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 Paediatric Diabetes Audit (NPDA)

1.2. The name of the organisation carrying out the programme

The Royal College of Paediatrics and Child Health (RCPCH)

1.3. Main website for the programme

https://www.rcpch.ac.uk/work-we-do/quality-improvement-patient-safety/national-paediatrics-diabetes-audit

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

November 2018, v1

Domain 2: Aims and objectives

2.1. Overall aim

The NPDA aims to:

- Monitor the incidence and prevalence of all types of diabetes amongst children and young people receiving care from a paediatric diabetes unit (PDU) in England and Wales.
- Establish which key care processes are being received by children and young people with diabetes.
- Enable benchmarking of performance against standards of care specified by the National Institute for Health and Care Excellence (NICE) guidance at PDU and national level
- Determine the prevalence and incidence of diabetes-related complications amongst children and young people with diabetes.

2.2. Quality improvement objectives

The quality improvement objectives of the programme are to:
1. Increase the proportion of children and young people receiving NICE recommended key health checks for diabetes.
2. Increase the proportion of children and young people achieving NICE recommended HbA1c targets indicating optimum blood glucose control.
3. Identify units who are positive and negative outliers on these metrics to support local improvement/sharing of good practice.
4. Encouraging the sharing of good practise through dissemination of case studies and hosting of a national conference.
5. Support parents and patients to use the audit's outputs to ensure they are receiving recommended standards of care.

Domain 3: Governance and programme delivery

3.1. Organogram

NPDA Organogram

3.2. Organisations involved in delivering the programme

Diabetes UK: UK's leading diabetes organisation, provides essential information.
https://www.diabetes.org.uk/
DUK have a representative on the Project Board and have been commissioned to deliver two workshops to understand parent/carers views on the audit and paediatric diabetes care.
The National Children and Young People's Diabetes Network : 10 regional CYP diabetes networks were set up with support from NHS Diabetes in 2010 and were then joined by the Wales CYP Diabetes Network. These networks together form the National CYP Diabetes Network to share good practice and maintain high quality standards.
http://www.cypdiabetesnetwork.nhs.uk/. The network has a member on our project board, and the NPDA funds 50% of the national meetings of the network, in collaboration with Diabetes UK.

3.3. Governance arrangements

NPDA governance
group membership

The NPDA is governed by a Project Board, which meets quarterly. The group is chaired by Professor Anne Greenough, Vice President of the RCPCH and includes representation from stakeholder groups and organisations (see attached 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 NPDA project team reports to the Project Board and is responsible for delivering the programme. It includes an audit Coordinator (1 WTE), data analyst (0.5 WTE), project manager (1 WTE) and administrators (0.3 WTE).

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

Note:

Evidence that declarations and conflicts of interest have been considered, declared and where appropriate, mitigated appropriately :
- DOI / COI process and policy outlining how DOI and potential conflicts of interest are identified and managed
- A web URL to the publicly published DOI/COI register for all individuals involved in the programme and where appropriate, information about how these have been mitigated

All members of the Project Board have completed conflict of interest forms, which have not indicated any conflicts to be present. A standing item on the project board for any new conflicts will be added in December 2018.

Domain 4: Information security, governance and ethics

4.1. The legal basis of the data collection

Note:

A description of the legal basis for the data collection, specific to each country where the data are collected. Examples include:
- Informed consent
- Section 251 (NHS Health and Social Care Act 2006) approval
- Other types of patient controlled data permission

This could include links to:
- Consent forms
- Information provided to patients about participation and usage of data
- Further information about how patients can control the use of their data
- Information about ethical committee review

The NPDA has approval under section 251 of the NHS Health and Social Care Act 2006 to collect identifiable data without consent (CAG approval number ECC 2-03 (c) 2012). Patients can opt out of data collection by contacting their local clinical team or can exercise their rights under GDPR by contacting the audit team directly. A full privacy notice and parent-friendly privacy notice are available within the Transparency and Open Data section of the NPDA website.

