



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

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

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| 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: <ul style="list-style-type: none"> • 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 |

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. Meetings 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

| | |
|---|----|
| Understanding Practice in Clinical Audit and Registries (UPCARE)..... | 1 |
| FAQ..... | 2 |
| Domain 1: Organisational information | 6 |
| 1.1. The name of the programme | 6 |
| 1.2. The name of the organisation carrying out the programme | 6 |
| 1.3. Main website for the programme..... | 6 |
| 1.4. Date of publication and version number of the tool on your website | 6 |
| Domain 2: Aims and objectives..... | 7 |
| 2.1. Overall aim | 7 |
| 2.2. Quality improvement objectives..... | 7 |
| Domain 3: Governance and programme delivery..... | 8 |
| 3.1. Organogram | 8 |
| 3.2. Organisations involved in delivering the programme | 8 |
| 3.3. Governance arrangements | 10 |
| 3.4. Declarations and Conflicts of interest..... | 10 |
| Domain 4: Information security, governance and ethics..... | 10 |
| 4.1. The legal basis of the data collection..... | 10 |
| 4.2. Information governance and information security..... | 11 |
| Domain 5: Stakeholder engagement | 12 |
| 5.1. Approaches to involving stakeholders..... | 12 |
| Domain 6: Methods | 13 |
| 6.1. Data flow diagrams | 14 |
| 6.2. The population sampled for data collection | 16 |
| 6.3. Geographical coverage of data collection..... | 16 |
| 6.4. Dataset for data collection..... | 16 |
| 6.5. Methods of data collection and sources of data | 17 |
| 6.6. Time period of data collection | 17 |
| 6.7. Time lag between data collection and feedback | 17 |
| 6.8. Quality measures included in feedback..... | 18 |
| 6.9. Evidence base for quality measures | 18 |
| 6.10. Case ascertainment..... | 19 |
| 6.11. Data analysis | 19 |
| 6.12. Data linkage..... | 20 |
| 6.13. Validation and data quality..... | 20 |

| | |
|--|----|
| Domain 7: Outputs..... | 21 |
| 7.1. The intended users or audience for the outputs..... | 21 |
| 7.2. Editorial independence..... | 21 |
| 7.3 The modalities of feedback and outputs..... | 21 |
| 7.4 Recommendations..... | 23 |
| 7.5 Comparators and benchmarking..... | 24 |
| 7.6 Motivating and planning quality improvement..... | 25 |

Domain 1: Organisational information

1.1. The name of the programme

The National Maternity and Perinatal Audit (NMPA).

1.2. The name of the organisation carrying out the programme

The Royal College of Obstetricians and Gynaecologists, The Royal College of Midwives, The Royal College of Paediatric and Child Health and the London School of Hygiene and Tropical Medicine.

1.3. Main website for the programme

<http://www.maternityaudit.org.uk/pages/home>

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

18/10/2019, Version 1

Domain 2: Aims and objectives

2.1. Overall aim

The National Maternity and Perinatal Audit (NMPA) is a large scale audit of the NHS maternity services across England, Scotland and Wales.

Using timely, high quality data, the audit aims to evaluate a range of care processes and outcomes in order to identify good practice and areas for improvement in the care of women and babies looked after by NHS maternity services.

Example:

"The aim of the audit programme is to improve the effectiveness, safety and experience of care provided to patients admitted to hospital in England. Current provision of care varies widely between hospitals, with only 52% of acute hospitals meeting the quality standards set by.... The programme aims to help healthcare organisations provide the best care in Europe for patients with XXX by 2020"

2.2. Quality improvement objectives

The overarching aim of the NMPA is to produce high-quality information about NHS maternity and neonatal services which can be used by providers, commissioners and users of the services to benchmark against national standards and recommendations where these exist, and to identify good practice and areas for improvement in the care of women and babies. The NMPA consists of three separate but related elements:

- an organisational survey of maternity and neonatal care in England, Scotland and Wales providing an up-to-date overview of care provision, and services and options available to women
- a continuous clinical audit of a number of key measures to identify unexpected variation between service providers or regions
- a programme of periodic 'sprint' audits on specific topics

The NMPA measures a range of care processes and outcomes and provides these data to maternity providers to facilitate quality improvement.

