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

[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.

IPR and copyright

© 2018 Healthcare Quality Improvement Partnership Ltd (HQIP)

Contents

Domain 1: Organisational information

1.1. The name of the programme
National Prostate Cancer Audit (NPCA)

1.2. The name of the organisation carrying out the programme
The Clinical Effectiveness Unit at the Royal College of Surgeons of England

1.3. Main website for the programme
https://www.npca.org.uk/

1.4. Date of publication and version number of the tool on your website
Version 1.1/ 11.01.21

Domain 2: Aims and objectives

2.1. Overall aim

The aim of the NPCA is to assess the process of care and its outcomes in men diagnosed with prostate cancer in England and Wales. The NPCA aims to contribute to changes in clinical practice in England and Wales that will save lives and improve quality of life.

2.2. Quality improvement objectives

Key objectives include:

- Increased use of active surveillance to treat men with low risk prostate cancer, and thus avoiding potential over-treatment.
- Increased use of multimodality therapy (external beam radiotherapy and hormones; combined treatments with surgery and radiotherapy) for men with high risk or locally advance prostate cancer, and thus avoiding potential under-treatment.
- Improved safety and toxicity profile of prostate cancer therapy.
- Reduced variation in prostate cancer management among NHS providers.
- Improved experience of care among men with prostate cancer.

Information produced by the Audit is used by NHS providers to assess their care against national standards/clinical guidance and the performance of other trusts. For example, the Audit outputs show whether trusts are following national recommendations such as those published by NICE and whether there is any variation in the provision of care.

Risk-adjusted outcomes such as 90-day re-admissions following radical prostatectomy enable the identification of potential outlier trusts, which are notified of their outlier status and will investigate the causes (these may be related to data quality issues or clinical practice) in accordance with the NPCA Outlier Policy.

https://www.npca.org.uk/resources/npca-outlier-policy-2020/

In cases where clinical practice is identified as contributing to poorer outcomes, provider teams' review and improvement of practices can have a direct impact on patient care.

Provider level Clinical Outcomes Programme measures have been selected with the involvement of relevant professional bodies to enable evaluation of prostate cancer care and support improvements in outcomes. These measures are publicly available, providing transparency and supporting patient choice.

https://www.npca.org.uk/provider-results/

Domain 3: Governance and programme delivery

3.1. Organogram

https://www.npca.org.uk/content/uploads/2021/01/NPCA_Organogram_260520.pptx

Patient representative organisations, Prostate Cancer UK and Tackle PC, are embedded within the governance structure of the NPCA ensuring that the voice of their membership is heard and valued. Tackle PC is a patient- led organisation. The NPCA PPI Forum was established in 2020.

https://www.npca.org.uk/resources/npca-patient-and-public-involvement-ppi-forum/

3.2. Organisations involved in delivering the programme

The NPCA is a collaboration of a number of organisations.

https://www.npca.org.uk/about/

The audit is based at the Clinical Effectiveness Unit of the Royal College of Surgeons of England (RCS), an academic collaboration between the College and the London School of Hygiene and Tropical Medicine (LSHTM).

https://www.rcseng.ac.uk/standards-and-research/research/clinical-effectiveness-unit/

Contracted by HQIP to manage and run the NPCA, the CEU, RCS also provides the statistical methodology and the analysis presented in the annual report and associated short reports/ journal papers as well as a clinical fellow to provide day to day clinical input.

Clinical leadership is provided by the British Association of Urological Surgeons (BAUS) and the British Uro-oncology Group (BUG).

https://www.baus.org.uk/

https://bug.uk.com/

Public Health England's (PHE) National Cancer Registration and Analysis Service (NCRAS) and the Wales Cancer Network (WCN), Public Health Wales (PHW) act as the audit's data partners.

https://www.npca.org.uk/about/data-partners/

The Health Data Insight company (HDI) is subcontracted by the RCS to provide NCRAS, PHE's data collection services to the NPCA.

https://healthdatainsight.org.uk/

The Healthcare Quality Improvement Partnership (HQIP) - https://www.hqip.org.uk/
Commissions the NCAPOP programme of which GICAP is a part.

