

# How to use clinical audit forms

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## **The purpose of forms relating to clinical audit**

Standardized forms can be helpful for defining and explaining the clinical audit process to clinical staff working in a healthcare organization. They also serve to structure the systems to be used in an organization to carry out key stages related to the clinical audit process, including getting support for a clinical audit or presenting findings of a clinical audit.

Forms that may help to structure the way an individual clinical audit is carried out follow. They are:

- a clinical audit proposal form
- a clinical audit data recording and collating form titled Clinical Audit Data Matrix
- a clinical audit abstract form titled Clinical Audit Case Abstract
- a clinical audit data presentation form
- a clinical audit summary report form.

## **The clinical audit proposal form**

The clinical audit proposal form is a useful way to document the entire design for a clinical audit, including the clinical audit measures. The form can be used to inform others about the intended clinical audit and, where relevant, gain support from key stakeholders to undertake the clinical audit.

A copy of the form is on the next two pages. Guidance for completing the form is in the box on page 4.

(front of form)

**CLINICAL AUDIT PROPOSAL**

DIRECTORATE, SERVICE OR TEAM .....

CLINICAL AUDIT TITLE .....

CLINICAL AUDIT OBJECTIVE(S) .....

BACKGROUND TO THE CLINICAL AUDIT (Reason(s) subject and objective(s) were selected) .....

**STAKEHOLDERS AND THEIR INVOLVEMENT (those involved in or affected by the clinical audit and how they will be involved)**

Involvement (tick as many as apply)			
Design	Data sources	Review findings	Plan action
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**ETHICS SCREENING LIST — Does the clinical audit... Any yes response requires ethics review**

- infringe on any patient's rights or risk breaching any patient's confidentiality or privacy?  Yes  No
- pose any risk for or burden on a patient beyond those of his or her routine care?  Yes  No
- involve any clinically significant departure from usual clinical care?  Yes  No
- gather any information about a patient beyond that collected in routine patient care?  Yes  No
- collect data directly from any patient or carer, and if so, could the audit subject a patient or carer to more than minimal burdens or risk?  Yes  No
- involve the use of any untested clinical or systems intervention?  Yes  No
- involve a potential conflict of obligation to patients such as a trade-off between cost and quality or patient safety?  Yes  No
- allocate any interventions differently among groups of patients or staff?  Yes  No

**COMMITMENT AND SUPPORT**

I will ensure that the team undertaking this clinical audit is supported to achieve improvement in the quality of care or service or to refer recommendations for improvement to those responsible and accountable for the service.

Clinical Director/Service Manager/Team Leader

signature .....

date .....

signature .....

date .....

Clinical Audit Lead

(back of form)

**POPULATION DESCRIPTION (patients, service users, events or situations)**

Include these .....

Exclude these .....

Patient or service user ages  All ages  Only between ..... and ..... years of age  
 Number in a year ..... or 6 months ..... or 1 month ..... or 1 week .....

**POPULATION OR SAMPLE AND TIME PERIOD FOR THE CLINICAL AUDIT**

Population ..... cases from ..... date ..... to ..... date .....  
 Sample Type ..... sample ..... Size ..... number .....

**DATA COLLECTION STRATEGY**

Retrospective  Concurrent  Other (specify) .....

**DATA SOURCES TO BE USED**

Patient or service user records  Other (specify) .....

**CLINICAL AUDIT MEASURES (see form)**

**Source of clinical audit measures**

- National standard or guideline  Research study(ies)  Other (specify) .....
- Systematic review or meta-analysis  Group consensus .....
- Local protocol or guideline .....

Additional data to be collected for information only .....

**WORK PLAN**

Planned date(s) .....

Start by ..... Problems and causes analysed by .....  
 Data collected by ..... Action plan implemented by .....  
 'Flagged' cases reviewed by ..... Repeat measurement completed by .....  
 Findings reviewed by ..... Report submitted by\* .....

\*The report may be updated if more than one measure – at – measure cycle is needed to achieve any desired improvements.

