Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 14th November 2024

09:00 – 14:00

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser)
Kirsty Irvine (KI)	AGD independent member (Chair)
Andrew Martin (AM)	NHS England member (Data Protection Office Representative (Delegate for Jon Moore))
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
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:**
Garry Coleman (GC)	NHS England SIRO Representative
Wendy Harrison (WH)	Deputy Director of IG Delivery for Data and Analytics, Privacy, Transparency and Trust (PTT), Delivery Directorate (**Presenter**: item 2.1)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Delivery Directorate
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Delivery Directorate
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS NOT IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)

Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
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)
EXTERNAL STAFF IN ATTENDANCE (ITEM 4.1)	
Jenny Thompson (JT)	Head of Health Intelligence, NHS Arden and Greater East Midlands Commissioning Support Unit (**Presenter**: item 4.1)

1	**Welcome and Introductions:** The AGD Chair welcomed attendees to the meeting.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 7th November 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 BRIEFING PAPER(S) / INTERNAL DATA DISSEMINATION REQUESTS:	
4.1	**Title:** Internal data flow request for Clinical Registry Data **Presenters:** Wendy Harrison and Jenny Thompson The purpose of the briefing paper was to advise AGD, that a data extract from the National Haemoglobinopathy Registry (NHR) relating to Thalassemia patients, has been requested under the Data Services for Commissioners Directions 2015. The intention is to link this with a Secondary Uses Service (SUS) extract to provide additional clinical details. Analyses from this combined extract will be used as part of a Health Needs Assessment (HNA) commissioned by the National Healthcare Inequalities Improvement Programme. The HNA will be carried out by NHS Arden and Greater East Midlands Commissioning Support Unit; who will aim to objectively describe the burden of disease, the epidemiology, the unmet health needs and the service user experience of children and adults living with thalassemia nationally. The HNA will be used to help inform future commissioning decisions.

	NHS England were seeking general advice on the briefing paper **Outcome of discussion:** AGD welcomed the briefing paper and made the following observations / comments: **4.1.1** The Group noted that they were supportive of the proposed use of the NHR and recognised the need for the HNA. **4.1.2** AGD were keen to ensure sufficient transparency to patients in the NHR; and noted that while NHS England had updated their own privacy notice consideration needed to be given to how likely individuals on the NHR would be to see the update. In line with the eighth principle of The Caldicott Principles, *"A range of steps should be taken to ensure no surprises for patients and service users*…", the Group highlighted that due attention should be given to routes which would be more likely to be accessed by the relevant patients. **4.1.3** AGD noted that there was a clear legal gateway to ingest and process the data in the NHR, however, they also noted that the patient information leaflet contains contradictory statements. The leaflet refers to individual rights and choices regarding data, but also suggests there's no option to choose how medical data is stored. The Group suggested that this was reviewed and aligned to reflect the correct information. This was relevant to the transparency points highlighted in 4.1.2. **4.1.4** AGD discussed whether an opt-out could be applied and suggested that a justification was provided in the relevant documentation and transparency materials as to the opt-out options (if available) or why a non-registry specific opt-out could not be applied. **4.1.5** AGD suggested that the Article 9 UK General Data Protection Regulation (UK GDPR) conditions in the Data Protection Impact Assessment (DPIA) were reviewed and updated to reflect the correct information. **4.1.6** AGD discussed the confidentiality of the data in the NHR, and were advised that steps may be taken such as suppression of the data, noting that this may be identifiable.	
5 EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-737139-W2B7S-v0.5 **Applicant and Data Controller(s):** Cardiff University **Application Title:** MulTI-domain Self-management in Older People wiTh OstEoarthritis and Multi-Morbidities (TIPTOE) **Application:** This was a new application. The purpose of the application is for a randomised, multi-centre, two-arm trial aiming to evaluate the clinical and cost-effectiveness of a holistic, personalised self-management support intervention for adults with knee and/or hip Osteoarthritis and	

