

## Assessing and Improving quality in national clinical audits

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### Purpose and audience

This guide is aimed primarily at those setting up and running national audits and clinical databases in the UK, to enable them to assess their current or intended project against various indicators of quality, and thus enable their audit to be of maximum utility and value.

The guide will also be useful to others who use or participate in clinical audits, such as patients, commissioners, service managers and local services, in order to make an assessment of the value of the audit concerned, especially in relation to deciding whether to participate.

### Introduction

Clinical audit is a long established method in measuring compliance with best practice in healthcare and making improvements as a result. National clinical audits are still very much a cycle of improvement, although they may have added purposes at the national level, except that different

people carry out different parts of the whole cycle – the data collection, analysis and subsequent action.

The various leaders, participants, policy makers, managers and consumers of clinical audit all have their own perceptions of what makes a ‘good’ or effective clinical audit. Their requirements and perceptions of the purpose of clinical audit may not be the same and they may not all want the same thing or share exactly the same expectations of a clinical audit. This guide attempts to review all the various factors that can be, or are used to assess the value of clinical audits by all these different parties and to give an overview, synthesised from learning from stakeholders and our own experience of running, contract managing and supporting the use of national clinical audits.

This guide uses the terms ‘good’, ‘quality’, ‘utility’ and ‘useful’ and ‘value’ at various points in describing assessment in regard to national clinical audit. Whilst all closely related they are not the same, and the criteria that constitute them are different for different people. This guide looks at various aspects held subjectively by different stakeholders.

## **Issues to consider**

### ***What is the purpose of the project?***

There is general consensus that the primary purpose of any clinical audit is to drive changes in practice that improve healthcare outcomes and deliver improvements in the way patient care is provided in line with best practice standards. There are other benefits and purposes but this has primacy.

Clinical Audits can also have a variety of other purposes and uses:

- To gather data that demonstrates clinical outcomes
- To compare practice between different services or even individuals
- To inform and assure patients
- To provide a reserve of information that can be used for research
- To enhance the status of a specific intervention or area of practice through providing evidence of outcomes
- To inform clinical practice on a longer term basis
- To gather information to maintain patient safety
- To inform commissioning and policy
- To measure and improve equity of care

These purposes are not exclusive, but the predominant intention built in by the audit designers inevitably shapes the balance and form of the audit and affects perceptions of its value to the variety of audiences given above. The specific mix of emphasis in any particular audit will lead to features being present in the audit that will make it less or more useful for its primary purpose of driving change, and more or less useful for the other purposes. These various factors which cloud or obstruct the achievement of the primary purpose, can mean that that aim of improving care is sometimes diminished or obscured.

Those who create national audits need to consider what the interests of **all** those persons with stakeholder interest in audit are, when designing and improving their audit, starting with its

purpose. A national audit must achieve: local utility and value for local people if it is to improve local patient care and outcomes; alongside meeting any other needs existing within the team leading the audit; and satisfy the needs of policy makers at the national level. However there should also be a clear focus – collecting too much varied data, to please and meet the needs of too many stakeholders, is not going to improve the value of the audit.

Anyone nationally designing a national clinical audit must give consideration of its value at local level given that the hard work of collecting the data is done by local people. At a local level there may not be much choice whether to participate, but the national context and the rationale for the audit should be clearly defined and communicated, and the needs of those who supply the data respected. This is not something that should happen only once the audit has started; ideas for national audits need to be grounded in the clinical needs of local clinicians too; there must be dialogue at the design stage of audit about its utility to local specialists.

### **Quality/Utility**

There are many ways to assess the quality of an audit, depending on what your criteria are from your perspective, and this is partly related to the issue of purpose discussed above. The simplest assessment of the value of an audit is based on whether it achieves its purpose, that it has utility. 'Quality' is not quite the same as utility; knowing something has quality against some criteria but has limited value overall to all those who take part or use it is not a good, or sufficient reason for them to participate or for it to be run.

