icnarc | intensive care national audit & research centre

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Data access and analyses request policy

1 Background

ICNARC runs national clinical audits of adult critical care (the Case Mix Programme, CMP; and Irish National Intensive Care Unit Audit, INICUA, run on behalf of the [Irish] National Office of Clinical Audit) and in-hospital cardiac arrest (the National Cardiac Arrest Audit, NCAA, run in conjunction with the Resuscitation Council UK). ICNARC actively encourages the use of such important data resources for quality improvement, service evaluation and planning, and research purposes to improve patient outcomes and drive up standards of care.

In addition, ICNARC conducts primary research within our UKCRC registered Clinical Trials Unit. We recognize that data generated from research can be used to address many important questions beyond those planned in the original trial or study and we seek to make data from our research available to the wider scientific community in line with the *Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials* (MRC 2015).

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

2 Principles

ICNARC is committed to ensuring that data collected through our audits and research studies 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 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 aims to provide access to data or analyses within an agreed timeframe, but requesters should be mindful that all requests are resource intensive and costs have to be recouped.

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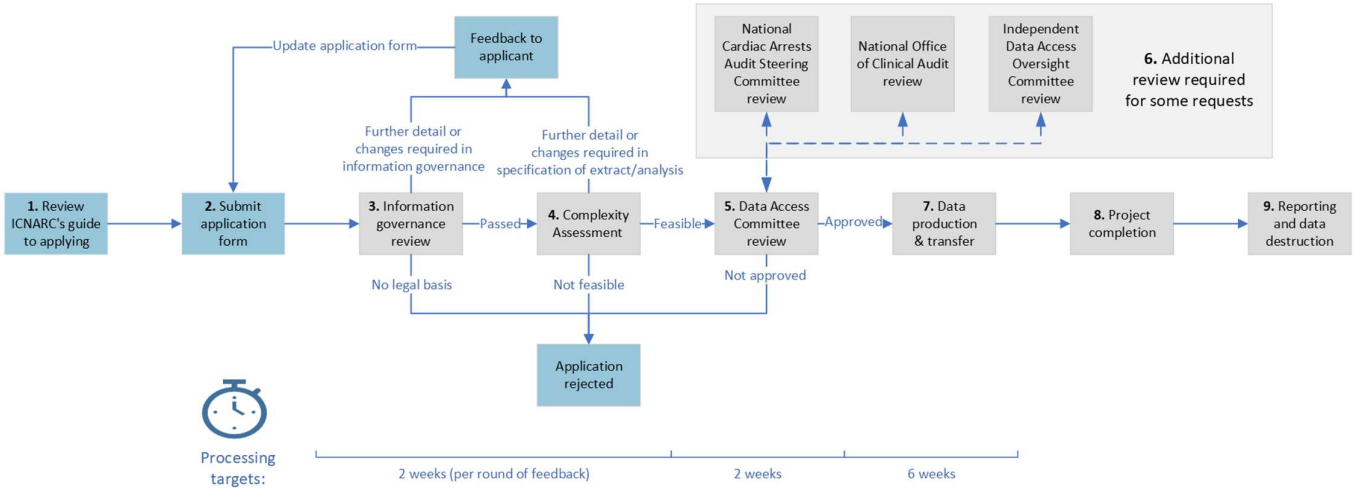
3 Process

The steps in ICNARC's data application process are outlined below:



1. Review ICNARC's guide to applying for data or analysis services
See ICNARC's guide to applying for data or analyses services and complete interactive tool to determine whether to complete an application form, and what information to include with your request.

2. Submit your data request
If advised to do so, complete and submit a data request form.

3. Information governance review
Preliminary screening by ICNARC's Statistics Project Manager, with input from ICNARCs Data Protection Officer and Statisticians regarding compliance of the request with information governance laws.

4. Complexity assessment
ICNARC's Statisticians will review your request to estimate the time required to produce the data or analysis, which will be the basis for your quote (please see Data access and analyses policy for costs).

5. Data Access Committee review
ICNARC's Data Access Committee (DAC) will consider alignment of the request with ICNARC's mission, any risks to patients, the public or healthcare service providers that have not been identified, and the operational capacity of ICNARC to support to the request.

6. Review by external committees
Requests for INICUA data must be additionally approved by (Irish) National Office for Clinical Audit. Requests for NCAA data must additionally be approved by the NCAA Steering Committee, which includes representation from Resuscitation Council UK. Requests that fall outside of 'precedent set' pathways that have been established with the Independent Data Access Oversight Committee (IDAOC), requests for which specific risks have been identified by the DAC, and all requests for commercial purposes, will be referred to ICNARC's Independent Data Access Oversight Committee (IDAOC) for additional review. Requests requiring input from the IDAOC will require additional time for processing.

