

Guide to Ensuring Data Quality in Clinical Audits

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Healthcare Quality Quest

Clinical audit tool to promote quality for better health services



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1 Introduction

1.1 Who this guide is for

This guide is for leads, managers and staff carrying out or supporting participation in national clinical audits and for the following people who are involved with clinical audits in individual healthcare organisations:

- Clinical audit or clinical governance managers and staff
- Clinical audit leads
- Clinical audit committee chairs and members.

1.2 How the guide is intended to help

Clinical groups are sometimes expected to make changes in patient care, based on findings of clinical audits. Clinical groups need to have **confidence in clinical audit data** in order to agree to change their practices.

Retrieving data from electronic or paper health records for clinical audits is inherently more complex than clinicians may imagine.¹ Factors such as imprecisely worded directions for making decisions about the quality of care, vague definitions of key terms, poorly designed data collection tools, inappropriate interpretation by data collectors, and poor or missing recording of data in data sources may compromise data quality.¹

This guide describes how a clinician or group carrying out a clinical audit can ensure the quality of data collected for the audit. It includes:

- what data quality means
- what's involved in achieving quality data for clinical audits
- how to ensure that the purpose or objective of a clinical audit is so clear that it identifies the nature of the data needed for the audit
- how to ensure that the cases selected to be included in or excluded from a clinical audit are the right cases and that cases selected won't produce biased results
- how to test the validity of clinical audit standards
- how to check if data collection processes are producing reliable data
- how to select data collectors for a clinical audit and ensure they are doing the right job
- how to quality control data collection and data entry
- how to avoid pitfalls in data collection
- how to make arrangements for sharing data for clinical audit purposes across healthcare organisations and ensure that information governance requirements related to clinical audit data are being met.

Examples relating to data quality for clinical audits are provided in the guide.

2 What's involved in data quality

2.1 What data quality means

Data quality has been recognised as an issue in the NHS²⁻⁶ and NHS organisations are implementing strategies to audit and improve the quality of data produced.⁷ Data quality has been defined by dimensions or characteristics including accuracy, availability, completeness, relevance, reliability, timeliness and validity.^{3, 8-14} In addition, some informatics experts define data quality as data that are 'fit for purpose'.¹¹ The key terms related to data quality are defined in the box, particularly as they apply to data about patient care.^{3, 8-14}

| Characteristics of data quality and their meanings | |
|--|---|
| Characteristic | Meaning |
| Accurate | Data are correctly input and reflect exactly patient care transactions. There are no mistakes in the data in comparison to data in an original data source or to what actually happened. |
| Available or accessible | Data enable identifying exact patients or events correctly and can be retrieved relatively rapidly when needed. |
| Complete | All the elements of information needed are present in the designated data source and no elements of needed information are missing. |
| Fit for purpose | Data are suitable for their intended purpose . |
| Relevant | Data are of interest to data users to enable them to meet the intended purpose of the data. |
| Reliable | Data are the same no matter who collects the data or when a person collects the data . |
| Timely | Original data are recorded contemporaneously with the provision of patient care or service and are available in time to make safe decisions about the quality of patient care or service. |
| Valid | Data meaningfully represent exactly what they are intended to represent . |

Patient care data also must be **secure** and **confidential**.

2.2 What's involved in achieving data quality for clinical audits

Data quality in a clinical audit is not simply about data collection. Achieving data quality is embedded in **all the stages in a clinical audit**.

Key questions about data quality should be asked at each stage of a clinical audit. The questions are in the box, along with an explanation of what's involved in each stage and the related characteristic of data quality. **To provide clinical groups with a true picture of the quality of patient care that justifies changing current clinical practice, the answers to all the questions have to be yes.** In addition to the characteristics of data quality described in section 2.1, there are other characteristics of standards used in clinical audits and these are also included in the box.

| Stages of a clinical audit that involve data quality and questions about data quality at each stage, what's involved and the characteristic of data quality involved | | |
|--|--|---|
| Clinical audit stage and key question | What's involved — Being sure that: | Data quality characteristic |
| Design — Is the purpose or objective of the clinical audit right ? | The purpose, aim or objective of a clinical audit is explicit about confirming current good practice or improving current practice. | Fit for purpose |
| Design, especially case selection — Are the right cases selected to be included in the audit? | There is no bias in the selection of the intended or actual cases included in an audit. The cases to be included in and excluded from an audit and the directions for making the inclusion and exclusion decisions are explicit. All the intended cases are retrieved for an audit and there are no missing cases . | Unbiased and complete (for case selection) |
| Development of standards — Are the right things being measured about quality? | The objective(s) of an audit is(are) translated into specific aspects of the care to be measured in the audit. | Valid Relevant |
| Development of standards — Are the measures right for the things being measured? | The measures, such as standards, developed for a clinical audit are capable of pinpointing instances of good and not-so-good patient care consistently and efficiently . | Sensitive and specific (see page 18 for definitions) |
| Development of standards and data collection — Can data be retrieved for the things that are being measured? | The data needed to make explicit decisions about whether or not there is compliance with agreed standards exist or are capable of being gathered relatively efficiently . Depending on what is being measured in an audit, data also can be collected contemporaneously with the provision of care. | Available or accessible Timely |

Stages of a clinical audit that involve data quality and questions about data quality at each stage, what's involved and the characteristic of data quality involved

| Clinical audit stage and key question | What's involved — Being sure that: | Data quality characteristic |
|---|--|---|
| Data collection — Are the data collection processes right for what is being measured? | The way data are collected for a clinical audit produces data that enable clinical groups to be confident that the data are consistent no matter who collected the data or when the data were collected. | Reliable |
| Data collation and validation — Are the data being checked prior to analysis ? | Data collected for a clinical audit are correct and complete . | Accurate Complete (for clinical audit standards) |
| Data analysis — Are the data being analysed the right way ? | The analysis and presentation of clinical audit data enable clinical staff to see easily if current patient care is or isn't consistent with the audit standards used to measure quality of care. | Fit for purpose |

The following sections of the guide suggest how to ensure data quality at each of the clinical audit stages described in the box.

3 How to ensure that the purpose of the clinical audit is right

The purpose of a clinical audit is to:

- **confirm** that the **current quality** of care is **consistent with best practice** or
- **demonstrate that the quality of care is improved** by acting on shortcomings shown in current care and repeating data collection to show the effect of actions taken.

An objective for a clinical audit has to be clear about the **aspect(s) of the quality of care** that is(are) to be measured in comparison to best practice. A model for writing an objective for a clinical audit is in the box.¹⁵

| Objective model | | | | |
|---|---|--|---|--|
| Verb | + | Quality focus | + | Subject |
| The intention for doing the clinical audit—exactly how the audit relates to confirming or improving quality | | The feature(s) of quality to be measured by the audit—what the audit will focus on | | The specific care or service the audit is about—what the clinical subject of the audit is |
| <i>Enables fit for purpose</i> | | <i>Indicates data to be collected</i> | | <i>Indicates cases to be included and excluded</i> |

The quality focus part of the objective identifies the **nature of the quality of care to be measured, and therefore, the data** to be collected in an audit. An example is in the box.

Objective for a clinical audit on chest drains and how the objective relates to audit standards and data

Background

A clinical group in an acute hospital wants to carry out a clinical audit on chest drains.

Objective

Following discussion on what the group wants to achieve, the group members agree that the objective of the clinical audit is to ensure that **chest drain insertion and management** are carried out **effectively**, that is, consistent with the British Thoracic Society (BTS) guidelines for the insertion of a chest drain.¹⁶

What has to be measured

According to the objective, the clinical audit has to measure the **effectiveness** of chest drain insertion and management. The effectiveness of care is as defined in the BTS guidelines that describe the **right way to insert a chest drain and manage a patient with a chest drain**.¹⁶

Audit standards and data that have to be collected

The audit standards will specify the exact process to be followed in inserting and managing a chest drain. The data to be collected are about **whether or not the stages in the process of inserting a chest drain and managing a patient with a chest drain have been followed**.

The group's objective does not require any other data to be collected.

4 How to ensure that the right cases are selected for a clinical audit

There are several decisions involved in selecting the right cases for a clinical audit including:

- what exactly are the cases to be **included in** and **excluded from** the audit
- how the selection of the **right cases** for the audit can be assured
- if it is **feasible** to include **all** the cases specified for the audit **in a given time period**
- if it is **not feasible** to include **all** the cases specified for the audit, **how** a subset of cases will be **selected** for inclusion in the audit
- what to do if cases selected for the audit don't work out for some reason, including that some cases are missing.

4.1 Cases to be included and excluded

Specify exactly the patients, cases, situations, circumstances or events to be **included** in a clinical audit. Consider all of the following when specifying patients or cases to be included:

- the specific **diagnosis, condition, surgical procedure or special procedure**, if the subject of the audit is care provided to patients with a diagnosis, condition, surgical or special procedure. Agree on the **codes** to be used to retrieve the cases from your organisation's information system. If previous history of the diagnosis or condition is relevant, specify the history in detail. For example, an audit may be focused on patients who have had a stroke for the first time or it may be focused on patients who have had a repeat stroke.
- the **age** range of patients to be included, if age is important to the subject of the audit. For infants and children, specify age in days or months, depending on the subject of the audit.
- the specific **referrals** by reason, condition, source of referral or time period, if referrals relate to the subject of the audit
- the specific **visit** by reason for visit, diagnosis, number of visits or time period, if GP or clinic visits relate to the subject of the audit
- the **exact events or circumstances** and how they will be identified, if events or circumstances, such as patient falls, relate to the subject of the audit.

