Advisory Group for Data (AGD) – Meeting Minutes

Thursday, 21st May 2026

09:00 – 13:00 (AGD business as usual meeting)

13:00 – 16:00 (AGD plenary meeting)

(Remote meeting via videoconference)

AGD INDEPENDENT / NHS ENGLAND MEMBERS IN ATTENDANCE:	
Name:	**Role:**
Paul Affleck (PA)	AGD independent member (Specialist Ethics Adviser) (Items 9.1 to 9.6 and 10.1 only)
Mr Christopher Barben (CB)	AGD independent member (Specialist Clinician Adviser)
Claire Delaney-Pope (CDP)	AGD independent member (Specialist Information Governance Adviser)
Dr. Jon Fistein (JF)	AGD independent member (Chair)
Prof. Jo Knight (JK)	AGD independent member (Specialist Academic / Researcher Adviser)
Narissa Leyland (NL)	NHS England member (Data and Analytics Representative (Delegate for Michael Chapman))
Dr. Jonathan Osborn (JO)	NHS England member (Caldicott Guardian Team Representative)
Jenny Westaway (JW)	AGD independent member (Lay Adviser) (Items 9.1 to 9.6 and 10.1 only)
Miranda Winram (MW)	AGD independent member (Lay Adviser) (Items 9.1 to 9.6 and 10.1 only)
NHS ENGLAND STAFF IN ATTENDANCE:	
Name:	**Role / Area:**
Jack Bennett (JB)	Senior Project Manager, NHS DigiTrials, Data and Analytics, Transformation Directorate (**Presenter**: item 4.1)
Garry Coleman (GC)	NHS England SIRO Representative (not in attendance for part of item 9.1 and items 9.7 to 9.8)
Dave Cronin (DC)	Applications Service Owner, Data Access and Partnerships, Transformation Directorate (**Presenter**: item 9.1 to 9.2)
Suzanne Hartley (SH)	Data Applications Service (DAS) - Senior Manager, Data Access and Partnerships, Transformation Directorate (**Observer**: item 9.1)

Maddie Laughton (ML)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer**: item 5.2)
Tiaro Micah (TM)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer**: item 5.1)
Karen Myers (KM)	AGD Secretariat Officer, Privacy, Transparency and Trust (PTT), Technology, Digital and Data
Humphrey Onu (HO)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer**: item 9.1)
Andy Rees (AR)	NHS DigiTrials and Research Products Operations Manager, Data and Analytics, Transformation Directorate (**Presenter**: item 4.1)
Jodie Taylor-Brown (JTB)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer**: item 9.1)
Emma Whale (EW)	Data Access and Partnerships, Data and Analytics, Transformation Directorate (**Observer**: items 5.3 and 9.1)
Vicki Williams (VW)	AGD Secretariat Manager, Privacy, Transparency and Trust (PTT), Technology, Digital and Data
AGD INDEPENDENT MEMBERS / NHS ENGLAND MEMBERS NOT IN ATTENDANCE:	
Name:	**Role / Area:**
Michael Chapman (MC)	NHS England member (Data and Analytics Representative)
Dr. Robert French (RF)	AGD independent member (Specialist Academic / Statistician Adviser)
Dr. Mark McCartney (MM)	AGD independent member (Specialist GP / Clinician Adviser)
Jon Moore (JM)	NHS England member (Data Protection Office Representative)

1	**Welcome and Introductions:** The AGD 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.

