

Clinical Audit in Primary Care: From Evidence to Practice

Oreste Capelli^{1*}, Silvia Riccomi², Marina Scarpa², Nicola Magrini³,
Elisabetta Rovatti⁴, Imma Cacciapuoti¹ and Antonio Brambilla¹

¹The District Primary Care, Emilia-Romagna Region, Bologna,

²General Practitioner, Dept of Primary Care, Modena,

³Drug Evaluation Unit, Emilia-Romagna Health Agency, Bologna,

⁴Dept of Pneumology – University Hospital – University of Modena and Reggio Emilia,
Italy

***Ma anche fra i cultori di scienze, fra i medici pratici, taluni han l'inclinazione intellettuale a trovare sufficiente qualunque mediocre spiegazione, mentre altri durano gran fatica ad acquietarsi.*

Augusto MURRI, Professor of Internal Medicine, Bologna University, Italy, 1905.

1. Introduction

The word *Audit* is borrowed from economics and stands for the examination of records or financial accounts with the purpose of checking their accuracy. In a wider sense, an *audit* can be described as an inspection of the accounting procedures and records by a trained accountant, as it happens in business management or information technology (Simon, 2008).

Clinical Audit is a term which has acquired different meanings over time in relation to health care quality. Ten years ago the National Institute for Clinical Excellence (NICE, 2002) published the first manual of Clinical Audit, with the classical definition "Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change".

More recently, a new definition has been proposed by the National Clinical Audit Advisory Group (NCAAG, 2010): "Clinical audit is the assessment of the process (using evidence-based criteria) and/or the outcome of care (by comparison with others). Its aim is to stimulate and support national and local quality improvement interventions and, through re-auditing, to assess the impact of such interventions."

The basic requirements to match a well-designed Clinical Audit to clinical praxis are:

* Corresponding Author

**Both among scientists and clinical practitioners, some find it easier to rely upon trivial explanations, while others never stop looking for answers.

- changing the usual clinical praxis (care) into the best available practice (**improvement process**),
- basing it on a **systematic review** of knowledge and praxis,
- conducting it with **explicit criteria**, sustained by evidence based knowledge and with **measurable end-points** (indicators),
- completing it with an **implementation pathway**, putting knowledge into praxis.

Further, and not less important, benefits are connected with a good clinical audit: opportunities for education and training, easier relationships among clinicians, clinical teams, managers and patients, improvements in service delivery and patient outcomes (NHS Wirral, 2012).

2. Clinical Audit in Primary Care (PC): What it is and what it isn't

*(Quality) is the point at which subject and object meet.... Quality is not a thing. It is an event.... It is the event at which the subject becomes aware of the object. (Pirsig, 1974)****

2.1 Audit and Clinical Governance

In the last 40 years, a dramatic evolution in healthcare protection has taken place, starting a race towards the sustainable effectiveness of health procedures. Managers and directors have mainly focused on the economic aspects of healthcare, planning therefore all activities in terms of availability of resources. Later on, more and more importance was given to the quality of care, where effectiveness was to be associated with appropriateness, safety, fair and equal participation of every individual user. All these characteristics concur to the Clinical Governance (CG) of a healthcare system.

The CG is “a system through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish” (Scally & Donaldson, 1998). The CG is also a system centred on the patient's needs. Effective involvement of both patients and carers is essential in order to attain the main target of quality of care. (Zwanenberg & Harrison, 2004). The CG is not just a new organizing facility, but the very core of a health policy based on the quality of care, through strong interactions among its multiple components (Table 1), as reported by Starey (Starey, 2001). Clinical Audit is an essential and integral part of CG (Burgess, 2011; Zwanenberg & Harrison, 2004; Wienand, 2009).

2.2 What is Clinical Audit (in Primary Care)

“Audit & feedback” continues to be widely used as a strategy to improve professional practice. Healthcare professionals should be obviously prompted to modify their practice once they are given feedback that their clinical practice is inconsistent with that of their peers or accepted guidelines. A Cochrane systematic review (Jamtvedt et al, 2006), evaluated

***Pirsig Robert M. (1974) “Zen and the Art of Motorcycle Maintenance” Publisher: William Morrow & Company, first edition, ISBN 0-688-00230-7.

118 clinical trials to assess the effects of audit and feedback on healthcare professionals' practice, and patients' outcomes. Jamtvedt et al. conclude that their effects on the improvement of professional practice are generally modest to moderate. The effectiveness of "Audit & feedback" is likely to be greater when baseline adherence to recommended practice is low and when feedback is delivered more intensively.

Clinical Audit has been more extensively applied in secondary care, where the majority of the scientific literature comes from. Since the role of the PC is being considered by all healthcare policy makers as an increasingly important part of future healthcare provision, clinical audit should be applied to this level of practice in order to assess whether patients are receiving the best quality of care (Burgess, 2011). A fundamental part of a good practice implies regular monitoring of standards of care and the willingness to make changes. Measuring the practice through Clinical Audit provides the best available tool to know when change is needed. (Benjamin, 2008).

- Participation of all professionals in Clinical Audit;
- Evidence-based practice is supported and applied routinely in everyday practice, use of guidelines and implementation of recommendations;
- Effective monitoring of clinical care with high quality systems for clinical record keeping, the collection of relevant information and assessing outcomes;
- Clinical risk systematically assessed with programmes in place to reduce risk
- Critical incident reporting ensures that adverse events are identified, openly investigated, lessons are learned and promptly applied
- Complaints procedures accessible to patients and their families
- Involvement of patients and their families
- Education and training
- Research and development

Table 1. Elements of Clinical Governance (CG) (adapted from Starey, 2001)

According to Benjamin (2008), there are several elements (or tools) to perform an effective Clinical Audit in PC:

- The audit should be part of a structured programme and should have a local leader;
- Clinical audit should assess structure, process, or outcomes of care;
- Audit should ideally be multidisciplinary;
- Patients should ideally be part of the audit;
- Audit topics should be chosen in relation to high risk, high volume, or high cost problems or in relation to national clinical audits;
- Standards should be selected from good quality guidelines;
- Action plans should be devised so as to overcome the local obstacles to changes, and to identify the right people for service improvement;
- Audits should be repeated in order to find out whether improvements in care have been implemented as a result of a previous cycle;
- Specific mechanisms and systems should be developed to monitor and reinforce service improvements once the audit cycle has been completed.

Clinical Audit in PC should be part of the ordinary working procedures, where professionals share and compare their daily activity with evidence-based standards adapted to fit their settings. However, clinical practice in PC is hard and complex and can seldom be

assessed by means of a linear cause-effect approach: too many ungovernable and unpredictable events occur between a physician's prescription and a clinical outcome, i.e. understanding of information, patient's compliance, drugs tolerability, facilities presence or absence in the local healthcare system, etc. Other obstacles may be found in the very habits, attitudes and motivations of the professionals themselves (see paragraph 3.4 on audit barriers). Since the outcome is never guaranteed, that is the main reason why, at the end of any process, a re-assessment of the performance is needed.

2.3 What Clinical Audit is not (in Primary Care)

*“Research is concerned with discovering the right thing to do;
Audit with ensuring that it is done right “(Smith R, 1992)*

Clinical Audit in PC is neither a case report discussion, nor a way of managing healthcare resources, though its results can give useful suggestions in this direction. Furthermore, Clinical Audit is not simply a means of producing data and statistics, especially with control purposes. Finally, Clinical Audit is not a synonym for research: it aims to assess to what extent a process is consistent with best practice and/or achieves expected outcomes.

Research helps to answer the question *‘What is best practice?’*. It is concerned with creating new knowledge about which treatment works better in a given clinical situation. It lays the foundations of consensus about the type of care that we should be providing. Clinical Audit answers the question, *‘Are we following agreed best practice?’*. However, research and audit are closely linked. Without research, it is impossible to know what best practice actually is; without audit, it is impossible to know whether we are following best practice (Simon, 2008). Both research and clinical audit may involve measurement of patient outcomes, even though their purpose is different: if the objectives are clear, one should concentrate on three questions:

1. Is the purpose of your project to try and improve the quality of patient care?	Yes	No
2. Will the project involve measuring current practice against standards?	Yes	No
3. Does the project include anything being done to patients beyond their routine clinical management?	Yes	No

If the answers are ‘yes’ to the first two questions and ‘no’ to the third, the project is very likely to fall within the remit of clinical audit (Potter et al, 2010).

Research and Clinical Audit are distinct activities with different goals (table 2).

However, Audit and Research are interrelated in four ways (Black, 1992):

- Clinical Audit can provide high-quality data for non-experimental evaluative research;
- Research provides a basis for defining good-quality care for audit purposes;
- Research into the effectiveness and cost-effectiveness of clinical audit is essential in order to establish the value of different interventions;
- Research is to be audited in order to ensure that high-quality work is performed.

