Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 25th July 2024

09:00 – 11:35

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
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))
Narissa Leyland (NL)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
Jenny Westaway (JW)	AGD independent member (Lay Adviser)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Garry Coleman (GC)	NHS England SIRO Representative
Suzanne Hartley (SH)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.1 and 6.2)
Lucy Legge (LL)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.1 to 6.4)
Tiaro Micah (TM)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.1 to 6.5)
Humphrey Onu (HO)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.1 to 6.5)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
James Watts (JW)	Data Access and Partnerships, Data and Analytics (**Observer:** item 6.5)

Emma Whale (EW)	Data Access and Partnerships, Data and Analytics (**Observer:** items 6.1 and 6.2)
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS NOT IN ATTENDANCE:	
Name:	**Role / Area:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser)
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)
Miranda Winram (MW)	AGD independent member (Lay Adviser)

1	**Welcome and Introductions:** The AGD meeting Chair welcomed attendees to the meeting. AGD noted that, due to unforeseen circumstances, only two AGD NHS England members were in attendance for the meeting. Noting that the AGD Terms of Reference state that *"The quorum for meetings of the Group or a Sub-Group is five members, including at least three independent members, one of whom may be the Chair, Deputy Chair or Acting Chair and **two of the three NHSE Members**…",* the Group agreed that, as there were two AGD NHS England members present, the meeting was still quorate for **all** agenda items and agreed to proceed on that basis.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 18th July 2024 were reviewed and, after several minor amendments, were agreed as an accurate record of the meeting.
3	**Declaration of interests:** Kirsty Irvine noted a professional link to NIC-642373-Z3P7N (Imperial College London) as part of her role at the Royal College of Obstetricians and Gynaecologists; but noted no

	specific connection with the PPIE for the application or staff involved, and it was agreed that this was not a conflict of interest.	
4	**AGD Action Log:** *The action log was not discussed.*	
5 BRIEFING PAPER(S) / DIRECTIONS:		
There were no items discussed.		
6 EXTERNAL DATA DISSEMINATION REQUESTS:		
6.1	**Reference Number:** NIC-427962-M3K1W-v0.14 **Applicant:** Intensive Care National Audit & Research Centre (ICNARC) **Application Title:** Intensive Care Unit Randomised Trial Comparing Two Approaches to OXygen Therapy (UK-ROX) – **Consent** **Observers:** Suzanne Hatley, Emma Whale, Tiaro Micah, Humphrey Onu and Lucy Legge **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) meeting on the 8th July 2021. **Linked applications:** This application is linked to NIC-754519-V1T5M (item 6.2). **Application:** This was a new application. The purpose of the application is for a large-scale, multi-centre, data-enabled, registry-embedded, randomised clinical trial, aiming to evaluate the clinical and cost-effectiveness of conservative oxygen therapy versus usual oxygen therapy, in adults receiving invasive mechanical ventilation (MV) with supplemental oxygen following an unplanned Intensive Care Unit (ICU) admission. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments: **6.1.1** AGD noted that there was an online privacy notice, however, suggested that this was updated to be clear as to how participants could withdraw their consent from the study. **6.1.2** AGD noted and commended the applicant on the bespoke benefits outlined in section 5(d) (Benefits) of the application, that were reflective of the work being undertaken.	
6.2	**Reference Number:** NIC-754519-V1T5M-v0.3	

