

Review Article

Basic concepts of evidence-based clinical audit

實証臨床審計的基本概念

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Clinical audit has gained popularity nowadays. By generating criteria based on data drawn from properly done clinical trial, clinical audit acts as a balance to weigh our performance in healthcare delivery against evidence-based guideline. The basic steps in clinical audit involves choosing a topic, setting up criteria and standards, measurement of performance, implementing changes and second performance measurement after changes implemented. The basic principles in all these steps are discussed in this article and psoriasis patient care will be used to illustrate the principles in setting criteria and standards. The ultimate aim of clinical audit is improvement in quality of healthcare. It is hoped that readers can have a basic grasp of clinical audit and are stimulated to have in-depth study and subsequently carry out one in their own practice.

臨床審計現時越來越普及。以臨床研究資料為基礎的臨床審計標準能有效平衡醫療服務及實証醫學指引。臨床審計的基本步驟包括：選取項目，建立審計準則及標準，量度表現，落實改進措施及量度改進後的表現。本文將討論臨床審計各基本步驟，並以銀屑病病人的治療為例，說明臨床審計準則和標準建立的原則。臨床審計的最終目標為改善醫療服務質量。希望讀者能對臨床審計有基本了解，並能作更深入研究及進行一次臨床審計。

Keywords: Clinical audit, evidence-based medicine

關鍵詞：臨床審計，實証醫學

Introduction

Clinical audit is getting more popular nowadays. The Hong Kong College of Physicians has included

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clinical audit as an integral part of the continuous professional development for specialists. In clinical research/trial, we aim at finding whether a particular intervention/factor can affect outcome/development of disease. However, clinical audit is an activity that measures how well we are performing in our daily care. By setting criteria and standards based on properly done clinical research/trial, clinical audit provides an interception point between evidence-based medicine and clinical practice. The current review summarises basic concepts on clinical audit.

What is clinical audit?

Clinical audit is the attempt to improve quality of medical care by measuring the performance of those providing that care by considering the performance in relation to desired standards, and by improving on this performance.¹ Essentially, there are three components: measuring performance, comparing performance with

desired evidence-based standards and improving performance. The ultimate aim of clinical audit is to improve care either in terms of quality or cost-effectiveness. The steps that are necessary in clinical audit is summarised in Table 1. It is important to measure our performance after implementing change so that we know how well we have improved by the clinical audit (Figure 1).

Table 1. Steps for carrying out clinical audit²

1. Choose a topic and identify aims
2. Setting agreed target criteria and standards
3. Measure performance and compare with target criteria and standards
4. Agree and implement changes within members of healthcare team
5. Measure performance again to document changes

