NHS England

Clinical audits and registries: A best practice guide

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Contents 1

Summary 4
Purpose....Error! Bookmark not defined.
Objectives.... 4
1. Introduction 5
1.2 Scope of audits and registries 5
1.3 Principles 6
2. Clinical leadership and support 7
2.1 Clinical leadership 7
2.2 Roles and responsibilities 8
2.3 Partnership working 9
2.4 Bespoke data collection 10
2.5 Workforce training and education 10
3. Working in partnership with people and communities 11
3.1 How NHS England works with people and communities 11
3.2 Setting standards for working in partnership with people and communities 11
4. Methodology, analysis and reporting 13
4.1 Methodology principles 14
The principles are: 14
4.2 Data analysis principles 15
The principles are: 15
4.3 Identifying outliers 15
4.4 Benchmarking data 16
4.5 Reporting principles 17
4.6 Turning recommendations into actions 18
5. Data collection, processing and access 18
5.1 Guiding principles 18
5.2 Potential benefits of adoption of principles 19
5.3 Implementation approach 20
6. Quality management to support quality improvement 21
6.1 Introduction to quality 21
6.2 Understanding quality improvement 21

6.3 Examples of QI from clinical audits 22
7. Commercial 23
7.1 Objectives 23
7.2 Procurement selection criteria 24
7.3 Strategic alignment and continuous improvement 24
7.4 Commercial considerations 24
7.5 Policies governance and market engagement 25
8. Legal and statutory responsibilities 26
8.1 Legal framework supporting national clinical audits and registries (England only) 26
8.2 NHS England specialised commissioning 27
8.3 Caldicott Guardian 28
8.4 Compliance with the UK General Data Protection Regulations 2018 and the Common Law Duty of Confidentiality 28
8.5 Quality accounts 29
9. Governance 29
9.1 Principles of governance 29
9.2 Contractual and data governance 30
9.3 Clinical leadership and programme management 31
10.4 Quality and safety governance 33
9.5 New overall clinical audits and registries governance 34
10. Checklist 35
Annex: Current sources of NHS England commissioning 40
Medical - National Clinical Audits and Patient Outcomes Programme (NCAPOP) 40
Finance directorate, specialised commissioning 41
Transformation directorate 41
References **Error! Bookmark not defined.**

Summary

This document sets out a unified approach for commissioning and overseeing clinical audits and registries across the NHS in England and within the audit and registry community. Its primary aim is to ensure systems deliver timely, actionable insights that support clinical decision-making, enhance patient safety, improve healthcare quality and reduce inequalities in access and outcomes. It is aimed at both owners and administrators of new and existing health care audits and registries, including NHS England.

While focused on England, the guide acknowledges the cross-border relevance of many audits and registries, including those involving Wales, other devolved nations, crown dependencies and international collaborations.

This document does not set out the future direction for audits and registries or how commitments arising from the 10 Year Health Plan and the Dash Review of Patient Safety across the Health and Care landscape will be implemented. The guide is, however, aligned to the aims of both the 10 Year Health Plan and Quality Strategy. It has been designed to support audits and registries owners and commissioners to work in partnership with NHS England, and as a reference tool for those participating in the process.

It is a dynamic working document which may be amended to align with evolving needs and the new quality strategy. The guide will be regularly reviewed and updated by NHS England in partnership with colleagues from the audits and registries community.

Objectives

The objectives are to:

- establish a standardised approach for conducting clinical audits, managing registries and identifying outliers to ensure data is consistent and comparable.
- ensure the data collected through clinical audits and registries is accurate, reliable and valid, and used for continuous improvement in quality of patient care and outcomes.
- facilitate collaboration between clinicians, researchers and policymakers to maximise the value and impact of clinical audit and registry data on healthcare policy and practice.
- align with the latest NHS digital developments to enhance their effectiveness and reduce burden.

1. Introduction

Clinical audits and registries have been used in the NHS over decades to monitor adherence to clinical guidelines and enable healthcare services to benchmark performance, identifying where services are doing well and where improvements are needed.

- A **clinical audit** is one of the main types of quality improvement activities. It is a way to determine if healthcare is being provided in line with standards. It helps care providers, commissioners and patients understand where services are doing well and where improvements are needed in line with evidence-based standards.
- A **registry** is a record of all cases of a particular disease or condition in a defined population. The data collected can vary, but often includes personal identifiers, sociodemographic information, disease status, treatment and other interventions and outcomes.

With a complexity of care pathways and range of healthcare settings, there can be no one size fits all model. However, regardless of category, all audits and registries need strong clinical, academic and analytical leadership.

Many audits and registries draw on bespoke data collections and skilled clinical analytics to understand clinical speciality areas and the operational delivery of healthcare services. They produce academically validated insight into clinical delivery that may not otherwise be known. They also require suitable data systems and resources to independently analyse, report and publish findings.

The NHS has used clinical audits and registries to facilitate quality improvement (QI), as sources of data for research studies and QI initiatives. In some cases, they also assist in direct patient care and allow for a recall function where safety concerns are raised.

There is an opportunity with the changing NHS digital architecture to drive QI at pace, tackling variation across the NHS, and with this further evolution of audits, registries and databases should be expected and supported. While large scale change takes time, there are still lessons to be learnt from global healthcare systems about what digital systems and funding models can improve efficiency and positively impact on population health.

1.2 National commissioning sources:

NHS England commissions and supports numerous clinical audits and registries across the NHS and these divide into four broad categories:

1. **National Clinical Audits and Patient Outcomes Programme (NCAPOP),** those clinical audits that are directly or indirectly funded and commissioned by NHS England's Medical Directorate via the Healthcare Quality Improvement Partnership (HQIP) contract. All are required for quality accounts.
2. **Additional national clinical audits** – those that are required for annual quality accounts reports but are not part of NCAPOP.
3. **Funded clinical audits, databases and registries**:
    - specialised commissioning clinical audits, databases and registries that NHS England fully, partially or indirectly funds
    - registries run by NHS England: for example, the National Disease Registration Service (NDRS), which includes the two population-based disease registers NCRAS (the national cancer registration and analysis service) and NCARDRS (the national congenital anomaly and rare disease registration service)
    - national clinical registries developed with the Outcomes and Registries Programme (ORP)
4. **Specialised commissioning clinical audits, databases and registries** not funded by NHS England but contractually required by trusts as part of standard NHS England contracts.

1.3 Key considerations:

NHS England and the owners of clinical audits and registries must consider the following principles:

1. **Compliance with NHS England's statutory responsibilities** that set out**:**
    - routine collection of data to minimise collection burden.
    - patient involvement in design, execution and oversight.
    - a responsive design to ensure health inequalities are highlighted.
    - measurement of clinically meaningful outcomes and process.
    - alignment to QI, productivity and safety aims.
    - data available at national, regional, integrated care board (ICB), provider and primary care network (PCN) level and made publicly available where no patient will be identifiable.
    - data acquisition across the whole patient pathway.
    - strategic objectives of prevention using a population health management approach.

- access to high quality data for research purposes.

2. **Ensure there is a joined-up approach to clinical leadership and governance** across NHS England and external stakeholders and partners.
3. **Ensure there is an appropriate data use and analysis,** to allow its timely use by managers and clinical decision makers. Data should be analysed, visualised and reported to provide actionable insights and recommendations.
4. **Provide data and analytics infrastructure to streamline information governance.** This will leverage NHS England's digital and data infrastructure to ensure cyber security provides timely data linkage, improve data cleansing and optimise data flows.
5. **Clarify responsibilities for ensuring detection of unwarranted variation and outliers** to drive clinical improvement.
6. **Provide a clear process for commissioning and decommissioning audits and registries**, while understanding their care impact and value for money.

