

Advisory Group for Data (AGD) – Meeting Minutes

Thursday 2nd February 2023

09:30 – 17:30

(Remote meeting via videoconference)

INDEPENDENT ADVISORS IN ATTENDANCE:	
Name:	Role:
Paul Affleck (PA)	Specialist Ethics advisor
Maria Clark (MC)	Lay advisor
Prof. Nicola Fear (NF)	Specialist Academic advisor (In attendance for items 1 to 3)
Dr. Robert French (RF)	Specialist Academic / Statistician advisor
Kirsty Irvine (KI)	Chair
Dr. Imran Khan (IK)	Specialist GP advisor
Dr. Maurice Smith (MS)	Specialist GP advisor (In attendance for items 1 to 3)
Jenny Westaway (JW)	Lay advisor
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	Role / Area:
Laura Bellingham (LB)	Associate Director – Data Services Integrated Care (Presenter: item 4.1)
Michael Chapman (MCh)	Data and Analytics representative (not in attendance for item 8.2)
Dave Cronin (DC)	Data Access Request Service Senior Approval Team (DARS SAT) (Presenter: items 5.1 to 5.2)
Garry Coleman (GC)	Senior Information Risk Owner (SIRO) representative
Louise Dunn (LD)	Data Access Request Service Senior Approval Team (DARS SAT) (Observer: items 5.1 to 5.2)
Liz Gaffney (LG)	Head of Data Access, Data Access Request Service (DARS) (Observer: Item 4.1)
Dickie Langley (DL)	Data Protection Officer (DPO) representative (Delegate for Jon Moore)
Karen Myers (KM)	Secretariat Team
Dr. Jonathan Osborn (JO)	Caldicott Guardian Team representative

Frances Perry (FP)	Digi-Trials (Presenter: item 5.2)
Vicki Williams (VW)	Secretariat Team
INDEPENDENT ADVISORS NOT IN ATTENDANCE:	
Dr. Geoffrey Schrecker	Specialist GP advisor
NHS ENGLAND STAFF NOT IN ATTENDANCE:	
Dr Arjun Dhillon	Caldicott Guardian Team representative (Delegate for Dr. Jonathan Osborn)
Jon Moore	Data Protection Officer (interim)

1 Welcome and Introductions

The NHS England Senior Information Risk Owner (SIRO) Representative advised attendees that, noting the statutory guidance and the AGD Terms of Reference (ToR) had not yet been agreed, the meeting could not be held under the draft ToR, until they have been approved, and recognised that the draft ToR may change as the statutory guidance evolves. As NHS England would like to seek advice on a number of areas, the NHS England SIRO Representative therefore proposed that:

- The meetings scheduled on a Thursday will be of the AGD;
- Kirsty Irvine (as an independent advisor) will be asked to Chair the AGD meetings;
- The meeting will be minuted, with advice and minutes published;
- Attendees will include both independent advisors from outside NHS England and non-independent representatives from within NHS England. Attendees from NHS England include representatives covering the offices of the Data Protection Officer (DPO); Privacy, Transparency, Ethics and Legal (PTEL); the Caldicott Guardian; and the SIRO. Attendees would not be listed as “members” in minutes during the transitional period;
- NHS England representatives would not, during the transitional period, be formally part of any consensus that is reached, but would be active participants in the meeting;
- An early item on the agenda will be asking advice from the group in relation to the continued use of the Data Access Request Service (DARS) Standards / Precedents in relation to applications for external data sharing;
- If independent advisors advise that use of the (DARS) Standards / Precedents is appropriate, NHS England would ask for advice on a number of applications later in the meeting.

The attendees present at the meeting considered the proposal put forward by the NHS England SIRO Representative and, as no objections were raised, it was agreed that the meeting would proceed on this basis.

Kirsty Irvine noted and accepted the request from the NHS England SIRO Representative to chair; and welcomed attendees to the meeting.