	multiple long-term conditions, that will help them to develop the knowledge, skills and confidence they need to manage their own health. NHS England were seeking general 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 were supportive of the application and wished to draw to the attention of the SIRO the following substantive comment: **5.1.1** AGD noted that NHS England's DAS had explored data controllership with the applicant in respect of Swansea University, however the answers provided raised questions for AGD and they suggested that this was explored further by NHS England to determine whether Swansea University should be a Data Controller in line with the NHS England DAS Standard for Data Controllers, It was suggested that the application was updated as may be necessary to reflect the correct / factual information. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.1.2** AGD suggested that section 5(a) (Objective for Processing) was updated to be clear that in addition to the information already provided on the roles and responsibilities of the individuals at Swansea University; that it was also clear on everything that Swansea University were responsible for, for example, the Secure Anonymised Information Linkage (SAIL) Databank. **5.1.3** AGD noted that, if a cohort member initially provided consent, and then lost capacity but continued in the study by way of consultee advice, AGD were of the view that the individual **should** be able to remain in the cohort and that the National Data Opt-out (NDO) would **not** be applied, as they did have capacity at the time they provided the initial consent. The Group advised that they did **not** support the removal of those in the study under consultee advice unless they were only in the study via consultee advice only. **5.1.4 Separate to the application:** AGD noted that the practice by some researchers of excluding certain parts of their cohort, to avoid the cost of two flows of data due to the technical application of the NDO, and suggested this was explored further by NHS England Data and Analytics, AGD were concerned that the costing model was potentially weakening research and wasting the contribution to research of individuals included in studies under consultee advice (the consultee advice individuals being excluded so as to avoid a second flow of data with the NDO applied) **ACTION:** NHS England Data and Analytics to explore whether there was a lower cost charging model, or technical solution, to stop the practice by some researchers of excluding certain parts of their cohort, due to the technical application of the NDO.	D&A Rep

	5.1.5 AGD suggested that NHS England clarify with the applicant, that the individuals accessing, processing and / or analysing the data are covered by the relevant Data Security and Protection Toolkit (DSPT), noting that each of the DSPTs cited in the application for the Data Controller and the Data Processor currently covers **only** staff working in the Cardiff University Centre for Trials Research and the SAIL DATABANK and SeRP UK respectively. **5.1.6** In addition, it was suggested that section 5(b) (Processing Activities) was updated to be clear that the DSPT covers staff working in the Cardiff University Centre for Trials Research and the SAIL DATABANK and SeRP UK. **5.1.7** AGD noted that the age range of the cohort was inconsistent in the NHS England Data Access Service (DAS) internal application assessment form that states this was greater than or equal to 70; and the patient information sheet provided as a supporting document, that states 65 and above. It was therefore suggested that this was reviewed and aligned, and that the application was updated with the correct information. **5.1.8** AGD suggested that section 5(a) was updated with further information on the involvement of the social enterprise, the design of the model and any potential commercial benefits to the social enterprise. **5.1.9 Separate to the application:** AGD suggested that when the NHS England DAS Standard for Commercial Purpose is updated to include consideration to other organisational models, for example, social enterprise. **ACTION:** NHS England Data & Analytics to consider other organisational models, for example, social enterprise when updating the NHS England DAS Standard for Commercial Purpose. **5.1.10** AGD queried the statement in section 5(b) of the application *"Access is restricted to employees or **agents** of…"* and suggested that either further information was provided as to who would be covered by "*agents*", and whether this aligned with the Data Sharing Framework Contract (DSFC); or that this word was removed as may be necessary to reflect the facts.	D&A Rep
5.2	**Reference Number:** NIC-695075-J7Y2H-v1.5 **Applicant:** The University of Manchester **Data Controllers:** The University of Manchester and The University of York **Application Title:** Quality, safety and clinical governance in NHS and independent hospitals **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meetings on the 5th September 2024 and the 25th January 2024. **Application:** This was an amendment application.	

