NHS
Health Research Authority

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HRA Board Cover sheet
15 November 2023

Title of paper:	CAG Annual Report
Submitted by:	Paul Mills, Confidentiality Advice Service Manager
Summary of paper:	Annual Report of the CAG's activity in the year 22/23
Reason for submission:	For discussion
Further information:	Tony Calland, CAG Chair attending.
Budget / cost implication:	N/A
Dissemination:	Not for sharing until after HRA Board
Time required:	20 minutes

Annual Report for the HRA Confidentiality Advisory Group 2022/23

Reflections by the Chair

The world of electronic data never sleeps and although the remit of the CAG is narrow and focussed it is not unaffected by the way this data world is changing, both rapidly and in significant ways.

It is the magnitude of the changes which are so interesting. The merger of NHS England and NHS Digital is a very significant realignment which is still in the "bedding in" stage but hopefully will be better able to place the UK PLC medical data world in an optimum position for years to come.

The very rapid development of Artificial Intelligence will require careful management and the CAG is pleased to have recently recruited new members with expertise in this evolving field. This will help CAG better understand the nuances and risks involved in future applications for access to confidential data involving AI processing.

Secure Data Environments are being rolled out across the NHS and research world but the details of function and the interaction between these large data repositories is still being developed. CAG will have to understand these details to be able to discharge its responsibilities effectively and safely so public trust in the proper use of confidential medical data can be maintained.

During the pandemic the Control of Patient Information Regulations (COPI) were used to allow urgent research into the COVID virus, which enabled the timely and hugely beneficial development of vaccines. These Regulations are currently being reviewed and CAG and the HRA are among other stakeholders in discussions with NHS England to ensure that the protections of the use of confidential medical data are maintained whilst ensuring that the processes enabling data use are as streamlined as possible.

I reported last year on the work being done by CAG and the Health Quality Improvement Programme (HQIP) to allow some National Audits to be exempt from having to apply the National Data Opt Out. The loss of significant data from non random groups of patients would, in some audits, create a substantial medical risk to patient safety and CAG successfully produced principles which it applied to applications for an exemption whilst balancing the risks to safety against the principle of patient autonomy to opt out their data. This work has now been successfully completed with no controversy and praise from HQIP.

The work of the CAG is increasing outside of its role to review applications and I would like to thank the HRA for their continuing support with staff and resources which has enabled the committee to have to time and space to function effectively. I would also like to commend and thank the Confidentiality Advice Team for their hard and dedicated work over the past year.

1. Introduction

This report provides a summary of the activity considered by the Confidentiality Advisory Group (CAG) during 2022/23. The CAG provides a statutory function under the Care Act 2014 to provide advice on applications to process confidential patient information without consent (research and non-research) and provides advice, on request, to NHS England on issues related to the dissemination of information. The CAG consists of 28 expert and lay volunteer members. Expert members have a range of backgrounds, including clinical, research and information governance.

The past year has been an excellent one for the Confidentiality Advisory Group. A settled Confidentiality Advice Team (CAT) - the staff who support the CAG and advise applicants - that has been continually improving and aligning with the Approvals Operations Team has contributed to high performance figures shown in section 4.

CAG members have continued to dedicate a substantial amount of time to their role freely. In 2022/23 members considered 38 requests from predominantly non-research applications to be exempted from applying the national data opt out. The majority of these were submitted during the summer of 2022 and necessitated setting up a number of additional sub-committee meetings. This was a developing area for CAG and applicants previously rejected were invited to resubmit where the CAG position developed. The work was praised as fair timely and transparent by the Healthcare Quality Improvement Partnership (HQIP) a key stakeholder in this process.

Following this CAG has been working closely with the National Data Guardian to ensure NHS England provide transparent information to patients on what activities the National Data Opt Out will not be applied to. This is an ongoing process and has involved a group of members attending a National Data Guardian panel meeting to discuss. Close links are maintained with the National Data Guardian, both at an office level and a chair level.