2	<p>Declaration of interests:</p> <p>Michael Chapman noted a previous professional link to item 5.2, NIC-156334-711SX University of Cambridge and would not be part of the discussion. It was agreed that Michael would not remain in the room for the discussion of that application.</p> <p>Paul Affleck noted a personal connection and membership of the INTERVAL and TRACK-COVID cohorts relevant to item 5.2, NIC-156334-711SX University of Cambridge. It was agreed this did not preclude Paul from taking part in the discussions about this application.</p>
3	<p>AGD Operations</p>
	<p>The AGD attendees in attendance discussed a number of operational points of the group during the transitional period, including, governance, meeting logistics (before, during and after each weekly meeting), Standard Operating Procedures, AGD Deputy Chair(s).</p> <p>An independent advisor commented on the tabled draft document, ‘<i>Authority of AGD Chair / AGD Deputy Chair</i>’, noting they agreed with the draft text as follows:</p> <p style="padding-left: 40px;"><i>The voting members and Chair of AGD are all independent, that is they will not otherwise have substantive employment contracts with NHS Digital.</i></p> <p>An independent advisor made the point that this implied the NHS representatives would not have voting rights on the proposed AGD. It was noted that this position would be clarified in the finalised Terms of Reference.</p> <p>AGD noted the following actions once the statutory guidance, and AGD Terms of Reference (ToR), have been finalised:</p> <p>ACTION: Text to be drafted for reference to the AGD on the existing IGARD webpage and to create a new AGD landing page for the group on the NHS Digital website.</p> <p>ACTION: AGD Secretariat to liaise with NHS England web team colleagues to arrange publication of AGD meeting minutes on the newly created AGD landing page on the NHS Digital website (an interim measure until AGD is added to the NHS England website).</p> <p>ACTION: AGD Secretariat to produce a forward planner for AGD agenda items, and meet weekly with the AGD Chair and SIRO representative.</p> <p>ACTION: AGD Secretariat to produce an ‘action log’ for AGD meeting actions.</p> <p>ACTION: AGD agreed to formally appoint two Co-Deputy Chairs. AGD attendees agreed that the Co-Deputy Chairs should be independent advisors and it was agreed that Paul Affleck and Dr Imran Khan would be the co-Deputy Chairs of AGD.</p> <p>ACTION: AGD Secretariat to liaise with NHS England IT colleagues to rename the existing ‘IGARD’ mailbox to “AGD”, or to create a new mailbox (only once the name of the group is finalised in the TOR), until that time, the IGARD@NHS.net mailbox would continue for an interim period.</p> <p>ACTION: It was agreed that service improvement would be an integral part of the AGD work programme and as part of the AGD service improvements, AGD attendees would provide regular feedback on the AGD meetings, i.e. structure, processes etc to the Secretariat Team.</p> <p>ACTION: AGD discussed the possible attendance of “applicants” at future AGD meetings, and its practicality (logistics, governance, pilot etc.) and asked that this be brought to a future meeting of AGD.</p>

	<p>ACTION: AGD to consider / agree how they communicate with the public / stakeholders moving forward, i.e. blogs, twitter etc. and asked that this be brought to a future meeting of the AGD.</p> <p>ACTION: it was agreed that the AGD Secretariat would create a forward plan of work for the Standard Operating Procedures which underpin the group.</p> <p>In addition, the AGD discussed outstanding actions from the Independent Group Advising on the Release of Data (IGARD), as outlined in the final IGARD minutes from the 26th January 2023. It was agreed that this would be discussed at the AGD meeting on the 9th February 2023, to determine an agreed process for reviewing outstanding actions, and how this could be made transparent to the public.</p> <p>ACTION: the NHS England representatives agreed to discuss the outstanding IGARD actions outside of the meeting, and bring the proposed way forward at the AGD meeting on the 9th February 2023.</p> <p>ACTION: NHS England advised that independent advisors would in the future be in scope of IR35, and noted the impact this may have on advisors who were previously on IGARD. The NHS England representatives noted that NHS England was committed to working with independent advisors to secure business continuity over the time of change and is considering the issue.</p>	<p>AGD</p> <p>VW/KM</p> <p>MC</p> <p>DL</p>
4	Internal Data Flows	
4.1	<p><u>Internal Data Flow Approval Process (Presenter: Laura Bellingham)</u></p> <p>4.1.1 NHS England attended the meeting to provide attendees and observers with a verbal overview of the draft Internal Data Flow Approval Process.</p> <p>4.1.2 NHS England advised the AGD that further discussions would take place at future AGD meetings, as the process is refined / developed further. In addition, NHS England noted that there would be further engagement with the AGD in respect of the development of Precedents for the Internal Data Flow Approval Process.</p> <p>4.1.3 The Chair and attendees thanked NHS England for attending the meeting, and for the verbal overview of the Internal Data Flow Approval Process. attendees also noted the future engagement in respect of the Precedents for the Internal Data Flow Approval Process, and advised that they would encourage this as early in the process as possible, with the relevant supporting documents, including, but not limited to, the escalation criteria referred to in the presentation.</p> <p>ACTION: NHS England to attend a future AGD meeting (provisional date: 23rd February 2023), to provide an update on the Precedents for the Internal Data Flow Approval Process and Precedents.</p>	<p>LB</p>
5	EXTERNAL DATA DISSEMINATION REQUESTS:	
5.1	<p>Reference Number: NIC-686058-N9C5V-v0.4</p> <p>Applicant: London School of Hygiene and Tropical Medicine (Data Controller)</p>	