	The purpose of the application is for a research project, with the overall aim of providing evidence on the quality and safety of patient care in NHS and independent hospitals and the effectiveness and impact of shared arrangements for clinical governance. NHS England were seeking general 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents. **5.2.1** AGD noted and commended NHS England's Data Access Service (DAS), and the applicant, on the diligent work undertaken to address the previous points raised by the Group, in particular the letters of support that have been collated, and the engagement with the Royal College of Surgeons of England. **5.2.2 Separate to this application:** AGD reiterated the previous query, what the current process / policy is for approving the use of consultant code, noting that NHS Digital previously required the review / support of the Independent Group Advising (NHS Digital) on the Release of Data (IGARD) and that this was noted in the public domain. **ACTION:** The SIRO Representative to clarify NHS England's current process / policy for approving the use of consultant code.	SIRO Rep
5.3	**Reference Number:** NIC-734773-Y3P3J-v0.5 **Applicant and Data Controller(s):** University College London (UCL) **Application Title:** Recording Antimicrobial Resistance during Death Certification in England **Application:** This was a new application. The purpose of the application is to calculate the burden of antimicrobial resistance (AMR) on mortality in England. AMR has been declared a top 10 threat to humanity by the World Health Organisation. Precise estimation of the mortality burden of AMR is important, as it raises awareness regarding the magnitude of the problem among relevant stakeholders, including governments and the public. It also allows accurate epidemiological monitoring of drug-resistant infections and correct allocation of resources to address the infections with the highest burden of disease. NHS England were seeking general 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: **5.3.1** AGD noted that NHS England's DAS had explored data controllership with the applicant, and noted the conclusion reached that UKSHA were a Data Processor and **not** a Data Controller. The Group discussed and agreed that on the facts presented, it would be reasonable to determine that UKHSA were a Data Processor, however, noted wording in the collaboration agreement between UCL and UKHSA that may support UKHSA being a Data Controller. The Group suggested that NHS England query this point further, by clarifying how many honorary contracts are held by UKHSA employees and if the balance of honorary contract holders suggested that UKHSA were a Data Controller. **5.3.2** AGD noted the outdated information in respect of the Data Security and Protection Toolkit (DSPT) in section 1(b) (Data Controller(s)) of the application; and suggested that this was updated with the most recent information. The Group suggested that unless the DSPT status was updated to Standards Met or Approaching Standards (with an appropriate action plan in place), then **no** data should flow until this was resolved. **5.3.3** Noting that the cohort were deceased, it was suggested that references in section 3(b) (Additional Data Access Requested) and section 5(a) (Objective for Processing) to the UK General Data Protection Regulation (UK GDPR) were removed. **5.3.4** AGD noted the information in section 5(b) (Processing Activities) in respect of the processing activities, however suggested that this was reviewed and updated further, to be clear as to who will be accessing the data and at which point from which organisation, including, but not limited to Great Ormond Street Institute of Child Health and in line with NHS England DAS Standard for processing activities. **5.3.5** Noting this was a one year DSA, AGD suggested that, to future proof the application in the event of a renewal or extension, section 6 (Special Conditions) of the application was updated to include a special condition relating to the Annual Confirmation Report (ACR), in line with NHS England DAS Standard for Special Conditions.	
5.4	**Reference Number:** NIC-771368-F4G0V-v0.2 **Applicant and Data Controller(s):** University of Warwick **Application Title:** PARAMEDIC-3 (Pre-hospitAl Randomised trial of MEDICation route in out-of-hospital cardiac arrest) – Consenting Subset of the Cohort **Linked applications:** This application is linked to NIC-733084-C6R1J (item 5.5) **Application:** This was a new application. The purpose of the application is a pragmatic, allocation concealed, open-label, multi-centre, superiority randomised controlled trial, aiming to evaluate the clinical-	

