## Getting ClinicalAudit Right to Benefit Patients

Contents	Page
Foreword	v
Acknowledgements	vii
Purpose	1
<ul> <li><b>1 — The clinical audit process</b></li> <li>Why do clinical audit</li> <li>Clinical audit defined</li> <li>The clinical audit process</li> <li>Rapid-cycle approach to clinical audit</li> <li>Clinical survey versus clinical audit</li> <li>Clinical audit and research</li> <li>Relating research and clinical audit to providing clinically</li> <li>effective care</li> <li>The quality improvement process</li> <li>Risk management processes</li> <li>Patient safety processes</li> </ul>	2 2 3 5 6 7 9 11 14 17
An accountability framework	18
<ul> <li>2 — How to design a clinical audit</li> <li>The importance of doing clinical audit effectively</li> <li>Expectations for clinical audit</li> <li>How to design a clinical audit</li> <li>How to select subjects for clinical audit</li> <li><i>Quality impact analysis</i></li> <li>How to develop a clinical audit objective</li> <li>Selecting a verb to express intent</li> <li>Defining quality</li> <li>Formulating the clinical audit objective statement</li> <li>How to title a clinical audit</li> <li>How to select the right cases for a clinical audit</li> </ul>	<ul> <li>20</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>25</li> <li>26</li> <li>27</li> <li>27</li> <li>29</li> <li>30</li> </ul>
How to think about the number of cases to include and how they will be selected	31

#### Contents

How many cases should be included	32
How to decide on a population or a sample	33
How to select a sampling method	35
How to decide on sample size	37
How to decide on a data collection strategy	40
3 — How to draw up measures for a clinical au	ıdit 42
Why 'measures'	42
Clinical audit measure defined	42
How to draw up a clinical audit measure	45
How to convert a clinical audit objective to a clinical	l audit measure 47
How to define a standard	48
Templates for clinical audit measures	50
For a measure on access (measured in time)	51
For a measure on appropriateness	52
For a measure on effectiveness	53
For a measure on efficiency	54
For a measure on acceptability (patient experience)	55
For a measure on efficacy (benefits or outcomes)	56
Approaches to measures	57
Outcome versus process measures	58
Types of clinical audit measures	59
How to define the denominator and the numerator	- 60
Exclusions versus exceptions for individual clinical and	udit measures 63
How to measure a complication	67
Characteristics of a clinical audit measure	70
How to test the validity of a quality-of-care measure	e 71
How to evaluate a clinical audit design and measure	es 74
How to convert evidence into clinical audit measure	es 75
4 — How to collect and collate data for a clinic	al audit 78
How to develop a data collection protocol	78
Data sources	80
Data collectors	80
How to test the reliability of data collection	81
Case selection	82
Data collection tools	83
Timing of data collection	87
Data protection and control	87
How to pilot test a clinical audit design and data co	ollection 89
What data collection involves	90
How to document decisions and observations	91
How to collate preliminary clinical audit findings	94
How to calculate preliminary compliance	95

\_

Contents	Page
How to calculate preliminary compliance for a complication measure	100
5 — How to review findings of a clinical audit	101
The importance of careful review of preliminary findings of a clinical audit	101
What's involved in reviewing preliminary findings Sensitivity and specificity	101 102
How to test the sensitivity and specificity of a clinical audit measure	102
How to review individual cases	104
How to carry out review of preliminary clinical audit findings	105
How to calculate final compliance	106
How to calculate final compliance for a complication measure	107
What the preliminary review of clinical audit findings achieves How to carry out review of final clinical audit findings	108 109
How to display and analyse variation in clinical audit findings	105
Types of causes of variation	112
Common cause variation	113
Special cause variation	114
How to determine the type of variation	115
How to act on variation How to present the findings of a clinical audit	119 120
6 — How to analyse problems and their causes	122
The importance of taking time to analyse problems How to focus on improvement	122 123
Problems and causes	123
How to state a problem	124
How to find the root causes of a problem	125
Fishbone (cause-and-effect) diagramming	125
Asking why five times	129
Process analysis	130 134
Causes of problems	154
7 — How to implement change for improvement and repeat measurement	136
Clinical audit paradigm	136
Audit and feedback model	136
Quality improvement model	136
Implementing change	137
Where 'theory of change' fits in	138
The $I-M-P-R-O-V-E-S$ model	139
Identifying the improvement Express the improvement	140 141
	1-11

Contents	Page
Identify the types of changes needed	142
Moulding (or mobilizing) opinion	143
Preparing a strategy for change	145
Redesigning current practice	149
Operating the new way	152
Verifying that the new way works	154
Eliminating unwanted variation	154
Stabilizing change	154
Measuring the impact of actions	155
Continuing the clinical audit process	155
How to plan repeat measurement	156
Repeat data collection strategies	157
How to carry out follow-up	157
8 — Putting clinical audit in context	159
Organizational support	159
Ethical considerations	160
Glossary	163
References	181
Appendix	193
Index	195



# The clinical audit process

### Why do clinical audit — To improve and account for quality

If you provide or manage a healthcare service, you have to know about the quality of health care being delivered. Clinical audit is a process for finding out how well care is being provided and learning if care and outcomes can be improved.