Example:

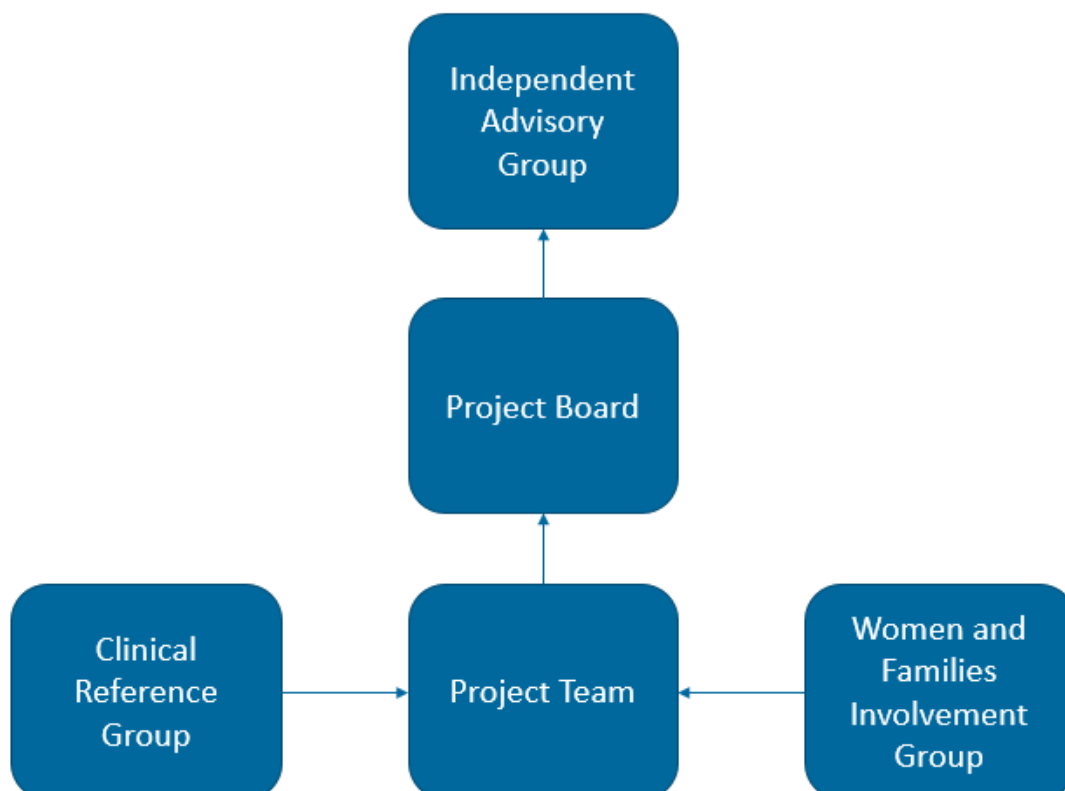
"The quality improvement objectives of the programme are to:

1. Increase the proportion of patients receiving NICE recommended treatment for XX [clinical area]. The objectives align with the COMET initiative and Core Outcome Sets (COS) identified from work in this clinical area.
2. Reduce the time from assessment to intervention/procedure [clinical area]
3. Increase the proportion of staff trained to assess the mental health of patients at admission"

Domain 3: Governance and programme delivery

3.1. Organogram

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3.2. Organisations involved in delivering the programme

Royal College of Obstetricians and Gynaecologists (RCOG)

www.rcog.org.uk

The Royal College of Obstetricians and Gynaecologists is the contract holder and host organisation for the NMPA. There is a member of the RCOG, in the role of a Senior Clinical Lead, on the Project Team.

Royal College of Midwives (RCM)

<https://www.rcm.org.uk/>

The Royal College of Midwives is a partner and collaborator with the NMPA. There is a member of the RCM, in the role of a Senior Clinical Lead, on the Project Team.