2. Clinical leadership and support

This section explains how NHS England maintains consistent clinical leadership and support, both internally through policy teams and externally with clinical partners and stakeholders.

2.1 Clinical leadership

In this context, there is an expectation that clinical leadership should:

1. **Drive a culture of data driven clinical decision making and quality improvement (QI)** by using data collection and audit.
2. **Co-design and co-produce clinical** audits and registries with patients.
3. **Ensure effective collaboration and partnership working** with:
   - the relevant expert faculties (that is, the subject matter experts leading the national clinical audits and registries)
   - national bodies such as: Royal Colleges, speciality associations and national clinical societies for medicine, nursing, allied health professions (AHPs), public health and health science
   - frontline clinicians, multidisciplinary teams and their clinical audit and registry staff within healthcare providers.
4. **Understand workforce training and development needs** at all levels.

2.2 Roles and responsibilities

The models of leadership and clinical advice structures in place to support the prioritisation, development and evaluation of audits and registries vary across specialty areas. Implementing a standardised model will help avoid duplication and the formation of siloes.

A best practice approach to clinical leadership at each level is outlined below.

Frontline clinicians and managers to:

- provide opinion on design, use of routine data sources, implementation and data collection for new and revised clinical audits and registries.
- raise awareness among clinical teams of registries that automatically flag and enrol eligible patients in their services.
- support clinical services to use near real time data to drive QI in patient care for best possible outcomes.
- understand the needs of their patient populations and that data should be segmented by known risk factors for healthcare inequalities such as ethnicity and deprivation.

Healthcare providers should:

- provide access to accredited training (such as use of statistical process control charts and other benchmarking tools) to support frontline clinicians.
- support clinicians and clinical audit teams with training to interpret data outputs, enabling comparison and benchmarking across peer providers and, in turn, supporting learning and clinical service improvement.
- ensure trust executives, senior managers and chief clinical information managers use information to understand how services are performing and take necessary board level action.

Regional commissioners and ICBs should:

- provide guidance on national policy and strategy requirements to executives and clinical directors.
- provide assurance that trusts are analysing, interpreting and comparing data and have strategies to address identified gaps and areas for improvement.

NHS England should:

- set strategic direction regarding leadership requirements for the development and evaluation of new and revised clinical audits and registries.
- use information to understand variance between ICBs (where possible sub ICB and PCN) and at local service level.
- provide assurance that data security rules and measures are in place and compliant.
- seek feedback from stakeholder; challenging assumptions and myths where needed, while relaying any key concerns or information to senior decision-makers
- ensure the domain specific expert faculties (clinical, academic, analytical and patient teams) leading current national audits and registries define what 'good' looks like

Example: National cardiac audit programme

The national cardiac audit programme has an expert faculty leading national reporting on quality of care and outcome measures across 10 cardiovascular domains. The programme works with NHS England, the Medical Devices Outcome Registry and GIG Cymru (NHS Wales). Its work is led by clinicians and patients and underpinned by highly specialised analytical staff and technical architecture designed to support effective reporting and surveillance outcomes.

- ensure alignment of clinical leadership models for NCAPOP, specialised commissioning clinical databases and the ORP, with input from all relevant NHS England directorates through the national audits and registry senior leadership team. For more information, see section 8 on governance.

2.3 Partnership working

Partnership working and co-production with Royal Colleges, specialty associations and national clinical organisations for medical, nursing, AHPs, public health and health scientists provides essential support for clinical audits and registries.

Supporting bodies such as the National Quality Improvement (including) Clinical Audit Network (N-QI-CAN) facilitate collaborative working between trusts clinical audit, clinical effectiveness and QI teams.

2.4 Bespoke data collection

Clinical leadership can also support bespoke data collection by defining participation thresholds to ensure data completeness and validity. It is important to note that thresholds will depend on whether audits are local, regional or national and vary by specific topic area.

Other considerations include:

- a review process for audits that do not meet the participation threshold to identify issues and improvement strategies.
- advising on incentivising participation, that is, improving access to individual clinician and hospital level data and providing tools that support routine clinical work and QI projects.
- streamlining and automating data collection through the Electronic Patient Record (EPR), to reduce the burden of manual data entry and minimise cost.
- publishing data on positive and negative outliers.
- mandating participation via contracts or sanctions.
- making audit and registry data publicly available to drive better engagement and higher data quality from providers.
- identifying risks and unintended consequences of data collection.

2.5 Workforce training and education

Healthcare providers need to support appropriate training of the clinical workforce (for example, doctors, nurses, AHPs) and health scientists, both by protecting time for staff to undertake training and giving them opportunities to participate in audit and QI.

Examples of how they can do this are:

- align consultant job planning with professional activities that support training, development and participation in clinical audits and registries or to carry out/supervise QI projects.
- implement audits or QI projects conducted by resident doctors to facilitate improvements in quality as an integral component of their training.
- use available training offers for example, the Royal College of Surgeons provides clinical epidemiology training which is specifically designed for senior trainee doctors and includes designated audits and registries that provide funding. The N-QI-CAN's

education and training resources directory is available on National Clinical Audit Learning Community - Futures workspace.

- allocate protected time for nursing staff, health scientists and AHPs to support the delivery of audits and registries.

3. Working in partnership with people and communities

3.1 How NHS England works with people and communities.

Statutory guidance on working in partnership with people and communities sets out how NHS England, ICBs, NHS trusts and foundation trusts should work with people and communities to improve services and meet the public involvement legal duties It is also relevant to other health and care organisations to ensure we team up to involve people and communities in ways that are meaningful, trusted and lead to improvement.

Legal duties

- **NHS commissioners have a legal duty** under the National Health Service Act 2006 (as amended) to "make arrangements" to involve the public in the commissioning of services for NHS patients ('the public involvement duty').
- **NHS England also has a legal duty** to involve patients (and their carers) in their own health and care by:
  - giving them the power to manage their own health and make informed decisions about their care and treatment.
  - supporting them to improve their health and give them the best opportunity to lead the life that they want.
- **The NHS Constitution** sets out the rights and responsibilities for patients and the public, including: "the right to be involved, directly or through representatives, in the planning of healthcare services commissioned by NHS bodies, the development and consideration of proposals for changes in the way those services are provided and in decisions to be made affecting the operation of those services".

3.2 Setting standards for working in partnership with people and communities

NHS England expects all owners of clinical audits and registries to:

- have a plan to involve patients, parents, carers and the public in the design, implementation and evaluation of clinical audits and registries.
- meet their public involvement legal duties (see section 9.2: Contractual and data governance) by communicating effectively with all patients about how the data in a registry is used.
- have mechanisms to take further action where patients or public raise safety concerns.

However, theses requirement will need to be flexible, proportionate and appropriate taking into consideration the varying size, scope, financial position, commissioning origin and developmental stage of the clinical audit or registry.

A plan could include patient and public involvement:

- when developing a specification for delivery
- within the procurement and contract award stage
- in the development and inclusion of patient experience and/or satisfaction measures
- when developing improvement tools
- developing easy access and the clear communication of findings, including how patient engagement has supported the development and findings of the work (using plain language in accessible formats)
- clarity on how to work with patient representative groups and established patient, parent, carer and community networks
- ensure the diversity of people and communities is represented (patient representative groups can support here)
- seek to address inequalities and promote disadvantaged groups through involvement
- ensure inclusion in the ongoing evaluation of the audit or registry.