For some, a good quality audit is one that drives clinical practice effectively at an immediate level; an audit which appears to be mostly a research project may not appear to be as good in quality to local clinicians, for example. For others, quality is primarily determined by how accurate the data is. This guide attempts to look at the **various** elements which define quality and does not emphasise one against another, give that a variety of people, with different perspectives, are making a judgement, based on their particular view of the intended purpose.

However, if the primary purpose is driving change, then it is worth quoting these remarks which appear on p 308 in the US textbook on databases and registers, by Gliklich and Dreyer (2010), a useful guide for anyone designing or operating registers of various types, and found at

<http://effectivehealthcare.ahrq.gov/ehc/products/74/531/Registries%20nd%20ed%20final%20to%20Eisenberg%209-15-10.pdf>:

*'Registries may be very useful vehicles for providing clinically relevant real world information, even when they meet relatively few of the basic elements of good practice (typically because of budgetary limitations). In many cases, some data are better than no data, and even registries that fall short of including all the basic elements of good registry practice may still provide valuable insights about real-world medical and consumer practices and disease etiology, and may be particularly valuable for modeling exercises.*

*Evaluations of the quality of any registry must therefore be done with respect to the specific purpose of the registry, must take into account both the internal and external validity of the data, and should be tempered by considerations of cost and feasibility.'*

## **Existing criteria of audit quality and value**

HQIP have produced a document, based on extensive consultation, that defined criteria for best practice in clinical audit: <http://www.hqip.org.uk/criteria-of-best-practice-in-clinical-audit/>

Whilst this sets out the components of high quality audit this is by its nature a high level document which covers audits of different types, both national and local; and audits at these levels do have different characteristics. Nonetheless this document is a useful starting place to determine whether an audit meets basic principles, agreed by those working in audit, for what constitutes good quality audit. Some of these aspects are also covered in the guide 'New Principles of Best Practice in Clinical Audit (Burgess ed. 2011). Other HQIP resources also recommend aspects of good audit quality.

NCAAG, the Department of Health's advisory group, has set out what for them are their criteria for why an audit will be chosen for national funding, which of course is not the same as an overall set of criteria for quality; and in their list of audits to be included in quality accounts, a further set of criteria for inclusion on that list. These are found at:

<http://www.hqip.org.uk/assets/Downloads/NCAPOPTopicproposalcriteria.pdf> and

<http://www.hqip.org.uk/national-clinical-audits-for-inclusion-in-quality-accounts#criteria>.

## **A set of criteria for assessment of value of national audits**

Over time, as well as clear purpose and intent, a further set of key features have come to be associated with the most effective national audits, especially with regard to estimating their value at the local level in driving and assisting change to happen:

### **Cost**

Some audits are funded nationally, some by levy or capitation fee; some by subscription from local trusts. The cost may be a factor used to judge quality by those who pay nationally or have to pay locally. A very effective audit can be very cheap to run; there is no necessary relationship between cost and value; but high cost, low return is a major factor in many people's assessment of quality.

### **An audit must address a clinically important topic**

In general terms, to lead to an audit becoming funded at the national level, this tends to mean coverage of a condition or procedure which is common, or expensive, or causes the most challenges in service provision. This is because the burden of cost associated with that condition at a national level justifies the level of spending needed to run a national audit. This cannot be measured simply in number of cases and the costs associated with them, because these costs at an individual patient level vary between conditions which have individually large costs, through long patient stays for example, as compared to conditions involving a very large number of short consultations with less cost per event, or very expensive procedures. In nearly all cases of audits funded by government there are likely to be heavy costs or demand in nearly all local healthcare settings, and as such most providers and other stakeholders will see the value of the audit because they will share recognition of the burden the issue causes.

