DRUG INFORMATION

Developing standard treatment guidelines in Malawi

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From experience gained in the course of developing the Malawi Standard Treatment Guidelines (MSTG), some lessons were learned on a practical approach to producing similar documents. This article provides readers with practical guidance on the steps involved in this process, and gives those planning similar work insight into the problems they may face and how these may be overcome. The article is based on a DAP technical report[1] which gives a detailed account of all stages involved in the development of the first two editions of the MSTG. This report should be of particular interest to those directly responsible for the development of such documents.

National drug and therapeutic information documents are vital reference texts for any country or health institution striving to rationalise the treatment of diseases and utilization of the drugs needed. Rational use of drugs is a prerequisite if optimal use is to be made of the scarce resources available, in terms of staff, time, drugs and medical supplies, to many countries, particularly in less developed parts of the world. Standard treatment guidelines, which give recommended regimes for treating commonly occurring conditions, are useful as ready reference texts for consultation during daily clinical work and as resource materials for basic and in-service prescriber training. They are also indispensable for morbidity based estimation of drug requirements.

For these reasons Malawi decided on national standard treatment guidelines in order to:

- improve the overall quality of prescribing;
- reduce the waste of drugs due to inappropriate prescribing habits;
- enable more accurate estimation of drug requirements, thereby facilitating efficient and effective drug procurement.

This article describes the stages involved and problems experienced in the production of the MSTG. Although this is only one kind of drug and therapeutics information publication, and was produced for use in a specific country, many of the steps followed, experiences gained, problems faced and lessons learned in this process are applicable to production of similar documents in any (developing) country.

Important lessons learned during production of the MSTG are given in the form of tips.

Reasons for developing MSTG

Although several excellent therapeutics/prescribing reference materials are available from other countries, e.g. the *British National Formulary* (BNF), and the *Essential Drugs List for Zimbabwe* (EDLIZ), the development of a national guide has several distinct advantages:

- treatments in the guide refer only to drugs on the national essential drugs list (in our case, the Malawi Standard Drug List). This may not include many of the drugs available in developed countries but may include others, such as those for treatment of tropical conditions;
- therapies are tailored to suit local experience, practices and requirements. For example, in Malawi:
  - the recommended route for administration of rabies vaccination is intradermal (i/d) because of the significant savings possible compared with intramuscular administration (i/m). In the USA the i/m route is still recommended;
  - due to the high level of malarial resistance to chloroquine and the high cost of other alternatives, oral sulfadoxine/pyrimethamine combination (SP) is now the recommended first line treatment for uncomplicated malaria and is made freely available from all drug outlets without prescription. In most other countries, this drug is only available on prescription;
- it may be possible to ensure the availability of the locally produced guide to all prescribers at low unit cost, compared with the costs of procuring texts from abroad;
- a high level of consensus can be reached by involving local prescribers, pharmacists and health administrators in the production of the guide. The guide thereby acquires credibility and authority, and prescribers are much more likely to accept it and be committed to using it;
- applicability to the local health situation can be ensured by only including information relevant to national morbidity patterns and treatment practices;
- local production of the guide permits the establishment of systematic review and updating procedures.

Preparation

The development of the first edition of the MSTG began in late 1988 using a spreadsheet with summary treatment schedules provided by WHO.

This first draft, adapted from the spreadsheet, was sent to all public sector medical practitioners in the country. A covering letter requested comments on the treatment regimes, document design, presentation of dosage information and suggestions on other conditions to be included. A rather low (approximately 30%) response rate was obtained.

Tip #1: Stimulate the maximum response to material distributed for comment.

You may consider:

- active written or telephone follow-up of respondents;
- inclusion of a stamped addressed return envelope with mailed material sent for review;
- workshops to discuss the material developed for review;
- requesting key specialists to develop or review specific areas.

During the preparation of subsequent drafts incorporating proposed amendments, the table was first converted into text using a word processor, then transferred to a desktop publishing programme for final layout. For the second edition it was decided to revert to a word processor which provided equally good text enhancement but was much easier to use.

Tip #2: Decide at an early stage which computer software to use and whether to prepare a camera-ready publication yourself.

