



Health Research Authority

Agenda item:	11
Attachment:	A

HRA Board Cover sheet 21 September 2022

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 21/22
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Annual Report for the HRA Confidentiality Advisory Group 2021/22

Reflections by the Chair

The last twelve months have been busy for the members of the Confidentiality Advisory Group (CAG) and their administrative support group the Confidentiality Advice Team (CAT).

Since March 2020 the General COPI Notice has provided a legal basis to share confidential patient information without consent, for COVID purposes. Whilst this meant that an application to CAG was not necessary, CAG during this time has provided informal advice to activities on what to consider if this processing continued. Over the past year CAT and CAG have focussed on supporting activities to transition from relying on the General COPI Notice (which ended on 30 June 2022) to a more permanent legal basis through submission of a CAG application. Alongside this, other research projects and changes to the NHS such as the introduction of Integrated Care Boards has meant there has been a steady flow of applications for consideration.

At the time of the ending of the COPI Notice the mandatory introduction of the delayed National Data Opt Out (NDO), which allows patients to opt out of their data being used for research and planning purposes where that activity operates under CAG support, came into force which has created a whole new area of work for CAG consideration. Many, but not all, of the National Audits deliver critical analysis of NHS performance in real time with a heavy influence on patient safety. The loss of data through the application of the NDO could cause significant distortion to some patient safety critical programmes and the CAG has spent several months determining which of these programmes could justify the exemption of the NDO. The NDO represents the exercising of an individual's right to prevent their medical records being used for secondary purposes, a decision that should not be overridden without very clear and convincing reasons. CAG started with a blank sheet of paper but has now developed a series of principles which it can apply with some consistency, work that has been done in a short period of time and through the generous donation of brain power and time by both the CAG members and the CAT. I give my thanks to both groups.

During the year there have been a number of changes to both the CAG membership and the CAT. CAG has seen some resignations from the committee, mainly due to the pressure on time for those that have "proper" jobs and occasionally from members who have served the committee for a number of years and now wish to retire from their "retirement" jobs. Later this year there will be a recruitment process to ensure that the committee gets back to full strength so as not to overburden the remaining members.

Recently, there has been a very significant staff change in the CAT with the loss of Natasha Dunkley. She has accepted a secondment to the Information Governance team in Welsh Government. Wales's gain is very definitely CAG's loss as she has been invaluable to CAG over many years. We wish her well and thank her for her contribution. However, the good news is that Paul Mills, as service manager, has been very impressive with his leadership of the CAT during this very busy period of work on the NDO.

There have been a number of other staff changes in the CAT with welcome additions to the team to ensure that this team can remain able to address this rapidly changing landscape with both confidence and competence. The CAG is grateful for these additions to the CAT and the support from the HRA Board and senior management to the committee which plays an important role in ensuring there is a continuing flow of confidential data to applicants who satisfy the criteria for CAG support.

I am very hopeful that the CAG will continue to provide thoughtful and sustainable advice to the HRA and the Secretary of State over the next twelve months.

Dr Tony Calland Chair CAG

1. Introduction

This report provides a summary of the activity considered by the Confidentiality Advisory Group (CAG) during 2021/22. 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 Digital on issues related to the dissemination of information.

The use of the general 'COPI Notice' continued throughout 2021/22, until its recent expiry on 30 June 2022. This meant that many COVID-19 related activities continued to operate with an appropriate legal basis, without the need to seek CAG advice. The focus of the Confidentiality Advice Team (CAT) and CAG since September 2021 has been to ensure that all activities have an appropriate legal basis on expiry of the COPI notice.

During the latter part of 2021/22 the CAG chair team and CAT have been working to prepare for a number of requests to defer the application of the National Data Opt Out, following work by the NHS Transformation Directorate at NHS England. The impacts of this work are being seen in 2022/23 with a number of additional sub-committee meetings convened to consider these requests.

We have continued with improvement activities, such as running a pilot to test the impact that a coordinated CAG/REC review process can have for applicants. This also tested a potential new application question set., as well as applicants attending the meeting. At the time of writing, the evaluation report is being written but initial outcomes, including applicant feedback, is positive. To complement this work, the CAT are also refreshing applicant guidance to provide applicants with an understanding of CAG expectations before applying, as well as updating the precedent set criteria.