However national audits from specialist bodies where there is no government funding may not be able to meet these criteria; the topic may be very clinically important to that speciality, but aggregated nationally, may not compare with other conditions in terms of either national or local clinical or financial burden. In these circumstances the concept of 'a clinically important topic' can only be subjective. For a specialist provider unit, say in orthopaedic procedures, women's health, or paediatric medicine, a specialist audit in their clinical area may be very clinically important; but for a general hospital for example, local factors, such as the volume of complaints and incidents, and local demography will affect local perceptions of value and utility. A patient group will have its own perceptions of value dependent on their perspective.

### **The audit must have professional endorsement and leadership**

Audits can be led by any kind of organisation, but realistically a national audit needs to be led by specialists in their field. Typically this will include clinicians in the relevant discipline who are recognised as expert and have experience and support from their professional body. An audit ought to have proper connections with a Royal College or specialist society – this includes practical and actual support and endorsement. There should be a clear clinical lead who has a track record in projects of this type.

## **There must be adequate methodological and IT capacity, aptitude and infrastructure**

All audits should be technically capable of collecting and analysing data to a high level of quality and rigour. Without functional credibility an audit will not be supported or valued nor achieve the aims it sets itself.

Audits should be able to describe how they address these issues, ideally in a clear protocol document for the audit:

- Ensuring good data quality, with proper procedures for checking and reviewing data, on sampling and data definition, the target population, case ascertainment, the size and duration, assessment of bias, data linkage, use of pre-existent data sets and many other technical points
- Proper data release and control processes, with proper attention to data security and data storage, consent and release within proper Information Governance protocols and legal requirements
- How case mix adjustment is undertaken and what evidence base is used to justify this
- Data collection systems (ideally on-line, by CSV file, or by extraction methods, using validated data tools) and the timeframes and systems for organisation of data entry and supply
- The systems and approaches used in data analysis and statistical process review
- Ethical issues relevant to conduct of the audit have been considered

These are not the only methodological issues but they are important ones. A team should be able to show they have adequate IT and methodological capacity and competence in their governance and operations.

## **Reporting and communicating findings**

Before reporting, good methodological and analytical work will have taken place to ensure the report is professionally credible and fit for purpose. This should involve suitable and adequate checking, ideally by a third party with suitable expertise.

More generally the audit should be able to say when they are going to report and how, and in what formats to which audiences, and carry this through to realistic timetables. They should be able to say clearly the level of reporting (i.e. Trusts/units/individual doctors etc) and whether the data will be reported to different audiences – such as regionally, in a form for patients, for hospital managers and commissioners and so on, to support and enable personal decisions about accessing particular centres of care, to compare results nationally and to aid local commissioning and contract management. The best audits will clearly say when their reports are to be made available and what they will contain. They should deliver as promised.

Audit reports should be in the public domain. That said there are effective audits which only publish data to those who took part, and then not in comparative form – i.e they can't see themselves compared to their named peers. Whilst this position is understandable, in practice where the process has been paid for using public funds this data should be available to the public. All audits funded by the Department of Health (the NCAPOP programme) are publicly available and will over

time all work to show information publically to the level of local provision, in a variety of formats for different audiences. Non-NCAPOP funded audits will need to consider how they can widen access to their reports. Whilst clinical teams may take part in some audits only on the condition that their data is not made public to third parties or the public, and some national audits guarantee this to them, it should be recognised that the public – that is consumers, and also commissioners, have a right to view these data and a good audit is one in which the findings are widely available.

Where funded by central government, there must be full compliance with the requirements for full consultation before reports are issued.

