

Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 9th May 2024

09:00 – 12:20

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	Role:
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair)
Dr. Phil Koczan (PK)	NHS England member (Caldicott Guardian Team Representative (Delegate for Dr. Jonathan Osborn))
Andrew Martin (AM)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
Miranda Winram (MW)	AGD independent member (Lay Adviser)
Tom Wright (TW)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	Role / Area:
Ben Cromack (BC)	Data Access and Partnerships, Data and Analytics (Observer: items 5.2 and 5.3)
Suzanne Hartley (SH)	Data Access and Partnerships, Data and Analytics (Observer: items 5.2 and 5.3)
Dickie Langley (DL)	NHS England SIRO Representative (Delegate for Garry Coleman)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate (Presenter: item 11.1)
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics (Observer: item 5.1)

James Watts (JW)	Data Access and Partnerships, Data and Analytics (Observer: items 5.4 and 5.5)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate (Presenter: item 10.1)
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS <u>NOT</u> IN ATTENDANCE:	
Name:	Role / Area:
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Prof. Nicola Fear (NF)	AGD independent member (Specialist Academic Adviser)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
NHS ENGLAND STAFF <u>NOT</u> IN ATTENDANCE:	
Garry Coleman (GC)	NHS England SIRO Representative

1	Welcome and Introductions: The AGD meeting Chair welcomed attendees to the meeting.
2	Review of previous AGD minutes: The minutes of the AGD meeting on the 2 nd May 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
3	Declaration of interests: There were no declarations of interest.
4	AGD Action Log: <i>The action log was not discussed.</i>
5 BRIEFING PAPER(S) / DIRECTIONS:	
<i>There were no items discussed</i>	
6 EXTERNAL DATA DISSEMINATION REQUESTS:	

6.1	<p>Reference Number: NIC-49826-T0J7C-v5.2</p> <p>Applicant: University College London (UCL)</p> <p>Application Title: Centre for Longitudinal Studies Birth Cohort Studies Data Linkage: 1970 British Cohort Study</p> <p>Observer(s): Jodie Taylor-Brown</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented / discussed at the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) meetings on the 13th January 2022, 6th August 2020 and the 2nd March 2017.</p> <p>The application and relevant supporting documents were previously presented / discussed at the IGARD COVID-19 response meeting on the 29th September 2020.</p> <p>Linked applications: This application is linked to NIC-51342-V1M5W, NIC-49297-Q7G1Q and NIC-384504-N2V5B.</p> <p>Application: This was an amendment application.</p> <p>The amendment is the addition of 1) Mental Health Minimum Data Set, 2) Mental Health and Learning Disabilities Data Set and 3) Mental Health Services Data Set, to cover the period 2006 – 2023.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> 1. The legal basis (compatibility with the consent); and, 2. The justification for the mental health datasets. <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following substantive comments. AGD noted that this support for advice points 1 and 2 (above) does not remove the need for attention to be paid/corrective action taken on the following comments.</p> <p>AGD noted that they had only been provided with limited documentation and noted that they would be providing observations based on these documents only.</p> <p>In response to points 1 and 2:</p> <p>6.1.1 AGD noted concern that a consent review had not been provided as a supporting document (as would be usual practice and especially noting the advice point 1), and were therefore unclear as to whether earlier iterations of the applicant's consent materials made any express, restrictive statements about mental health data. However, the Group advised that they had no reason to think there were such statements and, given the good track record of the applicant in communicating with the cohort, they were of the opinion that it would be appropriate for NHS England to flow the mental health data.</p>	
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6.1.2 AGD advised that they were supportive of the assessment made by NHS England in the internal Data Access Service (DAS) escalation form, that it would be reasonable for the mental health datasets to be included as part of the “*health*” data described in the provided supporting documents.

6.1.3 AGD noted that the advice provided on this application in relation to points 1 and 2, could also be used as a ‘reusable decision’ that would also be applied to the three other linked studies / applications; and advised that it was the view of the Group, that it would be appropriate to include the mental health datasets across the other studies.

6.1.4 AGD noted in the internal DAS escalation form, that there was a public engagement session planned later in the year to seek the views of participants on the addition of the mental health datasets. Since they could be seen as seeking support for data that would probably have already flowed by the time this takes place, the Group suggested that this consultation is reframed as a transparency exercise to inform of the changes that have taken place and to remind participants of their ability to withdraw their consent. It was suggested by the Group that in addition to the planned public engagement, UCL review and update their transparency material to ensure that the addition / processing of the mental health datasets was made transparent to the public / participants.