	Applicant: Intensive Care National Audit & Research Centre (ICNARC) **Application Title:** Intensive Care Unit Randomised Trial Comparing Two Approaches to OXygen Therapy (UK-ROX) - **Section 251 and Consultee** **Observers:** Suzanne Hartley, Emma Whale, Tiaro Micah, Humphrey Onu and Lucy Legge **Linked applications:** This application is linked to NIC-427962-M3K1W (item 6.1). **Application:** This was a new application. The purpose of the application is for a large-scale, multi-centre, data-enabled, registry-embedded, randomised clinical trial aiming to evaluate the clinical and cost-effectiveness of conservative oxygen therapy versus usual oxygen therapy, in adults receiving invasive mechanical ventilation (MV) with supplemental oxygen following an unplanned Intensive Care Unit (ICU) admission. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments: **6.2.1** AGD noted that Article 6(1)(f) of the UK General Data Protection Regulation (UK GDPR) had been cited as the legal basis for processing data where consultee advice has been provided. However, the Group suggested that NHS England explored this further and request the applicant to provide further clarification as to why this legal basis had been cited; or that the application is updated to reflect an alternate / more appropriate legal basis. **6.2.2** AGD noted that there was an online privacy notice, however suggested that this was updated to reflect current language in respect of the s251 support, noting that this was now in place; and to make reference to the National Data Opt-out policy.	
6.3	**Reference Number:** NIC-739822-Q8R6Y-v0.4 **Applicant:** University of Manchester **Application Title:** Investigating Causal Effects of Mental Healthcare Provision on Labour Outcomes: A Case Study of Talking Therapies in England **Observers:** Tiaro Micah, Humphrey Onu and Lucy Legge **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 6th June 2024. **Application:** This was a new application. The purpose of the application is to aid in improving the service delivery of NHS Talking Therapies for Anxiety and Depression services (formerly Improving Access to Psychological Therapies (IAPT)), and provide real-world evidence of the effect of	

	mental healthcare treatments on labour market outcomes needed to better understand the relationship of mental health and labour supply in England. This is to support the NHS to better meet the demands for treatment of the English population, and potentially further reduce the lost productivity caused by mental health conditions. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments: **6.3.1** AGD noted that a number of points had been made on this application at the AGD meeting the 6th June 2024 and that responses had been provided on each of the points raised in the Data Access Service (DAS) internal application assessment form. **6.3.2** AGD noted the response to the previous point raised on the 6th June 2024 (6.1.6) in respect of the IAPT data and suggested that NHS England ensure that the applicant is aware that in terms of determining occupational status, being a benefit recipient may not be an accurate proxy for someone being unemployed. **6.3.3** AGD noted that they had previously raised the point on the 6th June 2024 (6.1.8), that in addition to the data sharing agreement (DSA), there was also a 'User Agreement' for those individuals accessing data in NHS England's Secure Data Environment (SDE), that covers off key points, including, but not limited to, specific user access and restrictions on exporting data. The Group noted the response provided on this point, which suggested that a user could **not** breach the SDE User Agreement; and suggested that this was reviewed and updated to reflect the correct / factual information. **6.3.4** AGD reiterated the previous point raised on the 6th June 2024(6.1.9), that the application was updated to specifically reference the 'User Agreement' document, and that this was linked to the compliance with the DSA, for example, by the addition of a special condition in section 6 (Special Condition) of the application, stating that any breach of the 'User Agreement' would also be a breach of the DSA. **6.3.5** AGD noted the information in section 5(a) (Objective for Processing) of the application in respect of data minimisation; and suggested that this was updated to be clear that the applicant will **not** have access to any other data in the SDE other than the minimised data as outlined in the application. **6.3.6** AGD noted and commended the applicant and NHS England's DAS, on the work undertaken to identify the benefits to health and social care and not just the work to the PhD student, noting that this was in response to a previous point made by the Group.	

	6.3.7 AGD noted and commended the applicant on the bespoke benefits outlined in section 5(d) (Benefits) of the application, that were reflective of the work being undertaken.	
6.4	**Reference Number:** NIC-656847-K4L8H-v2.4 **Applicant:** University of Newcastle-Upon-Tyne **Application Title:** Investigating inequalities in utilisation of targeted therapies **Observers:** Tiaro Micah, Humphrey Onu and Lucy Legge **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meeting on the 23rd February 2023. The National Disease Registration Service (NDRS) datasets requested under this DSA had previously flowed from Public Health England (PHE) prior to its closure at the end of September 2021; and therefore, had not had a previous independent review. **Application:** This was an amendment application. Previous work undertaken has found inequalities in novel treatment receipt for both lung and breast cancers. In the most common type of lung cancer (non-small cell lung cancer (NSCLC)), patients living in the most deprived areas of England were found to have reduced access to targeted therapy and immunotherapy drugs. The purpose of this application is for a project to examine the "real world" outcomes (survival) of patients who utilise these drugs, and whether this varies by deprivation and other socio-economic/clinical variables and provide a more up-to-date investigation of socio-economic inequalities in targeted treatments and immunotherapy receipt for cancer patients in England. NHS England were seeking advice on the following points: 1. The new datasets and variables; and, 2. The broadened purpose / scope to new cancer types and longer duration. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments: **In response to points 1 and 2:** **6.4.1** AGD advised that they were unable to locate a published privacy notice, and suggested the applicant was reminded that they were required to maintain a UK General Data Protection Regulation (UK GDPR) compliant, **publicly accessible** transparency notice(s) for the lifetime of the agreement, in line with the contractual requirement in section 4 (Privacy Notice) of the data sharing agreement (DSA).	