Examples of special situations that relate to defining cases for a clinical audit are in the box.

| Special situations for defining cases to be included in a clinical audit | |
|---|---|
| Clinical audit subject depends on identifying procedures | A clinical audit on the effectiveness of completion of the consent process depends on being able to specify the procedures for which consent is required and then finding a 'perfect' list of patients who have had one of the procedures for which consent is needed. |
| Finding cases for a clinical audit depends on the accuracy and completeness of coding | For an audit on the effectiveness of use and management of chest drains , finding the patients to include depends on whether or not chest drain insertion has been recognised and coded correctly in the organisation's information system. If the cases are not coded or are not coded consistently, a clinical group needs to work out the best way to identify cases. |
| Finding cases for a clinical audit relies on verifying cases and collecting data concurrent with the delivery of the care involved | A clinical audit on the effectiveness of providing special clinical diets to hospital inpatients may require collecting data as meals are delivered, if the exact meals actually delivered to patients aren't routinely recorded for patients for whom a special clinical diet is requested. |
| Finding cases for a clinical audit requires screening of possible cases | For some clinical audits, it may be relatively easy to specify the patients to be included in the audit but difficult to actually identify the exact patients to be included. For example, a clinical audit on the effectiveness of implementation of the Mental Capacity Act would include patients who lack mental capacity temporarily or continuously. However, specific indicators would be needed to identify the patients whose care should be measured for the clinical audit and patient records would have to be manually screened to identify those patients who meet the indicators for lacking mental capacity. |

If the description of the patients or cases to be included isn't comprehensive, it may be necessary to also specify the patients or cases to be **excluded**, for example, patients with co-morbidities, patients in a particular age group for which the audit subject is not intended or non-NHS patients. An example is in the box.¹⁷

Example of specifying patients or cases to be included in or excluded from the national clinical audit on chronic obstructive pulmonary disease (COPD)

Diagnosis — To ensure accurate diagnosis of COPD exacerbation, the lead clinician at each unit was encouraged to review the medical notes of patients included in the audit to check for any evidence of misdiagnosis. Any patients whom the lead clinician considered to have been misdiagnosed (i.e. diagnosis appeared to be COPD on admission but later deemed incorrect) were to be excluded from the audit. Also excluded were any patients where the diagnosis was changed to exacerbation of COPD from another presenting condition, as this would have affected the patient's early management in hospital. Sites were asked to include only the index admission for patients having more than one admission within the data collection period. A very small number of patients with repeat admissions were identified within sites and these were excluded.

Admission — For the purposes of the National COPD Audit 2008, an admission is defined as 'an episode in which a patient with an acute COPD exacerbation is admitted to a ward and stayed in hospital for 4 hours or more (this includes Emergency Medicine Centres and Medical Admission or similar units but excludes Accident and Emergency Departments) prior to discharge or acceptance to an early discharge scheme.' A stay in hospital of less than 4 hours is a non-admission and is not included.

Early discharge scheme — Early discharge schemes have a variety of names, including 'hospital at home', or may be known by local acronyms. Sites were asked to include in the audit those patients who presented to hospital with COPD exacerbation and were then accepted onto an early discharge or hospital at home scheme, so reducing length of stay. Patients seen at home by such schemes but not presenting to hospital were excluded from the audit.

4.2 How to confirm that cases identified for a clinical audit are the right cases

For every clinical audit, those carrying out data collection or data validation should confirm that the cases intended for inclusion in an audit are actually included. The method for confirming that the cases identified are the right cases may depend on the sources used to identify cases. Examples are in the box.

Approaches to confirming that the right cases for a clinical audit are included

For clinical audits that involve patients with a specific diagnosis or having had a specific procedure, for example, for a national clinical audit

For cases for a particular diagnosis or procedure, compare the number of cases identified as needed according to the data source agreed for the clinical audit and the time period over which the cases occurred with the number of cases that are recorded by Hospital Episode Statistics (HES) for the same time period. Errors in coding can contribute to errors in HES data.^{18–19}

Use robust and reliable organisational records such as clinic or therapy lists, perfusion registers or pathology reports to validate that all eligible cases for a clinical audit are being identified.^{20–22}

Approaches to confirming that the right cases for a clinical audit are included

For other local clinical audits

Before collecting data for each case, check that the case meets completely the description of cases to be included in the audit. A person overseeing data collection or another data collector can check the cases. If cases to be included are missing from the data sources to be abstracted for the audit, make every effort to locate the missing cases. Substituting cases by using patient records that are readily available can produce biased results.

For clinical audits that rely on electronic systems in general practices

Use Data Quality Probes, which involves posing a query in a clinical information system where the result can be used as a measure of the performance of that system, that is, there is strict concordance of the association between one data item and another.²³ An example is that all patients identified as having diabetes have an estimation of HbA1c recorded in the system.

4.3 How to decide on the number of cases to include in a clinical audit and how they will be selected

Clinical audit staff members sometimes recommend that local clinical audits do not need to include more than 30 or 50 cases. The basis for this recommendation is that if care is not being provided in accordance with clinical audit standards in 30 or 50 cases, there is no need to look at more cases. Clinical groups need to take action to improve compliance with the standards.

This approach may be suitable for clinical audit subjects that are limited to reasonably small numbers of patients handled by a reasonably consistent clinical group. Where performance may vary by clinical service, location, primary care centre, staff shift pattern, or time of year, a single sample of 30 or 50 cases may produce biased results, particularly when the cases are consecutive.

A systematic approach is needed to decide on the number of cases to include in a clinical audit and how to select the cases. There are several considerations that will affect these decisions, such as those in the box.¹⁵

Considerations that can affect decisions about the number of cases to include in a clinical audit

1. **How many cases** of what you want to include in the audit **are there** in a given time period, such as a week, a month or a year?

Suppose an emergency department group is interested in the **effectiveness of assessment of patients who come to the emergency department with symptoms of substance abuse**, including alcohol or drugs, as a subject for a clinical audit. If the group estimates that about 100 patients a day with such symptoms come to the department, and the group recognises the shift patterns of staff working in the department and possible seasonal variations in patient presentations as well as staffing, the group will have to decide how to get an unbiased sample for the audit. A sample could include a designated number of cases, that is, a cohort, by week or month, for example.

Considerations that can affect decisions about the number of cases to include in a clinical audit

2. How difficult is it to find cases that would be eligible for inclusion in the audit?

If identifying cases eligible for inclusion for an audit, such as people who lack mental capacity in an acute hospital, is itself time-consuming, the audit may have to include a relatively small sample.

3. How difficult is it to find the exact information needed for the audit for each case that is to be included?

For example, suppose an objective of an audit concerns an aspect of quality that may not routinely be documented, such as the provision of special clinical diets to the right patients. If data are to be collected concurrently, staff need to be available to collect data when meals are delivered. Therefore, the number of cases and/or time period for data collection may be affected by staff availability for data collection.

4. Does a clinician or a group want to be able to generalise the audit findings to other cases?

If a clinical group wants to generalise the findings to other cases, then sampling has to be done the right way to enable the right conclusions to be made. Normally, the sample will need to be representative.

5. What is the level of statistical confidence a clinician or a group wants to have that the findings of the audit will be representative of what happens to all similar cases?

For example, if a change in practice has significant financial or clinical implications, clinical groups and managers may not be convinced about making the change on a sample that is smaller than a 90%, 95% or 99% statistical confidence level would provide.

6. How much time is available to collect data for the audit?

If time is limited, a small number of cases may have to be selected. A group could use small cohorts of cases over a longer time period, for example, 5 cases per week for 10 weeks, with the cases selected using a random sampling technique.

4.3.1 How to decide to include a population or a sample and the type of sample

It is important to be clear about the difference between a population and a sample of cases for a clinical audit and types of samples. The terms and their meanings are in the box.¹⁵

Sampling terms and their meanings

Population

All, the entire collection of, the patients, events or things in which you are interested. A population can range from a relatively small number to a large but finite number to an infinite number, depending on the time period you refer to or the number of clinical services or healthcare organisations included.

Examples of populations are: all the patients who had a chest drain inserted in hospital X last week; all the patients who had a chest drain inserted in the UK last year; or all the people in the UK who have had a chest drain inserted sometime in their lives.

Sampling terms and their meanings

| | |
|---|--|
| Sample | Some, a specific collection , of the patients, events or things that are drawn from a population in which you are interested. Samples can be representative or non-representative of the population. |
| Representative (or probability) sample | A sample that attempts to ensure that the sample contains cases that represent the population An example of a representative sample is every 5th patient who had a chest drain inserted in hospital X in the last month from a list of all patients arranged in date sequence of a drain insertion. |
| Non-representative (or non-probability) sample | A sample that does not attempt to ensure that the sample contains cases that represent the population. A non-representative sample is used when it is not feasible, desirable or economical to use a representative sample. An example of a non-representative sample is the first 10 patients in each of the hospitals in the South who had a chest drain inserted last year. There may be bias in the first 10 patients, for example, if they were all cases having the drains inserted in the emergency department. |

Clinical audit findings could be biased if the decision on including a population or a sample of cases for a clinical audit is not made carefully. The questions in the box can help in making the decision on using a population or a sample.¹⁵ If you want to be able to say that the audit findings from a sample of cases can apply to all cases, you have to select a **representative** sample.

How to decide on a population or a sample for a clinical audit

Specify the patients, cases, events or circumstances to be **included in** and **excluded from** the audit, and/or the intended time period for including the cases. Then consider the following.

1. Can you **find** with certainty **all** the patients, cases, events or situations needed for the audit, that is, can you get a perfect list?
If Yes, go on to question 2.
If No, use a **non-representative sample** because every patient does not have an equal chance of being included in the audit.
2. Do you **need to include all** the patients, cases, events or situations in the audit?
If Yes, go on to question 3.
If No, do you want a sample that attempts to represent the population?
 - **If Yes**, use a **representative sample**.
 - **If No**, use a **non-representative sample**.
3. **Is there time or resources to include all** the patients, cases, events or situations in the audit?
If Yes, use the **population**.
If No, do you want a sample that attempts to represent the population?
 - **If Yes**, use a **representative sample**.
 - **If No**, use a **non-representative sample**.