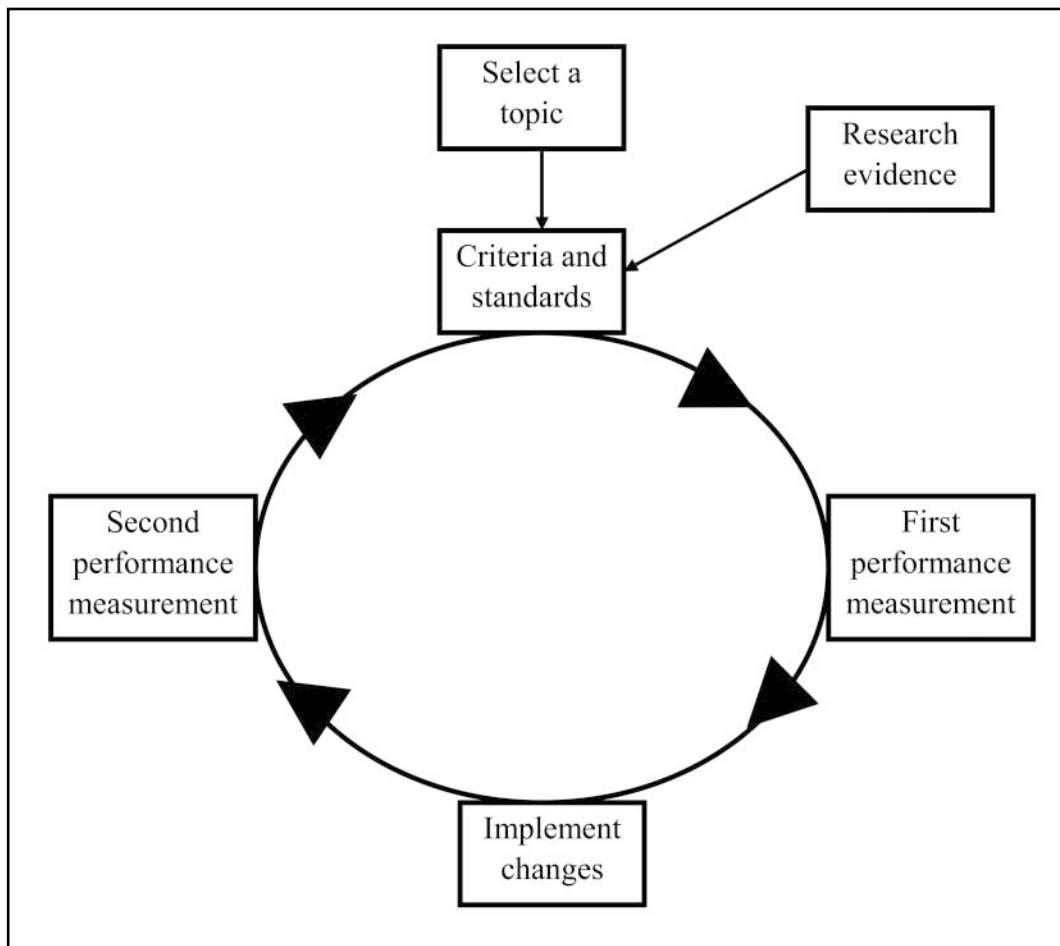


Figure 1. The quality improvement cycle.

How to choose a topic for clinical audit?

There are several factors that may be considered for choosing a subject for study. Firstly, whether the disease is common or not can be considered, as carrying out a clinical audit in a rarer disease, e.g. granuloma annulare, has less impact than a more common disease, e.g. eczema. In addition, we should think of whether the improvement in care can bring about a significant impact on the health status of patient. For example, an audit of the waiting time for new melanoma case referral is more meaningful than an audit of waiting time of all new skin cases. Thirdly, healthcare team members may be more motivated to improve themselves if there is pre-existing well established evidence-based data on the audit items. Lastly, for practical reasons, we should think of whether the current resources in our services can support the proposed improvement or changes. Depending on the aims, manpower, time and various resources, we can select to audit all aspects of health care of particular skin disease, e.g. psoriasis, or we can just audit part of disease care that we are interested in, e.g. how well we are monitoring side effects when psoriasis patients are given methotrexate.

Setting criteria and standards

After deciding upon the aim of a clinical audit, it is essential to set criteria and standards. Criteria have been defined as "systemically developed statements that can be used to assess the appropriateness of health care decisions, services and outcomes".² On the other hand, standard is defined as "the percentage of events that should comply with the criterion".² In simple terms, criterion is a statement that describes ideally how we should carry out healthcare and standard describes how well we should comply with the standard. An example of criterion statement for patients taking methotrexate is "the records show that the liver function test is monitored at an eight

weekly interval and when the dose is increased, an extra liver function test is carried out one week later". Standard of the above criterion can be "in at least 95% of the cases the above criterion should be complied with" and of course the appropriate percentage should be set according to the local clinic/service scenario. It is prudent to set a reasonable standard after discussion with team members as setting an inappropriately high standard may be detrimental to their morale and hence motivation to change.

Criteria should be evidence-based since it is the gold standard against which our activities are compared. It should also be prioritised, based on strength of research evidence and impact on outcome. It has been suggested that criteria can be prioritised into three levels.² "Must do" criteria refer to criteria that are strongly evidence based and have great impact on patient outcome. "Could do" criteria refer to those without much good evidence to support its routine application and with only slight impact on health outcome. "Should do" criteria refer to intermediate criteria between "must do" and "could do" criteria. In order to concentrate our efforts on important items, we usually do not measure "could do" criteria. Moreover, criteria should be measurable and be explicit to avoid misunderstanding. For example, the criteria "liver function test should be measured six times yearly" is not good enough as we can check liver function test six times in consecutive six months to pass the criteria, leaving the other six months unmonitored. So an explicit criteria is to state "liver function test should be monitored at an eight weekly interval".