	AGD noted that, due to an urgent work commitment, there would not be an NHS England SIRO Representative or delegate in attendance for part of item 9.1 and items 9.7 to 9.8). Noting that the AGD Terms of Reference (ToR) state that: *"…a representative of the SIRO must also be in attendance for any meetings of the Group or a Sub-Group…"*, the Group were advised that, prior to the meeting, the NHS England SIRO Representative had confirmed contentment for part of item 9.1 and items 9.7 to 9.8 to be discussed in their absence; and noted that he would be in attendance for the rest of the meeting.
2	**Review of previous AGD minutes:** The minutes of the AGD meeting on the 14th May 2026 were reviewed and were agreed as an accurate record of the meeting.
3	**Declaration of interests:** There were no declarations of interest.
4 BRIEFING PAPER(S) / DIRECTIONS:	
4.1	**Title:** NHS DigiTrials Branding Risk Framework **Presenters:** Jack Bennett and Andy Rees The briefing paper provided information to AGD on a proposed Branding Risk Framework to support consistent, risk-based decisions on how and if/when NHS DigiTrials branding is applied to trials and studies communications. The proposed approach, risk domains and escalation routes have been developed with input from, and reviewed through, the NHS DigiTrials Programme Board to ensure they are proportionate and operationally workable. It also sets out our proposed approach to uplift the existing NHS DigiTrials invitation letter standard (used for recruitment invitations) to include additional risk domains that were not previously covered. NHS England were seeking advice on the following points: 1. Provide advice on the proposed methodology and structure of the Branding Risk Framework, including whether it is proportionate and supports consistent and defensible decision-making. 2. Confirm whether the risk domains identified appear complete and appropriate, and highlight any material risks, domains or considerations that are missing or require reframing. 3. Confirm whether the risk rating definitions (low/medium/high) are sufficiently objective noting the rational provided for this approach, or suggest an alternative assessment approach. 4. Advise whether any "red-line" criteria should apply (i.e. scenarios where branding should be withheld/paused by default, or where AGD would always expect escalation), to support consistent decision-making and safe operational delivery. 5. Provide general views on the approach to assess branding risk across the clinical trial lifecycle (from EOI, through onboarding, to live delivery) and plans to uplift the

existing NHS DigiTrials invitation letter standard to incorporate additional domains not previously included.

6. Support piloting the approach and note the intention to iterate and formally update the Framework as operational insights and learning are gathered.

Outcome of discussion: AGD welcomed the briefing paper and made the following observations / comments:

In response to point 1 above:

4.1.1 AGD discussed the proposed methodology and structure of the Branding Risk Framework, and noted that whilst the content was proportionate, there did appear to be some confusion between risk assessments related to the use of the NHS DigiTrials service; and those related to the use (or not) of the branding when the NHS DigiTrials service was being used. AGD advised that a clear separation was made between these and updated within the briefing paper for future reference.

4.1.2 AGD advised that there was a clearer rationale / criteria within the briefing paper on the following:

4.1.2.1 when it would be acceptable for a trial to proceed without the branding; and

4.1.2.2 when it would be unacceptable for a trial to proceed unless there was branding.

In response to point 2 above:

4.1.3 AGD advised that the risk domains seemed sensible when relating to NHS DigiTrials as a whole; however, advised that there was a clearer statement in the briefing paper clarifying how the risk domains lead to a decision as to whether a trial will go head, or not, with / without branding.

In response to point 3 above:

4.1.4 AGD commended the idea of having risk rating definitions, however, advised that having more categorical / binary answers might be more manageable.

4.1.5 AGD queried the escalation procedure, noting that although the intention is to have an objective risk assessment, there may be circumstances in which this could be reviewed at a more senior level. AGD advised that this be clarified within the briefing paper.

In response to point 4 above:

4.1.6 AGD discussed whether any “red-line” criteria should apply, and advised that this relates to the advice provided under point 4.1.2, and would be a condition in cases where branding would not be appropriate. AGD advised that NHS England should assess the risk of:

4.1.6.1 branding being used; and

4.1.6.2 branding not being used.

In response to point 5 above:

4.1.7 AGD noted that general views were captured as part of the discussion on points 1 to 4.

In response to point 6 above:

	4.1.8 AGD advised that they were supportive of the pilot, and note the intention to iterate and formally update the Framework as operational insights and learning are gathered. In addition to their advice on the specific points raised by NHS England, AGD made the following observations on the application and / or supporting documentation provided as part of the review: **4.1.9** AGD welcomed the briefing paper and supporting documents and noted the importance of this programme of work; and noted the work undertaken by NHS England on this work to date. **4.1.10** AGD looked forward to receiving an update on this programme of work at a future meeting.	
5 EXTERNAL DATA DISSEMINATION REQUESTS:		
5.1	**Reference Number:** NIC-782147-P6W3K-v0.1 **Applicant and Data Controller:** The Institute of Cancer Research (ICR) **Application Title:** "English Paediatric & (Adolescents and Young Adults) AYA Cancer Survivor Cohort" **Observer:** Tiaro Micah **Application:** This was a new application. NHS England were seeking advice on the following points: 1. There is sufficient evidence to support ICR being the sole Data Controller. 2. The data minimisation is appropriate. 3. Is there sufficient justification given for not accessing the data via the NS England Secure Data Environment (SDE). 4. If data is provided via an extract, are there are sufficient controls in place around downloading of record level data from ICR servers. 5. Has suitable consideration has been given to any ethical considerations of the research (noting that Health Research Authority Research Ethics Committee HRA REC is not required). Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** AGD advised that significant concerns had been identified and advised against the proposed data access (dissemination / release). The Group advised that the following should be addressed by NHS England before any further steps are taken: **In response to point 1:** **5.1.1** AGD discussed whether there was sufficient evidence to support ICR being the sole Data Controller, and advised that based on the information provided, it was their view, that Imperial College London did appear to have data controllership responsibilities, for example, they are named as the lead academic institution; the privacy notice for the study was on their website; and they have a fundamental role on the governance structures for the study. The Group advised that NHS England discuss this further with the applicant, and update the	

internal form / application to reflect the correct / factual information, in line with NHS England DARS Standard for Data Controller(s).

5.1.2 AGD noted that they were in agreement with the applicant that UK Health Security Agency (UKHSA) were not considered a Data Controller.

In response to point 2:

5.1.3 AGD discussed the data minimisation and advised that this was not sufficiently justified. The Group advised that NHS England should discuss this further with the applicant, and update the internal form / application as may appropriate, in line with NHS England DARS standard for Data Minimisation.

5.1.4 AGD noted they were broadly comfortable that the age range requested was compatible with the definition of Adolescents and Young Adults (AYA) patients, however, advised that the definition of this was made clear in the internal form / application for example by providing a reference, noting there were different definitions in the public domain.

5.1.5 AGD noted that the objective for processing outlined in section 5(a) stated that a broad follow-up would be undertaken as part of the study, and noted that there was potentially a justification for the broad range of data requested alongside the fact that the cohort of patients was small; however, noted that there was a narrower definition in section 3(a), and advised that it should be aligned and updated to reflect the correct / factual information in line with NHS England DARS standard for Data Minimisation and NHS England DARS Standard for Objective for Processing.

In response to point 3:

5.1.6 AGD advised that this appears to be a good candidate for accessing the data via the NHS England secure data environment (SDE), to mitigate any risks of extracts of this type; and strongly advised NHS England that they give this further consideration.

In response to point 4:

5.1.7 AGD agreed that NHS England should seek assurances from the Data Controller that appropriate technical controls are in place to ensure record level access and downloads are adequately managed; and that this would be in addition to contractual controls, and set out in the data sharing agreement (DSA).

In response to point 5:

5.1.8 AGD noted that the ethical considerations of the research were not currently adequately expressed in the application, however, were advised by NHS England that further evidence is due to be provided by the applicant on this point. The Group noted the importance of a local ethical review and advised that NHS England follow this up with the applicant.

In addition to their advice on the specific points raised by NHS England, AGD made the following observations on the application and / or supporting documentation provided as part of the review:

5.1.9 AGD noted that the internal form / application stated that *"the Data will not be linked with any other data outside of this agreement";* and the protocol stated *"Death rates and causes of death… will be obtained from linkage to civil death registrations";* and advised that