4.2. Information governance and information security

Note:

Include:

- The Information Governance Toolkit score and URL to the organisation's Information Governance Toolkit Assessment Report
- If the IG toolkit score is less than satisfactory, indicate how the organisation is improving its security processes to achieve a satisfactory score and when the programme will be re-assessed
- Details of any other information governance and security accreditations achieved by the registry (e.g. ISO 27001)

The Information Governance Toolkit details for the RCPCH are below:

i.   IG Toolkit organisation code: **8HV48**
ii.   IG Toolkit score (if already in place): **82%**
iii.   IG Toolkit reference: HPOV 60797
iv.   IG Toolkit version: **Version 14.1**
v.   Date of contact with Exeter Helpdesk: **Publication Date: 13/03/2018**

The score indicates that its programmes can be trusted to handle personal information securely.

Domain 5: Stakeholder engagement

5.1. Approaches to involving stakeholders

Note:

A description of how stakeholders are involved in designing and carrying out the programme

Examples of types of involvement that might be listed here include:

- Designing the programme
- Selecting quality metrics
- Defining aims and objectives
- Setting priorities
- Collecting data
- Contributing to data analysis and interpretation
- Governance
- Disseminating feedback and communications

Patients and Parents have been involved in the development of Patient/Parent Reported Experience Measures designed to help paediatric diabetes units understand how they might improve their services by:
- Attending focus groups to identify common themes in good or poorer diabetes care
- Being involved in cognitively testing the proposed data items

Other examples of parent /parents engagement are:
- One parent is a member of the Project Board providing strategy and governance to the programme, and comments on our parent facing publications.
- Commissioning Diabetes UK to host workshops for parents to comment on our parent-facing outputs to help us understand how we could improve them, and raise the profile of the audit amongst parents.
- Ensuring patient voice is included in each NPDA annual conference.

Clinicians are involved by:
- Having a clinical lead as a member of the core NPDA team, who co-authors all national reports and provides interpretation of findings
- Being members of our Project Board and Dataset and Methodology groups, ensuring that the audit measures are appropriate and are collected and reported appropriately.
- Presenting key findings from the audit at the professional annual conference.

Domain 6: Methods

6.1. Data flow diagrams

Note:

A data flow diagram showing each data flow into and out of the audit/registry. The diagram should indicate:

- What organisations are flowing data in/out of the programme
- What data items are within each data flow in/out of the programme
- The legal basis for each data flow, e.g. section 251, consent

NPDA data flow map

6.2. The population sampled for data collection

Note:

A description of the patient population or sampling frame for data collection. This might include:
- Details of inclusion and exclusion criteria
- Standard nomenclature to define patient populations (e.g. ICD codes, SNOMED terms)

All children and young people with diabetes receiving care from a paediatric diabetes unit in England and Wales.

6.3. Geographical coverage of data collection

Note:

A description of the geographical coverage of the data collection. Include details of both:
- geographical areas eligible for inclusion
- geographical areas that actually participated in data collection

This could include:
- A text description of coverage
- An illustration or map to visualise the coverage
- Summary data
- Links to data files containing geographical identifiers

All paediatric diabetes units in England and Wales have submitted data to the audit since 2012.

6.4. Dataset for data collection

Note:

A list (or web URL to online documentation such as a data dictionary) of the items included in the data collection

State how the dataset chosen aligns with the QI objectives and COMET Core Outcome Sets (COS) as described in section 2.2.

The core dataset for data collection, and the questions for the spotlight audits are published on the NPDA website.

The core dataset is based on the most recent NICE guidance for the diagnosis and management of children and young people with diabetes (NG16). The spotlight audit questions are drawn from previous national surveys of workforce and insulin technology access and support.

6.5. Methods of data collection and sources of data

Note:

A description (or web URL to online documentation) of how the data were collected and the sources of data.

Examples include:
- Online, e.g. webtool or portal
- Retrospective case record review
- Linkage to existing data sources
- Extracts of administrative data
- Surveys
- Extractions from electronic health records

The core audit requires paediatric diabetes units to enter data for each patient visit to clinic within the audit year. This data is submitted to the NPDA via an online portal, either by csv upload

or online 'questionnaire'. Data can be submitted throughout the audit year, or up until two months after the end of the audit year (01 April- 31 March).

Spotlight audit data was submitted on a one-off basis via an online survey.

Hospital Episodes and Statistics (HES) and the Patient Episode Database for Wales (PEDW) data is obtained tri-annually and linked to the NPDA core dataset to produce the Hospital Admissions report.

PREM data is collected from patients and parents completing surveys online.