There are established forums which can support engagement with people and communities and signpost clinical audits and registries to key patient representative groups, especially for smaller seldom heard patient groups and communities. These forums include National Voices and the Patient's Association, both of which have trusted relationships with vulnerable groups and large established networks across England.

4. Methodology, analysis and reporting

This section makes the case for using appropriate methodological methods and tools to ensure best practice in data analysis and reporting.

Expert faculties (domain specific experts in clinical, technical and analytical areas) for clinical audits and registries work closely with multidisciplinary clinical groups and patients. This faculty is important for defining the patient cohort, the clinical pathway or service as well as the users and uses of the data.

The different users of clinical data will set out the questions the data is trying to answer and for what purposes. This will inform the methodological approach, data required and timeline.

Examples of use for frontline teams, provider executives (including those for independent sector providers) and across ICBs, as well as regional and national NHS teams (adapted from NDRS strategic plan):

- supporting direct care and improving patient outcomes:
  - point of care decision making and referral management
  - clinical peer review, appraisal of outcomes and quality
  - risk profiling/stratification to support targeted interventions
  - support all patients in their care and decision-making
- improving population health and reducing inequalities:
  - epidemiology and population health management
  - analyses by population segment/cohorts/demographics
  - inequalities analysis, monitoring and impact assessment
  - support move from disease management to prevention
  - improve engagement with people and communities
- planning and improving services:
  - benchmarked insights to support service planning
  - quality and safety surveillance and oversight reporting
  - quality improvement (QI) and pathway redesign
  - clinical effectiveness reporting and productivity
  - commissioning, service monitoring

- supporting research and innovation
    - Royal College or specialist association research
    - life science and research supporting innovation
    - pharma, tech, devices R&D and NICE/MHRA review
    - evaluation of programme interventions and innovations

These examples also demonstrate the wide range of external organisations and networks that use clinical data including patients, their communities and charitable societies; public health teams in local authorities, Office for Health Inequalities and Disparities (OHID) and the UK Health Security Agency (UKHSA); Clinicians in the Royal Colleges and specialist associations; life science and research teams; DHSC; Care Quality Commission (CQC); Medicines and Healthcare products Regulatory Agency (MHRA); National Institute for Health and Care Excellence (NICE); medical device and pharmaceutical manufactures; and Private Healthcare Information Network (PHIN).

4.1 Methodology principles for Audit and Registry Owners

The principles are:

- **automate data collection:** reduce manual data entry by using existing data sources, such as Electronic Patient Records (EPR) and apply international coding standards.
- **streamline data flows:** minimise duplication by aligning data collection with audit and QI needs.
- **ensure data timeliness:** use real time or near real time data where appropriate, recognising that some metrics change slowly and require less frequent updates.
- **flexible approaches:** adapt methods to suit diverse uses, data types and user needs, including clinical decision making and management insights.
- **patient involvement:** involve patients in data usage decisions to ensure transparency, privacy and trust. Where possible, include patient experience data.
- **whole pathway view:** link data across the patient care pathway, from prevention to treatment and account for health inequalities through longitudinal analysis
- **system capacity:** acknowledge capacity limits within healthcare systems when making recommendations.
- **evaluation plan:** include evaluation processes to assess the impact of audits and registries, informing future improvements.

4.2 Data analysis principles for Audit and Registry Owners

The principles are:

- **appropriate skills:** analysis needs to be led with senior clinical input and the appropriate analytical and statistical skills to ensure intelligent insights.
- **wide expert input:** analysts and clinical leads need to work closely with data service/technical colleagues to ensure integration of the data collection, processing, curation, reporting and understanding the information governance of the data and limitations. This is likely to require input from a diverse group of clinical leads rather than a single clinician.
- **appropriate analytical methods:** need to align with the purpose for the data being used and should consider the structure and size of the dataset, to select the most appropriate statistical methods and account for where there are small numbers and/or incomplete data.
- **appropriate analysis:** collaboration across analysts and clinical experts is vital to ensure data is correctly interpretated. Clinical evidence base, clinical standards, epidemiology and practicalities will inform how the data should be analysed and reported to provide actionable insights.
- **timely (near real time) data** allows for the appropriate level of data cleansing and quality assurance for its proposed use. Some key indicators need to be provided quickly over others. Real time data is required by users for clinical decision making and referral management; with that rapid feedback being more effective at creating change with frontline teams. There needs to be consideration for how this is decided as the proposed use may require different levels of data cleansing (for example, operational data of activity needs to be more regular to support commissioning vs. cleansed/quality assured data for research needs)
- **definition of data**: it is essential to note the differences in analysis of crude unadjusted real-time data (within trusts) versus adjusted quality assured near real time data.

4.3 Identifying outliers

Defining outliers and the management process should link to the CQC with clear routes for escalating patient safety and quality risks. For example, The HQIP Outlier management for national clinical audits sets out the definition and statistical process used to identify alarms and alerts. It includes the need to identify positive outliers to celebrate clinical excellence and include non-participation as an outlier flag. In contrast, the National Joint

Registry (NJR) adopts a more intensive ‘accountability and transparency’ model than the HQIP guidance and is clinically overseen. This approach recognises outliers can include hospitals but also clinicians and medical devises. Therefore, while the CQC serves as a regulatory body, the NJR also deals with MHRA for devices. Lesson learnt from this model of accountability and transparency can be applied to other medical device registries.

Individual consultant outcomes require expert clinical and academic statistical input to develop, maintain and iterate risk models as they clearly shift over time. Outputs of this work should be published (ideally as methodological research) and metadata available to allow transparency. This is essential for any analysis that may affect an individual’s right to practice. The risk of not doing the above is that it may deter clinicians from taking on complex cases.

Risk models need to be developed for individual consultants and for whole teams when the care cannot be linked with one consultant. Consideration needs to be given to the concept of outliers, and which organisation is responsible especially where outcomes may be affected by non-patient or service level factors (for example, funding of services). There also needs to be consideration of the appropriateness of the terms ‘alert’ and ‘alarm’ in different circumstances.

Outlier identification works best for discrete care events, where there is a specific intervention or procedure which an organisation is responsible for and then leads to a specific outcome.

4.4 Benchmarking data

Data should be presented at trust, service or clinical network level and at a population level based on an ICB or sub ICB level, regardless of the provider the patient uses. Data should be viewed through both lenses and enable comparison of similar providers or geographies (aligns to Model Health System).

Analyses used should be documented, including how statistical differences and case mix adjustment for known, measurable patient characteristics for the specific metric are reported. If the data is presented as quartile/decile ranges, it should be noted whether this is unadjusted or adjusted. Metadata documents for each clinical audit and registry should enable the replication of analyses.

Statistical process control (SPC) analytical techniques use statistical tools to monitor and control processes, minimising variation and enhancing quality. Work with the clinical expert group to identify measures which will support action, are clinically valuable and present opportunities for improvement in alignment with Making Data Count and NHS IMPACT.

The extent of missing data and any potential bias should be documented as data that is missing at random can introduce bias into the results. This should include methodology for imputing missing data and ensure it is reflected in metadata documents and the extent of supressing small numbers and the impact this could have on interpretation of data where there is not sufficient statistical power.

Segmenting data by age, sex, deprivation and ethnicity is a minimum standard for understanding healthcare inequalities. It is beneficial to include other known factors (for example, learning disabilities, severe mental illness, inclusion health groups) that are linked to a higher risk of healthcare inequalities. This approach aligns with NHS England » National Healthcare Inequalities Improvement Programme).

