Standards for a National Clinical Audit or a Quality Improvement Study
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Healthcare Quality Quest (HQQ) was asked to evaluate an individual national clinical audit being carried out in the UK. We are aware of the limitations of a subjective assessment of a national clinical audit, even if carried out by an organization with considerable, recognized expertise in clinical audit.

However, we were unable to locate published standards against which a national clinical audit could be compared. We checked with recognized international and academic experts in the conduct of international or national quality measurement. They stated that they were not aware of internationally accepted standards on the conduct of a national clinical audit or a national quality improvement project or equivalent activity.

Therefore, for purposes of completing the evaluation of the national clinical audit for which we were commissioned, we needed to establish a more objective basis for making judgements about the conduct of a national clinical audit. Thus, we searched literature describing aspects of good or best practice relating to a national activity intended to measure and improve the quality of patient care, and from the literature, derived what we consider to be standards for the conduct of a national clinical audit, quality improvement study or equivalent activity.
Executive summary

Large-scale studies or clinical audits of the quality of patient care provided in healthcare organizations have been carried out in the UK for nearly two decades. Consensus or evidence-based national or international standards for the operation of national clinical audits or equivalent activities have not been published. In the absence of agreement on best practice for such activities, variation in the management and potential effectiveness of national clinical audits is inevitable. It can be uncertain if an individual national clinical audit or equivalent activity is beneficial to the healthcare system and the patient population served.

Literature has been searched to identify aspects of current practice in the conduct of national or international clinical audits, quality improvement studies, quality indicator measurements or equivalent large-scale initiatives that have the purpose of driving improvement in the quality of care provided in one or more healthcare systems. From the literature, 30 ‘standards’ for the conduct of a national clinical audit have been identified. The standards are on structural, process and outcome aspects of a large-scale activity that involves measuring and improving healthcare services. The standards identified relate to the following aspects of a national clinical audit or equivalent activity:

- **Structural aspects**
  - Ethical basis
  - Governance
  - Stakeholder involvement
  - Resources
  - Roles and responsibilities and project plan

- **Process aspects**
  - Recruitment
  - Improvement–driven aims and objectives
  - Population or sample
  - Data collection strategy
  - Quality-of-care measures
  - Data elements and data sources
  - Data collection protocol
  - Protection of patient identity
  - Identification and handling of ethics issues
  - Training and support for data collectors
  - Pilot testing
  - Reliability testing
  - Data linkages
  - Data quality management, analysis and assurance
  - Preliminary data and peer review
  - Identification of good practice and shortcomings in quality of care
  - Analysis of causes of shortcomings in quality
  - Facilitation of improvements
  - Reports
  - Communication
• Outcome aspects
  – Level of participation
  – Reliability of data
  – Timeliness of preliminary reports
  – Timeliness of complete reports
  – Evidence of improvements

It is hoped that these standards for the conduct of a national clinical audit will facilitate debate on the value of adopting such standards for the operation of national clinical audits or equivalent activities.
Background

National clinical audits have been carried out in the UK since 1994. Equivalent activities have been carried out in other countries under names such as national (and international) quality indicator projects, national quality improvement (QI) studies or national performance measurement projects. In the UK, the purpose of national clinical audits has been to seek to improve patients’ experiences and health through the systematic review of healthcare delivery and to ensure that all patients receive the most effective, up-to-date and appropriate treatment, delivered by clinicians with the right skills and experience. Considerable financial support is needed for these audits and related activities. In the UK, public funding has supported many national clinical audits.

Best practice for the conduct of clinical audits has been described in the UK. However, the publications on best practice are focused on clinical audits carried out by clinicians or clinical teams working in an individual healthcare organization, so-called local clinical audits. Guidance on assessing and improving quality in national clinical audits has been published recently in the UK. The guidance is not explicitly based on national or international evidence related to best practice in the design and conduct of a national clinical audit or equivalent activity. Also, the guidance does not provide explicit standards against which all aspects of a national clinical audit can be assessed objectively.

In the absence of agreement on best practice for such activities, variation in the management and potential effectiveness of national clinical audits is inevitable. In view of the cost of national clinical audit projects in England funded directly by public funding, the current financial pressures on the National Health Service, and the review of data returns for NHS organizations, it is timely to expect that organizations that operate national clinical audits work to standards that are intended to assure best practice in the conduct of such audits. Adoption of best-known practice in the conduct of a national clinical audit should enable demonstrating the effectiveness of a national clinical audit in achieving improvements in the quality of patient care as well as the cost-benefit of participation in national clinical audits.
The purposes of the work presented in this report were to:

- identify from available literature explicit or implicit standards for the design and operation of a national activity that involves measuring and facilitating the improvement of the quality of healthcare services delivered to patients
- find examples of best practice in the performance of such activities that could be used as benchmarks for national clinical audits or equivalent activities
- develop a set of standards for the design and conduct of a national clinical audit.