6.6. Time period of data collection

Note:

The time period for data collection, using a start date (DD/MM/YYYY) and end date as applicable. For a continuous prospective data collection then this may only be a start date.

The NPDA started collecting core audit data in 2004.

6.7. Time lag between data collection and feedback

Note:

A description of the time lag between data collection and feedback to participants in the programme – try and be as specific as possible

If 'real time' please describe exactly what this means, e.g. monthly, daily, minute-by-minute

This could also include details about time intervals for the various steps between data collection and feedback/publication such as waiting for linked data to be supplied or for sign off

The online portal generates a summary report with service level and patient level results calculated upon every submission of core audit data. Following the end of the submission period, the audit data is cleaned and analysed. In advance of the publication of the national and official unit level reports, units are sent unit level summaries of their results as soon as the data and report template have been prepared. This is typically four months after the end of the collection period.

6.8. Quality measures included in feedback

Note:

A list (or web URL to online documentation) of the quality measures reported by the programme

Provide a mapping to classify these as:
- Process metrics
- Outcome metrics
- Organisational/structure metrics

Please state what metrics are provided at trust level and how often this trust level information is made available, e.g. quarterly, 6-monthly. If 'real time' please describe exactly what this means, e.g. monthly, daily.

The NPDA reports diabetes related outcomes including percentages of CYP with type 1 diabetes meeting HbA1c targets, percentages with comorbidities, and percentages with complications of diabetes. The audit reports percentages receiving the key health checks recommended for CYP with diabetes by NICE. There are too many reported to list, but they can all be found within NPDA Results Online.

6.9. Evidence base for quality measures

Note:

A list or description of the sources of evidence used to define the quality metrics. Examples include:
- Clinical guidance (e.g. NICE guidance)
- Clinical standards
- Systematic reviews
- Professional society recommendations
- Policy documents
- Clinical trials

The quality measures were defined to measure adherence to guidance within *Diabetes (type 1 and type 2) in children and young people: diagnosis and management (2015)* NICE guideline NG18, and the previous NICE guidance for CYP with diabetes.

6.10.   Case ascertainment

Note:

Describe the level of case ascertainment achieved. Include links or detail for additional information about methodology

Historical comparison with regional registries suggested an overall case ascertainment rate of ~95%. Recent comparison of 2015-16 data with NDA suggested a case ascertainment rate of 97.7% up to age 14 for Type 1 diabetes, and 80% for Type 2 diabetes for same.

6.11. Data analysis

Note:

A description (or web URL to online documentation) of the methods of data analysis. Important considerations in the analysis of audit and registry data include:

- Missing data, and how these were handled
- Sources of measurement error and bias, and how these were addressed
- Methods and algorithms used for:
    - case mix adjustment
    - benchmarking
    - outlier detection
    - visualising and interpreting time series data
- Algorithms and statistical models used to process data

This might include:

- References for peer reviewed publications of methods used in the data analysis
- Links to:
    - analytical code
    - more detailed descriptions of the methods already published elsewhere

The methods used to clean and analyse the audit data are described within these documents:

Notes on data analysis 201617 Final. Casemix adjustment brief updated March

6.12. Data linkage

Note:

A description of any data linkage carried out as part of the audit or registry. Include details of:
- Data sources
- Methods of linkage
- Evaluation of the quality of data linkage

If no data linkage carried out, state "No linkage performed"
This could include details about the impact of patient opt outs where these apply, e.g. the proportion of patients before and after opt outs are applied; changes in key characteristics of patient group following opt out such as gender, ethnicity

Patient level data is linked to HES and PEDW data to enable analysis of diabetes-related hospital admissions.

Patient level data is also shared with the NDA for analysis and production of the NDA's transition audit, which compares care and outcomes either side of transition to adult services.

6.13. Validation and data quality

Note:

A description of how data quality and analyses have been validated. Examples of validation include:

- Piloting and refining data collection methods and dataset changes
- Building in validation processes at the point of data entry
- Validation by clinical teams
- Data cleaning
- Statistical analyses of data quality (e.g. missing data)
- Validation of statistical models and algorithms
- Quality assurance and unit testing of analytical code

The processes for validating the NPDA core dataset are described within this document:

Validation steps for NPDA dataset

Domain 7: Outputs

7.1. The intended users or audience for the outputs

Note:

A list or description of the intended users or audience of feedback data produced by the programme. Examples include:

- Clinical commissioning groups or Health Boards
- Specialist commissioners
- Trust/hospital boards
- Clinical teams
- Individual clinicians
- General public
- Patients
- Carers
- Policy makers
- Politicians
- Media
- National agencies

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

Note.