4.5 Reporting principles for Audit and Registry Owners

For each proposed use, the clinical expert facility must develop clear documentation, incorporating input from patients and domain specific subject matter experts, including academics, data technicians, statisticians and analysts which support reporting and data visualisation for all clinical audits and registries. The documentation should specify the following:

- who reviews the data entered
- how data parameters are set
- how we avoid the risk of focusing only on previously observed issues and missing new ones

Other considerations include:

- **integration of data sources:** When users access audit and registry data for patient safety purposes, they should triangulate this information with other sources of safety data, such as the Learn from Patient Safety Events (LFPSE) data, using its published data principles
- **action to take for identified signals:** There should be a clear process for documentation on how to address any identified safety signals. This includes specifying who is notified, by whom, what actions need to be taken and how this information will be incorporated into wider quality governance and risk management structures
- **process for making recommendations:** must be documented, including identification of the responsible team for making, reviewing, costing and prioritising recommendations. It is important to clarify who is responsible for the action. NHS

England's patient safety team has developed a 'Safety Action Development Guide' to support organisations in their development and oversight of safety actions following patient safety learning responses

- **process for communicating findings:** When recommendations and actions necessitate organisational or structural changes which require intervention from national bodies, it is important to communicate this process and its outcomes transparently to frontline teams and the audit and registry providers which have been entering the data

4.6 Turning recommendations into actions for Audit and Registry Owners

Recommendations must be translated into best practice actions for impact and deliver change and QI. Effective reporting and data visualisation should highlight findings and guide actions, with end user input and representation through data user groups. Visualisation can support understanding.

Recommendations

- Reports should be generated within 6 months and include health inequalities data for actionable insights, aligning with NHS England's Improvement Programme.
- Ensure alignment with NHS England's quality and safety architecture and internal programmes (like GIRFT) while collaborating with external partners.
- Clinicians, managers and commissioners must stay informed about national audits and work with support organisations to implement improvements.
- Evaluating the impact of reports on patient outcomes is essential, primarily through platforms like the NCIP, which requires clarity on usage and effects.

5. Data collection, processing and access

This section sets out how data collection, processing and access should be undertaken in line with a core set of principles to ensure consistency.

5.1 Guiding principles for Audit and Registry Owners

- **Minimise data collection**: Collect data once and use many times to support patient safety, clinical improvement and better patient outcomes.
- **Be clear on multiple user needs and 'purpose':** ensuring there is a robust legal basis supporting data collection.
- **Apply standards** across the sectors: full practice reporting, analysis and surveillance should be enabled by the adoption of common data standards and framework data sharing agreements between NHS and IS provider bodies. Adoption of common NHS

data standards / NHS Data Dictionary (for example, the use of fields such as NHS number) to enable linkage and reduce the need to duplicate collections of certain data.

- **Focus on value:** maximise impact, share insights, reduce burdens to create a sustainable infrastructure, service and ecosystem.
- **Be transparent:** (data, method, purpose and code) and accountable to enable public trust and support continuous improvement.
- **Leverage central investments:** in data strategy and transformation, for example using NHS England to collate, process and link data where possible to enable enrichment of existing registries and to enable future research through secure, trusted research environments.
- **Commit all collections to industry good practice:** in cyber security, data protection and resilience standards, for example:
    - data security protection toolkit (DSPT)
    - cyber essentials (plus - Cyber, information governance and data protection guidance)
    - ICO registered and compliant
- Develop a **central hub of consistent foundation information:** with links to specialist bodies/registries and a multidisciplinary approach for expert insights, reports, knowledge and learning.

NHS England should aim/commit to:

- open benchmarking of summary statistics at provider, specialty and neighbourhood and/or system level.
- maintaining and publishing a central register of registries/audits with clear links out to 'spokes' that deliver these registries.
- cataloguing data for research – enable access processes for all registries through Data Access Request Services (DARS) and Secure Data Environments (SDE) programmes.
- transparent publication of aggregate summary information (for example, coverage, compliance and volumes for core procedure, device and demographic information).

Use data as a catalyst to **create a vibrant, collaborative ecosystem** for clinical registries, audits, information and insights, bridging silos and enabling innovations in research, surveillance and QI.

5.2 Potential benefits of adoption of principles

When successful, a coordinated approach to data collection, processing and access should deliver multiple benefits. By agreeing coordinating principles, standards and guidelines on

how to collect, analyse, present and disseminate clinical data, audits and registry information, the following opportunities could be realised:

- **release clinician time and focus** (within registries) to focus on clinical leadership, strategy and improvement, by engaging data professionals to lead on technical challenges around infrastructure, legal permissions, linkage, processing, access, etc.
- **wider access to new technologies** and data/tech investments made by DHSC and NHS England by building on/within/aligned to our central NHS England data infrastructure investments to maximise flexibility and future adaptability.
- **centralised management of data access requests** for research through leveraging the investments in secure data environments with clearer/quicker responses with clear safeguards.
- **potential to reduce data collection burden** and enable ready access to linked data assets (for example, including HES data activity) through centralised processing, linkage and onward sharing.
- **increased transparency and public awareness** of data assets, uses and outputs through the transparent sharing of headline benchmarked information, research information available through SDEs/DARs and routine reporting in line with outcomes and registries directions.
- **higher quality data and analyses through the adoption of common data standards** to enable interoperability, linkage, consistency/familiarity and novel analyses to support QI.
- **improved patient care and outcomes** through better surveillance, QI, research and innovation

5.3 Implementation approach

There are several mechanisms to aid implementation of the principles captured in 6.1 above:

- **evaluation of registries readiness:** Use a self-assessment questionnaire to evaluate the current state and digital maturity of clinical audits and registries used within the NHS. Headline outputs of this should be shared and common requirements should drive any future development efforts to support the sector.
- **create patterns for technical adoption** to evaluate, iterate on and improve existing data collection, workflows and analyses. Registries are not compelled to use a specific provider or technology; however, the patterns of underlying standards and

expectations should be articulated to support future procurements and/or requirements for development.

- **adopt consistent visualisation mechanisms** (for example, statistical process control) to aid benchmarking and comparative analyses, enabling national level variation analyses to be provided in tools such as the Model Health System. This should complement registry and specialty specific analyses and insights reporting / research produced by expert faculty while also providing a consistent baseline across sectors and areas.
- **access and linkage:** NHS England is well placed to undertake data linkage based on data feeds from clinical audits and registries, thereby eliminating the need for duplicate data capture across related registries. An example is the potential enrichment of registry data by linking patient records to the NHS Spine. NHS England will enable linked data to be accessible via SDEs using the DARS process.

6. Quality management to support quality improvement

This section sets out how clinical audits and registries are a key part of a wider NHS quality management system and how they support quality improvement (QI).

6.1 Introduction to quality

The Health and Social Care Act 2012 defines quality as encompassing three dimensions: clinical effectiveness, patient safety and patient experience. The National Quality Board (NQB) encourages the NHS to use a wider definition which also recognises that high quality care is well led, sustainable and equitable (including addressing inequalities)

Quality management has three key stages to ensure improvement: quality planning, quality control/assurance and QI. Ensuring clinical audits and registries are supporting all stages and dimensions is important in securing them as a key tool to improve patient care now and in the future.

6.2 Understanding quality improvement

Quality improvement (QI) is a fundamental component of the healthcare quality cycle, focused on systematically enhancing systems and services to deliver safer, more effective, patient centred care.