The purposes of this report are to:

- provide a synthesis of available literature on explicit or implicit standards for the design and operation of a national activity that involves measuring and facilitating the improvement of the quality of patient care and examples of best practice
- present a draft of standards for the design and conduct of a national clinical audit for debate on the value of adopting such standards for the operation of national clinical audits or equivalent activities.
Method

Search strategy

For purposes of identifying sources related to standards for national clinical audits, any activity that involves the measurement of an aspect of the quality of patient care, including clinical processes or outcomes, was included. The types of activities referred to included national clinical audits, national outcome studies, national performance indicator monitoring, national or international quality indicators measurement, national quality improvement studies, and registries.

The following sources were used to find information: Medline and CINAHL databases using PubMed, Ovid and EBSCOHost as search engines; websites for the Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH) and for selected organizations known to operate a national clinical audit or quality improvement study; journals known to publish studies related to measuring and improving quality; professional organizations known to be concerned with measuring and improving the quality of healthcare services; and Google and Yahoo search engines.

The terms used for the searches included: criteria or standards or indicators or measures with clinical audit or audit or quality improvement; performance or quality indicators or measures; scope of work or statement of work and national quality indicators; and registry. Where limits could be set, the years searched were limited to 2000 to 2011. Reference lists in publications retrieved or on websites searched were scanned for additional relevant sources.

Information included and abstracted

Any document that described or specified an expectation related to the design or operation of a national clinical audit or equivalent activity was identified from the source material. All documents were screened and relevant documents were abstracted by one reviewer and the screening and abstracts were validated by a second reviewer.

Much of the material published about what should be included in a clinical audit is written for clinicians carrying out their own clinical audits in an individual clinical service in a single healthcare organization. This information was included selectively in the review if a point was thought by the reviewers of the literature to be relevant to the conduct of a national clinical audit.

Limitations of the search and the literature

The literature search was deliberately focused to identify defined aspects of practice in relation to the conduct of national clinical audits or equivalent national or international activities. Descriptions or reports of national clinical audits were not included unless they made points about the performance of key aspects of a large-scale audit or equivalent activity or to potential standards for the conduct of a national audit.
The literature on the conduct of large-scale studies of the quality of care is not uniform or systematic in the description of methodology used in carrying out the work. This shortcoming is recognized through the publication of the SQUIRE (Standards of Quality Improvement Reporting Excellence) guidelines for quality improvement reporting. In addition, some of the projects carrying out this type of work do not make available detailed descriptions of their methods due to proprietary concerns.

Finally, the literature focuses extensively on processes involved in carrying out a national clinical audit or quality improvement study, for example, the quality of the measures used and many aspects of the measurement process. A good faith assumption is made that high quality measurement and related processes will make a significant contribution to the improvement of the quality of clinical care provided to patients.

Review of drafts

Individuals who are actively involved in clinical audits or quality-of-care measurement at national or international levels reviewed drafts of the standards and changes were made in response to reviewer comments.
Definitions of terms

A national clinical audit is defined in the UK as a project that meets all of the following criteria:\textsuperscript{2}

- achieved or intended coverage at national level
- main focus is the quality of clinical practice
- evaluates practice against clinical criteria or guidelines and/or collects outcomes data
- applies the audit cycle and/or monitors clinical or patient outcomes data in an ongoing way
- is prospective, that is, does not include retrospective reviews of adverse outcomes such as is carried out for confidential enquiries
- includes patients in their governance and includes patient provided data.

The purpose of national clinical audits is to engage all relevant healthcare professionals in systematic evaluation of their clinical practice against standards and to support and encourage improvement in the quality of treatment and care.\textsuperscript{2}

For purposes of formulating the standards, the definition of clinical audit used is as follows:\textsuperscript{4} a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.

The use of this definition has major implications for the conduct of a national clinical audit. The SQUIRE guidelines define intended improvement as ‘changes or improvements in care processes and patient outcomes’.\textsuperscript{12} Guidance for large-scale improvement initiatives in a healthcare system emphasize the importance of the following factors:\textsuperscript{13–14}

- Motivation of the stakeholders — Founding stakeholders have high levels of intellectual and emotional engagement in the initiative and are explicit about what they want to accomplish.