A statement about the independence of the programme in regards to the content, e.g. findings, recommendations.

As an independently commissioned programme, the contents of the outputs are written by the Clinical lead, the NPDA Manager, and other members of the NPDA project team. These are quality assured by the Board through the governance processes described in previous sections.

7.3 The modalities of feedback and outputs

Note:

Examples of types of feedback commonly used in audits and registries include:
- Summary written reports
- Comprehensive written reports
- Online feedback
- Dashboards
- Slidesets
- Data visualisations
- Infographics
- Data tables
- Interactive tools
- Maps
- Meetings and workshops
- Professional conferences
- Verbal feedback by a national peer
- Verbal feedback by a local peer
- Information resources for patients (e.g. NHS Choices)
- Data that will be adapted and synthesised by other organisations (e.g. CQC) and programmes (e.g. GIRFT)
- Press releases
- Case studies
- Examples of best practice

The audit provides feedback for the following types of participant:

- Patients, parents and carers: A lay summary of the annual report, and a guide to interpreting unit level results displayed within NPDA Results Online.
- Clinicians: Real time feedback on their unit's performance every time data is submitted to to the online data capture system, pdf summaries of unit level results; NPDA Results Online, professional conferences and workshops, comprehensive national reports.
- CCGs and health boards: Data files (csv) with data presented at CCG and Trust level
- STPs: 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

Note:

The programme, in making specific recommendations about how to improve the quality or safety of healthcare services should provide a web URL to any documents making recommendations to participants

As a general principal, recommendations should:
- be specific, action oriented, and tailored to the intended audience
- agreed and signed off through an agreed process
- reviewed (e.g. annually)
- be underpinned by evidence and be supported by data collected by the programme
- be designed to have impact

Recommendations are made to accompany all key findings reported in all National reports, and are published alongside them. Previous reports can be found here.

7.5 Comparators and benchmarking

Note:

A description or list of if/how performance is compared between healthcare providers or areas, and the benchmark against which performance is measured.

This should provide a high level overview of how comparisons are made using the programme data, not a detailed list of all indicators and how they are individually used to benchmark or compare performance.

Examples of benchmarks include:
- National
- International
- Regional
- Organisational
- Clinical team
- Individual clinician
- Audit/registry standards
- Relative benchmarks (e.g. top 10%)
- Temporal (e.g. changes over time)
- Results from randomised controlled trials

The audit provides comparative performance data for paediatric diabetes units, regions and CCGs/LHBs within NPDA Results Online. This interactive reporting tool enables comparisons between units, regions and CCGs, and against national averages.

The tool also enables year on year comparison of results where possible, and the user can pick from caterpillar, column and bar charts to show performance.

NPDA Results Online also enables you to view funnel plots for audit metrics used to define outliers, showing each unit's performance relative to the national mean, and other units in their region.

7.6 Motivating and planning quality improvement

Note:

A short description of the approaches the programme uses to motivate and support quality improvement.

Programmes are not expected to provide a bespoke service to support trusts to interpret the findings or recommendations. The programme should, however, provide information in a format that is easy to digest and ready to use for the intended audience.

Examples of approaches include:
- Recommendations for action
- Action plans
- Education and training
- Supporting peer learning
- Providing positive feedback
- Workshops
- Including motivating statements as part of feedback

The audit supports participants in QI by:
- Producing recommendations for national action in response to key audit findings
- Enabling benchmarking of services on key audit measures and the tracking of year on year results
- Providing online guides to interpreting published results
- Hosting a national conference and workshops to aid the dissemination of examples of good practice
- Collecting and sharing case studies
- Co-hosting meetings of the National Network for Children and Young People with Diabetes with Diabetes UK, to promote regional support for improvement
- Funding the establishment of a QI collaborative and Quality Assurance Programme for paediatric diabetes units.
- Developing and delivering national Parent and Patient Experience Measures (PREMs) to highlight parent/patient priorities for improvement.