Understanding Practice in Clinical Audit and Registries tool: UPCARE-tool

A protocol to describe the key features of clinical audits and registries

FAQ

Who should complete the tool?

This tool is designed to be completed by individuals and organisations planning and implementing clinical audits and registries. It has been specifically designed for national clinical audits and registries commissioned by the Healthcare Quality Improvement Programme (HQIP; Part of the National Health Service in England) as part of the National Clinical Audit and Patient Outcome Programme (NCAPOP), but can be adapted and used by audits and registries in other settings.

What is the tool for?

The tool is a protocol for audits and registries. It has been designed to provide a "one-stop" summary of the key information about how clinical audits and registries have been designed and carried out. It is expected that this will be published openly for anyone to view, and help users of audit/registry data and audit/registry participants understand the methods, evaluate the quality and robustness of the data, and find information and data that is most relevant to them. For national clinical audits and registries commissioned by HQIP, the intention is that publishing this information openly will reduce the requirement for reporting ad hoc and contract monitoring data and information to HQIP and other national agencies.

What type of information is contained within UPCARE?

It is intended that the responses to the tool are factual and written concisely. Where possible, documents can be embedded and hyperlinks provided if information is published elsewhere. This document is intended to be a complete account of the information for the audit or registry. Please be vigilant about keeping any links included in the document up to date so readers can access full information about the audit or registry.

This tool is not intended to be used to formally "score" the quality of the responses. The design of this tool has been inspired by reporting checklists used for clinical guidelines (e.g. AGREE[1]) and in reporting research studies (e.g. STROBE[2], SQUIRE[3]).

Who is the intended audience for the tool?

The information contained within the UPCARE tool will enable audit and registry stakeholders to access in one place and in a standard format key information about the audit/registry and evaluate the integrity and robustness of the audit.

Examples of audit/registry stakeholders include:
- Patients / Carers / Public / Patient representative organisations
- Clinicians / Allied health professionals / Healthcare providers / Multi-disciplinary teams / Primary, secondary and tertiary care providers
- National agencies
- Commissioners
- Healthcare regulators

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[1] AGREE stands for the Appraisal of Guidelines for Research & Evaluation. See https://www.agreetrust.org/about-the-agree-enterprise/introduction-to-agree-ii/, last accessed 24 April 2018.
[2] STROBE stands for Strengthening the Reporting of Observational Studies in Epidemiology. See https://www.strobe-statement.org/index.php?id=strobe-home, last accessed 24 April 2018.
[3] SQUIRE stands for Standards for Quality Improvement Reporting Excellence. See http://www.squire-statement.org/, last accessed 24 April 2018.

FAQ (cont'd)

How should the responses be written?

Please try and write responses clearly as this will help to make the tool accessible and useful. Some tips and suggestions for writing clearly include:

- avoiding technical jargon where possible
- using short paragraphs and bullet points
- using the "active" voice rather than passive
- keeping sentences short

Where information is published openly elsewhere please provide links and references rather than duplicating information that is already available

When and how often should I complete the tool?

The tool is intended to provide accurate and up to date information about the audit/registry, and so can be updated whenever and however frequently it is relevant to do so. For national clinical audits and registries commissioned by HQIP it is intended that the tool is updated annually, although audits can update the tool more frequently if they wish to.

Each version of the tool should include a date of publication and version number.

Where should the completed UPCARE report be published?

The completed tool should be published online e.g. on the website for the audit or registry.

How was UPCARE designed?

HQIP commission, manage and develop the NCAPOP (National Clinical Audit and Patient Outcomes Programme) under contract from NHS England and devolved nations. The work was led by HQIP who set up a Methodological Advisory Group (MAG) consisting of methodological, statistical and quality improvement experts. Meeting were held on a six monthly basis and the structure and content of the eight quality domains and their key items were agreed by the MAG. The tool was piloted by 5 programmes within the NCAPOP and re-edited in light of comments received. Other comments received by MAG members was also considered as part of the re-editing process. The final version of the UPCARE tool was signed off by the HQIP MAG and will be reviewed annually.

