Clinical practice guidelines

Bandula Wijesiriwardena*

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Prof. Janaka De Silva, past presidents, council members, fellows, members of the Ceylon College of Physicians, ladies and gentleman.

At the very outset I wish to thank the College for electing me as the president. It is with a deep sense of humility and responsibility that I accept this position. I fully understand what it means to be elected by my peers as their leader. For me, this acknowledgement is the highest accolade that one can receive as a professional. I am also quite aware of the responsibilities that accompany this high position. I promise to give my best at all times and to uphold the values and traditions of this high office.

I thank Prof. Janaka de Silva, the outgoing president, for his very generous introduction. We had an exceptional year under his leadership and the high point was the annual academic session, which was one of the best we have ever had. I congratulate Janaka on a job so well done. My task has been made that much tougher because I have to step into Janaka's big shoes. However, I will do my best to uphold the high standards that he has set.

I will never be short of advice as I have so many past presidents in the council! At all times, I will look upon them for guidance. I expect the young legs to provide all the energy and to be the driving force behind the council and the senior members to provide wise counsel.

At this time in the history of our island, we stand as a shattered nation. We are all attempting to recover from the effect and the aftermath of gigantic tsunamis that ravaged our coastal towns. As we stood among the debris and the dead, we knew that the only path forward was to rebuild our nation, and to rebuild in unity and strength. In this process of rebuilding our nation, we know that we must use our best minds, our expertise, our best efforts and the best practices.

However, we should not restrict the use of our best efforts and best practices to the process of rehabilitation and rebuilding. It is crucial for our nation that we embed this best practices into the fabric of our daily lives.

We, physicians should lead the way and use best practices in the application of our medical expertise. In order to do so, we need to have guidelines based on scientific evidence that will provide the base from which such best practices evolve.

There is an awareness that the common and important medical conditions are not being managed appropriately. It is common knowledge that many doctors do not practice even highly effective, proven and low-cost therapies such as aspirin, for prevention of myocardial infarction and stroke. This is most often due to failure to apply evidence-based medicine. Ceylon College of Physicians recognized this a few years ago and at the request of the then president Dr. Kolitha Sellahewa, decided to embark on a programme that would develop clinical practice guidelines. Kolitha knew that I was very interested in this topic, as we had already discussed this subject. I was appointed the chairman of this programme and assigned the task of identifying priority areas and selecting members for the guidelines groups. We started with simple consensus guidelines. From there we moved on to more extensive and exhaustive evidence linked guidelines; for example guidelines on Ischaemic Heart Disease and Chronic Heart Failure. I am happy and proud to say that we have been able to publish 11 guidelines in a relatively short time.

There was no funding for this project. All the expenses incurred were born by the members of the guidelines group. This included surfing the worldwide web, purchasing stationery, writing to various guidelines publishing organisations for clarifications etc. This required a heavy input of time and on average, about one year was required to formulate a major guideline. Printing was only possible through kind and generous sponsorship of the pharmaceuticals industry. I am glad to say that there were no strings attached to this sponsorship. At this point, I wish to express my gratitude to GlaxoSmithKline, Pharma Associates and AstraZenaca for providing much needed sponsorship.

* *Consultant Physician, Colombo South Teaching Hospital, Kaulubowila.*

President CCP yr 2005.

The target groups of the CCP guidelines were practicing physicians and post graduate trainees in medicine. Ideal management was discussed in detail because the main objective was educational and when variation was necessary due to lack of facilities, this was specifically indicated. This is in contrast to the national guidelines development by the Sri Lanka Medical Association, which targeted medical practitioners of all levels. CCP guidelines were never meant to be national guidelines but could provide the basis for such guidelines.

I feel that now the time is opportune for us to reflect on what we have achieved so far, assess strengths and weaknesses, look at opportunities and challenges and thereby identify future directions for the project. Let me introduce the topic of clinical practice guidelines and assess gaps and needs.

What are clinical guidelines?