Use the simplest programme compatible with needs.

If possible it is much better to produce a camera-ready (i.e. in a form ready for printing) final product yourself using word processor, spreadsheet or desk-top publishing software. This allows total control over the design and layout of the publication, and significantly reduces direct publication costs.

Despite the involvement of a large number of (senior) clinicians in the early stages of the review and development process, concern was expressed by senior health policy makers that the concepts and aims of the MSTG were not made clear to all concerned. It required another large review stage by the National Drug Committee (NDC), at considerable delay and expense, to address this problem.

Tip #3: Reach wide consensus with all interested parties.

Involve representatives of a wide range of interests and expertise, including senior policy makers, senior clinicians (especially at university level) and of all levels of the intended target audience, in the development of the publication. Consider briefing them at a national workshop on the aims of the publication and the benefits expected from its use.

Documents of this nature are often perceived to be restrictive, especially by senior prescribers. Address these "feelings" as early as possible. Make it clear from the beginning that treatment guidelines are to be used with clinical judgement, and that while the treatment protocols should represent the best practice for most patients, individual patients may still require different treatment.

In order to get their support, actively involve influential people, even though they may not contribute much to the actual content of the publication. List them as contributors to enhance the credibility of the document.

The process of review by the NDC simply involved starting with the first condition and working through each page in sequence asking for comments from the whole Committee. Although this approach was comprehensive, it was also rather long and inefficient.

Tip #4: Follow a systematic process of preparation and review, making optimal use of the time and expertise available.

An individual or small committee should be appointed to prepare the first draft. Send out sections of this to the appropriate specialists for comments and prepare a revised draft. Distribute this to the members of the national drug committee (or its equivalent). Call a special meeting to review the material and agree on the final version. Co-opt additional members to ensure that all the necessary expertise is available. This minimises the extent of any follow-up after the meeting to seek advice or confirmation on specific issues.

Split the document into several sections for review by smaller working groups with specific expertise. These report their findings and recommendations to a plenary meeting for further discussion and final agreement.

Getting draft new material is much more difficult than obtaining comments on existing material. It was not until some 11 months after the NDC meeting that the first edition of the MSTG was in a form ready for printing. For the second edition this still took six months, despite careful planning.

Tip #5: It may take a long time to reach consensus, draft and re-draft material, edit and prepare the document for printing.

Delays due to unexpected problems can set back the estimated date of completion. The timeframe should be flexible enough to allow for changes to be made.

A few months after distribution of the first edition, the need for an updated version already became apparent. Several changes in the treatment of important diseases, including HIV/AIDS, malaria, STDs, and ARIs, occurred around this time. For each of these conditions, draft new treatment schedules were prepared, either by the editor or the relevant disease control programme. They were reviewed by the appropriate specialists and subsequently submitted for approval at a special meeting of the NDC. For this second edition a sample page was also prepared to illustrate the improved format and layout of the text and the presentation of dose information.

Any future review and the preparation of new editions will be a continuous process. Prescribers will be more actively induced to send in their comments. Regular articles on the MSTG and other reference texts in the quarterly *Malawi Drug Bulletin* (MDB) will aim to stimulate such involvement. As previously, all comments for amendments received will be submitted to meetings of the National Drug Committee for discussion and approval. Once a sufficient proportion of the current MSTG becomes out-dated, and certainly within the three-year interval between editions agreed by the NDC, a new edition will be prepared.

Printing

For both editions three quotations were obtained from preselected printers. For the first edition the printing costs were fully covered by the MEDP. The printing cost of the second edition was partly funded by the National AIDS Control Programme, as it contained a greatly improved and much more extensive section on the treatment of clinical presentations in HIV and AIDS patients.

Tip #6: Seek multisource funding of the document to reduce the cost burden.

Co-funding should be possible, particularly if other departments or programmes are involved in the preparation of the material and if the final product is able to promote and satisfy their interests.

Printing of the first edition proceeded according to schedule. For the second edition, however, it did not take the estimated one month, but nearly three months, to complete printing. This meant that distribution of this edition and the start of planned introductory workshops had to be delayed.

Tip #7: Detail all specifications in a written contract to ensure that the printer produces the document exactly as and when required.