**HELP NEEDED**

Is help or support from any other department or service needed to complete the audit?  Yes  No  
 If yes, describe whose help is needed and the nature of the help .....

**COPY** — Send a copy of the signed proposal, including the clinical audit measures to the following: .....



On the front of the form, enter the following information.

1. The name of the **Directorate, specialty, department, service or team** in which the clinical audit is being carried out. If more than one group is involved, enter the names of all groups.
2. The **Clinical audit title** – A useful way to express the title of a clinical audit is to include the feature(s) of quality the audit is about, the subject of the audit and the patients, events or situations the audit applies to. An example of a clinical audit title is Appropriateness and effectiveness of the care provided to people with deep vein thrombosis (see chapter 3).
3. The **Clinical audit objective(s)** – Be sure the reason for carrying out the audit is clearly stated including the **intention for improving** practice if the audit shows the need for improvement. An example of a clinical audit objective is Determine if people with deep vein thrombosis receive appropriate and effective care and change practice to increase the appropriateness and effectiveness of care, if needed.
4. The **Background to the clinical audit**, that is, a brief explanation of the reason(s) the subject was selected for audit and the reason(s), if not obvious, for the objective(s). The explanation of the background can relate to:
  - the need to confirm implementation of a national guideline
  - the intention to measure actual practice that is related to a pattern of complaints or incidents, an identified risk issue or a problem in the day-to-day running of a clinical service
  - a clinical team working through a systematic process to select the highest priorities for clinical audits and that this audit is a high priority.
5. The **Stakeholders** in the audit **and their involvement** in the audit. List those individuals or groups who are involved in the subject of the audit or might be affected by the findings of the audit, and tick the boxes to indicate how they will be involved in the clinical audit process.
6. **Ethics screening list** – Use the questions to check if there could be any ethics issues arising through carrying out the clinical audit. If any question is answered yes, the Clinical Audit Proposal should be sent to the person or group in the organization who screens possible ethics issues for clinical audits.

When the back and inside of the form is completed, submit it to the Clinical Director(s), Department Head(s), Team Leader(s) or other individual(s) who is(are) responsible and accountable for the care or service covered by the subject of the clinical audit. Ask the individual(s) to review the proposal and the statement at the bottom of the cover page, and sign the proposal.

Also submit the form to the Clinical Audit Lead, if there is one, for approval for the clinical audit to proceed.

On the back of the form, enter the following information:

1. The **Population description**, that is, the group of patients, events, situations or cases that will be included in and excluded from the audit. Note the patient ages if age is an important consideration in the description of the population. Note the number of patients, events, situations or cases that happen in a given time period, such as a year, 6 months, 1 month or 1 week.
2. The **Population or sample or time period for the clinical audit** selected for the audit. Identify the number of cases that make up the population. Describe how the population or sample is to be selected for the clinical audit.

3. The **Data collection strategy** selected for the audit
4. The **Data sources to be used** for the audit
5. The **Source** or basis for the **clinical audit measures** to be used for the audit. Tick one or more of the boxes to note the source.
6. The **Work plan**, namely, dates for the completion of major stages in the audit
7. The **Help needed** to carry out the clinical audit, if any, with a description of the nature of the help needed
8. To whom **copies** of the **Clinical audit proposal** form are being sent.

On the inside of the form, enter the **Clinical audit measures** being used for the audit as follows.

- The **Evidence of quality of care or service** is what you are looking for to tell you if quality is being provided, that is, the **minimum essential** or **most important** evidence that would satisfy you that quality care or service is being provided.
- The **Standard** is how frequently you should find the evidence of quality, that is, the **percentage** or proportion of cases for which you expect and accept compliance with the evidence of quality of care or service, for quality improvement purposes. The standard sets a define level or degree of compliance or non-compliance that will serve as a ‘trigger’ for more intensive analysis of the quality of care.

