UNIT NO. 2

CLINICAL PRACTICE AUDIT

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ABSTRACT

Clinical practice audit provides a method for systematically reflecting on and reviewing practice. It is a process of planned activities based on performance review and enhancement with the aim of continually improving standards of patient care. Over time, the technical aspects of the clinical quality audit have become clearer and the methodology is more consolidated and uniform. Even then there will be minor differences as we look at the methodology and literature across the United States and the United Kingdom. In the United Kingdom, the key change in thinking is that at least two cycles of clinical audit activities are needed. This is the methodology that has been prescribed by the Royal College of General Practitioners in the clinical audit component of the MRCGP Examination. We have also adopted this same methodology of two cycles of clinical audit in the audit case in the MMed (Family Medicine) Examination requirements. This same methodology is also adopted in the College Membership (MCFP) and Fellowship (FCFP) certification requirements. This is the seven stage-two cycle audit. The seven stages can be remembered as made up of topic-plan-do-check (or study)-act-check (or study) again-act again. The last two stages belong to the second cycle of audit.

INTRODUCTION

Clinical practice audit provides a method for systematically reflecting on and reviewing practice. It began with the quality assurance cycle and also the threatening name of medical audit in the 1980s. Over time, the purpose of such an activity has been more clearly defined, namely the purpose of the clinical audit is for "continuous improvement" as the ideal for health care and not looking for "bad apples" of poor performance. This view was championed by Donald Berwick in a paper in the New England Journal of Medicine in 1989[1] and this view and purpose is happily now firmly entrenched.

Over time too, the technical aspects of the clinical quality audit have become clearer and the methodology is more consolidated and uniform. Even then there will be minor differences as we look at the methodology and literature across the United States and the United Kingdom.

In the United Kingdom, the key change in thinking is that at least two cycles of clinical audit activities are needed. This is the methodology that has been prescribed by the Royal College of General Practitioners in the clinical audit component of the MRCGP Examination. This is the seven stage-two cycle audit that is described in this paper. The seven stages can be remembered as made up of topic-plan-do-check (or study)-act-check (or study) again-act again. The last two stages belong to the second cycle of audit.

We have also adopted this same methodology of two cycles of clinical audit in the audit case in the MMed (Family Medicine) Examination requirements. This same methodology is also adopted in the College Membership (MCFP) and Fellowship (FCFP) certification requirements.

The Institute of Healthcare Improvement (IHI) in the United States has consolidated the clinical audit methodology into the Model of Improvement. This model is based on addressing three questions and uses the Plan-Do-Study-Act (PDSA) Cycle to do that. The PDSA cycle may be repeated as a continuous improvement activity.

It should be pointed out that in essence the IHI Model of Improvement and the seven stage- two cycle audit are variations of the same thing and have many features in common. Compare Figure 1 below and Figure 1 in Unit 6 for yourself to see the minor differences. In daily practice, either methodology can be used.

CLINICAL AUDIT AS EXAMINATION REQUIREMENT

From 2005, a clinical practice audit case will be included in the written submission for summative assessment in the Master of Medicine (Family Medicine) Examinations in addition to the one-week practice profile and five case commentaries[2]. This paper is a guideline to the processes involved in the conduct of a clinical practice audit project for daily practice and also a framework for the written submission. This paper is also relevant to doctors in the College Membership (MCFP) and Fellowship (FCFP) programmes.

Figure 1. The Clinical Audit Cycle – Seven Stages-Two Cycles

Stage 1 – Topic - Are we doing what we should be doing or what can be improved? **Decide on topic of audit.**

First PDSA or PDCA Cycle

Stage 2 – Plan - What best practice guidelines can be used? Or what goals do we want to achieve? And how can this be measured? **Establish the indicator, the criterion, and the standard to use.**

Stage 3 – Do - What information needs to be collected? **Collect first set of data on the indicator.**

Stage 4 – Study (Check) - What does this information mean? **Compare first set of data collected with quality criteria and standard chosen.**

Stage 5 – Act - How can patient care be improved? How can the changes be managed? **Take action to close the gap between performance and standard.**

Second PDSA or PDCA Cycle

Stage 6 – Do again - What information needs to be collected? Collect second set of data on the indicator.

Stage 7 – Study (Check) again - What does this information mean? **Did we achieve what we set out to do? Compare second set of data collected with quality criteria, standard, and first set of data and ask if the gap between performance and standard has now been closed.**

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QUALITY CONCEPTS

The terms quality assurance, quality assurance cycle, and clinical practice audit can be confusing. The following attempts to clarify matters.

Quality assurance

Quality assurance for general/family practice is a process of planned activities based on performance review and enhancement with the aim of continually improving standards of patient care[4]. This definition has been specifically developed for WONCA, the World Organization of Family Doctors. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery[1].

