



HQIP

Healthcare Quality
Improvement Partnership

Guide to Carrying Out Clinical Audits on the Implementation of Care Pathways

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Clinical audit tool to promote quality for better health services

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1 Introduction to this guide

1.1 Who this guide is for

This guide is intended for anyone considering carrying out a clinical audit on the implementation of a care pathway including:

- clinical audit and clinical governance managers and staff
- clinical audit or clinical governance leads
- clinicians who want to audit the use of their care pathways
- others who are interested in the implementation of care pathways.

1.2 How the guide is intended to help

This guide is intended to help you carry out clinical audits on care pathways including how to:

- identify what is important to audit for a care pathway
- select the right focus for the clinical audit on a care pathway
- develop the right standards to measure quality for a clinical audit on a care pathway
- make decisions about how data will be collected for an audit on a care pathway
- ensure that the right provisions for data protection and communication are in place for an audit on a care pathway
- consider the right way to analyse the data for the clinical audit on a care pathway.

1.3 Different meanings of care pathway and forms care pathways can take

A care pathway aims to improve the continuity and coordination of care received by patients from various professions and organisations across the continuum of care in order to improve patient outcomes, safety and satisfaction and make the best use of resources.¹ A care pathway can support treating the **right patient right** at the **right time** and in the **right way**.²

Integrated care pathway (ICP) is the commonly used name for care pathways in the UK. ICPs also are referred to as care pathways, clinical pathways, critical pathways, multidisciplinary pathways, collaborative care pathways, care paths, case management plans or care maps. ICPs do the following:²⁻⁸

- specify the desired goals and outcomes for a group of patients with a diagnosis or care need
- describe care activities needed to achieve the goals for 70% to 80% of the patients with the diagnosis or need, including the sequence, timing and responsibility for each activity by professional, the patient or a carer
- are based on evidence of good practice, that is, guidelines and protocols, where they are available, or local consensus
- integrate what the evidence says with local knowledge, experience and conditions such as the needs of local patients and structures and systems for delivering care
- form some or all of the patients' records for the episode of care
- include monitoring and evaluation of variances from the pathway and achievement of outcomes.

1.3.1 Typical ICP documentation

The ICP document can take different forms but usually includes the following:^{3,5}

- a cover sheet or section for patient identification information
- a grid or checklist of activities and outcomes in chronological order
- a variance tracking section
- a signature and initials sheet or section for staff providing the care.

An ICP document also can include:^{3,5}

- eligibility criteria for deciding if it is appropriate to use the ICP for specific patients
- assessment forms, medical order sets, patient and family educational materials, graphic record sheets for monitoring and consent forms for procedures
- a summary sheet expressed in a way that patients can understand, perhaps with a section for patient comments
- references used for evidence of good practice.

1.3.2 Distinguishing care pathways and guidelines and protocols

ICPs incorporate evidence-based recommendations from guidelines and locally-based processes of care from treatment protocols. The terms are defined in the box.

Term	Meaning
Guideline	Systematically developed statements designed to help practitioners and patients make decisions about appropriate health care for specific clinical circumstances, but not to replace their knowledge and skills ⁹⁻¹¹
Treatment protocol	A local adaptation of a guideline that is a summary of the recommendations from a guideline taking account of local patients and experience and structures and systems for care provision. A protocol is a structured outline of how patients with a given diagnosis are to be treated. ¹²
Care pathway	A multidisciplinary, locally agreed, evidence-based plan describing the expected progress of a specific patient group that forms all or part of the clinical record. By facilitating the evaluation of outcome, a care pathway can be a quality improvement tool for use as part of clinical governance ⁴

ICPs support quality improvement because they involve:

- reviewing current practice
- getting feedback on the use and effectiveness of the pathway in achieving its aims
- redesigning the process of care delivery and/or documents used for the ICP as needed, based on the feedback and evidence of good practice.