The CAT are also undertaking a project to ensure that the CAG registers are accurate and that there is clarity on the current status of applications that have not

submitted a recent annual review. The CAT are reviewing these applications and contacting the applicants to ascertain the status, and this work will continue.

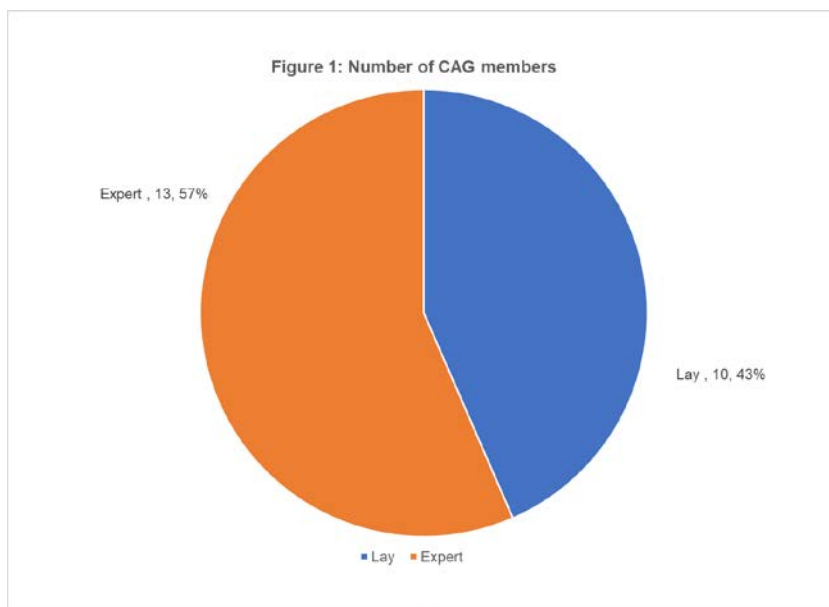
Work of the CAG members has continued virtually and will remain as such. Members got the chance to reconnect, or meet for the first time, at a successful CAG away day in April 2022.

The CAT at the end of the 2021/22 reporting period moved under the reporting of the Head of Approvals Operations. This brings CAT together with the other HRA Approvals functions and we look forward to closer working and the benefits this brings.

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 clinical research or information governance. Lay members bring a range of experience from different areas.

Four members extended their membership for a further term of five years which provides continuity to the CAG. Five members however resigned from CAG predominantly citing workload impacts of their career. Most of these have been late 2021/22. Two further members were also granted breaks in service which means the working CAG membership is currently at 21.

This obviously puts pressure on the remaining CAG members, and a new recruitment campaign is due to begin in September 2022 to bring the membership up. This recruitment will focus on new expert members as this is where existing CAG members have been lost. This will ensure a balanced spectrum of views when

providing its specialist advice to the Health Research Authority or Secretary of State for Health and Social Care

3. 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	68	27 days	96%	↑ 14%
Non-Research	22	31 days	95%	↑ 10%
Total	90	28 days	95%	↑ 13%

There was significant staff changes within CAT during 2020/21, with most of the team joining during this period. Since then, and during 2021/22 the CAT has increased its technical and process knowledge, staff have embedded as a team and as such were able to consistently manage full applications within the KPI target.

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	40	24 days	78%	↑ 16%
Non-Research	7	17 days	100%	↑ 57%
Total	47	22 days	82%	↑ 22%

Whilst the precedent set applications had a lower KPI percentage they demonstrated a significant increase in performance against 2020/21. During 2022/23 we will look to build on this improvement further, working closely with colleagues in Approvals Operations to share good practice.

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	116	8 days	89%	↓ 3%
Non-Research	39	22 days	77%	↓ 11%
Total	155	12 days	86%	↓ 6%

Whilst disappointing to see the amendment performance drop, it should be noted this is the result of two dips in performance, rather than prolonged under-performance. The first, significant, dip in performance was summer 2021 because of reduced staff capacity due to two long term sickness absences within the small CAT. The second, more minor, dip came in January 2022 after Christmas. In both instances' performance returned to more acceptable levels after a return to full capacity. Current work to further integrate CAT within wider Approvals Operations teams while retaining CAT expertise, will mitigate susceptibility of CAT metrics to issues associated with very small teams.