There are three types of standards:

- A **screening standard** is set at **100%** (for things that should **always** happen for patients) or **0%** (for things that should **never** happen for patients) so that the **data collector(s) will automatically ‘flag’ every case that isn’t consistent with a clinical audit measure for analysis** by the clinical team. The purpose of the clinical analysis is to determine if the case represents or doesn’t represent good care and if it doesn’t, find out why good care was not provided and act to prevent such cases in the future. A screening standard does not necessarily express a realistic standard for day-to-day practice. However, it helps clinicians establish empirically safe standards for day-to-day practice.
- An **acceptable standard** is the percentage **cited in the literature** or found as a **benchmark** in best practice services.
- A **target standard** is the percentage you are aiming to achieve.  
Cases that are not consistent with a clinical audit measure that includes an acceptable or a target standard are not flagged for individual case review.
- An **exception** is a case or time the evidence might not be present but it would be clinically justified, that is, a **clinically acceptable** reason or circumstance that would account for not complying with the evidence of quality of care or service. If you use an acceptable or a target standard, leave Exceptions blank.
- **Definitions and instructions for data collection** specify how the evidence and exceptions are defined for data collection purposes. Definitions include clear and objective **terms** to be used to judge compliance with the evidence of quality of care or any exceptions including **synonyms or numerical values**. Instructions specify the most reliable **data source** for the evidence or any exceptions. They also provide directions to the data collector(s) on **how to make decisions** on whether or not an individual case is consistent with the evidence or any exceptions. Complete and accurate definitions and instructions are essential to get reliable data, especially if more than one person is involved in collecting data for an audit, and to ensure reliability in repeat data collection.

If you are including complications as Clinical Audit Measures, use the following model for expressing complications as clinical audit measures.

Complication expressed as a clinical audit measure				Model		
Name of complication	+	Screening standard	+	Critical management (key actions to prevent, recognize or treat)	+	Definitions and instructions for data collection

Enter the complications as clinical audit measures as follows.

How to develop a clinical audit measure for a complication	Guide
<ol style="list-style-type: none"> <li>1. Use the <b>name of the complication</b> as the <b>evidence</b> of quality.</li> <li>2. Use a <b>screening standard of 0%</b>, for audit purposes. This standard will enable you to flag every case in which the complication occurred.</li> <li>3. Substitute <b>critical management</b> for <b>exceptions</b> in the clinical audit measure model. For critical management, list the evidence that would tell clinicians any of the following, as applicable: <ul style="list-style-type: none"> <li>• Appropriate and effective action is being taken to <b>prevent</b> the complication, for example, prophylaxis for deep vein thrombosis.</li> <li>• Appropriate and effective <b>action</b> is being taken promptly <b>when signs and symptoms</b> of a complication are evident, for example, a culture and sensitivity is requested as soon as the signs and symptoms of an infection are observed in a hospitalized patient.</li> <li>• Appropriate and effective action is being taken to <b>manage</b> the complication when it is diagnosed.</li> </ul> <p>Include the few critical aspects of management, not everything that could be done for a patient.</p> </li> <li>4. Clearly and completely <b>define any terms</b> and <b>give instructions for data collection</b>.</li> </ol>	

## The data collection forms

The data collection forms are generic forms to document data collected for any clinical audit. The forms use simple codes to stand for decisions on each case in the audit as follows.

- If the case is consistent with the **evidence**, use **EV**.
- If the case is not consistent with the evidence but is consistent with an **exception**, use **EX**. If you have more than one exception for the same clinical audit measure, you can letter each exception and also record the letter of the exception.
- If the case is not consistent with either the evidence or any exception, use **R** for **review**. The clinical team should consider these cases more carefully.

Copies of the two data collection forms are on the next page.





## The Clinical Audit Data Matrix Form

The Clinical Audit Data Matrix is a paper spreadsheet. It is used to record data on compliance with each clinical audit measure for all cases in the clinical audit, as a data collector is screening the data sources. The form enables easy tallying of clinical audit findings.

Guidance for completing the form for each case in an audit is in the box.