1.3.3 Variance reporting

A key feature of ICPs is variance reporting and analysis. Key terms are defined in the box.
5, 8, 13-14

Term	Meaning
Variance	<p>An unplanned or unusual event that is the difference between an activity, time period or outcome that should have been achieved and what actually occurred for a patient</p> <p>Can allow for individualising care for each patient's needs for the 20% to 30% of patients whose needs are different from those on which the ICP is based</p>
Variance analysis	<p>Recorded data about a patient's variance are analysed and acted on concurrent with care to rectify a departure from care and goals for an individual patient and to identify patients who are exemptions from the ICP</p> <p>Recorded and aggregated data on variance are analysed retrospectively to identify trends and possible causes and decide on actions such as to modify and/or update the evidence base for the ICP</p>
Types of variance	<p>Variance can be avoidable or unavoidable and positive or negative:</p> <ul style="list-style-type: none">• avoidable/unavoidable<ul style="list-style-type: none">– Avoidable variance could have been prevented with good planning, for example, delayed results from a laboratory investigation.– Unavoidable variance could not have been prevented, for example, a patient has an allergic reaction to a drug and the patient didn't know about the allergy in advance.• positive/negative<ul style="list-style-type: none">– positive, for example, a patient recovers more quickly– negative, for example, a patient has a wound infection delaying discharge to home.

Examples of variance, variance analysis and types of variance are in the box on the next page. These examples are adapted from a presentation on an ICP on admission of patients to adult mental health inpatient services.¹⁵

Outcome that should have been achieved

Nutritional assessment is completed within 24 hours of admission.

Concurrent analysis and action on outcome variance for a patient and the types of variance found

Mrs X was admitted on 25 March. Review of achievement of outcomes for Mrs X by a clinical team member on 27 March revealed that a nutritional assessment had been started but not completed. The clinical team member found out that the assessment was not completed because Mrs X had not felt able to continue answering questions at the time. The clinical team member did the following:

- approached Mrs X about her feeling able to continue with the assessment
- completed the assessment with Mrs X's permission
- learned that Mrs X had not been eating most of her meals because she had sensitivities to certain foods
- documented the assessment
- organised that meals would accommodate Mrs X's needs
- documented the variance that had occurred and the action that was taken.

The variance was **negative** and **avoidable**. Some might consider the variance unavoidable because the patient's condition did not permit completion of the assessment. However, the increased time to completion of the nutritional assessment could have been prevented if it had been spotted earlier and Mrs X approached earlier to see if she was able to answer questions.

Retrospective analysis of aggregated data on outcome variance and the types of variance found

Collated data for a 3-month period revealed that 62.7% of patients had a nutritional assessment within 24 hours of admission, 26.4% did not, and for 10.9% of patients, the data were missing.

The variance was **negative** with a mixture of **avoidable and unavoidable** causes.

Avoidable	Unavoidable
Assessment tool not available	Unable to complete due to patient's condition
Assessment tool not suitable	Patient declined
Assessment started and not finished	Patient discharged or left within 24 hours of admission

The clinical team took the following actions:

- ensured that adequate copies of the right assessment forms were available in each clinical area
- reviewed the nutrition assessment forms being used by other services and updated the current form as needed
- reminded staff to carry out daily review of outcomes to be achieved.

1.4 The importance of carrying out appropriate clinical audits on the implementation of care pathways

ICPs can support clinical audit. Care that should have occurred is specified and care that was provided is clearly documented in the ICP. So if the patient's ICP record is the primary data source, data collection for a clinical audit should be simplified.

ICPs are developed for patient groups or conditions that happen frequently. They include consideration of risks and problems associated with the patient groups and the related care, including patient safety concerns and complaints or issues raised. They also may consider aspects of service where there has been unacceptable variation in clinical practice or for which national guidelines have been issued or expectations set by commissioners. Thus, the patient care covered by ICPs is important for patients as well as healthcare organisations that are involved in providing the care. The ICP development and implementation processes include monitoring and acting on variances in order to refine the ICP.

Clinical audit on the implementation of an ICP assures the clinical team involved that the ICP is being used as intended and is achieving its defined purposes. However, if clinical audits of ICPs are not well designed and carried out the right way, there are missed opportunities to improve the quality of care provided to the patients affected by ICPs. In addition, clinicians can waste their time and healthcare organisations can waste resources.

2 How to identify what's important for a clinical audit on an ICP

2.1 Planning an audit on an ICP

A group wanting to carry out a clinical audit on an ICP needs to consider and agree on:

- the people who will be part of the group doing the clinical audit, including representatives of the professions and organisations involved in delivering care and patients or other service users
- the key stakeholders in the audit, including those who may have to act on findings, and how they will be involved in the audit, for example, participating in designing the audit, providing views on the service, helping to identify why variances may occur or implementing actions needed for improvement
- the staff who will support carrying out the audit.