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Contents

Domain 1: Organisational information

1.1. The name of the programme

National Neonatal Audit Programme (NNAP)

1.2. The name of the organisation carrying out the programme

Royal College of Paediatrics and Child Health (RCPCH)

1.3. Main website for the programme

www.rcpch.ac.uk/nnap

1.4. Date of publication and version number of the tool on your website

Date of publication: 03 October 2019, v1.1

Domain 2: Aims and objectives

2.1. Overall aim

The aims of the NNAP are:
- To assess whether babies admitted to neonatal units in England, Scotland and Wales receive consistent high-quality care in relation to the NNAP audit measures that are aligned to a set of professionally agreed guidelines and standards.
- To identify areas for quality improvement in neonatal units in relation to the delivery and outcomes of care.

2.2. Quality improvement objectives

The quality improvement objectives of the NNAP are to:
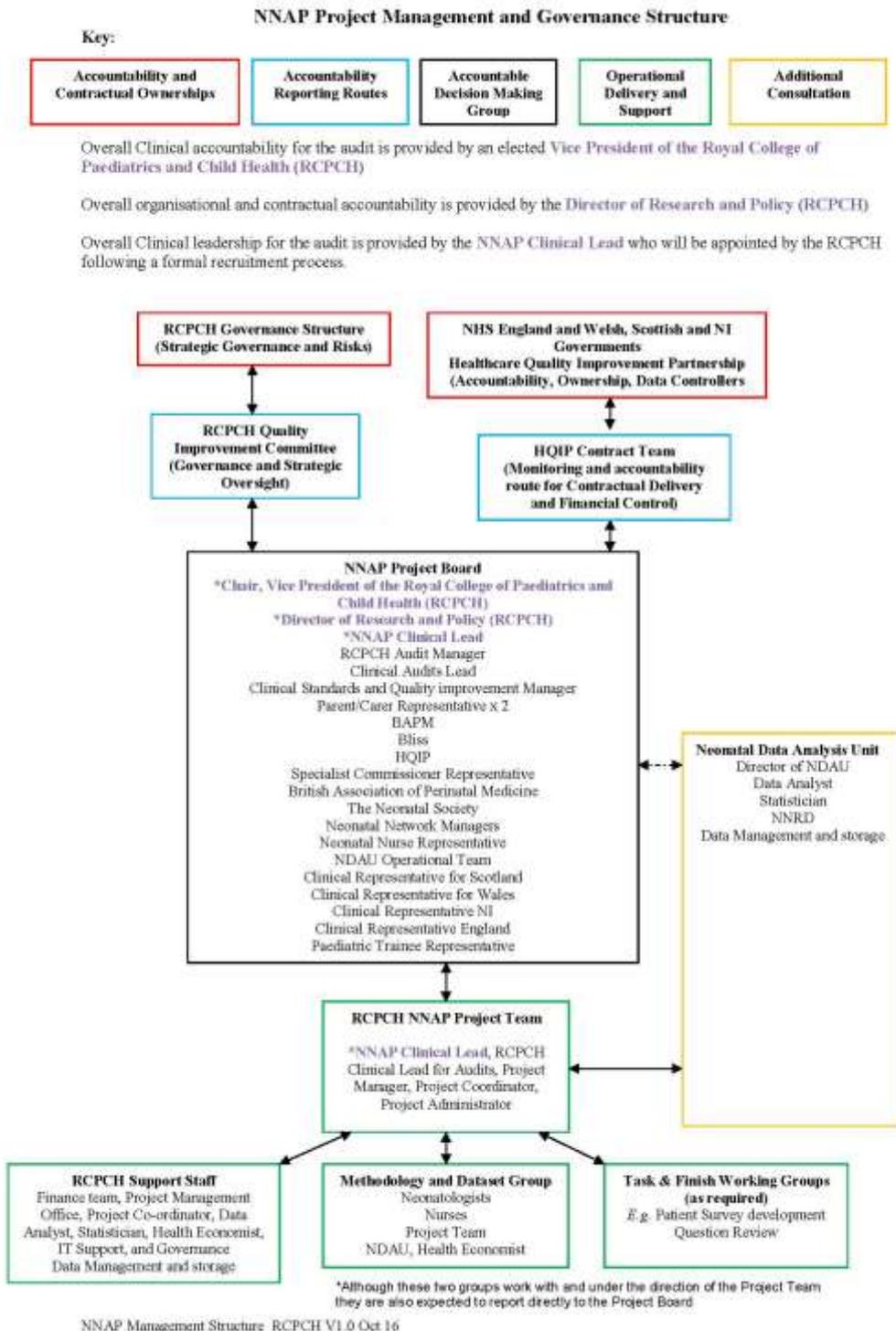- To increase rates of compliance with guidelines and standards of care in relation to the NNAP audit measures, to improve outcomes for babies in neonatal care.
- Identify units who are positive and negative outliers on these metrics to support local improvement/sharing of good practice.
- Share best practice through sharing of case studies and hosting national stakeholder

