WHO Model Formulary: the future

This document, responding to the Secretariat’s Report on WHO Model Formulary, has been prepared by the BNF editors most closely involved with the preparation of the WHO Model Formulary (WMF).

Background

Editorial work on the third edition of the WMF was completed recently. The aim is that a new edition should follow each revision of the Model List of Essential Medicines.

A model formulary was first proposed in 1995 and the WHO began consultation on the construction of the document soon after. A number of international experts contributed to the discussion on the shape and content of the model formulary. Editorial work on the WMF was started by personnel at the WHO, with external experts being asked to comment on the drafts.

In view of the difficulties encountered in completing the editorial work, the British National Formulary (BNF) offered its services in bringing the project to fruition. The first edition of the WMF was published in 2002.

It is entirely proper for the WHO to review the impact of the first two editions in order to decide on future approach. In reviewing how the WMF should be developed, these questions seem relevant:

- How well have the 2002 and 2004 editions been received?
- Do the scope and remit of the WMF need to be modified?
- What quality criteria should be applied to the content?
- Who should take responsibility for the content and editorial standards?
- How should the WMF be disseminated?
- How can the WHO obtain the best value for money in updating the WMF?

Impact of the WMF

The Secretariat’s Report has some information on recipients’ comment on the value of the WMF. It is disappointing that despite the distribution of several thousand copies of the 2004 edition, only 60 comments are available and these provide limited information on the WMF’s value in the field. The positive response summarised in Table 4 of the Report is consistent with the reaction to the 2002 edition and anecdotal reports received by the BNF office.

The BNF has provided to WHO details of surveys and research used to test the BNF’s influence on clinical practice. It was hoped that the WHO would be able to draw on this experience to measure the influence of the WMF.

Despite the positive comments about the WMF, it is most important to learn more about the value of the WMF to users. It would be inappropriate to make fundamental decisions about the content, presentation and dissemination of the publication without properly exploring the perceived benefits and shortcomings of previous arrangements. User information can provide very useful pointers on how a publication should evolve in order to satisfy the majority of medicines-information needs.
Given that the scope and remit of the WMF is broadly similar to that of the BNF, research (involving a survey of 600 health professionals in December 2006) on usage of the BNF might of interest. This information is summarised in the Figure 1.

![Figure 1: How the BNF is used](image)

**Scope and remit of the WMF**

The scope and remit of the WMF were established by the WHO’s expert group. However, changes have been introduced by the BNF’s editorial team to improve the utility of the information. These include elements such as ‘Patient Advice’ (advice on the safe use of a medicine that is provided by the health professional to the patient) and ‘Reconstitution’ (information on the reconstitution of injections or infusions).

The WMF should ideally fill the gap between standard treatment guidelines and categorical information (e.g. pack sizes and prices). The information should be sufficiently authoritative and comprehensive to allow clinical decisions, even in the absence of other supporting guidance.

Although its primary purpose is to provide guidance on the choice and use of drugs in the Model List of Essential Medicines, BNF editors have introduced mention of a number of additional drugs that are effective and are commonly used but are not on the List; omeprazole and selective serotonin reuptake inhibitors (SSRIs) are examples. Even for drugs on the List, editors have ‘extended’ the indications beyond those shown on the List where there is good evidence of safety and efficacy; for example, the WMF reflects the evidence of efficacy of ACE inhibitors in long-term management after myocardial infarction and of spironolactone in heart failure.

BNF editors have introduced further enhancements, such as the inclusion of the full Model List of Essential Medicines and the changes made to the most recent List.

Since the irrational use of antibacterials is of very considerable concern, BNF editors have constructed guidance on the choice of antibacterials for common infections with the aim of introducing it into the 2006 WMF; the information was derived from *WHO Model Prescribing Information* 2001 as well as reliable, evidence-based resources that the BNF uses to construct its own information on antibacterial choice. Regrettably, the WHO considered there was insufficient time to comment on these guidelines and they have not therefore been introduced.

It is the WHO’s intention that the *Model Formulary* is adapted for local use and the original remit of the WMF was that it should also serve as a model not only for the scope and quality of the content but also for the final product. Many countries are unlikely to be able to sustain a programme of producing local adaptations every 2 years. It is therefore hardly surprising that the WMF has been widely used in its original format, with no attempt made to produce a local adaptation.

BNF editors have assumed that the WMF is likely to be used by health professionals with varying level of skills. For this reason, great care has been taken to avoid unnecessarily
technical language and the presentation has been designed to allow quick and accurate retrieval of information.