- Foundation and leadership — Stakeholders understand the place of the initiative in the context of the healthcare system and what is needed to achieve desired improvements and they ensure there is respected leadership of the initiative and support of key opinion leaders for the initiative.

- Quantifiable aim and specific timeframe — The intended outcome of the initiative is stated explicitly and there is a clear timeframe for the achievement of the outcome.

- Planning and management, with appropriate resources — The initiative is carefully planned, considering the range of changes that may be needed, including system levers and policy changes that may be needed to effect change in participating organizations. Resources are appropriate at both central and local levels.
• **Performance measures and evaluation** — The impact of change intended to achieve improvement is measured through the collection of reliable and valid data linked to the change initiative.

• **Defined changes or actions to be adopted** — Participating organizations know what change has to take place and how to achieve the change. It is likely that participating organizations will adopt the intervention intended to achieve improvement.

• **A healthcare system environment that broadly supports the initiative** — The healthcare system in which the initiative is being carried out is fully understood by the leaders of the initiative and the system can cope with the initiative.

• **A structured process for spreading changes throughout participating organizations** — The initiative includes mechanisms for disseminating learning across participating organizations, that is, builds a learning network among the organizations involved.

Recognized features of a quality improvement process, as judged by an expert panel, include the following:15

• **Iterative process** — The initiative involves iterative design and implementation of a set of specific changes for improving care, ie, a change package.

• **Feedback at meetings involving participant leaders** — Leaders of the improvement initiative at participating organizations meet at local level to review information on its implementation.

• **Feedback of systematically collected data** — The improvement initiative includes feedback of systematically collected data on implementation of change for improving care.

• **Recognized change method** — One or more recognized change methods are used in the improvement initiative.

• **Data-driven** — The design and/or implementation of a set of changes for improving care is driven by data collected systematically during implementation.

• **Local conditions** — Local conditions at participant organizations are taken into account in the design and/or implementation of the set of specific changes for improving care.
Standards for a national clinical audit

A summary of standards for national clinical audits or equivalent activities derived from available literature is in the table. The standards cover structure, process and outcomes aspects of a national clinical audit.

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Summary of literature supporting the standards

Structural aspects of a national clinical audit or equivalent activity

**Ethical basis**

The justification for the conduct of a national clinical audit or equivalent activity needs to include analysis of benefits and risks to patients in the current healthcare delivery system and whether or not the proposed clinical audit or equivalent activity responds to the risk–benefit analysis.16–17

Considerations for a risk–benefit analysis could include the following:8, 18

- the incidence or prevalence of the condition in the intended population
- the impact the condition has for patients, families or carers, healthcare and/or social services
- evidence that current care is sub-optimal
- evidence of variation in the quality of care among providers and populations
- evidence available from which good quality care is defined such as a national guideline or systematic review
- evidence that significant improvements in health or social care might be achievable
- support for the audit from relevant clinical professions
- evidence that an audit might reduce inequalities in care
- support for national health policy objectives.

The rationale for carrying out a clinical audit should include a statement recognizing the ethical basis for the audit, and specifically relate to the need to improve or assure the quality of patient care.

**Governance**

For purposes of this work, governance refers to direction, oversight, high-level decision-making and accountability for a national clinical audit. Decision-making by the governance function should include design, funding, execution, reporting and dissemination of information concerning the clinical audit. A goal of proper governance and oversight should be transparency to all stakeholders in the audit on its operation, accountability for decision-making and reporting of results.19–20

There should be a named governance board for a national clinical audit, the board consisting of representatives of all the key stakeholders in the clinical audit including patients or their immediate representatives.20 The roles of the governance board should be defined explicitly,
reviewed periodically and revised as needed.\textsuperscript{20} The roles should include the assumption of responsibility and accountability for at least the following:\textsuperscript{20}

- **Executive or steering functions** — Making major scientific, design, liaison, financial, resource, ethical and legal decisions concerning the objectives and operation of the audit. These decisions should be made with appropriate input from clinical, clinical audit and quality improvement experts and others as needed.

- **Scientific functions** — Overseeing the technical design, execution and reporting relating to the audit. The design of the audit, including the quality-of-care measures to be used, should reflect the input of experts in the clinical subject of the audit, clinical audit and quality improvement, information systems and possibly statistics and change management.

- **Liaison and communication functions** — Maintaining relationships with stakeholders in the audit, including monitoring the satisfaction of participants with the operation of the clinical audit; health care organizations and services participating and not participating in the audit; patients or service users and their representatives; funders; and other key stakeholders.

- **Data access, use and publication functions** — Overseeing access to and use of the data created through the clinical audit, presentation of the findings at scientific meetings and publication about the audit in scientific journals.