meeting.

Domain 3: Governance and programme delivery

3.1. Organogram

NNAP Project Management and Governance Structure

Key:

| Accountability and Contractual Ownerships | Accountability Reporting Routes | Accountable Decision Making Group | Operational Delivery and Support | Additional Consultation |

Overall Clinical accountability for the audit is provided by an elected Vice President of the Royal College of Paediatrics and Child Health (RCPCH)

Overall organisational and contractual accountability is provided by the Director of Research and Policy (RCPCH)

Overall Clinical leadership for the audit is provided by the NNAP Clinical Lead who will be appointed by the RCPCH following a formal recruitment process.

RCPCH Governance Structure
(Strategic Governance and Risks)

NHS England and Welsh, Scottish and NI Governments
Healthcare Quality Improvement Partnership
(Accountability, Ownership, Data Controllers)

RCPCH Quality Improvement Committee
(Governance and Strategic Oversight)

HQIP Contract Team
(Monitoring and accountability route for Contractual Delivery and Financial Control)

NNAP Project Board
*Chair, Vice President of the Royal College of Paediatrics and Child Health (RCPCH)
*Director of Research and Policy (RCPCH)
*NNAP Clinical Lead
RCPCH Audit Manager
Clinical Audits Lead
Clinical Standards and Quality improvement Manager
Parent/Carer Representative x 2
BAPM
Bliss
HQIP
Specialist Commissioner Representative
British Association of Perinatal Medicine
The Neonatal Society
Neonatal Network Managers
Neonatal Nurse Representative
NDAU Operational Team
Clinical Representative for Scotland
Clinical Representative for Wales
Clinical Representative NI
Clinical Representative England
Paediatric Trainee Representative

Neonatal Data Analysis Unit
Director of NDAU
Data Analyst
Statistician
NNRD
Data Management and storage

RCPCH NNAP Project Team
*NNAP Clinical Lead, RCPCH
Clinical Lead for Audits, Project Manager, Project Coordinator, Project Administrator

RCPCH Support Staff
Finance team, Project Management Office, Project Co-ordinator, Data Analyst, Statistician, Health Economist, IT Support, and Governance
Data Management and storage

Methodology and Dataset Group
Neonatologists
Nurses
Project Team
NDAU, Health Economist

Task & Finish Working Groups (as required)
E.g. Patient Survey development
Question Review

*Although these two groups work with and under the direction of the Project Team they are also expected to report directly to the Project Board

NNAP Management Structure_RCPCH V1.0 Oct 16

3.2. Organisations involved in delivering the programme

Royal College of Paediatrics and Child Health (RCPCH)

www.rcpch.ac.uk

The RCPCH is the professional body for paediatricians (doctors specialising in child health) in the United Kingdom. It is responsible for the postgraduate training of paediatricians. The RCPCH is contracted to deliver the NNAP from April 2017 to March 2021.

