Data access and analyses request policy

1 Background

ICNARC runs the national (England, Wales and Northern Ireland) clinical audit of patient outcomes from adult critical care units, the Case Mix Programme.

The CMP has been in existence since 1995 and holds over two million admissions to adult critical care units in its database. Participation levels in the CMP are exceptional, with all adult, general units in England, Wales and Northern Ireland regularly sending and validating data prior to their receiving regular comparative reports for benchmarking and local quality improvement.

ICNARC actively encourages the use of such an important resource for research purposes to improve patient outcomes and drive up standards of care.

This policy provides a guide to the process for requesting access to CMP data or analyses from ICNARC and related information on costs, timescales and publications.

2 Principles

ICNARC is committed to ensuring that data collected through the CMP are used as widely as possible by clinicians (doctors, nurses and allied health professional), commissioners, providers, researchers and anyone with an interest in adult critical care.

ICNARC aims to make the process for requesting access to CMP data and analyses as transparent and as efficient as it can, whilst acting within the bounds of legal requirements concerning information governance and data confidentiality. ICNARC calls on CMP data are also subject to this policy.

ICNARC aims to provide access to data or data analyses within an agreed timeframe, but requesters should be mindful that all requests are resource intensive and costs have to be recouped.

3 Process

ICNARC has produced a flow diagram (see overleaf) which outlines the process for requesting data and analyses from the CMP.

- All requests, including ICNARC’s own use of the CMP data for research purposes, must be made on the official ICNARC ‘Request for analyses/data’ form.

- Where a request is based on collaboration with ICNARC, the resources required and deployed to fulfil the request will be made explicit and judged on the same criteria as other requests.

- Requests solely related to local quality improvement are managed by ICNARC and are considered against the timeliness of a participating CMP unit’s participation (and whether this is deemed ‘active’ or not).
• Completed forms (not relating to local quality improvement requests) are then passed to the Data Access Advisory Group (DAAG) for consideration.

• The DAAG is independent of ICNARC and has its own Terms of Reference.

• The DAAG consists of an independent chair, clinicians put forward by the Critical Care Leadership Forum along with relevant ICNARC technical staff.

• The DAAG makes the final decision on which requests are taken forward, whilst taking into account current ICNARC statistical workloads.

• The DAAG meets virtually by email to consider requests.

Where issues of ICNARC’s capacity to fulfil a request or a group of requests are highlighted to the DAAG, these are considered against the extent to which the request(s) meets any of the following principles:

- improving quality of care and patient outcomes
- supporting research into critical care
- supporting the training, education or continuing professional development of critical care professionals.

The DAAG will reject requests which cannot demonstrate how they meet these criteria, or which are deemed to be in direct conflict with current information governance requirements.

• The outcome of all requests, whether approved or declined, will be made publically available via the ICNARC website.

• Should the receipt of data or analyses cause the requester to ask for further data or analyses, this will be processed as a new request. Requesters are therefore urged to consider listing all their data/analyses request needs at the start of the process and to ensure these are all included on their ‘Request for analyses/data form’.

• Requesters have 365 days, from receipt of the data access or data analyses from ICNARC, to publish their findings. After this point, access to the same data or analyses may be granted to others.
CMP statistical analyses/data request pathway (external and ICNARC requests)

- Completed Analyses/Data Request Form received
  - Yes
  - Do we have data to fulfil request?
    - Yes
    - Further clarification from requester asked for if required
    - ICNARC Statistical Team assess complexity of request
      - Yes
      - Request related to local quality improvement?
        - No
        - Consider participation record
      - No
    - No
    - Request sent to DAAG for advice/opinion
      - Should we fulfil request?
        - Yes
        - Request approved
        - Communicate timescales to requester
        - Actions for Data Access Advisory Group (DAAG)
          - Request sent to DAAG for advice/opinion
            - Should we fulfil request?
              - No
              - Contact requester, declining analyses/data request
              - Log on internal analyses/data request spreadsheet
              - Update public log
    - No
  - No
- To: Statistical analyses undertaken/data extracted (overleaf)
Statistical analyses undertaken/data extracted

Analyses/data provided (invoice sent if required)

Log on internal analyses/data request spreadsheet

Update public log

From: Communicate timescales to requester

END
4 Costs

All data access and analyses requests take time and resources to complete. ICNARC’s Board of Management (Trustees) have stipulated that as a registered charity, the cost of meeting these requests must be met by the requester.

Requests from participating units relating to the use of their own data for local quality improvement purposes are usually covered within the annual Case Mix Programme subscription rate. All other requests incur a charge.

Requests for data analyses and extraction are categorised and costed by the time taken to produce the analyses. These are categorised as ‘simple’, ‘medium’ and ‘complex’ and determined by Statisticians at ICNARC in discussion with the DAAG.

<table>
<thead>
<tr>
<th>Request type</th>
<th>Cost + VAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple (up to one day)</td>
<td>£475</td>
</tr>
<tr>
<td>Medium (up to two days)</td>
<td>£951</td>
</tr>
<tr>
<td>Complex (up to five days)</td>
<td>£2,375</td>
</tr>
</tbody>
</table>

Requests which will take longer than five days to produce will require additional costing of time/resources.