- **Improvement implementation** — Overseeing the effectiveness of the clinical audit in facilitating improvements in the quality of patient care in comparison to an intended level of improvement agreed by the governance board, and acting as needed to increase the effectiveness of the audit in achieving improvements in the quality of care.\textsuperscript{21}

### Stakeholder involvement

Stakeholders in a national clinical audit include clinicians, including doctors, nurses and other healthcare professionals; clinical audit and quality improvement specialists; patients or service users and their representatives; managers of healthcare provider organizations; commissioners or funders of healthcare services; professional bodies; public health specialists; and potentially researchers, regulators, and representatives of government or other groups. Stakeholders in a national audit should include representative participants in the audit and users of the data collected.

All relevant stakeholders, including patients or service users and their representatives, should be involved from the beginning of the clinical audit through to completion of the audit process,\textsuperscript{6, 22} including the proactive facilitation of improvements as needed. The views of all stakeholders in a national clinical audit should have equal weight in decision-making by the group responsible for governance of the audit.

When people are stakeholders in a national clinical audit, but do not have knowledge or previous experience with clinical audit, appropriate training on clinical audit and their roles and responsibilities in the national audit should be provided.\textsuperscript{6}
Resources

Finite resources are available to support national clinical audits. The resources needed to operate a national clinical audit at national level and the burden on participating sites should be carefully considered when the audit is designed.19–20 The most efficient approaches or methods that are likely to be effective in meeting the audit objectives should be used. In particular, entire population-based audits are not justified when extensive time is required for data collection and validation, especially when appropriate statistically determined samples could be used. Resources allocated to a national clinical audit should consider needs for:

- effective IT systems for collecting, quality controlling and reporting data
- facilitating changes in practice to achieve improvements in the quality of patient care in participating sites.

Roles and responsibilities and project plan

The roles and responsibilities of all people who are involved in the conduct of a national clinical audit at national and participating site levels should be defined.20 Defined roles for the national organization operating the clinical audit should cover at least the following:

- governance functions related to the clinical audit
- design of all stages of the audit
- specification of the standards to be used as the basis for measuring quality
- data collection and submission, including preparation of data collectors
- data collation, analysis and management, including data security and data quality
- identification of good practice and shortcomings in care
- facilitation of analysis of shortcomings and action intended to achieve improvement
- liaison and ongoing communication with participants in the audit
- project management and regular performance reviews against the published project plan.

Defined roles for the national clinical audit at participating site level should cover at least the following:

- leadership and accountability for participating in the clinical audit, including participating in any training required, submission of data and acting on the findings
- data collection, reliability testing of data collection and validation of the completeness and accuracy of data submitted
- action on any problems associated with the collection and submission of data
- review of preliminary data and review of cases in which care has not been consistent with good practice as measured by the clinical audit
- analysis of the root causes of shortcomings in the provision of care at site level
- action to achieve improvements in care as indicated by the audit findings.
Standards for a National Clinical Audit or a Quality Improvement Study

Individuals with responsibility for a national audit at national organization and participating site levels should actively demonstrate commitment to the audit and provide necessary leadership for participation in the audit. Commitment should include accepting responsibility to implement change as needed.

The project plan should be clear about all timelines for the national organization and participating sites and services and the published timelines should be routinely met.

**Process aspects of a national clinical audit or equivalent activity**

**Recruitment**

Factors that may motivate clinicians or organizations to participate in a national clinical audit include the perceived relevance, importance and scientific credibility of the audit; the ability to compare a site’s data with national data and use the information at site level; the risks and burdens of participation; and the presence of any incentives for participation, including availability of technical support. Recruitment and retention can affect how well an audit represents the target population; therefore, well-planned strategies for enrollment and retention are critical.

Goals and processes for recruitment and retention should be described clearly and their effectiveness assessed periodically. Variations between intended and actual levels of recruitment and actual participation should be continuously evaluated for their risk of introducing bias in the audit findings. Reasons for non-participation and non-continuation in the audit should be identified and acted on by the governance board for the audit.

The recruitment process should be fully transparent providing for early and full disclosure of the requirements for participation to potential participating sites, including access to the complete project plan, defined roles and responsibilities, data collection tools to be used and a realistic estimate of resources needed for participation.

**Improvement–driven aims and objectives**

The stated aims and objectives of a national clinical audit should be explicit about the intention to have participating sites use the audit to drive improvements in the quality of care, where the audit demonstrates the need for improvement. The aims and objectives also should be explicit about the intention of the organization operating the audit to lead and support the implementation of any needed improvements in quality.