	NHS England discuss this with the applicant, and the relevant document is updated to reflect the correct / factual information. **5.1.10** AGD noted that patient and public involvement and engagement (PPIE) was ongoing, and advised that if the data was provided as a data extract, NHS England should satisfy itself that this was in line with the expectations of the participants. **5.1.11** AGD welcomed the application and noted the importance of the study.	
5.2	**Reference Number:** NIC-757820-S7F8B **Applicant and Data Controller:** Intensive Care National Audit & Research Centre (ICNARC) **Application Title:** "ICNARC National Clinical Audit Programme" **Observer:** Maddie Laughton **Previous Reviews:** The application and relevant supporting documents were previously presented / discussed at the AGD meetings on the 16th April 2026 and the 5th March 2026. **Application:** This was a new application. NHS England were seeking advice on the following points: 1. Whether the points previously raised by AGD have been sufficiently addressed. Should an application be approved by NHS England, further details would be made available within the Data Uses Register. **Outcome of discussion:** In response to the specific points, AGD advised that the following should be addressed before access (dissemination / release) of data proceeds: **In response to point 1:** **5.2.1** AGD noted the work undertaken by NHS England and the applicant to address the points raised by the Group on the 16th April 2026; and advised that the majority of the points had been adequately addressed. **5.2.2** AGD noted that in relation to the response provided on the previous point raised in relation to sub-licensing (point 5.6.1 from 16th April 2026), that NHS England would need to clarify whether data is derived or not; and advised that that NHS England have sight of ICNARC's internal processes, to ensure that this is stated as clearly as possible. **5.2.3** AGD advised that in relation to the response provided on the previous point raised in respect of the balance between public and commercial benefits within the ICNARC Data Access Committee's (DAC) Terms of Reference (ToR) (point 5.6.2 from 16th April 2026) that the ToR is reviewed and is in line with NHS England DARS Standard for Commercial Purpose.	
5.3	**Reference Number:** NIC-758591-Z7W0W **Applicant and Data Controller:** University College London (UCL) **Application Title:** "Improving health and education outcomes in young people with hearing loss: using linked national birth cohort, routine health, education and screening data to identify intervention targets"	

Observer: Emma Whale

Application: This was a new application.

NHS England were seeking advice on the following points:

1. Is there sufficient justification given for not accessing the data via the NHS England Secure Data Environment (SDE).
2. If data is provided via an extract, are there are sufficient controls in place around downloading of record level data from ICR servers (note the additional question below)
3. The data minimisation is appropriate.
4. The approach to transparency is aligned with NHS England DARS standards.
5. There is sufficient evidence to support UCL being the sole Data Controller.

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 advised that significant concerns had been identified and advised against the proposed data access (dissemination / release). The Group advised that the following should be addressed by NHS England before any further steps are taken:

In response to point 1:

5.3.1 AGD advised that there was a sufficient justification provided for not accessing the data via the NHS England SDE, noting that not all of the data required was currently available; and that there was a clear rationale for providing a data extract at the current time.

In response to point 2:

5.3.2 AGD agreed that NHS England should seek assurances from the Data Controller that appropriate technical controls are in place to ensure record level access and downloads are adequately managed; and that this would be in addition to contractual controls, and set out in the data sharing agreement (DSA).

In response to point 3:

5.3.3 AGD discussed the data minimisation and advised that this large volume of data was not currently justified, and advised that NHS England discussed this further with the applicant, and the internal form / application was updated as may appropriate, in line with NHS England DARS standard for Data Minimisation.

5.3.4 AGD noted that the data requested was from 2006, when the screening programme started, however, advised that the applicant provide NHS England with a clear justification of:

5.3.4.1 why the applicant requires data from 2006 provides them with what they need for the study;

5.3.4.2 whether they need comparative data prior to 2006; or

5.3.4.3 how the data requested aligns with the aims of the study (noting the reduction in data requested due to cost).

5.3.4.4 why it is not possible to reduce the range of the data they are currently requesting, for example, the last 10-years (2016 onwards); and

5.3.5 AGD noted in the internal form / application, that the applicant required includes a *"…comparator sample of 10% of children who were screened and 'not referred' (clear response; unaffected by hearing loss), from January 2006 to January 2024, sampled randomly from each year of screening"*; and advised that further details of this were provided by the applicant before any data flows.

In response to point 4:

5.3.6 AGD advised that the transparency for the study was not adequate, for example, there was no study website, and participants were instead relying on the wider UCL transparency. AGD advised that NHS England discuss this further with the applicant in line with NHS England DARS Standard for Transparency and UK General Data Protection Regulation (UK GDPR); and that no data should flow until this has been adequately addressed.

In response to point 5:

5.3.7 AGD noted that Great Ormond Street Hospital NHS Foundation Trust was the study sponsor, but were not named as a Data Controller, The Group advised that this did **not** align with the latest UK Research and Innovation (UKRI) guidance, that states "i*n health research the sponsor is likely to be the (data) controller"*. The Group advised that the applicant:

5.3.7.1 provide a clear justification as to why the sponsor is not considered a Data Controller; or,

5.3.7.2 the internal form / application is updated to reflect that GOSH are a joint Data Controller.