Some clinical audit staff think of representative sampling as any group of cases that are likely to be ‘typical’ and that can be chosen from any convenient data source. However, **representative sampling involves giving each case eligible for inclusion in the audit an equal chance of being selected for inclusion** in the audit. Representative sampling **requires** having a ‘perfect’ list of all eligible cases and selecting cases for the audit from the perfect list in accordance with the rules for random sampling. Key ideas about representative sampling are in the box.¹⁵

| An explanation of representative sampling | |
|---|--|
| What it is | A representative sample has the best chance of reproducing in the sample the key characteristics of the population in the same proportion as they occur in the population. |
| Why use it | Use representative sampling when you want to draw inferences about what is happening to a population based on a sample. |
| When to use it | You can use representative sampling only if you can identify all cases in the population (to give each case an equal chance of being in the sample). |
| How to use it | Use a random sampling technique. |

4.3.2 Representative sampling techniques

Some types of representative sampling techniques are described in the box.¹⁵

| Representative sampling techniques and their meanings | | |
|---|---|--|
| Sampling technique | Meaning | When to use |
| Simple random sampling | A given number of people, events or things is selected from a complete list of people, events or things eligible for inclusion (the population) in such a way that each has an equal chance of being included in the sample. | When the population is more or less the same or highly similar for the characteristics that are key to the objective of the audit and every person, event or thing in the population can be identified |
| Stratified random sampling | All people, events or things eligible for inclusion (the population) are divided into groups or strata on the basis of certain characteristics they share such as age, diagnosis, medication, clinic or day of the week. Then a random sample is selected from each group. | When the population is not the same or highly similar for the characteristics that are key to the objective of the audit and every person, event or thing in the population can be identified |

| Representative sampling techniques and their meanings | | |
|---|---|--|
| Sampling technique | Meaning | When to use |
| Systematic (interval) random sampling | A fixed interval is specified . The people, events or things are arranged in a sensible order such as by date of receipt of referral. The first person, event or thing eligible for inclusion is selected at random and then every person, event or thing that falls at the fixed interval thereafter is selected for the sample. | When the population is more or less the same or highly similar for the characteristics that are key to the objective of the audit; people, events or things can be arranged in a natural sequence; it is believed that there is no underlying bias in selecting every nth person, event or thing; and every person, event or thing in the population can be identified |

4.3.3 Non-representative sampling techniques

You could use a non-representative sampling technique if you are not interested in making inferences about a whole population with any degree of statistical confidence or you are unable to identify every person, event or case in the population, but you are interested in using an audit to understand a situation or a problem. Some non-representative sampling techniques are described in the box.¹⁵

| Non-representative sampling techniques and their meanings | | |
|---|---|---|
| Sampling technique | Meaning | When to use |
| Purposive sampling | People, events or things for inclusion in the sample are selected for specific purposes , particularly to provide data related to the purposes. | When the population is known, a small sample will suffice and you want to exercise judgement in selecting the sample and not leave selection to chance |
| Convenience sampling | People, events or things for inclusion in the sample are selected because you can get them relatively easily . | When you don't want to generalise the findings to a population and you want a manageable sampling method |
| Quota sampling | Subgroups or strata of a population are identified and a desired number of people, events or things from each subgroup is set for inclusion in the sample. Then, people, events or things are sought until the quota for each subgroup is achieved. | When: <ul style="list-style-type: none"> • a list of the eligible population from which to draw a random sample is not available • the data need to be collected faster and cheaper than random sampling methods would allow • just knowing something about each group is sufficient, even if the findings may not be representative |

Clinical audit staff sometimes refer to snapshot sampling by which they appear to mean a small number of cases designed to give a quick 'picture' of patient care. Snapshot sampling, therefore, can be an example of convenience sampling as described in the box.

4.4 How to decide on sample size

Use the questions in the box to consider how many cases should be included for a sample.¹⁵

How to decide on the size of a sample for a clinical audit

How many patients, events or situations will a clinician or a group want to include in order to be willing to act on the findings of the audit?

Will a clinical group want to generalise the findings of an audit from a sample of cases to a population?

If a clinical group wants to draw inferences from a sample to a population, the sample has to be **representative**, that is, drawn using a representative sampling technique, and **sufficiently large** to enable the clinician or the group to be confident in the 'trueness' of the data. Use a statistical formula to determine what a sample size should be. Then when the audit findings are collated, the clinical group is able to state how sure it is that the true population value falls within a confidence interval.

For example, for an audit finding of 84% compliance with a clinical audit standard, using a sample size sufficient for a 95% level of confidence and a 5% range of accuracy, you could say, 'I am 95% sure that the true value is 84%±5% or that the true value lies between 79% and 89%.' In other words, you can say that you are 95% confident that the compliance with the audit standard in the entire population would be between 79% and 89%.

See the table in the appendix to decide on the number of cases for an audit when a clinical group wants to be reasonably confident that the audit findings from a sample can be generalised to a population. The formulas for determining the number of cases needed for different confidence levels for any population are also in the appendix.

4.5 What to do if cases selected for the audit don't work out

The protocol for the clinical audit should instruct the person retrieving cases for inclusion in the clinical audit about how to handle all of the following:

- missing cases from the list of cases intended for inclusion in a clinical audit
- cases needed for a clinical audit cannot be made available for data abstraction in the time available for data collection for the audit
- cases in the list intended for the clinical audit that do not meet the inclusion description
- the needed number of cases cannot be achieved.

Clinical audit staff sometimes add extra cases to those to be retrieved for data collection to deal with problems related to finding cases. However, this approach may produce biased findings for an audit. For example, if an audit includes only cases for which paper patient records could be retrieved on the first attempt, there is the possibility that the patients are not representative of all patients eligible for inclusion in the audit. One or two extra cases may be acceptable to add but adding more extra cases may result in biased findings.

5 How to check on the validity of clinical audit standards

5.1 What validity of clinical audit standards means

Validity has been defined in several different ways, depending on whether the activity described as having validity is a research study, an examination or test, or a measurement tool. Clinical audit **standards are** intended as **tools to measure** the **quality** of patient care. The term validity applied to clinical audit standards is defined in the box.¹⁵

The term validity applied to clinical audit standards

| | |
|-----------------|---|
| Validity | <p>The extent to which clinical audit standards have the capability to give a true picture of what is being audited.</p> <p>Validity relates to the confidence that clinical staff have that they will draw the right conclusions about the quality of patient care based on the standards used in the audit. Validity is about the relevance of the standards being used in the audit in relation to the objective(s) of the audit.</p> |
|-----------------|---|

Four types of validity theoretically could apply to clinical audit standards, which are:

- content
- face
- criterion-related
- construct.

The terms, as they apply to clinical audit standards, are defined in the box.¹⁵

Types of validity and their meanings

| | |
|-------------------------|--|
| Content validity | <p>The clinical audit standards selected include all the key aspects of clinical practice that relate to the objective(s) of the audit.</p> <p>Content validity of clinical audit standards can be demonstrated by showing that the standards cover all the key aspects of quality for the audit objective and don't omit any key aspects that are capable of measurement.</p> |
| Face validity | <p>The clinical audit standards relate to the aspect(s) of quality in the audit objective in the opinion of the clinical group members, that is, 'on the face of it' clinical staff think there is a direct relationship between the clinical audit objective(s) and the audit standards.²⁴ Face validity also includes consideration of whether or not the audit standards are good measures of the aspects of quality that the audit is about as stated in the objective(s).</p> <p>Face validity can be very closely related to content validity where there is an evidence base available to identify standards for a clinical audit and when clinicians are familiar with and believe in the evidence base.</p> |

Types of validity and their meanings

| | |
|-----------------------------------|---|
| Criterion-related validity | <p>The correlation between a result or outcome of an aspect of the quality of patient care and specific clinical audit standards that are believed to represent that aspect of quality.</p> <p>Criterion-related validity of clinical audit standards can be demonstrated by correlating outcomes of care with clinical audit standards that are considered to provide a direct measure of an aspect of the quality of care. Criterion-related validity can be predictive or concurrent. Predictive validity indicates the extent to which a future level of performance on outcomes can be predicted from prior or current performance. Concurrent validity indicates the extent to which outcomes estimate present performance in relation to the standards. Predictive or concurrent criterion-related validity underpins tests that assess an individual's suitability for a job, for example.</p> |
| Construct validity | <p>When a clinical group is interested in measuring an aspect of quality that is not easy to define operationally and therefore measure, such as quality of life, the attributes that are thought to be involved in that aspect of quality are identified and measured.</p> <p>Construct validity is demonstrated by using a tool that measures each of the individual attributes and then measuring the degree to which the individual attributes identified account for overall results.</p> |

Examples of how the types of validity could apply to clinical audit standards are in the box.

Examples of types of validity applied to a clinical audit on the effectiveness of the use and management of chest drains

| | |
|-------------------------|---|
| Content validity | <p>The British Thoracic Society guidelines for the insertion of a chest drain describe the following aspects of clinical practice that relate to the effective process of inserting and managing a chest drain:¹⁶</p> <ul style="list-style-type: none">• getting the patient's written consent• assessing the need for antibiotic prophylaxis and prescribing accordingly• having the right equipment available• selecting the size of the drain• giving premedication, particularly analgesia• positioning the patient• confirming the site of drain insertion• using image guidance to insert a drain for fluid• using aseptic technique• providing local anaesthetic• inserting the chest tube• securing the drain• managing the drainage system• managing the chest drain. <p>There is a detailed list of equipment and materials that are required to insert a chest drain. A clinical group may agree that it is unlikely that there will be any record kept of the availability of all the items on the list for the insertion of a chest drain for an individual patient.</p> |
|-------------------------|---|

Examples of types of validity applied to a clinical audit on the effectiveness of the use and management of chest drains

The **standards for a clinical audit on the insertion and management of a chest drain** could be said to have **content validity** if there are **audit standards for each one of the aspects of inserting and managing a chest drain**, except for the presence of the equipment listed in the guideline. **All the other aspects of inserting and managing a chest drain are needed to ensure that chest drains are being inserted effectively, which is the objective of the clinical audit.**

Face validity

Suppose a clinical group was interested in the safety of chest drain insertion. A clinical audit standard stating that the chest drain was inserted by a doctor who has completed formal training in chest drain insertion could be said to have **face validity**.

Criterion-related validity

A clinical group may want to know if patients whose drains are inserted and monitored according to the guidelines were also the patients who did not develop complications or infections.

Suppose a group decided to collect data on the outcomes of the patients who have chest drains inserted. The **clinical audit standards on the effectiveness of insertion and management of a chest drain** could be said to have **criterion-related validity if there was a strong positive correlation between compliance with these standards and the absence of complications and infections.**

The criterion-related validity could be predictive if the group wished to assert that future positive outcomes are associated with the clinical audit standards on the effectiveness of the use and management of chest drains. The criterion-related validity could be concurrent if the audit showed a correlation between compliance with the effectiveness standards and outcomes related to complications and infections in the same patient group.

Construct validity

Suppose a clinical group wanted to extend the objectives of the clinical audit to include satisfaction of patients who have chest drains inserted. The group would have to identify attributes of patient satisfaction, for example, relating to pain relief, explanation of the need for the chest drain and the procedure by clinical staff, doctor and nurse courtesy, relief of symptoms, and so on.