Neonatal Data Analysis Unit (NDAU), Imperial College London

https://www.imperial.ac.uk/neonatal-data-analysis-unit

The Neonatal Data Analysis Unit (NDAU) was established to improve the quality of operational clinical data captured at the point of clinical care and promote their best use to support neonatal services and facilitate research. The NDAU are subcontracted to analyse data for the NNAP.

Bliss

www.bliss.org.uk

The leading UK charity for babies born needing neonatal care. The charity is a member of the NNAP Project Board.

British Association of Perinatal Medicine (BAPM)

www.bapm.org

The British Association of Perinatal Medicine (BAPM) is a professional association and registered charity. Established in 1976, BAPM improves standards of perinatal care by supporting all those involved in perinatal care to optimise their skills and knowledge, promote high quality, safe and innovative practice, encourage research, and speak out for the needs of babies and their families. The association is a member of the NNAP Project Board.

Neonatal Nurses Association (NNA)

www.nna.org.uk

The Neonatal Nurses Association is a national organisation representing neonatal nurses, steered by neonatal nurses to promote neonatal nursing for the benefit of sick newborns and their families throughout the country. The association is a member of the NNAP Project Board. The association is a member of the NNAP Project Board. The association is a member of the NNAP Project Board.

The Neonatal Society

http://www.neonatalsociety.ac.uk/

The Neonatal Society is a leading academic society, the aim of which is to promote neonatal science. The society is a member of the NNAP Project Board.

3.3. Governance arrangements

The audit is governed by a Project Board, which meets four times a year. The Board is chaired by the RCPCH Vice President, Science and Research, and includes the organisations and individuals listed on the organogram (see section 3.1)

The Board is responsible for overseeing the audit and providing oversight and advice to the programme. The Board is the guarantor of the data from the audit and is responsible for signing off the annual report. Overall clinical accountability is provided by the Vice President, Science and Research. Overall organisational and contractual accountability is provided by the Director of Research and Policy, RCPCH.

The Project Team reports to the Project Board and is responsible for delivering the audit. Data analysis, statistical expertise, data management and data storage are provided by the Neonatal Data Analysis Unit.

3.4. Declarations and Conflicts of interest

Members of the Project Board have completed a declaration of interests, as part of the RCPCH register of interests process. A standing item is included on the Project Board agenda notifying members of their responsibility to ensure that their declaration is up to date.

Domain 4: Information security, governance and ethics

4.1. The legal basis of the data collection

The legal basis for using this information is that it allows us to carry out a task that is in the public interest. In respect of the National Neonatal Audit Programme the public interest is protected through ensuring that high standards and quality of neonatal care continue (In this case, the legal bases for processing under General Data Protection Regulations (GDPR) are Article 6 (1) (e) and Article 9 (2) (i)). A family can choose to opt their baby out of the audit by speaking to the staff providing neonatal care to the baby.

The Neonatal Data Analysis Unit has approval under section 251 of the NHS Health and Social Care Act 2006 to collect identifiable data without consent (CAG reference ECC 8-05(f)/2010).

4.2. Information governance and information security

The RCPCH Information Governance Toolkit score achieved on 13 March 2018 was 82% (satisfactory). This indicates that the programme can be trusted to handle personal information securely. The link is:
https://www.igt.hscic.gov.uk/AssessmentReportCriteria.aspx?tk=431206760201656&Inv=3&cb=283e01d9-5e6f-4e26-adf0-15d5226c9fc4&sViewOrgId=42801&sDesc=8HV48Version%2014.1,%20score:%2082%25,%20Publication%20Date:%2013/03/2018

The NNAP has completed a privacy impact assessment, which is available at:

https://www.rcpch.ac.uk/resources/national-neonatal-audit-programme-transparency-open-data

Domain 5: Stakeholder engagement

5.1. Approaches to involving stakeholders

Three parents with experience of neonatal care are members of the Project Board. The neonatal charity Bliss are represented on the Project Board and Methodology and Dataset Group. They are involved in:

- Developing and approving audit measures
- Setting priorities and strategic objectives
- Developing communication strategy
- Selecting key findings and developing recommendations
- Communicating with audit participant units via meetings
- Governance, risk and issue management
- Designing the parent and carer guide, Your baby's care
- Designing infographics