	Clinical Audit	Observational Research	Experimental Research
Purpose	To evaluate how closely local practice resembles best practice.	To formulate questions on a theme relating to practice or policy	To establish the best or most effective practice.
Questions	Are we doing the right thing? Are we actually doing what we think we are doing?	What happens about this thing under the present circumstances?	What is the right thing to be done?
Knowledge	It provides knowledge primarily about the service being audited.	It provides knowledge primarily about the relationship between an event and its (possible) cause/s	It aims to add new knowledge to the large body of published research knowledge.
Methods	No allocation to treatment groups; final results should be influenced by auditors who identify areas of non-conformity with evidence-based practice and apply changing strategies before re-audit	Clear sampling methods, with reasonable response rate (>40%); final results shouldn't be influenced by researchers' intervention	Pre-specified research plans together with hypotheses related to the objective of the intervention; final results shouldn't be influenced by researchers' judgement
Sample size	The number of cases, based on previous findings, should be large enough to influence practice	The size should be sufficiently large to avoid sampling bias, so that surveys can have wide applicability	Statistically supported sample size (depending on expected effect)
Data analysis	Simple statistics (e.g. means, frequencies) to compare audit cycles	Simple descriptive statistics	Data analyses are required for inference making
Results compared	with standards that define good practice.	with a cohort of not exposed subjects	with a randomized control group
Implications of results	The results mostly have implications for the service being audited.	The results mainly have implications for specific populations and context	The results have implications for the whole field of health-care and often beyond it.
Reports	Results are often only reported locally and the identity of clinicians is protected.	Results are reported publicly and the researcher is open to scrutiny.	Results are reported publicly and the researcher is open to scrutiny.
Ethical approval	Not required	Often not required	Always required
Outcome	Strategies in place to improve clinical practice	Leading to clinical effectiveness strategy (e.g. guidance or audit)	Improved basic or/and applied knowledge

	Clinical Audit	Observational Research	Experimental Research
Afterwards	Practice changes, then the audit is repeated in the same way to see if the changes obtain the desired effect.	The research may be repeated with different populations or in different contexts to expand the knowledge about causes and effects	Other people will repeat the research to test or add to the validity of the result, or to challenge the hypothesis.

Table 2. Similarities and differences among Clinical Audit and Research (Observational or Experimental) - modified and integrated from Brain et al, 2009; Clark & Rowe, 2002; and Potter et al, 2010.

3. How to conduct a Clinical Audit: The circular pathway (Audit cycle)

Good preparation is crucial to the success of a clinical audit project. Topic choice will be determined by a number of factors, but the focus should be one of identifying opportunities for improving care. Clinical audit involves looking at one's own practice, not that of others, but the priorities of those receiving care can differ quite markedly from the priorities of those giving care. User involvement is therefore fundamental to successful, meaningful audit. For this reason stakeholders need to be involved in the process at all stages, appropriately using their skills in and knowledge of the audit topic. All those involved in audit need access to training and/or advice in conducting audit projects to develop their skills and to ensure the effectiveness of projects undertaken (Burgess, 2011).

Clinical audits are best conducted within a structured program, adequately funded, with clearly defined roles, effective leadership to drive the process, participation by all relevant staff, and an emphasis on team working and support. A timetable to maintain momentum is also essential. Protected time needs to be made available to those involved in audit work if its aim is to achieve improving quality in healthcare (Burgess, 2011).

Clinical audit can be described as a cycle or a spiral (see Figure 1), formed by the succession of determined steps or stages that follow:

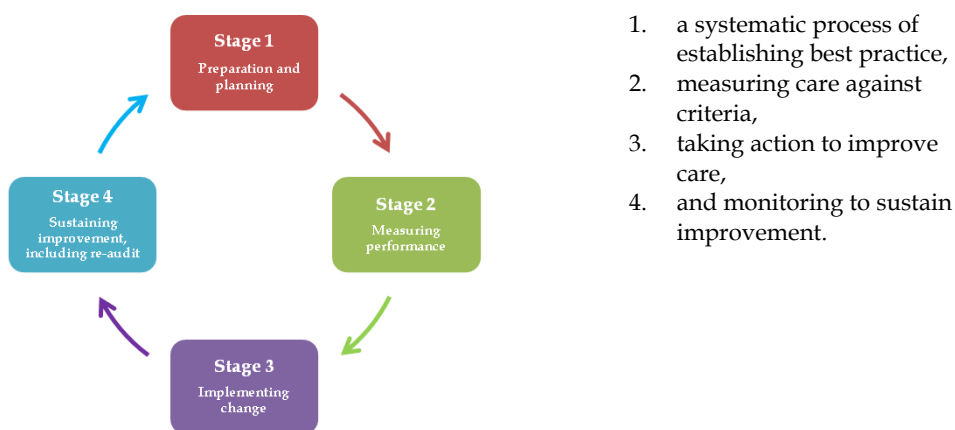


Fig. 1. The cycle of AUDIT - essential steps (modified from Burgess, 2011).

Questions about clinical praxis Bhopal & Thomson, 1991		NICE, 2002	Actions (Stages) to answer the questions (to implement change of the praxis)
What do we do? What should we do?	What are we trying to achieve?		Stage 1: preparation, planning and organisation of clinical audit
Do we do what we think we do? Are we doing what we should be doing?	Are we achieving it?		Stage 2: measuring level of performance (and comparing it with standards)
How can we improve what we do?	Why are we not achieving it?		Stage 3: making improvements (after analyzing the barriers to change)
Did we improve?	Have we made things better?		Stage 4: sustaining improvements (after the re-audit)

Table 3. Clinical audit answers to some questions with a step-by-step process.

The spiral suggests that as the process continues, each cycle aspires to a higher level of quality (NICE, 2002), to drive up standards of healthcare and service provision (Burgess, 2011). To maintain adherence to the praxis, different questions must find answers in the corresponding steps of the “Audit cycle” (Table 3).

3.1 Clinical Audit: First of all be clear with terms

In clinical audit, criteria, indicators and standards are used to assess a wide range of aspects of the quality of care provided by an individual, a team or an organisation.

Before studying the single steps of the “Audit cycle” we need to focus on the use of some terms that may be either used as synonyms or with different meanings.

Recommendation: it represents the “best practice”, as it answers the following question: “*which is the right thing to do (or the worst thing to keep from doing)?*”. Choosing a recommendation for an Audit should come from reviewing and comparing existing Guidelines (GLs) (Baker & Fraser, 1995) in order to enhance the transferability of evidence to different settings (see paragraph 3.2).

Criterion: it is a term used when a recommendation goes from general to specific, measurable and contextualized. It answers the question “*What is the right thing to do for this particular patients in the present situation?*”. Audit criteria are clearly defined, measurable, explicit statements of what should be done to patients, and whenever possible it should be based on up-to-date evidence (Burgess, 2011). There should be adequate research evidence that the recommendations from which they are derived are related to clinical effectiveness, safety and efficiency (Wollersheim et al, 2007). Some examples are outlined in the Quality and Outcomes Framework 2010/11 of the English NHS (QOF, 2012).

Indicator: it is the qualitative and quantitative measure to determine the distance between practice and its standard (Hermens, 2011). Indicators should be explicitly defined as measurable elements of practice performance, for which there is evidence or consensus that they can be used to assess the quality of care. They should therefore change the quality of

patient care, clinical support services, and organisational function that affect patient outcomes (CCHSA, 1996; Lawrence 1997). An indicator usually is a mathematical function sometimes measuring the ratio between a number of subjects fulfilling the criterion and the general population, sometimes referring to mean values (e.g. scores at a questionnaire or at a validated scale) (Hermens, 2011). Indicators come from data obtained in field research and therefore depend upon its completeness and precision. In 1966 Donabedian distinguished 3 types of indicators: structure, process and outcome (Table 4).

What indicators measure?	Questions...	...and Answers (with some examples)
The structure of care	<i>What do you need?</i>	Staff and resources that enable healthcare: eg. resources such as the presence of a dedicated stroke unit or a diagnostic facility;
The process of care	<i>What do you do?</i>	Investigations, treatments, procedures: eg. waiting times in clinics, or number of diagnostic procedures performed;
The outcome of care	<i>What do you expect?</i>	Measurable change in health status: eg. reduction of blood pressure or the number of hospital admissions in response to therapy.

Table 4. Indicators in Clinical Audit: some examples..

Many examples of all three types of indicators in the Primary Care setting are outlined in the Quality and Outcomes Framework 2010/11 (QOF, 2012).

Standard: it represents the optimal level of performance. It is the value a specific indicator should have, had the criterion been applied in optimal conditions, eluding known exceptions (e.g.: asthmatic patients with an acute myocardial infarction should not receive beta-blockers). Standards are quantifiable statements detailing the specific aspects of patient care and management that one intends to measure current practice against. According to Bristol Clinical Audit Team standards should be **SMART**: Specific, Measurable, Agreed, Relevant and Theoretically sound (UHBristol NHS, 2009).