The group will need to decide on the subject of the clinical audit, specifically the part or parts of the ICP or group of ICPs to be included. For example, a clinical team from a primary care setting could decide to do clinical audits on any of the following related to an ICP on self harm:¹⁶

- assessment of a patient's mental state and mood
- completion of an assessment of risk of self harm
- provision of immediate management and treatment consistent with the ICP and, if a patient is known to mental health services, consistent with the clinical management plan within the Integrated Care Programme Approach (ICPA) for the patient
- follow up of patients at risk of self harm or who self harm

- referral of patients at risk of self harm or who self harm
- implementation of the clinical management plan
- use of the entire ICP on self harm.

Depending on the ICP, clinical audits can involve more than one organisation such as another NHS organisation, primary care centre, social services and/or other providers. For example, possible audits on self harm could be carried out by a primary care team only or along with walk-in centres, minor injury units, an ambulance service, acute general hospitals or mental health services.

If more than one organisation is involved, the group needs to consider joint working principles, confidentiality, data exchange and information governance among the involved organisations. For a more detailed description of what's involved in doing a clinical audit across organisations, see *Guide to Facilitating Clinical Audit across Different Settings* at www.hqip.org.uk.

2.2 Selecting the right focus for a clinical audit on an ICP

After deciding on the ICP or part of an ICP a group wants to audit, the group members need to decide **why** are they doing an audit on this ICP, that is, the objective(s) for the audit. The group members have to take the time to be **absolutely clear why** they want to do the audit. The statement of exactly **what the group wants to achieve** becomes the basis for all the other decisions that go into designing a clinical audit.

An **objective** for a clinical audit should include these three ideas:¹⁷

- a **verb** that describes the group's **intention** for doing the clinical audit and **commitment** to act on the audit findings
- the feature(s) of **quality** the group wants to focus on in the audit
- the **specific care or service** the audit is about, in this case, the name of the ICP or part of the ICP that is the subject of the audit.

A model for writing an objective for a clinical audit is in the box.¹⁷

Objective model				
Verb	+	Quality focus	+	Subject
The intention for doing the clinical audit—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 is the clinical subject of the audit

In phrasing the objective for the audit, the group needs to think carefully about verb use and the link to quality improvement, considering the following:

- **Changing** verbs, such as ‘**increase compliance with**’, ‘**ensure that guidelines are being followed**’ or ‘**reduce the level of**’, tend to express most clearly the direction for improvement of current practice.
- **Comparing** verbs, such as ‘determine if standards are being followed’ or ‘indicate the level of compliance with standards’ need a phrase added about taking action if needed. Without such a phrase, it can be unclear if anything will be done about the audit findings.
- **Counting** verbs, such as ‘find the rate of’ or ‘determine the number of’ can leave others thinking you intend to describe current practice for information purposes and not to improve anything.

Focus the clinical audit by deciding on the one or two features of quality that are currently most important for the subject. The features of quality that may be important for a clinical audit on an ICP are in the box.¹⁸

Term	Meaning
Acceptable (as an experience)	Patients or service users and their carers or others are satisfied with their care or service and the way the care or service was or is being given.
Accessible	Patients or service users can get access to the care or service they need reasonably promptly and conveniently .
Appropriate	The right decisions are made about a patient’s or service user’s problem and about the treatment or service needed, given current evidence from valid research or professional consensus—and these decisions are shared with the patient or service user to the greatest extent possible.
Effective	Care or service is provided to patients or service users in the right way , ie, consistent with scientific knowledge and refraining from providing services that are unlikely to benefit patients.
Efficacious	The right outcomes for the patient or service user are achieved, ie, the patient or service user experiences the benefits of care or service that the treatment is supposed to provide.
Efficient	The desired effect is achieved with a minimum of effort, expense or waste of equipment, supplies, ideas or energy.
Safe	The way care or service is provided avoids injuries to patients from care that is intended to help them.
Timely	Care or service is provided to patients or service users when it is needed , ie, avoiding sometimes harmful delays for patients.

After the group has decided on the subject and the objective(s) for the audit, the audit design can be completed, including deciding on the cases or events from what time period to include as the population or sample, any other stakeholders in the care being audited and the data collection strategy to be used to carry out the audit.