To support the day-to-day role, continuous improvement work undertaken within the CAT in 2022/23. This includes:

1. Introduction of updated precedent set criteria, with new criteria added and additional clarity provided to existing ones.

2. Publishing of new guidance for applicants on CAG expectations, to aid applicants applying to CAG.

3. Introduction of updated validation criteria and associated processes to ensure applications are appropriately validated and are of a sufficient standard for CAG review.

4. The pilot to coordinate REC and CAG review continues. To date 10 applications have submitted through the pilot with reduced overall timelines for CAG and REC review, and positive feedback from staff and applicants. An interim report was provided to senior management in the Approvals Directorate in Spring 2023 outlining next steps.

5. Encouraging CAT and Approvals Operations Teams to discuss applications to resolve queries and issues for the benefit of applicants.

Early 2023/24 has seen the implementation of a number of other initiatives that we will continue to monitor throughout the year (as detailed in the looking forwards section) but these were the result of substantial work in the 2022/23 period.

Two CAG away days have been held where CAG members have listened to and discussed a variety of topics. There have been key presentations from NHS England on the future of the NHS data landscape and Secure Data Environments which will prepare CAG for future applications. Valuable discussions were had with the communication team on how to promote the work of the CAG, and the importance of patient and public involvement with the team from the HRA.

In addition to all this close links are maintained with relevant teams internally and key stakeholders externally to ensure that CAG and the HRA can influence key developments in the health data landscape.

2. Membership

The membership of the CAG is set out in Figure 1 below. The CAG manages the equivalent activity of two research ethics committees and operationally aims for up to 30 members, with members attending meetings and reviewing applications on a rota. This model provides greater flexibility than managing two distinct committees.

Figure 1: CAG membership
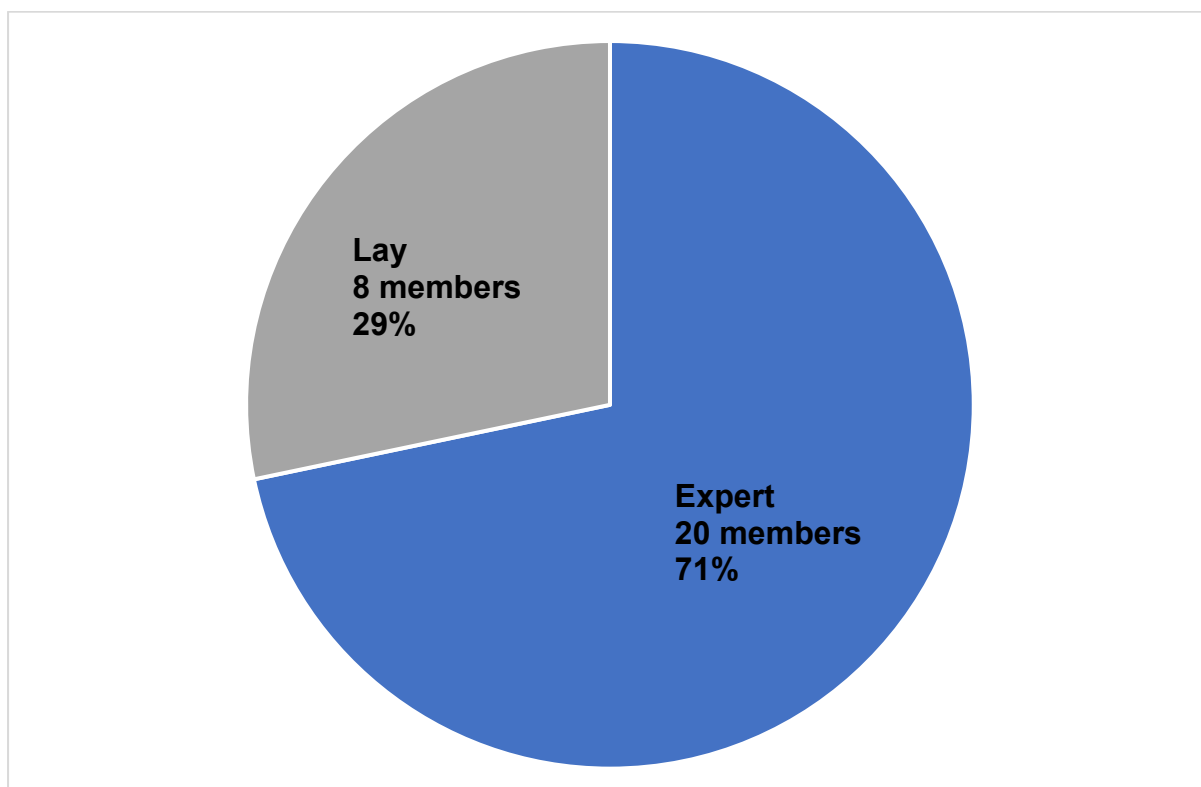
For CAG purposes expert members are defined as those with professional expertise in a clinical area, research or information governance. Lay members bring a range of experience from different areas.