The **standards for a clinical audit on patient satisfaction for patients having a chest drain** could be said to have **construct validity if each of the attributes of patient satisfaction were strongly positively correlated with the overall results of patient satisfaction measurement.**

5.2 How to test the validity of clinical audit standards

If a clinician or a group is concerned about the validity of clinical audit standards, any of the types of validity described in the previous section can be tested, using accepted statistical tests developed for this purpose. Practical ways to check content and face validity of proposed clinical audit standards are in the box.¹⁵

| Ways to check content and face validity of proposed clinical audit standards | |
|--|---|
| Content validity | <p>Compare each proposed clinical audit standard with the evidence base related to the subject and the objective(s) of the clinical audit. Check the following:</p> <ul style="list-style-type: none">• Is each standard completely consistent with the wording in the relevant evidence base and consistent with the objective(s) of the audit?• Is there a standard for each important aspect of care referred to in the evidence, if it is feasible to measure compliance with the standard?• Are there complete definitions for words or terms used in the audit standards?• Are there complete and unambiguous directions for how to decide if each standard is complied with or not and how to record decisions? <p>Call to the clinical group's attention any standard for which the answer to the questions above is not unequivocally yes. Ask for clarification on the clinical audit standards for which the answer is not yes.</p> |
| Face validity | <p>Submit the clinical audit standards to clinical staff that know about the audit subject. Ask the clinical staff if the standards appear 'on the face of it' to be 'true' measures of what the clinician or the group is interested in.</p> <p>You can give the people who are asked to judge face validity a questionnaire with yes–no questions or a rating scale for each standard. You can collate and analyse the responses to determine the number or percentage of staff that agreed that the standards are valid and the findings of a clinical audit using the standards can be acted on accordingly.</p> |

5.3 The efficiency of clinical audit standards in identifying good and not-so-good quality of care

Clinical staff members sometimes observe that clinical audit standards don't 'screen' or 'filter' cases included in the audit in order to identify the occasions in which patient care should or could have been better. On other occasions, clinical groups can be concerned that clinical audit standards are identifying a large number of cases in which the quality of care has not been consistent with best practice. They may question if the standards used in the audit were appropriate for measuring the quality of care.

In either of these circumstances, a clinical group could be assured that the clinical audit standards are **sensitive** and **specific**. These terms as they apply to clinical audit standards are defined in the box on the next page.¹⁵

Terms related to clinical audit standards and their meanings

| | |
|--------------------|--|
| Sensitivity | <p>The likelihood that a case will be identified, through data collection using a clinical audit standard, as representing poor care and the case really is poor care</p> <p>A clinical audit standard is sensitive if it ‘flags’ all or almost all cases in the audit for which there is a problem about the quality of care provided and doesn’t miss cases in which care was poor.</p> |
| Specificity | <p>The likelihood that truly good care will be identified, through data collection using a clinical audit standard, that is, that a case identified as representing good care really is good care</p> <p>A clinical audit standard is specific if it doesn’t flag cases or flags few cases for review when the care provided is clinically acceptable.</p> |

5.4 How to test if clinical audit standards are sensitive and specific

The process for testing the sensitivity and specificity of a clinical audit standard is in the box.¹⁵

How to test sensitivity and specificity of a clinical audit standard

1. Carry out data collection in accordance with the clinical audit standard and related definitions and instructions for data collection.
2. For any cases that are found not to be consistent with the audit standard, ask one or more clinicians to review the cases and make a decision on whether or not the case represents acceptable or unacceptable quality.
3. Ask one or more clinicians who have not been involved in the case review to review all of the cases that have already been screened according to the audit standard and make decisions independently (without knowing the results of screening against the audit standard) about whether or not the cases represent acceptable quality.
4. Compare the cases flagged by the audit standard and the cases that did not represent acceptable quality as judged by clinicians.
5. Display the figures in a table to show the sensitivity and specificity of the audit standard, such as the one in the box on the next page.
6. Draw conclusions about the sensitivity and specificity of an audit standard as follows.
 - A **clinical audit standard** is a **sensitive** measure **if it identifies most of the cases that represent a problem about quality** and perhaps a few that did not (true-positive cases and false-negative cases).
 - A **clinical audit standard** is a **specific** measure **if it identifies most of the cases that did not represent a problem about quality** and perhaps a few that did (true-negative cases and false-positive cases).

Guidance for interpreting the sensitivity and specificity of a clinical audit standard is in the box.¹⁵

| How to interpret sensitivity and specificity of a clinical audit standard | |
|--|---|
| <p>True positive</p> <p>Number of cases in which a clinical audit standard and independent clinician review identified the same cases as representing a problem about quality</p> | <p>False positive</p> <p>Number of cases in which a clinical audit standard flagged a case but independent clinician review did not find a problem about quality in the case</p> |
| <p>True negative</p> <p>Number of cases in which a clinical audit standard did not flag a problem and independent clinician review did not find any problem about quality in the same cases</p> | <p>False negative</p> <p>Number of cases in which a clinical audit standard did not flag a case but independent clinician review found a problem about quality in the case</p> |

6 How to check if data needed for a clinical audit can be found

The data source(s) for each clinical audit standard should be specified. Being absolutely clear about where a data collector is to look to find evidence of compliance with a standard, and the sequence for looking at data sources when more than one is specified, promotes reliable data. No one data source is likely to be perfect. The clinical group carrying out a clinical audit could identify more than one potential data source and some clinicians may favour one source over another.

The aim is to have the data source(s) that yield(s) the most quality data for the least amount of effort. Consider if the data source(s) for clinical audit standards are likely to produce quality data for a clinical audit. Possible data sources and issues related to them are in the box.^{13–14, 20, 24–27}

| Issues related to potential data sources for clinical audit standards | |
|--|---|
| Data source | Issues |
| <p>Patient care records, including inpatient, outpatient, primary care and home care, both paper and electronic</p> | <p>Records are lost, missing or destroyed.</p> <p>Records are incomplete.</p> <p>The contents in the record are disorganised, making it difficult to find needed information.</p> <p>There is bias relating to what is or is not typically recorded.</p> <p>Information about the episode of care of relevance to the audit has not been filed in all the records.</p> <p>Handwriting is illegible.</p> <p>Authorisation for access may be required and it can take time to get authorisation.</p> <p>Technological expertise is needed to access electronic records.</p> |

Issues related to potential data sources for clinical audit standards

| Data source | Issues |
|---|---|
| Departmental reporting systems, such as pathology and radiology reporting systems | <p>The systems generally include accurate and complete records of results of investigations, directly linked to patient identifiers. Normally, the results are quality controlled before they are accessible to staff outside the service. Authorisation for access may be required and it can take time to get authorisation.</p> <p>Technological expertise is needed to access electronic records.</p> |
| Routinely collected data in local departmental and organisational information systems and national information systems | <p>Routinely collected data:</p> <ul style="list-style-type: none"> • tend to focus on processes of care or patient care transactions • can fail to include data that are relevant to some aspects of quality of care • may not be complete and comprehensive • involve little if any additional cost to obtain and use • can be the same as data collected at other organisations so there is potential for comparisons • are not always complete, accurate and precise. <p>Authorisation for access may be required and it can take time to get authorisation.</p> <p>Technological expertise is needed to access electronic records.</p> |
| Regional and national systems such as cancer registries | <p>Registries may have the benefit of being population based; however, the data may be incomplete or inaccurate or not as timely as needed. Data specifications are typically already in place before the initiation of an audit, limiting the scope of data that can be retrieved to what already exists in the registry.</p> <p>Authorisation for access may be required and it can take time to get authorisation.</p> <p>Technological expertise is needed to access electronic records.</p> |
| Specially collected data such as patient interviews or diaries | <p>Patients or carers may have inaccurate or incomplete recall of events. Information may not be recorded completely or correctly.</p> |
| Forms completed by clinicians during a patient encounter | <p>Because forms are not embedded in essential patient care records, they often are filled in after the encounter because of workload, which can provide unreliable or incomplete data, or not filled out at all. Form filling is seen as additional work that does not relate to normal care.</p> |
| Audio or video recording | <p>Recordings of actual transactions:</p> <ul style="list-style-type: none"> • affect privacy, confidentiality and anonymity, and therefore, require explicit consent • can produce a Hawthorne effect • can take considerable time to analyse. |
| Postal survey questionnaires | <p>Surveys can experience poor response rates. Clinicians or patients can be overloaded with survey questionnaires. It may be difficult to maintain anonymity of responses.</p> |

To check on the data quality for data sources for a clinical audit, use the questions in section 7.2.

7 How to ensure that data collection processes produce reliable data

Data collection processes define **how** data will be collected, **where** the data will be recorded and stored, and **who** will collect data.²⁸ To ensure that data collection processes produce reliable data, carry out the following.

- Ensure that operational definitions of key terms in the clinical audit standards and instructions for data collection are specified completely.
- Design and test data collection tools or systems, including electronic systems for capturing or providing data.
- Develop and test the clinical audit data collection protocol.
- Pilot test data collection and amend definitions, instructions, tools or systems, and the protocol as needed.
- Select and prepare the data collectors for the clinical audit.
- Test the degree of inter-rater reliability.

7.1 How to ensure that key terms are defined and instructions for making decisions are specified

Clinical staff sometimes assume that because they know what the clinical audit standards mean, collecting data about compliance with the standards is straightforward. However, any valid and reliable measurement process requires definitions and a system for doing the measuring,²⁷ beginning with the 'rules' to be used by data collectors to decide if what is observed during data collection of cases complies or does not comply with a standard.²⁰ These rules are essential to produce reliable data for the first round of data collection for a clinical audit as well as for rounds of repeat data collection that may not be carried out by the original data collectors.

For each clinical audit standard, **terms** used in the standard need to be **defined** and **detailed instructions** for making decisions provided.^{15, 20, 24, 27} Definitions and instructions for data collection are explained in the box.^{15, 24}

Clinical audit standard definitions and instructions terms and their explanations

Operational definitions

Definitions of key terms apply to the clinical audit only. They describe how each key idea in a clinical audit standard can be expressed in the data source(s) for the audit, including synonyms, symbols and abbreviations that clinical staff might use.

For example, suppose a data collector is to look for evidence of hypertension being managed. First, the data collector needs to be told the **exact operational definition of hypertension** to be used for the audit. Operational definitions of hypertension could include evidence of any or all of the following: reference to the word 'hypertension' or 'high blood pressure' in the patient record, a single blood pressure reading (abbreviated BP) more than 140/90, two or more readings of B/P140/90, or a note of BP. If it isn't clear which definition(s) should be accepted, data retrieved will not be reliable.