This should include:

- the full name and address of the client;
- the size of the publication and number of copies required;
- the agreed cost;
- the type of print process to be employed, e.g. offset litho;
- the type, colour and weight of paper to be used for the cover and the inside pages;
- the type of binding;
- the required artwork;
- the colour(s) of ink to be used;
- the date of delivery of, and number of copies in, each batch or complete consignment;
- the timing and method of payment.

Tip #8: Collaborate closely with the printer to ensure that the final product is produced according to requirements.

This begins during the selection of the printer and continues up to the packing and delivery of the finished product. The printer should be chosen according to several criteria. These include:

- ***cost.*** The cheapest may be the most attractive but must also be assessed according to other criteria.
- ***quality.*** Ask for examples of similar publications produced by the printer. Check these for clarity of print (Is the inking too heavy or too faint? Is there any smudging? Are small font sizes easy to read?), neatness and strength of the binding, position of pages (is the text in the right horizontal and vertical position?), and the quality of trimming (are the edges of the publication smoothly cut?).
- ***delivery date.*** Can the printer complete the work within the time required? Will the printer deliver the finished product to you or will you have to collect it yourself?
- ***general reliability.*** Consult with others who have used the printer to confirm that the printer is able to adhere to the agreed terms and requirements.
- ***accessibility.*** Choose a printer who is close and whom you can therefore visit easily to check on progress.

Make regular checks on how the work is proceeding, both in terms of quality and timing. Make sure that the printer first produces a ***blank copy*** of the publication, so that you can check on the general quality and appearance. Ask for a ***galley proof*** before you give the final approval. Carefully check that all pages of this are present in the right position (odd pages on right, even on left).

Specify the packaging required and check its quality. Select pack sizes suitable for distribution to save time and effort.

The quality of the second edition was a significant improvement on the first, largely due to the attractive cover and greatly improved layout and presentation of information.

Practical advice from the Malawi Prescriber's Companion

Tip #9: Facilitate use and enhance acceptability of the publication through good layout and attractive presentation.

Consider the following:

- size of the publication. This should be related to its intended use, i.e. as a pocket guide or desk-top reference;
- type and size of the fonts used, both for the body (main) text and for chapter and section headings;
- use of text enhancement such as bullets, boxes, shading, underlines, bold and upper case (capital) letters to highlight certain words, sentences or blocks of text;
- inclusion of a table of contents, index, use of cross-referencing and headers or footers showing section or chapter names, to facilitate the location of information on particular topics;
- use of tables, graphs or drawings/photographs, to summarise information or illustrate certain points in the text;
- careful design of the cover to give a good appearance to the publication. Use of colours, special fonts and a cover illustration should be considered along with the type of cover material.

Consider carrying out pilot (field) testing of alternative layouts and presentations of the publication to determine which is the most acceptable to the intended target group.

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Distribution

It was difficult to estimate the number of health facilities, health workers and the numbers of students expected to enter the various health training institutions during the three-year life-span of each edition. Even though a margin of 5–10% was added to cover contingencies, insufficient copies were printed.

Tip #10: Carefully calculate the size of your target audience.

This process may be complicated and lengthy depending on how difficult it is to obtain reliable and up-to-date information on numbers of personnel and health units.

- Sufficient time should be allowed to estimate requirements;
- The process should be carried out well before the anticipated completion of the document for printing;
- Sufficient copies should be printed to last until any future edition is produced and to cover unexpected demand.

For the first edition, 5,000 copies were distributed to all prescribers and health workers throughout the public and private health sectors. For the second edition, the number of copies was increased first to 9,000, and later to 12,000 to take account of the formal recognition of all nurses as prescribers and the expected increased output of health training institutions.

Methods of distribution

A combination of methods were used including the existing drug distribution system through Central Medical Stores and District Hospital Pharmacies. The system generally worked efficiently, but took longer than expected due to intermittent problems with availability of spare transport capacity to carry the relatively large loads (weight and volume).

Tip #11: Carefully plan distribution to ensure prompt and efficient delivery.