6.1.5 In addition, it was suggested by the Group that the transparency materials were clear as to how participants could withdraw from the study.

In addition, with the agreement of the SIRO representative, AGD made the following significant observations on the application and / or supporting documentation provided as part of the review:

6.1.6 Noting that the suite of longitudinal studies had been subject to a number of reviews by the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) and AGD; it was suggested by AGD, that a careful review was undertaken on the previous points raised; and that for future reference, it was clearly noted in the internal DAS escalation form, or separate supporting document, how each point had been addressed. Some of the studies had had significant points raised during previous reviews and it was **not** apparent whether those issues had been addressed. Furthermore, some of the studies been clearly identified as **not** suitable for precedent route in the future and should have been considered for a full review by AGD. The Group therefore expressed the view that while they were happy to give advice on the specific points as noted above, they were **not** offering their support for all aspects of every application and would expect each of the applications to undergo a thorough review and independent oversight in the future.

6.1.7 AGD noted in the internal DAS escalation form, that the applicant had reported a “*low risk*” breach to NHS England in February 2024, and thanked NHS England for the information provided on this. The Group noted that it was clear that NHS England was not at fault for this breach. However, the Group queried whether there

	<p>should have been further discussion with UCL, noting that no information was provided to AGD as to whether the data subjects concerned had been notified.</p> <p>6.1.8 Separate to this application: Reflecting on this application, and recognising that the points may already be covered, the Group felt it helpful to make some observations for the AGD NHS England Data Protection Officer (DPO) representative to consider. Firstly, that consideration of whether to inform research participants should include possible ethical obligations to participants as well as data governance considerations. Secondly, to consider whether the flow of data from NHS England needs to be assessed as a breach, separate to the flow of data into NHS England</p> <p>ACTION: the AGD NHS DPO representative to consider the two observations outlined in point 6.1.8</p> <p>6.1.9 In addition, the Group suggested that the AGD NHS England Data and Analytics representative, consider / discuss with colleagues, whether applications should progress via NHS England's Precedent route if a breach had occurred, or whether these applications should have independent oversight for a period of time and / or be subject to an audit.</p> <p>ACTION: The AGD NHS England Data and Analytics representative, to consider / discuss with colleagues, whether applications should progress down NHS England's Precedent route if a breach had occurred, or whether these applications should have independent oversight for a period of time and / or be subject to an audit.</p> <p>6.1.10 AGD suggested that, for transparency and public reassurance, UCL disclose any breaches on their website, and advise the steps taken following the breach; and clarify how a similar breach will be prevented in the future.</p> <p>6.1.11 The Group queried whether the applicant had notified their Health Research Authority Research Ethics Committee (HRA REC) about the breach; and suggested that NHS England discuss / clarify this with the applicant; and that appropriate steps were taken by the applicant as may be appropriate.</p> <p>6.1.12 Noting the public engagement planned later this year (see point 6.1.4); it was suggested that the breach be discussed with the participants, for example, in respect of transparency to the cohort / public and any lessons that can be learned.</p> <p>6.1.13 AGD noted the special conditions in section 10 (Sub-licensing) of the application, in respect of the applicant publishing a release register including the details of the sub-licences, which must be updated on a quarterly basis no more than 3 months in arrears; and suggested that NHS England clarify with the applicant that this was up to date and was an accurate record of the sub-licences. It was noted that failure to have an up to date release register would be a breach of the data sharing agreement (DSA).</p>	<p>DPO Rep</p> <p>D&A Rep</p>
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	<p>6.1.14 In addition, AGD suggested that the applicant ensure that the up to date sub-licences release register is easily accessible, noting that this is currently not easy to locate online.</p> <p>6.1.15 The Group noted that the DSA expressly prohibits data access to commercial organisations for research or for commercial purposes; however, noted concern that the UK Data Service (UKDS) process for sub-licensing (which is permitted under the DSA) applies different criteria to NHS England when designating project applications as commercial. This may unintentionally or inadvertently allow access to commercial organisations for research or for commercial purposes; and suggested that this was explored further by NHS England.</p> <p>6.1.16 AGD noted the special condition in section 10 “<i>The Data Sharing Framework Contract (DSFC) sets out the legal terms and conditions which apply to the transfer and use of Data supplied to [Organisation] under this DSA</i>”; and suggested that this template wording was reviewed and completed to include the correct organisation name throughout.</p>	
6.2	<p>Reference Numbers: NIC-748645-R5G3D</p> <p>Applicant: Office for National Statistics (ONS)</p> <p>Application Title: NHS Diabetes Prevention Program (DPP)</p> <p>Observers: Suzanne Hartley and Ben Cromack</p> <p>Linked applications: This application is linked to NIC-748653-S9J4H (item 6.3).</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for ONS to use the data for its health and labour market statistical work programme, which is currently sponsored by His Majesty’s (HM) Treasury and potentially other funding bodies in the future. The statistics this will enable are in line with ONS’s function to produce statistics for the public good.</p> <p>NHS England were seeking initial advice on the application.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD noted that they were specifically asked to provide initial advice, and that the application was subject to additional work. However, to assist in the development of the application, AGD provided the following advice to the SIRO (noting that the points may not be relevant once additional detail is added to the application):</p> <p>6.2.1 AGD welcomed the review of the application, and advised that they were happy to provide input on review panel proposals as they take shape, noting the AGD NHS England Caldicott Guardian Team and Data Protection Office (DPO) representatives form part of the Group and therefore reference to AGD was both appropriate and welcomed.</p>	