**Quality of the WMF**

Authoritative information requires robust and secure editorial processes. Not only does the information need to be reliable and up-to-date, but it needs to be presented in a way that facilitates accurate retrieval and application to clinical situations.

A regularly updated global formulary such as the WMF requires a robust infrastructure to update, produce and disseminate the formulary; a great many users will not have recourse to other independent guidance.

The BNF editorial office has many, many years of experience of producing formularies, experience that is possibly unrivaled throughout the world. BNF publications provide medicines information primarily for the UK, but the publication is used internationally. BNF publications have developed the necessary infrastructure to maintain a demanding formulary programme; the infrastructure comprises a highly skilled and very clinically aware editorial team, fully supported by an IT and knowledge management team. BNF publications are stored and manipulated on a bespoke content management system that enables secure updating of the text. Work on the WMF takes advantage of the full infrastructure developed for the BNF.

For each edition of the WMF, BNF editors process up-to-date information on the entire content of the WMF. It is important that readers of the WMF have confidence that the information presented throughout is clinically reliable; it is not sufficient to simply focus on changes to the List of Essential Medicines. Figure 2 illustrates the main sources of information that each edition of the WMF benefits from.

![Figure 2: Input into the WMF](image)

The combination of clinical knowledge and editorial skills currently applied to the WMF ensures evenness and balance throughout the publication. In order to maintain a cohesive formulary, it is important that information is not added in a piecemeal fashion. Text and monographs in one
section can affect information given elsewhere in the publication; therefore, a very close eye needs to be kept on cross-references and on duplicated and related information to ensure that all updating is synchronised.

The editorial expertise applied to the WMF ensures that the information is reliable and that it is presented in an easily accessible form. Intricate cross-referencing is used throughout the WMF and the end-of-book index has been constructed to provide rapid access to the information of interest. As with the main body of the book, information in the appendices is also updated and cross-referenced as necessary.

The WMF is subjected to rigorous checks at every stage until the files leave the BNF editorial offices. All the processes applied to the WMF parallel those of the BNF and benefit from input from over 20 editors.

The Secretariat correctly points out that the production of the 2006 edition of the WMF was delayed by a number of months. In part this was because editorial work on BNF publications was put under the great strain of starting up a new publication – BNF for Children. This work is now on a much better footing, having recruited and trained more clinical editors. But the WMF has also gained from this: information generated for BNF for Children is being transferred into the WMF.

Editorial responsibility

When the BNF first undertook to carry out the editorial work on the WMF, it was understood that the BNF would take responsibility for the reliability of the editorial content, relieving the WHO of having to continuously monitor the entire content of the publication. Indeed, the vast majority of decisions on important points such as dose, precautions and interactions are made by BNF editors on the basis of all the evidence available to the BNF.

However, it was also recognised from the outset of this project that advice provided by the WMF and that provided in other WHO publications should be coherent. Therefore, editors worked with WHO personnel to ensure that editorial work on the WMF was kept fully informed of drug-related guidance issued by the WHO. To this end, BNF editors ran a seminar in Geneva to appraise the various departments and clusters of the formulary activity.

While editors actively seek out all WHO guidance relating to drug therapy, WHO departments are given an additional opportunity to review the text in case any further information is available. Where inconsistency or gaps in advice are identified, BNF editors raise these for the WHO’s comment. Ultimately, however, it is the editors’ responsibility to ensure that the information published is as robust as it can be; to transfer this responsibility to various WHO departments could be problematic in many ways. This model worked extremely effectively for the first two editions of the WMF.

We accept absolutely that the approach suggested above must be reviewed should serious flaws become apparent in the quality of information in the WMF.

Dissemination of the WMF

The means of disseminating the WMF should be dictated first by the audience to whom the publication is addressed and second by the use to which the publication is to be put.

If the primary audience comprises policymakers who wish to adapt the publication for local use then the product should be delivered as digital files capable of easy manipulation.
However, the little evidence that exists suggests that many users value the publication as a book and there is a suggestion that it is actually used in clinical practice (22 respondents working in primary and secondary healthcare versus 12 in health ministries).

It is unclear if data have been collected on how frequently the WMF has been used to produce local adaptations. Given the very wide distribution (and demand) of the book, it has to be assumed that health professionals value the hardcopy as distributed centrally from Geneva.