Clinical guidelines are systematically developed statements designed to help practitioners and patients make decisions about appropriate health care for specific circumstances.

These may deal with several aspects of a clinical situation (for example investigations, diagnosis, acute treatment and long term management) or be much more restricted (for example, how to carry out a procedure).

Many people ask whether guidelines and protocols are synonymous.

Protocols are specific guidelines, which should be followed in detail with little scope for variation. Protocols are used in high-risk areas; for example emergency resuscitation, or where legislation regulates the practice, for example forensic psychiatry.

The broad interest in clinical guidelines has its origin in issues that most healthcare systems face. These are:

1. Rising health costs, fuelled by increased demand for care, more expensive technologies, and an ageing population;
2. Variations in service delivery among providers, hospitals, and geographical regions and the presumption that at least some of this variation stems from inappropriate care, either overuse or under-use of services; and
3. the intrinsic desire of healthcare professionals to offer, and of patients to receive, the best care possible.

A clinical guideline is a tool for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports.

The concept of recommendations providing guidance is not novel and for many years Clinicians have used treatment recommendations, immunization schedules, algorithms, textbooks and practice bulletins, to guide practice. Over the last decade, difference has been the increasing focus on systematically summarizing research evidence in order to develop more evidence-based recommendations. This more rigorous approach involves multidisciplinary teams representing various stakeholders and perspectives, which systematically locate and appraise research evidence to produce explicit, evidence based guidelines.

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, there is a risk that practice will become tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, there is a risk that practice will became rapidly out of date, to the detriment of patients.

Evidence based medicine is not 'cookbook' medicine. Because it integrates the best external evidence, clinical expertise and patients choice, it cannot result in slavish, cookbook approaches to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision.

The purpose of clinical practice guidelines is to identify effective diagnostic, screening and treatment strategies and to encourage the use of these to improve the quality of healthcare delivered and thus patient outcomes. Defining quality in healthcare can be difficult. One simple definition of quality in healthcare is "providing the right care, at the right time for the right person in the right way". Quality healthcare should be

appropriate, accessible, effective, safe and provided by someone who is competent and accountable for practice. Improvements in healthcare quality should result from better decisions recommended by practice guidelines at a clinical level and by influencing policies that promote allocation of resources and better delivery system.

I will now discuss briefly clinical practice guidelines under following topics.

1. Developing guidelines
2. Potential benefits, limitations and harms
3. Legal considerations

What are the methods available for producing a set of guidelines?

- Consensus
- Evidence linked

Traditionally, guidelines have been based on consensus amongst experts. This method is also known as GOBSAT (Good Old Boys Sat Around a Table) and has its limitations. This involves experts formulating a series of recommendations. It usually only includes some but not all perspectives and can lead to flawed conclusions. Expert opinion does not always reflect the state of current knowledge. It should no longer be used or encouraged as these statements are based on perceived wisdom, clinical judgment and experience, rather than current scientific evidence.

Modern guidelines are produced by the Evidence-linked method. Recommendations are linked to the quality of evidence available. Scientific evidence is systematically reviewed and the evidence is graded. Likewise, the recommendations are graded and linked to the evidence.

An Evidence-linked guideline can be developed de novo or locally adapted.

Developing guidelines de novo involves many steps;

1. Organisation of guideline development
2. Selection of guideline topics
3. Composition of the guideline development group
4. Systematic literature review
5. Formation of recommendations
6. Consultation and peer review
7. Presentation, dissemination and implementation
8. Evaluation
9. Scheduled review

As one can see, the development of an evidence-linked guideline is a major undertaking that usually requires national or regional funding, heavy time input and manpower. Most healthcare organizations do not have the resources and skills to develop valid guidelines from scratch. This is one of the reasons for the failure of the guidelines movement to gather momentum in developing countries. For a region in a large country or a developing country, a more realistic strategy would be local adaptation of internationally accepted guidelines. The clinical practice guidelines committee of the Ceylon College of Physicians (CCP) has followed this method.