Representatives from the neonatal clinical and nursing community and neonatal networks are members of the Project Board and Methodology and Dataset Group. They are involved in:

- Developing and approving audit measures
- Developing audit methodology
- Setting priorities and strategic objectives
- Developing communication strategy
- Selecting key findings and developing recommendations
- Communicating with audit participant units via stakeholder events and meetings
- Governance, risk and issue management

Audit participants are involved by:

- Providing feedback via an annual user feedback survey which seeks feedback on various aspects of the audit.
- Attending, presenting and providing feedback at stakeholder events
- Using, and providing feedback on, quarterly reports designed to ensure data quality and completeness

Domain 6: Methods

6.1. Data flow diagrams

National Neonatal Audit Programme, RCPCH: Data flow diagram

Date completed: 3 October 2019   Completed by: Rachel Winch, NNAP PM   Version 1.3
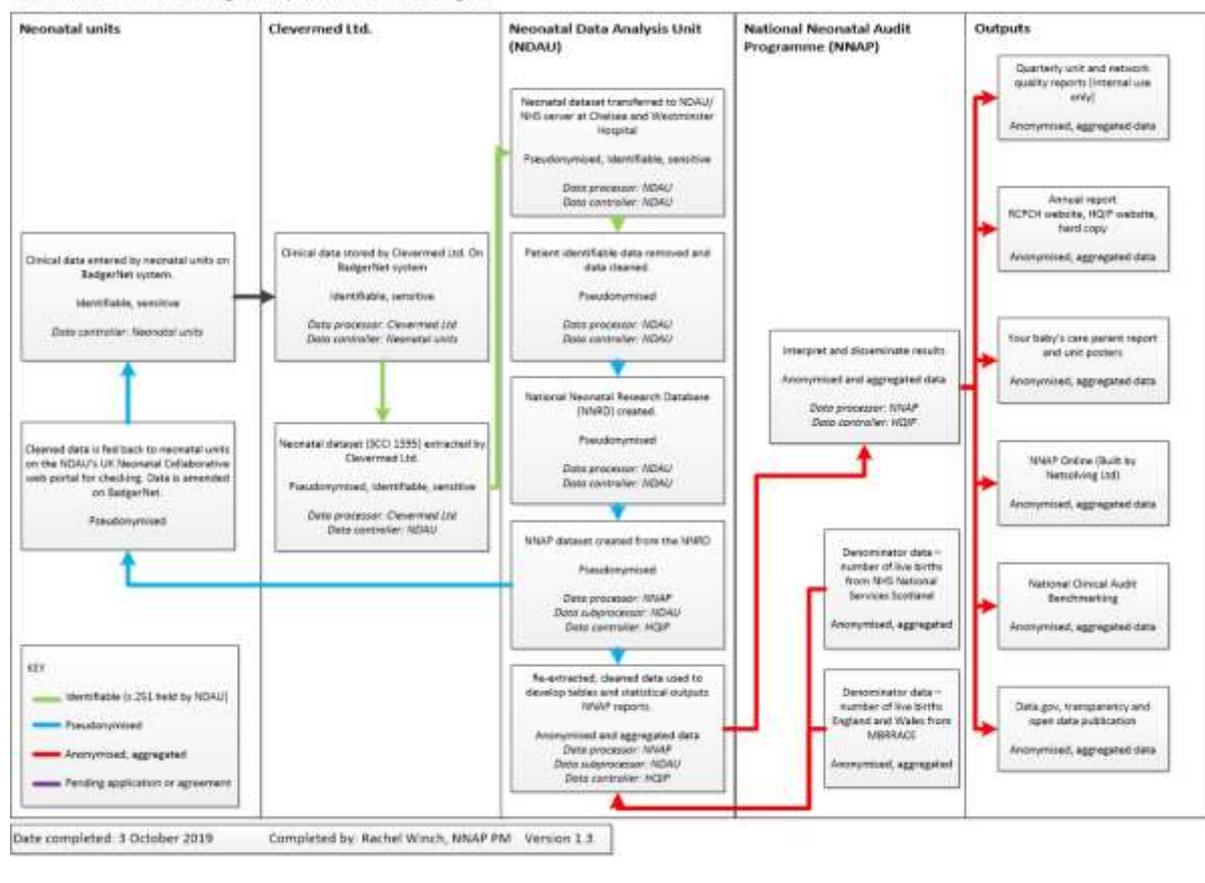
6.2. The population sampled for data collection

Patients admitted for neonatal care in an NHS funded neonatal service in England, Scotland and Wales.