How to complete the Clinical Audit Data Matrix form	Guide
	<ol style="list-style-type: none"><li>1. Under <b>Measure number</b>, enter the numbers of the clinical audit measures for the audit, eg, 1, 2, 3.  For each case in the clinical audit, record the following in a column at the right of the form.</li><li>2. The <b>case code number</b>, which is a unique randomly assigned code number to ensure confidentiality. A list of case code numbers and the cases to which they refer should be kept in a secure place by the data collector in order to identify a patient, case, event or situation, if needed and appropriate when a clinician or a team reviews the preliminary findings.</li><li>3. The patient <b>age and gender</b>, if appropriate for the audit design</li><li>4. The <b>professional code</b>, if appropriate for the audit design. The professional code used should be a unique randomly assigned code number to ensure confidentiality. A list of professional code numbers and the professionals to whom they refer should be kept in a secure place by the data collector to identify an individual professional, if needed and appropriate.</li><li>5. The <b>location code</b>, if appropriate for the audit design. The location code used should be a unique randomly assigned code number to ensure confidentiality. A list of location code numbers and the locations to which they refer should be kept in a secure place by the data collector to identify a ward, clinic or practice, if needed and appropriate.</li><li>6. The <b>length of stay</b> (LOS), if it is appropriate for the audit design.</li><li>7. The number of <b>activities</b>, eg, treatments, visits, or appointments, if appropriate for the audit design.</li><li>8. Next to the appropriate measure number, your decision about the case based on review of the data sources.<ul style="list-style-type: none"><li>• If the case meets the <b>evidence</b>, enter <b>EV</b>.</li><li>• If the case meets an <b>exception</b>, enter <b>EX</b> and the letter of the exception that is met when there is more than one exception.</li><li>• If the case does not meet the measure, enter <b>R</b> for <b>review</b>.</li><li>• If the measure is a <b>complication</b> and if the case meets the <b>critical management</b>, enter <b>CM</b>.</li></ul></li></ol>

## The Clinical Audit Case Abstract Form

Complete a **Clinical Audit Case Abstract** when a case **requires review** (the case was coded **R**) to inform a clinician or a team why you judged a case not to meet a clinical audit measure having a 100% or 0% standard. Guidance for completing the form is in the box.

How to complete the Clinical Audit Case Abstract form	Guide
<ol style="list-style-type: none"><li>1. Before starting to retrieve data for a particular clinical audit, prepare a master copy of the Clinical Audit Case Abstract form for the specific audit.  To prepare the master copy, copy from the Clinical Audit Measures form the following information on to a single copy of the Clinical Audit Case Abstract:<ul style="list-style-type: none"><li>• <b>subject</b> of the audit</li><li>• <b>measure number</b></li><li>• <b>evidence</b> of quality and <b>percentage</b> (also include <b>exceptions or critical management</b>, abbreviated if necessary).</li></ul></li><li>2. Make some copies of the master copy so you have them when you find a case that requires review.</li><li>3. <b>Complete</b> a Clinical Audit Case Abstract <b>only when you find a case that does not meet one or more measures</b> (when the measure uses a screening standard of 100% or 0%).</li><li>4. Enter the <b>case code number</b> and any <b>other information</b> needed.</li><li>5. Enter the <b>date</b> on which the Clinical Audit Case Abstract form is completed.</li><li>6. Record the findings for each clinical audit measure in the column marked <b>Decision</b> using the following abbreviations.<ul style="list-style-type: none"><li>• If the case meets the <b>evidence</b>, enter <b>EV</b>.</li><li>• If the case meets an <b>exception</b>, enter <b>EX</b> and the letter of the exception that is met when there is more than one exception.</li><li>• If the case does not meet the measure, enter <b>R</b> for <b>review</b>.</li><li>• If the measure is a <b>complication</b> and the case meets the <b>critical management</b>, enter <b>CM</b>.</li></ul></li><li>7. If the case does not meet a clinical audit measure, ie, you entered <b>R</b>, in the <b>data collector notes</b> column, document the reason(s) why or any other information that may be useful to a clinician or a team when the preliminary findings are reviewed.</li></ol>	

## The clinical audit data presentation form

The clinical audit data presentation form illustrates how the findings of clinical audit can be presented for review. Any data collected about the ages and/or gender of patients in the audit can be displayed on the front of the form, along with the distribution of any other information collected such as lengths of stay, time from referral to appointment, etc.

