

<b>Agenda item:</b>	10
<b>Attachment:</b>	A

## HRA Board Cover sheet

### 22 September 2021

<b>Title of paper:</b>	Confidentiality Advisory Group (CAG) Annual Report 2020-21
<b>Submitted by:</b>	Natasha Dunkley, Head of Confidentiality Advice Service
<b>Summary of paper:</b>	The 2020-21 CAG annual report is attached for approval and covers the period of 01 April 2020 – 31 March 2021
<b>Reason for submission:</b>	For approval
<b>Further information:</b>	The Board is asked to approve the Report.
<b>Budget / cost implication:</b>	N/A
<b>Dissemination:</b>	HRA website (in conjunction with RES annual report)
<b>Time required:</b>	10 minutes

## **Annual report for the HRA Confidentiality Advisory Group 2020/21**

### **Reflections by the Chair**

Whilst the pandemic has caused much pain, grief and anxiety throughout the world paradoxically there have been some benefits to society through the focus on medical solutions to the pandemic and changes to the regular order of medical research and the use of medical data. The use of what has come to be known as “the COPI notice” has been welcomed but it must be remembered that the controls it temporarily replaced were there for a reason and that was to ensure that people could trust government and the research community to use their personal medical records responsibly whilst protecting their personal confidentiality. These controls must not be suspended for longer than is absolutely necessary.

The CAG is keen to develop new mechanisms to facilitate applications to access confidential data for research, increased proportionality and giving better guidance to applicants so they understand better what information the committee requires. As Chair of the CAG I would like to thank the HRA for their recognition of the importance of the committee’s work and their increase in resources to support applicants and the vital work of the CAG.

The CAG provides expert independent advice and its role and recognition is essential to maintaining public trust. It is an important part of a system of scrutiny of data use to ensure high standards of ethics and process are maintained. In conclusion I have to mention the very sad passing of a truly great confidentiality champion, Dame Fiona Caldicott. Through her hard work, determination and charm she raised the profile of data governance and showed how to square the circle of the use of confidential data for the public good and maintaining the confidentiality and privacy of the individual patient. A great loss.

### **1. Introduction**

This report provides a summary of the activity considered by the Confidentiality Advisory Group (CAG) during 2020-21. 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 introduction of national measures following the start of the pandemic meant that face to face meetings were converted to virtual meetings in March 2020. The introduction of the general ‘COPI Notice’ issued to support the pandemic response in relation to research and planning led to the CAG providing a different type of advice in addition to its normal functions. A system was set up for the expedited review of urgent COVID-19 research; the CAG supported the fast track ethics review of COVID-19 studies for research through providing informal advice to the Research Ethics Service where patient information was being processed under the general COPI Notice. CAG

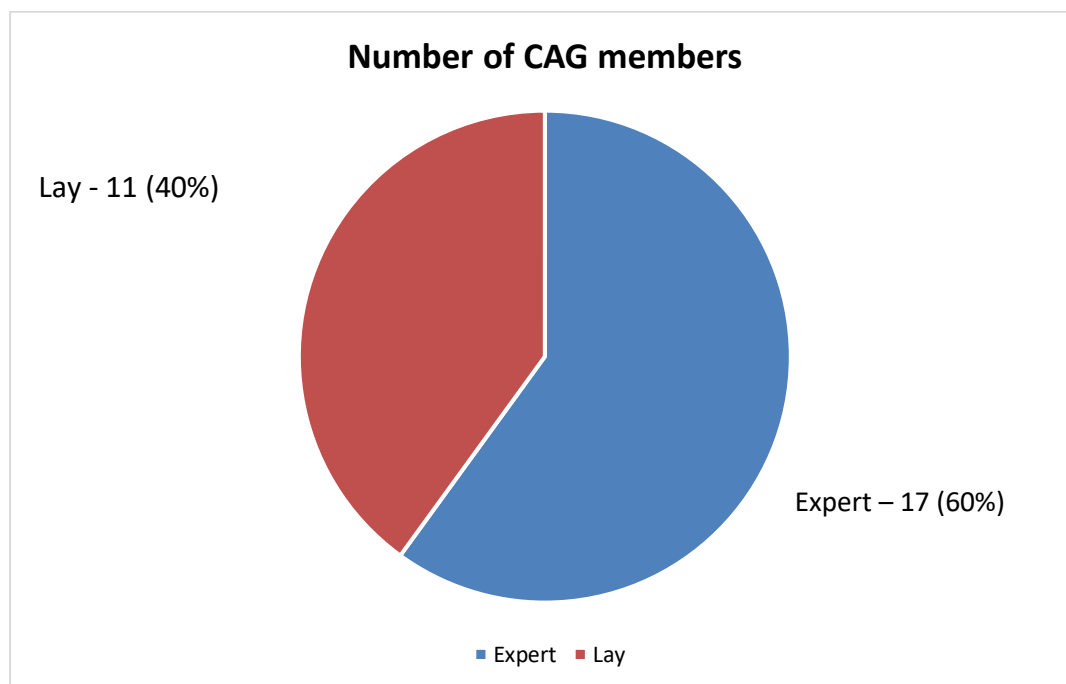
also provided this informal advice to NHSX in supporting their consideration of access to large national datasets. CAG members adopted a rapid and regular light-touch review process throughout the pandemic to support activities taking place under the COI Notice.