Clinical audit is a systematic activity that applies knowledge about good clinical practice to day-to-day delivery of patient care. So it is a professionally acceptable way to participate in performance evaluation and a way to show accountability for quality of care. Benefits of carrying out the clinical audit process are in the box.

Guide

#### Benefits of the clinical audit process

The clinical audit process:

- shows that the care you provide is routinely consistent with evidence of good practice
- when there is no valid evidence available that defines good practice for an aspect of care, shows that your practice is consistent with good practice as agreed by consensus among your colleagues
- helps you **find** exactly **where improvements** in practice **are needed and** helps you **make** these **improvements**
- **raises** your **awareness** of the **information** that has to be documented in a patient's record in order to assess the quality of care, whether the record is electronic or paper
- **facilitates learning** about current practice among members of a clinical team and **working together** to make improvements.

### Clinical audit defined — To improve care

The meaning of clinical audit, as described in this book, is explained in the box on the next page.<sup>1</sup> A definition of quality improvement is also provided.<sup>2–3</sup>

Term	Meaning	Definitions	
Clinical audit	A <b>quality improvement process</b> that seeks to improve pati outcomes through systematic <b>review</b> of care <b>against explic</b> <b>and</b> the <b>implementation of changes</b> in practice if needed		
	and systematically compared with explicit measures of go Where indicated, changes are implemented at an indiv	spects of the structure, processes and outcomes of care are selected nd systematically compared with explicit measures of good practice. /here indicated, changes are implemented at an individual, team r service level and <b>further measurement</b> is carried out <b>to confirm</b> <b>aprovement</b> in healthcare delivery.	
Quality improvement	Systematic, data-guided activities designed to bring about positive changes in the delivery of health care in particula		

### The clinical audit process — *Measuring quality and acting on the findings*

The steps in the clinical audit process are in the box. The process involves:

- defining best practice for patients with a condition or experiencing an aspect of care or service
- checking if patients actually receive care that is best practice
- changing the way care is delivered to make improvements, if needed.

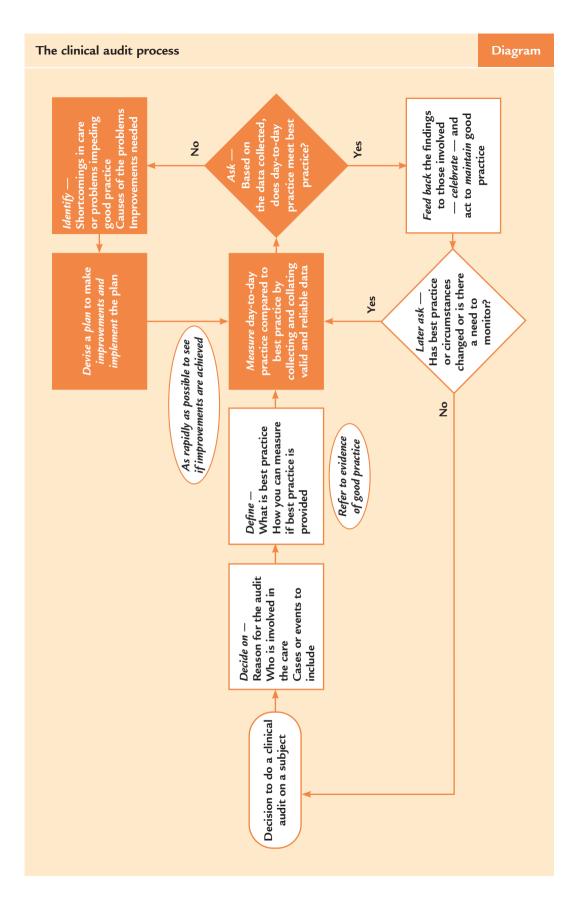
#### The clinical audit process

In the clinical audit process, a clinical team works through these steps:

- agrees on an important subject for clinical audit and the objective/s of the audit
- designs carefully how the audit will be carried out
- **formulates** precise **measures of** the **quality** of care or service, which may incorporate standards or evidence of good clinical practice
- uses the clinical audit measures as the basis for collecting data on day-to-day practice
- evaluates the findings and any cases or events that did not meet quality expectations
- *if the findings show that the clinical audit measures are being met, gives feedback* on good practice to those involved and acts to maintain good practice
- if the findings show that the *clinical audit measures* are *not* being *met*:
  - analyses the shortcomings in care or the problems revealed and finds their root causes
  - **takes action** to eliminate or minimize the causes of the problems and achieve the intended improvement
  - **measures again** when action is taken to see if patient care is improved.

