for the research element only (17/CAG/0078), they will be able to as part of the refreshed application.

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. In particular, it was noted that the current national average is over 5%, and a small number of practices have recorded rates of over 30% objections. The applicants reasoned that data used for national clinical audit purposes needs to be as representative as possible of the whole population to ensure accurate conclusions can be drawn. If the NDO was applied, certain patient groups, (on the basis of demographics and/or rare conditions) may not be fully accounted for, which will minimise the ability of the audit to identify potential problems and implement corrective measures. The paper explained that studies have shown that certain groups are more likely to opt out with clustering by age, geographic location, or ethnicity. This non-random nature would pose difficulties in determining whether every patient admitted with a cardiac issue receives optimal care. The population bias introduced into datasets with opt-outs applied cannot be treated with the same statistical methods used to treat missing data, and any attempt to correct for these data may add further bias to the results. These issues jeopardise the accuracy and full applicability of the audit results both to those who have opted out and those who have not opted out.

Members were supportive of the justifications provided regarding bias.

3. Deferral rationale: technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, and increase the cost to the NHS. It was also noted that if the NDO were not applied, then Trusts could continue to enter data directly into the central NICOR database, and continue to have access to their own data for their own clinical purposes at Trust level.

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

Informing the patient population

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

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

Additionally, the Members viewed the NICOR website as part of this review, and found that parts of the website state that the NDO is being applied currently. The applicant is reminded to ensure that all communications, including all areas of the website, surrounding the application of the NDO are coherent and consistent.

Members were not content with the privacy notice text provided for NICOR, and the applicant is requested to split this communication into a shorter patient notification, that leads on to a longer privacy notice. The content of the text should be refreshed and improved, and be more accessible for a lay audience. Updated versions of each should be provided to CAG, ensuring that the wording regarding not applying the NDO was clear and appropriate.

A communications plan should be provided to CAG to explain how this information will be disseminated.

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 particularly strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

However, CAG was very clear that any requests for deferral from the NDO must have in place a clear communications strategy as it would represent a significant deviation from published information. In particular, CAG noted that changes to privacy notices only is a limited piecemeal solution that risks criticism and strongly agreed that there is no transparency in introducing a major change to earlier information provided to the public through editing previous privacy information without considerable, detailed and wide notification. It was noted that the CAG receives external scrutiny from privacy campaigners and journalists therefore CAG is not prepared to compromise its position of public trust and strongly advised that intended information given to the public when requesting a deferral from the NDO when operating under Regulation 5 support, is correct, understandable and available.

The CAG felt that they would like to see evidence of patient and public involvement and engagement that supported the non-application of the National Data Opt-Out. The CAG asked that feedback from this was provided within three months of the issue of the final outcome letter. The members noted that the applicant may be able to approach a unique set of individuals for their opinion, as during the meeting it was commented that there are some participants in a consented clinical trial who had initially opted out using the NDO.

Taking the issue of communication into account, 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 17/CAG/0071. 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. However, this recommendation was subject to an acceptable communications strategy and supporting text being clearly defined and in place before final support could be issued.

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

Request for further information

1. Set out clearly into a communications strategy, the various communication routes that will be used to inform the patient population that the National Data Opt-Out will

not be applied to the NICOR audit activity. Approach/dissemination/communication methods should be proportionate to the requested change.

2. Please provide all associated patient notification materials, which should be layered, and made clearer than the current draft.

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/0071
2. The National Data Opt-Out must be applied in relation to processing for research purposes, specifically in relation to 17/CAG/0078
3. A local patient objection mechanism must continue to be used in relation to 17/CAG/0071
4. The applicant is requested to submit full refreshed applications in relation to 17/CAG/0071 and 17/CAG/0078 to ensure to scope of support is clear regarding research and non-research activity. This should be submitted in lieu of the next due annual review.
5. 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 the final outcome letter.

○ 17/CAG/0152 - Barts Health (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI)

This is a request to defer the national data opt out for 17/CAG/0152, non-research application. The Healthcare Quality Improvement Partnership (HQIP) commissions the cardiac audits on behalf of the Department of Health and Social Care (DHSC).

17/CAG/0152 superseded CAG 5-07(c)2013 due to a change of data controller from University College London (UCL) to Barts Health NHS Trust. TAVI has been supported since 2014 (through various data controller changes), with consistent submission of annual reviews since that time.