How are the guideline topics chosen?

Theses are chosen on the basis of the burden of disease, the existence of variation in practice, and the potential to improve outcome.

Composition of the guideline development group

There should be participation by representatives of key groups and disciplines affected as the balance of disciplines within a guideline development group has considerable influence on the end result of guideline recommendations. Guidelines should not be developed by academics and senior clinicians insulated from the day to day pressures involved in providing medical care. Guideline should accurately reflect the routine working practices of most doctors. Therefore, widespread multidisciplinary participation is important.

How does one find valid guidelines for adaptation?

It is essential that guidelines from guideline development programmes, which employ rigorous methodology and include formal appraisal within the programmes be used.

For example, Scottish Intercollegiate Guidelines Network (SIGN), The National Institute for Clinical Excellence (NICE) in England and Wales, Agency for Health Care Policy and Research guidelines (AHCPR) in the USA, WHO, New Zealand guidelines group, Canadian Medical Association Clinical Practice Guidelines InfoBase.

Once guidelines of acceptable quality have been identified, these need to be adapted by a

multidisciplinary group. The composition and function of this group will parallel that of the original guideline development group, but members will not need systematic reviewing and evidence summarizing skills.

The task of the group is to adapt the guideline and then plan the presentation, use, and evaluation of the guideline within the local setting and its services.

What are the resource implications and feasibility issues?

Whilst the guideline may represent the optimum management of a particular condition in terms of effectiveness, it may not be the most economic or efficient strategy overall.

Feasibility issues worth considering include the funds, time, skills, staff, and equipment necessary for the provider to carry out the recommendations, and the ability of patients and systems of care to implement them.

Guidelines should be pilot-tested prior to publication. This is more appropriately carried out at a local level as part of the translation of the national guideline into local guidelines for implementation. Guidelines should receive external review to ensure content validity, clarity, and applicability.

What are the methods available for presentation ?

Guidelines can be presented in different forms:

- Full guideline,
- Executive summary of recommendations,
- Quick-reference-guide (desk-top or wall charts).

There is little information available on the effect that style and format have on the adoption of guidelines. From whatever little feedback that we get from the users, it is clear that most of them read only the quick reference guide for want of time. However, clarity of definitions, language, and format is obviously important. Guidelines should be written in unambiguous language and should precisely define all terms.

What are the strategies available for dissemination and implementation?

There is no single effective way to ensure the use of guidelines in practice. Therefore, multifaceted interventions should be adopted to disseminate and implement guidelines.

The choice of strategies should be informed by available resources, perceived barriers to care, and research evidence about the effectiveness and efficiency of different strategies.

They include;

1. Educational approaches in the form of seminars and workshops.
2. Audit and feedback.
3. Social influence approaches.
4. Reminders and patient mediated interventions.

Guidelines are more likely to be effective if they are disseminated as part of an educational initiative as we found with the MD trainees. If you make it a point to have at least some questions based on guidelines, it will not be a difficult task to get them to read and follow them.

The next step is evaluation

Evaluation ensures that the process of care reflects guideline recommendations. The data needed for this should be specified at the outset and should be linked to areas of strong evidence within the guideline.

Guidelines should be reviewed and updated regularly

A predetermined date for review is recommended; for example in two years. It is not intended that these should be applied rigidly. Guidelines may be reviewed sooner if there are important developments in the evidence base or the review may be postponed if, for example, the results of ongoing studies are awaited.

What are the potential benefits, limitations, and harms?

Let us first consider the potential benefits

There are benefits to all 3 stakeholder groups; patients, healthcare professionals and healthcare systems.

What are the potential benefits for patients

Guidelines that promote interventions of proved benefit and discourage ineffective ones have the potential to reduce morbidity and mortality and improve quality of life, at least for some conditions. Guidelines can also improve the consistency of care: all will be cared for in the same manner regardless of where or by whom they are treated.

What about healthcare professionals?