Clinical audit standard definitions and instructions terms and their explanations

Instructions for making compliance decisions

The instructions for data collection should include:

- the data source(s) to be used by the data collector for observing practice and the sequence of looking at sources when more than one data source is specified
- how to make a decision about what has been observed, that is, whether or not the information in the data source complies or does not comply with an audit standard
- how to record the decision about compliance with a standard.

For example, guidance for making a decision on compliance with a standard would include directions about what to do if two designated sources of data have different information about compliance and which data source takes priority. Directions also specify what to do if there is incomplete information in the data source to make a decision, for example, is the data collector supposed to record 'no', 'information not available', or 'unable to decide'.

The person who is assuming responsibility for the clinical audit should develop or lead the development of the definitions and instructions for data collection and confirm the decisions made with colleagues as needed.

7.2 How to design and test data collection tools or systems

Data collection tools or systems are dependent on the data sources specified for clinical audit standards and the extent to which data have to be located and recorded for the audit. For example, if patients are the data source for a standard, a questionnaire that patients will complete themselves or that will be administered by an interviewer can be used. If the data source is a paper or electronic patient record, a data abstraction form or system is needed.

Regardless of the nature of the data collection tool or system, forms used for data collection for a clinical audit need to:²⁴

- promote accurate data recording
- limit the likelihood of missing information
- promote efficient and accurate entry of data onto databases or spreadsheets for collation and manipulation.

Whether a data collection tool is in paper form or is electronic, key recommendations for the design of data collection tools are in the box on the next page.^{1, 13, 24, 27}

Recommendations for the design of data collection forms for a clinical audit

| Design aspect | Recommendation |
|--|--|
| Classes of data to be collected | Group data by the classes of data to be collected. Classes of data for a clinical audit can include: a patient identifier such as a unique code for the audit, demographics such as age and gender, audit-specific data such as symptoms or medications, and compliance with audit standards. |
| Sequence of standards and other questions | Arrange the questions according to the sequence in which the information appears in a data source. If there is more than one source, group questions according to source or have a form for each source. |
| Use of number codes and pick lists to record data | Devise and use number codes to record decisions. Using the numeric keypad, number codes require less time to enter than alpha codes. Use the same codes throughout the form, for example, 1 is yes and 2 is no. When data are missing, use 9 or as many 9s as needed for the response field, rather than leave blank spaces. Use a code such as 8 when a question or standard is not applicable. When a response to a question leads to branching, for example, 'If No, go to question 15,' fill in the response fields for the skipped questions, for example, with a not applicable code. To simplify data recording and increase accuracy, depending on the question, provide a pick list for categorical data with either one-only (mutually exclusive) or multiple choices. When a question lists a selection of responses from which the data collector must choose, but the list is not logically exhaustive, provide a code for 'other' to eliminate the possibility of a blank space. |
| Use of free text | Limit the use of free text, but allow space for data collectors to record any issues or reasons for decisions particularly when standards are not met. |
| Reduction of transcription errors | Having the right number of response fields, that is, spaces or slots or boxes for entering the data. Line up response fields so they all end at the right margin of a page, if possible. Align response fields visually, that is, vertically with a question and horizontally with parallel formats and decimal points aligned. Use a leading zero when a single digit number is inserted in a two-digit field. Do not have blank spaces or permit blank spaces in a data collection tool. Build in error checks to prevent recording or entering a value outside a specified range. For recording of medications, record the drug name, strength, dose, route, start time and stop time consistent with the clinical audit standard. Use a master list of medications with the ability to enter any not on a list using free text. |

Recommendations for the design of data collection forms for a clinical audit

| Design aspect | Recommendation |
|---|--|
| Format and review design | <p>Consider which format for recording data is preferred for the data collector(s):</p> <ul style="list-style-type: none"> • Are data to be entered exactly as found in the data source and later another process is to be used to decide if the clinical audit standard is met or not? • Are data in the data source to be interpreted by the data collector at the time of data collection and the data collector records if a standard is met or not? |
| Incorporating decision rules into the form | <p>To support data collectors to make decisions, use a three-column format that includes (1) the questions to answer or decisions to make, (2) answer choices and codes, along with instructions for interpreting information and any 'skip to' directions where applicable and (3) response box(es) for the choice or code that represents the data collector's decision.</p> |
| Electronic or paper | <p>Consider the cost-benefit of using electronic versus a paper data collection system. If there are more than 30 questions and/or more than 50 records, an electronic data abstraction tool may be more cost-effective in time needed to enter and analyse data.</p> <p>Electronic systems can skip automatically to the next relevant question, have embedded the acceptable ranges and/or types of data that may be entered in the spaces for responses, and have drop-down menus and pick lists, thereby promoting valid data entry.</p> <p>If an electronic system is used, build in routine backup of the data and have a backup paper system in case there are problems with the electronic system when people are available to collect data.</p> |

Prepare directions for using the data collection tool or system and carry out a test of the tool or system using the steps in the box.^{1, 14-15}

How to test a data collection tool or system for a clinical audit

| Step | Questions |
|---|--|
| 1. Select 5 cases from the cases intended for inclusion in the clinical audit. | <p>If you were using an electronic system:</p> <ul style="list-style-type: none"> • Was a list of cases available and accessible? • Could a query be written to access the list? |
| 2. Retrieve the data source(s) for the 5 cases you picked. | <p>If you were using an electronic system:</p> <ul style="list-style-type: none"> • Was the system able to access the records for the 5 cases? • Were the right cases accessed? <p>If you were using one or more manual data source(s), did the data sources work as intended?</p> |
| 3. Go to the first case, refer to the clinical audit standard and look through the data source, using the definitions and instructions for data collection. | <p>Did the data collection form allow for entry of your decision for each standard or question?</p> <p>Were there any data you wanted to record but there was no place to record the data?</p> |

How to test a data collection tool or system for a clinical audit

| Step | Questions |
|--|---|
| Decide if the case complies with the clinical audit standard(s) and record the information requested on the data collection form. Note the time you started and the time you finished reviewing the case. | Were any parts of the form confusing to use? Did the instructions for use of the data collection form tell you how to complete the form for the case? If you were using an electronic system or interrogating an existing database or system, were the data you wanted downloaded to the right fields? How long did it take to collect data for the standard(s) for the first case? |
| 4. Carry out data collection for the remaining 4 cases. | Answer the questions above for each additional case. |
| 5. Collate your findings from the test and report on your experience to the clinician or group carrying out the audit. | For how many cases could you: <ul style="list-style-type: none">• find the information needed?• complete the data collection form as instructed?• enter any additional information or comments? How long did it take to collect data for all 5 cases? Is the time needed feasible in relation to the timeframe for completing the audit? What changes are needed, if any, to improve the validity and reliability of the tool or system? If a specially developed spreadsheet or database has been created, can the paper or electronic information collected be entered? |

In testing the data collection tool and system, problems with the clinical audit standards may be identified.¹ For example, the definitions and instructions for the standards may have been incomplete or confusing. Additional definitions of terms may be needed to limit the possibility that different data collectors could reach different decisions about compliance with the standards.

7.3 How to develop and test a protocol for data collection

A data collection protocol **documents the entire data collection process**, ensures a common understanding of how the audit data are to be collected, and supports measuring again after any changes in practice have been implemented. The term is defined in the box on the next page.¹⁵

The person who is assuming responsibility for the clinical audit should develop or lead the development of the data collection protocol and confirm the protocol with colleagues as needed. The protocol can be tested as part of the pilot test.

Data collection protocol meaning

Data collection protocol

A description for data collectors and other stakeholders in a clinical audit of how a clinical audit design and standards are being operationalised, that is, details on **how data** for a clinical audit **are to be collected**. It documents decisions on the following:

- definitions and instructions for data collection for the standards to be used in an audit
- data source(s)
- data collector(s)
- case selection method(s)
- data collection form(s) and how to complete it(them), including directions on how to make decisions
- timing of data collection
- coding cases to protect anonymity
- actions to ensure confidentiality, consent and ethical considerations
- storing clinical audit data.

7.4 How to select and prepare data collectors for a clinical audit

For some audits, one person or a few people will be the data collector(s). For others, because of the number of cases to be included or to help staff learn about clinical audit or to involve stakeholders in the audit, several people could participate in data collection. To get reliable data for a clinical audit, you need consistency in following the data collection protocol by:¹⁵

- selecting carefully the person or people who will be the data collector(s)
- training him or her (or them) to collect data the way the data are supposed to be collected for a clinical audit
- testing the reliability of the data collected
- adjusting the data collection protocol as needed following reliability testing of data collection.

Use the advice in the box to select the 'right' data collectors for a clinical audit.

How to select data collectors for a clinical audit

1. Decide on **the number of data collectors** you are likely to need, recognising that until you know the availability of people and the time required to collect data, the number may change.
2. Define **what's needed from a data collector**, such as interest in participating, previous experience collecting data, and availability for training and data collection.
3. Identify **potential data collectors** from members of the group carrying out the clinical audit; clinical audit, clinical governance or quality improvement support staff; or others who may need to gain experience in clinical audit such as trainees.
4. **Select data collectors**, which may involve considering what will contribute most to reliable data collection.

For national clinical audits and audits involving a large number of organisations, it is not feasible for the national clinical audit staff to identify and select the data collectors. The organisations participating in the audit should identify and select their own data collectors based on the number and skills needed as specified by the group leading the national audit.