Royal College of Paediatrics and Child Health (RCPCH)

www.rcpch.ac.uk/

The Royal College of Paediatrics and Child Health is a partner and collaborator with the NMPA
There is a member of the RCPCH, in the role of a Senior Clinical Lead, on the Project Team.

London School of Hygiene and Tropical Medicine (LSHTM)

www.lshtm.ac.uk

The London School of Hygiene and Tropical Medicine is a partner and collaborator with the NMPA
We have three methodologists from LSHTM on the Project Team.

Healthcare Quality Improvement Partnership (HQIP)

www.hqip.org.uk

The NMPA is commissioned by the Healthcare Quality Improvement Partnership

Example:

"National Charity for Patient Outcomes

www.healthcharity.org

The leading national charity for patient outcomes in the UK, campaigning for better care, supporting survivors and help to fund research into new treatments. The charity is a member of the Steering group and helped to co-design the programme"

3.3. Governance arrangements

A list of all the individuals within the governance groups associated with the NMPA are list from p56 onwards within the second clinical audit report (<https://maternityaudit.org.uk/filesUploaded/NMPA%20Clinical%20Report%202019.pdf>).

Example:

"The audit is governed by a Programme Board, which meets 3 times a year. The group is chaired by XXX and includes the following list of organisations and individuals [LIST]. 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. The chair of the Programme Board is the accountable officer of the programme.

The Operations Group reports to the Programme Board and is responsible for delivering the programme. It includes members with expertise in quality improvement (XX WTE), data analysis (XX WTE), patient engagement (XX WTE), clinical informatics (XX WTE) and project management (XX WTE).

The Board minutes with actions are in the public domain. Decisions are only taken at meetings where meetings are quorate. There is a process for reviewing membership to ensure an active Board, quorate meetings and which leads the direction of the programme"

3.4. Declarations and Conflicts of interest

TBC

Example:

"The policy and register of declaration and conflicts of interest for the programme is published at www.healthaudit.org/COI. All DOI are collected in advance of meetings and decisions regarding whether a COI exists and appropriate actions are made by the Chair. Any new DOI are also requested at each meeting as a standing agenda item. All DOI and COI are comprehensively documented in a publicly available register.

Domain 4: Information security, governance and ethics

4.1. The legal basis of the data collection

Under the new EU rules on confidentiality (the General Data Protection Regulations) the NMPA have a lawful basis to hold information on women and their babies. The purpose of the audit is to provide information to NHS maternity care providers to help them improve the quality of care women and their babies receive during pregnancy and childbirth. These uses are classified as justifiable purposes for using personal information (or a legitimate interest, GDPR Article 6(1)(e) and 9 (2) (i)).

English and Welsh law allows the NMPA to handle data on pregnancies and births to audit NHS

services without the informed consent of each woman and baby covered by the audit (Section 251 of the National Health Service Act 2006 – Control of Patient Information).

A copy of the NMPA Section 251 approval letter is available at:

<http://www.maternityaudit.org.uk/pages/resources>

Example:

"The registry has approval under section 251 of the NHS Health and Social Care Act 2006 to collect identifiable data without consent (CAG approval number XXXXXXXX). Patients can opt out of data collection by contacting their local clinical team or notifying the registry directly at www.healthregistry.org/patients"

"Patients provide informed consent to have their data included in the registry. Consent is obtained by clinical teams prior to surgery. The consent form and information factsheet proved to patients is available at this URL"

4.2. Information governance and information security

The Royal College of Obstetricians and Gynaecologists obtained an IG Toolkit score of 100% (satisfactory) as of 23/05/2018. Please see:

<https://www.igt.hscic.gov.uk/AssessmentReportCriteria.aspx?tk=435006606443212&cb=f9fe1bd5-3a5b-485f-9968-2253955af740&sViewOrgId=45022&sDesc=8HP31>

Example:

"The Information Governance Toolkit score achieved on DATE was xx% (satisfactory). This indicates that the programme can be trusted to handle personal information securely. The link is www.xxxx.xxx"

Domain 5: Stakeholder engagement

5.1. Approaches to involving stakeholders

A number of organisations representing women using maternity services have been involved in the design and implementation of the audit and will continue to be consulted on the running of the audit and its priorities.