Standards should always be based on the strongest up-to-date evidence of what constitutes best practice, possibly based on the most widely applicable GLs available. If GLs/protocols do not exist, or existing ones are out of date, it is necessary to undertake a systematic literature search to identify current best practice. Before Clinical Audit starts, on-the-spot agreement on standards is essential. It is hard to improve practice if there is disagreement as to what constitutes best practice.

However according to Anderson in his "ABC of Audit" (2012) there are several types of standard:

a **minimum standard** describes the lowest acceptable standard of performance; minimum standards are often used to distinguish between acceptable and unacceptable practice;

an **ideal standard** describes the care that should be possible to give under ideal conditions, with no constraints. By definition such a standard cannot usually be attained;

an **optimum standard** lies between the minimum and the ideal. Setting an optimum standard requires judgement, discussion and consensus with other members of the team; optimum standards represent the standard of care most likely to be achieved under normal conditions of practice.

Acceptable Performance Level (APL): Performance levels, expressed as a percentage of the standard, should be agreed at the outset of the audit for each audit criterion. They are a compromise between clinical importance, practicability and acceptability (Crombie et al, 1993). APL overlaps Anderson's "minimum standard" (Anderson, 2012) and represents the objective difficulty of transferring ideal criteria (coming from controlled studies) to the real settings. Selecting and developing appropriate performance levels is the core of audit. It is generally agreed that each audit criterion should have a performance level or target assigned to it. Indeed, failure to do this can lead to missed opportunities for improvement, even where practice appears to be good. Open discussion among the audit team members and relevant stakeholders needs to take place in order to agree on the most appropriate performance levels. These are necessary to determine to what degree the audit criteria should be achieved, and to identify whether or not change needs to be implemented (Burgess, 2011).

Benchmark: it is the best real value for a definite indicator; in other words, the best existing performance to which a comparison can be done. It is not always easy to compare results coming from different contexts (geographical, ethnic, cultural), therefore benchmarks must be the best performance of a specific context, referring to settings homogeneous enough to neglect possible discrepancies.

3.2 Stage 1 of the Audit cycle: Preparation, organisation and planning



*What do we do? What should we do?
What are we trying to achieve?*

The impact of a local audit will be maximized if the topic is relevant to the health system and is likely to improve care delivery; if not only the management is involved, but there is also the involvement of a committed and supportive team, with a committed opinion leader. Furthermore the methodology should be robust, with a limited number of recommendations to be implemented, that identify specific actions, and results presented in a simple, clear manner. A clear plan for improvement needs to be defined since the beginning (Potter et al, 2010).

Choosing a topic. Clinical Audit is a complex time-consuming process. In order to ensure that the audit may also be meaningful to the clinicians involved, it is essential to select an appropriate topic. In Table 5 some questions are reported that may be a useful guide for discussion about prioritizing clinical topics (Potter et al, 2010).

The multiprofessional team has an important role in prioritising clinical topics. The same questions can emerge both from clinicians' offices and from the administrators' desks, but it's clear enough that the objectives might be quite different. Usually, audits are carried out if a service improvement can be achieved, as it is neither effortless nor unexpensive in terms of time and costs.

A project that lacks clear objectives cannot achieve significant goals, so a clear sense of purpose must be established before appropriate methods for audit being considered. Therefore once the clinical audit topic has been agreed upon, the reason(s) for the project must be clearly defined. In team audits this ensures that everyone involved in the audit is working to a common purpose in order that a suitable audit method can be chosen. A discussion on the nature of the problem, first highlighting the need for the audit, is beneficial to ensure clarity of purpose, since there is no guarantee that everyone involved clearly understands the reason(s) for undertaking the audit (Burgess, 2011).

-
- Is the topic related to high costs, volumes or risks to staff or users?
 - Is there any evidence of a serious quality problem (e.g. patients' complaints, high complication rates)?
 - Is there strong evidence available to inform standards (e.g. systematic reviews or national clinical guidelines)?
 - Is the problem amenable to change?
 - Is a sustainable improvement possible?
 - Is there any potential for involvement in a national audit project?
 - Is the topic pertinent to national policy initiatives?
 - Is the topic a priority for the organisation?
-

Table 5. Main questions for prioritising clinical topics (modified from Potter et al, 2010)

Selecting recommendation(s) and criteria. After choosing the topic for the clinical audit (*What do we do?*), it is necessary to define which one is the best clinical practice (*What should we do?*) and what aims the clinical audit pursues (*What are we trying to achieve?*). With regard to that, great attention must be given in choosing the recommendations (best practice) that lead to criteria and standards (*What should we do?*). Choice of recommendations to be implemented will be more and more accurate with a better definition of the clinical issue.

In 2006, Brown et al. (BMJ) proposed the EPICOT scheme (Evidence, Population, Intervention, Comparison, Outcome(s) and Time), in order to help researcher address appropriate questions about grey areas lacking clear evidence. Viceversa, in the Clinical Audit, topics should come from areas where strong evidence already exists (see paragraph 2.3), so that the clinical question, sectioned in PICOT fractions, helps choose the best "Evidence" (as "recommendations") for the chosen topic. The complete acronym will become PICOTE. In table 6 a practical example is reported.

Applying the PICOTE scheme to the topic of the Clinical Audit helps define the main points to be examined by means of the audit itself: population, intervention, indicators, outcomes, timing, etc. (see also the Planning Data Collection paragraph).

There should be adequate research evidence that the chosen recommendations are related to clinical effectiveness, safety and efficiency. The information required can be derived by using systematic or non-systematic methods. Non-systematic methods, such as case studies, play an important role in comparing experiences, but they do not tap into available evidence. Systematic methods can be based directly on scientific evidence by combining the best available evidence with expert opinion, or they can be based on clinical guidelines (Wollersheim et al, 2007).

Topic to be audited: How many people with stable severe COPD who receive an antibiotic prescription to prevent or treat an acute exacerbation of COPD (AECOPD) have been admitted to the hospital?

What is the Population interested by this topic?	P	All COPD patients with a severe degree of disease (FEV1 less than 50%)
Which Intervention would we like to improve?	I	An antibiotic treatment (to be defined) to prevent/treat an AECOPD
Is there an alternative intervention (Comparison) we would like to consider?	C	An alternative treatment (e.g. another antibiotic, or an oral course of steroids, to be defined) to prevent/treat an AECOPD
On the basis of which Outcomes should we evaluate the effectiveness of I or C?	O	hospital admission or death; antibiotic or steroid course of therapy for each patient; type of antibiotic more used; number of visits for AECOPD; etc.
What is the Time necessary for a complete observation of the topic?	T	e.g. One year (or more or less)
What is the Evidence about this topic? (the more recent and robust)	E	<i>Recommendation from NICE COPD GLs (2010)</i> : Giving people at risk of exacerbations a course of antibiotic and corticosteroid tablets ready for use at home. Monitoring the use of these drugs and advising people to contact a healthcare professional if their symptoms do not improve.

Table 6. An example of the PICOTE scheme application to an Audit in General Practice.

Sources of possible evidence-based audit criteria are (Burgess, 2011):

- *Recommendations derived from evidence-based guidelines*: when contextualized in the local setting, they establish the standard (Best Practice) with which to compare the current practice.
- Where there is no national or local guidance available, a literature search of *specific journals* or good-quality *systematic reviews* can be undertaken to identify the best and most up-to-date evidence that can be used to generate audit criteria.
- Sometimes it may be necessary for a *group of professionals* to formulate their own criteria where national guidance or evidence-based literature are not available, and here the use of formal *consensus methods* is preferable.

A greater number of opportunities is now available to work *collaboratively with users (doctors or patients)* in the choice of appropriate and relevant audit criteria. Users can bring a different perspective to those aspects of the verification they consider important to measure.

Establishing acceptable standards (see also paragraph 3.1). Since standards represent audit targets, by which the entity of quality improvement is measured (and often incentivated!) it is very important to pay attention to some “more relational, less technical” aspects (Burgess, 2011), as:

- Who has been consulted about the proposed standards?
- How have standards been selected and agreed upon ?
- Are the standards defined clearly and understood by all?
- If national standards are to be used, do they need to be tailored to local circumstances? (see the Acceptable Performance Level (APL) in paragraph 3.1)
- Do the standards support the ethos of continuous quality improvement by providing a target over and above current practice? (see more in paragraph 7)

Planning Data Collection. A critical issue for audit in General Practice is data collection. It is not a problem of good/bad recording electronic systems, but of data entering. The GPs are often very busy, thus they have difficulties in inserting data properly. Yet, the validity of the data is dependent on the care that is taken to enter data into the records, therefore in some occasions data recording may be useless. The data may be available in a computerised information system, but it may also be appropriate to collect data manually, depending on the outcome being measured (e.g. a questionnaire). In either case, one will need to consider what data he needs to collect, where he will find the data, and who will collect them.