	<p>6.2.2 AGD noted and applauded the utilisation of the National Statistics Data Ethics Advisory Committee (NSDEC) as outlined in the application, and thanked NHS England and the applicant for the helpful correspondence provided in relation to this. It was noted however, that a number of points had been raised by NSDEC. A link had been provided to research undertaken by ONS in relation to the points raised, however some of these research findings pointed to a lack of public acceptability in some aspects of this type of data sharing, rather than support. No information had therefore been provided to clarify how the NSDEC points had been addressed; and there was no confirmation provided to confirm that NSDEC were satisfied with how the points raised had been addressed. It was suggested that NHS England clarify with ONS that the points had been suitably addressed and that NSDEC were satisfied, including, but not limited to, the points raised in relation to public acceptability, engagement and transparency. It was suggested that any updates on the NSDEC points were included in a supporting document for future reference and uploaded to NHS England's customer relationships management (CRM) system.</p> <p>6.2.3 AGD suggested that Health Research Authority Research Ethics Committee (HRA REC) support may be required, given that that some aspects of the work outlined were health research, with the applicant receiving identifiable data.</p> <p>6.2.4 AGD noted the references to 'NHS Arden and Gem Commissioning Support Unit (CSU)' in the cover note provided as a supporting document; and noting that they were not referenced within the application. It was suggested that further clarification be provided in the application, as to the role of NHS Arden and Gem CSU, including, but not limited to, what data they would be handling / providing.</p> <p>6.2.5 AGD noted that patient objections do not apply; and noted the statement in the National Data Opt-out (NDO) policy (point 7.6) that "<i>The national data opt-out does not apply to data flowing into the Office for National Statistics (ONS) solely for the production of official statistics</i>"; and noting previous discussions on this point, suggested consideration was given as to whether all of the intended activities fall under the production of official statistics.</p> <p>6.2.6 AGD advised NHS England that they would welcome further discussions on this application and other ONS applications as may be required.</p>	
6.3	<p>Reference Numbers: NIC-748653-S9J4H</p> <p>Applicant: Office for National Statistics (ONS)</p> <p>Application Title: Waiting List Minimum Data Set Acquisition</p> <p>Observers: Suzanne Hartley and Ben Cromack</p> <p>Linked applications: This application is linked to NIC-748645-R5G3D (item 6.2).</p> <p>Application: This was a new application for initial advice.</p> <p>The purpose of the application is for ONS to use the data for its health and labour market statistical work programme, which is currently sponsored by HM Treasury</p>	

and potentially other funding bodies in the future. The statistics this will enable are in line with ONS's function to produce statistics for the public good.

NHS England were seeking initial advice on the application.

Should an application be approved by NHS England, further details would be made available within the [Data Uses Register](#).

Outcome of discussion: AGD noted that they were specifically asked to provide initial advice, and that the application was subject to additional work. However, to assist in the development of the application, AGD provided the following advice to the SIRO (noting that the points may not be relevant once additional detail is added to the application):

6.3.1 AGD welcomed the review of the application, and advised that they were happy to provide input on review panel proposals as they take shape, noting the AGD NHS England Caldicott Guardian Team and Data Protection Office (DPO) representatives form part of the Group and therefore reference to AGD was both appropriate and welcomed.