Clinical audit criteria can be divided in to structure, process and outcome. Structural criteria refer to the hardware of medical care, e.g. the availability of phototherapy machine in psoriasis clinic. Structural criteria are easy to measure but are obviously not directly related to patient outcome. Outcome criteria are usually most difficult to measure but they are the ultimate performance indicator of the quality of health care. Process

criteria refer to how we are delivering care, e.g. consultation, carrying out investigation and drug prescription. Usually in clinical audit, we set process criteria and standards and use these to check how well we are doing. But one must remind that sometimes, even if we are doing well in delivering healthcare, patient outcome may still be poor. For example, we may have already given proper drug treatment, proper monitoring of complications, proper health and food education in diabetic patients; but some patients who are not compliant with either drug or diet may still develop premature diabetic complications.

To set appropriate criteria for audit, the easiest way is to perform search to look out for pre-existing clinical audit criteria. But one must be aware of the way in which the criteria are developed, i.e. whether they are evidence-based or not. Moreover, one must also carry out literature search again to check whether there are any new findings, published after the criteria have been written, that may modify the pre-existing criteria. If there are no pre-existing criteria, then one has to undertake the difficult process of literature search, rating the evidence and setting the appropriate criteria. We would illustrate how to set criteria with psoriasis as an example.

Psoriasis care: an example of setting criteria

Firstly, we should identify the key elements of delivering care to psoriasis patient. Table 2 outlines

how we deliver healthcare to psoriasis in daily practice. An attempt is made to prioritise some of the items in Table 2 (in italics) into criteria based on research evidence. But sometimes professional judgement and agreement have to be made as not every elements of care has enough evidence-based data.

Documentation of how we diagnose psoriasis is important as it is the basis of recruiting patients into the psoriatic clinical audit. For most of the time, we diagnose psoriasis clinically, although sometimes we take clinical photo and perform skin biopsy in doubtful cases. To be good enough to substantiate a clinical diagnosis of typical plaque type psoriasis, description such as "well defined monomorphic silvery scaly plaques with positive Auspitz's sign distributed over....." is adequate. However, description such as "psoriatic plaque over...", especially in the first consultation, is not acceptable. Moreover, in the service that the author is working, the clerk will enter the diagnosis printed on the front cover of medical record into the computer. Such entry is important to create a database for subsequent data retrieval. So this should be a "must do" criterion.

Psoriatic arthropathy has an important bearing on quality of life of patients. Effective treatment is also available. Literature search shows that traditional disease modifying agents such as methotrexate, cyclosporin and sulfasalazine are of benefit to peripheral arthritis but less so to spondylitis. Moreover, impact on progression of joint destruction has not been adequately

Table 2. Elements of care in psoriasis patient

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1. *Documentation of clinical diagnosis of psoriasis: clinical description or photos, +/- histology*
 2. Clinical evaluation: skin area involvement, *arthropathy*, *nail involvement*, past health
 3. Assessment of drinking, smoking and psychological/quality of life impairment
 4. *Indications for systemic/phototherapy treatments: disease severity, effects on quality of life*
 5. Baseline screening and monitoring of side effects of systemic treatment
 6. General skin care, use of drugs and *advice on psoriasis care*
 7. Target skin surface area control or quality of life measurement
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Italics: elements of care under discussion in psoriasis care: an example of setting criteria section

addressed.³ In contrast, biologic treatments like etanercept and infliximab have been showed to be useful to control joint symptoms in double-blind, placebo-controlled randomised trials and uncontrolled radiographic data at one year also indicate a beneficial effect on the progression of joint disease.⁴ It is essential for dermatologist to identify psoriatic patients with arthropathy and appropriate referral or care should be delivered for symptom control with or without prevention of further joint destruction. For example, medical records should document "no symptoms/signs of joint disease" or "joint pain, deformity and swelling distributed symmetrically over the distal phalangeal joints of both hands, refer rheumatology for further treatment". There is no evidence that indicates the optimum interval for arthropathy screening so professional judgment and agreement can be exercised here and one year seems to be a reasonable interval.

There are no randomised trials that point out the difference of whether recording down the indications for systemic/phototherapy would have significant effects on patient outcome. But these are important aspects in care as systemic therapy carries a higher potential side effect profile and we need to justify the use of more toxic therapy in patients. Examples are "psoriasis affecting more than 50% body surface area" and "palmar pustular psoriasis affecting work". It should be classified as a "must do" criterion.