Clinical guidelines can improve the quality of clinical decisions. These provide authoritative recommendations that reassure practitioner about the appropriateness of their treatment policies. Clinical guidelines can support quality improvement activities and these are a common point of reference for prospective and retrospective audits of clinicians' or hospitals' practices. Medical researchers benefit as guidelines shine on gaps in the evidence as critical appraisal of evidence identifies flaws in existing studies.

What are the potential benefits for healthcare systems?

Guidelines are effective in improving efficiency, often by standardising care. The implementation of certain guidelines reduces outlays for hospitalization, prescription drugs, surgery, and other procedures.

Now let us look at the potential limitations and harms of guidelines

The most important limitation of guidelines is that the recommendations may be wrong or at least wrong for individual patients. This can occur due to many reasons in addition to inadvertent oversights by busy or weary members of the guideline group. Firstly, scientific evidence about what to recommend is often lacking, misleading, or misinterpreted.

Secondly, recommendations are influenced by the opinions and clinical experience and composition of the guideline development group. Thirdly, patients' needs may not be the only priority in making recommendations.

The use of flawed guideline can encourage the delivery of ineffective, harmful, or wasteful interventions. The same parties that stand to benefit from guidelines may all be harmed.

Now let us look at the legal considerations

Guidelines could be introduced to a court by an expert witness as evidence of accepted and customary standards of care, but they cannot be introduced as a substitute for expert testimony. Courts are unlikely to adopt standards of care advocated in clinical guidelines as legal 'gold standards' because the mere fact that a guideline exists does not of itself establish that compliance with it is reasonable in the circumstances, or that non-compliance is negligent. Fortunately, the courts continue to place the testimony of expert witnesses about what constitutes reasonable practice above the recommendations of prestigious works of reference.

Are the authors or sponsors liable?

Authors of clinical guidelines cannot be held liable for incorrect or misleading statement in circumstances where patients have suffered harm. "While an action could be taken against a clinician for not keeping up to date, a College is probably not actionable, as it would be difficult to show it owes a duty or obligation directly to the patient."

Next, I will discuss the gaps and needs of adapting guidelines in Sri Lanka. There are many identifiable gaps.

- There is no formal system for identifying priority areas or areas where there are variations in service delivery. There is an urgent need for clinical audits; for example in IHD, DM, stroke care and hypertension.
- There is no government funding whatsoever. Funding is obtained at a personal level from the pharmaceutical industry, which is most undesirable.
- There are disparities in care among different areas of the country and between the state and private sector, which makes it difficult to provide uniform recommendations. Data on cost-effectiveness issues are scarce.
- Resource implications and feasibility issues are often not considered, as health care providers are only rarely involved in the process. Feasibility issues worth considering include the funds, time, skills, staff, and equipment necessary for the provider to carry out the recommendations, and the ability of patients and system of care to implement them.
- Severe shortage of personnel experienced in and committed to guideline development is a huge handicap.
- Peer reviews are difficult to obtain, as there is lack of cooperation for want of time. Draft guidelines are never returned or returned with hardly any comments and as a result, critical evaluations are sadly lacking.
- There is no formal mechanism for dissemination and implementation. Dissemination and implementation are erratic as it is difficult for the individual organization to effect. Printed versions are posted to the stakeholders and that generally is the end of the process. There is no evaluation at all.

How do we overcome these gaps?

What recommendations can we make ?

Clinical guidelines have become an integral part

of and are essential for the practice of medicine as they help to integrate individual clinical expertise with the best available external clinical evidence. These are an absolute necessity.

