

National Asthma and COPD Audit Programme (NACAP)

Pulmonary rehabilitation audit - Frequently asked questions (FAQs): Information Governance

Version 5: January 2023

A general FAQ is available separately.

1. Who is involved in running the audit?

- The National Asthma and COPD Audit Programme (NACAP) Pulmonary Rehabilitation (PR) audit is managed and operated by the **Royal College of Physicians, London (RCP)** in collaboration with:
 - **Healthcare Quality Improvement Partnership (HQIP)** – who commission the audit and are **data controllers** for all NACAP audit data
 - **Crown Informatics** – who provide the audit web tool and data management services
 - **Imperial College London** – who provide statistical data analysis services.

The RCP, Crown Informatics and Imperial College London are all **data processors**.

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

- Given the comparatively low acuity of the patient cohort accessing PR and the prolonged exposure to the service, the PR audit will operate under a consent model. This means patients will be required to provide written/verbal consent for their information to be entered into the audit.
 - Consent forms and patient information sheets are available on the audit [web tool](#) and the [RCP website](#).
- **England and Wales**
 - Approval from the Confidentiality Advisory Group (CAG) is not needed for the above reason, however, the Caldicott Guardian (CG) at each service must give approval for that service to be part of the audit. For more information or for a copy of the [CG approval form](#) please contact the audit team.

3. What are PR services required to do?

- Services will need to manage a process of informed consent. The procedure for patient consent is outlined below:

<p>Audit lead responsibilities</p>	<p>The audit lead must ensure there are clear and systematic processes in place so that their team is able to:</p> <ol style="list-style-type: none"> 1. Display the patient information poster in an appropriate location. 2. Provide patients with the patient information sheet. 3. Obtain written/verbal consent from patients (using the patient consent form). 4. Keep consent forms in accordance with Caldicott principles.
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	5. Keep a record of the number of patients who are asked to consent; and how many refuse consent (this information is needed for case ascertainment and workforce planning requests).
Staff Responsibilities	<p>No specific staff training is required to obtain consent but service staff should do the following when obtaining consent:</p> <ol style="list-style-type: none"> 1. Provide each patient with a patient information sheet, provide an explanation of the audit and give the patient the opportunity to ask questions. 2. Record consent from willing patients on the consent form provided. Please note, the patient will need to sign and initial the document to give consent. 3. For consent given verbally or over the phone, then 'V' should be inserted into the signature box in place of a physical signature from the patient. 4. Retain the signed patient consent form in the patient's notes (do not send completed forms or copies to the audit team). 5. Please feel free to provide patients with copies of their consent forms.
General Information	<ol style="list-style-type: none"> 1. We recommend that patients are approached by a member of the PR service team to give their consent at their initial assessment/first appointment. If this is not possible, consent can be given at a later point during the programme, but you must not input any data into the audit web tool before written consent <small>Error! Bookmark not defined.</small> has been obtained from the patient. 2. If a patient does not wish to be included in the audit, please make this clear in the patient's notes and inform the audit lead. 3. If a patient initially gives consent but later withdraws it, please make this clear in the patient's notes, inform the audit lead and contact the RCP audit team to arrange for any data to be deleted. Any withdrawal of consent must be communicated to the RCP before data is extracted for analysis – after this point it will not be possible to locate and delete individual records. This is clearly explained in the patient information sheet.

4. What are the data flows?

- The PR data flows are publicly available on the [PR resource](#) webpages.
- Approved users at each registered service enter data into a bespoke web tool (www.nacap.org.uk) hosted by Crown Informatics.
- 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) for reporting purposes.
- Third party organisations may also request to use the data for research, audit and service evaluation purposes. Normally this data will not contain any personal identifiable data (PID). However, in very rare cases data may need to be shared for statutory reasons (see details on page 3 about identifiable information flowing to NHS England). Data will not be shared unless the appropriate legal, ethical and security arrangements are in place to keep data safe and secure.
- If third parties need more data than the audit collects to answer their questions, they may also require a 'linkage' to other sources of information. In these cases, identifiable data will be sent to the NHS organisations listed previously. They will link the audit data to the other datasets, so that the third party can understand more about patient care.

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5. Who has access to the data?

a. Patient identifiable data

- Data from each service is only visible to authorised users within that service according to the audit profile and to named, trained and certified individuals at 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 PID is involved. Examples might include duplicate checks 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 Digital or DHCW (Data Health and Care Wales)).
 - Subject access requests - when a patient requests their audit details.
- 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.
- Access to data is via secure client software that operates over secure encrypted firewalled networks using secondary application layer security.
- NHS England receive identifiable patient information (monthly) to inform nationally planning and commissioning of PR services and production of a PR dashboard. This is sent by Crown Informatics via secure DSCRO system (HQIP data access request group reference: HQIP 426).
- NHS England has an NHS Data Security and Protection Toolkit (DSPT) (ODS code: X24) rating of Standards Met and meets all NHS guidelines and requirements.
- They are also registered with the Data Protection Authorities (DPA) under reference: Z2950066.

b. Non-identifiable patient data

- Only members of the Imperial College London analysis team will have 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 aggregated level data

- Members of the NACAP team at the Royal College of Physicians receive anonymised and aggregated data from Imperial College London.
- The Royal College of Physicians has a 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.

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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).
- Data is transferred to NHS England via their secure DSCRO system.

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 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 the patients with COPD who attended PR and consented to be part of the audit.
- At the point of audit end, the funders of the audit will decide how data will be retained and destroyed. The decision will be in line with the [Information Governance Alliance \(IGA\)'s Records Management Code of Practice for Health and Social Care 2021](#), which specifies that clinical audit records must be kept securely for a minimum period of 5 years after the audit has been completed.

NACAP has been funded by HQIP until 31 May 2023, at which point a decision will be taken about the future of the work.

Scotland

Scotland ceased to commission NACAP as of 1 March 2021. All data not in the public domain held by NACAP or its subcontractors was destroyed in late summer 2021.

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