6.3. Geographical coverage of data collection

Neonatal units in England, Wales and Scotland are eligible for inclusion in the audit. All neonatal units in England and Wales participate. Fifteen of the 18 neonatal units in Scotland participated in the 2017 data year.

6.4. Dataset for data collection

The audit questions, inclusion criteria, attribution and data sources are set out in The NNAP Guide to 2019 audit measures, available at: https://www.rcpch.ac.uk/work-we-do/quality-improvement-patient-safety/national-neonatal-audit-programme-nnap/about#_019-audit-measures

The data items used in the NNAP are included in the National Neonatal Dataset, available at: https://www.imperial.ac.uk/media/imperial-college/medicine/dept-medicine/infectious-diseases/neonatology/Neonatal-dataset-ISB1595-release-1-version-22.pdf

6.5. Methods of data collection and sources of data

Data for the NNAP analyses are extracted from the National Neonatal Research Database (NNRD) held at the NDAU. The NNRD contains a predefined set of variables (the National Neonatal Dataset) obtained from the electronic neonatal patient records of each participating NHS Trust. Data are downloaded from the BadgerNet patient record system used in neonatal units and transferred to NDAU with health board and trust Caldicott Guardian approval. For Scotland a separate approval was received from the Public Benefit and Privacy Panel for health and social care.

6.6. Time period of data collection

The audit reports by calendar year. The current period of data collection underway is 1 January 2019 to 31 December 2019.

6.7. Time lag between data collection and feedback

Audit participants receive quarterly data completeness and quality reports through the data collection year. The annual report is published approximately 9-11 months after the end of the data period, for example data for the period 1 January 2018 to 31 December 2018 is expected to be published in November 2019.

6.8. Quality measures included in feedback

The audit questions, inclusion criteria, attribution and data sources are set out in The NNAP Guide to 2019 audit measures, available at: https://www.rcpch.ac.uk/work-we-do/quality-improvement-patient-safety/national-neonatal-audit-programme-nnap/about#_019-audit-measures

6.9. Evidence base for quality measures

Relevant guidance and standards and background information are included by measure in The NNAP Guide to 2019 audit measures, available at: https://www.rcpch.ac.uk/work-we-do/quality-improvement-patient-safety/national-neonatal-audit-programme-nnap/about#_019-audit-measures

6.10. Case ascertainment

In usual practice, every baby admitted to a participating neonatal unit entered on the BadgerNet patient record system, and is eligible for inclusion in NNAP; the audit therefore achieves 100% case ascertainment in the participating organisations. Babies receiving special care in transitional care areas or postnatal wards can also be entered, but it is known that some units do not enter data for such babies and for this reason measures do not concentrate on care outside neonatal units.

6.11. Data analysis

The methods used to clean and analyse audit data are described on pages 54 to 61 of the 2018 annual report on 2017 data, available at: https://www.rcpch.ac.uk/resources/national-neonatal-audit-programme-annual-report-2018-2017-data

The full NNAP statistical analysis plan is available at: https://www.rcpch.ac.uk/sites/default/files/2018-09/nnap_statistical_analysis_plan_for_2017_data_final.pdf

We report outlier analysis and main report measures using a "no imputation" approach. By this we mean that rates of adherence to standards, or rates of clinical outcomes are described for the babies where the outcome is known. Numbers of patients with an outcome are included under "with outcome" in results tables.

6.12. Data linkage

No linkage is performed in the NNAP.