While there is no single definition or tool for QI, it is characterised using structured, evidence-based methods. These methods involve engaging a broad range of stakeholders, conducting

rapid cycles of testing and learning and using real-time data to assess, progress and drive change.

In April 2023, NHS England introduced NHS IMPACT a unified, system wide approach to improvement. This initiative equips NHS organisations, systems and providers with the skills, tools and shared learning needed to embed continuous improvement into everyday practice.

Clinical audits and registries play a pivotal role in driving QI. They support a continuous cycle of monitoring and improvement through:

- live dashboards for real time insights
- regular peer reviews
- strong clinical leadership
- structured feedback loops

6.3 Examples of QI from clinical audits

This best practice guide reinforces the essential role of clinical audits and registries in supporting a modern, evidence-based approach to QI across the NHS.

- **Getting It Right First Time (GIRFT)** collates data from over fifty national audits to facilitate benchmarking and its clinically led, in depth reviews of services, presenting a data driven evidence base to support QI. The data from the audits was combined with local insights to understand where unwarranted variation in quality of care might be occurring and to apply learning from comparable high performing teams. The programme emphasises the importance of re-auditing and continuous monitoring to assess the impact of changes and to refine them over time curating a set of key metrics within the Model Health System which are updated monthly.

- **National Cancer Audit Collaborating Centre (NATCAN):** each NATCAN audit develops explicit QI goals. The aim is to improve the results of all forms of cancer care, as well as patient experience during diagnosis and treatment. The QI goals are developed in collaboration with a wide range of stakeholders including professional bodies, patient charities and patients themselves. Where available, national evidence-based standards of care, such as those published by NICE, underpin the improvement goals of each cancer audit. NATCAN and the audit teams review clinical performance against these goals and shine a light on areas where improvements are needed.

- **The Cardiovascular Disease Prevention Audit (CVDPREVENT)** is a national primary care audit that automatically extracts routinely held GP data. The data and improvement tool provides open access to the data, with clear, actionable insights for those tasked with

improving cardiovascular health in England. Specific QI tool: Quality Improvement | CVDPREVENT.

- **The Sentinel Stroke National Audit Programme (SSNAP)** measures the quality and organisation of stroke care in the NHS across England, Wales and Northern Ireland. SSNAP - Using SSNAP reports.

- **National Audit of Eating Disorders (NAED)** depending on the findings of the audit, services will receive QI support from an NAED QI expert and coach, offering help in project design and QI methods through resources, online training workshops and webinars. This new topic has yet to report but it will have a QI component.

- **National Audit of Psychosis (NCAP):** The collaborative consists of enhanced and core programmes of QI support based on the outcomes of the audit. NCAP Quality Improvement.

- Other general quality improvement tools:
  - National benchmarking reports for each topic area led by clinical experts.
  - National Consultant Information Programme (NCIP) provides dashboards that allow clinicians to audit their individual performance
  - National Clinical Audit Benchmarking - benchmarked audit data that CQC uses for CQC hospital inspections and other purposes
  - outlier management processes for NCAPOP: Outlier management for National Clinical Audits – HQIP identifies positive (best practice) as well as negative outliers

7. Commercial

7.1 Objectives

The commercial strategy underpinning clinical audits and registries must focus on building strong, value driven partnerships that support programme delivery and long-term sustainability. The key objectives are to:

- **secure best fit solutions**: procure market leading solutions which align with clinical, technical and financial requirements.
- **prioritise clinical value and data security**: focus on audits and registries with high clinical impact, while proactively identifying and mitigating data security and supplier risks

- **maximise value for money**: identify opportunities for efficiency, collaboration and shared investment across the health system.
- **enable future flexibility**: design contracts that are adaptable to evolving clinical and digital priorities.
- **protect intellectual property (IP):** ensure appropriate IP rights are in place to support innovation, reuse and NHS ownership where appropriate.
- **maintain service continuity**: safeguard ongoing delivery of existing services and minimise disruption or risk to patient care.

7.2 Procurement selection criteria

Procurement decisions will be based on a balanced evaluation of both technical and commercial factors technical assessments should be led by clinicians and technical experts to evaluate the quality, performance, interoperability and data security of the proposed solutions. A commercial assessment involves evaluating the supplier's financial standing, pricing models and overall value proposition.

This dual approach ensures selected suppliers meet both the operational needs and strategic ambitions of NHS England.

7.3 Strategic alignment and continuous improvement

This guidance will evolve, informed by market feedback, lessons learnt from previous procurements and emerging best practices. The commercial team will:

- apply insights from past contract successes and challenges.
- prioritise high impact audits and registries with potential for significant clinical or financial return.
- minimise investment in legacy systems, while ensuring continuity of service and patient safety.
- develop clear transition and exit strategies to support a smooth migration to future state solutions.

7.4 Commercial considerations for Audit and Registry Owners

To support effective delivery and long-term value, the following commercial considerations must be embedded:

- **procurement strategy** defines and implements a procurement approach which supports open, competitive and inclusive market engagement.

- **effective contract management plans** need to be established to ensure successful implementation and ongoing oversight.
- **data collection and analysis:** Collect data on total cost of ownership and identify opportunities for savings. Distinguish between essential and non-essential features to guide investment decisions.
- **collaboration and synergy:** Explore opportunities for collaboration and data sharing with other healthcare organisations for example, UKHSA, OHID, PHIN, HDRUK, as highlighted in the Sudlow Review, to enhance interoperability and reduce duplication
- **minimal standards for new registries:** Introduce proportionate, flexible standards to ensure new registries are interoperable, scalable and aligned with NHS digital infrastructure.

7.5 Policies governance and market engagement

All procurement and contract activity must comply with:

- NHS England Standard Financial Instructions (SFIs): a framework for the financial management and control of NHS England resources. It only applies to contracts issued by NHS England; other organisations and devolved administrations will have their own arrangements. SFIs cover the following:
    - purpose: designed to ensure the effective and efficient use of NHS resources in compliance with financial standards and laws.
    - scope: applies to all employees, including directors and senior managers, involved in financial management and decision making within NHS England.
    - management of finances explains the roles and responsibilities of personnel in financial management, ensuring accountability and clear governance.
    - budgeting: covers everything from creating and maintaining budgets to monitoring revenue and expenses in relation to them.
    - NHS England's procurement policy outlines the processes for acquiring goods and services while fostering cost effectiveness.

Other policies and guidance include:

- Business Case and Procurement Policies, fair, transparent, and open procurement processes and NHS Standard T&Cs.
- Spend controls, NHS England policies, DHSC, Cabinet Office and technology boards.

- Statutory and Legal Procurement Law – Public contracts regulation (PCR 2015) and the Procurement Act which came into effect February 2025.
- NHS England Contract Management Framework (CMF).
- Best practice guidance and Procurement Policy Note (PPNs).

8. Legal and statutory responsibilities

This section sets out NHS England's legal and statutory responsibilities for delivering clinical audits and registries, in line with our corporate responsibilities.