3.3. Governance arrangements

The **NPCA Project Board** provide project governance for the NPCA and oversee delivery of the contract. Professor Tim Terry, RCS Council member is the Chair of the NPCA Project Board. The Project Team reports to the Project Board, providing formal accountability for the delivery of the audit to lead professional bodies, the commissioning body (HQIP) and the commissioned organisation (RCS). The Project Board are responsible for monitoring the delivery of the audit's milestones, for agreeing tolerances and providing the escalation route for key risks and issues.

Representatives of the Board are comprised of members from the RCS, BAUS, BAUS Oncology, BUG, patient representatives, Prostate Cancer UK, Tackle Prostate Cancer, NCRAS, PHE, WCN, PHW and HQIP. The Project Board meets twice a year.

The **NPCA Clinical Reference Group (CRG)** support development of the audit by representing a number of interested stakeholders (including patients and professional organisations), jointly providing audit governance through the professional oversight of the clinical direction. This group acts as a consultative group to the Project Team, reviewing the methodology and findings in the annual reports and short reports, advising on the clinical focus of the audit, dissemination of findings, and collaboration with relevant partners. The CRG is chaired by Professor Roger Kocklebergh, Chair of the NCRAS Urology Expert Advisory Group.

Representatives of the CRG are comprised of members from the NPCA Project Team, BAUS, BAUS Oncology, BUG, BAUN, patient representatives, Prostate Cancer UK, Tackle Prostate Cancer, NHS England, NHS England's Specialise Cancer CRG, NHS Cancer Screening Programmes, NCRAS, PHE, WCN, PHW. The NPCA CRG meets twice a year.

The Project Team meets monthly to manage routine matters relating to the project.

Membership of the 3 groups outlined above can be found here:

https://www.npca.org.uk/about/our-team/

3.4. Declarations and Conflicts of interest

On appointment to the NPCA Project Board or Clinical Reference Group, members are asked to identify any actual or potential current conflicts of interest (COI).

At the start of each meeting of the NPCA Project Board or CRG, the chair asks for declarations of any COI in relation to the day's agenda, which are recorded in the minutes of the meeting.

Domain 4: Information security, governance and ethics

4.1. The legal basis of the data collection

NPCA has approval under section 251 of the NHS Health and Social Care Act to link health care information without consent under Section 251 (reference number: CAG 8-03(PR9)/2013) for all patients diagnosed with prostate cancer in Wales. Support is required for processing of date of death only.

Following NHS Digital confirmation that processing of 'date of death' is no longer classed as identifiable but instead as 'sensitive' and can be released without the need for an exception to the common law duty of confidentiality, Public Health England have adopted the same approach. As a result, support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 is no longer required for processing of English data and exit from section 251 for England only was approved 20.10.20.

As the same approach has not been adopted by the NHS Wales Informatics Service (NWIS) to date support under Regulation 5 for processing of confidential patient information without consent continues.

The National Cancer Registration and Analysis Service (NCRAS) in England and the Wales Cancer Network are allowed to collect data on patients diagnosed with cancer. Information on how to opt out of data collection is provided here.

All patient identifiable information including name, address, date of birth, address, postcode and NHS number is removed by NCRAS (England) and WCN (Wales) from the data extracts before they are securely transferred to the NPCA Project Team at the Clinical Effectiveness Unit at the RCS.

The patient information leaflet and privacy notice are available here:

https://www.npca.org.uk/resources/npca-patient-information-leaflet/

https://www.npca.org.uk/resources/npca-privacy-fair-processing-notice/

4.2. Information governance and information security

The NPCA is run and managed by the Clinical Effectiveness Unit at the Royal College of Surgeons of England (RCS). The RCS has completed and met the standards of NHS Digital's Data Security and Protection Toolkit on 09/03/2020 - https://www.dsptoolkit.nhs.uk/OrganisationSearch/8HM21

Domain 5: Stakeholder engagement

5.1. Approaches to involving stakeholders

Please refer to section 3 for NPCA stakeholder representation

- Clinical input is provided by members of the Project Team and CRG across all of the NPCA activities, particularly providing their expertise on matters relating to selecting quality metrics, defining data items, contributing to analysis and interpretation. They have a key role in disseminating feedback and communications to clinicians in provider organisations and presenting key findings during professional annual conferences.
- Our patient and charity representatives are particularly involved in our communications including the patient information leaflet and the annual report.
- The data collection partners manage the data collection process including responding to user queries, communication with users regarding data quality and access to their own data and provision of linked de-identified data extracts to the NPCA Project Team for analysis.