To make sure that the data collected are precise, and that only essential data are collected, certain details about what is to be audited must be established from the outset, like the user group to be included, the healthcare professionals involved in the users’ care and the time period over which the criteria apply (NICE, 2002).

According to Burgess (Burgess, 2011), when planning data collection, in order to ensure the effectiveness of a process, it is important to check a list of questions:

- What type of data do I need to collect (quantitative and/or qualitative)?
- What data items will need to be used to show whether or not performance levels have been met for each standard?
- What data sources will be used to find the data?
- Will a data collection tool need to be designed?
- Will I need to collect data prospectively and/or retrospectively?
- What size is the target population and will I need to take a sample?
- How will data be collected (manually and/or electronically)?
- How long will it take to collect the required amount of data?
- Who will be collecting the data?

Finally the population to be audited should be clearly defined, the data required should be made readily and reliably accessible and the measures to be assessed should be meaningful (Burgess,2011).

The sample dimension should be wide enough to be representative of the local clinical practice, but not too wide to make the sample evaluation impossible or too expensive. On the other hand, as Quality and Outcomes Framework 2010/11 shows, a constant monitoring of health quality indicators of a whole population is possible (QOF, 2012).

3.3 Stage 2 of the Audit cycle: Measuring levels of performance

Stage 2:
Measuring
performance

Do we do what we think we do?
Are we doing what we should be doing?
Are we achieving it?

Once the criteria have been defined, we must choose the proper indicators to answer the question *Do we do what we think we do?* As one can see in paragraph 3.1, an indicator is the (quantitative and/or qualitative) measure of the distance between practice and standard (Hermens, 2011). Here we can find the answer to the question: *Are we doing what we should be doing? Are we achieving it?*. The characteristics of the indicators that guarantee the quality and pragmatism of an Audit are listed in Table 7.

As mentioned indicators and field data are not synonyms. The latter are essential for the construction of the former.

Although clinical records are frequently used as the source of data, they are often incomplete. Electronic Information Systems (EISs) are useful not only for collecting data but also for improving access to research evidence, prompting change through record templates, and introducing revised systems of care (Benjamin, 2008). Unfortunately in many countries, with very advanced care plan (like Canada and the U.S.), there is lack of performance data from the Primary Care because of the non-use of Electronic Medical Records (EMRs) by GPs. (Hogg & Dyke, 2011).

Relevancy	Relevant to important aspects (effectiveness, safety and efficiency) and dimensions (professional, organisational and patient oriented) of quality of care
Validity	Strong correlation with the current quality of care Valid on the basis of good scientific proof and experience
Reliability	Low inter- and intra-observer variation Available and reliable data sources Statistically reliable, i.e. reported as an average or median with confidence intervals and valid for comparison, i.e. corrected for case mix and socio-demographic variables
Feasibility	Easily available Applicable to quality improvement; i.e. easy to build in improvement initiatives Sensitive to improvement in time Useful to base decisions on caregivers, patients, regulating agencies In relation to those who should use them

Table 7. The quality characteristics of the indicators (modified from Wollersheim et al, 2007)

The audit data can be quantitative (numerical data that can be counted in order to determine whether or not performance levels have been achieved), or qualitative data (concerned with words rather than with numbers).

A qualitative data collection may include descriptive elements, such as additional comments within questionnaire, interviews, narrative based medicine, focus groups and analysis of documents. In some cases a single method may be used while in others a combination of

methods may be employed. The emphasis in qualitative research on understanding meanings and experiences makes it particularly useful for quality assessment. If data are to be collected qualitatively, it is advantageous to consult appropriate publications, and to enlist the support of audit staff or others with skills in designing qualitative data collection tools (Burgess, 2011; Pope et al, 2000).

The following key questions need to be asked when determining which method will be used (Burgess, 2011):

- How are the data stored?
- Where are the data stored?
- Who will be collecting the data?
- Where will the data be collected?
- Are data being collected retrospectively or prospectively?

Retrospective audit increases the possibility of identifying all patients meeting the inclusion criteria, e.g. complete patient numbers. However it does depend on being able to identify patients through coding or other record systems which fit the inclusion criteria.

Prospective audit increases the chance of good quality data collection, but there is the risk that some patients, in particular those who it might be important to audit, will be missed and there will be incomplete patient numbers. Furthermore there is a risk that, because teams are aware that an audit is on-going, clinical practice may be altered. In some ways this is a good thing if it means patients get better care, but it may result in a false evaluation of routine care. (HQIP, 2009).

Data collection can be implemented both by in- or out-personnel, with a good knowledge of the clinical process and of the data they have to pick up and specifically trained in working with survey instruments.

Data analysis can be performed with different methods, from the simplest (percentages, quotients) to the most sophisticated statistical techniques. In the majority of cases, simpler methods are preferable, as any of the personnel can easily understand them and what they mean. In this line, it is essential to complete data analysis with easily understandable reports, where differences with standard values, and both positive and negative results must be clearly shown. If the discussion on how well the standards were met generates the answer “quite good” the audit could stop, or the objectives may be changed (for example, changing levels of APL); but if the standards were not met, an analysis of the reasons for the divergent results (Stage 3) and a plan on how to make improvements are recommended.

3.4 Stage 3 of the Audit cycle: Implementing change, making improvements

Stage 3:
Implementing
change

*How can we improve what we do?
Why are we not achieving it?*

To improve current clinical practice, it is necessary to find the causes of suboptimal performances (*Why are we not achieving it?*), i.e. low resources, professionals' or patients'

characteristics. If a cause can be detected (*What are the barriers to change?*), a shorter way to its solution is at hand (*How can we improve what we do?*).

Clinical audit is a structured change process. All audit projects must include a programme of change activity and post-identification of the findings from audit (re-audit), to ensure that necessary changes will happen. An accurate planning for implementation is probably the most important element for the implementation of change (Burgess, 2011).

Implementing change. Implementing new knowledge into practice requires deliberate and planned effort. Implement knowledge is “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services”. It includes the study of influences on healthcare professional and organisational behaviour. (Eccles & Miiman, 2006).

Grol and Grimshaw emphasizes the need for an implementation plan. There should be a good basis for change: this could be either new scientific knowledge, or perhaps the identification of a particular practice problem or of a best practice. Afterwards, the implementation should be planned: **when, where, how, and by whom the implementation will occur.** An in-depth analysis can reveal the target group and behaviours, and identify barriers and facilitators to change. The general principles of planning are similar across different projects and circumstances. They include plan development, testing, adapting and scheduling, and evaluation and organisation of the implementation (Grol et al, 2005).

It may be helpful to undertake a diagnostic analysis to identify factors that will influence the likelihood of change before selecting the most appropriate strategies and interventions for implementing change. The Healthcare Quality Improvement Partnership (Schofield & Jenkins, 2009) has recently released useful examples for a pragmatic approach to a plan of implementation (Table 8).

Barriers to change. Most theories on implementation of evidence in health care emphasize the importance of developing a good understanding of possible barriers to change, in order to develop an effective intervention (Grol, 1997). Whether considered in the context of models for quality and safety improvement or guideline implementation initiatives (Ashford et al 1999; Grol et al, 2005; Lomas, 1994; Robertson et al, 1996), systematic reviews of improvement interventions (Chaillet et al, 2006; Grimshaw et al, 2004) or guideline adoption (Cabana et al, 1999), barriers are believed to influence the success of improvement strategies in a very important way.

A recent Cochrane Review analyzed 26 studies to assess the effectiveness of interventions tailored to identify barriers to change on professional practice or patient outcomes. Authors' conclusions stated that interventions tailored to prospectively identified barriers are more likely to improve professional practice than no intervention or the simple dissemination of guidelines (Baker et al, 2010).

Barriers to change have been classified by the Cochrane Effective Practice and Organisation of Care Group (EPOC, 2002) into nine categories: information management, clinical uncertainty, sense of competence, perceptions of liability, patient expectations, standards of practice, financial disincentives, administrative constraints and other.

The barriers can act at individual, team or organisation levels (Ferlie & Shortell, 2001; Garside, 1998). The possible barriers to a plan of implementation should be identified by means of (Burgess, 2011):

- interviews with key staff and/or users;
- discussion at a team meeting;
- observations of patterns of work;
- identification of the care pathway;
- facilitated team meetings, with the use of brainstorming or fishbone diagrams.

Step	General objective	Specific actions
1	Enlist the support and involvement of key people	Identify key stakeholders and ensure that they are involved and their contribution is valued. Use the stakeholder team as agents of change across the wider organisation(s) and try to achieve a good mix of skills, authority, resources and leadership. Create a simple plan for life span of the project, which clearly defines roles and responsibilities.
2	Develop a clear project plan	Get people involved in the plan, especially if they are directly affected by it. Make sure that the plan is built in small, achievable chunks with realistic timescales.
3	Support the plan with consistent behaviours	Whatever the characteristics of the change are, either cost-cutting, behavioural, or ways of working, it is important to be seen to be “walking the talk”. People are only likely to adopt change if it is demonstrated by all levels (and particularly senior levels) of the organisation
4	Develop “enabling structures”	Recognise what needs to happen to support the change. Training workshops, communication sessions, team meetings that are aligned to the change will help people understand the reasons for the change, and buy-in to the process.
5	Celebrate milestones	When milestones are achieved, celebrate the fact that progress has been made. Recognising progress will maintain motivation and stakeholder interest, and give confidence that the longer term vision is achievable.
6	Communicate relentlessly	This is probably the most important activity of all. Communicating effectively can motivate, overcome resistance, lay out the pros and cons of change, and give employees a stake in the process.