Some lessons about data collection for quality improvement purposes have been published. For example, in a quality improvement project involving review of patient records, previous experience reviewing records promoted inter-rater reliability, whereas prior training as a healthcare professional led to over-interpretation of the information in records introducing bias.¹ In a large ‘structured implicit’ review of 7533 pairs of patient care records, 127 doctors reviewing records gave their subjective opinions about the cases using agreed guidelines. The amount of experience the doctors had in reviewing records tended to increase the level of agreement.²⁹

Data quality depends on the training of the data collectors and staff who input data or maintain databases.³⁰ Data collectors should be trained before starting to collect data in order to allow for testing the reliability of data collection and making adjustments to the process to resolve any problems.^{15, 27} Training need not take an extensive amount of time. Guidance for providing training for data collectors for a clinical audit is in the box.

| How to prepare for training data collectors for a clinical audit | |
|--|---|
| Requirement | Explanation |
| Identify the amount of time available and timing for the training | <p>Identify, and perhaps negotiate, the time data collectors can be available for training, for example, no more than an hour for training due to the data collectors’ other commitments.</p> <p>Given the project plan for the clinical audit, decide when the training needs to take place.</p> |
| Decide on the objectives and activities | <p>List what the data collectors need to know and know how to do, including the following:</p> <ul style="list-style-type: none"> • the importance of the clinical audit • the importance of the role of the data collector • the clinical audit design and the data to be collected • the objectives of data collection • the importance of correct, complete and timely data • the process of data collection, including when data are to be collected, how cases are to be selected, what data are to be collected, definitions and directions to guide decisions, directions for completion of any forms and the length of time data are to be collected for • the process for monitoring data collection • who can be contacted and how, if there are any questions. <p>The training should include the opportunity to practise what is being taught and should involve collecting data for a small number of cases.</p> |
| Develop the teaching plan | <p>For the objectives listed, identify the activities that will be used, for example, presentation on the background to the audit with discussion, explanation of the standards or practising collecting data.</p> |

How to prepare for training data collectors for a clinical audit

| Requirement | Explanation |
|--|--|
| Decide the mode for delivering the training | Consider the mode for delivering training that will be most appropriate among options that might be available, including: <ul style="list-style-type: none">• face-to-face training• web-based training• sessions based on a DVD made by the trainer• cascade training (A core number of data collectors are trained centrally and they train people locally.). |
| Identify and arrange for the resources needed | Identify and arrange for the space needed for teaching, the trainer, equipment, trainer materials, sample records or other data sources for examples and practising, and learner materials. |
| Decide who will be the trainer(s) | Select members of the group leading the audit to participate in some or all of the training, for example, to describe the background to the audit. Identify others who have the knowledge and skills to deliver the training and ask them to participate. |
| Decide what materials will be provided to data collectors | Provide the data collectors with a clearly written and well-illustrated data collection protocol and other materials for use during training and for reference during data collection. The contents should include: ^{1, 24} <ul style="list-style-type: none">• the data collection protocol• copies of any documents or printouts that are to be used• needed information such as lists of medications or a random number table• examples of the data sources• examples of properly completed data collection forms that include commonly encountered situations such as missing or conflicting information. |

7.5 How to test the degree of inter-rater reliability

Even when data collectors have the same training and guidance for data collection, you can't assume that they will collect data the same way or retrieve the same data. To assure reliability of clinical audit data, you need to test the reliability of data retrieval between or among data collectors.²⁴ This process is known as testing inter-rater reliability, which is defined in the box.^{1, 15}

Inter-rater reliability meaning

Inter-rater reliability The **degree of agreement among people collecting data** or making observations on what they decide when collecting the **same** data from the **same** data sources for the **same** cases using the **same** directions

It is measured as the percentage of agreement when either:

- Several people collect data from the same sources for the same cases, or
- One person collects data from the same sources for the same cases at different times.

Data collectors may not always agree on data they collect, but if they consistently do not agree, the reliability of the data is seriously compromised. Error and/or systematic bias is(are) being introduced. The clinical audit group needs to decide on the degree of inter-rater reliability that is acceptable for the audit. Generally, a minimum level of agreement of 85% is set and 90% to 95% is preferred.^{1, 24, 31}

Guidance for testing inter-rater reliability within an organisation is in the box.¹⁵

How to do inter-rater reliability testing for a clinical audit

1. Decide on the degree of inter-rater reliability that will be accepted.
2. Have at least two data collectors who have been trained to collect data for the audit.
3. Describe the purpose and process of inter-rater reliability testing to the data collectors.
4. Provide the data collectors with the materials they will need, for example, the data collection protocol, forms, access to a computer or a random number table. Include a small number of cases, for example, 5 or 10, depending on the amount of data to be collected per case.
5. Have the data collectors:
 - collect the same data from the same sources for the same cases using the same data collection tools and guidance materials without any discussion among them until all data are collected and recorded by each data collector
 - make notes of any issues they identify when collecting data.
6. **Compare the decisions** made by the data collectors and count the following:
 - the total number of bits of data (items) for which there was complete agreement, that is, there were no discrepancies among the data collectors
 - the total number of bits of data (items) collected. The total number of bits of data is the number of items collected per case multiplied by the number of cases in the test. It doesn't matter how many people were data collectors in the test.
7. Note that if continuous variables are used, agree a margin of error, for example $\pm 10\%$, that will be considered as agreement.¹
8. Divide the total number of bits of data (items) for which there was complete agreement by the total number of bits of data (items) collected and multiply by 100 to get a **percentage of inter-rater agreement**.
9. Decide **if the percentage of inter-rater agreement** is the same as or better than the acceptable level set for the audit.
10. Note the reasons for any discrepancies and issues identified by the data collectors and take action to resolve reasons for threats to reliability, such as revising definitions and instructions or the form or screen layout.
11. Repeat the steps described until the desired level of reliability is achieved.
12. When there is only one data collector, the person uses the data collection forms and collects data from the same set of data sources for the same cases twice with a time interval between the two sessions of data collection. Then steps 6 to 11 above are carried out to compare the decisions and calculate the percentage of agreement.

For national clinical audits or audits involving a large number of organisations, two data collectors, or more if there are more, at each site participating in the audit can carry out reliability testing. Guidance for carrying out the process can be provided by the group leading the audit through a written pack sent to each site or web-based materials available to data collectors at the participating sites.

An example of calculation of inter-rater reliability is in the box.¹⁵

| Calculation of percentage of agreement for inter-rater reliability | | | |
|--|--|-----------------------------------|---------|
| A. | Number of bits of data (items) collected per case including data related to standards and additional information such as patient age or location for care | = | 25 |
| B. | Number of cases for which data are collected | = | 5 |
| C. | Total number of bits of data (for example, 25 bits of data per case x 5 cases) | = | 125 |
| D. | Number of bits of data for which there was complete agreement among the data collectors (<i>each of the 5 cases was reviewed by each data collector</i>) | = | 113 |
| E. | Inter-rater reliability | = $\frac{D}{C} = \frac{113}{125}$ | = 90.4% |

Other statistical tests of inter-rater reliability could be used such as kappa statistics, which take account of agreement that could occur by chance alone and provide a basis to judge the 'goodness' of the strength of the agreement. A report on inter-rater reliability testing for a national clinical audit is available at The Clinical Effectiveness and Evaluation Unit, Royal College of Physicians of London. *National Clinical Audit of Falls and Bone Health in Older People, National Report*. November 2007. Available at: www.rcplondon.ac.uk/clinical-standards/ceeu/Documents/fbhop-nationalreport.pdf.

There is a trade-off between increasing the validity and the reliability of measurement of the quality of patient care and the increasing costs of data collection or decreasing discrimination of the data. A clinical group may have to consider if the degree of reliability for some of the data collected is more critical than for other data.¹

7.6 How to pilot test data collection

Pilot testing data collection for a clinical audit is vital to test the reliability and validity of the data collection protocol and forms or systems.²⁴ A pilot test of data collection for a clinical audit:¹⁵

- tests the feasibility of a clinical audit design
- tests the reliability of the data collected
- estimates the time and resources needed to collect data for all cases in the audit
- practises checking data for completeness and accuracy
- practises displaying and presenting data for the clinical group
- anticipates the findings and how the rest of the audit process might proceed
- identifies where the audit design, the definitions and instructions for the standards, the data collection forms and the data collection protocol have to be amended to increase reliability, accuracy, completeness, timeliness and efficiency of data collection.

For very large clinical audits where data are collected at many sites, 50 or more cases should be included in the pilot test to have an adequate representation of the differing data that may be encountered.²⁴ For smaller, local audits, 5 to 10 cases can suffice. The steps in pilot testing data collection for a clinical audit are in the box.¹⁵

How to carry out a pilot test of data collection for a clinical audit

1. Carry out inter-rater reliability testing in accordance with the directions in the box in section 7.5.
2. Have the data collectors record the time they start and finish collecting the data.
3. Calculate the total time taken and the median, modal and mean time taken to collect data per case.
4. Summarise and present the findings of the pilot test to the clinical group carrying out the audit. Check if the findings presented from the pilot test are in the form that the clinical group expected and would be prepared to act on, following data collection for all the cases.
5. Decide if the following are acceptable:
 - inter-rater reliability of data collected
 - time needed to collect data
 - presentation of findings.If not, decide on action to be taken to improve data reliability, reduce time needed for data collection or improve the presentation of findings.
6. Repeat the steps until the desired level of reliability, efficiency and fit-for-purpose data are achieved.

A clinical group carrying out a clinical audit needs to be confident in the audit findings. The group will not be able to draw accurate conclusions about the quality of patient care or take appropriate actions to improve care if the team does not know that threats to reliable and valid data have been identified and acted on. To ensure and improve data quality, the measurement and data collection process can be tested during development (pre-pilot), just before data collection (pilot) and during data collection (monitoring).¹

8 How to validate data collection and data collation

The care that has been taken to achieve data quality for a clinical audit needs to continue through the data collection and collation stages by:

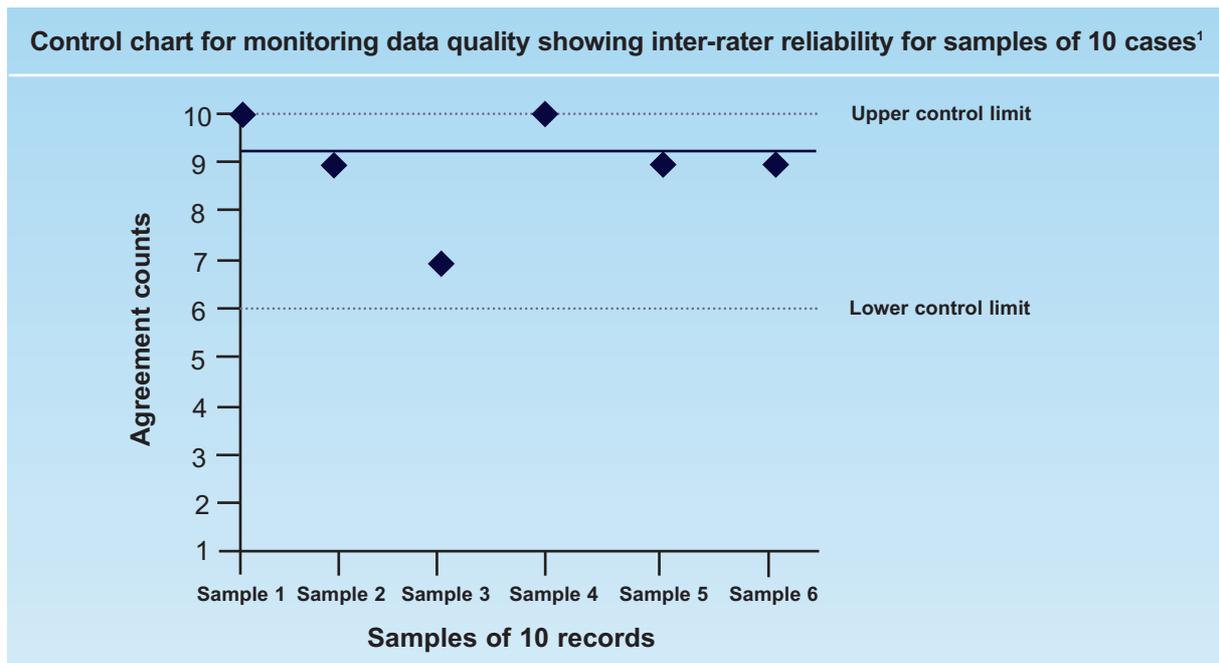
- monitoring case selection, adherence to the data collection protocol and data completeness and consistency
- acting to prevent and resolve issues in data collection and collation.

8.1 How to monitor adherence to case selection and the data collection protocol and process

Suggestions for monitoring adherence to the planned case selection are in section 4. Methods for monitoring adherence to the data collection protocol and data completeness are in the box on the next page.^{1, 13, 27-28, 31} The methods selected may be influenced by the number of cases in the audit and the length of time over which data are collected.

| What is being monitored | Ways to monitor |
|---|--|
| <p>Adherence to the data collection protocol</p> | <p>Carry out inter-rater reliability testing during data collection in addition to pre-pilot and pilot tests by using a sample of records abstracted by two data collectors. For national clinical audits and audits involving a large number of organisations, a sample of records developed for reliability testing could be provided to each site by the group leading the audit. A request could be made to complete data collection for the sample when a cycle of data collection begins, when new data collectors are appointed, or from time to time as unscheduled spot checks.</p> <p>Decide how the clinical audit data will be analysed and presented. Do the analysis and presentation of findings on sub-sets of cases, given the number of cases, and track the results over time.</p> <p>Group the data into time-ordered sets, for example, the first 10 cases then the next 10, or cases from week 1 then cases from week 2. Analyse the data by group and compare the findings.</p> <p>Use run charts or control charts to track data over time for a dynamic approach to analyse variation.</p> |
| <p>Data completeness and consistency</p> | <p>As data are received, review the data to identify missing information.</p> <p>Visually scan forms or screens for typographical errors.</p> <p>If data are transferred from a data collection form to a paper or electronic database, scan the database for typographical errors.</p> |

Use control charts to document and act on data quality as well as on audit findings. The control chart in the illustration shows the results of monitoring the quality of data collection by showing the number of times data collectors agreed on the data in samples of 10 records.



Control charts can be used for a clinical audit in two ways, to identify:

- a possible decrease in data quality and help to decide if there is a systematic (special) cause for the decrease that must be dealt with immediately or if there are random causes for the decrease that may not require any action.¹
- the amount and type of variation for the processes being measured in the clinical audit to help a clinical group know the type of action to take, that is, to find and act to eliminate a special cause or to redesign a process to limit the random variation.

8.2 How to prevent threats to data quality during collection and collation

Although it is important to act when problems in data quality are revealed, it is better to act to prevent threats to data quality. Actions can include:

- testing data and processes
- tracking data
- transferring data
- tidying up data
- triangulating data.

8.2.1 Testing data

Pre-testing data collection definitions and instructions, pilot testing the entire audit design, and tests during data collection can identify audit designs that can not be implemented reliably, insensitive and poorly defined standards, confusing forms, or impractical data collection protocols. In addition, carrying out trials of collating and analysing data can highlight issues such as:²⁷

- Have potential outliers been identified and evaluated?
- Have appropriate methods been used to provide summary measures of the clinical audit findings?
- Have measures of precision been presented with the clinical audit findings, for example, confidence levels and accuracy ranges?
- Have appropriate methods been used to consider the impact of factors that may confound the findings, for example, shift patterns by day of the week?

8.2.2 Tracking data

Set up systems to track both the data collection process and the data. Have a mechanism to report instances of missing data to the clinical audit group and approaches to analyse the data for any patterns as well as methods to account for the causes.²⁷

8.2.3 Transferring data

A well-designed database can provide important controls over data quality that may arise from erroneous data collection or entry errors when transferring data. For example, database controls can prevent entry of clearly erroneous values such as those outside a specified range for a data item, provide prompts to check values that are not within an expected range, or limit entries by use of drop-down menus or pick lists.²⁷

8.2.4 Tidying up data

Tidying up data, also known as data cleaning or data scrubbing or data validation, is defined in the box.³²

| Tidying data meaning | |
|--|---|
| Tidying data (Data cleaning, data scrubbing or data validation) | A process used to determine inaccurate, incomplete or unreasonable data and then improving the quality of the data through correction of detected errors and omissions and improvement of the error prevention procedures to reduce future errors |

The data cleaning process may include:³²

- checks on the format of data, the completeness of data and the reasonableness of the data
- review of the data to identify outliers or other errors
- assessment of data by subject experts, for example, members of a clinical audit group or other stakeholders
- flagging, documenting and subsequent checking and correction of suspect data or cases
- checking for compliance against applicable standards, rules and conventions.

8.2.5 Triangulating data

Data triangulation is a method aimed at overcoming the errors in measurement that can occur if only one approach to studying a subject is used. The term is defined in the box.^{33–35}

| Triangulation meaning | |
|-----------------------|---|
| Triangulation | <p>A strategy to reduce systematic bias by using multiple methods in which different types of data produce cross–validity checks, in order to promote understanding of what is being observed and to increase confidence in the findings. It is based on the premise that no single method adequately describes an area of study, each method can have errors linked to it and using multiple methods can help facilitate deeper understanding.</p> <p>There are four types of triangulation:</p> <ul style="list-style-type: none">• triangulation of methods, which involves assessing the consistency of findings generated by different data collection methods such as patient surveys for qualitative data on views about care and criterion-based measurement for quantitative data on the same care• triangulation of sources, which involves assessing the consistency of findings generated by different data sources such as data collected at different times or from patients compared with staff or with visitors or from record review compared to interview• triangulation of data collectors, which involves assessing the consistency of findings when multiple data collectors, reviewers or analysts are used, such as two data collectors collecting data on the same cases and comparing the data, not to seek consensus but to understand the reasons for the differences |

Triangulation meaning

- **triangulation of theory or perspective**, which involves assessing the consistency of findings generated by multiple theories or perspectives, such as having different stakeholders provide views on actions to be taken because different groups can have different perspectives.

A common misunderstanding about triangulation is that the point is to demonstrate that different methods yield essentially the same result. The point of triangulation is to look for such consistency, but realise that different methods can yield different results because different methods are sensitive to different things. Triangulation offers the opportunity to understand the reasons for inconsistencies. Inconsistencies should not be viewed as weakening the credibility of findings, but as offering opportunities for deeper insight into the relationship between methods used and the subject of a study.³⁴ The advantages of triangulating data for a clinical audit are increased understanding of the audit subject and increased confidence in the findings.

8.3 How to act to resolve issues in data collection and collation

Actions may need to be taken to improve data quality after data collection has begun. When actions are required to resolve data collection issues, they must be feasible in the context of the clinical audit. Clinical groups must strike a balance between rigour and feasibility when selecting methods to quality control and enhance data quality.²⁷

Possible issues identified by monitoring include under-entry of data, inaccurate data entry and selective choice of data used. Interventions to improve data quality for these issues are in the box.^{13–14, 27, 32, 36–40} Where possible, involve the people who are direct stakeholders in an audit as data collectors so that they are intrinsically motivated to collect data accurately and completely.

| Issue | Possible actions to resolve |
|--|---|
| Data input errors | <p>Emphasise to data collectors that tedium, boredom and lapses in concentration can lead to missing or inconsistent information being entered. Therefore, it is important for data collectors to take breaks from data collection.</p> <p>Use pre-coded response choices and tick boxes that provide for single-choice or multiple-choice responses rather than free text where possible.</p> <p>Use bar codes, optical readers or optical character recognition systems to limit use of keying in data, if feasible.</p> <p>Confirm that the pick lists for responses on compliance with standards and any other information collected are complete and are not causing confusion or bias.</p> <p>Build a feature into an electronic data collection form and/or database that flags 'illegal' entries.</p> |
| Interpretation errors for clinical terms or standards | <p>Provide training sessions for new and existing data collectors. Use web-based training if feasible and desirable, or an interactive workshop to review definitions and instructions, practise collecting data on a sample of cases and develop skills for data collection.</p> |

| Issue | Possible actions to resolve |
|--------------------------------|--|
| | <p>Use continuous cycles of assessment of data collection, feedback and training.</p> <p>For multiple sites, have the lead data collector for a site, who has participated in inter-rater reliability testing, periodically carry out random quality assurance using a sample 5–10% of cases and check the accuracy of data abstraction and coding.</p> <p>Provide timely support to data collectors through a helpline, emails of updates to data collection materials and sessions to discuss and resolve issues.</p> <p>Review and update the definitions and instructions for the standards and the protocol as needed when problems are identified.</p> |
| Under-entry of data | <p>If necessary, go to the initial data source to obtain missing data.</p> <p>Have a rigorous system of checking each data item before analysis begins using collated frequency counts for the standards and any additional data being collected.</p> <p>Use control charts to monitor data.</p> <p>Notify the lead for the clinical audit about missing or anomalous data.</p> <p>Create an audit trail for a problem by entering a problem into a log and recording the actions taken to resolve the problem.</p> |
| Selective entry of data | <p>Educate those collecting and those whose care is being audited about the purpose of the audit and remind people about how the data will be used.</p> <p>Consider obtaining the data via another data source, for example, a laboratory system, instead of asking clinicians to record the data.</p> <p>Have informal meetings without feedback to discuss data quality issues.</p> <p>Provide any feedback on the data in a non-judgemental way and with findings anonymised.</p> <p>Consider using incentives.</p> |

9 How to avoid pitfalls in data collection for clinical audits

No matter how well designed a clinical audit is, pitfalls in data collection can emerge and threaten the effectiveness, timeliness and successful completion of the audit. The pitfalls can show up anywhere in the stages of carrying out a clinical audit. Generally, there are two types of pitfalls: pitfalls related to those involved in the clinical audit and pitfalls related to data.