6.13. Validation and data quality

Quarterly reports are produced by the NNAP project team and disseminated to all neonatal unit NNAP clinical leads to provide regular updates on their data completeness and adherence to the NNAP standards. All neonatal units are provided with a summary report of their annual data in January after which they are given a final six-week window of opportunity to review and amend their data on the BadgerNet system. The final data download used in the report is extracted from BadgerNet after the reviewing period has closed.

A data cleaning and validation process is applied to the raw dataset before creation of the NNAP dataset that is used to produce the data included in this report. That process includes:

- Checking the providers included in the dataset against a master list to identify new providers.

- Removal of episodes which are complete duplicates or do not have birth year and gestation at birth or admission times entered.

Only babies who were finally discharged in the NNAP reporting year of interest are kept in the NNAP dataset. The exception to this dataset is the cohort used for the Encephalopathy measure, this dataset is based on those babies with a birth year in the NNAP reporting year of interest.

For each NNAP audit measure, there is an associated rate of missing entries. The rate of missing entries is described as M/T, where M is the number of missing entries and T is the number of all cases. To summarise data completeness across all NNAP measures, an average was taken of the rates of missing entries associated with a given unit. More information is available in the NNAP 2018 annual report on 2017 data: https://www.rcpch.ac.uk/resources/national-neonatal-audit-programme-annual-report-2018-2017-data

Domain 7: Outputs

7.1. The intended users or audience for the outputs

The audit designs and produces individual feedback for:

- Parents and carers
- Clinical teams
- Neonatal networks
- The Care Quality Commission
- The public

7.2. Editorial independence

As an independently commissioned programme, the contents of the outputs are written by the Clinical Lead and Project Team and quality assured by the Board through the governance processes described in the previous sections. Key findings and recommendations are developed by members of the Methodology and Dataset Group and the Project Board.

7.3 The modalities of feedback and outputs

The audit provides feedback for the following types of participant:

- Parents and carers: A parent and carer guide to the main annual report, focussed around infographics. Unit level results posters which are displayed in the neonatal unit. NNAP Online; interactive web reporting tool.
- Clinical teams: Quarterly reports through the audit year showing unit and national level performance, data quality and completeness; national stakeholder meeting and presentations at regional meetings; comprehensive annual report. NNAP Online; interactive web reporting tool facilitating benchmarking with other neonatal units and networks.
- Neonatal networks: Quarterly reports through the audit year showing network and national level performance, data quality and completeness; national stakeholder meeting and presentations at regional meetings; comprehensive annual report. NNAP Online; interactive web reporting tool facilitating benchmarking with other neonatal units and networks.
- The Care Quality Commission: data files with data presented at neonatal unit level for use in CQC dashboard.
- The public: Participation in the Clinical Outcomes Publication programme – selected NNAP measures displayed on NHS Choices/MyNHS.

The report is quality assured at team level before submission to the Board for sign off. Sign off is required before submission of the report to commissioners/HQIP.

7.4 Recommendations

The NNAP made recommendations for specific audiences in the 2018 annual report on 2017 data. Recommendations are made for:

- Neonatal units and neonatal teams
- Neonatal networks
- Perinatal services
- The NNAP and other national audits

The full set of recommendations are summarised by audience in Appendix B on page 149 of the report: https://www.rcpch.ac.uk/resources/national-neonatal-audit-programme-annual-report-2018-2017-data

7.5 Comparators and benchmarking

The audit provides comparative performance data for neonatal units. Each neonatal unit has performance measured against:

- Other neonatal units in the neonatal network
- All neonatal units in England, Scotland and Wales
- Previous performance data for the neonatal unit showing changes over time (longitudinal data stick plots).

7.6 Motivating and planning quality improvement

The audit supports participants in quality improvement by:

- Providing specific, achievable recommendations for action that are targeted to the audience.
- Sharing quality improvement case studies through the annual report, national stakeholder meeting and website.
- Highlighting areas of improved performance through the annual report and NNAP Online.
- Writing to positively outlying units.
- Using neonatal networks to support quality improvement activities through quarterly reporting at network level.