Six members extended their membership for a further term of five years which provides continuity to the CAG. Two members however resigned from CAG

predominantly citing workload impacts of their career. One member is on a break of service. The Chair of the CAG also extended his term for two further years.

Because of a number of resignations in late 2021/22 from expert members a recruitment drive was undertaken to recruit expert members. This was very successful and resulted in the appointment of six new expert members. New members have a range of research, clinical and information governance expertise. Two of these have expertise in Artificial Intelligence to support CAG consideration on these application types. As such CAG currently has 28 members.
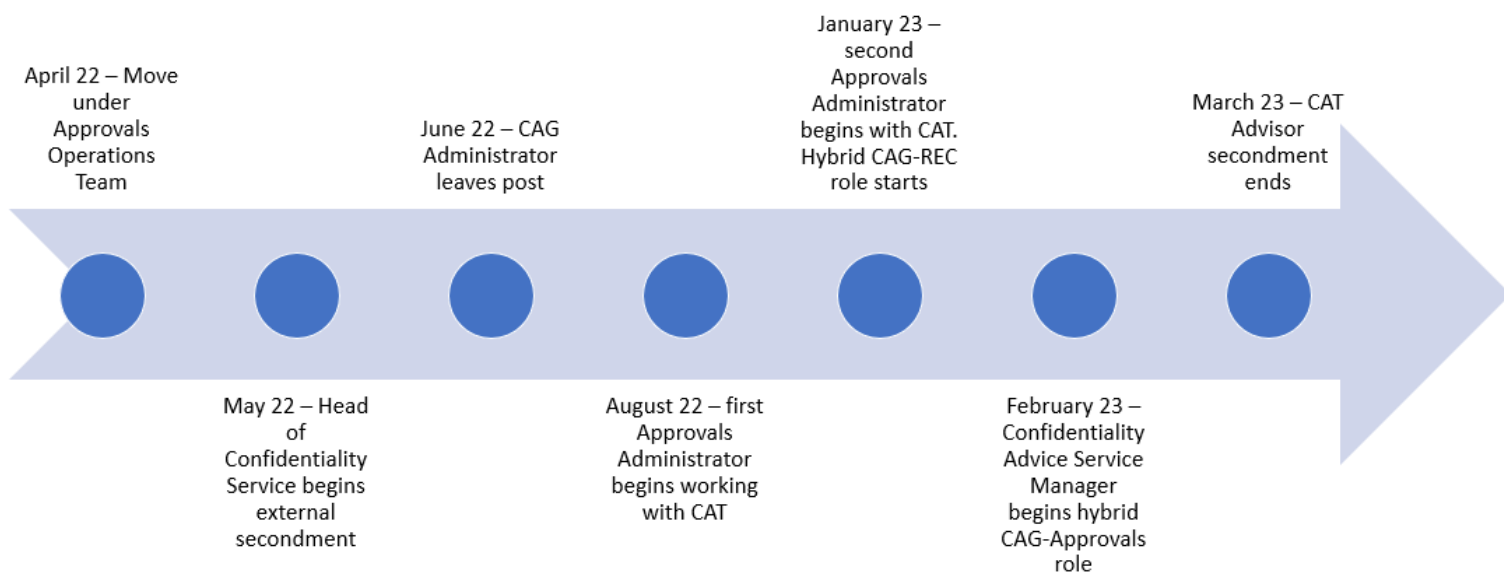
Because of the recent recruitment of expert members there is a current imbalance in expert vs lay members. We expect to address this through future recruitment of lay members.