	6.4.2 AGD noted and commended the applicant on liaising with the patient and public involvement and engagement (PPIE) group, who had provided support with the refinement of the purpose of the research. It was also noted by the Group that the PPIE group were supportive of the collection of the data for the purposes described and were keen that research on these drugs should include all cancer sites for which the drugs are used. **6.4.3** AGD noted and commended the applicant on the updates to the benefits in section 5(d) (Benefits), which had been expanded to reflect the new flow of data. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **6.4.4** AGD noted and commended the applicant on the bespoke benefits outlined in section 5(d) of the application, that were reflective of the work being undertaken. **6.4.5** Noting the yielded benefits to the health and social care outlined in section 5(d) (iii) (Yielded Benefits), AGD suggested that the yielded benefit that refers to *"…resident in **greater areas** of deprivation…"* was reviewed and updated as may be necessary, for example to state *"greater deprivation",* if this was correct. **6.4.6** In addition, the Group suggested that the following yielded benefit in section 5(d) (iii) *"In contrast, two week wait patients were aged 60-80 years old, of white ethnicity, resident in areas greater deprivation and tended to have no comorbidities"*, was reviewed and updated as may be necessary. For example, were the patients in the two week wait also from areas of greater deprivation? If so, the Group suggested that the benefit was updated to be clear that the contrast is in relation to ethnicity. **6.4.7** The SIRO representative noted that the Data Security and Protection Toolkit (DSPT) reference number provided in section 1(b) (Data Controller(s)) of the application, was for a specific part of the University of Newcastle Upon Tyne ('University of Newcastle Upon Tyne Health and Social Care Data') and suggested that NHS England ensure that the applicant is aware of this.	
6.5	**Reference Number:** NIC-642373-Z3P7N-v0.7 **Applicant:** Imperial College London **Application Title:** National Maternity Research Database pilot **Observer:** James Watts, Tiaro Micah and Humphrey Onu **Application:** This was a new application. The purpose of the application is for a research project, with the aim of **1)** to create a UK maternity dataset to include outcomes from all stages of pregnancy, the postnatal period, and for neonates not admitted to neonatal units; **2)** to support local, regional, and national service improvement and audit in maternity services to improve pregnancy outcomes in the UK; and **3)** to facilitate participation of women in pregnancy in local, regional, and national clinical and epidemiological observational	

research and Randomised Controlled Trial (RCTs) using routinely collected clinical outcomes.

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

Outcome of discussion: AGD were supportive of the application and wished to draw to the attention of the SIRO the following comments:

6.5.1 AGD welcomed the application and noted the relevance of the subject matter at the current time; and the potential benefits of the National Maternity Research Database.

6.5.2 AGD queried whether the applicant had engaged / coordinated with the National Maternity and Perinatal Audit, noting that they had already addressed some of the questions that the National Maternity Research Database is aiming to address, and suggested that NHS England explore this further with the applicant.

6.5.3 In addition, the Group suggested that one of the anticipated outputs of the National Maternity Research Database could be to fed into the questions being explored by the National Maternity and Perinatal Audit.

6.5.4 AGD noted the helpful information / transparency throughout the supporting documents provided, in respect of future plans for a national research database (noting that this was a pilot) and linkage with identifying data. The Group noted that application was currently very restrictive, and highlighted that the future plans as outlined would require an amendment to the data sharing agreement (DSA), which would need to go via the usual NHS England Data Access Service (DAS) process.

6.5.5 AGD queried whether the application could have reflected / addressed any of the future plans outlined, noting that Health Research Authority Confidentiality Advisory Group (HRA CAG) support was in place for the linkage of identifying data, however this was not currently reflected / permitted in the application.

6.5.6 AGD suggested that as part of any future plans, that the applicant should ensure that they were able to satisfy NHS England, that the proposed plan for sub-licenses will add sufficient value and comply with the NHS England DAS Standard for Sub-licencing and Onward Sharing of Data.