For example, the stakeholders and process involved in selecting the audit measures is described on p7 of the second clinical audit report.

Women who have used the maternity services are also consulted via the NMPA Women and Families Involvement Group to focus on desired measures and desired impact, review of key documents and lay summaries, discuss website design and functionality, understand impact and opportunities to feed into improving information provision in pregnancy.

Example:

"Patients and carers are involved by:

- Carrying out focus groups of patients to help select quality metrics
- Including patients and carers in the multi-stakeholder workshop carried out to co-design the programme
- Two patients are members of the Steering Group providing strategy and governance to the programme
- Working with the National Charity of XXX to develop patient friendly infographics of data from the audit

Clinicians are involved by:

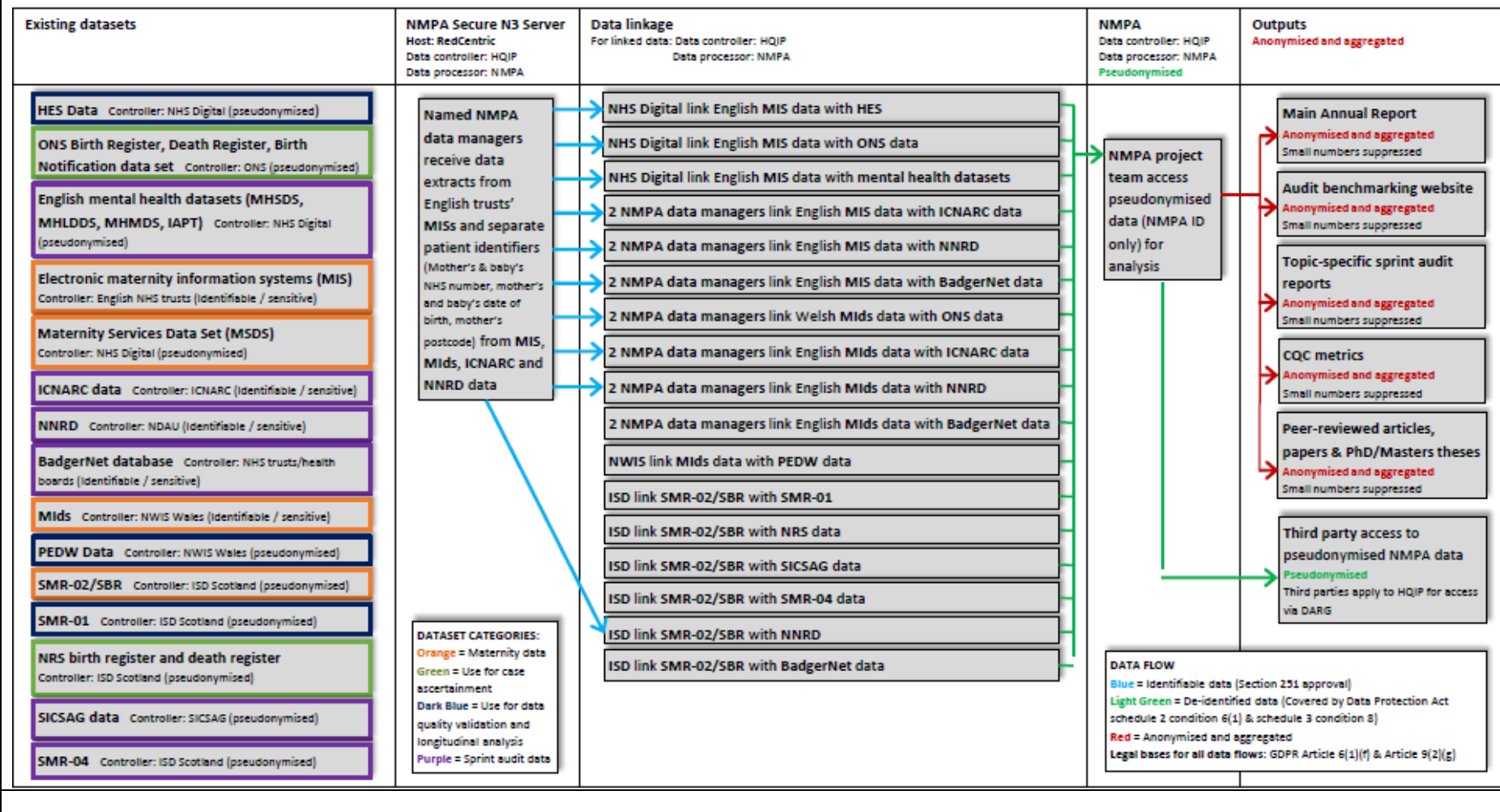
- Presenting key findings from the audit at the professional annual conference
- Carrying out an online survey to help identify and select quality metrics"