On the inside of the form, actual findings of compliance with the clinical audit measures can be displayed along with any information learned about why an individual case did not comply with an audit measure. On the right, notes can be entered as to whether or not individual cases that varied from a clinical audit measure are acceptable and the final compliance for each measure can be noted. Rate-based measures can be further analysed on the back of the form.

Guidance for completing the form is in the box.

How to complete the Clinical Audit Data Presentation form	Guide
<p>On the front of the form, enter the following information.</p> <ol style="list-style-type: none"><li>1. The <b>Subject</b> of the audit, the total <b>Number of cases</b> in the audit and the <b>Date</b></li><li>2. If information about the <b>Age or gender</b> of patients in the audit was requested, display this information in the table under Age/Gender Distribution. Determine the age ranges to be included, eg, 21–30, 31–40, 41–50. Count the number of Males and Females in each age group and record the Totals.</li><li>3. If <b>Location</b> information was requested, display this information in the table under Location Distribution. Record the code number of each location, then the number of cases for each code.</li><li>4. If <b>Length of stay, treatment, visit or appointment times</b> were requested, display this information in the table under Activity Distribution. First establish ranges, for example, of time, then record the Totals in each range, eg, under 5 days, 5–10 days, etc.</li><li>5. If any information items were requested, such as day of week treatment provided, display the information under <b>Information Items</b>.</li></ol> <p>On the inside of the form, enter the following information.</p> <ol style="list-style-type: none"><li>1. The <b>Subject</b> of the audit, the total <b>Number of cases</b> in the audit and the <b>Date</b></li><li>2. The <b>Measure number</b> and <b>Evidence of quality</b> (and exceptions or critical management for complications) for each of the clinical audit measures</li><li>3. The <b>Expected %</b> of cases that should meet the Evidence or exception(s)</li><li>4. The <b>Actual %</b> of cases that met the Evidence or exceptions</li><li>5. Any <b>notes</b> made by the <b>Data collector</b> that would explain the findings</li><li>6. Whether or not (<b>Yes or No</b>) the cases that have not met the evidence of quality or exception were determined to represent acceptable care and the <b>Reason</b></li></ol>	

7. **Adjustments** to the % because of **Acceptable Variations**.

On the back of the form, enter the following information:

1. The **Subject** of the audit, the total **Number of cases** in the audit and the **Date**
2. For rate-based measures, display the rates under **Rate Distribution**
3. Whether or not (**Yes or No**) the rate is acceptable to the audit group and the **Reason**.

The form is illustrated on the next two pages.





## How to calculate final compliance with a clinical audit measure

When calculating final compliance with clinical audit measures, add the number of cases meeting the **evidence of quality** and the number meeting **exceptions**, along with any adjustments to the numbers following **review**. The formulas are in the box.

How to calculate final compliance with a clinical audit measure	Formulas
<p><b>Item-by-item (measure-by-measure) compliance</b></p> <p><b>Percentage compliance with a clinical audit measure following review</b></p>	$  \begin{array}{c}  \text{from data collection} \qquad \qquad \qquad \text{from review} \\  \left( \begin{array}{c} \text{Number of cases meeting} \\ \text{the Evidence} \\ \text{of quality} \\ \text{of care} \end{array} + \begin{array}{c} \text{Number of cases} \\ \text{meeting any} \\ \text{Exception(s)} \end{array} \right) + \left( \begin{array}{c} \text{Number of cases} \\ \text{determined as} \\ \text{meeting the Evidence} \\ \text{of quality of care} \\ \text{or any Exception(s)} \end{array} \right) \\  \hline  \text{Number of cases to which the measure applies}  \end{array} \times 100  $
<p><b>All-or-none (all measures) compliance</b></p> <p><b>Percentage compliance with all clinical audit measures following review</b></p>	$  \begin{array}{c}  \text{from data collection} \qquad \qquad \qquad \text{from review} \\  \left( \begin{array}{c} \text{Number of cases} \\ \text{meeting the} \\ \text{Evidence of quality} \\ \text{of care for all the} \\ \text{clinical audit} \\ \text{measures that} \\ \text{applied to them} \end{array} + \begin{array}{c} \text{Number of cases} \\ \text{meeting any} \\ \text{Exception(s) for all} \\ \text{the clinical audit} \\ \text{measures that} \\ \text{applied to them} \end{array} \right) + \left( \begin{array}{c} \text{Number of cases} \\ \text{determined as meeting} \\ \text{the Evidence of quality of} \\ \text{care or any Exception(s)} \\ \text{for all the clinical} \\ \text{audit measures that} \\ \text{applied to them} \end{array} \right) \\  \hline  \text{Number of cases to which at least one of the measures applied}  \end{array} \times 100  $