2.3 Selecting and developing the right clinical audit standards for a clinical audit on an ICP

Drawing up clinical audit standards to measure quality involves developing thoughtful and complete answers to the four questions in the box.¹⁷

Question	Part of clinical audit standard
What should we look for to tell us if we are providing quality?	Evidence of quality of care or service—the criterion for judging quality
How frequently should we expect to find the ‘evidence’—if we are providing quality?	Percentage or proportion of cases for which there should be evidence of quality
Are there any cases or times the evidence might not be present but it would be clinically justified ?	Exceptions
How will we define the evidence (and exceptions) for data collection purposes?	Definitions and instructions for data collection

A model for a clinical audit standard is in the box.¹⁷

Evidence of quality of care or service	+	Frequency	+	Known exceptions	+	Definitions and instructions for data collection
States the way the feature(s) of quality is(are) to be observed for the subject of the audit		The percentage compliance desired		Circumstances that are clinically acceptable for not complying with the evidence of quality		How terms in the evidence of quality of care or service and known exception(s) are defined for data collection purposes and where evidence should be obtained

3 How to make decisions about data collection and analysis

3.1 Defining terms and instructions for data collection

Complete, 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. Define terms used in the clinical audit standards, including synonyms or numerical values, and develop precise instructions for the data collection process.

Instructions for data collection specify the most reliable **data sources** for the information in the clinical audit standards. For an audit on an ICP, data sources will include the ICP documentation and perhaps information held in other parts of a patient record or information systems, or information to be learned directly from patients. Instructions 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 being sought or any exceptions.

To structure the data collection process, answer the following questions:

- In addition to the ICP documentation, what **data sources** are needed to find evidence of standards being met, if any? Are the data sources the most likely to give the truest picture of patient care with the least effort?
- Who will be the **data collectors** and how will they be **trained**?
- How will the **cases** to be included in the audit **be selected**? If a population or a representative sample of cases is to be used, how will a list of all cases be obtained?
- What will serve as **data collection forms** to record the data?
- **When** can **data** be **collected** given any timing considerations?
- How will clinical audit **data** be **coded and stored to control anonymity and confidentiality**?

Use the decisions to develop a data collection protocol. The term is defined in the box.¹⁷

Term	Meaning
Data collection protocol	<p>A description for data collectors and other stakeholders of how a clinical audit design and standards are being operationalised, ie, details on how data for a clinical audit are to be collected. It documents decisions on the following:</p> <ul style="list-style-type: none">• 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• storing clinical audit data.

3.2 Pilot testing

Even when data collectors have the same training and directions and when the group members have taken the greatest care writing a data collection protocol, it can't be assumed that data collectors will collect data the same way or retrieve the same data. It is important, therefore, to carry out tests on:

- the completeness, effectiveness and efficiency of the data collection protocol
- the level of inter-rater reliability among the data collectors in order to identify any unclear instructions or other threats to reliable and complete data.

Carry out a pilot test of the clinical audit to accomplish both tests. The group won't be able to draw accurate conclusions about the quality of patient care and take the right actions to improve patient care if the group doesn't know that all possible threats to reliable and valid data have been thought about and acted on.

3.3 Requiring data protection processes

Clinical audit data need to be handled safely and sensitively to protect the identity and privacy of patients and the privacy of healthcare professionals whose care is being judged in the audit. Ensure that anonymity and confidentiality of audit data are maintained. Guidance for maintaining confidentiality of clinical audit data is in the box.¹⁷

Data collection provisions to maintain confidentiality of clinical audit data

Do not include the following in data collection forms for a clinical audit (or the presentation of clinical audit data on an ICP):

- **names** of patients or healthcare professionals
- patient record or **NHS numbers**
- professional or practice **identification numbers**
- **any easily linked identifying information.**

Use codes to protect the identity of patients, professionals, wards, primary care centres or clinics involved in the audit on the ICP.

Restrict access to completed data collection forms and any other forms related to the audit to those given clearance by the group carrying out the clinical audit on an ICP.

Store clinical audit **data in a secure place.**

Use code lists to record names and code names or numbers assigned for the audit to allow for linking a code number on a data collection form to an actual case, should the need arise.