The design and conduct of the audit should use several strategies that are likely to facilitate improvements in the quality of care in participating sites.

**Population or sample**

The population or sample for a national clinical audit should be clearly defined and selected to approximate the relevant characteristics of the target population as much as possible. Cases to be included in and excluded from the audit should be well specified to ensure that
findings are valid, and where relevant, the specification should be tested to ensure that intended cases are not excluded, for example, by poor coding.

The number of cases to be included, how cases are to be selected including confirmation of a diagnosis or condition when relevant, and the length of time over which data are to be collected, including when data collection should stop, should be planned in accordance with the overall purpose of the audit. The desired number of cases should be selected considering the magnitude of an expected, clinically meaningful effect; practicality; cost; and the intention to show the effects of interventions to achieve improvement from one data collection period to another. Also, the population or sample, along with the data collection strategy and data sources, should be selected to enhance representativeness and to minimize potential sources of bias, and if consistent with the audit’s objectives, enable international comparisons. The number of cases in the population or sample should not place an unnecessary burden of data collection on participating sites.

The organization carrying out a national clinical audit should seek information on the populations or samples used in similar audits in other countries to enable comparisons of findings.

Provision should be made for reporting missing cases to enable judging the potential of bias in the findings.

Data collection strategy

The strategy selected for collecting data, that is, retrospective, concurrent or prospective, for the audit should be suitable for the stated objectives of the clinical audit, the availability and accessibility of data required, and the timing of the audit. The strategy should not put an undue burden on those supplying data.

Quality-of-care measures

Clinical audit measures enable numeric quantifications, usually as percentages or ratios, of healthcare quality for the subject and objectives of a clinical audit.

Criteria should be established by the governance board for the national clinical audit for the selection of quality-of-care measures to be used in the audit. Criteria could include any or all of the following:

- Evidence based — Each measure must be based on a strong foundation of research. A measure of clinical process must be based on research showing that the process addressed by the measure, when performed correctly, leads to improved clinical outcomes. Any process-focused measure should address a clinical process quite proximate to the desired outcome, with relatively few intervening processes. The beneficial effect of processes that are far upstream from outcomes can be nullified if important processes closer to the outcome are not performed effectively. Therefore, the measurement of processes not proximate to outcomes can be of little value. An exception can be for conditions for which there is a low level of scientific certainty of the link between processes of care and outcomes such as the care of people with Parkinson’s disease.
If there is no clear valid published evidence of best practice available for the subject of the clinical audit, the measures used in the audit should be developed through a consensus-building process that involves key stakeholders.35–39

- **Scientifically acceptable** — The measure is fully specified. It accurately captures whether intended care has been delivered.27 The measure is tested and demonstrated to produce credible (valid) and consistent (reliable) information about the quality of care.35, 40–43

- **Important to measure and report** — The measure is important to enable making significant gains in healthcare quality. There is evidence available that demonstrates that current practice and/or health outcomes are less than optimal and that there is an obvious opportunity to improve quality of care through the use of the measure.

- **Usable and relevant** — Intended users of the national clinical audit findings can understand the results of the measure and are likely to find the results useful for quality improvement and decision-making.

- **Feasible to collect** — Data needed to demonstrate compliance with the measure is readily available and retrievable without undue burden on participants in the data collection process, including patients.

- **Efficient** — Measures used in a national clinical audit do not duplicate measurement of current practice or outcomes that may be undertaken through another national audit, programme or activity in the healthcare system. If the national clinical audit needs such data, safe and secure arrangements for data linkages should be used to avoid duplication of effort in capturing data.

- **Measures the patient experience of care** — Depending on the subject and objectives of the clinical audit, measurement should include patient perceptions of the care experience.44–45

- **Avoids risks to patients** — The measure has minimal or no unintended adverse consequences (such as giving an antibiotic before laboratory confirmation of the need for an antibiotic to meet an imposed time limit for treatment).27

Each measure specification should describe at least the following:26–28, 46–48

- the exact aspect of care that is being measured about the provision of quality of care for the target group, often called the criterion

- complete description of the target group to be included for the measure, including reference to the time period in which cases are eligible for inclusion

- any clinically acceptable reasons or explanations that would provide justification to a clinical peer group of the failure to provide quality of care as defined, often called exceptions

- detailed explanation of how to collect the information needed, including definitions of terms used

- exactly how the numerator and denominator will be expressed and calculated for the measure

- if ratings are used, exactly how a rating is to be assigned

- if a measure is based on a survey, for example, of patient experience, the instructions for obtaining the sample, conducting the survey and guidance on minimum sample size.
The quality-of-care measures used in a national clinical audit should have at least content and/or face validity, which should be established by the organization leading the audit. In tests of validity, the sensitivity or positive predictive value (PPV) of the measures should be determined. Cases identified as ‘false positives’ should be identified and subject to individual case review to identify how the measures should be improved.