7. Data production and transfer
ICNARC's Statistics or Data Management team will produce your data extract or analysis and arrange any necessary data transfers.

8. Project completion
The applicant uses data within the agreed scope of data use outlined in any Information Sharing Agreement.

9. Reporting and data destruction
The applicant reports outputs of data use to ICNARC for publication in our data use register and conducts any archiving and data destruction activities agreed in the Information Sharing Agreement.

4 Costs

All requests for data or analyses 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.

Subject to approval by ICNARC's Data Access Committee, requests for data or analyses to support local quality improvement initiatives by service providers participating in ICNARC's national clinical audits may be provided for free, as part of each provider's clinical audit participation agreement. Typically, such requests will be in response to specific concerns about quality of care that were identified through clinical audit, and will not involve provision of any patient-level data other than that provided by the participating service provider. All other requests will incur a charge.

For non-commercial requests for data extracts or analyses, costs include the following components:

i. A fixed fee covering administration of the request: £800 + VAT for patient-level data or £400 + VAT for aggregate data requests

ii. A variable fee reflecting the estimated number of days required for ICNARC's statisticians or data managers to produce the extract or analysis: £410 + VAT per day

    For requests involving data linkage and extraction, a typical quote will include 10 days of production time for establishing the initial linkage and extraction, plus 2 days for each update required.

iii. For extracts of patient-level data, a variable fee reflecting a proportion of the operating costs of ICNARC's clinical audits, proportional to the number of records included in the extract:

    a. £200 + VAT per 1,000 records or part thereof for the first 10,000 records

    b. £200 + VAT per 10,000 records or part thereof for additional records up to 200,000 records

    c. £200 + VAT per 100,000 records or part thereof for additional records above 200,000 records.

    For requests involving more than one extract with the same specification, this fee will only be charged once.

Where requests involve greater involvement from ICNARC than the provision of data or analyses (for example, substantial input to development of the request or analysis plan), requesters will need to ensure this is fully recovered, for example, through external research grants.

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

5 Timescales

The DAC deals with all requests fairly while recognising that all requests for data or analyses take time to complete. All requests should provide a target date for delivery and should avoid use of 'as soon as possible'. While every effort is made to meet requested timelines for delivery, all approved requests must fit within current ICNARC workloads. Requests with a deadline of less than six weeks are unlikely to be met. Requesters should consider any potential requests for data or analyses well in advance of their own personal deadlines to avoid disappointment. ICNARC cannot be held responsible for failing to meet 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.

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 Mimecast Large File Send or *our online secure file sharing system 'File Exchange'.* Instructions on the use of either system will be provided as required.

Information Sharing Agreement

Depending on the requirements of a data access request, ICNARC may determine that an Information Sharing Agreement must be established between ICNARC and the applicants before sharing can take place. The Information Sharing Agreement will outline what the shared data will be used for and establish the terms of use for the shared data.

Patient identifiable data

Both the Case Mix Programme and the National Cardiac Arrest Audit have approval from the Secretary of State for Health under Section 251 of the National Health Service Act 2006 for the collection and use of confidential patient information (approval numbers PIAG 2-10(f)/2005 and ECC 2-06(n)/2009). ICNARC's specific approvals cover:

- 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)

All requests for data or analyses that involve use of patient identifiable data will be assessed as to whether they fall within ICNARC's existing approvals or whether additional approvals are required.

Data Protection Act

ICNARC is registered with the Information Commissioner's Office under the Data Protection Act 2018 (Registration Number: Z6289325).

Caldicott Principles

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

1. Justify the purpose(s) for using confidential information
2. Use confidential information only when it is necessary
3. Use the minimum necessary confidential information
4. Access to confidential information should be on a strict need-to-know basis
5. Everyone with access to confidential information should be aware of their responsibilities
6. Comply with the law
7. The duty to share information for individual care is as important as the duty to protect patient confidentiality
8. Inform patients and service users about how their confidential information is used

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.

Requests for patient data for the purposes of research will require evidence of approval from the NHS Research Ethics Committee via the Health Research Authority approval process.

Alternatively, the requestor should demonstrate that approval is not required for their request via providing evidence that they have used the Health Research Authority decision support tool and determined that their project does not require NHS REC review.

Requests for patient identifiable data will require Section 251 approval from Confidentiality Advisory Group, or suitable evidence of a legal basis under the Common Law Duty of Confidentiality.

Requestors should also ensure all necessary internal governance approvals from their organisation have been undertaken and that they have authority to enter into a data sharing agreement with ICNARC.

8 Disclaimer

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

9 Publications

Decisions over authorship of publications using ICNARC 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 ICNARC data must acknowledge the source of the data. Appropriate wording for this acknowledgement will be provided by ICNARC.