Store the document that converts names or patient record numbers to audit codes **in a different secure place.**

For a more detailed description of handling information governance requirements for clinical audits, see *An Information Governance Guide for Clinical Audit* at www.hqip.org.uk.

3.4 Communicating about the clinical audit

Clarify with the clinical team how communication about the clinical audit will be done and what the rules are for sharing information about the clinical audit and the findings. For example, consider the following:

- Who needs to know about the clinical audit on the ICP and how will they be informed?
- Who needs to be updated on the progress of the clinical audit on the ICP and how will they be informed?
- Who will participate in the peer review of the cases that did not meet the audit standards to decide if the 'flagged' cases represent previously unrecognised exceptions that are acceptable or cases of unacceptable care?
- What information will be shared at group meetings and what can or can't be shared?
- Who needs to be aware of the audit findings and how will they be informed and what can they share?
- Who needs to be aware of the actions taken based on the clinical audit findings and when and how will they be informed?

For a more detailed description on how to report on a clinical audit, see *Template for Clinical Audit Report* at www.hqip.org.uk.

Carry out the remaining stages of the clinical audit including:

- collecting, collating and analysing the data
- reviewing the cases that did not meet the standards
- identifying any problems revealed by the findings and the causes of any problems
- implementing actions to improve practice if improvement is needed
- measuring again to determine the effectiveness of actions taken.

These stages for an audit of an ICP do not differ from those for other clinical audits.

4 An example: The Liverpool care pathway and a clinical audit design, standards and data collection protocol and form

The Specialist Palliative Care Team at the Royal Liverpool and Broadgreen University Hospitals NHS Trust and the Marie Curie Hospice, Liverpool developed an ICP for end-of-life care. It is referred to as the Liverpool Care Pathway for the Dying Patient (LCP).¹⁹⁻²³ The second national audit of the LCP was carried out in 155 hospitals from October to December 2008 and the report was published in September 2009. The purposes of the audit were comprehensive and the report included the findings of an organisational audit and a patient level audit as well as identification of key performance indicators.

Goals of care for patients in the dying phase are in the box on the next page.¹⁹

Goals of care for patients in the dying phase

Comfort measures

Goal 1—Current medications are assessed and non-essential medications discontinued.

Goal 2—As required, subcutaneous drugs are prescribed according to a protocol for pain, agitation, respiratory tract secretions, nausea or vomiting.

Goal 3—Inappropriate interventions (blood tests, antibiotics, intravenous fluids or drugs, turning regimens or vital signs) are discontinued; not for cardiopulmonary resuscitation is documented.

Psychological and insight issues

Goal 4—Ability to communicate in English is assessed as adequate (translator not needed).

Goal 5—Insight into condition is assessed.

Religious and spiritual support

Goal 6—Religious and spiritual needs are assessed with the patient and family.

Communication with family or others

Goal 7—How family members or other people involved are to be informed of the patient's impending death is identified.

Goal 8—Family or other people involved are given relevant hospital information.

Communication with primary healthcare team

Goal 9—The patient's general practitioner is aware of patient's condition.

Summary

Goal 10—The plan of care is explained and discussed with the patient and family.

Goal 11—Family or other people involved express understanding of the plan of care.

An example of a possible locally-based clinical audit on the LCP, based on the goals in the box, follows. The example includes a draft clinical audit design with standards, data collection protocol and data collection form. The example includes clinical audit standards for the goals specified. However, a team could decide to focus a local audit on only one or two aspects of care about which they have the most concern, for example, effectiveness of communication with the patient and the patient's family, or the appropriateness of use of drugs or other interventions.

Clinical audit design for an audit on the effectiveness of care of patients in the dying phase

Audit title	Effectiveness of care of patients in the dying phase
Objective	Ensure that care of patients in the dying phase is carried out effectively, that is, consistent with the LCP for patients who are dying.
Stakeholders and involvement	<p>The stakeholders for the audit include patients, families and friends of patients, clinicians providing care including doctors, nurses and therapists, and commissioners of care.</p> <p>Representatives of each clinical profession will direct the audit, analyse the findings, plan actions and measure the impact of the actions. Data will be collected by ward sisters and the palliative care team. The results of the clinical audit will be shared with clinical staff and commissioner stakeholders and will be available to patients, families and carers.</p>
Patients and time period	<p>The population is all patients who have died on hospital wards in the last month, whether or not the death was sudden or anticipated, for whom at least two of the following are documented in the record:</p> <ol style="list-style-type: none">the patient is bed bound and/orthe patient is only able to take sips of fluids and/orthe patient is semi-comatosed or comatosed and/orthe patient is no longer able to take tablets
Data collection strategy	The records of all patients who died will be compared with the standards retrospectively.