Measures used in a national clinical audit should be reviewed annually to ensure that each measure is still clinically relevant and continues to meet the criteria established for inclusion in the national clinical audit.

**Data elements and data sources**

Data elements are derived from the quality-of-care measures and their specifications. All terms used in the measures should be carefully defined including exact specifications of ranges of any laboratory values if relevant, findings of investigations and synonyms and acceptable abbreviations.

Data specified for collection should permit judging compliance with quality-of-care measures in accordance with the objectives of the audit, and precise directions should be provided for making decisions concerning whether or not data available is consistent with the measures. A driving force for specifying data elements should be that the data could be used to support quality improvement efforts at local level.

The collection of extraneous, that is, ‘nice to know’ or optional, data should be collected for a clear purpose related to the audit objectives and kept to a minimum.

Preferred sources for data to be retrieved or abstracted should be specified, especially when there are duplicate sources, for example, electronic and paper patient records. Directions for selecting the more valid data source should be provided. If secondary data sources, such as existing databases, are to be used, the reliability of the data in the secondary source should be tested and confirmed.

Measurement of patient-reported outcomes should use only tools that have been designed and validated for this purpose. Measurement of patient experiences with the process of care should use only tools that have been designed and validated for this purpose.

**Data collection protocol or manual**

A complete protocol should describe all aspects of data collection for a national clinical audit, including at least the following: data definitions; instructions for making decisions about compliance with quality-of-care measures used in the audit; data sources to be used; intended data collectors and the competences needed to collect data correctly and completely; how cases to be included in the audit are to be selected; how data are to be recorded or captured; time frames for collection and submission of data; how the identity of patients involved in the audit is to be protected; and how data are to be maintained at local level in case data have to be validated or individual cases need to be identified for some reason; and how data are to be managed, collated, analysed and quality assured.
The data collection protocol should be easily accessible to all stakeholders in an audit prior to the need for participating sites to make a decision on participation in the audit.

**Protection of patient identity**

The governance board of a national clinical audit must assure that the systems and processes designed to protect the identity of patients or service users whose care is measured in the audit are robust and consistent with applicable national laws and regulations, and that they are continuously implemented in all sites participating in the audit. Data submitted by participating sites should be anonymized.

**Identification and handling of ethics issues**

Ethics issues in a clinical audit arise at three stages in the conduct of a clinical audit and provision should be made to handle ethics issues that emerge at each stage: 17, 65–66

- **At the design stage** — The governance board for a national clinical audit should ensure that all aspects of the design of a national clinical audit are checked against criteria that would flag a potential ethics issue in the design of the clinical audit and enable appropriate judgement about the issue.66

- **When the findings of data collection for a national clinical audit are available** — Findings of a national clinical audit should be reviewed by the governance board to identify if there was any risk for patients in the audit if their care was not provided consistent with good practice; if there are any patients in the audit for whom a life-threatening or quality-of-life-threatening shortcoming in care occurred; if data that could be used to identify any patient was disclosed; or if the audit revealed any clinically significant departure from usual clinical care. The board should assure that relevant sites are aware if any of these situations occurred and take appropriate action.

- **When findings from repeat data collection for a national clinical audit are available** — A clinical audit that does not address needed changes in practice should be reviewed by the governance board because of the potential failure to meet the ethical responsibilities of healthcare professionals and organizations to improve quality. If an audit indicates that effective practice is not being provided to patients, it is unethical to continue to provide substandard care and to withhold improvements from patients.

**Training and support for data collectors**

At each participating site, an individual should be named to be accountable for the completion and submission of data for an audit.20

Training on carrying out data collection and submission for a national clinical audit should be available for all clinical or non-clinical staff who will be responsible for collecting and submitting data. 20–21, 35, 42, 46, 67–69 The training can be provided in a variety of ways including online training or case studies, e-learning, at network or other regular meetings, or live workshops. Training or operational manuals for all people with a role in the audit, but particularly for people doing data collection and submission, should be easily accessible.20 Web-based, electronic and live support, with prompt response times, should be routinely and easily accessible for data collectors for a national clinical audit.
Feedback from data collectors about the value of the training, materials and support provided should regularly be sought and the findings acted on.