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

The applicants submitted this request in relation to 2 non-research applications, 17/CAG/0152 and 17/CAG/0071 (which is provided as a separate outcome letter). The ensuing paper provided by the applicants mentioned research. This outcome letter relates only to the non-research activities undertaken under CAG reference 17/CAG/0152.

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 NICOR.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and reduce the ability to monitor individual Trust performance
2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data
3. Technical impacts – the systems are not designed to apply the national data opt out on a direct entry system which will add workload to direct care teams to apply the national data opt out, and increase associated costs to the NHS

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 at both individual cardiac consultant level, and at Trust level. The data is also used as a surveillance tool for cardiac medical devices such as stents, heart valves, defibrillators, and pacemakers, to ensure that treatment decisions are safe, effective and evidence based. As such the audit can be used to notify hospitals of relevant patients should a medical device be recalled, or a safety notice issued, which has direct impacts on patient safety, and would require all individuals to be included.

Members were strongly 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. In particular, it was noted that the current national average is over 5%, and a small number of practices have recorded rates of over 30% objections. The applicants reasoned that data used for national clinical

audit purposes needs to be as representative as possible of the whole population to ensure accurate conclusions can be drawn. If the NDO was applied, certain patient groups, (demographics and rare conditions) may not be fully accounted for, which will minimise the ability of the audit to identify potential problems and implement corrective measures. The paper explained that studies have shown that certain groups are more likely to opt out with clustering by age, geographic location, or ethnicity. This non-random nature would pose difficulties in determining whether every patient admitted with a cardiac issue receives optimal care. The population bias introduced into datasets with opt-outs applied cannot be treated with the same statistical methods used to treat missing data, and any attempt to correct for these data may add further bias to the results. These issues jeopardise the accuracy and full applicability of the audit results both to those who have opted out and those who have not opted out.

Members were supportive of the justifications provided regarding bias.

3. Deferral rationale: Technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, and increase the cost to the NHS. It was also noted that if the NDO were not applied, then Trusts could continue to enter data directly into the central database, and continue to have access to their own data for their own clinical purposes at Trust level.

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

Informing the patient population

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

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

Additionally, the Members viewed the NICOR website as part of this review, and found that parts of the website state that the NDO is being applied currently. The applicant is reminded to ensure that all communications, including all areas of the website, surrounding the application of the NDO are coherent and consistent.

Members were not content with the privacy notice text provided for NICOR, and the applicant is requested to split this communication into a shorter patient notification, that leads on to a longer privacy notice. The content of the text should be refreshed and improved, and be more accessible for a lay audience. Updated versions of each should be provided to CAG, ensuring that the wording regarding not applying the NDO was clear and appropriate.

A communications plan should be provided to CAG to explain how this information will be disseminated.

In addition, the CAG were not clear if there were specific separate notifications provided for TAVI, or if this was part of the same notifications as 17/CAG/0071.

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 particularly strong and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

However, CAG was very clear that any requests for deferral from the NDO must have in place a clear communications strategy as it would represent a significant deviation from published information. In particular, CAG noted that changes to privacy notices only is a limited piecemeal solution that risks criticism and strongly agreed that there is no transparency in introducing a major change to earlier information provided to the public through editing previous privacy information without considerable, detailed and wide notification. It was noted that the CAG receives external scrutiny from privacy campaigners and journalists therefore CAG is not prepared to compromise its position of public trust and strongly advised that intended information given to the public when requesting a deferral from the NDO when operating under Regulation 5 support, is correct, understandable and available.

The CAG felt that they would like to see evidence of patient and public involvement and engagement that supported the non-application of the National Data Opt-Out. The CAG

asked that feedback from this was provided within three months of the issue of the final outcome letter. The members noted that the applicant may be able to approach a unique set of individuals for their opinion, as during the meeting it was commented that there are some participants in a consented clinical trial who had initially opted out using the NDO.

Taking the issue of communication into account, 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 17/CAG/0152. 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. However, this recommendation was subject to an acceptable communications strategy and supporting text being clearly defined and in place before final support could be issued.

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

Request for further information

1. Set out clearly into a communications strategy, the various communication routes that will be used to inform the patient population that the National Data Opt-Out will not be applied to the TAVI audit activity. Approach/dissemination/communication methods should be proportionate to the requested change.
2. Please provide all associated patient notification materials, which should be layered, and made clearer than the current draft.

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/0152.
2. A local patient objection mechanism must continue to be used in relation to 17/CAG/0152.
3. 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 the final support letter.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Professor William Bernal, CAG Alternate-Vice Chair		*17 July 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*14 July 2022*