The CAG has continued to consider applications as normal throughout this period and members continue to show their dedication and commitment to providing advice to support the trusted use of data for research and planning purposes.

## **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. Five members reaching the end of their first term extended their membership for a further term to provide continuity during the pandemic and a subsequent recruitment campaign was successfully carried out in early 2021 to increase the number of lay members by an additional five members.

**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.

Prior to the member recruitment in February 2021, 72% of members were classified as expert therefore the focus of the recruitment was to specifically increase the number of lay membership. The Committee aims to reach a membership split of 55% expert to 45% lay membership to 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

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

<b>Type of activity</b>	<b>Number reviewed</b>	<b>Median time to final decision</b>	<b>Reviewed in less than 60 days</b>
Research	70	42 days	82%
Non-research	12	37 days	85%
Total applications	82	41 days	82%

A reduced number of non-research applications were received due to the COPI Notice and that management by NHSX.

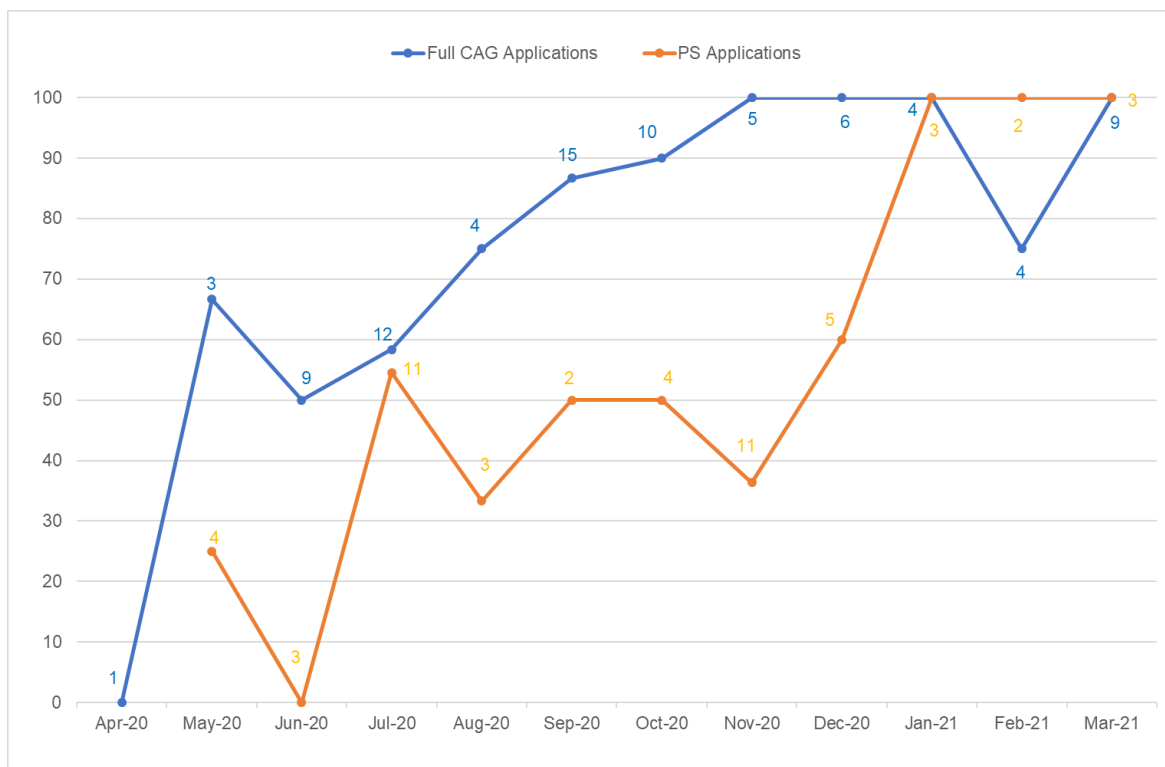
#### Applications reviewed by Precedent-Set review

**Table 2: Applications reviewed at precedent-set meetings**

<b>Type of activity</b>	<b>Number reviewed</b>	<b>Median time to final decision</b>	<b>Reviewed in less than 30 days</b>
Research	44	28 days	62%
Non-research	7	31 days	43%
Total applications	51	29 days	60%

The Advice team supporting the CAG significantly increased in April and June 2020. A detailed training and support programme was implemented to develop the advisors and following this there was an increase in compliance from November 2020 onwards. This is shown in the figure below which shows the percentage of applications meeting the KPI targets for full and precedent set applications by month.