Obtain the names and addresses of all the intended recipients and enter these into a distribution table. Use this as a record of the distribution process. Add the number of copies to be distributed, the date of distribution and a column for confirmation that copies have been received. Identify a contact person at each of the main distribution points who is responsible for the onward distribution process and able to confirm at any time the status of the distribution.

Inform as many as possible of the intended recipients (eg. through small announcements or articles or radio messages) when they should expect to receive copies of the publication. Advise them to contact the distribution centre for further advice if copies have not been received by a certain date.

Actively follow up during distribution to keep the process moving and deal promptly with any distribution problems which may occur.

Introduction to health professionals

For both editions a covering letter was sent to the main distribution centres which were requested to pass on the information to health personnel and institutions within their distribution area. It explained for whom the MSTG was intended and briefly how it should be distributed and used.

A foreword in the booklet itself described the aim and function of the guidelines, summarised the process by which the content had been agreed and asked for prescribers to assist in future modification and improvement of the booklet. Other than this, for the first edition there was no formal introduction of the MSTG to prescribers.

For the second edition some active follow-up of distribution was carried out in the form of telephone contact with major institutions and distribution centres. The prescriber training team checked whether individual prescribers had received copies. A questionnaire was sent out in February 1994 to all District Health Officers and hospital superintendents. Information was sought regarding the status of distribution and whether additional copies were required. Over 60% response to the questionnaire was obtained and most districts and hospitals had received and distributed their allocated copies of the documents.

Articles about the second edition of the MSTG appeared in the *Malawi Drug Bulletin* with requests for prescribers to contact the MEDP if they had not received their copies.

Tip #12: Ensure, through a formal introduction process, that the target audience is fully informed on the aims and benefits of the publication.

Possibly the easiest way to achieve this would be to hold a national workshop to introduce the book to senior prescribers, pharmacy personnel, nurses and health policy-makers. This could then be followed by regional/district workshops or training seminars at which the book would be introduced to all other prescribers. Widespread publicity covering the introduction and use of the book should be secured through the use of newspaper/magazine articles and radio/TV news or feature programmes.

Unlike the first edition, the second was formally introduced to prescribers in the course of numerous prescriber training workshops which commenced immediately following the distribution of the documents (see below).

Feedback

For the first edition there was no systematic follow-up of its distribution and usefulness or its impact on prescribing patterns. However anecdotal information and physical evidence of this was obtained during visits to health units and discussions with prescribers.

Feedback on the second edition was received through the introductory workshops for all prescribers at health centre and hospital out-patient department level (more than 150 workshops covering 4,500 prescribers), correspondence from individual prescribers and through the use of a (new) health centre support visit checklist. The latter has been designed to assist in the improved structuring of such visits by senior clinical staff to peripheral units.

Tip #13: Obtain feedback on the acceptability and usefulness of the publication to assess its impact on drug use/therapeutic practices.

Obtain feedback through the use of questionnaires sent out to a representative sample of individuals in the target audience and through direct interviews with health workers. Ask senior health staff to assist in obtaining comments and feedback in the course of clinical, drug committee or other health staff meetings. Such feedback is invaluable in the preparation of revised editions.

Measure the impact of the introduction of the publication using pre-introduction (base-line) and post-introduction surveys. The questionnaire must be carefully designed to permit the investigation and evaluation of certain aspects of drug use and therapeutic practices which are intended (expected) to be improved or modified through the correct and regular use of the publication.

What is not yet known is whether the systematic introduction of the MSTG through the district prescriber workshops has had any impact on prescribing practices and thus whether there is greater compliance with recommended treatment protocols. Although a national base-line study on prescribing practices was not performed prior to the introduction of the new text, prescribing data for one district is available in the form of out-patient registers (see below). Thus for this district at least, it will be possible to compare prescriber compliance before and after the introduction of the texts.

Use of MSTG

Apart from daily use in clinical practice, the MSTG is also being used for drug utilization and prescription monitoring. Patient and prescribing records from (pilot) out-patient registers and duplicate prescription pads are used to compare actual prescribing practices with MSTG recommended treatment regimes. The MSTG will also function as a basic reference text for rational drug use related modules of revised curricula for all health professionals.