Domain 6: Methods

6.1. Data flow diagrams

https://www.npca.org.uk/resources/npca-dataflow-2018/

6.2. The population sampled for data collection

Patients are eligible for inclusion in the NPCA prospective audit if they are newly diagnosed with an ICD-10 diagnostic code of "C61" (malignant neoplasm of the prostate).

6.3. Geographical coverage of data collection

All patients newly diagnosed with prostate cancer in England (from 1st April 2014) and Wales (from 1st April 2015).

6.4. Dataset for data collection

https://www.npca.org.uk/resources/npca-minimum-dataset/

The NPCA Spring newsletter was published 28.03.19 providing information to teams in England regarding dataset changes.

https://www.npca.org.uk/news/npca-spring-newsletter-2019/

MDS1 and MDS2 will be collected for patients diagnosed to 31.03.19. The final submission date for these data items is 15.10.19.

The minimum dataset on the NPCA website will be updated at this time.

6.5. Methods of data collection and sources of data

The NPCA Prospective Audit does not 'collect' clinical data directly from patients. The NPCA works with the National Cancer Registration and Analysis Service (NCRAS), Public Health England as data collection partner in England, which collects patient-level data from all NHS acute providers and from a range of national data-feeds. This includes the Cancer Outcomes and Services Dataset (COSD), which specifies the data items to be submitted routinely by service providers via MDT electronic data collection systems to the National Cancer Data Repository (NCDR) on a monthly basis. Clinical sign-off of data submitted to NCRAS is not currently mandated in England.

The Wales Cancer Network (WCN), Public Health Wales is the NPCA's data collection partner in Wales however the data collection process in Wales differs from England. The NPCA dataset is captured through a national system, Cancer Information System for Wales (CaNISC), after identification by hospital cancer services and uploaded via electronic MDT data collection systems. Prior to submission of NPCA data to the WCN each patient record is validated, frequently

by an MDT coordinator, and signed off by a designated clinician. Patient records are signed off when all key data items have been completed.

https://www.npca.org.uk/about/data-partners/

6.6. Time period of data collection

Prospective audit data collection started on the 1st April 2014 in England and one year later in Wales (from 1st April 2015).

6.7. Time lag between data collection and feedback

Users can monitor their monthly data submissions to NCRAS, PHE using the cancerstats portal.

Currently there is a lag of 15 months between the end of the diagnostic cohort and the availability of cancer registry data linked to HES, RTDS and SACT from NCRAS, PHE. For example, data for men diagnosed 1 April 2017 – 31 March 2018 was delivered to the NPCA Project Team for analysis in June for the 2019 Annual Report.

The time from report submission to commissioners and funders, to publication of the report is dependent on HQIP/NHS England's SRP in relation to public facing reports.

6.8. Quality measures included in feedback

The outcome measures reported by the NPCA to date include:

Organisational measures:

• Available diagnostic facilities:
Multiparametric MRI
• Available treatments:
Radical prostatectomy
Robot-assisted laparoscopic prostatectomy
Laparoscopic prostatectomy
External beam radiotherapy
Intensity-modulated radiotherapy
Low-dose rate brachytherapy
High-dose rate brachytherapy
• Available support services:
Clinical nurse specialist
Sexual function services
Specialist continence services
Psychological counselling

Process measures:

• Proportion of men with low-risk localised prostate cancer undergoing radical prostate cancer therapy (potential 'over-treatment')
• Proportion of men with locally advanced disease receiving radical prostate cancer treatment (potential 'under-treatment')

Outcome measures:

• Proportion of men diagnosed with metastatic disease presented at the level of specialist MDTs
• Proportion of patients who had an emergency readmission within 90 days of radical prostate cancer surgery
• Proportion of men with severe genitourinary toxicity following radical prostatectomy
• Proportion of men with severe gastrointestinal toxicity following radical external beam radiotherapy

See the provider results sections on the NPCA website for the complete list of measures

https://www.npca.org.uk/provider-results/

Quality measures reported by the programme are published in annual reports:

https://www.npca.org.uk/reports/?audience%5B%5D=professional

6.9. Evidence base for quality measures

Although the NPCA started prior to the publication of the NICE Quality Standards in 2015,[4] the Audit provides results that can be used to evaluate to what extent prostate cancer care providers meet most of these standards:

1 QS 1: men with prostate cancer have a discussion about treatment options and adverse effects with a named nurse specialist.
2 QS2: men with low-risk prostate cancer for whom radical treatment is suitable are also offered the option of active surveillance.
3 QS3: men with intermediate- or high-risk/locally advanced localised prostate cancer who are offered non-surgical radical treatment are offered radical radiotherapy and ADT in combination.
4 QS4: men with adverse effects of prostate cancer treatment are referred to specialist services.
5 QS5: men with hormone-relapsed metastatic prostate cancer have their treatment options discussed by the urological cancer MDT.

Results from the NPCA patient survey provide information about how men were informed about their treatment options, how treatment decisions were made and to what extent they had access to a named clinical nurse specialist (CNS) (QS1). Further patient surveys are planned.

We also present results for indicators of possible over-treatment in men with low-risk disease and potential under-treatment in men with high-risk/locally advanced disease (QS2 and QS3).

In our organisational survey, originally performed in 2014 and updated each year (see NPCA website), we describe whether providers of cancer services have specialist services on-site (QS4).

[4] Prostate Cancer. NICE Quality Standard 91, 2015.

Prostate cancer often has a protracted natural history and with further follow-up of patients in later years, the NPCA will assess to what extent the treatment options of men with hormone-relapsed metastatic cancer have been discussed at an MDT (QS5).

In addition to the results linked directly to the NICE Quality Standards, the NPCA reports on aspects of care that capture ongoing developments in the way men with prostate cancer are being assessed and treated. The Audit also provides evidence on the adoption of newer technologies (e.g. use of multiparametric MRI scanning before the prostate biopsy and the type of biopsy used) and treatments (robotic-assisted prostatectomy and intensity-modulated radiotherapy), as well as the impact on patient outcomes.

Further to the publication of updated NICE guidelines in May 2019[5] we will also present in the next annual report (NPCA Annual Report 2019) the uptake of docetaxel in men with newly presenting metastatic disease, the use of hypofractionated radiotherapy and the use of brachytherapy boost in men with high-risk/locally advanced prostate cancer.

6.10. Case ascertainment

As the NPCA includes all men newly diagnosed with prostate cancer within the cancer registry, we no longer report case-ascertainment (as this is per definition 100%). The completeness of key data items provides a measure of data quality.

6.11. Data analysis

The methods used to analyse the NPCA prospective audit data including

- inclusion and exclusion criteria
- level of reporting
- data quality
- definition of disease status and disease risk stratification algorithm
- definition of radical prostate cancer treatment
- definition of NPCA performance indicators
- risk adjustment and generation of funnel plots

are described on pages 12-15 in the NPCA Annual Report 2018.

https://www.npca.org.uk/reports/npca-annual-report-2018/

More detailed methodology including the development of key indicators can be found in the following peer-reviewed publications:

https://www.npca.org.uk/publications/

[5] Prostate cancer: diagnosis and management. NICE Guideline 2019.

6.12. Data linkage

The National Cancer Registration and Analysis Service (NCRAS), Public Health England, and the Wales Cancer Network (WCN), Public Health Wales, are the NPCA's data collection partners.