9.1 Pitfalls related to people and organisations

Information that creates the threat of reputational damage or the possibility of gaining kudos can stimulate action on clinical audit findings. However, actions taken in response to these

circumstances may not be appropriate⁴¹ and there may be dysfunctional consequences of the wrong actions being taken. Some pitfalls relating to dysfunctional behaviours and attitudes of people and organisations participating in clinical audits include that they can:^{14, 41-42}

- fixate on measurement, which can include that they:
 - concentrate on clinical areas being measured to the detriment of other important areas
 - pursue narrow organisational objectives or targets at the expense of strategic coordination
 - focus on short-term issues and neglect long-term implications
 - emphasise not being exposed as an outlier rather than on a desire to improve
 - be disinclined to experiment with new and innovative approaches for fear of appearing to perform poorly
- alter measures of quality, standards or behaviour to gain strategic advantage, which is known as gaming
- falsify or misrepresent data, including using selective and creative data gathering, classification and coding, and perhaps misreporting and fraud
- avoid participation in clinical audits because of concerns such as peer review or information governance.

Ways of reducing potential dysfunctional consequences are in the box:^{39, 41-44}

Possible actions to reduce potential dysfunctional consequences of clinical audit

Ensure that staff at all levels whose care is covered by a clinical audit are actively involved in or at least given information about the clinical audit.

Keep the number of standards in a clinical audit small and manageable.

Make use of evidence-based standards, if possible, to increase acceptability.

Ensure the audit standards include a balanced selection covering the care processes, outcomes and patient satisfaction including standards of interest to clinicians.

Be flexible and careful about how the audit standards are used.

Seek expert interpretation of the audit standards, using both local and external, independent experts.

Use intrinsic motivation of clinical staff, which is the desire to perform as well as possible for the common good or the desire to conform to a person or a team's self-image.

Plan strategies that use implicit incentives that recognise individuals' desires to respect themselves and the organisation. Use direct and indirect incentives such as giving positive feedback to the managers of staff involved in an audit, local awards or submission of posters or papers to conferences and journals.

Identify if staff who do not participate or do not complete forms accurately and completely are not motivated or are unable to undertake data collection for some reason. Use an appropriate strategy to address the causes.

Provide feedback to motivate change, which is perceived by clinicians as valid, credible, timely and from reliable data sources.

In addition, the organisation should have clear leadership for clinical audit, clearly stated expectations about participation in audit, provision of support to clinicians to carry out audits, effective training in the clinical audit process and policies on confidentiality, ethics and information governance for clinical audit.⁴³

9.2 Pitfalls related to data

Data-related pitfalls and possible interventions to prevent or address the pitfalls are in the box.^{14, 20, 45-50}

| Data pitfall | Possible actions |
|---|--|
| Incomplete and/or inaccurate data sets | <p>Carry out a pilot test prior to data collection to identify potential problems.</p> <p>Monitor and clean data as they are received.</p> <p>Identify any patterns that can lead to bias such as samples excluding patients because their records are in continual use.</p> <p>Provide feedback to data collectors.</p> <p>Revise the data collection forms or protocol as needed.</p> <p>If incomplete data in the audit are due to problems with data quality in the data sources, report this as part of the clinical audit findings and take actions to address the problems with the data sources.</p> |
| Information sharing | <p>Involve stakeholders from participating services and organisations to design the audit and standards, overcome any information technology issues, agree on the protocol for sharing data consistent with data protection and information governance requirements, and clarify data ownership.</p> <p>Start the process of getting permission for data sharing as early as possible.</p> <p>Carefully set up data flow agreements with named people responsible in each organisation to manage the sharing.</p> <p>Monitor data sharing and act immediately to resolve any problems.</p> <p>Use a trusted third party or honest broker as a means to link data.</p> |
| Audit fatigue | <p>Consider if it is possible to select a population or sample that does not include the same individuals or organisations that have already had to carry out a large number of audits and retrieve vast amounts of data.</p> <p>Ensure that the amount of data collected and the length of time for data collection is a balance between a 'perfect' data set and a realistic data set. Collect 'just enough' data and don't be tempted to collect 'just in case' data.</p> <p>For ongoing data collection, consider if the amount of data collected can be less than that collected for the baseline and early repeat measurements.</p> <p>Incorporate measurement with another existing work activity or existing data collection system.</p> <p>Simplify data collection forms and automate the data collection process as much as possible.</p> |

| Data pitfall | Possible actions |
|---|--|
| | Involve people who directly provide a service in data collection so they can claim ownership of the data quality. Set aside time to review data with those who collect it before completion of the clinical audit to promote their understanding of how the data are being used and provide positive feedback for their efforts. |
| Maintenance of local confidentiality and anonymity | Consider the sampling strategy, for example, using consecutive cases from a known date could threaten confidentiality. Remind people about the importance of following the requirements of information governance. |

10 How to make arrangements for sharing data for clinical audit and ensure that information governance requirements are met

Some clinical audits involve more than one organisation. Examples include national clinical audits or clinical audits carried out by organisations providing a particular service in a geographical area, a set of organisations involved in the continuum of care for patients with particular needs or diagnoses such as patients included in an agreed care pathway, or a group of organisations that receive services provided by one organisation. In all of these examples, the groups undertaking clinical audits must ensure that arrangements for sharing clinical audit data are agreed and followed and information governance requirements are met.

10.1 Agreeing on and following arrangements for sharing clinical audit data

If a clinical audit involves getting or sharing information from other organisations, there are specific requirements to be met for arranging for security and confidentiality of the data. Start by learning your organisation's policy and processes for sharing information with other organisations or people. Consider if the clinical audit might involve linking databases among organisations and the arrangements in place in your organisation for making use of a 'trusted third party' or 'honest broker'. The NHS Information Centre for Health and Social Services is developing an honest broker service. See www.ic.nhs.uk for further information. Also see *Guide to Facilitating Clinical Audit Across Different Care Settings* at www.hqip.org.uk.

10.2 Ensuring that information governance requirements are met

Ensure that processes are set up to control and monitor the sharing of any data among organisations and test the processes prior to moving from the planning stage to data collection stage for a clinical audit. For a more detailed description of undertaking clinical audits that involve more than one organisation and arrangements for sharing information for clinical audits, see *Guide to Facilitating Clinical Audit Across Different Care Settings* at www.hqip.org.uk.

For a more detailed description of information governance for clinical audits, see *An Information Governance Guide for Clinical Audit and A Quick Guide to Undertaking an Information Governance Compliant Clinical Audit Project* at www.hqip.org.uk. For more information on information governance, see the National Information Governance Board for Health and Social Care at www.nigb.nhs.uk.

For a description of ethical issues related to clinical audit including some related to data, see *Ethics and Clinical Audit and Quality Improvement (QI) — A Guide for NHS Organisations* at www.hqip.org.uk.

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Appendix. Table for selecting sample size for a clinical audit and formulas for calculating sample size for a clinical audit

The numbers in the box assume an expected incidence of 50% for the thing(s) being measured, that is, you assume that the patient care you are looking for in the audit happens about half the time. Also, the numbers assume that the data being collected are binomial, i.e. two discrete categories, such as yes or no, or present or absent.

Recommended sample sizes for ±5% accuracy (when you expect the care you are measuring to happen about 50% of the time) and data are binomial

| Population | 90% confidence ±5% accuracy | 95% confidence ±5% accuracy | 99% confidence ±5% accuracy |
|------------|--------------------------------|--------------------------------|--------------------------------|
| <30 | all | all | all |
| 30 | 27 | 28 | 29 |
| 50 | 42 | 44 | 47 |
| 100 | 73 | 79 | 87 |
| 150 | 97 | 108 | 122 |
| 200 | 115 | 132 | 154 |
| 250 | 130 | 151 | 182 |
| 300 | 142 | 168 | 207 |
| 350 | 153 | 183 | 229 |
| 400 | 161 | 196 | 250 |
| 450 | 169 | 207 | 268 |
| 500 | 176 | 217 | 286 |
| 600 | 186 | 234 | 316 |
| 700 | 195 | 248 | 341 |
| 800 | 202 | 260 | 363 |
| 900 | 208 | 269 | 383 |
| 1000 | 213 | 278 | 400 |
| 2000 | 238 | 322 | 499 |
| 3000 | 248 | 341 | 545 |
| 4000 | 253 | 350 | 571 |
| 5000 | 275 | 357 | 587 |

If there is more than one measure in a clinical audit, the sample sizes could vary for each measure. For example, if there are two standards and a clinical group estimates that one standard is about something that is likely to happen 50% of the time and the other is about something that is likely to happen 80%, the recommended sample sizes for the same confidence level and level of accuracy will vary. In this situation, use the larger of the recommended sample sizes because the larger sample will ‘cover’ both measures and make it easier to carry out the audit.

How to calculate sample size for a clinical audit⁵¹

For 90% confidence level and $\pm 5\%$ accuracy and data are binomial

$$\text{sample size} = \frac{1.645^2 \times N \times p(1-p)}{(0.05^2 \times N) + (1.645^2 \times p(1-p))}$$

For 95% confidence level and $\pm 5\%$ accuracy and data are binomial

$$\text{sample size} = \frac{1.96^2 \times N \times p(1-p)}{(0.05^2 \times N) + (1.96^2 \times p(1-p))}$$

For 99% confidence level and $\pm 5\%$ accuracy and data are binomial

$$\text{sample size} = \frac{2.58^2 \times N \times p(1-p)}{(0.05^2 \times N) + (2.58^2 \times p(1-p))}$$

1.645 = constant for a 90% confidence level

1.96 = constant for a 95% confidence level

2.58 = constant for a 99% confidence level

N = the number in the population

0.05 = the required range of accuracy

p is the percentage of cases for which you estimate the measure of quality will be present (or absent)