Clinical audit standards for an audit on the effectiveness of care of patients in the dying phase

Evidence of quality of care or service	Screening frequency	Exceptions	Definitions and instructions for data collection
1. The patient's current medications were assessed	100% of dying patients	None	Look for a note on the prescription record or the progress notes that indicates that the assessment has been done.
2. Oral medications were prescribed	0% of oral medications prescribed for 100% of dying patients	None	See the prescription record for any oral drug prescribed and note the reason for the prescription, if documented.
3. A PRN prescription was written for subcutaneous drugs to control pain or discomfort	100% of dying patients	None	Look for prescriptions for any of the following drugs: to control pain (diamorphine or morphine), agitation (midazolam), respiratory tract secretions (hyoscine hydrobromide), nausea or vomiting (cyclizine), or dyspnoea (diamorphine). Note any other drugs prescribed and the reason for the prescription, if documented.
4. Unnecessary interventions were carried out	0% of dying patients	None	'Unnecessary interventions' means any of the following: blood or other lab tests, intravenous fluids or drugs, turning regimens or vital signs.
5. 'Not for cardiopulmonary resuscitation' was recorded in the patient's record	100% of dying patients	A. The patient's family does not agree to this action	See notes in the patient's record for reference to 'do not resuscitate' or reference to the exception.
6. The patient's record includes notes about the assessment of the patient's insight into his or her condition	100% of dying patients	A. The patient is in hospital less than 2 hours before dying B. The patient is comatosed	See notes in the patient's record for the doctor's assessment of the patient's perception of his or her condition or reference to one of the exceptions. 'In hospital less than 2 hours' means time recorded that the patient arrived in the Emergency Department or, if patient was a direct admission, the time recorded that the patient arrived on the ward, until the time of the notation that patient was assessed is less than 2 hours.
7. The patient's record includes notes confirming that religious and spiritual needs were assessed with the patient and the patient's family	100% of dying patients	A. The patient had no family present and the patient was unable to express his or her needs	See notes in the patient's record for the doctor's assessment or reference to the exception.

8. The patient's record refers to how the patient's family or other people want to be informed of the patient's death	100% of dying patients	A. The patient had no family or others present	See notes in the patient's record for how people involved with the patient want to be informed of the patient's death by hospital staff or reference to the exception. Examples of notes could be: contact family at any time, not at night-time, the family wishes to stay overnight in the hospital.
9. The plan of care for the patient was explained and discussed with the patient and the patient's family or other involved people	100% of dying patients	A. The patient was not able to participate in discussion B. The patient had no family or other involved people present	See the patient's record for a plan of care in the dying phase and for reference to the plan of care being explained and discussed with the patient and the patient's family or other involved people or reference to one of the exceptions.
10. The patient's family or other people involved expressed understanding of the plan of care	100% of dying patients	A. The patient had no family or other people present B. The patient was admitted following a traumatic injury or sudden serious illness	See the patient's record for reference to the response to the plan of care by the patient's family or other involved people or to one of the exceptions.

Standards 2 and 4 could have been expressed with 100% rather than 0% as follows:

2. Oral medications were NOT continued	100% of dying patients	None
4. Unnecessary interventions were NOT carried out	100% of dying patients	None

The 0% frequency is used in the example to emphasise aspects of care that should **never** happen for a dying patient.

Additional information to be collected will include:

- the clinical specialty responsible for the care of the patient
- the ward or wards on which the patient received care when dying
- if the patient's death was anticipated or sudden
- the presence of a notation in the record that the patient was dying
- if the palliative care team was notified
- which of the following clinical conditions the patient had:
 - a. the patient is bed bound
 - b. the patient is only able to take sips of fluids
 - c. the patient is semi-comatosed or comatosed
 - d. the patient is no longer able to take tablets.