Through this partnership, the Audit receives de-identified data extracts including Trust/Health Board submissions linked to selected data items from national datasets (cancer registry data, HES, PEDW, ONS, RTDS and SACT) to provide information on the diagnosis, management and treatment of every man newly diagnosed with prostate cancer in England and Wales including staging, mode of admission, comorbidities, surgical procedure or intervention details, radiotherapy and chemotherapy details, readmissions and complications.

All patient identifiable information including name, address, date of birth, address, postcode and NHS number is removed (de-identified) by NCRAS in England and WCN in Wales before they are securely transferred to the NPCA Project Team. The NPCA presents analyses of these data in annual reports to provide information regarding the type and extent of prostate cancer and the quality of prostate cancer services and treatment in England and Wales.

The NPCA has Section 251 permission from the Confidential Advisory Group for data linkage without patient consent (CAG 8_03(PR9)_2013_NPCA) in Wales. As described in section 4.1, approval for CAG exit in England only was approved on the 20.10.21.

6.13. Validation and data quality

The NPCA reports methodologically rigorous and technically robust performance indicators, which have been peer-reviewed (see below). High levels of data completeness are required to provide a representative indicator of clinical practice. Adjustment and outcome variables are considered missing if each does not meet a number of initial range and consistency checks.

https://www.npca.org.uk/publications/

Domain 7: Outputs

7.1. The intended users or audience for the outputs

The audit designs feedback for the following intended audiences:

- Patients with prostate cancer, their carers and charitable groups
- Commissioner organisations
- Trust board and clinical teams
- Policy makers
- Quality Assurance initiatives eg CQC, NCAB
- Quality Improvement initiatives eg GIRFT
- General public

7.2. Editorial independence

As an independently commissioned programme, the contents of the outputs are written by members of the Project Team and quality assured by the Clinical Reference Group and the Project Board including the NPCA Data Collection Partners.

7.3 The modalities of feedback and outputs

The audit provides feedback for the following types of participant

- The Annual Report is used by Clinicians, Providers and Commissioners; this contains data tables, graphs, provider-level results, interpretations and recommendations. The report includes infographics and an executive summary.
- A “patient friendly” report is produced which is aimed at patients and their carer’s. It is a simpler to read document with infographics, clear explanations of clinical terms and references.
- A short report is published year focussing clinical topics or methodological developments.
- Peer-reviewed publications are published from the NPCA.
- NPCA Project Team members present findings at national and international conferences.
- An interactive website allows comparison of provider results to those locally and nationally. Provider-level pdfs are produced and are publically available on the NPCA website so any interested party can access them.
- The audit has a twitter feed to improve its online presence, make announcements and publicise findings.
- Metrics used by national organisations such as CQC in their reviews of Providers, NCAB, and GIRFT.
- Audit results are presented on Data.gov.uk.
- The launch of the report is accompanied by independent media related activities of the charitable organisations.
- Information for patients is published on NHS Choices and on the NPCA website.

7.4 Recommendations

The annual report publishes key findings and makes recommendations on the quality of care received by patients.

Key findings and recommendations for appropriate target audiences in the 2018 Annual Report and Patient Summary can be found here:

https://www.npca.org.uk/reports/npca-annual-report-2018/

https://www.npca.org.uk/reports/npca-patient-summary-2019/

7.5 Comparators and benchmarking

The audit provides comparative performance data as appropriate for Trusts, Health Boards, Specialist MDTs and surgical/radiotherapy centres measured against national performance data.

7.6 Motivating and planning quality improvement

The annual report publishes key findings and makes recommendations on the quality of care received by patients.

The audit produces local reports for each trust/specialist MDT to enable them to review their performance in comparison to the national performance on the NPCA website.

https://www.npca.org.uk/provider-results/

The clinical leads and the members of professional organisations in the Clinical Reference Group engage with their colleagues in trusts to discuss how trusts can action the recommendations.

Potential outliers are followed up according to the NPCA's Outlier Policy

https://www.npca.org.uk/resources/npca-outlier-policy-2019/

Publication of data via the Clinical Outcomes Publication makes unit-level provider performance data available via NHS Choices/ My NHS. As well as potentially outlying units being notified in writing the audit's clinical lead, representing the professional body, communicates directly with them.