

Developing HIV/AIDS treatment guidelines



UNAIDS Best Practice Collection
KEY MATERIAL

Acknowledgement

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Developing HIV/AIDS treatment guidelines



Joint United Nations Programme on HIV/AIDS

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How to use this booklet

*T*his document introduces the methods used to appraise and develop clinical guidelines, making specific reference to HIV/AIDS. It is recommended for use by policy makers, guideline development committees and other people responsible for ensuring the validity of guidelines. It is intended to support the development of guidelines that lead to improved health. Guidelines come in different forms; some take the deterministic form of statements, algorithms, flowcharts and diagrams, giving specific instructions to be followed all the time; others are in “branching” form, recommending a course of action depending on the information available to the clinician.

Part 1 describes how to appraise HIV/AIDS clinical guidelines that are currently in use and which may need updating. The aims are to identify their essential elements and make the necessary adjustments to improve their validity. The guideline appraisal tools in the appendix are intended to support this process.

Part 2 introduces how to develop new HIV/AIDS guidelines and gives the specific steps to take. It describes different methods applicable in both developed and developing countries. The degree to which these steps apply will differ in each country depending on what funding and expertise are available.

An annotated bibliography gives details of the sources referred to in the text and further reading on guideline development.

Glossary

Terms used in this booklet are defined as follows:

Appraisal: assessment of the usefulness of specified characteristics of the guideline.

Evidence: the scientific basis upon which the appraisal, validation, or recommendations of the guidelines is made.

Guideline: a document that contains specific recommendations for clinical management of a specified condition. Commonly this will be used to refer to HIV/AIDS clinical treatment guidelines.

Guideline development: the process of making a guideline, from an idea to the finished product. This also includes the dissemination and implementation strategies adopted.

Methodology: the specific steps taken in making the guideline.

Recommendation: advice, given as statements, narrative, algorithms, flowcharts or diagrams, that describes the steps taken in applying the correct and appropriate diagnosis or treatment for a specific clinical condition.

Validation: the authentication or endorsement of the recommendations given in a guideline, based on scientific evidence.

Part 1

Appraisal and validation of existing guidelines

Applying the guideline assessment tool and reporting the results

*F*irst, the process used to develop the guideline is reviewed, then the content of the guideline is examined to assess its validity. Assessment of the guideline's suitability for clinical practice by interviewing users gives the process greater objectivity.

The use of rapid appraisal forms (given in the appendix) quickly reveals pitfalls such as inadequate evidence and subjective opinion. The process encourages rigorous guideline development and supports the validity of recommendations. The appraisal involves questions covering the key issues in guideline development. Responses to the questions are "yes", "no", or "not applicable" (N/A), and are simply arranged. A quick look through a completed form gives an impression of the guideline under review and of the various aspects requiring improvement.

A quantitative analysis can be made to give a percentage of "yes" and "no" responses. Such results are easily interpreted. It may not be easy to identify a cut-off point suggesting the level of acceptability, as the interpretation of some questions is subjective. A useful cut-off could be, for example, "affirmative 50%", with other positive responses being accepted as an indication of the appropriateness of the guideline. More research needs to be conducted on the interpretation and use of this information.

The appraisal results can also be used in the design of questionnaires to interview clinicians who routinely apply the guideline in clinical practice. The results of these questionnaires, in combination with those of the appraisal, would form a consolidated report on the whole process.

The results of an appraisal should be reported by the committee appointed to review the guidelines. The report should promote confidence in the appraisal's use or, when applicable, provide for amendment or revision of any deficiencies. This report should be made widely available to all the parties concerned, so that they can take appropriate action.

The appraisal report will be a useful source of information to local practitioners planning to adapt the guidelines to local practice and resources.

Part 2

Developing valid HIV/AIDS guidelines

Introduction

The terms “standard treatment guidelines”, “treatment protocols”, “practice guidelines” or “prescribing policies” are used to indicate systematically developed statements that help clinicians to decide on appropriate treatments for specific clinical conditions¹. For the purposes of this document, the clinical condition is HIV infection.

Several effective and efficient methods for developing clinical practice guidelines have been developed over the years. It is important to anticipate the biases inherent in the guideline development process so as not to produce an invalid tool. Extensive literature reviews suggest that the validity of clinical guidelines depends on three crucial issues²:

- the specialties of members included in the guideline development committee;
- how the evidence is identified and synthesized;
- how the guideline recommendations are developed.

These three principles form the framework for the guideline development process outlined in this document.

The use of clinical practice guidelines has been shown to be an effective means of improving the way clinicians manage patients. Guidelines can:

- reduce the cost of health care by minimizing the excessive use of treatments and tests;
- contain costs by judicious and rational allocation of care resources;
- lead to the training of health-care workers in the diagnosis and clinical management of HIV infection;
- facilitate monitoring and auditing to indicate the changes required in health staff education;
- change prescribing habits as a means to improving health care.

Over the years, the factors that influence the development of good clinical guidelines have been much better understood. What facilitates their introduction into clinical practice has also been identified. Much work, however, still remains to establish these factors in relation to HIV/AIDS.

Increased participation from patient groups and service providers assures the development of comprehensive and patient-sensitive guidelines. As the number of people infected with HIV and living with AIDS continues to rise, it becomes a priority to establish valid clinical standards, so that effective and efficient care is ensured. The

dynamic changes in treatment for HIV/AIDS and the ever-increasing data on that subject require a secure review process so that benefits are quickly approved, assessed, and passed on to patients, families and communities.

This document outlines the ideal procedure, which can be expensive. However, a less ambitious approach might compromise the quality of the guidelines developed. Initially, only some of the principles and procedures need be applied to ensure the success of the process. A minimum number of steps would include those described in sections 3 to 7, 10 and 11 below. Over a period of time, the expertise and capacity to conduct a more extensive process can be built up, incorporating the full range of the steps and principles described.

Steps in developing HIV/AIDS treatment guidelines

1. Target groups and type of guideline

Early decisions should be made on the type of guideline required, the target group that will use it and the levels at which it will be used. These issues can be determined by a survey of individuals currently requiring an HIV/AIDS clinical management guideline. The scope of the guideline should also be decided well in advance. Commonly it will be for various levels of the health-care system throughout a country. The guideline's value and relevance need to be checked for each different country in which it is to be used.

Two types of guidelines could be developed depending on their use: either HIV/AIDS-specific, or general medical treatment guidelines incorporating HIV/AIDS-specific recommendations. Additional outcomes of this are a summary that busy clinicians can use as a convenient quick reference, and a consumer's guide for use by people living with HIV/AIDS (PWAs) and carers in the home. The summary should give the recommendations in diagrammatic form or flowcharts. This could be a starting point for making locally relevant protocols or guidelines that take into account the disease patterns of HIV and the practices common to a particular area.

2. Stakeholder mapping exercise

A stakeholder mapping exercise identifies which individuals and organizations will affect the guideline development process. This could be conducted by the AIDS programme manager or by whoever takes the initiative to develop the guidelines. It is a useful exercise that serves two purposes: to solicit the support and participation of several stakeholders; and, as an advocacy tool, to influence others to participate in guideline development and promotion.

Identifying stakeholders in HIV/AIDS guideline development

- *List* all important persons and institutions;
- *Identify* the main interest of each stakeholder and the likely role to be played;
- *Distinguish* stakeholders by the level of influence they have on individuals, the community and institutions;
- *Prioritize* the groups according to importance;
- *Get* details of important stakeholders (characteristics, interests, fears, strengths, weaknesses, how they will be affected/will influence, how they can be influenced).

3. Setting up a guideline development committee

*I*n most countries the Ministry of Health will be responsible for setting up a committee or a group of persons to look into the development of an HIV/AIDS guideline. Sometimes this responsibility is delegated to the National Drugs and Therapeutics Policy Advisory Committee or to the National AIDS Control Programme. The guideline development committee should include people from different disciplines; their complementary skills will aid the development process.