8.1 Legal framework supporting national clinical audits and registries (England only)

NHS England manages its corporate responsibilities through a variety of mechanisms and corporate functions, such as finance, human resources, legal and communications. These functions provide support to the organisation in carrying out its responsibilities in relation to the commissioning and delivery of audits and registries. Other mechanisms include:

- **leadership and governance**: NHS England is led by a chief executive and a board of directors which is responsible for the overall strategic direction and performance of the organisation. The board is accountable to the Secretary of State for Health and Social Care
- **legal and regulatory framework:** NHS England operates within a complex legal and regulatory framework, including the National Health Service Act 2006 and the Health and Social Care Act 2012. These acts set out the powers, duties and responsibilities of NHS England
- **performance management:** NHS England has a robust performance management framework in place to monitor and evaluate the performance of its services including audits and registries. This includes setting targets, collecting data and conducting regular reviews.
- **risk management:** NHS England has a comprehensive risk management framework to identify, assess and mitigate risks to the organisation. This includes developing and implementing risk registers, conducting risk assessments and putting in place appropriate controls.
- **transparency and accountability:** NHS England is committed to transparency and accountability. It publishes a wide range of information about its activities, including its annual report and accounts, performance data and board papers.

Additionally, there are various legal and statutory responsibilities that underpin NHS England's commissioning and delivery of national clinical audits and registries. These include:

- **Health and Social Care Act 2012:** (1) promotes accountability and encourages clinical audits for performance improvement. (2) S254 of H&SC Act 2012 SoS directs NHS England to collect and analyse data for various healthcare and adult social care purposes
- **NHS Act 2006:** defines NHS duties, including clinical audits for quality and safety improvement.
- **Health and Social Care Act 2008:** established the CQC mandating clinical audits for quality assurance.
- **Health Act 2009 and NHS (Quality Accounts) Regulations 2010:** Outlines requirements for quality accounts content and format
- **CQC (Registration) Regulations 2009:** Requires providers to monitor and enhance service quality, including clinical audits.
- **UK GDPR and the Common Law Duty of Confidentiality** ensures data protection and privacy when managing patient information. It is important audits and registries are confident the processing of data centrally, both of core data sets and of the data shared with the central databases within NHS England, is fully compliant and continues to be so.
- **Independent sector:** data from independent sector providers can be required but not mandated. Work will be required though the implementation strategy to address this issue.
- **The Mental Health Act 1983 (amended 2007):** includes references to quality improvements which can involve clinical audits.
- **The Children Act 1989 and 2004:** suggests the role of clinical audits in child health services.

8.2 NHS England specialised commissioning

NHS England has a statutory responsibility for the direct commissioning of prescribed specialised services, health and justice and armed forces health services, under section 7A public health services. Service specifications and clinical commissioning policies for specialised services often specify a requirement for service providers to submit data to relevant clinical databases and registries. These requirements are reinforced within schedule 6 (information schedule) as part of the contracts placed between NHS England and

providers of directly commissioned services. NHS England can use its powers under directions issued by the Secretary of State for Health to collect, link and analyse data from the registries.

8.3 Caldicott Guardian

The Caldicott Guardian function advises on the use of personal information in a manner which is legal, ethical and appropriate, ensuring confidentiality is maintained. It provides leadership and informed guidance on complex matters involving confidentiality and information sharing. All registries and audits collecting patient identifiable data must comply with Caldicott principles and be approved by the Caldicott Guardian within the organisation, at NHS England this is the National Medical Director (The Caldicott Principles - GOV.UK)

8.4 Compliance with the UK General Data Protection Regulations 2018 and the Common Law Duty of Confidentiality

For NHS England to collect data from clinical registries/audits/databases, it must be satisfied initial processing by the organisation responsible for the data is lawful. The privacy, transparency and trust (PTT) information governance (IG) team assess each registry independently.

Where a new data collection is required, the Secretary of State for Health has issued two directions to NHS England under the Health and Social Care Act (HSCA) 2012:

- Data services for commissioners Directions 2015 - NHS England Digital
- Outcomes and Registries Directions 2024 - NHS England Digital
- National Disease Registration Service Directions 2021 – NHS England Digital

The PTT IG team will assess which of the directions should be relied on and support the relevant programme with the completion of a data protection impact assessment (DPIA). There are associated governance documents which may also need to be completed by the programme which IG can advise on but are not responsible for:

- requirement specification
- data specification
- the issuing of a data provision notice under s259 of the HSCA 2012
- the development of a privacy notice
- burden assessment
- Caldicott Guardian review
- advice from the advisory group for data (AGD)

- information standards board review

All the above actions ensure NHS England can meet its legal obligations under data protection legislation to collect, analyse and disseminate (if required) registry data. Different IG arrangements can include s251 where data is collected by non-NHS England organisations. Data from the independent sector relating to the provision of self-funded or private healthcare can be requested but not demanded.

8.5 Quality accounts

NHS providers are legally required to prepare and publish quality accounts annually to ensure transparency and accountability, provided they meet certain criteria (for example, provide services on an NHS standard contract). The quality account sets out how clinical areas are prioritised – for example, relevance to patient care, risk and areas for improvement; how stakeholder have been engaged and reports on those topics named on the NHS England's quality accounts list where they provide relevant services.

9. Governance

This section sets out governance functions across clinical audits and registries commissioned by NHS England. Detailed are the existing and new overarching clinical governance model arrangements within NHS England; setting out high level principles for good governance and setting standards all audits and registries should meet.

9.1 Principles of governance for Audit and Registry Owners

- **Leadership ensure alignment with objectives:** governance establishes clear frameworks, roles, and decision-making processes, ensuring the project or programme stays aligned with its strategic goals and desired outcomes.
- **Accountability, transparency, and integrity:** governance creates structures for accountability, ensuring stakeholders understand their roles and decisions are made transparently, fostering trust among teams and sponsors.
- **Compliance:** ensures governance meets standards, processes and regulatory requirements, maintaining high quality output and compliance within legal, financial, and operational guidelines.
- **Resource optimisation:** with effective governance, resources (time, money, people) are allocated efficiently and address any issues flagged to prevent resource wastage.
- **Risk management:** proper governance helps identify, assess, and mitigate risks early, with proactive management and reducing the likelihood of costly delays or failures.

- **Safety:** governance on quality and safety ensures any variation in service delivery, such as safety concern or unwarranted variation, and acted on as quickly as possible. There is a clear process to identify, and categories concern clear routes to escalate and act on risk quickly.
- **Participation and engagement:** ensuring there are mechanisms to connect with internal and external stakeholders, including clinicians and service users, to feed into the program systematically and continuously.

9.2 Contractual and data governance for Audit and Registry Owners

A core part of governance is concerned with effective contractual data management which includes adhering to NHS England's standard financial instructions, the procurement and business case approval process, contracts management and delivery, risk escalation and mitigation, use of data and IG compliance (notably being able to demonstrate ongoing IG compliance).

All new contract and award extensions must:

- comply with healthcare legislation (see section 7: Commercial)
- comply with NHS England's standing financial and procurement instructions, including business case approval.
- comply with NHS England's contract terms and conditions.
- deliver against the agreed specification.
- have a legal basis for collecting, processing, analysing and reporting data under UKGDPR and the Common Law Duty of Confidentiality (CLDC) (for example, clear informed consent or support under section 251 of the NHS Act 2006), see data governance.
- have clear technical process and functional capacity for delivering required data outputs.
- have appropriate IG arrangements. Where NHS England is responsible for the provision of a registry/database, either by contractual arrangements with a data processor or where it hosts the registry IG arrangements, it must be assessed by NHS England in the first instance to ensure data is collected lawfully. Where audits or registries are outside of NHS England's direct involvement, IG arrangements must be lawful and independently assessed by the organisation(s) hosting them.
- have clear IG arrangements signed off by all parties (for example, GDPR and CLDC requirements)

- clearly communicate with patients about what is happening to their data (including a clear privacy notice)

Other points to consider are:

- we should be working towards principles of only collecting what is needed and not duplicating collections. Digital solutions to join up existing collections, automate data flows, electronic collections and digital methodologies should be explored.
- requested data for other research should be made available with the appropriate safeguards in place.
- understanding that meeting research needs may conflict with collecting minimal data.
- patient expertise and alignment with the infected blood inquiry recommendations
- consideration and flexibility given to how things could be done differently in future.