There are different terms used with regards to quality assurance – each to express a new idea or nuance. Table 1 illustrates part of the confusion: select any term from each column, put them together and a synonym can be arrived at for any other combination!

Table 1. What's in a name?

Medical	Care	Evaluation
Health	Standards	Assessment
Clinical	Activity	Assurance
Professional	Quality	Audit

Source: Shaw, 1980[2]

The terms indicate that development has taken place. First concepts in the field were mainly concerned with assessing or auditing quality. A further development came with the recognition that this alone was insufficient to allow for an evaluation and hence guidelines and standards came into being. Quality can only be assured by recognizing where change is needed followed by action to achieve change. There must be subsequent monitoring to see if there are any effects of the change.

From quality assurance to quality assurance cycle

Hence the quality assurance cycle is an activity incorporates all these elements: Establish guidelines – Collect Data – Take Action – Monitor Results – (Establish guidelines)[3]

From quality assurance cycle to clinical practice audit

The quality assurance cycle can also be called the clinical practice audit and incorporates all of the following elements:

Define criteria and standards – Data collection – Assess performance against criteria and standards – Identify changes – (Define criteria and standards)[8]

There are other ways of expressing the clinical practice audit using slightly different naming of the elements. What is important is that all the elements of quality assurance should be incorporated into the cycle with the ultimate aim of continuous improvement.

CLINICAL PRACTICE AUDIT CYCLE TASKS

The clinical practice audit cycle used in the MMed(FM) examination requirements and College certifications is a process comprising 7 stages and two cycles (Table 1). A detailed description of the tasks in the stages is given below.

Stage 1 – Topic - *Are we doing what we should be doing or what can be improved?* Decide on topic of audit.

This topic of audit may come from a personal experience, a problem encountered during everyday practice, observations by healthcare staff or clinical practice guidelines etc. Donabedian introduced the SPO model of quality assurance: structure, process, and outcome[2]. Structure refers to the input of care such as manpower, premises and facilities. Process refers to the provision of care, looking at what is done and how it is done. Outcome refers to the result of clinical intervention. Each dimension has two aspects to it: technical competence and patient satisfaction. Table 2 shows the SPO model with the two aspects and some examples of topics that can be considered.

Table 2. The SPO Model of Quality Assurance with examples under each dimension and possible audit topics.

	Technical	Interpersonal
Structure	o Premises – laboratory too far away o Medical records – no summary sheet o Equipment – glucometers not properly coded and tested with controls	o Patient has to wait until next visit before knowing the HbA1c results o Patient needs to walk to the laboratory to get blood tests done o Proportion of trained to untrained staff
Process	o Inappropriate or non-referral o Failure to do twice yearly HbA1c on diabetic patients o Failure to do a yearly review for diabetic patients	o Satisfaction with the doctor-patient encounter o Ease of access to the doctor
Outcome	o Number of diabetics with HBA1C<8 o Morbidity e.g. amputation rate o Mortality e.g., death from stroke in patients with controlled hypertension	o One time visit only o Having a family doctor

Perspectives also play a role in the choice of topic audit i.e. from the point of view of the patient, physician, payer or policy maker. There are also different levels that quality assurance can be organized into i.e. national, local, practice and individual level with different methods and procedures for the different levels. While the variety of topics that could be chosen is very large, whoever makes the choice will focus on topics close to their own experience. Though not inappropriate, others will have different perspective and that will have to be considered as well.

Stage 2 – Plan - *What best practice guidelines can be used? Or what goals do we want to achieve? And how can this be measured?* Establish the indicator, the criterion, and the standard to use.

An indicator is a measure used to assess quality e.g. random blood pressure as an indicator of blood pressure control. It is explicitly defined and must be a quantifiable variable. It should provide a valid and reliable measure of the process or outcome of medical care. Unfortunately, indicators can be imperfect measures and there is a temptation to fix the indicators rather than address the real quality issues. Indicators are useful in highlighting areas of differences which then needed to be investigated further to see if the differences are due to variations in quality or not.

A criterion is an item of care or some aspect of care that can be used to assess quality. The chosen criterion is written as a statement e.g. all HbA1c should be done and results available for review while the patient is in the clinic (structure); all diabetic patients should have their HbA1c checked 2 times a year (process); all diabetic patients should have their HbA1c within the recommended limits (outcome). A criterion can be defined from recent medical literature and the best experience of clinical practice. Systematic review of published audits is a good place to start[3].

A Standard describes the level of care to be achieved for any particular criterion. The level of standard can often be controversial. There are basically 3 options:

- 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 it should be possible to give under ideal conditions, with no constraints. Such a standard by definition cannot usually be attained.
- An optimum standard lies between the minimum and the idea. Setting an optimum standard requires judgment discussion and consensus with other members of the primary care team. Optimum standards represent the standard of care most likely to be achieved under normal conditions of practice.