There are three types of guideline development committees:

- internal groups which are composed entirely of clinicians who use guidelines;
- intermediate groups which include some clinicians who use guidelines; and
- external groups which include no clinicians³.

The size of these groups will depend on the number of topics or diseases selected for inclusion in the guidelines. Studies have established that guidelines produced using this grouping system lead to significant changes in clinical behaviour, however, guidelines developed by internal groups lead to less compliance⁴. This may be attributed to local guideline developers being less likely to conduct an extensive search for evidence, owing to a lack of resources when compared with a national guideline development process. Findings from implementation also suggest that guidelines from local groups are less likely to inspire confidence and credibility in peers than those developed by outsiders. This, however, is not always the case: in some cultures local groups have significantly more credibility and acceptance in their community than national ones.

The participation of clinicians and nurses with experience in HIV/AIDS care is critical to successful HIV/AIDS guideline development. As they may lack skills in the methodology of guideline development, review and assessment of clinical evidence, it is important also to include persons with these skills on the committee.

When available, experts from other disciplines should be included in the development efforts. Their participation will contribute to the quality and credibility of the guideline. For example, economists could estimate the cost implications of guideline implemen-

tation, and social workers could consider its impact on society. Counsellors could reflect the concerns of patients in relation to psychosocial problems and their impact upon clinical care and interactions with practitioners.

Various HIV/AIDS guideline development efforts around the world have used multidisciplinary teams. In the development of HIV/AIDS guidelines for the Caribbean, an ad-hoc committee to oversee the process was selected from the countries of the region. The participants included physicians, paediatricians, venerologists, microbiologists, an evaluation specialist and a dermatologist. A consensus workshop was later organized involving more experts (ward sisters, infection control nurses, a surveillance nurse and a psychologist). Their perspective was important in the finalization of the guidelines⁵.

The WHO guidelines for adapting HIV clinical management guidelines to country needs⁶ recommend a consensus workshop involving a maximum of ten persons. These include representatives from the national AIDS control programme, the Ministry of Health, nursing and medical schools, the essential drugs programme and the regional/district health officer. It is also suggested that representatives from relevant United Nations agencies participate in the workshops.

In the United States of America, guidelines for the evaluation and management of early HIV infection⁷ were developed by a multidisciplinary team of experts from medical and nursing professions, AIDS directors, AIDS researchers, health educators and counsellors. Their selection and appointments were made by the United States Agency for Health Care Policy and Research (AHCPR).

Involving HIV-positive individuals at the workshop stage may not yield much useful information as the discussion will tend to be very technical. It would be better to involve patient representatives or PWA groups. Unfortunately, PWAs and their representatives do not often participate, as the clinicians who decide on the participants tend to select medical staff. A more appropriate time to involve HIV-positive individuals, families and community representatives is when reviewing a consumer guideline. Information from these groups can be collected in focus group discussions, as was the case in the development of the United States guidelines for early HIV infection⁷.

4. Role of the committee members

*T*he committee members' roles should be stipulated at the time of recruitment so that members clearly understand what is required of them. This is especially important where the members make a long-term commitment. Incentives for participation may have to be considered as the work of the committee can be time-consuming and may require absence from members' regular work. The terms of reference for members of a typical committee would be as follows:

- (i) **Group leader(s)** will ensure that the guideline development group effectively achieves its task according to the terms of reference for the committee. This individual or individuals will have skills in facilitating groups and have experience in the guideline development process.
- (ii) **Group members** will have experience in developing clinical recommendations in the light of scientific evidence related to their particular specialty and skills in developing guidelines.
- (iii) **Specialists** in the different disciplines will review the literature, summarize relevant papers and lead the group members in discussing these as they develop recommendations.
- (iv) **Technical assistants** will support the committee in the literature review, data searches and presentation of this information, in a form that enables the committee to develop recommendations efficiently.
- (v) **Administrative assistants** will prepare papers for distribution at meetings, take notes, compile the outcomes of the discussions and arrange schedules, meetings and venues.

To promote confidence, credibility and transparency in the process of committee member selection it is advisable that those appointed declare their institutional affiliations and relationships with interest groups. These include drug and diagnostic firms, health ministries, medical associations or professional bodies. The following table is an example of criteria that can be used to achieve this.

Table 1: Declaration of potential sources of conflict of interest

Interest	Example
Personal, specific	<i>Personal consultancy held by committee members on the specific drugs or diagnostic tests being discussed/evaluated</i>
Personal, non-specific	<i>Personal shares, consultancy held in drug or diagnostic companies</i>
Non-personal, specific	<i>The department or unit the committee member works in supports the specific drugs or diagnostic tests being discussed/evaluated</i>
Non-personal, non-specific	<i>The department or unit the committee member works in supports drug or diagnostic companies</i>

Adapted from the Scottish Intercollegiate Guidelines Network⁸

5. Guideline scope

Guidelines can be deterministic or branching in structure, or a combination of the two. The choice of which form is most appropriate depends on the target group and the recommendations of the guideline.

Deterministic guidelines comprise a fixed list of elements to be followed regardless of what information is available to the clinician. An example would be guidelines developed to deal with a life-threatening condition. These would be restrictive and less appropriate for use in routine practice as they ignore the deductive and interactive nature of decision-making⁹.

Branching guidelines recommend a course of action at each stage of a situation, depending on the information available to the clinician. These are usually presented as algorithms (flowcharts) or as a narrative. An example of this is WHO's HIV clinical management guidelines for adults and children, which are presented as algorithms with annotations giving options on actions to take at each point of the decision tree. This allows the guidelines to be more detailed, comprehensive and useful. This format is also useful for training/teaching purposes and for reference. A disadvantage, however, is that it makes for bulky guidelines that are not easy to carry around, especially for the busy clinician.

HIV/AIDS recommendations can be incorporated into general medical practice guidelines. The expense of developing these guidelines is lower as they deal with other medical problems besides HIV/AIDS in one volume. Examples are the *Essential drugs list for Zimbabwe*¹⁰ and the *Standard treatment guidelines for Malawi*¹¹ which incorporate HIV/AIDS treatment recommendations. These are often more convenient to use on clinical ward rounds.

6. Identifying and applying scientific evidence

At present, expert committees develop guidelines without formal literature reviews. This approach relies heavily upon the group's knowledge of the literature and its members' experience of routine clinical practice. However, clinicians' knowledge of the literature is often incomplete and their clinical experience may be biased, causing them to overestimate or underestimate the effectiveness of treatments. A selection of articles dealing with the methods of identifying and synthesizing evidence can be found in the systematic review series of the *British medical journal*^{12,13}.

Developing a standard treatment guideline in Zimbabwe and Malawi

In Zimbabwe

The Essential drugs list for Zimbabwe (EDLIZ) has been evolving continuously since the first edition of the guideline document was released in 1981. The original idea was to have a standard list of essential drugs to promote rational drug prescribing, reduce drug costs and ensure an equitable quality of care in all health facilities. Its content has been expanded in the 1994 issue to include HIV-related disease. The section on HIV/AIDS promotes the use of consistent clinical methods and a balance between possible interventions and available resources. Graphics show cost comparisons between different options, promoting cost consciousness when prescribing. The success of the guideline is in part due to the change in focus, from expert clinicians, to users at all levels of the health care system. All had an input in constructing, field-testing and revising the guidelines. This rigorous process of preparation and review has been used over the years and refined to the needs of the country. A National Drug and Therapeutics Advisory Committee is responsible for regular review of the guidelines whenever necessary. Promotion of the guidelines and their production in sufficient quantities have encouraged wider usage. A national survey of prescribing habits in 1993 found that 94% of the drugs prescribed in the public sector were prescribed by generic name and all but 2.5% of prescribed drugs were EDLIZ drugs¹⁴. A training manual for the 1994 edition was published to attract wider usage.