	effectiveness of the intraosseous and intravenous drug routes for administration of adrenaline for out of hospital cardiac arrests. This subset of the cohort consists of individuals that have provided consent to participate in the study. NHS England were seeking general 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents. **5.4.1** AGD noted that section 3.5 (other minimisation) of the NHS England Data Access Service (DAS) internal application assessment form, made reference to an additional justification being added to the application for the ethnicity and date of death data, in line with NHS England DAS standard for data minimisation; and advised they were supportive of the update to the application once the information had been received from the applicant. **5.4.2** Noting this was a three year DSA, AGD suggested that section 6 (Special Conditions) of the application was updated to include a special condition relating to the Annual Confirmation Report (ACR), in line with NHS England DAS Standard for Special Conditions.	
5.5	**Reference Number:** NIC-733084-C6R1J-v0.4 **Applicant and Data Controller(s):** University of Warwick **Application Title:** PARAMEDIC-3 (Pre-hospitAl Randomised trial of MEDICation route in out-of-hospital cardiac arrest) – Section 251 Subset of the Cohort **Linked applications:** This application is linked to NIC-657032-T7Z5C-v0.4 (item 5.4) **Application:** This was a new application. The purpose of the application is a pragmatic, allocation concealed, open-label, multi-centre, superiority randomised controlled trial, aiming to evaluate the clinical-effectiveness of the intraosseous and intravenous drug routes for administration of adrenaline for out of hospital cardiac arrests. This subset of the cohort consists of individuals under s251 (including individuals recruited through consultee advice). NHS England were seeking general 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 were supportive of the application if the following substantive comment was addressed, and wished to draw to the attention of the SIRO the following substantive comment: AGD noted that they had been provided with a curated set of documentation and noted that they would be providing observations based on these documents. **5.5.1** AGD noted that prior to the meeting, an AGD member had raised a query with NHS England's Data Access Service (DAS), querying why the consent form provided as a supporting document (SD4) seeks consent for follow up via data held by other bodies, but the information sheet provided as a supporting document (SD6.1) states that if individuals don't want this to happen, they have to tell the research team. The Group queried if this was an accurate reflection of what happened, and suggested that NHS England clarify this with the applicant. **5.5.2 Separate to the application:** AGD noted the Health Research Authority Confidentiality Advisory Group (HRA CAG) support, and that point 5.5.1 was relevant to the question of whether consent had been practicable (because here some of the included individuals were seemingly asked for consent but did not give it) and it was suggested that an e-mail was shared with HRA CAG on this point for information. **ACTION:** AGD to send an e-mail to HRA CAG, to outline the conflicting information in the consent form and the information sheet. In addition, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **5.5.3** AGD noted that section 3.5 (other minimisation) of the NHS England Data Access Service (DAS) internal application assessment form, made reference to an additional justification being added to the application for the ethnicity and date of death data, in line with NHS England DAS standard for data minimisation; and advised they were supportive of the update to the application once the information had been received from the applicant. **5.5.4** AGD noted and commended the applicant on the excellent patient and public involvement and engagement (PPIE), and the involvement of some of the cohort members, as outlined in section 5(a) (Objective for Processing) of the application.	AGD
5.6	**Reference Number:** NIC-657032-T7Z5C-v0.4 **Applicant and Data Controller(s):** King's College London and University of Oxford **Application Title:** Motor Neuron Disease Register **Application:** This was a new application. The purpose of the application is to improve care planning, looking at regional differences, and enabling the applicants to provide answers associated with the	

	NICE MND Audit. Development of a mathematical model of MND. Such models can inform future studies, drug discovery and knowledge of pathogenesis of the disease. NHS England were seeking general 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 were supportive of the application and wished to draw to the attention of the SIRO the following comments: **5.6.1** AGD welcomed the application and noted the importance of the purpose and processing outlined in the application. **5.6.2** AGD noted that prior to the meeting, an AGD member had raised queries with NHS England's Data Access Service (DAS); that the proposal in the application is to accompany the individual level data with an anonymous dataset that excludes the "*s251 supported cohort*", and queried if this is reliant on processing confidential data (people have to be identified so as to exclude them), and whether this had Health Research Authority Confidentiality Advisory Group (HRA CAG) support; and whether seeking to capture the data of people who have opted out, albeit in an aggregated way, is compatible with what individuals have been told; and whether this was compatible with the statement in the HRA CAG annual review provided as a supporting document *"the applicant has confirmed that anyone who previously declined will not be added, and their dissent will be respected"*. In addition, it was noted that the MND Register states, *"If you do not wish for your data to be included in the MND Register you can opt-out"*. It was suggested that this would seem to be a bar to what is proposed. **5.6.3** The Group noted that the applicant had provided a swift response (via DAS) on the queries raised in advance. The applicant confirmed that they do not have HRA CAG support for the processing that would be required to **e**xclude individuals. The Group were advised that the purpose of this information in the application was to ascertain the coverage that the current MND Register Cohort provides. In addition, it was noted that the applicant were not seeking to necessarily capture the data of people who have opted out, however noted that requesting this information does give the impression that this is what was sought; and subsequently confirmed that they **do not** wish to seek the individual level data with an anonymous dataset that excludes the s251 supported cohort and advised that this would be removed from the application. **5.6.4** The Group suggested that NHS England discuss this further with the applicant, for example, requesting a tabulation of data, which would be anonymous, for the whole cohort, and that the application be updated as may be necessary. **5.6.5** The AGD member noted that the HRA CAG register provided as a supporting document (SD4.3) states *"The current consented register is used for the described non-research purposes";* and queried whether the applicant has checked that what is	