9.3 Clinical leadership and programme management

Strong clinical governance is essential to the success of clinical audits and registries outlined in section 1: Introduction. It ensures these programmes are clinically credible, strategically aligned and operationally independent, enabling them to drive meaningful improvements in patient care. NHS England's role is to support, fund, commission and function as custodian of audits and registries on behalf of the NHS. However, it does not directly manage them. This separation is critical to maintaining the independence and integrity of clinical leadership and outputs.

Core components of clinical governance for Audit and Registry Owners

- **Strategic and clinical leadership:** involvement of national clinical directors (NCDs), expert reference groups (ERGs), clinical reference groups (CRG) chairs and programme of care directors to guide and shape national programmes.
- **NHS England's role:** NHS England acts as a commissioner, funder and custodian of audits and registries but does not directly manage them. This separation safeguards the independence and objectivity of the data and findings.
- **Clinical independence:** audits and registries must operate with sufficient autonomy to maintain trust and transparency of output. Clinical leadership should be provided by an independent expert faculty, ensuring subject matter expertise and credibility.
- **Co-design of programmes:** national programmes and deliverables should be developed in partnership with clinical leaders to ensure relevance and impact.

- **Quality improvement leadership:** clinical leaders should drive the design and implementation of QI initiatives based on audit and registry data.
- **Risk oversight:** clear processes must be in place to identify, escalate and mitigating quality and safety risks.
- **Practical engagement:** ongoing collaboration with services and expert faculties ensures governance is grounded in real world application.
- **Strategic direction:** clinical leadership should guide the development of new registries and the evaluation of existing ones to ensure they remain effective and valuable.

Principles for clinical leadership for Audit and Registry Owners

To ensure consistency, credibility and impact, all clinical audits and registries, new and existing, must adhere to the following principles:

- have clearly defined clinical leadership.
- be led by a topic specific **expert faculty** comprising domain experts, clinicians, academics, analysts and patient representatives.
- have strategic clinical leadership and accountability within NHS England aligned to national programmes and service delivery.
- establish partnerships between programme teams and expert faculties. Where none exist, NHS England should facilitate its development.
- engage with the wider clinical community with NCDs and CRG chairs playing a key leadership role.

Role of the clinical lead in Audits and Registries

Each audit or registry must have a designated clinical lead responsible for:

- ensuring data quality and assurance
- leading report production and drafting recommendations
- managing outlier identification and escalation
- supporting clinical research and QI

The clinical lead should:

- focus on developing and delivering the QI plan.
- lead NHS engagement and improvement activities based on data insights.

- operate independently of NHS England to maintain objectivity and function as a critical friend.
- be supported by an expert faculty.

Clinical lead requirements

Clinical leadership must:

- be aligned to the external expert faculty.
- integrate existing clinical expertise, networks and evidence.
- be appropriate and proportionate to the scope and scale of the audits or registry.
- be transparent in purpose and development and declare any conflicts of interest.
- conduct fair and open recruitment of clinical leads (in line with NHS England processes)
- uphold the independence of audits and registries.
- follow procurement safeguards for contracting services.
- act solely in the interest of improving NHS patient care.

10.4 Quality and safety governance for Audit and Registry Owners

Understanding and analysing the information and findings should support effective quality and safety governance of care. Concerns should feed into wider governance processes and frameworks (for example, maternity surveillance groups). Using information to identify and understand of variance between ICBs and at service level allow action to be taken on safety risks and issues (for example, outliers) in a timely manner.

All clinical audits and registries must have processes in place for effective quality and safety:

Outlier identification and management:

- must have a clear, documented process for identifying, categorising and managing outliers in clinical findings.
- must notify the relevant provider or local team of any outlier findings promptly, even if preliminary, to enable immediate risk mitigation.
- must support NHS England and the CQC with provider oversight, particularly in relation to patient safety and regulatory responsibilities.

Benchmarking and data access:

- should enable benchmarking of providers or services to allow for meaningful comparisons and identification of variation.
- should provide access to dynamic data reports (for example, non-validated or near real time data) for providers and clinicians. These may need to be anonymised where data validation is pending.

Governance and review:

- must be reviewed through national clinical programmes and governance structures to ensure alignment with NHS quality frameworks.
- should include a defined QI plan to support frontline teams, including tools such as dashboards and peer engagement mechanisms.
- must have a mechanism for disseminating learning and insights derived from audit and registry data.

Patient and standards alignment:

- must include clear mechanisms for patient involvement and feedback (see section 2: Clinical leadership and support)
- must assess against NICE quality guidance and/or standards and best practice models where available.
- must reference clinical standards and service standards which are speciality specific.
- should actively focus on identifying and reducing health inequalities.

Other considerations:

- many registries are clinical information systems supporting the provision of clinical care in real-time to patients. A single model will not work.
- there will be variation in how safety mechanisms are delivered across clinical audits and registries due to the nature and set up.
- expert faculties identify service outliers.
- CQC, MHRA and NHS England should act with commissioners on outliers or safety concerns.

9.5 New overall clinical audits and registries governance in NHS England

A recently established NHS England clinical registries senior leadership team has been set up to bring together key directorate leads which commission and oversee clinical audits and registries. The team will ensure there is alignment of programme and clinical leadership

across the NCAPOP, specialised commissioning clinical databases and registries programme and the ORP.

10. Checklist

This section provides a checklist for NHS England and audit and registry providers and teams to consider when initiating or reviewing clinical audits and registries.

Scope	• Are the purpose and scope of the audit or registry clear? • Have the six key principles been considered?
Clinical leadership	• What clinical leadership and oversight is in place? • What expert faculties have been engaged? • Have clinicians been included within the design and structure of the audit or registry? • Have other national organisation and professional groups been engaged? • Have frontline staff been engaged in the design? Are there any training or specific processes needed?
Patient involvement	• Is there awareness of the working in partnership with people and communities guidance and the organisation's legal responsibilities. • Have patients, communities, parents and the public, been included within the design and structure of the audit or registry?
Methodology	• What are the questions the data is trying to answer and for what purposes? • Have you thoroughly explored what data already exists? • How will you define participation thresholds and has there been clinical involvement in this? • Are you employing the appropriate data analysis and appropriate skills to undertake this? • Have you consulted a wide range of experts? • Have patients been involved? • Is it possible and appropriate to collect patient experience data? • Have you considered the pathway?

	• What type of data are you collecting and analysing? Is this appropriate for the purpose? What is the frequency of reporting and what is the plan for evaluation? • How will you capture and report outliers? • Are you able to benchmark the data findings? • How will you document your analysis, and can it be replicated? • How will recommendations be made?
Data collection and reporting	• Do you have the appropriate IG in place to collect data? • How will the collected data lead to actionable insight? • Has consideration been given to the data collection burden? Is it practically possible? Is there duplication? • What wider technology or data platforms can be used? • Can the data be linked and shared? • How will data access requests be managed? • How will you ensure high case ascertainment and data completeness?
Quality	• How will this support quality planning, control, assurance and delivery of improvement? • How will your findings feed into wider quality governance structures?
Commercial	• Does this comply with NHS England's standard financial instructions (SFI)? • Has the appropriate business case process been followed? • Are there effective contract management arrangements in place?
Legal	• Have you considered how other key functions in NHS England will support and impact on the audit/registry? • How will NHS England legal and statutory responsibilities impact commissioning and delivery?
Governance	• Have clear governance routes been established? • Has approval been sought from the Caldicott Guardian? • Have you followed NHS England standard financial instructions? • Do you have a legal basis for collecting the data and are you IG compliant?