Domain 6: Methods

6.1. Data flow diagrams

National Maternity and Perinatal Audit (NMPA) Data Flow Diagram

15/02/2019 Lindsey Mamza Version 3.1



6.2. The population sampled for data collection

All mothers and babies cared for by NHS maternity services as follows:

In Scotland, the data used for this report comprised an extract of Scottish Morbidity Record 02 (SMR02) records linked with the Scottish Birth Record and Scottish Morbidity Record 01 (SMR01).
10

In Wales, an extract of the new Maternity Indicators data set (MIDs) was linked at record level with Admitted Patient Care (APC) records from the Patient Episode Database for Wales (PEDW).

In England, the NMPA requested an extract from each trust's individual electronic maternity information system. This was recoded internally and linked at record level to Hospital Episode Statistics (HES) inpatient records to allow longitudinal follow-up of mothers and babies.

The majority of measures are restricted to singleton, term births.

Example:

"Patients living in England with a new diagnosis of lung cancer"

"Patients aged ≥ 18 years admitted to hospital in England or Wales with acute ischaemic stroke [ICD 10: I63]

6.3. Geographical coverage of data collection

All Boards/ Trusts with maternity services within England, Scotland and Wales.

Example:

"All GP practices in England were eligible to contribute to data collection. Between 1st January 2016 and 31st December 2016, 58% (n= XXX) of GP practices submitted data"

"Maps A and B visualise the CCGs which were eligible (A) and actually participated (B) in data collection. Of 100 eligible CCGs, 92 (92%) participated in data collection. The list of participating CCGs is published at www.healthaudit.org.uk/participation"

6.4. Dataset for data collection

The data dictionary can be found here: <http://www.maternityaudit.org.uk/pages/resources>

Example:

"The core dataset for data collection is published at www.healthaudit.org/dataset. The COMET database was searched and the core dataset chosen for this audit aligns with the Core Outcome Sets (COS) from studies in this clinical area.

"The dataset for the time period XXXX-XXXX is published on www.data.gov "

6.5. Methods of data collection and sources of data

A description of how the data were collected and the sources of data can be found on p7 within the first clinical audit report.

Example:

"Clinical data were collected by clinical teams and entered into a secure online webtool designed specifically for the registry"

"Data were extracted from HL7 compliant electronic healthcare records by"

"Patient reported outcome measures were collected by postal survey. This was carried out by...."

"Data were extracted from Hospital Episode Statistics and linked using....."

6.6. Time period of data collection

The NMPA is a continuous, prospective audit. The data included starts on 1st April 2015.

Example:

"Data were collected for patients admitted to hospital between 01/02/2016 and 31/03/2016"

"The audit started prospective data collection in 01/01/2010"

6.7. Time lag between data collection and feedback

The first clinical audit report was published in 2017, it was revised and re-published in March 2018, which was two years after the end of the data collection period.

The second clinical audit report was published in September 2019, which was 18 months after the end of the data collection period.

Example:

"Participants receive real time (updated daily) feedback of data via the audit webtool. Benchmarking data are updated every 24 hours, allowing hospitals to compare their performance with others in each region"

"Feedback is via an annual report which is published 6 months after the end of data collection. The lag between data collection for patients included in the report ranges from 4 months to 16 months"

"The time from report submission to commissioners and funders on DATE, to publication of the report was 11 weeks."