Table 8. The Six Steps for Implementing Change (adapted from Schofield & Jenkins, 2009)

To understand and plan tailored strategies to overcome the barriers (Table 9) are critical step for the improvement process (Grol & Grimshaw, 2003). The greatest barrier to change is the attitude that nothing can be done. It should be part of the professional practice of all doctors

to be continually asking themselves: *“How could we be doing this better?”*. Having asked the question, they should think carefully how things could be done differently and consider with colleagues how to improve care. However, many do manage to improve services. To counteract the barriers in order to realize a Clinical Audit in Primary Care, it is necessary to stress and reinforce the already existing positive factors (Table 10).

Changes in care are not always associated with increasing costs: significant efficiency and cost saving can coexist with improved quality (Potter et al, 2010).

Making improvements. Audit is concerned with improving care, and an action plan should be developed to improve either the structure or process of care as this should lead to an improvement in outcome (Copeland, 2005).

When it has been agreed what changes are needed, it is necessary to implement those changes. Depending on the changes, it may be necessary to alter individuals’ roles and responsibilities to do this, and staff training may be necessary (Bristol NHS, 2009).

Practitioners need to consider what is the best way to feedback the results from their audit. Potential stages for dissemination include team meetings, departmental newsletters, local clinical audit meetings, professional development meetings. Results will generally include recommendations for improvement, which may relate to clinical practice or administration procedures. Any changes proposed as a consequence of the audit should be shared and developed with staff affected. Steps towards change should be identified, a timescale agreed and tasks for individuals decided. Implementing recommendations forms the more difficult part of the audit cycle (M.E.R.G., 2012).

In Figure 2 an example of activity planning from a Clinical Audit on Chronic Obstructive Pulmonary Disease (COPD) is reported. The principal objective was the improvement of diagnosis, severity classification and inhalatory therapy in COPD patients in a District in Northern Italy. Both General Practitioners and Hospital Specialists were involved.

	Potential barriers	Examples of barriers
Practice environment (organisational context)	Financial disincentives	Lack of reimbursement
	Organisational constraints	Lack of time
	Perception of liability	Risk of formal complaint
	Patient’s expectations	Expressed wishes related to prescription
Prevailing opinion (social context)	Standards of practice	Usual routines
	Opinion leaders	Key persons not agreeing with evidence
	Medical training	Obsolete knowledge
	Advocacy	Advocacy by pharmaceutical companies
Knowledge and attitudes (professional context)	Clinical uncertainty	Unnecessary test for vague symptoms
	Sense of competence	Self confidence in skills
	Compulsion to act	Need to do something
	Information overload	Inability to appraise evidence

Table 9. Example of barriers to implementation of evidence (modified from Grol & Grimshaw, 2003).

Audit Stage	Activity	Date				
		2005				
		March - May	May - July	September - October	November - December	January -
Stage 1	Appointment of multidisciplinary team					
	Selection of the recommendations and definition of standards and indicators					
	Writing Audit protocol and planning data collection					
	Clinical Audit accreditation for CME					
	Recruitment of GPs					
	Presentation of Protocol to GPs and Hospital specialist in the District					
Stage 2	Basal Data collection (from GPs and hospital specialists)					
	Data Analysis and Assessment of the gap between results and standards					
Stage 3	Evaluation of the results and Analysis of the Barriers					
	Educational Interventions (Problem Based Learning meetings with discussion of the results)					
	Time to implement the changes					
Stage 4	Re-Audit (Data collection, analysis and reporting)					
	Writing final report					
	Public presentation of Audit final report					

Fig. 2. Example of activity planning from a Clinical Audit - Gantt chart can be useful to summarize t

Facilitating factors	Barriers
Simplicity of design and ease of data collection (i.e. computerized medical records)	Lack of definition of the objectives Lack of details of the method
Strong leadership and management	Discontinuity in the organisational structure
Dedicated staff time and organisational facilities Good planning	Lack of management resources (time, suitable information systems, experience in planning of data collection and analysis, writing reports)
Final monitoring results	Lack of facilitating support (strategic and operational)
Positive climate (respect and trust between all actors)	Negative climate (difficult relationship)

Table 10. Facilitating factors and barriers to realize an audit in PC (modified from Potter et al, 2010).

3.5 Stage 4 of the Audit cycle: Sustaining improvements, re-audit

Stage 4:
Sustaining
improvement,
including re-audit

*Did we improve?
Have we made things better?*

After an agreed upon period of implementing changes, the data collection should be repeated (re-audit) (UBHT, 2005; Potter et al, 2010). A complete audit cycle ideally involves two data collections and a comparison of one with the other, following the implementation of change after the first data collection, in order to determine whether the desired improvements have been achieved (*Have we made things better?*). Healthcare organisations are expected to provide assurance that new evidence-based healthcare interventions are being implemented, and that poor performance or substandard quality is being addressed and corrected. The second data collection may provide evidence that the changes implemented have had the desired effect and have led to improvements in quality (*Did we improve?*). The same strategies for identifying the sample, methods and data analysis should be used to ensure comparability. The timing of the further phases of data collection is important, so that the second data collection provides valid and reliable data to be compared with those collected in the first data collection.

Collecting data for a second time, after changes have been introduced and have had time to bring about effect (figure 2), is central to both assessing and maintaining the improvements made during clinical audit. A re-audit should include all criteria where the original analysis demonstrated that acceptable levels of performance were not met and changes in practice were implemented. In table 11 the simple final report of the Clinical Audit, reported in figure 2, is shown as an example. Even if the Clinical Audit was successfully completed, many values did not improve enough to reach the ALP (Acceptable Level of Performance).

Recommendations (from GOLD guidelines, 2003)	Indicators	ALP*	First ro
			GPs pat (n. 174)
Brief tobacco dependence counseling is effective and every tobacco user should be offered at least this treatment at every visit to a health care provider. (Level of Evidence A)	% of COPD patients with tobacco history registered (last 2 ys)	≥70%	97 %
	% of COPD patients with tobacco dependence counseling registered	≥50%	100 %
For the diagnosis and assessment of COPD, spirometry is the gold standard as it is the most reproducible, standardized, and objective way of measuring airflow limitation. FEV1/FVC < 70% and a post-bronchodilator FEV1 < 80% expected, confirms the presence of airflow limitation that is not fully reversible. (Level of Evidence A)	% of COPD patients with a registered spirometry (last 2 ys)	≥50%	54%
	% of COPD patients with registered FVC and FEV1 (to define severity stage)	≥70%	11%
Bronchodilator medications are central to the symptomatic management of COPD. They are given on an as-needed basis or on a regular basis to prevent or reduce symptoms. (Level of Evidence A)	% of COPD patients with at least one prescription (last year) of short acting bronchodilators in any stage of disease	≥90%	26%
The addition of regular treatment with inhaled glucocorticosteroids (ICS) to bronchodilator treatment is appropriate for symptomatic COPD patients with an FEV1 <50% predicted (<i>Stage III: Severe COPD and Stage IV: Very Severe COPD</i>) and repeated exacerbations. (Level of Evidence A)	% of COPD patients with at least one prescription of ICS (last year) for stages III and IV and repeated exacerbations	≥70%	85%
	% of COPD patients with at least one prescription of ICS (last year) for Stages I and II.	≤20%	80%

*ALP: Acceptable Level of Performance Blue value: ALP satisfied Red value: ALP not satisfied

GPs pat: patients from General Practitioners' databases - Hosp pat: patients from Pulmonary Clinic databases

Table 11. Final Report for the Clinical Audit cited in figure 2 – Comparison of data obtained before a

Where further measurement is not deemed necessary, documented reasons are recommended to justify why this has not taken place. At this stage there may be justification for adjusting the desired performance levels in the light of the results obtained. If the expected results are not achieved, further cycles may be required. (Burgess, 2011).

The description of the conclusions is an essential part of the audit process, but one that is often omitted. Conclusions should be drawn as a team activity involving the whole audit team and other practice staff affected by the changes achieved in the audit process (Simon, 2008). The dissemination of audit results (both through management and governance systems and clinical channels) is an essential step to share methodology and solutions adopted to overcome barriers and involve participants and/or stakeholders (Potter et al, 2010).