	proposed is compatible with the consent that was given. It was noted that whilst consent was not being relied upon, the contents of the patient information sheet and consent form were relevant, since those are the grounds on which the individual joined the register. **5.6.6** The Group noted that the applicant had provided an additional PIS and consent form (via DAS), that were previously used for the MND Register. The Group noted the contradictory information in the PIS provided that states *"We will never share identifiable information outside the research team"* and the consent form that states *"I give permission for these individuals to use my details to access follow-up data from GP records and the NHS Care Records Service"*. Given the consent form statement is more prominent, it was suggested it was plausible to give it greater weight and not treat the PIS statement as a bar to using S251 support. **5.6.7** In addition to the data already requested in the application, the NHS England SIRO Representative queried whether the applicant would require date of death data and Emergency Care Data Set (ECDS); and it was suggested by AGD that NHS England explore this further with the applicant, and, if this was required, AGD felt that such changes would be supported but would need the justification referencing in section 5 (Purpose / Methods / Outputs) of the application. **5.6.8** AGD noted in section 5(b) (Processing Activities) that substantive employees of King's College London, University of Oxford, and London School of Hygiene and Tropical Medicine would access the data; and suggested the applicant may wish to consider whether access would also be required by students of the institutions, with appropriate controls in place and relevant updates to the application.	
6 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
There were no items discussed		
7 OVERSIGHT AND ASSURANCE		
There were no items discussed		
8 AGD OPERATIONS		
8.1	**Risk Management Framework** AGD has been previously informed that a risk management framework is being developed by Data Access, and had commented on early thinking about such a Framework. Nonetheless, presently AGD were still operating using the precedent and framework standard as an interim arrangement since March 2024 and AGD were concerned that the permanent Risk Management Framework was not in place. **ACTION:** The NHS England SIRO Representative to provide a written response to AGD on the progress, and expected time frame for implementation, of the risk management framework.	SIRO Rep

	The AGD Chair queried whether NHS England corporate risk management framework could usefully be utilised as a reference point for the Risk Management Framework required by the Statutory Guidance and AGD Terms of Reference (ToR). It was agreed that the AGD's understanding of the ToR is that the risk management framework is relevant to all AGD advice (Specific ToR reference is at Para 5.1.3). The Group discussed the NHS England corporate risk management framework, and its possible adaption for AGD advice, in the absence of the Risk Management Framework, and following discussion, AGD would write formally to the SIRO Representative with the proposal; and the SIRO Representative would consider with colleagues and respond. **ACTION:** AGD (via the ADG Chair) to write formally to the NHS England SIRO Representative with a proposal to use the corporate risk management framework, and the SIRO Representative to respond having discussed with colleagues. In addition, it was agreed that NHS England would ensure that the Group had a copy of the latest NHS England corporate risk management framework. **ACTION:** NHS England SIRO Representative to provide AGD with a copy of the latest NHS England corporate risk management framework.	AGD / AGD Chair SIRO Rep
8.2	**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.	
8.3	**AGD Stakeholder Engagement** The AGD Chair noted to the Group that she had met with Dr. Nicola Byrne, the National Data Guardian for health and adult social care in England, and Michael Chapman, AGD NHS England and Analytics Representative to discuss an action from the AGD minutes from the 3rd October 2024, where a point was discussed in respect of the NDO policy.	
8.4	**AGD Project Work** A brief update was given by the Group's Representative on the Federated Data Platform Information Governance Group.	
9 Any Other Business		
9.1	**UK Biobank** AGD noted that, prior to the meeting, an AGD member had raised a query with the NHS England SIRO Representative, following recent articles in the press, in respect of what steps NHS England has taken to ensure there are no implications for NIC-08472-V9S6K UK	

	Biobank, with regard to onward sharing, permitted uses, and the functioning of project oversight processes. The NHS England SIRO Representative noted the articles in the Press, but also noted the detailed responses from UK Biobank to each of the articles. The NHS England SIRO Representative restated some of the controls that NHS England has in place in relation to sharing of data via the Data Access Service (DAS). Data is shared by NHS England through DAS under the terms of the data sharing framework contract (DSFC) and data sharing agreements (DSAs); these set out what is permitted, and details are published within the Data Uses Register. The DSFC / DSA give NHS England the ability to audit organisations with whom data is shared, and NHS England has an active programme of such audits. The outcomes of the audits are published on NHS England's website. The NHS England SIRO Representative noted that UK Biobank is a very important UK resource for researchers, and AGD (and previously IGARD) have considered applications from UK Biobank since it started. UK Biobank, as with other recipients of data who have the ability to sublicence, are part of the audit programme, and are subject to audits which may cover all or part of any agreement. The Group noted and thanked the NHS England SIRO Representative for the update.

Meeting Closure

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