In Malawi

The Malawi guidelines have developed along more or less the same principles as

those applied in Zimbabwe. Additional lessons drawn from the Malawi experience included which technical problems to anticipate in the printing and production process¹⁵.

- Provision of a detailed specification of the guideline ensured that the printer produced the document exactly as and when it was required. The Malawi guidelines were delayed by almost two months before they were available for use in training seminars. Part of the costs for printing were covered by the National AIDS Control Programme thereby reducing the overall cost of printing. The benefit to the AIDS programme was the inclusion of more treatment recommendations for HIV/ AIDS.
- The layout and quality of the final guideline influences its acceptability. The cover design included an illustration in colour of a map of Malawi and some tablets, with special fonts for the wording. Durable paper was used to ensure it lasted longer.
- During the distribution a careful plan was made to have a formal introduction process attended by a respected political leader and the press. The audience was also informed about the aims and benefits of guidelines.
- The section on HIV/AIDS refers the user to the related section in the rest of the guideline. For example, the section dealing with chronic diarrhoea is detailed in the general section on diarrhoea. This promotes better integration of the guideline and reminds users that symptoms of HIV/ AIDS can be treated with commonly available drugs. References are also made to the Malawi HIV management guidelines based on the WHO HIV algorithms. Users requiring greater detail on conditions they are dealing with can refer to this document.

Studies conducted on HIV/AIDS clinical care are available from several sources. Databases such as Medline and Popline are easily accessible and can provide information on specific aspects of HIV/AIDS clinical care and guideline development. This can then be modified as the information required is identified. Some useful search terms are "HIV", "AIDS", "randomized controlled trial", "reviews", "meta-analysis", "clinical care", "opportunistic infections", "decision-making" and "treatment".

Research reports on HIV/AIDS clinical treatment conducted in the country should also be collected and reviewed. Information from physical searches of journals and publications or other bibliographic sources will supplement the databases. The current information on the nationwide morbidity patterns and clinical presentation of HIV infection would also be useful in determining the burden of disease and the quantity of drugs to procure.

Once the relevant articles have been identified, the committee prepares abstracts for review. Methods for assessing the quality of these studies and reports include consideration of the extent to which the studies provide valid information about the condition, and whether the results can be applied to other settings.

There are several ways to apply the evidence. The committee should adopt whichever is the most appropriate for sifting through the large mass of clinical data and arriving at recommendations. They include:

- clinician knowledge,
- unsystematic literature review,
- systematic reviews,
- ungraded systematic reviews,
- formal meta-analysis.

All five approaches have been successfully used to develop guidelines. Combining these different approaches will give the best possible interpretation of the evidence collected, although this may prolong the process and increase the overall cost of developing the guidelines.

The above approaches were specifically applied to HIV/AIDS clinical care to identify evidence for the development of the United States Public Health Service and the Infectious Diseases Society of America (USPHS/IDSA) Guidelines¹⁶. The lack of evidence in a specific area is a common difficulty encountered in attempting to frame evidence-based recommendations. The USPHS committee found more evidence in support of treatment of opportunistic infections than for counselling strategies, as many more studies have been conducted on HIV clinical management.

The United States AHCPR has developed a useful model for grading the level of evidence (Table 2). In most countries the commonest form of evidence is based on results of expert committees (Table 2, level IV) and often does not involve extensive review and analysis of scientific data. Increasingly, recommendations developed in the United States of America are based on scientific data using the levels Ib and IIa shown in Table 2. Where

Methods of synthesizing evidence

Clinician knowledge

This is commonly used when clinical information is lacking and only the clinician's experience of the condition under discussion is available. Various methods used to collect this information are discussed below in section 7. The information may however be incomplete owing to clinicians not having time to research, collate and interpret the data from a variety of sources. A bias may also be introduced by the patient's or physician's enthusiasm for a cure, leading to an overestimation of the effectiveness of the treatment. Guidelines developed in this way also tend to reinforce prevailing biases and practices rather than produce new approaches to care.

Unsystematic literature review

This method has no explicit search strategy, inclusion criteria or a formal method of synthesis. Information of variable quality is collected in a random manner and may be difficult to collate and interpret. This method may also result in a selection bias due to omission of some studies in the search.

Systematic reviews

These avoid the pitfalls encountered in the previous method by applying search criteria. Only studies deemed to be methodically correct are included in the search and utilized in the analysis, thereby increasing the validity and reliability of the outcome.

Ungraded systematic reviews

This method typically reviews only randomized trials and can consequently omit some very important studies with a different design methodology.

Formal meta-analysis

This pools all the information from multiple randomized trials and summarizes all the reviewed evidence by a single statistic. Pooled relative risk of mortality is a commonly used statistic which has the effect of increasing the power of studies that lacked a large enough sample size to produce significant results. Generally these studies are more reliable and yield more valid evidence. However, the selecting of only randomized trials may also result in wrong interpretation and misleading results.

a combination of levels of evidence is used to define recommendations, it is necessary to indicate their strength. An explanatory note of this should also be included in the final document. Another use of level IV evidence (Table 2) is in the formulation of prospective studies or trials that produce more convincing evidence.

Organizations like WHO and UNAIDS can facilitate the development of evidence-based guidelines, by supporting studies on opportunistic infections and the efficacy of preventive interventions. Multicentre studies can be conducted to allow for application of results in a number of countries.

WHO's Reproductive Health Library has a systematic review of clinical trials on priority reproductive health topics. This is aimed at promoting evidence-based guideline development in developing countries. It is accessible electronically and is free of charge to developing countries from WHO¹⁷ or through a paid subscription to Update Software Ltd., Summertown Pavillion, Middleway Oxford OX2 7LG, United Kingdom. A similar initiative for HIV/AIDS guideline development, if promoted by UNAIDS, would support countries that did not have the financial capability to conduct clinical trials.

A conference in 1997 on improving the use of medicines (ICIUM)¹⁸ identified progress in developing countries over the past decade. Over 120 papers on several themes were presented. Conference proceedings are available from the WHO/DAP web site (<http://www.who.int/dap-icium/index.html>).

Table 2: Levels of evidence

Level	Type of evidence (based on AHCPR 1992 ¹⁹)
Ia	<i>Evidence obtained from meta-analysis of randomized control trials</i>
Ib	<i>Evidence obtained from at least one randomized control trial</i>
IIa	<i>Evidence obtained from at least one well designed control study without randomization</i>
IIb	<i>Evidence from at least one other type of well designed quasi-experimental study</i>
III	<i>Evidence obtained from well designed non-experimental descriptive studies, such as comparative, correlation and case-control studies</i>
IV	<i>Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</i>

7. Methods of establishing consensus

*E*stablishing a consensus among experts helps to identify a common level of understanding on issues that may be controversial. This is usually conducted within a structured environment. The main methods used to achieve this are Delphi techniques, peer groups (nominal group techniques) and consensus conferences.

Four secondary methods of developing a consensus distinguished by the nature of the decision-making can be identified: informal consensus, formal consensus, evidence-linked, and explicit guideline development²⁰. These methods are not mutually exclusive; a combination of them can produce the required agreement. This approach has been used in developing guidelines in several countries. As is common in many issues of a controversial nature, consensus may not always be reached. In such a situation the document produced should indicate this.

Consensus methods

Informal consensus development

Commonly used as it is free of the analytical and research methodologies adopted by the others. However, the quality of guidelines developed in this way tends to be poor as meetings may be dominated by an interest group or individual. Many such guidelines lack user confidence owing to uncertainty in their development. Examples of this are the adult and paediatric HIV guidelines developed by The World Health Organization Global Programme on AIDS (GPA)^{21,22}. These guidelines have been adapted for use in Caribbean countries by WHO GPA and the Pan American Health Organization (PAHO)²³.