Ongoing monitoring arrangements should be agreed upon and set in place following completion of the audit, in order to ensure that performance is maintained over time and in order to identify any reduction in quality. These may involve further routine 'snapshot' audits and/or make use of other feedback mechanisms that could indicate performance issues.

Improvements should be maintained and reinforced over time by ensuring that practical and user-friendly processes are built into systems. A culture that embraces change and encourages feedback will assist with the smooth transition from old to new ways of working (Burgess, 2011).

4. Significant Event Audit

Significant Event Audit (SEA) is a particular type of Audit, very suitable for Primary Care. SEA is a recognized methodology, peer review, used to analyze important events in a practice. SEA implies seven stages (Table 12). Discussion of specific events can identify learning objectives and provoke emotions that can be harnessed to achieve change. For it to be effective, it must be practiced in a culture that avoids blame and involves all disciplines (Simon, 2008).

5. Audit and training (Continuing Medical Education)

A clinical audit is a planned education activity designed to help general practitioners (GPs) to systematically review aspects of their own clinical performance in practice (RACGP, 2007). In 1976 Paul Sanazaro stated that the clinical audit and continuing medical education (CME) are the mainstays of quality assurance in health organisations. The quality assurance increasingly represents a near-guarantee of appropriate treatment and fewest possible complications for every patient. Maintenance of the public trust rests on a firm commitment of the medical staff and board to this principle, implemented through an organized program of quality assurance. Under these conditions, medical clinical audit and continuing medical education can effectively improve care by improving physician performance.

However, 20 years later the issue of mandatory continuing medical education (CME) is debated (Donen, 1998). Whilst ongoing educational development is an important value for a professional, and there is an ethical obligation to keep up-to-date, there is no evidence that current approaches to CME, mandatory or voluntary, may produce sustainable changes in

Stage	Actions to do	Some more informations...
1	Awareness and prioritisation of a significant event	Staff should be confident in their ability to identify and prioritise a significant event when it happens.
2	Information gathering	Collecting and collating as much factual information on the event as possible from personal testimonies, written records and other healthcare documentation.
3	The facilitated team-based meeting	The team should appoint a facilitator who will structure the meeting, maintain basic ground rules and help with the analysis of each event. The team should meet regularly to discuss, investigate and analyse events. An effective SEA should involve detailed discussion of each event, demonstration of insightful analysis, the identification of learning needs and agreement on any action to be taken.
4	Analysis of a significant event	The analysis of a significant event can be guided by answering four questions: 1. What happened? 2. Why did it happen? 3. What has been learned? 4. What has been changed or actioned?
5	Agreement, implementation and change monitoring	Any agreed action should be implemented by staff designated to co-ordinate and monitor change in the same way the practice would act on the results of 'traditional' audits.
6	Write it up	It is important to keep a comprehensive, anonymised, written record of every SEA, as external organisations will require evidence that the SEA was undertaken to a satisfactory standard. The SEA report is a written record of how effectively the significant event was analysed.
7	Report, share and review	Reporting when things go wrong is essential in general practice. The practice should formally report those events where patient safety has, or could have, been compromised.

Table 12. The seven stages of Significant Event Audit (adapted from Bowie & Pringle, 2008)

physician practices or application of current knowledge. Viceversa, mandating self-audit of the effect of individual learning on physician's practices and evaluation by the licensing authority are effective ways of ensuring the public are protected.

Today, junior doctors can find that audit is helpful to acquire an understanding of the healthcare process (Benjamin, 2008).

- Junior doctors need to experience directly that clinical audit is a quality improvement process; they should have the opportunity to work through the improvement process as part of their clinical audit experiences (Dixon, 2010). Carrying out clinical audits is one way by which an individual doctor can demonstrate initiative, interest, and commitment to progress in his or her career.

Junior doctors should seek to participate in all phases of the audit cycle. Thus they can enhance their prospects of audit data being used not only locally but also disseminated more widely. (Potter, 2010).

There are at least two reasons why a junior doctor at any level of training should be motivated to carry out clinical audits and therefore provide evidence of:

- meeting training requirements at the current level of training;
- showing why he or she is interested in and committed to the next step in their career (Dixon, 2010).

Learning and education of doctors, not only when training but also in post qualification and as part of continued professional development are critical components to ensure high quality and improving care.

Such learning needs to include not only the clinical aspects of care, but also personal development such as clinical leadership, change management and effective function with the organisation. Clinical audit and associated change management techniques must be an increasingly important part of medical practice and medical training (Potter, 2010).

6. Clinical Audit and Ethics

Quality improvement activity is essential among professionals and healthcare organisations and has widely brought about benefits for patients (Casarett et al, 2002; Dixon, 2009). This activity is strictly connected with Ethics, which is “the inquiry into certain situations and into the language employed to describe them; the kind of situations referred to are those that have led or may lead to harms or benefits to others”. (Beauchamp & Childress, 1994).

Fundamental medical ethics assert (Childress, 1989; Eriksson et al, 2007; Tapp et al, 2010) that there are some principles to which doctors should abide:

- **Autonomy:** any person having the ability to make decisions should be treated with respect for that ability;
- **Utility:** benefit should be maximised and damage minimised;
- **Justice:** no person should be discriminated against, everyone should have equal access to equal treatment, and there should be solidarity with the less fortunate.

These basic medical principles should be used as a basis for judging the ethics of any system of quality improvement, including clinical audit.

On this basis, healthcare professionals, working in primary care settings, should actively participate in clinical audits and quality improvement projects for the same reasons as any other healthcare practitioners. Many primary care organisations are small, with a less formal accountability structure than the one existing in larger healthcare. It is less clear what method of ethics oversight of clinical audits and quality improvement activities might work best in these care settings (Burgess, 2011; Tapp et al, 2010).

Whereas widely accepted ethical standards exist for other activities in the clinical arena, the arrangements ensuring that clinical audit and quality improvement activities conform to

appropriate ethical standards are fragmented, lack clarity and have not been clearly or thoroughly articulated (Deming, 1986; Dixon, 2009; Fox & Tulsky, 2005; Gerrish & Mawson, 2005; Langley et al, 2009).

The starting point in any consideration of ethics is that an audit project should benefit patients and not harm them. When properly conducted, clinical audits and other quality improvement activities can be seen as an ethical imperative in healthcare, something from which both professionals and patients benefit and with which they both should cooperate (Burgess, 2011; Jennings et al, 2007).

When trying to ameliorate practice through audit, a professional must be both sensitive to ethical responsibility and managing responsibility in order to satisfy the rights and interests of patients (Dixon, 2009; Jennings et al, 2007).

Ethics of clinical audit has been a neglected area up to now (Cave & Nichols, 2007; Dixon, 2009; Dubler et al, 2007; Lo & Groman, 2003), yet audit or the analysis of previously collected data may happen to be unethical (BMJ, 2012).

Some key principles can be used to identify a clinical audit or quality improvement activity that should have an ethical review at the proposal stage. They include the following:

- **Each patient's right to self-determination is respected** (Burgess, 2011; Casarett et al, 2002; Diamond et al, 2004; Dubler et al 2007; Fox & Tulsky, 2005; Layer, 2003;)
- **There is a benefit to existing or future patients or others that outweighs the potential burdens or risks** (Burgess, 2011; Cretin et al, 2000; Casarett et al, 2002; Diamond et al, 2004; Fox & Tulsky, 2005; Jennings et al, 2007; Layer, 2003; Wade, 2005)
- **Each patient's privacy and confidentiality are preserved** (Burgess, 2011; Casarett et al, 2002; Diamond et al, 2004; Fox & Tulsky, 2005; Layer, 2003;)
- **The activity is fairly distributed across patient groups** (Burgess, 2011; Casarett et al, 2002; Fox & Tulsky, 2005; Layer, 2003).

Ethical oversight of clinical audit and quality improvement on the part of healthcare organisations ensures that these activities protect patients and their rights, and contributes to improve quality and safety of patient care.

7. Conclusions

Clinical Audit definitely is a very important method to practice ethics in the Primary Care setting. Its aim is to lead professionals to accomplish quality of care both for patients and for public health services, using the most appropriate, safe and cost-effective instruments.

Clinical Audit is also an instrument for "health's democracy", as it allows comparisons between health services and can therefore lead to the equalization of health performances.

Clinical Audit in PC should be part of the usual way to work, where professionals share and compare their daily activity with evidence-based standards adapted to fit their settings. However, deep changes in the organisation of work are needed in order to

introduce the Clinical Audit method in Primary Care steadily: clinical practice in PC is a hard, complex activity, that can be rarely assessed through a linear cause-effect approach. Too many ungovernable and unpredictable events occur between a physician's decision and a clinical outcome (i.e. understanding of information, patient's compliance, drugs tolerability, presence or absence of facilities in the local healthcare system, the domestic environment, etc.). Other constraining factors are the very habits, attitudes and motivations of the professionals themselves. Professionals and Health Service must share clinical data and information, the electronic standard of which is still unusual and therefore difficult to use. A virtuous process of improvement of professional conditions is fundamental, removing barriers to renovation and implementing really effective actions for the patients' sake.