The clinical audit process is shown in the diagram on the next page. The darker shapes show the quality improvement part of the process.

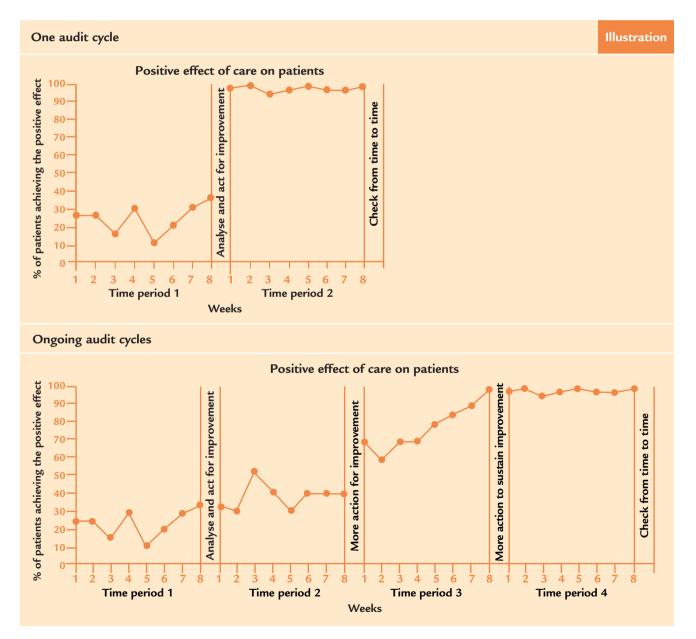
Guide



### Rapid-cycle approach to clinical audit — A classic before-after design

The graphs below show how clinical audit works as a quality improvement process. An audit is a study that can measure what happens before and after making a change in practice. The first measurement of actual practice establishes a baseline of current practice in comparison to best practice. If best practice is not being provided currently, the team carrying out the clinical audit plans and implements changes in the way care is being provided in order to improve practice — as rapidly as possible.

Then, the team has to repeat the measurement to find out if the change worked. The measure — act — measure cycle may need to be repeated several times to show that changes being made really are improving care.



### Clinical survey versus clinical audit — *Measuring what is or* what should be

People have used the term clinical audit to describe two different activities:

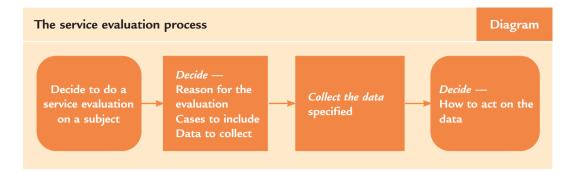
- **description** or **observation** of current practice. This type of activity is better referred to as a **service evaluation** as defined in the box.<sup>4</sup>
- **measurement** of current practice in comparison with specific qualityof-care **measures** or 'criteria'.

Term	Meaning	Definition
Service evaluation	<b>Collects</b> and interprets data about a service <b>without ref</b> <b>standard</b> that defines good practice or service	erence to a

Characteristic Service evaluation or Clinical audit Guide descriptive study What's Collect data to find out how many Collect data to find out how many involved times something happens to patients were treated consistent patients - counting the incidence with a criterion - measuring of certain events compliance with a stated expectation of quality Reason for Find out **what** current practice is Find out if current practice is doing Establish a baseline of current consistent with best practice Solve problems that impede practice Contribute to standards of good providing quality care Improve current practice if needed practice Identify specific aspects of care for a clinical audit Inferred from data collected How quality Explicitly defined in measures is measured No stated standard of care Stated standard of care Examine variation from measures Expect variation in practice Outcomes of Data on current practice – may Confirmation of good practice or the activity stimulate changes in practice improvement in practice

The characteristics of each type of activity are in the box.

The diagram of the service evaluation process on the next page shows that improvement could happen from a service evaluation, but it is not an explicit part of the formal process.



This book is about the criterion-based model of clinical audit because it is the clinical audit model more closely associated with achieving improvements in quality of care.

### Clinical audit and research — Differences in purposes

It is useful to understand the differences in purposes between clinical audit and research. The term research is defined in the box.<sup>5</sup>

Term	Meaning	Definition
Research	The attempt to derive <b>generalizable</b> or transferable <b>new knowledge</b> to answer or refine questions with scientifically sound methods	

Research is about generating hypotheses and verifying scientifically a predicted but not necessarily proven relationship between or among variables such as clinical processes and outcomes. Research studies in health care also observe the outcomes and costs of healthcare interventions.<sup>6</sup> The way research works is shown in the diagram on the next page.

Clinical audit and research are both scientifically sound methods of investigation. Clinical audit is about measuring current clinical practice compared with established good practice. Clinical audit is not about finding out which treatments or other interventions work best. The major differences between the activities are in the box on page 9.