## How to calculate final compliance for a complication measure

For a complication measure, use the formulas in the box below to determine final compliance.

How to calculate final compliance for a complication measure	Formulas
<b>Compliance with the entire measure</b>	
<p><b>Percentage compliance with a complication measure following review</b></p>	$= \frac{\left( \begin{array}{l} \text{from data collection} \\ \text{Number of cases meeting the Evidence of quality of care (and 0\% standard), ie, a named complication did not occur} \end{array} \right) + \left( \begin{array}{l} \text{from review} \\ \text{Number of cases determined as meeting the Evidence or Critical Management} \end{array} \right)}{\text{Number of cases to which the measure applies}} \times 100$
<b>True rate of the occurrence of a complication</b>	
<p><b>Complication rate</b></p>	$= \frac{\left( \begin{array}{l} \text{Number of cases in which a complication occurred and the case met the Critical Management} \end{array} \right) + \left( \begin{array}{l} \text{Number of cases in which a complication occurred and the case did not meet Critical Management} \end{array} \right)}{\text{Number of cases to which the measure applies}} \times 100$

The true rate of a complication is unlikely to change following case review unless there was an error in data collection.



## The clinical audit summary report form

The clinical audit summary report form shows how a clinical audit can be summarized in a brief report format. The team carrying out the audit, the subject and the objective(s) can be recorded on the front of the form, along with the findings from data collection in comparison to the clinical audit measures. There is space on the form to report the original data collection findings plus the findings of two rounds of repeat measurement.

On the inside of the form, problems revealed by the clinical audit and their causes can be summarized. On the right, the actions planned and implemented can be noted. This record of problems, causes and actions can be useful for future clinical audits.

Guidance for completing the form is in the box.

How to complete the Clinical Audit Summary Report form	Guide
<p>On the top front of the form, enter the following information.</p> <ol style="list-style-type: none"><li>1. The name of the <b>Directorate, specialty, department, service or team</b> in which the clinical audit was carried out. If more than one group is involved, enter the names of all groups.</li><li>2. The <b>Clinical audit title</b> – Include the feature(s) of quality the audit was about, the subject of the audit and the patients, events or situations the audit applied to.</li><li>3. The <b>Clinical audit objective(s)</b> – Include the intention for carrying out the clinical audit, including the intention for improving practice if the findings showed the need for improvement.</li><li>4. The <b>Patients, situations or events in the audit</b> – Describe the patient group, situations, events, records, referrals, etc involved in the audit, the number and how a sample was selected, if a sample was used.</li></ol> <p>Under <b>Findings</b>, enter the following information.</p> <ol style="list-style-type: none"><li>1. The <b>Measure number</b> and <b>Evidence of quality</b> (and exceptions or critical management for complications) for each of the measures in the clinical audit</li><li>2. The <b>Expected % (Standard)</b> of cases that should meet the Evidence or exception(s)</li><li>3. The <b>Actual %</b> of cases that met the Evidence or any exception or critical management for complications, from the <b>original baseline</b> data collection</li><li>4. The <b>Actual %</b> of cases that met the Evidence or any exception or critical management, from the <b>first repeat</b> of data collection</li><li>5. The <b>Actual %</b> of cases that met the Evidence or any exception or critical management, from the <b>second repeat</b> of data collection</li></ol>	