### **Helping local providers to act on findings**

Reporting is one thing; providing supporting material to each participating provider to help them act on the findings is another. In a local audit, the whole cycle of measuring and acting on the findings should be carried out by the same team. In national audit, the national collecting team cannot be the persons acting on the findings in terms of local healthcare practice. However the best national audits recognise that their role is not just to collect and report data and assume this is enough to drive change locally, but to actively help local people to use the data to make changes in their practice. This can partly be achieved, as above, through high quality reporting, but in the best audits reporting is not the only 'return' to local people and the 'offer' from the central team also involves tailored information for individual providers advising them how they can improve their services to address specific weaknesses or non-compliance. This can be in the form of written material, in many forms and levels of detail about the local provider's failure to match standards (taking into account case-mix in the best audits), or it can be in the form of workshops, training, advice and guidance on service change methods, templates for service re-design and action planning, opportunities to hear about high performing teams, and seminars to help people understand the findings and act accordingly. The change part of audit is often the weakest, both locally and nationally and historically some national audits have done little to drive change. The very best will see themselves as much more than the 'research' part of the audit cycle and that they can have a role and influence, as an informed national body, involving senior and respected clinicians, in being part of the 'action' or 'change' element of the cycle. Where an audit, for whatever reason, can't do this then perhaps it is a sign of a lack of roundness in the skill mix at the national level. Championing of change by senior clinical figures associated with audit is far more likely to lead to change in clinical practice than all the advanced statistical tests being applied to the data, valuable though these are. Analytical skills are not enough; there has to be promotion and communication as well.

Any audit should be able to set out, on request, how it will help local providers in line with the above.

### **Involving patients and consumers**

The best audits are partnerships between professionals, clinicians and methodologists working with patients. Typically this will be in the form of patient bodies being represented in audit governance and in audit content and design, but it should also mean the existence of a patient panel who are actively involved and consulted; the inclusion of standards and data that measure client experience; and, where appropriate it should also mean patients being involved in collecting and even analysing

their own data; and of course, as above, in good reporting in a way that patients, as non-technicians, can understand and use. Patient outcomes should form a part of most audits.

The level of patient involvement should be easily communicated. Practice should be in line with guidance produced by HQIP available on our website.

### **Responsiveness**

Many local providers often complain that their main problems with national audits are that they do not communicate well with local people, and do not say when they will collect data, respond to messages and queries, and do not report their findings when they say they will do. They do not try to fit their data schedule in with the needs of local practitioners

In contract management with NCAPOP audits HQIP tries to ensure the audits we fund are effective in these areas; there will always be occasions when practice falls short of what both we expect, and these will be addressed in contract monitoring; but HQIP will want to see evidence of established lines of communication and demonstrated methods of meeting the constituency of the audit, whether this is through an ebulletin, a website or a meeting, on top of the periodic audit report. That alone is not enough.

There should also be evidence of listening – ie that there are changes made in response to any critique made. The best audits are ones where they make real effort to find out the views of local people, and who are at the heart of networks of change in a specific discipline. The best audits are part of a wider drive to change and improve care and where the audit is organically part of clinical networks. A good audit will be able to describe clearly how communication can happen and how they can be contacted and discuss issues; and be responsive to points raised.

### **What is measured – outcomes and more**

Quite often local providers claim that national audits collect a lot of data that they do not see being valuable; or that they collect only a very small set of indicator data which does not seem to justify the cost and burden the audit creates. This is a tough area to consider, as what one local clinician and provider will judge a sensible burden may seem too much for another. It is also related to purpose, as described above, because measurement follows purpose. Any audit ought to be able to describe **why** they are collecting **what** – and justify the **cost/burden**.

HQIP has been working with audit providers to reduce down the volume of unnecessary data they collect to enable them to focus on what is most needed and useful, especially where it enables measurement of outcomes, as the current government requires. Not all audits, and not every part of every audit can measure meaningful outcomes, and it is still right to measure compliance with process that is proven by research *to be likely* to deliver better outcomes. Once again there will have to be a judgement whether the data to be collected, and what it says, is valuable to both local clinicians and national audiences.

There is also the issue of organisational versus practice audit. Organisational audits are perfectly meaningful as part of a wider programme that also measures the quality of care. However 'audits' which are really only a survey of whether such and such a service exists, and nothing more, are not really audits at all.