The criterion, together with the standard, is written as a statement e.g. '100% of all HbA1c should be done and results available for review while the patient is in the clinic.' '90% of all diabetic patients should have their HbA1c checked 2 times a year.' '60% of all diabetic patients should have their HbA1c within the recommended limits.'

Stage 3 – Do - *What information needs to be collected?* Collect first set of data on indicator.

Identify what data needs to be collected, how and in what form it needs to be collected, and who is going to collect it. Remember only collect information that is absolutely essential. There will always be a numerator and a denominator.

Stage 4 – Check - What *does this information mean?* Compare first set of data collected with quality criterion and standard chosen.

Analyze the information collected and identify any area of care below the predetermined standard of the criterion.

Stage 5 – Act - How *can patient care be improved? How can the changes be managed?* Take action to close the gap between performance and standard.

Since audit is a quality improvement process, problems and deficiencies identified should be rectified to improve either the structures or process of care which should lead to an improvement in outcome. The action plan should detail what needs to be done, how it needs to be done, who is going to do it and when is it going to be done. The action plan should include a review date.

Stage 6 – Do again - *What information needs to be collected?* Collect second set of data on indicator.

The audit cycle is now almost complete, but without re-evaluating the care the practice is giving, it is impossible to see if recommendations have been implemented and the level of care improved. In many instances process improvement alone may have to be used as a surrogate measure for outcome improvement. Action plan development may involve refinement of the audit tool particularly if measures used are found to be inappropriate or incorrectly assessed. In other instances new process or outcome measures may be needed or involve linkages with others.

Stage 7 – Check again - *What does this information mean?* Did we achieve what we set out to do? Compare second set of data collected with quality criteria, standard, and first set of data and ask if the gap between performance and standard has now been closed.

It is hoped that the re-audit would demonstrate improvements. If this is sustained, some form of monitoring should replace a full audit which could be re-activated when the need should arise. If standard is still not achieved, proceed to stage 6 and stage 7 of the audit cycle.

FRAMEWORK FOR WRITTEN SUBMISSION[4]

This section is for submission for the examination requirements. It is also encouraged that the practice of writing up the processes that the clinical practice quality audit cycle went through be done as this will then create a report that could be referred to at a later date. Table 3 shows the 8 headings of the audit report.

Table 3. Headings of Audit Report

Length of report: 3000 words.

1. Reason for choice of audit
   This should explain why the audit was chosen with emphasis on the potential for change and relevance to the individual or the practice.
2. Criteria chosen
   The criteria chosen should be relevant and justifiable in with reference to current literature if possible.
3. Standards set
   The standards set should have realistic targets and a time scale.
4. Preparation and planning
   This should describe the problems faced and other considerations that needed to be factored into the preparation and planning. Discussions with others and enlistment of assistance demonstrating teamwork should be described here.
5. Data collection (1)
   This first collection of data should be compiled and compared against the standard.
6. Description of change
   This should include at least one specific change incorporated into the practice.
7. Data collection (2)
   This should enable a comparison with data collection (1) and the standard to be made.
8. Conclusion

These should reflect the lessons learned from the carrying out the clinical practice audit project.

AUDIT VERSUS RESEARCH

It is important to note that there is a difference between auditing and research. A good place to look at audit reports for reference would be http://www.londondeanery.ac.uk/gp/audit/audit_audits.htm

Table 3. Research versus Audit

Research	Audit
Discovers the right thing to do	Determines whether the right thing is being done
A series of 'one-off' projects	A cyclical series of reviews
Collects complex data	Collects routine data
Experiment rigorously defined	Review of what clinicians actually do
Often possible to generalize the findings	Not possible to generalize from the findings

Source:
http://www.pdptpp;lot.co.uk/Files/Guide%20to%20the%20PDP/content/audit.htm

CONCLUSION

Why do audit? As an examination, audit is compulsory for summative assessment. As education drives learning, it is hoped that the need to do it will reduce the barriers to adopt clinical practice audit as part of the quality initiative and the transformation of primary care activities. On the positive side, audit leads to a sense of personal and professional achievement. Audit promotes learning by answering the following questions: What am I doing? How am I doing? Why am I doing it in that way? Can I do it better or in another way?

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LEARNING POINTS

- **Clinical practice audit provides a method for systematically reflecting on and reviewing practice.**
- **It is a process of planned activities based on performance review and enhancement with the aim of continually improving standards of patient care.**
- **The seven stage-two cycle audit is the methodology used as examination requirement for the [redacted]M) and the College Membership (MCFP) and Fellowship (FCFP) programmes.**
- **[redacted]en stages can be remembered as made up of topic-plan-do-check (or study)-act-check (or [redacted]gain-act again. The last two stages below to the second cycle of audit.**
- **[redacted]eadings of the audit report are: reason for choice of audit, criteria chosen, standards set, [redacted]tion and planning, data collection (1), description of change, data collection (2), and [redacted]on.**