Development of an essential drugs list for Bosnia and Herzegovina

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SUMMARY

Part of the impact of the war in ex-Yugoslavia and especially Bosnia and Herzegovina was to limit the supply of therapeutic drugs they had used before the war. The difficulties encountered made the health care system temporarily dependent on humanitarian assistance agencies which applied the concept of essential drugs; and, after initial difficulties, national health staff adapted to the need to prescribe from a very limited range of drugs. Meanwhile, national drug policy and procurement and prescribing practices were reviewed by working groups and a national List of Essential Drugs was drawn up by national experts with international support. This list has now been passed into legislation.

IMPACT OF THE WAR IN BOSNIA AND HERZEGOVINA

Before 1992 Bosnia and Herzegovina enjoyed a sound and well-distributed health care system and infrastructure. Population coverage was high and most health indicators were comparable to those of many Western European countries. Disease surveillance systems were well developed and immunization programmes offered protection against all vaccine-preventable diseases. Health care services were provided free of charge. The health system was nevertheless highly centralized and becoming increasingly dependent on specialized tertiary care to the neglect of disease prevention and health promotion.

The situation warranted reform from a number of perspectives, and in 1994, despite the exigencies of the war, the Ministry of Health elected to introduce a major process of change.

Before 1994 there had not been a clearly defined national drug policy. Although legislation and regulations existed to ensure the quality of drugs, drug procurement and prescribing practices were often irrational. Continuing medical education was not available and health professionals depended on the pharmaceutical industry for information on new products and developments. Meanwhile chronic inflation made it impossible to implement a drug pricing policy.

There was no central government warehouse and direct procurement by hospitals was not uncommon. Hospital and medical staff were visited regularly by representatives of pharmaceutical companies with information concerning new or alternative products. Immediately before the war there were some 1800 drugs on the market.

One of the primary acts of the conflict was the systematic targeting of key health installations. Drug production plants and warehouses, hospitals and water-treatment plants were all repeatedly shelled. In the case of the pharmaceutical plant in Sarajevo, it was quickly damaged to the point of virtual inactivity. The fact that it was in a highly exposed zone of the city made repair difficult if not impossible.

The blockade of Sarajevo (as well as other key towns) not only cut off water, fuel, gas and electricity, but also prevented the in-shipment of food, drugs and medical goods. War-related injuries, crowding, poor hygiene, poor sanitation, malnutrition, and stress all combined to exacerbate the devastating effects of war on public health. Some health workers were killed, some fled and others were diverted to other needs. Civilians suffered the main burden of the conflict. After two months of the war nearly all stocks of drugs and medical materials were exhausted and health staff were quickly confronted with the dilemma of how to adhere to the basic principles of medical ethics in a growing situation of hunger, poverty, and ever-shrinking medical resources.

HUMANITARIAN AID

Humanitarian assistance to Bosnia and Herzegovina began to arrive first through non-governmental organizations (NGOs) such as Médecins sans Frontières (MSF), and then through UN agencies and an ever-increasing number of

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NGOs. Delivery to Sarajevo and other besieged towns nevertheless remained precarious throughout the war, especially when the airlift had to be interrupted because of sniper fire directed at planes on the airport runway.

Many of the NGOs and UN agencies had experience in humanitarian relief and drug supply programming, but much of it had been gained in developing countries. First approaches taken to the situation in Bosnia and Herzegovina (BiH) struck many local staff as more appropriate to health care systems with few human resources and a poor infrastructure. The supplies that were sent often included only basic drugs. The New Emergency Health Kit, for example, included only 12 non-injectable drugs.

Some of the organizations working in BiH also assumed that local health authorities were unable to assess the situation and consequently failed to involve them in the early planning process. Meanwhile, local health workers often presented expectations that could not be met within the framework of humanitarian assistance. Many hoped they would be able to continue with established treatment procedures, not immediately recognizing that the war was imposing new requirements on medical practice including prescribing practices. International aid workers at times complained at requests for third-generation cephalosporins for use as first-line antibiotics. Before the war it had been usual for health workers to order and prescribe drugs by trade name, and this too complicated the initial relationship with aid agencies.

The ensuing gap between what local staff saw as the contribution by international aid and what agencies felt they were accomplishing persisted, and as late as the autumn of 1994 opinions about need—demand—supply remained divergent (Table 1).

REFORM OF THE SYSTEM

The growing dilemma of how to resolve the real and perceived drug requirements in Bosnia and Herzegovina led the authors, then part of the World Health Organization (WHO) office in Sarajevo, and the University of Sarajevo to initiate a series of working group discussions with Ministry of Health officials, members of the Commission for Planning

Table 1 Perceived impact of international aid; late 1994

	Aid workers (%)	Local staff (%)
Needs met	73	49
Requests met	52	49
Needs not requested	13	51
Inappropriate requests	29	10
Unused supplies	15	35

and Distribution of Drugs, and senior staff of the faculties of pharmacology and pharmacy. Through a process of reviewing and identifying optional short, medium and long-term strategies open to the national authorities, these meetings gradually moved towards the option of a BiH List of Essential Drugs. Documentation on the WHO concept of essential drugs was provided and the discussions were geared to analysing why other countries had seen fit to establish such lists. Emphasis was placed on the fact that the essential drug list is not simply an economic strategy but is a scientifically and epidemiologically based way of health care planning and management.