In the UK local formularies are often produced simply as lists (possibly enhanced with locally relevant information) which are then heavily cross-referenced to the BNF. This helps to set local policies on drug use while escaping the very onerous burden of having to support the policy with reliable, professionally produced, and up-to-date information.

Distribution to the end-user (either of the centrally produced WMF or of a local adaptation) also needs to be considered. Research on the BNF has consistently (and surprisingly) shown that an overwhelming number of health professionals prefer the publication in a book form, despite almost universal access to the BNF in digital formats. The case for distributing national or international formularies in the book format might be even stronger in developing countries.

**Cost-effective production of the WMF**

The basis for the Secretariat’s costing of work on the WMF takes into account the cost to the WHO but does not look at the other side of the equation: the benefits that the product can deliver. We would urge that the cost-effectiveness of the publication should be worked out using the same method as is used for medicines.

In any case, it is unclear if the production cost of the WMF is compared on a like-for-like basis with other WHO documents. What was the cost, for example, of producing the technical report at the end of the last meeting of the Committee when all the expenses for producing expert assessments and reviews, for meetings, and for staff time have been taken into account?

The BNF has made it abundantly clear that charges for the WMF are calculated purely on a cost-recovery basis. The BNF certainly does not expect payment for the WMF to cover opportunity costs or to provide a contribution in excess of the costs. Indeed, much of the work on the first edition was not charged and was undertaken in editors’ own time. Using the same basis as the Secretariat’s calculations, each page of the BNF costs about 3 times as much as each page of the WMF and even taking into account the BNF’s larger print area, the costs applied to the WMF are significantly lower.

In asking the important question, whether or not the perceived high editorial cost of the WMF is justifiable, consideration should be given to the quality and utility of the final product. If these considerations are not to be sacrificed then attention should focus on other ways of reducing the costs to the WHO.

Any decision about the future production of the WMF must also take into account the need to set up an enduring alternative infrastructure (staff with editorial and clinical expertise, information resources, equipment, and robust content management system are some that come to mind).

One way of controlling costs is to tender for the work but the tender document needs to be drawn up very carefully to ensure that the editorial standards and the accuracy and reliability of the information are not compromised. (It can be said in parentheses that many recent initiatives for providing medicines information have stalled or faltered seriously when it comes to maintaining the information: the work required for maintaining the reliability of all the drug information is invariably underestimated.)
Another option to sustain WMF work is to seek alternative means of funding. It is interesting to note that whereas the sales of the WMF generated a significant income, this was not offset against the costs. (In passing it has to be said that the price purchasers are willing to pay for the product is an indicator for the demand and value placed on the product!)

**Conclusion**

A review of the arrangements for producing the WMF is welcome. The review should properly test the impact the first editions of the publication; the BNF’s experience of conducting market research could be very valuable.

Decisions about the future production of the WMF should be made in the light of evidence of its use in the field. If the evidence shows that the product is wanted and that it makes a positive contribution to healthcare delivery then the WHO needs to continue investing in it. However, questions still need to be asked about how its content or its delivery can be modified to make it even more effective.

We take the view that for a model global product, the publication should lead the way in terms of the reliability of its content as well as its presentation. Thus far the BNF has applied to the WMF its globally recognised expertise in providing drug information for use during patient encounters.

Before moving to any new arrangements the WHO must consider the full implications and costs of alternative arrangements; the new infrastructure needs to be able to deal with a very wide range of information and to maintain the currency of the information on a continuous basis.

We believe that the relationship between the BNF and WHO to date has been immensely beneficial for both parties. The WMF benefits from BNF expertise and knowledge and, in turn, the BNF has access to the WHO’s authoritative knowledge on areas such as malaria and reproductive health. Through the WMF work BNF editors are exposed to clinical practice in developing countries, which is professionally very satisfying. But most importantly, the relationship allows individuals to make a direct contribution of their skills to a global audience.

In very short order *BNF for Children* has become an international resource on the drug management of paediatric conditions. It has developed a very considerable and possibly unique knowledge base to support the annual revision of the new formulary. Naturally, any work undertaken for the WHO benefits from this specialist knowledge.

It goes without saying that because we are fully committed to the WMF, we will continue to offer whatever help and advice is required of us in thinking about the next step in the WMF’s future.

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DKM and RSMR are on the staff of BNF publications. They derive no financial benefit from fees paid by the WHO for production work on the WMF. Their continued employment on the BNF is not dependent on WMF work.