11. Future developments

Areas to explore further over the next decade to enhance the quality improvement and clinical effectiveness benefit from clinical audits and registries may include:

Areas to explore	Detail
Better use of NHS data systems and platforms	• **Reducing burden and supporting a single version of the truth**: a plan for how data can be captured once and inputted onto a single system easing frontline burden. • **Seamless data sharing** that is, joining up data sets or implementing an integrated platform which capitalises on existing data collections. • **Simplifying data flows** into or out of audit and registry collections • **Interoperable data systems** used across NHS (for example, EPR), IS providers, primary and community care and third parties. • **Visuals and wider use:** work with HQIP, NCAPOP and CQC to make key clinical audit metrics available in Model Health System in a consistent format, available alongside other clinical and operational metrics. • **Research and innovation**: improving access and use of audit and registry data to fuel clinical research, trials and innovation, enabling rapid translation of evidence into improved patient care.
Speeding up data reporting where possible to support clinical decision making and QI	• **Real time data:** move towards near real time data collection and reporting. This allows for a more responsive and proactive intervention for patients and healthcare providers. • **Continuous monitoring:** shift from annual audits to continuous data monitoring for better tracking of performance and earlier detection of issues • **Outliers:** a consistent approach to understanding variation and outliers (both negative and positive). • **Disseminating findings** and outcomes effectively, in a timely and accessible manner to the frontline so it identifies good quality care, as well as areas for improvement.

Allowing for a longitudinal analysis and cross population comparisons	• **Developing systems that allow for long term follow up**: patient registries that track long term outcomes for chronic diseases, surgical interventions, or specific populations (for example, cancer patients, those with rare diseases) to improve longitudinal care and planning. • **Cross population comparisons**: enable comparison of care outcomes across different patient groups, settings and geographies to identify best practices and opportunities for improvement.
Use of advancing technology and AI	• **Predictive analytics**: use machine learning and predictive analytics to identify trends, flag potential risks and forecast future healthcare needs. • **Clinical decision support**: leverage AI to support clinicians when making evidence-based decisions, by providing insights directly from audit data and registries
Improved communication and feedback loops	• **Frontline and clinical feedback** of findings and outputs that is timely and accessible and be fed back to frontline services to improve the quality of care. • **Engagement** with medical professionals, managers, patients, policymakers, regulators and others to ensure clinical audits and registries deliver impactful results for multiple users. • **Public access to data**: improving transparency by offering open access to aggregated data, performance benchmarks and outcomes, enabling the public and healthcare professionals to make informed choices.
Supporting the workforce to get the most out of audits and registries	• **A plan to support local delivery** and use of audit and registry findings, including use of improvement resource. • **Data literacy**: ensure healthcare professionals are trained in data literacy and understand how to use audit and registry data to improve care delivery. • **Continuous improvement culture**: foster a culture of continuous improvement by embedding audit and registry use into daily practices and within core improvement functions, providing ongoing professional development on QI techniques.

Supporting patient experience and outcomes	• **Patient reported outcomes**: Include a wider spread of patient reported data (for example, satisfaction, quality of life) where possible to complement clinical data and provide a more holistic view of healthcare quality. • **Personalised care insights (patient experience)**: the use of data to personalise care pathways and track individual patient outcomes over time, particularly for chronic conditions or long-term treatment plans. • **Engagement and feedback loops**: involve patients, and caregivers in the audit process through feedback mechanisms, ensuring registries reflect real world experiences and are continuously improving as outlined by the recent Infected Blood Inquiry.
Supporting equity and inclusion	• **Address healthcare disparities**: ensure audits and registries track and address healthcare disparities across socioeconomic, ethnic and geographic groups to promote equitable healthcare delivery. • **Inclusive data representation**: ensure registry and audit data includes a representative sample of diverse patient populations to guide inclusive and targeted interventions. • **National equity and support across topic areas:** providing support to smaller topic areas or access to relative and proportionate funding.
Better alignment with national programmes	• **Alignment with internal NHS England quality improvement (QI) programmes** such as GIRFT, NHS Impact and Pathways. • **Better integration with the NICE technology appraisal process** to provide 'real world' evidence of efficacy. • **Enhancing the alignment between audit activities and national healthcare priorities.** Ensuring audit findings are hardwired into planning and improvement initiatives. • **Make explicit** the relationship between audits, registries and QI.
Clarifying standards	• **Development standards**: support the development of a set of standards to simplify the development (including use of appropriate methods) and management of registries for the future. This would make their management, platform and provider

	agnostic and ensure they can all be quickly updated simply through changes to nationally agreed standards. • **Assessment framework**: a methodology for assessment of audits and registries enabling commissioning, decommissioning of audits and registries and implementation
Learning from international practice	• **Learn from international systems and the implementation of new technologies**: The Netherlands uses advanced analytics and AI to analyse large sets of data from audits and registries to identify trends, predict health risks and improve patient care pathways. • **Inclusive data representation**: Sweden and Finland have adopted real time inclusive monitoring systems in their healthcare services, which include continuous data collection and feedback to clinicians.
Exploring alternative funding models	• **Incentive based models** that reward trusts and healthcare providers for improving their audit data quality, participating in registries and using insights from audits to improve patient care. • **Competitive grants** that offer competitive funding for specific initiatives, such as the development of new auditing techniques, implementation of AI driven registries, or research that assesses the impact of audits on clinical outcomes. • **Value based healthcare**: Link audits and registries to value-based healthcare models, where funding and reimbursement rates are influenced by improved care outcomes as indicated by audit results. This incentivises providers to focus on quality and patient centred care.

Annex: Current sources of NHS England commissioning

Medical - National Clinical Audits and Patient Outcomes Programme

- The medical directorate holds the NCAPOP (National Clinical Audit and Outcomes Programme) contract. The National Medical Director for NHS England is the Senior Responsible Officer (SRO).
- NCAPOP includes 40+ audits and registries, many are long standing and linked to NHS England's core clinical programmes (that is, maternity, diabetes, cancer and dementia).

- Most of these audits are listed on the quality account list for mandatory trust participation.
- HQIP runs the NCAPOP contract managing multiple audits suppliers, for example Royal Colleges, universities and ALBs, on behalf of NHS England.
- There is regular accountability through meetings and updates.
- National clinical directors (NCDs) lead speciality specific audits through the clinical programmes within NHS England. Each clinical programme has separate programme governance.
- There is a clear process for outlier identification and for feeding into the wider quality governance architecture.

Finance directorate, specialised commissioning

- Specialised commissioning sits within the finance directorate where there are six programmes of care.
- They are funded fully or partially by NHS England and are directly related to the commissioning of specialised commissioning services.
- Note NHS England has a commissioning responsibility here.

Transformation directorate

- The transformation directorate covers the Outcomes and Registry Programme (ORP).
- Focus on development of the Medical Device Outcomes Registry (MDOR).
- Development of new device registries, for example, National ligament Registry, Orthopaedic Trauma Registry and the National Hearing Impairment Registry.
- Includes the National Major Trauma Registry (NMTR), previously known as the Trauma Audit and Research Network (TARN).