In contrast, less data are present for importance of documentation of nail involvement and advice on psoriasis care on disease outcome. Nail deformity may impair quality of life, but in general,

to a lesser extent than arthropathy.⁵ There are some observational studies showing that in patients with psoriatic arthropathy, the severity of nail changes correlates with an increased severity of joint and skin symptoms.⁶ But there is no large scale randomised double blinded, placebo-controlled trial on an effective treatment of nail psoriasis. In the literature, there is no randomised placebo-controlled trial to test whether advice on psoriasis care may have a beneficial effect on disease outcome. But a case-control study has demonstrated that a cognitive-behavioural program involving teaching on psoriasis, stress reduction and cognitive techniques can reduce anxiety, depression and stress experienced by psoriasis patient.⁷ Without good evidence-based data and their relatively lower impact on overall health outcome, they are only classified as "could do" or even "should do" criteria.

Table 3 suggested some "must do" criteria for psoriasis patient care. They should be written with measurable and explicit terms so as to avoid confusion or misunderstanding during the process of audit. If possible, it is also advisable to send self-developed criteria for external peer and expert review to make sure that we have not miss important studies that may contribute to develop better criteria.

Measure performance and compare with targeted criteria and standards

After all the above preparatory work, we can start to collect data on our current performance. The index disease population can be identified by clinic

Table 3. Some "must do" criteria for psoriasis patient care

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1. Clinical description of morphology of skin lesions compatible with psoriasis (with or without clinical photo or histology) at visit when the diagnosis is first made and the diagnosis has been written on the front cover page to facilitate subsequent retrieval
 2. The record documents that assessment of symptoms or signs of psoriatic arthropathy is performed at least one time in a 12 month interval and, if present, referral to relevant specialists has been made
 3. The record shows that indications for systemic/phototherapy have been documented
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database. Existing sample size calculation formula is present and if the available patient population is much larger than the ideal sample size, we can collect data after proper randomisation.⁸ Special data entry forms can be used to facilitate data collection and entry. We calculate how well we comply with the criteria as percentage with confidence interval. Sophisticated statistics are usually not necessary. The results are compared with the pre-set standards to see whether we are deficient in particular areas of healthcare.

Implementing changes

After knowing what are suboptimal in our current practice, we can start to implement changes with a will to improve quality of care. As healthcare is usually delivered by a team, it is advisable to discuss the area of deficiency with team members and the ways to improve current situation. Most importantly, clinical audit is a means to improve care and no individual team members should be blamed.

A number of ways can be employed to implement changes or serve as reminder to implementing changes. These include seminars, site visit by senior staff, development of clinical guidelines, reminder poster, development of structured consultation forms for the studied disease and assigning special staff/team to be in charge of disease care, etc. But above all, as health care is a team work, it is better to reach a consensus amongst team members so that they are more motivated to implement changes.

Measure performance again to document changes

Although this is the last step for clinical audit, it should not be overlooked. After all, the aim of clinical audit is improvement of care and this last step is to document whether we can achieve this

goal. Performance is measured once again after changes have been implemented, to see whether healthcare team members have changed their healthcare delivery through the process of clinical audit. If the standards are not met even after the change, we have to consider better ways to implement changes or to re-set the standard to a level reasonable to the current resources within the team. If standards are met after the change and our standards are within reasonable level, we can claimed that our audit is successful. However, we may need to perform the audit again later to monitor our performance regularly as there may be change within the team, e.g. change of staff or change of behaviour with time, and there may be new research evidence that modify the criteria. So terms like "audit cycle" or "audit spiral" have been coined to highlight the repeating nature of clinical audit process.²

Conclusion

Clinical audit is the balance that helps us to weigh how well we are performing in our daily practice against criteria based on research evidence. It is a tool to improve understanding on our work as a team. The preparation of conducting clinical audit and participation in a clinical audit is itself an educational activity. Clinical audit is not only limited to doctors, but can be multidisciplinary involving every members of the healthcare team such as nurses, pharmacists, physiotherapists, occupational therapists and even clerical supporting staff. Neither sophisticated computer database nor complicated statistics are necessary. Audit support group for primary health care, like the primary and community care audit group in the United Kingdom, provides support and database for clinical audit in the primary care setting. Although the author is unaware of any similar support group for dermatology audit in the web, it not surprising to see one in the near future given the popularity that clinical audit has gained in recent years.

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