In addition to their advice on the specific points raised by NHS England, AGD made the following observations on the application and / or supporting documentation provided as part of the review:

5.3.8 AGD noted that some patient and public involvement and engagement (PPIE) was planned; however strongly advised the applicant to undertake some PPIE **prior** to the data processing and the results of this are shared with NHS England. The HRA guidance on Public Involvement is a useful guide.

5.3.9 AGD noted the information in the internal form / application that stated population datasets were being used so there should not be an issue of equity or bias. The Group was not convinced by this statement and advised that NHS England ask the applicant to provide further information as to why they believe there is no bias and/or to describe ways of accounting for or acknowledging some of the known bias present in routine data (e.g. incomplete data for precariously housed individuals).

5.3.10 AGD noted in the internal form / application in the section on AI that it implied that the applicant may not share their code wider; and advised that the applicant reviews / updates this, noting that they may be restricting the potential benefits that will flow from the study, by restricting the publication of the work in certain journals that require the provision of the code.

5.3.11 AGD were advised by NHS England that the territory of use would be updated to correctly state *"UK"* and not *"England and Wales"*.

	5.3.12 AGD noted that the title of the application is quite broad ranging, and advised that NHS England review this with the applicant and update the internal form / application as may be appropriate, noting the work covered under this application is for work package one only.	
6 INTERNAL DATA DISSEMINATION REQUESTS:		
There were no items discussed		
7 EXTERNAL DATA DISSEMINATION - SIRO APPROVED / SEEKING SIRO APPROVAL		
There were no items discussed		
8 OVERSIGHT AND ASSURANCE		
There were no items discussed		
9 AGD OPERATIONS		
9.1	**NHS England Data Access Request Service (DARS) internal form / application** AGD noted that following the presentation to the Group on the 26th February 2026 to discuss the NHS England DARS internal form / application form, the Group had provided feedback over recent weeks on the updated internal form / application. The Group noted the work that had been undertaken to date on the internal form / application by DARS colleagues, and acknowledged that the document was for a number of stakeholders. The Group made a number of comments on the form for DARS colleagues to consider, including but not limited to: 1. ensuring that all of the internal forms were clear (via colour coding), which text would be added to the data sharing agreement and which text was for internal use only. 2. being clear where an application is for 'early advice', i.e. is subject to further work / is only partially completed. 3. being clear at the start of the document the purpose of the internal form for example by provision of an executive summary. 4. removing / hiding any sections of the internal form that were not relevant for a specific internal form; or being clear where information was not required, rather than leaving section blank. 5. ensuring the table of contents at the start of the document is updated / correct prior to submitting to AGD for review to ensure page numbers align. 6. being clear within the document what the current position is, from an NHS England perspective, to help AGD with the review of the document, and subsequent advice. 7. ensuring bespoke benefits are included in the internal form where appropriate and not 'cut and paste'.	

	The Group noted that they would continue to share any further feedback on the internal form as may be appropriate. NHS England advised the Group that further information would be shared at a future AGD meeting, to clarify where further updates had been made to the form; and to give a further overview of how the form works.	AGD DARS
9.2	**Advice questions within internal forms / applications and process** AGD noted from April 2026, NHS England had been asking AGD for advice on specific questions / points when submitting internal forms to the Group; as opposed to asking for 'general advice'; and to further support this new way of working, noted that the AGD Chair had produced a draft internal document that summarised the themed questions / advice points, aligned with the NHS England Data Access Request Service (DARS) Standards. **Themed Questions** The AGD Chair discussed, with the Group, the draft themed questions / advice points; and advised that the document would be shared with the Group for review / suggested updates, following the meeting, and that the deadline for comments would be midday on the 5th June 2026.	AGD
9.2	**AGD ways of working Document** The AGD Chair discussed, with the Group, the draft AGD ways of working document; and advised that the document would be shared with the Group for review / suggested updates, following the meeting, and that the deadline for comments would be midday on the 5th June 2026.	AGD
9.3	**AGD Team Charter** The AGD Chair discussed, with the Group, the AGD Team Charter document; and advised that the document would be shared with the Group for review / suggested updates, following the meeting, and that the deadline for comments would be midday on the 5th June 2026.	AGD
9.4	**AGD Terms of Reference** The AGD Chair discussed, with the Group, the updated / revised draft AGD Terms of Reference; and advised that the document would be shared with the Group for review / suggested updates, following the meeting, and that the deadline for comments would be midday on the 5th June 2026.	AGD
9.5	**AGD Annual Report 2025/26** The AGD Chair advised that the draft AGD Annual Report 2025/26 would be shared with the Group for review / suggested updates at a later date.	
9.6	**AGD Co-Deputy Chairs** The AGD Chair noted, Claire Delaney-Pope and Prof. Jo Knight were to be the new co-Deputy Chairs from May 2026, and thanked them for volunteering. Jon thanked Paul Affleck for his significant support and contributions as Deputy Chair since 2022.	