CAG members have also undertaken a number of additional responsibilities as detailed throughout this report, as well as representing CAG on the community insights group.

3. Staffing

In April 2022 CAT had an establishment of five permanent staff plus two internal secondments. During the year there have been a number of changes to the staffing within the CAT that has fundamentally shifted how the team functions. This included the Head of the Confidentiality Advice Service beginning a two-year secondment to the Welsh Government in May 2022.

Following these changes (illustrated in the below timeline), by April 2023 the team consisted for four permanent staff (one on external secondment), one internal secondment, and two Approvals Administrators working in a hybrid CAG-Approvals role. The Confidentiality Advice Service Manager also now has a hybrid CAG-Approvals role, managing an Approvals Manager.

April 22 – Move under Approvals Operations Team

May 22 – Head of Confidentiality Service begins external secondment

June 22 – CAG Administrator leaves post

August 22 – first Approvals Administrator begins working with CAT

January 23 – second Approvals Administrator begins with CAT. Hybrid CAG-REC role starts

February 23 – Confidentiality Advice Service Manager begins hybrid CAG-Approvals role

March 23 – CAT Advisor secondment ends

The alignment work to bring two Approvals Administrators into a hybrid CAG-REC role has had benefits for the individuals to professionally develop, as well as to the Advisors, who have more time to support applicants through the application process.

The seconded Advisor working with CAT in 2022/23 operationally undertook the COPI notice transitions and then subsequently worked to contact applicants who had not submitted an annual review for a number of years. This allowed for the CAG public registers to be updated to accurately reflect the status of applications and for CAT to have proper oversight of all ongoing applications. This secondment has now ended, and the individual has returned to the Approval Operations Team where they are able to share their CAG knowledge gained with colleagues and support alignment.

The seconded Confidentiality Specialist remains with CAT to date and has been instrumental in many of the continuous improvement initiatives implemented over the year.

The Confidentiality Advice Service Manager is now embedded within the Senior Approvals Operations Management Team which allows for sharing of knowledge and good practice to support further alignment work. Managing an Approvals Manager also embeds this knowledge and cross-working.

4. Reviews undertaken

Applications reviewed at full CAG Meetings
Table 1: Applications reviewed at full CAG meetings

Type of Activity	Number Reviewed	Median time to final decision	% Reviewed in less than 60 days	% reviewed in 60 days difference to 2020/21
Research	60	32.5 days	98	↑ **2%**
Non-Research	11	28 days	100	↑ **5%**
Total	71	32 days	99	↑ **4%**

The significant increase in performance against KPIs reported in 2021/22 was maintained and improved upon this year. The support provided by the two Application Administrators has been a factor in this performance.

Applications reviewed by Precedent Set review
Table 2: Applications reviewed at precedent set meetings

Type of Activity	Number Reviewed	Median time to final decision	% Reviewed in less than 30 days	% reviewed in 30 days difference to 2020/21
Research	25	24 days	88	↑ **10%**

| Non-Research | 8 | 21 days | 88 | ↓ **12%** |
| Total | 33 | 24 days | 88 | ↑ **6%** |

Performance of precedent set applications was also high. Whilst the non-research performance is down by 12%, this equates to one application missing the KPI target over the period, with 4 applications in total missing the KPI for precedent set applications.

In general, the number of applications given an outcome by CAG reduced compared to 2021/22. This is predominantly due to a reduction in non-research applications seen in full CAG meetings (11 less) and research applications seen in precedent set meetings (15 less).