**Pilot testing**

The entire design, data collection process, protocol and tools to be used in a national clinical audit should be thoroughly pilot tested in several sites eligible for participation in the audit before a national clinical audit involves all intended sites in the audit.\textsuperscript{20, 35, 42-43, 67, 70} Pilot testing should consider at least the effectiveness of the audit design and data collection process; the time and cost involved in collecting and submitting data; the feasibility of collating data to demonstrate compliance with quality-of-care measures; and the likelihood that data collected can be acted on by the range of intended participant sites.\textsuperscript{46} Action should be taken on the lessons learned from the pilot test.

**Reliability testing**

Data collected for a national clinical audit should be tested for reliability using a methodology intended to produce statistical confidence in the consistency of the data reported, sometimes referred to as reabstracting data.\textsuperscript{35, 42, 68-69, 71-79} Reliability of data collection should be tested at each participating site,\textsuperscript{46} which can be done by staff working at the site. In addition, data should be independently reliability tested by the national clinical audit programme.\textsuperscript{19, 68-69, 71-73, 76-78, 80}

The reliability of data for a national clinical audit (both determined at site and national levels) should be reported routinely, along with the findings of the audit.\textsuperscript{69, 72, 75}

**Data linkages**

When a national clinical audit is making use of linkages with electronic records or databases to capture information about the care provided to individual patients, robust systems and processes must be implemented to ensure the continuous security of the linkages.\textsuperscript{8, 19}

To minimize the cost of duplicating data collection and collation by participating sites, when national clinical audits require the same or highly similar patient-specific information, the organizations operating the national audits should arrange to share the information through appropriate secure data linkages.

**Data quality management, analysis and assurance**

The quality of data submitted for a national clinical audit should be monitored and assured.\textsuperscript{19} Systems that use front-end logic to check data completeness, duplication and values at the time of data entry and provide data quality information to sites as they submit data should be used.\textsuperscript{19-22} The data entry system should enable sites to display and download their own data.\textsuperscript{21}

The data collection protocol or manual should describe how missing, invalid, erroneous or contradictory data are handled and how data collected are analysed.\textsuperscript{19-20} Participating sites in the audit should be provided with timely feedback on the quality of data submitted.\textsuperscript{20}
Quality assurance procedures concerning the quality assurance of data, procedures followed in all stages in the audit, and electronic systems used to support the audit should be included in the data collection protocol and evidence of their routine implementation should be provided to the governance board.20

The findings of quality assurance checks should be used to make changes in the conduct of the audit as needed.20

Analysis of data should use appropriate methods to consider sampling variability81 and risk adjustment, as appropriate, including reliability adjusting using Bayesian methods,82–83 as appropriate.

Observations about data quality should be included in reports.

Preliminary data and peer review of cases

Online, preferably real-time, reports of performance should be available for each site for participants to review site-specific performance in comparison to overall national performance; performance in equivalent care settings; and best performance, for example, the performance of the top 10% or the top quartile of participating sites.21

Data collected should be formally reviewed by participating sites through a local peer group process prior to the publication of data.19,68 Participant sites should be able to carry out ad hoc analyses of their data.19 The peer review process at site level should review the analysis of risk-adjusted results and cases not consistent with good practice at local level and should involve preparation for implementation of improvements.84–85

Participating sites should be able to correct or modify the data held in the national clinical audit related to their performance prior to publication, if evidence of error or inappropriate judgement in data collection is supplied to the national clinical audit. Although there can be concern about gaming of results if participating clinicians review their own data prior to publication of national clinical audit findings, a study of clinicians identifying 650 medical exceptions to quality-of-care measures concluded through a peer review panel that 93.6% of the exceptions identified were appropriate, 3.1% were inappropriate and 3.3% were of uncertain appropriateness.48 After clinical staff received direct feedback about inappropriate exceptions, 42% changed management. The peer review process took less than 5 minutes per case.48

Identification of good practice and shortcomings in quality of patient care

In addition to identifying areas of good practice as demonstrated through the audit, a national clinical audit should identify explicitly the gaps between the quality of care being delivered to patients or service users and what was agreed as best practice as represented in the quality-of-care measures used in the audit.5,19,86–88 Participating sites should easily be able to determine their levels of performance in relation to the identified shortcomings in quality of care.
Analyses of causes of shortcomings in quality

A national clinical audit should help participating sites to understand the causes of their shortcomings in care, through provision of examples of analysis of variation and root cause analysis of audit findings and case studies. The contributions of existing processes and systems; tools, including electronic prompts; policies (or the absence of needed policies or outdated policies); availability and allocation of staff with appropriate knowledge and skills; the care environment and facilities; lack of multi-professional teamwork approach to care; failures in documentation or information provision; breakdowns in communication, including with patients or service users and their carers; aspects of the organizational or clinical service culture; or other potential causes of shortcomings in quality should be recognized explicitly in order to guide participating sites to implement the right actions to achieve improvements in care.