Formal consensus development

Like the Delphi, peer and nominal group methods, this has a clear, identifiable and orderly methodology but may lack the development of explicit linkages between recommendations and quality of evidence. An example of this is the United States National Institutes of Health Consensus Development Programme which takes place over three days. Guidelines are developed in closed session by a panel following a plenary session and open discussion, and are then presented to an audience and press conference on the third day²⁴.

Evidence-linked guideline development

As the name suggests, the guidelines developed have recommendations that are linked to the scientific evidence, enhancing their validity. In the absence of scientific evidence this method cannot be applied and the resulting recommendations tend to be neutral and of little use to clinicians. A methodology that incorporates formal consensus methods has therefore been used to give the results some strength as in the case of the AHCPR. A formal assessment of scientific evidence is conducted followed by a panel meeting of experts and open forum sessions giving more input for practitioners.

Explicit guideline development

In this method guideline developers evaluate the benefits, harms, risks and costs of potential interventions and derive explicit estimates of the probability of each outcome. Several methods of identifying scientific evidence are applied in combination with consensus methods. This method is too complex, costly and time-consuming to be readily applied by the busy guideline developer²⁰.

A methodology for the adaptation of HIV clinical algorithms to local conditions⁶ using a nominal group process was developed by the World Health Organization Global Programme on AIDS. This is a cheaper method of guideline development but has inherent weaknesses. Examples of these are: domination of a group by forceful personalities, and the lack of an explicit methodological process to reassure the user of its validity. Despite this, most national HIV/AIDS guidelines currently in use in many countries are based on this methodology²⁵.

8. Deriving recommendations

When deriving recommendations a criterion is required which, when consistently applied, links the evidence to the recommendations. Guidelines normally contain many different recommendations based upon varying levels of evidence. For further adaptation of guidelines at lower levels of the health care system, it is important that local protocol developers and their users are aware of the type of evidence used to make the recommendations. It is advisable that explicit links between guideline recommendations and the supporting evidence are described to ensure user confidence in their validity²⁶.

The National Institutes of Health (NIH) of the United States of America have also developed guidelines for planning and managing consensus development conferences²⁷. This approach begins with a broad-based nongovernmental panel, which is selected to meet in public to review data on a specified topic. Presentations are made by invited experts and the panel concentrates on responding to questions about the topic. At the close of the meeting they come up with an agreed statement which is widely publicized.

A method of grading recommendations according to the evidence used has been proposed by the United States AHCPR (Table 3). For example, a recommendation based upon the results of at least one randomized controlled trial would thus be based upon level 1b evidence and would be termed a "Grade A recommendation".

Table 3: Grading recommendations

Grade	Recommendations (based on AHCPR 1994)
A (evidence levels Ia, Ib)	<i>Requires at least one randomized control trial, as part of the body of literature of overall good quality and consistency, addressing the specific recommendations</i>
B (evidence levels IIa, IIb, III)	<i>Requires availability of well conducted clinical studies, but no randomized clinical trials on the topic of recommendation</i>
C (evidence level IV)	<i>Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities; it indicates the absence of directly applicable studies of good quality</i>

In the USPHS/IDSA HIV guidelines, a modified version of the categories suggested by PL Gross *et al.*²⁸ has been used to reflect the quality and strength of each recommendation.

9. Drafting guidelines

*T*he purpose of the HIV/AIDS guidelines is to give clear recommendations to physicians about the treatment and management of patients with HIV/AIDS. As such, it is important to consider the way the actual document will be structured and written. The clinical guideline should include the following:

- an executive summary;
- a summary of the development process;
- a summary of literature review with grading of the evidence;
- specific recommendations graded according to the evidence (this forms the major part of the guideline document i.e. what to do and how to administer treatments) and may appear in the form of statements, algorithms or diagrams.

The desirable attributes to be emphasized in a guideline are: its validity, reliability (reproducibility of recommendations), clinical applicability and flexibility. The patient population and the clinical problems likely to be encountered should be described in clear and explicit terms. Options for the clinician if the recommended course of action is not available should also be included. The recommendations given should be reproducible in any context without producing a significant difference in outcome. A description of the development process should be given including some mention of its multidisciplinary nature for the benefit of the user. Those using it can thus accurately assess the information. Indication of a review date for the guideline document will promote assessment of information that is changing rapidly or is uncertain.

10. Involving external reviewers

*T*he draft document will need to be reviewed by people from outside the guideline development committee. This is a useful strategy to correct wrong information or recommendations and to ensure that the guideline is usable by practitioners in a clinical situation. The results of the stakeholder analysis can be used to appoint these individuals. Specialists in all areas of guideline development, including clinicians who use it, can be invited to examine their particular area of interest. Guideline development specialists would examine the methodology, while content experts would examine the ease of understanding, logic and clarity. The clinicians would assess the clinical applicability and usefulness of the guideline in practice. The reviewers' comments should be consolidated and sensibly classified so that they can be easily incorporated into the final document.

*Adapting the WHO clinical management guidelines for HIV infection:
The Ugandan experience, December 1991–September 1993*

A. The need for adaptation

The impetus for the adaptation came from a variety of factors:

- medical advisers of TASO were asked from time to time by donors to justify the clinical basis for the list of medicines requested,
- there were differences of opinion on the rational prescribing for AIDS patients during AIDS care clinical training seminars,
- two AIDS care physicians from Uganda, having participated in the development of the draft WHO HIV clinical management guidelines, had acquired the relevant skills.

B. The process of adaptation

Changes made to the draft WHO guidelines were accepted by the care sub-committee of the Uganda AIDS Commission as a programme activity. A steering committee was formed comprising: doctors from Lubaga and Nsambya mission hospitals, TASO, the Ministry of Health, the Medical School and the Uganda AIDS Commission.

A second draft was reviewed by the committee, finalized and circulated to participants who were to attend a consensus workshop. The meeting was organized on the basis of the WHO guidelines for adapting the HIV clinical management guidelines to country needs. An essential drugs list for AIDS care was also developed during this meeting.

C. Field-testing the new product

The guideline was tested before its formal launch for national use. Selected health centres were given training, supply of medicines, and copies of the draft guideline, as well as monthly supervisory visits. The clinicians' (doctors, nurses and medical assistants) use of the guidelines was assessed over a period of three months.

D. Use of the guideline

Adherence to the guidelines was checked by supervising clinicians working at the centres, using a review of a random sample of 10% of case records for each clinic day. Overall, 774 patient records were reviewed, 7% being paediatric cases. On reviewing a record, the supervisor decided whether the clinician had followed the guidelines. If not, the case was discussed with the clinician to assess the reasons why. The supervisor's impression was then entered on one form and the medicines used on another. It was found that the guidelines were followed in 60% of the cases.

During the field-test health workers got progressively more used to the guidelines and fewer problems were encountered. One centre noted a reduction in the quantity of drugs used and most patients did not return with the same symptoms. A significant reason given for not following the guidelines was a particular drug recommended not being available at the centre and the clinician having to improvise. However, in the majority of situations, non-compliance was due to poor prescribing habits and mistakes such as giving two different analgesics or antibiotics to a patient.

The participating clinicians shared their experiences and proposed further changes to the guidelines. Notably it emerged that clinicians were not recording the duration of symptoms, not prioritizing complaints and prescribing more than the recommended number of drugs. This indicated a need for additional dissemination and implementation strategies.

E. The final product

Major changes proposed included the writing of new chapters on: childhood

<p>immunizations, follow-up of patients' gynaecological conditions, HIV infection, pain in HIV disease and terminal care. Other recommendations included restricting prescriptions to five days and combinations of drugs to three or fewer at a time.</p>	<p>⋮ A final meeting of national health and AIDS care authorities in June 1993 approved the guidelines for national use. The guidelines were finally launched by the Uganda AIDS Commission in September 1993.</p>
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The Uganda example highlights some strengths and weaknesses of developing and testing HIV/AIDS guidelines²⁹. It also identifies problems that can be surmounted to improve guideline development and consequently also improve their use by clinicians. Three points need highlighting. First, the method used to assess clinicians' application of the guidelines by the supervisors was not rigorous enough. Secondly, the duration of symptoms was not always observed and noted down by the clinicians. Lastly, the restriction of prescribing drugs for five days only, due to drug shortages, defeated the purpose of developing standard guidelines.