9.7	**AGD Stakeholder Engagement** *There were no items discussed*
9.8	**AGD Project Work** **NIC-802985-K1J2M - National Institute for Health and Care Excellence (NICE)** Prof. Jo Knight and Dr Jonathan Osborn advised the Group that they had provided some support out of committee on NIC-802985-K1J2M – NICE; following the review by the Group at the AGD meeting on the 16th April 2026 AGD noted the update and since at the time of the discussion, the advice from the Profession Advisory Group (PAG) was not available, and that the advice would be shared with the Group at a later date, this had now been received and shared with the AGD Secretariat (please see appendix A). The NHS England SIRO Representative advised the Group that this application would return to a future AGD meeting under the 'SIRO approved' applications.
10 Any Other Business	
10.1	**Privacy and Electronic Communications (EC Directive) Regulations 2003** An AGD independent member queried whether the use of e-mail and texts, as part of NHS DigiTrials invitations, would be compatible with the Privacy and Electronic Communications (EC Directive) Regulations 2003. The NHS England SIRO Representative advised that this would be scheduled for a discussion at a future AGD meeting.
Meeting Closure As there was no further business raised, the Chair thanked attendees for their time and closed the meeting.	

Appendix A

Profession Advisory Group (PAG) Feedback Form - OpenSAFELY Pilot

(Out of Committee)

Meeting Details	
PAG advice sought by NHSE (via email) out of committee on:	7/4/2026
Date of PAG advice:	21/4/2026

Application Details			
NIC Reference:	DARS-NIC-802985 OpenSAFELY Ref: 371b	**Application version Number:**	V0
Applicant Organisation:	National Institute for Health and Care Excellence (NICE)		
Application Title:	Primary Care Eligibility Analysis - SGLT2 inhibitors (SGLT2i) and direct oral anticoagulants (DOACs)		

Attendees		
Representing Organisation	**Name**	**Role**
British Medical Association (BMA)	Mark Coley	BMA Representative
Royal College of General Practitioners (RCGP)	Tom Nichols	RCGP Representative

Declarations of Interest
There are no declarations of interest

Advice Required

OpenSAFELY Application

The OpenSAFELY Data Analytics Service Pilot Direction 2025 states:

The purpose of accessing the data is to establish a secure analytics service using the OpenSAFELY platform, for users approved by or on behalf of NHS England, to run queries on GP and NHS England pseudonymised patient data.

1a. Does this application meet the requirements of the OpenSAFELY Direction?

Yes

1b. Is this request in line with the following purposes as specified in the OpenSAFELY Requirement Specification?
NHS OpenSAFELY Data Analytics Service Pilot Directions 2025 - NHS England Digital

☐ Clinical audit
☒ Service evaluation
☐ Health surveillance
☐ Research
☐ Evaluation of the service
☐ Health & social care policy, planning & commissioning & public health

1c. Advice from the Profession

PAG welcomes the use of OpenSAFELY for service evaluation use and the commitment to publish findings. It is noted that the Innovation Scorecard, which will be populated by the aggregate results generated through OpenSAFELY, is not for performance management. Further details on which systems will be used to analyse the results and whether repeat analysis (possibly following interventions) will be needed in the future would be helpful.