Where requests involve greater involvement from ICNARC than the provision of data access or data analyses, requesters will need to ensure this is fully recovered through external research grants.

For commercial requests, the costs will be set by the ICNARC Board of Management (Trustees).

5 Timescales

The DAAG deals with all requests fairly whilst recognising that all data access and analyses requests take time to complete. While the categorisation of requests indicates the anticipated time to complete the request, it cannot determine when the request may be completed by ICNARC staff. While every effort is made to meet requested deadlines, all approved requests must fit within current ICNARC workloads.

All requests should provide a deadline and should avoid use of ‘as soon as possible’. Requests with a deadline of less than six weeks are unlikely to be met. Requesters should consider any potential requests for CMP data or analyses well in advance of their own personal deadlines to avoid disappointment. ICNARC cannot be held responsible for the missing of any deadlines set by the requester.

6 Information governance

Data security/confidentiality

ICNARC understands the importance of data security and confidentiality when dealing with patient identifiable data and takes proactive measures to ensure it fulfils all its responsibilities.

All participating CMP units sign a ‘Participating unit agreement’ that states that ICNARC will not share their data with a third party unless ICNARC has their express, written agreement to do so. Any requests that involve the identification of participating CMP units to a third party will require asking for a ‘waiving’ of the confidentiality of the units in question through the signing of an agreement between the unit, ICNARC and the requester. Units have the right to refuse to sign such agreements. While ICNARC can distribute written
agreements for the unit(s) to sign, it is the responsibility of the requester to follow up with the unit(s) on any unreturned agreements.

Data security and encryption

ICNARC recognises that it is bound by the same duty of confidentiality as all NHS bodies and that it has a responsibility for protecting information (data) it receives from the NHS. To this end, ICNARC’s preferred method of data transfer is via our online secure file sharing system ‘File Exchange’. Where individuals/organisations are not able to use File Exchange, other, suitable methods of encryption and transfer will need to be agreed.

Patient identifiable data

Section 251 support for the collection and use of patient identifiable data has been approved for the Case Mix Programme by the Confidentiality Advisory Group (CAG) within the Health Research Authority (HRA) - Approval Number: PIAG 2-10(f)/2005. ICNARC’s specific approval covers:

- Class IV - linking multiple sources; validating quality and completeness; avoiding error
- Class V - audit, monitoring, & analysis of healthcare provision
- Class VI - granting of access to data for purposes I-V (preventative medicine, medical diagnosis, medical research, approved by a research ethics committee, the provision of care and treatment, the management of health and social care services)

CAG within HRA approval has been agreed for ICNARC to collect/store minimal patient identifiable data (date of birth, postcode, sex and NHS number) as these are required in order to:

- validate the completeness and accuracy, and hence the quality, of the data;
- identify individual patients admitted more than once to a critical care unit; and
- provide meaningful comparisons of risk of death for all patients using the established risk prediction models.

Section 251 of the NHS Act 2006 makes provision for the use of patient identifiable information in the interests of improving patient care and in the public interest. Section 251 support is reviewed annually by CAG within the HRA (replaced NIGB from April 2013).

As part of this annual approval process, ICNARC is required to demonstrate knowledge and implementation of information security policies and procedures.

Data Protection Act

ICNARC is registered with the Information Commissioner’s Office under the Data Protection Act 1998 (Registration Number: Z6289325).

Caldicott Principles

The 1997 report of the Review of Patient-Identifiable Information, chaired by Dame Fiona Caldicott (the Caldicott Report), made a number of recommendations for regulating the use and transfer of patient-identifiable information between NHS organisations and to non-NHS bodies.

Central to the recommendations of the Caldicott Report was the appointment of a “Guardian” of person-based clinical information to oversee the arrangements for the use and sharing of clinical information. The committee stipulated that the Guardian should be:

- an existing member of the management board or senior management team of the organisation;
- a senior health or social care professional; and
- an individual with responsibility for promoting clinical governance.

The Committee also developed a set of six general principles for the safe handling of patient-identifiable information:

- justify the purpose(s) for using information;
- only use it when absolutely necessary;
- use the minimum that is required;
- access should be on a strict need-to-know basis;
 everyone must understand his or her responsibilities; and
understand and comply with the law.

ICNARC has appointed a clinical trustee on the Board of Management to the position of Caldicott Guardian. The clinical trustee is responsible for ensuring ICNARC’s compliance with the recommendations of the Caldicott Review.

7 Approvals

It is the responsibility of the requester to ensure they have the necessary approvals in place to receive the data or analyses requested.

8 Disclaimers

ICNARC accepts no responsibility for analyses produced by others using CMP data.

9 Publications

Decisions over authorship of publications using CMP data or requiring ICNARC expertise in relation to statistical analyses or data management, are subject to current International Committee of Medical Journal Editors authorship guidance.

Publications which use CMP data must acknowledge the data collectors in the participating CMP units who have both collected and validated the data. Appropriate wording for this acknowledgement is provided in the Request form.

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