11. Disseminating and implementing guidelines

Changing the behaviour of professionals responsible for prescribing is a widely acknowledged goal of guideline development. However, this is not easily achieved in practice, particularly when systematic methods have not been employed and where few sanctions exist against practitioners who do not follow guidelines. Studies have also shown that the success of guidelines is dependent on the choice of dissemination and implementation strategies³⁰. The development of effective guidelines does not end with the production of a guideline document.

The clinical guideline should be widely circulated to all health workers, professional staff and relevant organizations. Copies should be held centrally by the director of public health, in general practices and in provider units, making them readily available to interested parties. If resources are available, the guidelines can be summarized and made available either in a shorter format, or as a tear-out insert.

Guideline use depends on the dissemination and implementation strategies used following publication. Dissemination strategies focus on influencing clinicians' awareness, attitudes, knowledge and understanding of the guidelines, while implementation strategies remind clinicians of the availability of guidelines and the possibility of litigation or professional accountability when they are not followed. What applies varies from one country to another. It is clear that there is room for adoption of new and innovative strategies. These should be developed and continually monitored to document and quantify their relative efficacy. The information thus collected is useful to identify major changes in knowledge for incorporation into revisions of the guidelines.

Dissemination and implementation strategies

Dissemination strategies work best within an educational setting. Dissemination can best be achieved by incorporating guidelines into medical and nursing school curricula and promoting them as part of in-service training. Investment in the development of specific training courses for guideline use would enhance their acceptability.

Implementation strategies work best when applied within the work situation

or when the patient consults with health staff. They may take the form of reminders placed in patients' notes, printed on laboratory forms or prescription pads. Alternative strategies may involve appropriate incentives for clinicians that follow the guidelines laid down. Explicit marketing, peer review and auditing of clinician performance can also help to remind users of the availability of guidelines.

Adherence to guidelines in clinical care forms a strong basis upon which clinical auditing can begin². The results of such auditing can be used to determine research priorities and lead to the development of evidence-based guidelines. The HIV epidemic and economic decline in many countries have reduced the resources available for health care with consequent deterioration of care services. The need to maximize the limited care resources has become a major priority in many countries and increased use of guidelines and clinical auditing would be an effective way of coping with this situation³¹.

The effective use of mass communication in improving use of medicines for HIV/AIDS-related diseases was recently demonstrated in Zimbabwe. Unsubstantiated claims of HIV cures were indirectly promoting the irrational use of anti-tuberculosis drugs. One way of correcting the situation has been the effective use of a mass-media campaign. Several methods have been used, including phone-in radio programmes, TV debates and participant observation. The number of requests for a fake cure has been used as indicator. The campaign resulted in people wanting to know more about HIV/AIDS and the related opportunistic diseases such as tuberculosis (TB). A "TB day" is now on the Zimbabwe calendar. Activities will incorporate rational use of TB drugs using the mass media. Materials to educate the public on medicines have now been developed³².

Dissemination strategies adopted for HIV clinical guidelines in India

Training sessions

HIV clinical management guidelines were developed by the National AIDS Control Organization. After the guidelines were prepared, training of key physicians from states with extensive HIV/AIDS epidemics was conducted³³. The plan was to train sufficient numbers of physicians who would then train others on their return home. The training sessions were conducted by a team of highly skilled physicians and counsellors. Training was conducted using the same guidelines that the physicians were to use in their subsequent clinical work and training sessions.

Field training

To further consolidate their training the physicians were sent to Zimbabwe, Zambia and Uganda for short attachments to key institutions and physicians working in HIV clinical care. The training and field visits had a significant impact in stimulating the physicians to learn more about AIDS and to continue training

others on their return home. They were also able to learn how HIV clinical guidelines were applied in Africa.

Evaluation of the physician training programme

The programme of training physicians for AIDS care had a great impact in getting HIV on the health agenda. A large number of physicians have been trained in a very short period of time. There is more acceptance of AIDS patients among physicians and a greater reporting of AIDS cases countrywide.

Future activities to improve on the dissemination strategy will include:

- revision of the training modules (as they are over four years old);
- updating of the slide sets to reflect Indian patients and common pathologies seen in the country;
- more practical case demonstrations and field visits to institutions or projects that care for HIV/AIDS patients;
- regular refresher courses for all physicians.

12. Workplan for guideline development

Getting a timeframe agreed upon by all the interested parties and the committee members requires considerable planning and timetabling. This timeframe would include details of the activities to be conducted and the individuals and institutions responsible for those activities. Deadlines for the review of evidence and draft documents should also be included. A simple implementation plan can be developed to help guide the process of guideline development and to show in a quick way the activities to be conducted and who is responsible. The plan covering the development of the guidelines could take up to a year to complete as the example below shows. This is based on the WHO guidelines for adapting HIV guidelines to country needs.

Model implementation plan

Month	Activity	Objective/Result	Group responsible*
0	Appoint guideline development committee	Committee in place with clear terms of reference	NACP, NEDP
1–2	Review existing literature	Scientific evidence identified	Guideline committee
3–4	Assess scientific evidence	Recommendations based on evidence synthesized	Guideline committee
5	Hold consensus workshop	Clinical guidelines drafted	MOH, NACP
6	Edit draft guidelines	Guidelines edited	Guideline committee
7–8	Field test	Guidelines finalized	NACP
9–10	Alter standard treatments	Guidelines included in national treatment guidelines	NACP, NEDP
11	Estimate drug supplementation	AIDS drugs quantified and costed	NEDP
12	Publish guidelines	National document	NACP, NEDP
13–14	Disseminate guidelines	Health facilities	NEDP, NACP
15–ongoing	Train in standardized treatment	Health care personnel	NEDP, NACP
16–ongoing	Purchase and supply drugs	Distribution to health centres	NEDP, MOH
17–ongoing	Monitor guideline and drug use	Feedback received on guideline use and drug utilization	NEDP

*NACP: National AIDS Control Programme

*NEDP: National Essential Drugs Programme

*MOH: Ministry of Health

13. Budgeting for guideline development

*T*he budget provision for the development of clinical guidelines should cover all the activities planned. The cost of full production of a guideline can be substantial as it is dependent on the methods applied in its development. Some of the practical details and difficulties in developing guidelines were identified in the development of evidence-based guidelines for the primary care management of asthma in adults and stable angina in the north of England. The article identifies the difficulties in estimating the cost of the exercise²⁶. A theoretical example of a typical budget with specific line items from such a workplan follows.

Model budget line items for guideline development

Activity	Details	Estimated cost* (US\$)
1. Appoint guideline development committee	• administrative costs for committee meetings for the duration of the guideline development	5 000
	• reimbursement of costs to members/fee	5 000
2. Review existing literature	• library and database search	—
	• compilation of findings	1 000
	• committee meetings as in 1. above	—
3. Assess scientific evidence	• methodology for review and analysis by specialists	1 000
	• summarizing of findings	1 000
	• deriving of recommendations	—
	• committee meetings as in 1. above	—
4. Hold consensus workshop	• invitation of presenters and participants	500
	• per diem for participants	5 000
	• conference room	500
	• refreshments	1 000
	• transportation, fuel	2 000
5. Edit draft guidelines	• committee meetings as in 1. above and other administrative costs	1 000
6. Field test	• development of methodology for assessment	1 000
	• conduct of the assessment	5 000
	• analysis and reporting of findings	2 000
7. Alter standard treatments	• committee meetings for inclusion of guidelines into national treatment guidelines	—
	• cost of the inclusion process	5 000
8. Estimate drug supplementation	• required AIDS drugs quantified and costed	Cost to NEDP
9. Publish guidelines	• production costs	10 000
10. Disseminate guidelines	• distribution costs	10 000
11. Train in standardized treatment	• cost of establishing and implementing training programmes at various levels	10 000
12. Purchase and supply drugs	• cost of drugs and distribution to health centres	Cost to NEDP
13. Monitor guideline and drug use	• cost of establishing monitoring system for guideline and drug utilization	Cost to NEDP

**Example only, costs will vary from country to country*

14. Public policy implications of HIV/AIDS treatment guidelines

*T*he ultimate measure of the impact of guidelines is their effect on health outcomes. When improvements occur, the guidelines can be said to be useful and, if not, then there is a need to review them to identify the cause. The development of HIV/AIDS guidelines has policy implications in several areas of society that need to be examined, since the guidelines cannot be based only on the clinical criteria, without considering resource limitations and feasibility issues.