<p>Application Title: Homeless Health Peer Advocacy Evaluation: Primary analyses of Hospital Episodes Statistics</p> <p>Presenters: Dave Cronin</p> <p>SAT Observer: Louise Dunn</p> <p>Application: This was a new application.</p> <p>The purpose of the application is for a research project, which will evaluate how and to what extent the intervention changes the way homeless populations use outpatient and emergency services and how it shapes other health and social outcomes. Further details on the application can be found on NHS Digital Data Uses Register in due course, by searching by reference number (above) or applicant.</p> <p>NHS England were seeking advice on the following points:</p> <ol style="list-style-type: none"> 1. Consent material / information sheets stating NHS Digital (rather than NHS England) 2. Payments made as a thank you for participation in cohort studies <p>Outcome of discussion: The Group were supportive of the application and wished to draw to the attention of the SIRO the following high level comments:</p> <p>In response to point 1:</p> <p>5.1.1 Independent advisors discussed the consent materials and agreed that there did appear to be a legal gateway, based on consent, for the sharing of the data.</p> <p>5.1.2 Independent advisors noted a missing word in the statement within the patient information sheet (PIS) provided as a supporting document “...<i>returned to the research team who will work with it in an [sic] format</i>”; and suggested that the applicant updated future versions of the PIS and further explained to participants (as part of any future engagement) what was meant.</p> <p>5.1.3 Independent advisors discussed the consent materials and PIS referring to “NHS Digital” and referred to guidance co-produced by NHS England and the Health Research Authority; however, suggested that it would be good practice for studies to update cohort members at the earliest opportunity that it was now NHS England processing their data and not NHS Digital since they may feel differently towards NHS England than they do towards NHS Digital.</p> <p>In response to point 2:</p> <p>5.1.4 Independent advisors discussed the £10.00 payment to cohort members, as a thank you for participating in the study and agreed that this appeared to be reasonable in the circumstances and not coercive. They also advised that there was published advice on this point by the Health Research Authority, and that it was common practice within the research community to make modest payments to research participants.</p> <p>ACTION: Independent advisors suggested that NHS England should give consideration to updating the DARS Standard for Duty of Confidentiality to provide guidance and links to external resources on assessing whether payments or other inducements given to research participants could affect the validity of consent.</p> <p>In addition, the Group made the following observations on the application and / or supporting documentation provided as part of the review:</p>	<p>DARS</p>
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	<p>5.1.5 Independent advisors noted and commended NHS England on the information provided within the application assessment form, which supported the review of the application.</p> <p>5.1.6 Independent advisors noted and commended the efforts taken by the applicant on patient and public involvement and engagement (PPIE).</p> <p>5.1.7 Independent advisors noted the information in section 5(a) (Objective for Processing) relating to data minimisation, that included a number of bullet points outlining the inclusion criteria for the study cohort. In addition, they noted the information within the protocol, provided as a supporting document, which provided further information as to why the cohort excluded certain groups of society. They suggested that, for transparency, information in respect of the inclusion criteria was copied from the protocol and replicated / refined as appropriate within the public facing, section 5(a), of the application.</p> <p>5.1.8 Noting that inclusion criteria are not actually a form of data minimisation, independent advisors suggested that section 5(b) (Processing Activities) was updated further to include details of any data minimisation undertaken, in line with DARS standard for data minimisation.</p> <p>5.1.9 Independent advisors queried the statement in section 5(b) <i>“There will be no requirement and no attempt to reidentify individuals”</i>; and suggested that this was removed, noting that this was incorrect.</p> <p>5.1.10 Independent advisors noted that there may be challenges in respect of the linkage for this cohort and missing data fields, for example, GP postcode.</p>	
5.2	<p>Reference Number: NIC-156334-711SX-v9.3</p> <p>Applicant: University of Cambridge</p> <p>Application Title: INTERVAL, COMPARE and STRIDES Bio Resource trial cohorts: Long-term follow up of health outcomes and associations with genetic, biological and lifestyle traits</p> <p>Presenters: Frances Perry</p> <p>SAT Observer: Dave Cronin / Louise Dunn</p> <p>Application: This was a renewal application and amendment application.</p> <p>The amendments are 1) to extending the expiry date to a three year agreement under the new 'Term of Data Sharing Agreement' Standard; 2) the addition of STRIDES BioResource study participants to the agreement of approximately 83,000 further records; 3) the addition of annual release of National Diabetes Audit dataset, plus historic data back to June 2002 for the whole cohort of 156,000 study participants; 4) one drop of historic data from all the datasets previously requested, June 2002 to latest only for the additional 83,000 STRIDES participants; 5) continued quarterly drop of data products to cover the period most recent release to 16/02/2026 for the whole cohort of 156,000 study participants; 6) the addition of Onward Data Sharing of the Hospital Episode Statistics (HES), Cancer Registrations and Death registrations datasets only to external researchers (Sub-licencing) to the agreement; 7) Change of Territory of Use to Worldwide rather than UK.</p> <p>Further details on the application can be found on NHS Digital Data Uses Register in due course.</p> <p>Previous Reviews: The application and relevant supporting documents were previously presented at the IGARD meetings 21st June 2018, 5th November 2020 and the 29th April 2021.</p> <p>The application was previously reviewed as part of oversight and assurance, at the IGARD meeting on the 23rd January 2020.</p>	