However, these figures do not reflect the number of potential applications that the Confidentiality Advice team provided advice for which ultimately did not require a CAG application (45 applications). Whilst not reviewed by CAG, supporting these applicants is an important role for the team. In the coming year we will be exploring avenues for how we can support these applicants further, for example piloting a managed drop-in session for potential applicants.

Amendments
Table 3: Amendments

Type of Activity	Number Reviewed	Median time to final decision	% Reviewed in less than 35 days	% reviewed in 35 days difference to 2020/21
Research	146	10 days	94%	↑ **5%**
Non-Research	77	25 days	99%	↑ **22%**
Total	223	15 days	95%	↑ **9%**

There was a significant increase in the number of amendments received to CAG compared to 2021/22 (68 additional). Around half of this increase related to 30 amendments from non-research applications to be exempted from applying the national data opt out.

Whilst it may appear that non-research amendments took longer to process that research this is also impacted by the fact that the national data opt out exemptions were reviewed at a CAG meeting and took longer to consider.

Despite the increase in amendments, it is encouraging to see that performance of amendments improved across the year.

Annual Reviews
Table 4: Annual Reviews

Type of Activity	Number Reviewed	Median time to register update	% Reviewed in less than 30 days	% reviewed in 30 days difference to 2020/21
Research	233	14 days	94%	↑ **11%**
Non-Research	64	14.5 days	91%	↑ **6%**
Total	297	14 days	93%	↑ **9%**

The large increase in performance last year for annual reviews has been built upon this year with excellent performance in managing these. To note each annual review is, as a minimum, reviewed by HRA staff before the register is updated. Some annual reviews may be escalated to a CAG officer, or a full CAG meeting where issues arise so the workload is not insignificant.

Timely review of submissions and updates to the CAG registers ensures transparency of applications operating under support and provide assurances that each is working within the scope of support and meeting any conditions.

In addition to annual reviews CAT have been reviewing the status of a high volume of applications where the status of the application is unclear due to no current annual review submission. In total 455 applications were reviewed in 2022/23, with 306 applications closed and the remaining providing in most cases an annual review. The team continue to contact the last outstanding applications (approximately 100) to ensure that the register of supported applications remains accurate and there is clarity on the status of each supported application. In 2022/23 we have also implemented a rolling monthly check and contact of applicants that have not submitted an annual review to CAG.

5. CAG meeting advice outcomes

Meeting outcomes
Table 5 shows the combined full and precedent set review CAG advice outcome at first review.

Table 5: Advice outcome at first review

	Research	Non-Research
Fully Supported	2	2
Conditionally supported	12	8
Provisionally supported	66	7
Not Supported	0	1

No Recommendation (Deferred)	5	2

The majority of applications to CAG are supported though many, particularly research applications, initially receive a provisional outcome. Non-research applications are more likely to have tailored pre-application support due to specific complexities that may arise from these.

During the year we released new guidance on CAG expectations for applicants that has and is being promoted by the communications team through HRA updates and across social media. Given it may be the first time for many applicants coming to CAG we would like to pilot managed drop-in sessions to give potential applicants specific guidance on preparing their application to help for CAG review.

Application decisions

The CAG provides expert independent advice that is considered by either the HRA for research applications or the Secretary of State for Health and Care (SofS) (via the Department for Health and Social Care) for non-research applications. The HRA or SofS take the final decision on applications to access patient information without consent using the CAG advice as the initial basis for the decision.

Table 6 shows the number of times the HRA/SofS were required to formally take a decision on a specific use of patient information without consent. This includes significant changes to provisional outcomes and high-profile annual reviews.

Table 6: Number of decisions taken by HRA/SofS

	Number
Research decisions taken by the HRA	237
Non-Research taken by the SofS	100
Total decisions	337

The table shows that 70% of activity considered by CAG relates to research. This follows the same trend as previous years. During this time period there were no instances where the decision-maker substantively disagreed with the CAG advice.

Note that the table does not solely relate to decisions on initial applications and amendments. Some annual reviews may be considered by a decision maker as well as other ad hoc situations.