Practice guidelines may not be feasible if there are no resources to pay for the changes required in drug supply and in the capacity of the community to pay. In the field testing of the Uganda guidelines it was found that, if they were to be followed, the recommended drugs and supplies must be available. If these services cannot be paid for by the individual or the government, the whole exercise of guideline development becomes a futile attempt to improve prescribing. A cost analysis of the suggested treatment regimens would have to be considered as part of the guideline development, especially when expensive treatments are being considered for inclusion.

The recommendations in the guideline may also require a change in policies for the prescription of medicines. A review of the legal implications of each recommendation should therefore be made to keep in line with existing law or to recommend appropriate changes.

Other feasibility issues for consideration are: ability to use and remember the guideline; available staff and equipment; the use of the guidelines by the target population; and time pressures.

A p p e n d i x

Guideline appraisal tools

Part one: *Criteria for appraisal of validity of the guidelines development process*

Responsibility and support for guideline development	Yes	No	N/A*
1. Does the guideline report identify the agencies responsible for its development and ratification?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were potential biases or conflicts of interest in funding or support agencies satisfactorily taken into account?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Guideline development committee membership			
3. Is there a list of the individuals who were involved in developing the guidelines and their professional background or affiliation (e.g. medical, guideline development experts, interest groups including patients)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Did the committee have representatives with experience in HIV/AIDS clinical care and guideline development?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Did the committee include patients or their representatives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were potential biases or conflicts of interest among members satisfactorily taken into account?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identification and synthesis of evidence			
7. Is there a description of the method(s) used to collect (i.e. identify and retrieve) the scientific evidence on which recommendations are based?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are the methods for collecting scientific evidence satisfactory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Are the sources of information used in developing recommendations adequately referenced?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Is there a description of the methods used to seek the views of interest groups not on the guideline development committee?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Strength of scientific evidence	Yes	No	N/A*
11. Is there a description of the methods used to assess the strength of scientific evidence?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the guideline make explicit links between recommendations and the strength of the supporting scientific evidence?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Overall, are the methods used to rate or weigh the scientific evidence satisfactory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pre-testing and peer review			
14. Was the guideline subjected to independent peer review by experts outside the committee?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Was the guideline piloted or pre-tested?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. If the guideline was piloted or pre-tested, does it report the methods used and the results adopted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Future review and revision			
17. Does the guideline give explicit details of how it will be routinely reviewed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Does the guideline identify which bodies are responsible for the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Is a review form provided for users to send in their comments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Overall assessment of validity of the guideline development			
20. Is there, in the guideline development report, an accurate summary that reflects the methods, content and recommendations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Overall, do the potential biases or conflicts of the guideline's development appear to be adequately dealt with?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part two: Criteria for appraisal of the content and format of the guideline

Clinical applicability and flexibility	Yes	No	N/A*
1. Was the patient population(s) identified to which the guideline is meant to apply?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there a description of the professional groups to which the guideline is meant to apply?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the guideline indicate at what level of care it is to be used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there a description of the circumstances (clinical or non-clinical) in which exceptions might be made in using it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there a description of ethical issues likely to rise in using the guideline?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is there a description of how the patients' preferences should be taken into account in applying the guidelines?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Do the recommendations collectively cover all clinically relevant circumstances (including diagnostic process, clinical management and referral)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are the guideline recommendations consistent with each other?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clarity			
9. Are the main recommendations presented in a format that is easily understandable (statements, algorithms, or diagrams)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Does the guideline describe in explicit terms the condition to be detected, treated or prevented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the guideline describe in explicit terms the options for management of the condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the guideline identify and advise on unacceptable or ineffective current practice?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Are the recommendations written in unequivocal terms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Can each major recommendation be found easily?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Description of likely costs and benefits	Yes	No	N/A*
15. Is there an adequate description of the health benefits expected from the recommended clinical management?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Is there a description of the potential harm or risk that may occur as a result of specific clinical management?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Is there an adequate description of the costs or expenditure expected in a specific clinical management?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Are issues for consideration by managers in health boards and trusts/practices clearly identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Are the recommendations supported by the estimated benefits, possible harm and costs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical audit			
20. Does the guideline identify key clinical outcomes for the areas of care covered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Are targets or standards identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Does the guideline identify the core clinical data for reporting the relevant clinical care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Do the core clinical data include key indicators of risk and severity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*N/A: Not applicable

A n n o t a t e d b i b l i o g r a p h y



1. *Managing drug supply: the selection, procurement, distribution and use of pharmaceuticals*, 2nd ed. WHO Action Programme on Essential Drugs, Geneva, and Management Sciences for Health (Kumarian Press), West Hartford, Connecticut, 1997, **11**:13–14.

This chapter examines the development of treatment guidelines, essential drugs lists and formulary manuals. Insight into the development process and the important factors that need to be considered in making this process successful are given. Practical examples of the development of guidelines and their success or failure are given from different parts of the world. The guideline development process advocated is useful and effective as shown by the examples of the success of the process, however, there is very little guidance given about evidence-based guideline development.



2. Grimshaw JM, Russell IT. Achieving health gain through clinical practice guidelines I: Developing scientifically valid guidelines. *Quality in health care*, 1994, **2**:243–248.

There is considerable uncertainty about the effectiveness of clinical management guidelines and how to introduce them into clinical practice. Interest in their role in encouraging good practice and generating health gains is discussed. A systematic review of 59 rigorous evaluations of clinical management guidelines identified improvements in the process of care in 55 studies and suggested that guidelines can change clinical practice when they were appropriately developed, disseminated, and implemented.



3. Grimshaw JM, Russell IT. Achieving health gain through clinical practice guidelines II: Developing scientifically valid guidelines. *Quality in health care*, 1994, **3**:45–52.

A systematic review of 59 published rigorous evaluations of clinical management guidelines covering a wide range of clinical activities shows that all but four detected statistically significant improvements in the process of medical care. Two of the 11 that measured the outcome of care reported statistically significant improvements in outcome. It was concluded that guidelines improve clinical practice and achieve health gains when introduced in the context of rigorous evaluations. This evidence-based approach to the development of guidelines is comprehensive and produces valid guidelines but is time consuming and can be costly.



4. Putnam RW, Curry L. Impact of patient care appraisal on physician behaviour in the office setting. *Canadian medical association journal*, 1985, **132**:1025–1029.

The effect of patient care appraisal on physicians' management of patients' problems was assessed. Sixteen family physicians were involved. Eight in the experimental group helped in the selection of two of the five disease conditions to be audited and in the generation of optimum criteria of care for two of the conditions. It was concluded that patient care appraisal is an effective tool in continuing medical education that leads to improvement in the

quality of care, provided the process focuses on essential criteria of care. Patient care appraisal is an implementation strategy that is easily introduced as part of patient care but requires a system of monitoring to be effective.