6.5.7 AGD noted the DAS internal application assessment form stated that the processing of the data in NHS England's Secure Data Environment (SDE) was **not** currently an option; and advised that whilst there wasn't a reason provided for this view, agreed that it would be unlikely to be an option at the current time.

6.5.8 Separate to this application: AGD requested that the AGD NHS England Data and Analytics representative, ensure that for transparency, colleagues in DAS clarify in the DAS internal application assessment form, why data cannot be accessed / processed in NHS England's SDE.

	ACTION: The AGD NHS England Data and Analytics representative to ensure that colleagues in DAS clarify in the DAS internal application assessment form, why data cannot not be accessed / processed in NHS England's SDE. **6.5.9** The SIRO representative noted that the Data Security and Protection Toolkit (DSPT) reference number provided in section 1(b) (Data Controller(s)) of the application, was for a specific part of Imperial College London ('UK Small Area Health Statistics Unit') and suggested that NHS England investigate this further, as it would appear that this would **not** extend to the processing under this application. **6.5.10** AGD noted the expected benefits in section 5(d) (Benefits) of the application; and suggested that these were reviewed and updated as may be necessary in line with NHS England DAS Standard for Expected Measurable Benefits, to reflect the specific work under this application; and to also ensure that the inclusion of the templated wording in its entirety in this section was correct and appropriate (including because any Annual Confirmation Report or revised DSA would need to update progress against all of the expected benefits). **6.5.11** AGD noted the incorrect statement in section 7 (Ethics Approval) of the application *"Ethics approval is not required…"*; and suggested that this was updated to reflect that ethical approval was in place. **6.5.12** AGD noted the acronyms in section 5(a) (Objective for Processing), and suggested that these were reviewed, to ensure they were defined upon first use, for example *"UK NNRD"*.	D&A Rep
7 INTERNAL DATA DISSEMINATION REQUESTS:		
There were no items discussed.		
8 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
There were no items discussed.		
9 OVERSIGHT AND ASSURANCE		
There were no items discussed.		
10 AGD OPERATIONS		
10.1	**Risk Management Framework** As last noted in the AGD minutes from the 21st March 2024, the independent members noted the reference to reviewing materials in accordance with *"a clearly understood risk management framework"* within the published Statutory Guidance and advised that they were not aware of an agreed risk management framework, and reiterated a previous request that NHS England provide further information/ clarity on this to the Group, noting this topic had been raised by Lord Hunt in the	

	House of Lords on the 26th June 2023, and was answered by Lord Markham on the 5th July 2023: Written questions, answers and statements – UK Parliament. The NHS England SIRO Representative had provided further clarity on the risk management framework via email to the Group, which confirmed that NHS England were asking AGD (and previously the interim data advisory group) to use the NHS England DAS Standards and Precedents model to assess the risk factors in relation to items presented to AGD for advice; however the independent members noted that the wording in the statutory guidance "…*using a clearly understood risk management framework, precedent approaches and standards that requests must meet*…", suggested that the risk management framework is separate to the DAS Standards and Precedents, and asked that this be clarified by NHS England. The Group noted that plans for this work were in train. It had been noted previously by the interim data advisory group that the Oversight and Assurance Programme of applications that had not be subject to AGD review could form part of this Risk Management Framework. The NHS England SIRO representative noted an outstanding action in respect of providing a written response to AGD on the risk management framework; and noted that this was progressing under the NHS England Precedents and Standards work. **ACTION:** The NHS England SIRO Representative to provide a written response to AGD on the risk management framework	SIRO Rep
10.2	**AGD Standard Operating Procedures (SOPs)** 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 relevant AGD SOPs in line with the approved AGD ToR.	
10.3	**AGD Stakeholder Engagement** The AGD Chair noted to the Group that she had met with Dr. Tony Calland, the Chair of the Health Research Authority Confidentiality Advisory Group (HRA CAG) and Dr. Nicola Byrne, the National Data Guardian for health and adult social care in England, on Tuesday 23rd July 2024, as part of their regular engagement.	
10.4	**AGD Project Work** *There were no items discussed.*	
11 Any Other Business		
11.1	*There were no items discussed.*	

Meeting Closure

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