Last but not least, Clinical Audit is a strong instrument for continuing medical education, as it requires the professionals to review their past experiences and knowledge, and therefore to behave in order to minimize the gap between best practice and current praxis.

8. References

- Anderson DG. *ABC of audit*, Cleveland Vocational Training Scheme; accessed on February 2012:
<http://www.gp-training.net/training/tutorials/management/audit/audabc.htm>
- Ashford J, Eccles M, Bond S, Hall LA, Bond J. (1999) Improving health care through professional behaviour change: introducing a framework for identifying behaviour change strategies. *British Journal of Clinical Governance*; 4(1): 14–23.
- Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, Robertson N. (2010) Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*; (3):CD005470.
- Baker R. & Fraser RC. (1995) Development of audit criteria: linking guidelines and assessment of quality. *BMJ*, 31: 370-3.
- Beauchamp TL, & Childress JF. (1994) *Principles of Biomedical Ethics*. 4th ed. Oxford University Press.
- Benjamin A. (2008) Audit: how to do it in practice. *BMJ*; 336:1241-5
- Bhopal RS, Thomson R. (1991) A form to help learn and teach about assessing medical audit papers. *BMJ*; 303(6816):1520-2.
- Black, N. (1992) The relationship between evaluative research and audit. *Journal of Public Health Medicine*; 14: 361–366.
- BMJ anonymous. (2012) Ethics approval of research; accessed on February 2012:
<http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/ethics-approval-research>
- Bowie P, Pringle M. (2008) Significant Event Audit, Guidance for Primary Care Teams, National Reporting and Learning Service, NHS; accessed on February 2012:
http://www.rcgp.org.uk/pdf/CIRC_Significant_Event_Audit.pdf
- Brain J, Schofield J, Gerrish K, Mawson S, Mabbott I, Patel D and Gerrish P. (2009) A Guide for Clinical Audit, Research and Service Review – An educational toolkit designed

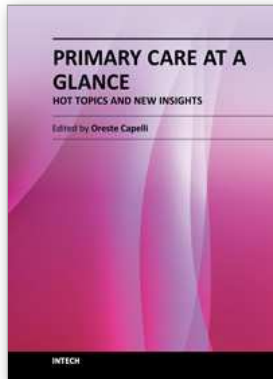
- to help staff differentiate between clinical audit, research and service review activities; accessed on February 2012:
<http://www.hqip.org.uk/assets/Downloads/Audit-Research-Service-Evaluation.pdf>
- Brown P, Brunnhuber K, Chalkidou K, Chalmers I, Clarke M, Fenton M, Forbes C, Glanville J, Hicks NJ, Moody J, Twaddle S, Timimi H, Young P. (2006) How to formulate research recommendations. *BMJ*; 333: 804-6.
- Burgess R. (2011) *New Principles of Best Practice in Clinical Audit*. Published by Radcliffe Publishing, Oxford, 2nd edition, ISBN- 13 :978-1-84619-221-0
- Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abbound PC, Rubin HR. (1999) Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA*; 282(15): 458-65.
- Campbell SM, Braspenning J, Hutchinson A, Marshall M. (2002), Research methods used in developing and applying quality indicators in primary care *Qual Saf Health Care*; 11:358-64.
- Casarett D, Fox E, Tulskey JA. (2002) Recommendations for the Ethical Conduct of Quality Improvement; accessed on February 2012:
http://www.ethics.va.gov/docs/necrpts/NEC_Report_20020501_Ethical_Conduct_of_Quality_Improvement.pdf
- Cave E, & Nichols C. (2007) Clinical audit and reform of the UK research ethics review system. *Theor Med Bioeth*; 28:181-203.
- CCHSA (Canadian Council on Health Services Accreditation) (1996) A guide to the development and use of performance indicators. Published by *The Council* in Ottawa: *ID Numbers Open Library* OL21074209M
- Chaillet N, Dube E, Dugas M, Audibert F, Tourigny C, Fraser W, Dumont A. (2006) Evidence-based strategies for implementing guidelines in obstetrics. *Obstetrics and Gynecology*; 108: 1234-45.
- Childress JF. (1989) The normative principles of medical ethics. In *Medical Ethics* ed. Veatch RM, Jones and Bartlett Publishers Boston, pp 27-48.
- Clark S. & Rowe F. (2002) Clinical Audit. *British Orthoptic Society*: accessed on February 2012:
http://www.rcgp.org.uk/pdf/CIRC_British%20Orthoptic%20Society.pdf
- Copeland, G. (2005) A practical handbook for clinical audit. Guidance published by the Clinical Governance Support Team; accessed on February 2012:
www.cgsupport.nhs.uk/downloads/Practical_Clinical_Audit_Handbook_v1_1.pdf
- Cretin S, Keeler EB, Lynn J, Batalden, PB, Berwick DM, Bisognano M. (2000) Should patients in quality- improvement activities have the same protections as participants in research studies? *JAMA*; 284: 1786.
- Crombie IK, Davies HTO, Abraham SCS, Florey CDV. (1993) The audit handbook-improving health care through clinical audit. 1st ed. *John Wiley & Sons* Chichester, ISBN:0-471-937665
- Deming WE. (1986) *Out of the Crisis: Quality, Productivity and Competitive Position*. Cambridge University Press; ISBN 0911379010, 9780911379013.
- Diamond LH, Klinger AS, Goldman RS, Palevsky PM. (2004) Quality improvement projects: how do we protect patients' rights? *American Journal of Medical Quality*; 19: 25-7.

- Dixon N, (2009) Review of Ethics Issues related to Clinical Audit and Quality Improvement Activities. *The Healthcare Quality Improvement Partnership (HQIP)*: accessed on February 2012: <http://www.hqip.org.uk/assets/Downloads/Ethics-and-Clinical-Audit-and-Quality-Improvement-Literature-Review.pdf>
- Dixon N, (2010) Guide to Involving Junior Doctors in Clinical Audit. *HQIP, Healthcare Quality Improvement Partnership*; accessed on February 2012: <http://www.hqip.org.uk/assets/5-HQIP-CA-PD-026-Guide-to-Involving-Junior-Doctors-in-Clinical-Audit-19-April-2010.pdf>
- Donabedian A. (1966) Evaluating the quality of medical care. *Milbank Mem Fund Q*; 44 (3 suppl):166-206
- Donen, N. (1998) No to mandatory continuing medical education, yes to mandatory practice auditing and professional educational development. *CMAJ*; 158, Issue 8: 1044
- Dubler N, Blustein J, Bhalla R, Bernard D. (2007) Information participation: an alternative ethical process for including patients in quality-improvement projects. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. *Health Care Quality Improvement: Ethical and Regulatory Issues*. Garrison NY: The Hastings Center; p. 69-87.
- Eccles M, Miiman B. (2006) Welcome to Implementation Science. *Implementation Science* [serial online] vol.1(1):[3 pages]; accessed on February 2012: <http://www.implementationscience.com/content/1/1/1>
- EPOC Author Resources (2002) Cochrane Effective Practice and Organisation of Care Group, Data Collection Checklist; accessed on February 2012: <http://www.epoc.cochrane.org/en/handsearchers.html>.
- Eriksson T, Nilstun T, Edwards A. (2007) The ethics of risk communication in lifestyle interventions: consequences of patient centeredness. *Health Risk Soc*; 9:19-36.
- Ferlie E, Shortell S. (2001) Improving the quality of health care in the United Kingdom and the United States: a framework for change. *Milbank Q*; 79: 281-315.
- Fitzpatrick R, Boulton M. (1994) Qualitative methods for assessing healthcare. *Quality in Health Care* vol: 3 pag: 107-13.
- Fox E, Tulskey JA. (2005) Recommendations for the ethical conduct of quality improvement. *J Clin Ethics*;16(1):61-71.
- Garside R. (1998) Organisational context for quality: lessons from the field of organisational development and change management. *Qual Health Care*; 7: S8-S15.
- Gerrish K, Mawson S. (2005) Research, audit, practice development and service evaluation: Implications for research and clinical governance. *Practice Development in Health Care*; 4(1):33-9.
- GOLD (2003). Global Strategy for Diagnosis, Management, and Prevention of COPD. Workshop final report; accessed on February 2012: <http://www.goldcopd.org/uploads/users/files/GOLDWkshp2003Clean.pdf>
- Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, Whitty P, Eccles MP, Matowe L, Shirran L, Wensing M, Dijkstra R, Donaldson C. (2004) Effectiveness and efficiency of guideline dissemination and implementation strategies, *Health Technology Assessment Monograph Series* Vol: 8(6): 1-72.
- Grol R., Grimshaw J. (2003) From best evidence to best practice: effective implementation of change in patients' care. *Lancet*; 362(Issue 9391): 1225-1230.