Facilitation of improvements

The Cochrane systematic review on audit and feedback concluded that feedback to healthcare professionals about how their clinical practice compares with that of their peers or accepted guidelines may not be effective in leading to improvements in practice. Healthcare organizations that have high levels of compliance with good practice guidelines tend to provide timely, individualized, non-punitive feedback of clinical audit findings to clinical staff.

A national clinical audit should adopt and implement a framework for spread of good practice among participating sites. The sites should have access to a robust quality improvement framework and tools for facilitating a culture of improvement of patient care. The national audit programme should identify what works best among improvement initiatives and encourage the rapid adoption of those initiatives among participating sites. As needed, the national clinical audit programme should assume responsibility for creating and marketing practical tools for participating sites to use to help improve their performance, including case studies, templates, risk stratification tools, pocket cards, drug dosing nomograms, discussion forums and educational materials available through webinars and slidesets.

The national audit should promote examples of improved or sustained excellent performance so that continually updated best practices are disseminated to all participating sites, including through access to existing professional meetings and conferences and the use of awards recognizing substantially improved practice. Poster and oral presentations of local improvement success stories at professional meetings and national conferences based on the national clinical audit experience should be encouraged.

Generic recommendations that relate to the need to implement best practice, as represented by the quality-of-care measures used in an audit, should be avoided.

Timely, complete and informative reports

The national clinical audit should produce complete and useful reports in accordance with a strict timeline. Reports should reflect the SQUIRE guidelines for reporting on quality improvement studies to the extent feasible.
Reports to participating sites should be designed to help sites quickly and easily identify their top areas of needed improvement in relation to their peers. Reports on national clinical audits should be provided for groups of identified stakeholders, including patients and service users.

**Communication among all stakeholders**

Communication with all stakeholders should be maintained throughout every stage of the clinical audit, particularly with management, clinicians and data collectors in participating sites. Communication should be provided in the manner and within timeframes specified in the governance arrangements, roles and responsibilities and project plan.

**Outcome aspects of a national clinical audit or equivalent activity**

**Level of participation**

The governance board should establish a target level of participation in a national clinical audit by eligible organizations or services and publish the participation rate in relation to the target.

**Reliability of data**

The governance board should establish a target level of reliability of data collected and publish the findings of reliability testing of data collected. Reliability testing or independent validation of data collection should demonstrate that the reliability of data collected for the clinical audit is at least 90% or an equivalent kappa score.

**Timeliness of reports on preliminary data**

Reports of preliminary data collected should be supplied to participating sites for local review in real time or within a deadline of weeks following submission of the data, the deadline to be established by the governance board.

**Timeliness of complete reports**

Complete reports of national clinical audits are supplied to participating sites and other stakeholders within a deadline of weeks of the deadline for review of preliminary data by participating sites, the deadline to be established by the governance board.

**Evidence of improvements in quality**

Evidence of improvements in the quality of care from one time period to the next of the clinical audit must be sufficient to justify continuation of a national clinical audit, in view of the resources committed to the audit. The governance board should establish and apply measures of success in judging the effectiveness of the clinical audit.
If the need for improvement is still evident but the level of improvement is not significant, the governance board should act to determine how data are being used to drive quality improvement. The board should make changes in the operation of the audit to influence the implementation of actions needed in participating sites to achieve needed improvement.
Summary

This report is intended to identify possible standards for the design and operation of a national clinical audit or equivalent activity, using available literature on national audits or equivalent activities and examples of best practice.

The conduct of a national clinical audit is dominated by a large number of process stages, each of which needs to be carried out in the best possible way in order to provide the best quality of data about patient care. In addition, there are key structural aspects of designing and operating a national clinical audit that are critical to the success of the audit. A national clinical audit should be accountable for the outcomes the activity actually achieves, and a short list of possible outcome measures is identified.

It is hoped that the possible standards in this report will be debated among stakeholders in national clinical audits, and that such standards become the basis for undertaking national clinical audits or equivalent projects in the future.
References


24. Harris AH, Reeder RN, Ellerbe LS, Bowe TR. Validation of the treatment identification strategy of the HEDIS addiction quality measures: Concordance with medical record review. BMC Health Serv Res 2011;11:73.


49. Davies S, McDonald KM, Schmidt E, Schultz E, Geppert J, Romano PS. Expanding the uses of AHRQ’s prevention quality indicators: Validity from the clinician perspective. Med Care 2011;49(8):679–85.


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