Given the limited clinical indications for DOACs (e.g. short courses post-surgery or longer-term courses after episodes of VTE or for those with clotting abnormalities or cardiac dysrhythmias), we would hope that everyone who was in need of one, or an alternative anticoagulant (such as warfarin) would already be being prescribed one. It would be helpful for there to be greater clarity on what exactly is being looked for, mindful that short courses of anticoagulants may not always be prescribed in general practice if the hospital has provided a supply. We note that where hospital medicines are issued, we are encouraged to record those within the GP EPR as “Hospital” issues in order to enable our clinical decision support tools e.g. drug to drug interactions, to function – that can give the impression of GP prescribing where it was not, so care must be taken to differentiate between the “Issue Method”. Sometimes low molecular weight heparins might be prescribed too (e.g. during pregnancy if there has been prior treatment with DOACs or warfarin) and again such prescribing may be done by the hospital directly. For the SGLT2 inhibitors there is likely to be more variance in their prescribing given they form but one part of treatment in diabetes/heart failure/chronic kidney disease. It may be that for some patients the medicines are started then stopped after side

effects, so a review of prescribing history may be helpful to suggest whether such medicines were tried but perhaps not tolerated.

While the focus of this study is on population health, cost effectiveness and health equity, we encourage consideration to be given to the other 2 components of the quintuple aims at least in write up if not in study design -

Patient experience – these treatments typically reduce the rates of unplanned admissions as well as repeat trips to health care, because they require less monitoring and titration than other treatments, as well as less venepuncture for DOACs vs warfarin

Staff experience – although a good shared-care protocol and good regional specialist support can really help, regional variations will often relate to the guidance from a local formulary, which may or may not align with best practice. Where there are variations in terms of both 'good' and 'bad' adherence to the NICE guidance, we hope that in write up these angles can be considered, to reduce the risk of a perception about what GPs are doing well or not.

The study team may wish to consider communication with the British Society for Health Failure in relation to their work on the 25 in 25 programmes, in which the data collection and dashboarding of SGLT2i in heart failure forms part of their long-planned dashboard. Lessons learned in the data collection may be useful here.

Please also be aware of a particular issue with the recording of reasons why a patient might not be taking an SGLT2i.

In March 2026 the following concept was introduced into SNOMED CT (UK edition)

- Adverse reaction to SGLT2i (sodium-glucose co-transporter-2 inhibitor) 2795521000000107 Active Clinical finding
- SGLT2i (sodium-glucose co-transporter-2 inhibitor) adverse reaction 2795521000000107 Active Clinical finding
- SGLT2i (Sodium-glucose co-transporter-2 inhibitor) not tolerated 2785281000000107 Active Situation with explicit context

In July 2025 the following novel concepts were introduced to SNOMED CT (UK edition):

- SGLT2i (sodium-glucose co-transporter-2 inhibitor) contraindicated 2570471000000107 Active Situation with explicit context
- SGLT2i (sodium-glucose co-transporter-2 inhibitor) declined 2570461000000100 Active Situation with explicit context
- SGLT2i (sodium-glucose co-transporter-2 inhibitor) not indicated 2570491000000106 Active Situation with explicit context
- SGLT2i (sodium-glucose co-transporter-2 inhibitor) therapy 2570481000000109 Active Procedure

When a new concept is introduced, it can take anywhere from months to years before they are integrated into the GP clinical systems and become 'selectable' to

users for data entry. The effect of this is that it is likely that until late 2025 at the earliest, the relevant clinical concepts to record reasons why an SGLT2i was not prescribed were not recordable in machine readable language. For example, there was no way to record that an SGLT2i was contra-indicated (which is a good reason to not prescribe it).

You may therefore expect to see variations between EMIS and TPP in terms of when the first codes appear in records, and may wish to clarify with the GP supplier systems when they made those codes selectable, in order to understand a clearer picture of which areas are or are not following the guidance.

The benchmark should probably be to compare “of the patients in whom an SGLT2i is not recorded as causing an ADR, and is not recorded as contraindicated / not tolerated etc, who is or is not taking an SGLT2i”. That modelling may be available to you through the British Society for Heart Failure on request, or collaboration.