Clinical audit data collection protocol for an audit on the effectiveness of care of patients in the dying phase

Data collectors	Ward sisters and the palliative care team. The number of deaths likely to occur in a month and the availability of the ward sisters and palliative care team members will determine the number needed for data collection.
Case selection method	<p>All patients who have died on hospital wards in the last month, whether or not the death was sudden or anticipated, for whom at least two of the following are documented in the record:</p> <ol style="list-style-type: none">the patient is bed bound and/orthe patient is only able to take sips of fluids and/orthe patient is semi-comatosed or comatosed and/orthe patient is no longer able to take tablets <p>The hospital's information system will be used to identify all patients who died on hospital wards in the last month. The care record for each patient who died will be reviewed for the presence of any two of the conditions a–d. If a patient does not have at least two of the four clinical conditions, the patient is not eligible for inclusion in the audit and the data collector will proceed to the next patient on the list.</p> <p>If the clinical record for any patient cannot be located or the patient does not have two of the necessary clinical conditions, the case will not be replaced with another case from another month. A record of the total number of patients who were excluded due to absence of two of the conditions a–d or to missing records will be presented as an audit finding.</p>
Sources of information	Patient records; requests for laboratory, radiology and other investigations and prescriptions from the relevant information systems
Data recording	A specially-designed form including standard-related and general data such as the specialty and ward(s) providing care will be used.
Definitions and instructions for data collectors	<p>Detailed directions for the data collectors will describe how to protect the confidentiality and anonymity of the audit data; determine the patients who are eligible for inclusion in the audit; use the code sheets; complete the data collection form including the general data to be collected and when to tick 'yes', 'no' or 'not applicable' for each standard; and what to do if they have any questions. For example, directions for standard 6 will be:</p> <p>6. The patient's record includes notes about the assessment of the patient's insight into his or her condition (100% of dying patients)</p> <p>Exception A. The patient is in hospital less than 2 hours before dying</p> <p>Exception B. The patient is comatosed</p> <p>See notes in the patient's record for the doctor's assessment of the patient's perception of his or her condition or reference to one of the exceptions. In hospital less than 2 hours means time recorded that the</p>

patient arrived in the Emergency Department or, if patient was a direct admission, the time recorded that the patient arrived on the ward, until the time of the notation that patient was assessed is less than 2 hours.

For the **evidence of quality**, do the following:

- Tick 'Yes' if there is evidence of assessment of the patient's insight into his or her condition.
- Tick 'No' if there is no evidence of assessment of the patient's insight into his or her condition.

For **exception A**, do the following:

- Tick 'Yes' if there is no evidence of assessment of the patient's insight into his or her condition but the patient was in hospital for less than 2 hours.
- Tick 'No' if there is no evidence of assessment of the patient's insight into his or her condition and the patient was in hospital for 2 or more hours.
- Tick 'NA' if there is evidence of assessment of the patient's insight into his or her condition, ie, the evidence of quality was ticked as 'Yes'.

For **exception B**, do the following:

- Tick 'Yes' if there is no evidence of assessment of the patient's insight into his or her condition but the patient was comatosed.
- Tick 'No' if there is no evidence of assessment of the patient's insight into his or her condition and the patient was not comatosed.
- Tick 'NA' if there is evidence of assessment of the patient's insight into his or her condition, ie, the evidence of quality was ticked as 'Yes' or exception A was ticked 'Yes'.

If the evidence of quality and exception A and exception B are all ticked 'No', explain the reason for your decision in the Comments section of the form by recording the number of the standard and your comment.

Timing of data collection

Data will be collected in the clinical audit department. A schedule for data collection will be developed that takes account of the availability of the patient records and data collectors, and space in the clinical audit department to accommodate the data collectors.

Data protection controls

For purposes of confidentiality and anonymity, the following must be strictly adhered to:

- Data collection forms will NOT contain any identifying information of the patient or the specialty or ward(s) providing care. Completed data collection forms will be stored securely in the clinical audit department.
- An audit case number will be allocated to each patient included in the clinical audit. A Case Code List will be used to record the code number assigned to the patient for the audit, the patient's name and the patient's NHS number so that any patient identification data such as name or NHS number are protected. The Case Code List enables allocation of code numbers for each patient in the audit and

acts as a back-up to retrace patient records if and when needed. The allocated two-digit case code number will be transferred onto the data collection form in the spaces that are titled 'Audit case code'.