6.3.2 AGD noted and applauded the utilisation of the National Statistics Data Ethics Advisory Committee (NSDEC) as outlined in the application, and thanked NHS England and the applicant for the helpful correspondence provided in relation to this. It was noted however, that a number of points had been raised by NSDEC. A link had been provided to research undertaken by ONS in relation to the points raised, however some of these research findings pointed to a lack of public acceptability in some aspects of this type of data sharing, rather than support. No information had therefore been provided to clarify how the NSDEC points had been addressed; and there was **no** confirmation provided to confirm that NSDEC were satisfied with how the points raised had been addressed. It was suggested that NHS England clarify with ONS that the points had been suitably addressed and that NSDEC were satisfied, including, but not limited to, the points raised in relation to public acceptability, engagement and transparency. It was suggested that any updates on the NSDEC points were included in a supporting document for future reference and uploaded to NHS England's customer relationships management (CRM) system.

6.3.3 AGD suggested that Health Research Authority Research Ethics Committee (HRA REC) support may be required, given that some aspects of the work outlined were health research, with the applicant receiving identifiable data.

6.3.4 AGD noted the references to 'NHS Arden and Gem Commissioning Support Unit (CSU)' in the cover note provided as a supporting document; and noting that they were **not** referenced within the application. It was suggested that further clarification be provided in the application, as to the role of NHS Arden and Gem CSU, including, but not limited to, what data they would be handling / providing.

6.3.5 AGD noted that patient objections do not apply; and noted the statement in the National Data Opt-out (NDO) [policy](#) (point 7.6) that "*The national data opt-out does*

	<p><i>not apply to data flowing into the Office for National Statistics (ONS) solely for the production of official statistics</i>"; and noting previous discussions on this point, suggested consideration was given as to whether all of the intended activities fall under the production of official statistics.</p> <p>6.3.6 AGD advised NHS England that they would welcome further discussions on this application and other ONS applications as may be required.</p>	
6.4	<p>Reference Number: NIC-682529-F0V1M-v0.10</p> <p>Applicant: Royal Free London NHS Foundation Trust</p> <p>Application Title: Investigation of 2018 National Cancer Diagnosis Audit (NCDA) results in London</p> <p>Observer: James Watts</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for the National Cancer Diagnosis Audit (NCDA), which seeks to investigate factors influencing early diagnosis in primary care by asking GPs to provide information about what happened in the leadup to a cancer diagnosis.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following significant comments:</p> <p>6.4.1 AGD noted that, based on the documents provided to the Group as part of the review, that the purpose of the application appeared to be for research and not service evaluation as outlined in the application. Noting the efforts made by NHS England to discuss this with the applicant, it was suggested that the applicant review this further, for example, via the Health Research Authority guidance on service evaluation.</p> <p>6.4.2 AGD noted that Article 9(2)(i) (<i>public interest in the area of public health</i>) of the UK General Data Protection Regulation (UK GDPR) had been cited as the legal basis to process the data; however, suggested that there may be an alternate / more suitable Article 9 legal basis to rely on for the work outlined in the application.</p> <p>6.4.3 The AGD NHS England Data Protection Office (DPO) representative suggested that NHS England may wish to review the applicant's Data Protection Impact Assessment (DPIA), if one was available, to review how the applicant had decided on their current Article 9 legal basis.</p> <p>6.4.4 The Group suggested that the Article 9 legal basis was reviewed and if possible, suggested that the applicant consult with their Information Governance Officers within the hospital, if possible, on this point; or to further consider the advice already provided by NHS England. If it was deemed that the Article 9 legal basis was</p>	