- Grol R, Wensing M, Eccles M. (2005) Improving patient care: the implementation of change in clinical practice. Elsevier Editor, Pages: 304, ISBN: 9780750688192
- Grol R. (1997) Beliefs and evidence in changing clinical practice. *BMJ*; 315:418–21.
- HQIP (Healthcare Quality Improvement Partnership) (2009) Criteria and indicators of best practice in clinical audit; accessed on February 2012: <http://www.hqip.org.uk/assets/Downloads/Criteria-and-indicators-of-best-practice-in-clinical-audit.pdf>
- Hermens R (2011) International Forum on Quality and Safety in Healthcare, Amsterdam 5-8 april 2011; accessed on February 2012: <http://video.internationalforum.bmj.com/events/amsterdam-2011/sessions?tracks=Clinical%20improvement%20and%20innovation>
- Hogg W, Dyke E. (2011) Improving measurement of primary care system performance. *Can Fam Physician*; 57: 758-760.
- Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD (2006). Audit and feedback: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews* Issue 2. Art. No.: CD000259. DOI: 10.1002/14651858.
- JCAHO (Joint Commission on Accreditation of Healthcare Organisations) (1989) Characteristics of clinical indicators. *Qual Rev Bull*; 11: 330–339.
- Jennings B, Baily M.A, Bottrell M, Lynn J. (2007) Health Care Quality Improvement Ethical and Regulatory Issues, Garrison, NY: *The Hastings Center*: accessed on February 2012: http://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/Health%20Care%20Quality%20Improvement.pdf
- Langley GJ, Moen RD, Nolan KM, Nolan TW, Norman CL, Provost LP. (2009) The Improvement Guide. A Practical Approach to Enhancing Organisational Performance, Second Edition, Published by Jossey-Bass, ISBN: 978-0-470-19241-2
- Layer T. (2003) Ethical conduct recommendations for quality improvement projects. *Journal for Healthcare Quality*; 25: 44–6.
- Lo B & Groman M. (2003) Oversight of quality improvement. *Arch Intern Med*;163: 1481–6.
- Lomas J. (1994) Teaching old (and not so old) dogs new tricks: effective ways to implement research findings. In: Dunn EV, Norton PG, Stewart M, et al, eds. Chapter 1. Disseminating research/changing practice, Sage Publication, University Michigan, ISBN: 0803957068, EAN: 978-0803957060
- M.E.R.G: Multi-professional Evidence-based practice and Research Group, (2012) NHS; Research & Development, accessed on February 2012: <http://www.researchdirectoriate.org.uk/merg/documents/Audit%20Info.pdf>
- Mancey-Jones M, Brugha RF. (1997) Using perinatal audit to promote change: a review. *Health Policy Plan*;12:183-92
- National Clinical Audit Advisory Group (NCAAG), accessed on February 2012 : http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103396

- National Institute for Clinical Excellence (2002), "Principles for Best Practice in Clinical Audit, Published by: Radcliffe Medical Press, ISBN: 1-85775-976-1: <http://www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf>
- NICE (National Institute for Clinical Excellence) (2010) Management of chronic obstructive pulmonary disease in adults in primary and secondary care - Clinical guidelines, CG101 (This guideline partially updates and replaces NICE clinical guideline 12); accessed on February 2012: <http://guidance.nice.org.uk/CG101>
- NHS Wirral (2012) Clinical Audit Team; accessed on February 2012: <http://www.wirral.nhs.uk/aboutnhswirral/directorates/corporateaffairs/governanceteam/clinicalaudit.html>
- Pope C, Ziebland S, Mays N. (2000) Qualitative research in healthcare. Analysing qualitative data. *BMJ*; 320: 114-16.
- Potter J, Fuller C, Ferris M. (2010) Local clinical audit: handbook for physicians. Healthcare Quality Improvement Partnership. Royal College of Physicians; August 2010; accessed on February 2012: <http://www.hqip.org.uk>
- Powell J, Lovelock R, Bray I et al. (1994) Involving users in assessing service quality: benefits of using a qualitative approach. *Quality in Health Care*; 3: 199-202.
- RACGP (Royal Australian College of General Practitioners) (2007) QA&CPD Program handbook for general practitioners: 2008–2010 triennium. Melbourne: The RACGP.
http://www.racgp.org.au/Content/NavigationMenu/educationandtraining/TheGeneralPracticeMentalHealthStandardsCollaboration/AccreditationofmentalhealthtrainingforindividualGPs/GPMHSCGuidelines_ClinicalAudits.pdf
- Robertson N, Baker R, Hearnshaw H. (1996) Changing the clinical behaviour of doctors - a psychological framework. *Quality in Health Care*; 5:51-4.
- QOF (2012) - Quality and Outcomes Framework 2010/11; accessed on February 2012: <http://www.ic.nhs.uk/qof>
- Scally G. & Donaldson L. J. (1998) Clinical governance and the drive for quality improvement in the new NHS in England. *BMJ*; 317(7150): 61-65.
- Schofield J. & Jenkins J. (2009) How to Implement Local Changes from National Clinical Audit – A Guide for Audit Professionals in Healthcare Organisations; accessed on February 2012: <http://www.hqip.org.uk/assets/Downloads/Implementing-Local-Change-from-National-Audit.pdf>
- Simon C. (2008) Audit in primary care. *InnovAiT*, Vol. 1, No. 4, pp. 281–287, 2008
- Smith R. (1992) Audit & Research, *BMJ*; 305(6859):905-6
- Starey N. (2001) 'What is clinical governance?' Evidence-based medicine, Hayward Medical Communications:
<http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/WhatisClinGov.pdf>
- Tapp L, Edwards A, Elwyn G, Holm S, Eriksson T. (2010) Quality improvement in general practice: enabling general practitioners to judge ethical dilemmas, *Journal of Medical Ethics*; 36: 184-8.
- UBHT Clinical Audit Central Office (2005): How to do clinical audit - a brief guide.
- UHBristol, NHS Foundation Trust, (2009), Clinical Audit Team:

- <http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/how-to-guides/>
- Wade DT. (2005) Ethics, audit, and research: all shades of grey. *BMJ*; 330: 468–71.
- Wienand U. (2009), Audit clinico: che cosa è e che cosa non è: l'uso inappropriato del termine depaupera il metodo. *QA*; 19(2): 82-90
- Wollersheim H, Hermens R., Hulscher M, Braspenning J, Ouwens M, Schouten J, Marres H, Dijkstra R, Grol R. (2007) Clinical indicators: development and applications. *Neth J Med*; 65(1):15-22.
- Zwanenberg V & Harrison J. (2004) *Clinical Governance in Primary Care*. 2nd edition. Radcliffe Medical Press - ISBN 10: 1857758617.



Primary Care at a Glance - Hot Topics and New Insights

Edited by Dr. Oreste Capelli

ISBN 978-953-51-0539-8

Hard cover, 446 pages

Publisher InTech

Published online 27, April, 2012

Published in print edition April, 2012

"Both among scientists and clinical practitioners, some find it easier to rely upon trivial explanations, while others never stop looking for answers". With these surprising words, Augusto Murri, an Italian master in clinical medicine, reminds us that medical practice should be a continuous journey towards knowledge and the quality of care. The book brings together contributions by over 50 authors from many countries, all around the world, from Europe to Africa, from Asia to Australia, from North to South America. Different cultures are presented together, from those with advanced technologies to those of intangible spirituality, but they are all connected by five professional attributes, that in the 1978 the Institute of Medicine (IOM)¹ stated as essentials of practicing good Primary Care: accessibility, comprehensiveness, coordination, continuity and accountability. The content of the book is organized according to these 5 attributes, to give the reader an international overview of hot topics and new insights in Primary Care, all around the world.

How to reference

In order to correctly reference this scholarly work, feel free to copy and paste the following:

Oreste Capelli, Silvia Riccomi, Marina Scarpa, Nicola Magrini, Elisabetta Rovatti, Imma Cacciapuoti and Antonio Brambilla (2012). Clinical Audit in Primary Care: From Evidence to Practice, Primary Care at a Glance - Hot Topics and New Insights, Dr. Oreste Capelli (Ed.), ISBN: 978-953-51-0539-8, InTech, Available from: <http://www.intechopen.com/books/primary-care-at-a-glance-hot-topics-and-new-insights/audit-in-primary-care-from-evidence-to-practice>

INTECH
open science | open minds

InTech Europe

University Campus STeP Ri
Slavka Krautzeka 83/A
51000 Rijeka, Croatia
Phone: +385 (51) 770 447
Fax: +385 (51) 686 166
www.intechopen.com

InTech China

Unit 405, Office Block, Hotel Equatorial Shanghai
No.65, Yan An Road (West), Shanghai, 200040, China
中国上海市延安西路65号上海国际贵都大饭店办公楼405单元
Phone: +86-21-62489820
Fax: +86-21-62489821

© 2012 The Author(s). Licensee IntechOpen. This is an open access article distributed under the terms of the [Creative Commons Attribution 3.0 License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.