Over 4 months, with weekly meetings often held under difficult conditions, an agreement was reached on the basic principles of a national essential drug approach. The scope of the meetings was gradually increased to bring in specialist departments from the local teaching hospitals, and the discussions became increasingly oriented to reviewing with a wider selection of people how the resources of the government and international aid organizations could not and should not sustain a return to the pre-war practice of an unlimited pharmaceutical product market. A group of local experts was encouraged to identify a core group of prophylactic and therapeutic substances judged capable of meeting the vast majority of health needs of Bosnia and Herzegovina. It was agreed that such a core group of drugs would merit priority in all purchasing and procurement schemes. To keep the list flexible, it was agreed that exclusion from the list would not be taken to mean rejection of the product in question.

The resulting draft list of essential drugs was produced with the aid of the WHO Model List of Essential Drugs (7th list) and handbooks on essential drugs published during the war in Croatia by MSF and by UNICEF Serbia. Drugs relevant to the treatment of tropical diseases were excluded and a selected number of alternatives were accepted and included to reflect the epidemiology of diseases in BiH, the type of treatment facilities available in the country, the type of training received by national health personnel and the possibilities that might present for post-war national production and procurement.

Other factors influencing the choice of drugs included local prescribing practices. Medical and nursing staff in BiH, for example, believe that the use of opioids as analgesic treatment will quickly produce addiction in the patient. There is thus a strong reluctance to use any opioid derivatives. In an attempt to compensate for this the committee included three non-steroidal anti-inflammatories (ibuprofen, diclofenac sodium, and ketoprofen). Oral morphine forms are not included.

Table 2 shows the relative compatibility between the WHO model list and the BiH list from the example of non-opioid and opioid analgesics.

 $\it Table\ 2$ Analgesics in the World Health Organization (WHO) and BiH lists

Analgesics	wно	ВіН
Non-opioid		
Aspirin	Tablet suppository	Tablet
Diclofenac		Tablet Suppository Injection
Ibuprofen	Tablet	Tablet
Ketoprofen		Tablet Suppository Injection
Paracetamol	Tablet Syrup Suppository	Tablet Syrup
Opioid		
Codeine	Tablet	Syrup (as a cough suppressant)
Morphine	Injection Oral solution Tablet	Injection
Methadone		Tablet Oral solution Injection
Pethidine	Injection Tablet	

The local availability (real and anticipated) of a manufacturing capability for selected drugs was also taken into account. The committee thus included ephedrine nasal drops, hexetidine mouthwash and the poorly absorbed antidiarrhoeal drug nifuroxazide, all of which had been produced locally. Similarly, local production capacity was probably important in determining the inclusion of clozapine, an expensive-to-produce antipsychotic drug.

The draft list was quickly circulated among a wide range of health personnel, but it initially received only a reserved welcome. Many saw it as an attempt to use the restrictions of the war as a way of cutting down their professional freedom of choice and discretionary medical powers. Care was then taken to explain that an essential drugs policy would enhance both the efficacy and the efficiency of the services they were providing. The reception of the list by local pharmaceutical manufacturing representatives was equally poor; even though the production capacity of the national factory in Sarajevo had been more than decimated,

there were expectations that the eventual end of the war would mean a full return to former practices. As a result it became necessary to organize discussions with industry representatives to explain how domestic production of essential drugs would serve to stimulate the industry's revival and would not conflict with the principle of comparative advantage.

Finally, in December 1994, the list was accepted by the State Drug Commission, and published in the *BiH Official Gazette*. The essential drug list was warmly welcomed by international aid workers, who saw in it a more rational basis for all drug procurement through their agencies, and a way of coordinating the work of different organizations in cooperation with national and local health authorities. It was seen as a first step toward introducing a rational prescribing practices scheme, and is now expected to stimulate the use of generic drugs rather than brand name products. Now that the war has ended it should reduce the country's dependence on imported drugs and help cope with the shortage of foreign exchange.

National authorities have since agreed to update the national drug legislation and registration procedures, publish a *BiH National Formulary*, begin a monthly drug bulletin, establish a programme of continuing education of health professionals, and revive local drug production capabilities.

CONCLUSION

The relevance of an essential drug list has been confirmed by experience in Bosnia and Herzegovina. The formulation of that list highlighted the fact that, while the WHO model list is important in helping describe the rationale for such a list and for making the case for eliminating unnecessary elements, many other factors will come into play when a national list is prepared. Local traditions, previous practices, past training and local/national manufacturing capacities must all be considered. Crises in health care services can provide unique opportunities for bringing about change.

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