**Figure 2: Percentage of applications meeting KPI**



## Amendments

**Table 3: Amendments**

Amendment type	Number reviewed	Median time to final opinion	Reviewed in less than 35 days
Research	107	10 days	92%
Non-research	41	13 days	88%
Total applications	148	11 days	91%

Most common amendment areas relate to a change in scope, additional processors handling data or additional data flows. Another trigger is where local controllers feel the activity requires support either due to local processes or where the support detail may not match the data access request.

Much of the non-compliance with amendments occurred in the first quarter of 20/21 when new staff were being recruited and trained. Since Autumn 2020 there was a high compliance with meeting the amendment KPI.

#### 4. CAG meeting advice outcomes

##### Meeting outcomes

Table 4 shows the combined full and precedent set review CAG advice outcome at first review.

**Table 4: advice outcome at first review**

	Research	Non-research
Fully supported	6	3
Conditionally supported	18	3
Provisionally supported pending further information	76	10
Not supported	1	0
No Recommendation (deferred)	13	4

Following a period of embedding and training new members and staff, the CAG is looking at how more conditional responses can reasonably be issued through process review and improved guidance; this is expected to be incorporated within the Streamlining Data Driven Research programme.

##### 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 5 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. The HRA aims to provide a decision within 3 days of receiving advice and achieved 99%.

**Table 5 – number of decisions taken by HRA/SofS**

	Decisions taken by HRA	Decisions taken by SoS
Research	227	Not applicable
Non-research	Not applicable	70
Total decisions	297	

The table shows that 76% of activity considered by CAG relates to research with 24% related to non-research activity. 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.

From time to time, the absence of an agreed national policy across has created a challenge that can prevent the CAG from reaching a conclusion e.g. circumstances where anonymisation can be undertaken by parties without involving a breach of confidentiality. The CAG continues to work closely and collaboratively with the HRA, DHSC and other national stakeholders to ensure that its advice remains credible, robust and facilitative.

### Application Themes:

The CAG has identified a number of areas over the year where improved guidance and support would assist in reducing the number of interactions within the CAG application pathway. The most frequent areas typically requiring additional applicant action relate to:

1. Undertaking of relevant patient and public involvement to support the public interest in the unconsented use of data
2. Understanding that reasonable steps should be taken to inform the relevant cohort of the activity
3. Security assurance processes

It is noted that the forthcoming 'Streamlining Data Driven Research' programme will look to implement user-focused process and guidance improvements in these areas to facilitate the submission of applications to the CAG.

### **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. Development was put on hold to support the immediate requirement in managing the pandemic and this is expected to be completed by end 2021.

### **6. COPI Notice – CAG informal advice**

The CAG provided informal advice on 84 COVID-19 applications to the research ethics service during this time period. This provided additional assurance to RECs and enabled the CAG to provide early advice if the applicant wished to continue the activity once the COPI Notice expired, helping establish the legal basis for the activity.

### **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 CAG continues to provide robust and proportionate advice to help support public trust in the appropriate use of patient information without consent and is keen to listen, adapt and tailor its advice to meet new types of activity.

An exciting area of work will be implemented under the HRA 'Streamlining Data Driven Research' programme. This will look to review and implement process and technical improvements to support the efficient and proportionate provision of CAG advice that is better targeted to meet the current and future needs of those needing to process patient information without consent. This programme is intended to deliver improved relevant guidance to reduce the need for bespoke support and look for efficiencies within processes. Work is also separately underway to update the CAG-specific questions within the IRAS system to remove unnecessary duplication, review necessity and ensure the questions are proportionate and clear in terms of expectation.

The CAG and HRA are supporting the transfer of applicants relying upon the COPI Notice to help them transition to a more permanent legal basis so that critical activities to support the pandemic continue. This is likely to bring in approximately 50% more applications than the CAG typically considers and additional project resource has been provided to manage this activity through proactive engagement with affected applicants and close working with all CAG members.

The area of data is be subject to evolution and CAG is often at the heart of these discussions through its application consideration. The CAG will continue to encourage and support appropriate national policy positions being reached collaboratively to allow consistency for those operating within the system.



Members continue to give generously of their time and have responded well to the challenges of virtual meetings. The CAG will continue to meet face to face for Education and Away days and we will review the format of meetings as we move through the pandemic response to support research and planning activities, while maintaining public trust and confidence in the advice of the CAG.