5. *Guidelines for the clinical management of HIV infection in adults and children.* CAREC, PAHO, WHO. Port of Spain, Trinidad and Tobago, West Indies, 1994.

Guidelines for the clinical management of HIV infection in children and adults in the Caribbean are elaborated in one document. The form of the guideline is algorithms with annotations based on the WHO model of HIV clinical management guidelines. The process of development was through an expert committee and a consensus workshop. A multidisciplinary approach to their development was used. Documentation of the process undertaken in identifying the scientific evidence before and during the workshop is lacking but the overall comprehensiveness of the guideline is evidence of the quality of discussion and the variety of participants in the meeting.



6. *Adapting WHO guidelines for the clinical management of HIV infection to country needs.* Geneva, World Health Organization, 1994 (unpublished document WHO/GPA/TCO/HCS/94.8 available on request from UNAIDS, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland).

These guidelines are to assist countries in adapting the WHO guidelines for the clinical management of HIV infection in adults and children to country needs. The methodology advocated involves organizing national or programme-based workshops using the nominal group technique. A step-by-step outline is given of the key activities to successfully conduct this. A coordinator is to be appointed to organize the meeting and an expert in the nominal group process is to be appointed to lead the discussions in the meeting. The outcome of the meeting is then used to develop country-specific HIV clinical management guidelines. These guidelines, however, do not emphasize the identification and statement of the strength of evidence upon which recommendations are based.



**7. United States Department of Health and Human Services. *Evaluation and management of early HIV infection.* United States Agency for Health Care Policy and Research (AHCPR), 1994, Publication No 94-0572, 13.
(Available at <http://www.cdcnac.org>)**

These are guidelines for the management of early HIV infection developed by the United States Department of Health and Human Services. In the guideline preparation, scientific evidence was identified and recommendations developed with a grading of the strength of evidence. The guideline document has a section explaining the procedures used in developing the document. A review was conducted first by a team of 45 outside peer reviewers including clinicians, AIDS directors, social workers, counsellors, health educators and clinical researchers. A consumer guideline was also developed and reviewed by 25 consumers, 16 providers and 100 HIV-positive individuals and their families before being disseminated. The procedures used were sufficiently comprehensive and rigorous to ensure the validity of the document.



8. *Criteria for appraising clinical guidelines for national use.* Scottish Intercollegiate Guidelines Network. Centre for Medical Education, University of Dundee 1995.

(Available at <http://www.pc.47.cee.hw.ac.uk/sign/home/html>)

Generic criteria for assessing the validity of clinical practice guidelines are provided focusing on the guideline development process, group selection and the key disciplines required for the appraisal. The identification, synthesis of evidence and linking of this to recommendations is discussed. The role of content and format of guidelines in assessing validity is also discussed. A tool for appraising guidelines is presented including the reporting format. This booklet sets out a clear and practical format for conducting a rapid appraisal of guidelines. The appraisal results also make evident which aspects of the guideline need improvement to ensure the development of a valid product.



9. Eisenberg JM. Sociologic influences on decision-making by clinicians. *Annals of internal medicine*, 1997, **90:957–964.**

Recent articles on clinical decision-making have proposed sophisticated quantitative methods for improving the physician's clinical judgement. Actual clinical decisions, however, are influenced by interactions between the clinician, the patient and the social cultural milieu as well as biomedical considerations. This paper explores four types of sociological factors that influence the clinician's judgement, the characteristics of the patient; the characteristics of the clinician; the clinician's interaction with his profession and the health-care system; and the clinician's relationship with the patient. Assessing the impact of non-clinical aspects of decision-making is important to ensure successful application of clinical guidelines.



10. *Essential drugs list for Zimbabwe.* Ministry of Health and Child Welfare, Zimbabwe, Causeway, Harare, Zimbabwe. 1994:95–117.

This guideline document includes an outline of biomedical principles for HIV/AIDS clinical care including prevention, control and counselling. Zimbabwe-specific clinical information and local knowledge are included. A proper consideration of the full spectrum of clinical manifestations is given. The treatment sections discuss the drugs, dosage, side-effects, availability and costs in the form of algorithms, flow charts and narrative. There are good cross-references to other sources elsewhere in the book.



11. *Standard treatment guidelines*, Ministry of Health, Malawi, Capital Printing Press, Lilongwe, Malawi, 1993:40–54.

This guideline is for all health-care workers who prescribe for all patient groups at all hospital levels. HIV counselling and testing are not covered. Clinical problems are considered and a proper consideration of the full spectrum of clinical manifestations and treatment (drugs, dosage, side-effects) is given as narrative. No algorithms or flow charts are included. Good cross-references to other sources are included elsewhere in the book and in the Malawi HIV management guidelines.



12. Mulrow CD. Systematic review: rationale for systematic reviews. *British medical journal*, 1994, **309**:597–599.

Health care providers, researchers and policy makers are inundated with unmanageable amounts of information; they need systematic reviews to integrate existing information effectively and to provide data for rational decision-making. Systematic reviews establish whether scientific findings are consistent and can be generalized across population settings and treatment variations. The methodologies proposed are intensive and appropriate for evidence-based guideline development.



13. Series on the systematic review of clinical literature to ensure its validity and acceptability for use as evidence in the development of clinical guidelines. *British medical journal*, 1994, **309**:597–599, 648–651, 719–721, 789–791, 1007–1010, 1286–1291, 1351–1355.

A comprehensive review of the methodologies and approaches used to identify and synthesize relevant and valid data from scientific studies. Different authors give their views including comments on the controversial issues in using the different approaches. Recommendations and suggestions for future action and research are also given.



14. Fourteen years with an essential drugs list: Zimbabwe experience. *Essential drugs monitor*. Geneva, World Health Organization, 1995, **19**:17–18.

The lessons learnt in developing the *Essential drugs list for Zimbabwe* (EDLIZ) are discussed, from inclusion of material, to reviews by expert groups and health workers at all levels. The importance given to distribution and training is emphasized. Further revision and incorporation of new information over the years has enhanced its use among all health care prescribers in the public sector resulting in 94% of drugs prescribed being generic.



15. Forshaw JC. *Production of national drug and therapeutic information materials: The Malawi approach to developing standard treatment guidelines*. Geneva, World Health Organization, 1994 (unpublished document WHO/DAP/94.14, available on request from UNAIDS, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland).

A practical and detailed account of the stages involved in the development of the first two editions of the Malawi standard treatment guidelines. This includes sections on the rationale for developing the guidelines, the preparations required before starting, issues in the formulation of the content of the guideline, and problems to anticipate in the printing, publication, distribution and use of the guidelines.



16. The United States Public Health Service and the Infectious Diseases Society of America (USPHS/IDSA) *Guidelines for the prevention of opportunistic infection in persons infected with HIV*. 1997, **3**:S299–350.

A detailed guideline for the prevention and treatment of opportunistic infections. Each opportunistic infection is described in detail and the recommended treatments for each is given. Features of interest that are included are:

- details of how the recommendations were developed from evidence and the criteria used to grade them,
- recommendations concerning each opportunistic disease are made by different panels,
- a bibliography of all the sources of evidence used is given at the end of each chapter,
- the qualifications and addresses of all the participating specialists are given,
- the recommendations have a consistent format and presentation.



17. World Health Organization press release No 27, 4 March 1997. Additional material available on WHO's Internet web site (<http://www.who.ch>).

The Reproductive Health Library's (RHL) main aim is to promote evidence-based care in the area of reproductive health by making available to health workers the most reliable and up-to-date medical information. This is being provided electronically on 3.5 inch diskettes so that the large volumes of data can be made available at low cost. RHL operates under the windows TM operating system and it requires no special knowledge of computers. Subscription is free to health workers in developing countries. Others can access the reviews through a paid subscription to The Cochrane Library.

(Available from <http://www.cochrane.dk./revabastr/ccabout.html>)



18. Recommendations of the First International Conference on Improving Use of Medicines (ICIUM), Chiang Mai, Thailand, April 1–4, 1997.