	<p>incorrect, then it was suggested that the application and any relevant supporting documents were updated to reflect the correct legal basis.</p> <p>6.4.5 AGD noted that consideration had been given to potential ethical issues but noted the use of incentives can raise concerns; and suggested that the applicant clearly demonstrates compliance with the NHS England DAS Standard for Ethical Approval.</p>	
6.5	<p>Reference Number: NIC-700547-S2M9L-v0.5</p> <p>Applicant: CorEvitas (trading name of Health IQ Ltd)</p> <p>Application Title: Epidemiology and treatment of HR+/HER2- breast cancer in England (ROTOR)</p> <p>Observer: James Watts</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for a study, aiming to understand the epidemiology, real-world treatment of hormone receptor-positive (HR+) and HER2-negative (HER2) breast cancer, and associated healthcare resource use in England.</p> <p>Should an application be approved by NHS England, further details would be made available within the Data Uses Register.</p> <p>Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:</p> <p>6.5.1 NHS England advised the Group, that the Data Sharing Framework Contract (DSFC) for Novartis Pharmaceuticals UK Limited DSFC expired on the 22nd March 2024, and the applicant was currently in the process of renewing; and that as outlined in the internal application assessment document, provided as a supporting document, no data would flow until an active DSFC was in place. The Group noted the verbal update.</p> <p>6.5.2 Separate to this application: AGD suggested that for transparency, and to support the assessment of all applications, it would be helpful to routinely receive further information as to why any outstanding aspects of a DSFC were not up to date, for example, was it due to resourcing issues within NHS England, a lack of action on the part of the applicant, or for technical reasons. It was suggested that the AGD NHS England Data and Analytics representative discuss this further with colleagues.</p> <p>ACTION: The AGD NHS England Data and Analytics representative to discuss with colleagues, that for all future applications further information was provided as to why any outstanding aspects to a contractual framework, for example a DSFC, were not up to date.</p> <p>6.5.3 The Group noted and commended the efforts of the applicant to determine whether there was a proportionate balance between public and commercial benefit</p>	D&A Rep

	<p>flowing; however, suggested that section 5(a) (Objective for Processing) was reviewed and edited / updated, to ensure that the “<i>commercial</i>” purpose / benefit was transparent, for example the realisation of commercial gain by the pharmaceutical company, plus the potential significant benefit to the public from this research.</p> <p>6.5.4 AGD noted in section 5(a) that there had been no patient and public involvement and engagement (PPIE); however, suggested that to further support the potential substantial benefits outlined, that the applicant should consider undertaking some PPIE. The HRA guidance on Public Involvement is a useful guide.</p> <p>6.5.5 It was noted that whilst the study protocol suggested that publishing the results “...<i>may be either submitted for publication and/or posted...</i>”, AGD suggested that, in line with the statement in the study protocol provided as a supporting document, a special condition was added to section 6 (Special Conditions) of the application to ensure that upon study completion and finalisation of the study report, the results are made public, for instance submitted for publication and/or posted in a publicly accessible database of results.</p> <p>6.5.6 Separate to this application: AGD suggested that the AGD NHS England Data and Analytics representative consider / discuss with colleagues whether it would be beneficial to include a standard special condition in applications, to ensure that the results of any research / studies should be made publicly accessible, particularly where the public benefit aspect of an application substantially depends on the creation and sharing of learning or insight from the use of the data. This would help to ensure the public good can be achieved.</p> <p>ACTION: AGD NHS England Data and Analytics representative to consider / discuss with colleagues whether it would be beneficial to include a standard special condition in applications, to ensure that the results of any research / studies should be made publicly accessible.</p> <p>6.5.7 AGD noted that the applicant was a Data Processor; and suggested that NHS England ensure that the data sharing agreement (DSA) is signed by the appropriate individual / organisation from the Data Controller organisation.</p>	D&A Rep
7 INTERNAL DATA DISSEMINATION REQUESTS:		
<i>There were no items discussed</i>		
8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
<i>There were no items discussed</i>		
9 OVERSIGHT AND ASSURANCE		
<i>There were no items discussed</i>		

10 AGD OPERATIONS

10.1 AGD Standard Operating Procedures (SOPs) (Presenter: Vicki Williams)

The ongoing forward plan of work for creating the AGD Standard Operating Procedures was discussed; and noting that the AGD Terms of Reference (ToR) had now been approved, it was noted that work was progressing in order to finalise the AGD SOPs in line with the approved AGD ToR.

It was noted that a further update would be provided to the Group in due course.

10.2 AGD Stakeholder Engagement

There were no items discussed

10.3 AGD Project Work

There were no items discussed

11 Any Other Business

11.1 Service Improvements (Presenter: Karen Myers)

A verbal update was provided to the group, in respect of the quarterly service improvement programme of work, where a number of 'observations' and 'actions' were highlighted following initial feedback from the AGD members and NHS England colleagues.

It was agreed by AGD and the AGD Secretariat that future service improvement feedback would be requested every four to six months.

Meeting Closure

As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.