Conclusions

The development of the first two editions of the MSTG involved much time, effort and expense. Through the lessons learned and the structured approach now developed, preparation of subsequent editions should be easier. Involvement of an increasing number of key health professionals in the development of the MSTG and its formal introduction to all prescribers has ensured both its practical clinical relevance and widespread acceptability and use.

It is hoped that the experiences described in this article may shorten the "learning curve" of those embarking on a similar exercise. ❑

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The MSTG is available from the MEDP, P.O. Box 30390, Lilongwe 3, Malawi and the Action Programme on Essential Drugs in both printed and diskette form as are other documents such as the Malawi National Formulary and Malawi Prescriber's Companion, a health centre training and management reference text.

Acknowledgement

Thanks are due to Dr Olivier Brasseur, former Project Advisor of the MEDP, who provided background information on the development of the first edition of the MSTG of the Guidelines.

Reference

1. Production of national drug and therapeutic information materials: the Malawi standard treatment guidelines, C.J. Forshaw, WHO/DAP/94.14, 1994, Action Programme on Essential Drugs, WHO, Geneva.

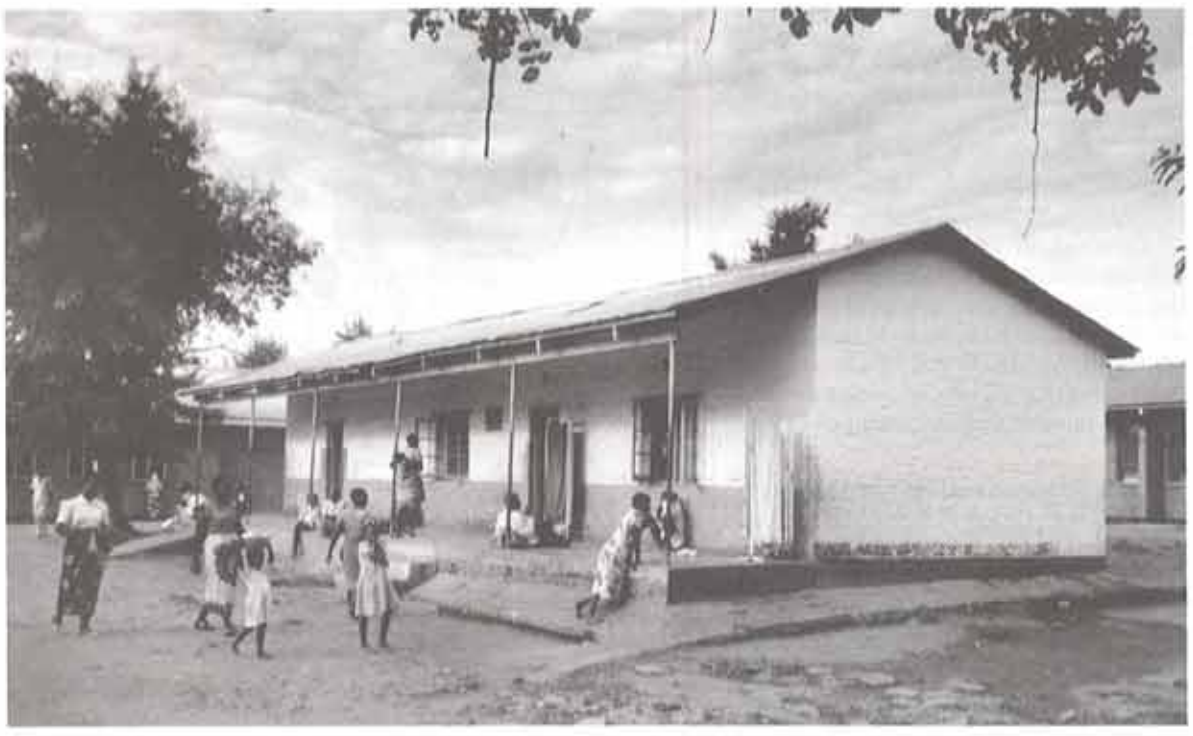

Photo: WHO/D. Brasseur

The Machinga District Hospital in Malawi. The success of the Standard Treatment Guidelines is based on their use in all the country's health facilities