### **Good, accepted standards**

All clinical audit is about measuring performance against agreed, measurable standards derived from a suitably authoritative source – or is it? Some local providers say that some national audits are not audits at all in that there are no obvious standards, or that the standards are identified as they go along by some national audits. In practice, it is said they simply collect data, and out of the data collected determine what good practice should look like – in practice a form of research. It is audits of this type, which tend to collect a lot of data, which are often the least appreciated locally, because they don't offer an easy benchmark of current practice against a norm nor drive local improvement in a dynamic, continuous way. Collection of data takes a long time, and standards are not defined at the start. Data is often supplied for some time (perhaps years or even tens of years) before it is clear that a certain level of practice does not have such good outcomes, and as a result, a standard can then be set for good practice that does. During that time, participation can be a trial for local people. At the end however, such audits can deliver often groundbreaking recommendations for different or improved ways of carrying out healthcare.

Weighing up the merits is difficult. However audit providers should be able to explain why there are not standards at the start and the timetable for how they will be produced, and when a local provider will be able to see comparative data being produced. The length of this timetable is clearly an important factor in assessment of quality.

It is also the case that some audits measure against clear standards, but these standards are not as widely accepted in ordinary practice, not because local clinicians are unaware of the standard, but because it is not universally accepted, or perhaps always practical. This may affect clinician buy-in and is an important factor to consider in the assessment of quality.

### **Fit with other demands**

Utility and value are often determined or can be determined, by the dual utility of an audit for various purposes or reporting requirements. The NHSLA have expectations, as do CQC for regulatory purposes and commissioners for performance management. NICE looks to see audits against its guidelines and new Quality Standards. An audit which enables data for use in other processes or evidences compliance, or avoids the need for local studies, has potentially greater utility.

## Putting it all together

The exact balance of these factors in weighing up audit quality and utility overall is a complex decision, because the needs of patients, commissioners, those who run audits, local clinicians and provider organisations, national governments, researchers, professional bodies and any other users and practitioners of audit may all be different. Despite the need to consider the utility of the audit from all these perspectives, there is still a pressing need to maintain a clear vision for the purpose of the audit and to ensure audit design is closely aligned to that vision so it does not become unwieldy – and not try to be all things for all people. That central purpose, of driving improvements and outcomes at the local level still needs to be pre-eminent.

In a national audit with the endorsement of central funding, the vision for the audit is determined by the relevant clinical groups, and informed and directed by the policy and practical interests of the Department of Health or other authority, HQIP, NCAAG and National clinical directors. Because it has gone through these filters, a centrally funded audit is *perhaps* more likely to be of higher quality and wider utility, but even national audits in this group need to continuously strive to achieve the indicators given above.

In other audits, from specialist clinical groups, the vision may not always be constructed collectively through several organisational and policy channels in quite the same way; it may come solely from a clinical perspective, or often through a joint patient/clinical perspective.

From either source, that vision should be communicable and intelligible to anyone hearing about the audit; and the method for its execution proposed or in place should be equally understandable and robust. Lastly, these factors need to be triangulated against cost. Audits of all types need to reflect constantly how they can meet these indicators of utility, value and quality in achieving their primary purpose.

Put in diagram form this interplay of factors looks a bit like this:



## **Where can help be obtained?**

HQIP advises those developing national audits or considering doing so, especially in the run up to national commissioning opportunities.

We offer practical advice, setting out the considerations above, and giving greater detail on these; but we also signpost to other sources of help. This includes referring people to the various texts HQIP has produced or commissioned, and available on our website; and to the reference works identified, and to other audit providers and those with specialist expertise in aspects of audit, such as methodology, who may be able to advise. Those who run audits are often prepared to share their experience with others. We can facilitate introductions.

HQIP also provides events, both larger conferences and smaller seminars, on matters of quality and improving value in national audits. These are announced well in advance to those signed up to our E-bulletin, and on our website.

In its procurement of national audits and the assembly of specifications for these, and in its contract management role, HQIP also consults widely to achieve the consensus view described as needed above, and offers guidance and sets expectations of audit providers. We channel issues arising from local services and other stakeholders to those we commission, to help them improve their audits and to design better audits in the future.