- A Specialty Code List will be used so that specialty identification is protected during data collection and analysis and other stages of the audit. The list will show the name of each specialty and the unique code number assigned to the specialty for this clinical audit only. The allocated two-digit specialty code number will be transferred onto the data collection form in the spaces that are titled 'Clinical specialty in charge of the patient's care'.
- A Ward Code List will be used so that specific wards are not identifiable. The list will show the name of each ward and the unique code number assigned to the ward for this clinical audit only. The allocated two-digit ward code number will be transferred onto the data collection form in the spaces that are titled 'Ward(s) for care and management of patient'.
- The code lists will be stored in the clinical audit department in a secure place separate to the one used for completed data collection forms.
- Completed data collection forms will not be shown to anyone except those authorised by the clinical audit lead for this audit.

Data collation and analysis

There will be two stages to data collation and analysis. The first will occur following data collection and the second following review of those cases which did not meet the clinical audit standards to determine if any variations from clinical audit standards are clinically acceptable.

Collation and presentation of the findings following data collection for the preliminary review will include counting the following for **each clinical audit standard**:

- a. the number of cases that met the evidence of quality of care
- b. the number of cases that met any exception(s)
- c. the number of cases requiring further review.

In addition, the number of cases that met the evidence of quality of care plus the number of cases that met any exceptions for **all the clinical audit standards** will be determined and presented.

Because a 'screening frequency' of 100% or 0% is being used in the clinical audit, cases that do not clearly meet the evidence or any exceptions will be subjected to clinical peer review by the audit group to determine if there are any acceptable reasons for the variation. Following the review, if any cases that are flagged for review are judged to represent acceptable care, the number and percentage meeting a clinical audit standard (and all standards) will be adjusted.

Clinical audit data collection form for an audit on the effectiveness of care of patients in the dying phase

Case data and information	Codes and responses		
1. Audit case code	<input type="checkbox"/>	<input type="checkbox"/>	
2. Clinical specialty in charge of the patient's care (code only)	<input type="checkbox"/>	<input type="checkbox"/>	
3. Ward(s) for care and management of patient (codes only)	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
4. Was death anticipated or sudden?	Yes	No	NA
a. Anticipated	<input type="checkbox"/>	<input type="checkbox"/>	—
b. Sudden	<input type="checkbox"/>	<input type="checkbox"/>	—
c. Unable to determine	<input type="checkbox"/>	<input type="checkbox"/>	—
5. Is there a notation in the record that the patient is dying?	<input type="checkbox"/>	<input type="checkbox"/>	—
6. Was the palliative care team notified that the patient was dying?	<input type="checkbox"/>	<input type="checkbox"/>	—
7. Were any of the following documented in the record?			
a. the patient is bed bound	<input type="checkbox"/>	<input type="checkbox"/>	—
b. the patient is only able to take sips of fluids	<input type="checkbox"/>	<input type="checkbox"/>	—
c. the patient is semi-comatosed or comatosed	<input type="checkbox"/>	<input type="checkbox"/>	—
d. the patient is no longer able to take tablets	<input type="checkbox"/>	<input type="checkbox"/>	—
NOTE: If the patient did not have at least 2 of the 4 conditions listed in question 7, stop collecting any further data on this patient and proceed to the next patient in the audit.			
Clinical audit standards	Yes	No	NA
1. The patient's current medications were assessed	<input type="checkbox"/>	<input type="checkbox"/>	—
2. Oral medications were NOT continued	<input type="checkbox"/>	<input type="checkbox"/>	—
3. A PRN prescription was written for subcutaneous drugs to control pain or discomfort	<input type="checkbox"/>	<input type="checkbox"/>	—
4. Unnecessary interventions were NOT carried out	<input type="checkbox"/>	<input type="checkbox"/>	—
5. 'Not for cardiopulmonary resuscitation' was recorded in the patient's record	<input type="checkbox"/>	<input type="checkbox"/>	—
Exception A. The patient's family does not agree to this action	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The patient's record includes notes about the assessment of the patient's insight into his or her condition	<input type="checkbox"/>	<input type="checkbox"/>	—
Exception A. The patient is in hospital less than 2 hours before dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exception B. The patient is comatosed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The patient's record includes notes confirming that religious and spiritual needs were assessed with the patient and the patient's family	<input type="checkbox"/>	<input type="checkbox"/>	—
Exception A. The patient had no family present and the patient was unable to express his or her needs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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