6.8. Quality measures included in feedback

Note:

A list of the quality measures reported by the NMPA can be found in the second clinical audit report:

<https://maternityaudit.org.uk/filesUploaded/NMPA%20Clinical%20Report%202019.pdf>

Two outcome measures were selected for outlier reporting. These were:

- proportion of vaginal births with a severe (3rd or 4th degree) perineal tear
- proportion of singleton, term, liveborn babies with a 5-minute Apgar score of less than 7

Example:

"The outcome measures reported by the programme are:

- 90 day case mix adjusted survival
- 7 day post-surgical wound infection rate
- Patient satisfaction"

"The following list of process measures are provided to participating hospitals through an online dashboard that is updated daily...."

"Quality measures reported by the programme are published at a dataset at www.healthaudit.org.uk/measures. The dataset maps each quality metric as a process, outcome or organisational measure"

6.9. Evidence base for quality measures

The rationale and process for agreeing the quality measures can be found on p7 of the second clinical audit report:

<https://maternityaudit.org.uk/filesUploaded/NMPA%20Clinical%20Report%202019.pdf>

Example:

"The quality measures were defined to measure:

- NICE quality standard QS22
- NICE clinical guideline CG33"

6.10. Case ascertainment

Data on Welsh and Scottish births were provided centrally and case ascertainment was performed by the relevant national organisations. In England, we compared the number of births reported by each trust against the numbers recorded for that trust in:

- 1 Hospital Episode Statistics 2015/16 financial year data
- 2 Office for National Statistics 2015 data (latest available at time of publication)

Neither of these data sources is a perfect 'gold standard' against which to measure case ascertainment. We investigated discrepancies where trusts supplied less than 90% of the expected number of births according to either source.

Based on these investigations, we excluded three trusts that supplied data for less than 70% of births within the time period. Six trusts supplied data for between 70% and 90% of the expected number of births within the time period; these trusts are included in our analysis.

More detail can be found on p9 the second clinical audit report (<https://maternityaudit.org.uk/filesUploaded/NMPA%20Clinical%20Report%202019.pdf>).

Examples:

"Case ascertainment was estimated to be 85% as compared to Hospital Episode Statistics data. The methodology for estimating case ascertainment is described in full at URL"

6.11. Data analysis

The description of data analysis can be found from p7 onwards within the second clinical audit report, which can be found here:

<https://maternityaudit.org.uk/filesUploaded/NMPA%20Clinical%20Report%202019.pdf>

Examples:

"The methods used to clean and analyse the audit are described on pages 12-18 for the Annual Report at www.healthaudit.org/annualreport/2016"

"Mortality outliers were identified using standardised hospital mortality ratios and funnel plots. Details of the case mix adjustment model and the methodology used to identify outliers are available at www.healthaudit.org/mortality and have been published at BMJQS 2016;14:88-94"

6.12. Data linkage

The only data linkage undertaken is described within the neonatal care sprint audit report, which can be found here: <http://www.maternityaudit.org.uk/pages/sprintaudits>

Examples:

"Patient level data were linked to ONS death certificate data in order to obtain date of death and causes of death. Data were linked using NHS number and date of birth. Linkage was carried out by NHS Digital, who provided Health Audit with a linked dataset after removal of patient identifiers. 5% of patients were not matched by NHS number "

6.13. Validation and data quality

A range of methods are used to validate data quality and analyses including testing and refining data management and cleaning techniques, validation by the Project Teams and statistical analyses of data quality. For example, at site level there are internal consistency checks (e.g. no C-sections in freestanding midwifery led units), review of data completeness with a minimum threshold of more than 70% and assessment of plausible distribution (e.g. gestational age mostly term).

The analysis in NMPA report is restricted to sites that pass NMPA data quality checks, as well as birth records within those sites that contain the required data to construct a measure.

The number of sites for which results are available therefore varies from measure to measure, depending on specific data requirements.