- Governmental involvement is essential as the main health care provider of the country. The Ministry of Health should spearhead the guidelines programme with representation of all associations and colleges. A guideline agency should be set up under the Ministry of Health, similar to those established in other counties, in order to ensure better organization and funding through agencies such as WHO and World Bank. The planning division of the Ministry is ideally suited to perform this task.
- Priority areas have to be identified. For this purpose, audits are necessary on existing care.
- Guideline development groups should be appointed.
- Relevant guidelines should be identified for local adaptation.
- Resource implications and feasibility issues should be considered.
- Feasibility issues worth considering include the funds, time, skills, staff, and equipment necessary for the provider to carry out the recommendations, and the ability of patients and systems of care to implement them.
- There should be a formal mechanism for dissemination and implementation – in the form of seminars, lectures and circulars in addition to printed versions. Guidelines should be disseminated as part of a CPD programme. Post-graduate trainees should be encouraged to read and follow guidelines during the training and they should be rewarded for their effort by having at least some questions at the examinations based on guidelines.
- Once the guideline agency has been set up, an official website should be set up for easy access and to receive feedbacks.
- The planning division of the Ministry of Health can carry out evaluation in the form of clinical audits. The service of DDHS, MOHs and postgraduate trainees in community medicine could be obtained to achieve this.

After that serious discussion, let us see, in a lighter vein, what can be done in the absence of evidence-based guidelines. There are seven alternatives to evidence based medicine;

- Eminence-based medicine
- Vehemence-based medicine
- Eloquence-based medicine
- Providence-based medicine
- Diffidence-based medicine
- Nervousness-based medicine
- Confidence-based medicine

Eminence-based medicine

The more senior the colleague, the less importance he or she placed on the need for anything as mundane as evidence. Experience, it seems, is worth any amount of evidence. These colleagues have a touching faith in clinical experience, which has been defined as 'making the same mistakes with increasing confidence over an impressive number of years'.

Vehemence-based medicine

The substitution of volume for evidence is an effective technique for brow beating more timorous colleagues and for convincing relatives of one's ability.

Eloquence-based medicine

The silk tie, Armani suit, and tongue should all be equally smooth. Sartorial elegance and verbal eloquence are powerful substitutes for evidence.

Providence-based medicine

If the doctor has no idea of what to do next, the decision may be best left in the hands of the people up in the heaven. Too many clinicians unfortunately, are unable to resist giving them a hand with the decision-making.

Diffidence-based medicine

Some doctors see a problem and look for an answer. Others merely see a problem. The diffident doctor may do nothing from a sense of despair. This, of course, may be better than doing something merely because it hurts the doctor's pride to do nothing.

Nervousness-based medicine

Fear of litigation is a powerful stimulus to over-investigation and over-treatment. In an atmosphere of litigation phobia, the only bad test is the test you didn't think of ordering.

Confidence-based medicine

This of course, is restricted to surgeons.

In summary, ladies and gentlemen, modern, evidence-linked clinical guidelines seek to make the strengths, weaknesses, and relevance of research

findings transparent to clinicians. Appropriate interpretation and application of such guidelines are likely to generate better clinical care and safer medico-legal strategy than either uncritical disregard or unthinking compliance.

Before I conclude, I wish to express my appreciation of a few people.

Single individuals cannot organize this type of function: it needs a team. I am thankful to Darrel, Riza and team from Pharmacia for their superb organization and all the hard work. I also appreciate the efforts of Mr. Deepal Fernando and his team at TransAsia. I with to thank Mr. Bertram Nihal and his crew for the camerawork.

I am grateful to Prof. Kumudu Wijewardena and Dr. Sriyanie Miththapala for constructive comments during the preparation of the speech. Mr. Maithriwardana and Madara; our office staff at the CCP were very supportive and I thank them for the help.

Last but not least, I thank you all for taking time off your very busy schedules to be here today.

Ladies and Gentlemen: Let me end my speech with the following quoting from a statement made in 1903 by William Osler, which I think is extremely apposite even today,

"We doctors do not "take stock" often enough, and are very apt to carry on our shelves stale, out-of-date goods. The colleges help to keep a man "up to the times", and enable him to refurbish his mental shop with the latest wares .... It keeps his mind open and receptive, and counteracts that tendency to premature senility, which is apt to overtake a man who lives in a routine".