Application themes

The CAG has identified a number of areas over the year that typically require additional applicant action. These commonly relate to:

1. Lack of relevant patient and public involvement to support the public interest in the unconsented use of data

2. Insufficient communication mechanisms to inform the relevant cohort of the activity

3. Uncertainty on the scope of request for support (i.e. lack of clarity of flows of data, identifiable data items, organisations involved and any pre-existing legal basis for data sources).

As above, we will be looking to pilot some managed drop in sessions to complement the guidance released during the year to help provide some tailored advice to potential applicants.

6. Advice Requests – NHS England

No requests for advice were received from NHS Digital or NHS England (who merged with NHS Digital) during the time period. However, it should be noted that the HRA/CAG instigated the advice process related to a specific research application which resulted in NHS Digital accepting the advice provided.

A memorandum of understanding that sets out more clearly the role of CAG in providing advice to NHS Digital has been signed. Confirmation was received that this novated to NHS England when NHS Digital merged with them.

7. Representations

No requests for reconsideration of CAG advice or final decisions were received under the formal representation process.

8. Complaints

No formal complaints were received related to the Confidentiality Advisory Group though the CAT supported the complaints team with a number of third-party complaints during the period.

9. Freedom of Information Act Requests

One freedom of information request related to the CAG function was received in the 2022/23 period.

The CAG maintains a high level of transparency of its advice on behalf of those relying upon approved applications through publishing each CAG rationale via

minutes on the HRA website and maintaining the statutory Register of supported applications on behalf of controllers.

10. Looking forwards

We will embed current developments in the coming year whilst undertaking further continuous development work in line with HRA strategic ambitions. We will continue to monitor the continuous improvements that have already been undertaken in 23/24:

1. An in-depth review of validation processes to understand where further improvement and support is necessary.

2. Release of updated work instructions for initial applications to ensure consistency of process.

3. Release of new email and letter templates to make outcomes shorter and easier for applicants to understand the outcome and any actions required.

4. Release of a new minutes template which aligns the format to REC. This allows consistency of working for hybrid Approvals Administrators whilst not losing the transparency of CAG considerations.

There are a number of other areas of the service that have opportunities for development, as well as continuing work to further align with the Approvals Operations team. This includes continuation of the CAG-REC coordination pilot, and work to transfer responsibility of CAG members to the Member Support and Improvement team which will provide consistent support to REC and CAG members and release time of the Confidentiality Advice Team to be focussed on operational processes.

There are significant developments expected in the health data field which have the potential to impact CAG. It is essential that the HRA and CAG play a central role to influencing these programmes of work. This includes:

1. NHS England continue to progress work in implementing a series of Sub-National Secure Data Environments, most of which will likely require an application to CAG. One application has been approved, and the HRA has a key role to support the smooth submission of future applications, building on lessons learned. There will be longer term work with NHS England to understand what the introduction of Secure Data Environments mean for other existing resources that may be operating under CAG support.

2. The Department of Health and Social Care have begun scoping work to amend the NHS (Control of Patient Information) Regulations 2002 (COPI Regulations). These Regulations determine the remit and scope of CAG so have the potential to impact its work. Initial positive conversations have already been had with an agreement to continue to work closely with CAG and HRA.

3. Interlinked to updates to the COPI Regulations is the planned review of the National Data Opt Out. CAG have long argued that the National Data Opt Out needs to be reconsidered and are keen to provide input, together with the HRA.

4. The CAG were highlighted in the Government Response to the O'Shaughnessy Report to work with the HRA to streamline the processes to approach patients about research, and look forward to doing so.

5. As well, an additional CAG meeting has been set up in for August 31 to consider 25 ICB applications to undertake risk stratification. This is a result of a year long engagement with NHS England to reassess this on a ICB level basis to provide assurance on the standards being used and maintain the public interest in this important activity operating under support via CAG.

We will continue to monitor membership closely with the potential to recruit more lay members during the next year as across CAG, REC, PIN, the HRA Community Group and the HRA we aim to include a more diverse, representative group of people in our work. We thank all members for their time and valuable insights that they provide so freely.