Examples:

"A validation study was carried out to evaluate the accuracy of data entry. This used double entry and retrospective case note review to check the accuracy of the data provided by hospitals to the audit. Further details are available at www.healthaudit.org/validation"

"The algorithm used to estimate case mix adjusted survival rates has been externally validated. Further details are available at BMJQS 2015;12:22-26"

"X% of cases are selected monthly for validation to ensure consistency of coding among the audit team"

Domain 7: Outputs

7.1. The intended users or audience for the outputs

The information produced by the National Maternity and Perinatal Audit is intended for the use of clinicians, NHS managers, commissioners and women to compare and evaluate services and support quality improvement work, where appropriate.

Example:

“The audit designs and produces individual feedback for:

- Patients and carers
- STP footprints in England
- CCGs and Health Boards
- Clinical teams
- The Care Quality Commission”

7.2. Editorial independence

As an independently commissioned audit, the contents of the outputs are written by the Project team and quality assured by the Clinical Reference Group through the governance processes described in previous sections.’

Example:

‘As an independently commissioned programme, the contents of the outputs are written by XXX and quality assured by the Board through the governance processes described in previous sections.’

7.3 The modalities of feedback and outputs

The audit provides the following types of feedback available at <http://www.maternityaudit.org.uk>:

- A full clinical report
- An executive summary
- The ability to view summary information about individual maternity services by site or trust/health board
- The ability to view details and compare selected measures relating to maternity and neonatal services at individual site or trust/health board
- A technical specification for NMPA measures
- A summary document of key findings

The outputs for the audit are intended for the use of clinicians, NHS managers, commissioners and women.

The clinical report is quality assured at team level and reviewed by members of the Clinical Reference Group before submission to HQIP.

Example:

“The audit provides feedback for the following types of participant:

- Patients and carers: An “Easy Access” written annual report; annual set of infographics
- Clinicians: Real time feedback through online dashboard for their hospital/trust and their individual performance; slide sets of benchmarking data and run charts; comprehensive annual report; regional peer review workshops
- CCGs and health boards: Written summary report; Data files (csv) with data presented at CCG and Trust level”

“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

All NMPA recommendations are available at: <http://www.maternityaudit.org.uk>

- The NMPA 2017 clinical report made:
 - 4 recommendations for clinicians
 - 12 recommendations for services
 - 7 recommendations for commissioners
 - 2 recommendations for system suppliers
 - 5 recommendations for national organisations, professional bodies and policymakers
- The NMPA 2018 report on Maternity Admissions to Intensive Care in England, Wales and Scotland in 2015/16 made 7 recommendations.
- The NMPA Technical Report Linking the National Maternity and Perinatal Audit Data Set to the National Neonatal Research Database for 2015/16 made:
 - 3 recommendations for organisations requesting neonatal data extracts
 - 2 recommendations for organisations supplying neonatal data extracts

7.5 Comparators and benchmarking

The audit provides comparative performance data at site and Board/ Trust, regional and national level, and against a national mean.

For three measures, an outlier analysis has been undertaken. Units with a rate above the upper limit have been asked to conduct an investigation.

Data will also soon be provided over time (year on year).

Example:

“The audit provides comparative performance data for hospitals. Each hospital has performance measured against:

- Other hospitals in the region
- All hospitals in England
- Previous performance data for the hospital showing changes over time (run charts)”

7.6 Motivating and planning quality improvement

The clinical and organisational reports provide a comprehensive overview of the care within England, Scotland and Wales, in addition to making recommendations for action by stakeholders at different levels of the system.

These findings have been presented at a number of conferences and events and have included us showcasing examples of local quality improvements that have come on the back of clinical audit findings.

In addition to the reports on the clinical audit and organisational survey, the team provide the data on an interactive website where users can interrogate the data, per measure, at site and Board/ Trust level.

Example:

“The audit supports participants in QI by:

- Providing online training materials in data interpretation and PDSA
- Highlighting areas of improved performance through the online dashboard
- Linking hospitals into peer networks to share learning and experience”