	<p>The application was discussed at the IGARD – NHS Digital COVID-19 response meetings on the 21st April 2020, 28th April 2020 and the 8th September 2020.</p> <p>The application was discussed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) meetings on the 28th October 2020, 26th May 2021 and the 25th May 2022.</p> <p>Outcome of discussion: The Group were supportive of the application and wished to draw to the attention of the SIRO the following high level comments:</p> <p>5.2.1 Independent advisors noted the assurance provided to cohort members that the data will be used by other researchers for ethically approved studies / further research and suggested that the applicant considered how the review board would assure themselves that the onward use / sharing of data will have the appropriate ethical approval, as per the assurance set out in the consent, and how this would be monitored.</p> <p>5.2.2 Independent advisors and the DPO Representative highlighted a reference to the “<i>UK General Data Protection Regulation (UK GDPR) consent</i>” as part of the advice sought and received from Privacy, Transparency, Ethics and Legal (PTEL) and advised that in this instance, UK GDPR consent was not relevant. AGD noted that the NHS England DPO Representative had agreed in-meeting to review this with PTEL colleagues to ensure there had not been any reviewing issues / misunderstandings.</p> <p>ACTION: NHS England DPO Representative to liaise with the office of the DPO in respect of the reference to the “UK GDPR consent” as part of the PTEL advice.</p> <p>5.2.3 Independent advisors noted the content of special condition point 8 in section 6 (Special Conditions), in relation to ‘limitation on world-wide data sharing and territory of use’ and the advice received from PTEL on the countries approved and suggested that this was updated further to expressly state that any further jurisdictions would require an amendment to the application, as well as approval from NHS England’s Legal Team.</p> <p>5.2.4 Independent advisors strongly suggested that the applicant carries out a Data Protection Impact Assessment (DPIA) before processing commences and that the DPIA addresses a number of issues, including but not limited to, ensuring all the limbs of the consent were adhered to, and that there was ethical approval for all aspects of the research.</p>	DL
6	<p>Meeting Closure</p> <p>As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.</p>	