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	309	14 days	83%	↑ 14%
Non-Research	88	14 days	85%	↑ 19%
Total	397	14 days	84%	↑ 15%

It should be noted that the large increase in performance of meeting the annual review KPI has come despite a significant increase in submissions; 397 in 2021/22 compared to 220 in 2020/21. This large increase is the result of the CAT pro-actively chasing applicants who had not submitted an annual review in the period 2019 to 2021.

4. 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	3	4
Conditionally supported	29	12
Provisionally supported	61	9
Not Supported	0	1
No Recommendation (Deferred)	14	3

The majority of applications to CAG are supported though many, particularly research applications, initially receive a provisional outcome. Much of these are due to the common issues seen in the application themes below. Work over the next year will look to mitigate these issues, as described below

Application decisions

The CAG provides expert independent advice that is considered by the HRA and the Secretary of State for Health and Care (SofS) (via the Department for Health and Social Care). The HRA and 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	194
Non-Research taken by the SofS	64
Total decisions	258

The table shows that 75% 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.

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. Security assurance processes
4. 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).

Point 4 is the most common reason for an application to be deferred (as per Table 5).

For all the above points, the CAT is working with CAG to develop improved guidance so applicants have clarity on the CAG expectations prior to submitting. This guidance is expected to be released in September 2022 and outcomes will be monitored over the coming year.

5. Advice Requests – NHS Digital

In relation to the CAG statutory function to provide advice to NHS Digital it is noted that the CAG only provides advice following a request from NHS Digital. No requests for advice were received from NHS Digital during the time period.

A memorandum of understanding has been undergoing development that sets out more clearly the role of CAG in providing advice to NHS Digital. Whilst delayed due to the pandemic response this MoU has now been agreed by both parties and is in effect.

6. COPI Notice – managing transition from the COPI Notice

The General 'COPI Notice', used to provide a legal basis for the use of Confidential Patient Information for the response to COVID-19, expired on 30 June 2022. Prior to this the CAT and CAG worked to ensure that those that required an ongoing permanent legal basis for their activity were able to transition to Regulation 5 support as appropriate.

Full details were presented to the Board in July 2022.

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.

9. Freedom of Information Act Requests

No freedom of information requests related to the CAG function were received. 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

The NHS data field is a constantly evolving one with a number of strategies recently published (e.g. Data Saves Lives). These strategies include commitments that the CAG and HRA can influence as they progress and expect to continue to do this over the next year.

One of these commitments is to review how patients are able to opt out of the use of their data. CAG is currently at the centre of considering requests to defer the use of the National Data Opt Out (NDO), on which there has previously been no precedent and principles are being established as this process is worked through. Given this, CAG has substantial experience and expertise in the issues that should be considered at a national policy level and look forward to contributing to a review of the current opt out system.

A current key stakeholder for CAG is NHS Digital, and the impending organisational changes to move NHS Digital functions to NHS England is one that will be closely monitored. This has the potential to destabilise the use of patient data that NHS Digital holds, and CAT/CAG will be proactive to mitigate any issues within its control.

We expect benefits of current improvement work to be realised over the coming year. Moreover, CAT and CAG will maintain continuous service improvement work to ensure that processes for the applicant are streamlined and an appropriate review route is used whilst maintaining the rigour of CAG review to ensure continuing public trust.

Continuous improvement will be supported by the recent move to come under Approvals Operations management and support, where appropriate, consistency in processes and staff. A recent example is trialling greater administrative cover for the CAT function through use of an Approvals Administrator, as well as focus on different activities that align to Approvals Operations (e.g. taking CAG minutes). This will release capacity at other levels to undertake other improvement activities. Other routes to release administrative burden on CAT staff will be explored as well as looking at how staff can provide cross-cover when there are busy periods or absence.

The hard work of the CAG members, who give their time freely and rise to numerous challenges, largely is undertaken 'under the radar'. This year we will look to raise the profile of CAG to the research community but also importantly with the public. Doing so will allow for a greater understanding of the role of the CAG and further embed

public trust in its work. Undertaking new member recruitment alongside this will provide welcome support to existing members and will allow for new views to be provided whilst maintaining continuity of service.