(Available from <http://www.who-int/dap-icium/summary.html>)

The objectives of the Conference were to synthesize the evidence for success of different strategies to improve use of medicines in developing countries, to develop policy guidelines for implementing proven strategies, and to identify important directions for future research. International teams of authors presented six critical reviews of experience from developing countries on improving pharmaceutical practice by health professionals, improving community drug use, and assessing economic and policy interventions on the use of drugs.



19. *Guidelines for clinical practice: from development to use.* National Academy Press, Washington DC, 1992.

This is a comprehensive review of the work of the Agency for Health Care Policy and Research. It outlines the criteria recommended for the development of clinical practice guidelines and the criteria used to appraise clinical practice guidelines. Numerous examples of practice guidelines are given in the appendix. A tool for the purpose of appraisal is provided including various examples of how guidelines are developed. This is a useful guide for persons interested in understanding the rationale for the development of practice guidelines and the use of appraisal tools.



20. Woolf SH. Practice guidelines—a new reality in medicine. II Methods of developing guidelines. *Archives of internal medicine*, 1992, **152**:946–975.

Four methods of guideline development are compared: informal consensus, formal consensus, evidence-based and explicit guideline development. Evidence-based development linking scientific evidence to recommendations is described and its benefits in developing valid guidelines outlined. Steps in the guideline development process are also given in detail.



21. Guidelines for the clinical management of HIV in adults. Geneva, World Health Organization, 1991 (unpublished document WHO/GPA/IDS/HCS/91.6 available on request from UNAIDS, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland).

The guidelines are to assist health care workers in the diagnosis and management of HIV infection in adults at the primary, secondary and tertiary levels of the health care system. They were developed by a group of international clinical experts working in the field of HIV using a nominal group process. The guidelines are presented in the form of algorithms with annotations on the common signs and symptoms of HIV disease. The notable features of the guidelines are:

- the guidelines are well written and have a clear layout,
- all the common symptoms in HIV infection and the required treatment are covered adequately,
- the guidelines have formed the basis for the development of many national guidelines.

However,

- concepts of comprehensive care and referral systems are not included,
- topics related to terminal care, counselling, pain relief and nutrition were not included in this edition,
- the source and grading of the scientific evidence used in the recommendations are not clearly indicated.



22. Guidelines for the clinical management of HIV in children. Geneva, World Health Organization, 1993 (unpublished document WHO/GPA/IDS/HCS/93.3 available on request from UNAIDS, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland).

The guidelines are to assist health care workers in the diagnosis and management of HIV infection in children at the primary, secondary and tertiary levels of the health care system. They were developed by a group of international clinical paediatric experts working in the field of HIV using a nominal group process. The guidelines are presented in the form of algorithms with annotations on the commonly seen signs and symptoms of HIV disease in children. The notable features are similar to those in the guideline for adults except that a section on counselling has been included.



23. Report on the sub-regional workshop on the development of HIV clinical management guidelines for the Caribbean. Geneva, World Health Organization, 1992 (unpublished document GPA/IDS/HCS available on request from UNAIDS, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland).

This report describes the process of adapting the clinical management guidelines for the Caribbean region and the outcome of this process. It also describes the current HIV/AIDS care activities in the region and the reported HIV prevalence and AIDS cases.

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24. Fink A *et al.* Consensus methods: Characteristics and guidelines for use. *American journal of public health*, 1984; 979–983.

Consensus methods are being used increasingly to solve problems in medicine and health. Their main purpose is to define levels of agreement on controversial subjects. Advocates suggest that, when properly employed, consensus strategies can create structured environments in which experts are given the best available information allowing solutions to problems to be more justifiable and credible than otherwise. The paper surveys several major methods, such as the Delphi nominal group and models developed by the National Institutes of Health and the guideline developer, Dr Glasser. It provides guidelines for those who want to use the techniques. Concerns raised are selection of problems, choosing members of consensus panels, specifying acceptable levels of agreement, proper use of empirical data, or obtaining professional/political support and disseminating results.

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25. Chela CM. UNAIDS consultant report of the assessment of national HIV clinical management guidelines. 1996 (unpublished document).

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26. Eccles M *et al.* Developing valid guideline methodologies from the North of England evidence-based guideline development project. *Quality in health care*. 1996, **5**:44–50.

This describes the development of explicit evidence-based guidelines for the primary care management of asthma in adults and for stable angina. The authors present the methodological issues considered during guideline development, both for those involved in the process and for those who wish to know more about the practical details of guideline development .

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27. Fergerson JH. The NIH development programme: The evolution of guidelines. *International journal of technology assessment of health care*. 1996, **12**(3):460–474.

The United States National Institutes of Health (NIH) Consensus Development Programme (CDP) Guidelines have undergone some modification over the programme's 18-year history. They have never been published in archival form. This article reviews the evolution of the NIH CDP Guidelines and then presents the complete 1995 version.

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28. Gross PA *et al.* Purpose of quality standards for infectious diseases. *Clinical infectious diseases* 1994, **18**:421.

Various quality standards are discussed in relation to clinical infectious disease medicine.

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29. Kalibala S. The development of the Uganda National HIV treatment guidelines for adults and children, 1996 (unpublished document).

This describes the process of developing guidelines in Uganda. The planning process and sources of encouragement are detailed. The difficulties encountered and the solutions are also elaborated. The method of pre-testing the guidelines is given.

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30. Sherman CR *et al.* The consensus development programme: Detecting changes in medical practice following a consensus conference on the treatment of prostate cancer. *International journal of technology assessment of health care*. 1992, **8**:33–36.

Prostate cancer treatment was reviewed by the United States National Institute of Health Consensus Development Conference in June 1987. Data from the US National Cancer Institute Surveillance, epidemiology and end results of tumour registers were analysed. This examination showed that the proportion of eligible prostate cancer patients receiving the recommended therapies did not increase at a faster rate than before. This highlights the importance of developing implementation and dissemination strategies for successful guidelines.

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31. Maher D. Clinical audit in a developing country. *Tropical medicine international health*, 1996, **4**:409–413.

The advantages are discussed of clinical audit in Malawi, a country with severe resource constraints. Measuring quality in health care raises the standard of care through decreased uncertainty in health care provision, rationalized choice and appropriate direction of limited resources.

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32. Nyazema NZ. Effective use of mass communication in improving use of medicines for HIV/AIDS-related diseases: Zimbabwe experience. *Proceedings of the First International Conference on Improving Use of Medicines (ICIUM)*, Chiang Mai, Thailand, 1997. (Available from: <http://www.who.int/dap-icium/index.html>)

The use of various forms of mass media to educate the public about use of anti-tuberculosis drugs has resulted in increased awareness of HIV/AIDS issues and development of plans to promote rational use of tuberculosis drugs.

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33. Kalibala S. Indian doctors learn HIV/AIDS care skills. *Global AIDS News*, 1993, **4**:14–15.

Twenty-two practising physicians from major health institutions in India were trained in counselling and clinical management. The report highlights the training methods used and the outcome. This was a successful initiative for the Indian National AIDS Control Organization (NACO). More workshops are planned along similar lines. The Christian Medical Association of India (CMAI) was a key to facilitating the workshop and has been contracted to conduct more workshops.

Notes:

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is the leading advocate for global action on HIV/AIDS. It brings together seven UN agencies in a common effort to fight the epidemic: the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the United Nations International Drug Control Programme (UNDCP), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO) and the World Bank.

UNAIDS both mobilizes the responses to the epidemic of its seven cosponsoring organizations and supplements these efforts with special initiatives. Its purpose is to lead and assist an expansion of the international response to HIV on all fronts: medical, public health, social, economic, cultural, political and human rights. UNAIDS works with a broad range of partners – governmental and NGO, business, scientific and lay – to share knowledge, skills and best practice across boundaries.



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