



National Respiratory Audit Programme (NRAP)

COPD Audit FAQs: Information Governance

Version 5: June 2023

A general FAQ is available separately.

1. Who is involved in running the audit?

- The audit is managed and operated by the **Royal College of Physicians, London** in collaboration with:
 - **Healthcare Quality Improvement Partnership (HQIP)** – who commission the audit and are **data controllers** for all NRAP audit data.
 - **Crown Informatics** – who provide the audit web tool and data management services.
 - **Imperial College London** – who provide statistical data analysis services.
- The Royal College of Physicians, Crown Informatics and Imperial College London are all **data processors** for the audit.

2. Has the audit got approval to collect identifiable information?

a. England and Wales

- The COPD secondary care continuous audit has Section 251 approval from the Health Research Authority's (HRAs) Confidentiality Advisory Group (CAG) to collect patient identifiable data (including NHS Number, date of birth, and postcode) without obtaining patient consent (reference: **23/CAG/0045**). This is a joint approval with the asthma audit.
- A record of the approval can be found at: <http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions> (April 2013 onwards; nonresearch).
- Each participating hospital's Caldicott Guardian must also provide written approval before any data can be entered.

3. What are hospitals required to do?

- Though patients do not need to be consented for inclusion in the audit (see response to question 2), hospitals must carry out fair processing activities. These include:
 - Display the patient information poster in all areas where patients with COPD may be treated.
 - If a patient asks for further information please hand them a copy of the patient information leaflet.
 - Copies of both the poster and patient information sheet are available to download from the [COPD resources page](#).

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- If a patient informs you that they do not wish to be included in the audit or have opted out under the National opt out Policy, please make this clear in the patient's notes and **do not enter their data into the audit.**

4. What are the data flows?

- The COPD data flows are publicly available on the [COPD resources page](#).
- Approved users at each registered hospital enter data into a bespoke web tool (www.nrap.org.uk) hosted by Crown Informatics.
- Data from each unit is only visible to authorised users within that hospital according to the audit profile and to Crown Informatics for web tool and data management purposes. Crown Informatics only access the data on very rare occasions, examples of which are listed below:
 - System 'de-bugging' investigations, if problems are experienced with processes where Patient Identifiable Data (PID) is involved. Examples might include duplicate checks, re-admission processing, and validation processing. Note, wherever possible, system tests are undertaken on test systems using dummy/fake PID. However, processing of live data may have to be examined in detail in rare but limited circumstances.
 - Data linkage exercises to validate linkage success - this is usually limited spot checks. Bulk access to PID is necessary to undertake linkage exercises (i.e. to prepare the files for transfer to NHS England or Data Health and Care Wales (DHCW)).
 - Subject access requests - when a patient requests their audit details.
- Non-identifiable patient level data is sent from Crown Informatics to Imperial College London for statistical analysis purposes.
- Following analysis, non-identifiable aggregated patient data is sent from Imperial College London to the audit team (at the Royal College of Physicians) on demand or periodically for audit administration and reporting.
- Non-identifiable patient level data may also be shared with third-parties for research, audit and service evaluation under Data Sharing Agreements (DSAs) which are arrangements agreed separately as required according to IG recommendations.

5. Who has access to the data?

a. Patient identifiable data

- Only nominated individuals at each hospital and Crown Informatics can see any patient related identifiable data. Access to data is carried out for necessary administrative purposes only by named, trained, and certified individuals.
- Crown Informatics has an NHS Data Security and Protection Toolkit (DSPT) (ODS code: 8J157) rating of Standards Exceeded and meets all NHS guidelines and requirements.
- They are also registered with the Data Protection Authorities (DPA) under reference: Z3566445.

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- Access to data is via secure client software that operates over secure encrypted firewalled networks using secondary application layer security.

b. Non-identifiable patient data

- Only members of the Imperial College London analysis team will access to anonymised patient level data sent to them by Crown Informatics.
- Imperial College London has an DSPT (ODS code: EE133887-SPHTR) rating of Standards Met and meets all NHS guidelines and requirements.
- They are also registered with the Data Protection Authorities (DPA) under reference: Z5940050.
- Data Sharing and Transfer Agreements duly authorised by the audit commissioners (HQIP) will govern the transfer of non-identifiable patient data to any approved third parties.

c. Anonymised and aggregates level data

- Members of the NRAP team at the Royal College of Physicians receive anonymised and aggregated data from Imperial College London.
- The Royal College of Physicians has an DSPT (ODS code: 8J008-CSD) rating of Standards Met and meets all NHS guidelines and requirements.
- Royal College of Physicians is also registered with the Data Protection Authorities (DPA) under reference: Z7085833.

6. How is data transferred?

- Data is collected over secure web/internet-based systems using high strength TLS (SSL) protocols (256 bit, SHA256 signatures and 4096 bit certificates. The web tool SSL certificate is 'organisationally verified' (OV) and issued by an established respected global certifier).

7. How and where is the data stored?

a. Crown Informatics

- Data is stored and processed at a secure UK based ISO 27001 certified data centre.
- The servers are owned and operated by Crown Informatics and are held in a secure locked rack, accessible to named individuals. All access is logged, managed and supervised.
- Data is stored in secure encrypted databases.
- Backups are encrypted (AES256), held in dual copies, and stored securely.

b. Imperial College London

- Data is stored on a password protected computer on an encrypted internal hard drive which sits in a locked room. Datasheets themselves are also password protected individually as well as the

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computer.

- Data is regularly backed up and access to servers is certified to ISO 27001.

8. What is the data retention schedule?

- Data will be retained for the duration of the audit in order to complete longitudinal analyses, including assessing long-term outcomes for adults who have COPD exacerbations.
- All data will be destroyed in line with Information Governance Alliance (IGA)'s Records Management Code of Practice for Health and Social Care 2016 (available at: <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care>) which requires that clinical audit records must be kept securely for a period of 5 years after a clinical audit has been completed. This will enable the RCP to answer any post-closure queries.
- This retention schedule has been approved by the CAG.

The National Respiratory Audit Programme (NRAP) has been funded by HQIP until 31 May 2026, at which point a decision will be taken about the future of the work.