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HEALTH TECHNOLOGY ASSESSMENT IN CENTRAL-EASTERN AND SOUTH EUROPE COUNTRIES: BOSNIA AND HERZEGOVINA

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Objectives: The aim of this study was to describe the healthcare system and health financing in Bosnia and Herzegovina and recent trends in health technology assessment (HTA) placement in the system.
Methods: A short review of PubMed published literature has been conducted using key words related to reimbursement, HTA, and health policy. We also revised legislation in Bosnia and Herzegovina published in Official Gazettes related to healthcare financing and organization.
Results: A deecentralized system in Bosnia and Herzegovina led to high differences in health policy. HTA has been recognized in legislation in Bosnia and Herzegovina, but it still has not been introduced in practice in full capacity. A small number of publications are found in PubMed treating these issues, but generally the problem of introduction of HTA in Bosnia and Herzegovina is lack of experts, as well as the political environment and education in this field.
Conclusions: HTA in the Federation of Bosnia and Herzegovina and the Republic of Srpska has a short history because of a huge political impact in the decision-making process, decentralized system, and multiple decision makers in these regions. Challenges remain in assessments, in development of more transparent approaches in different areas of the health system in these regions, and in consistent application of appropriate standards especially in education of professionals who will provide establishment of HTA in the health system of The Federation of Bosnia and Herzegovina and the Republic of Srpska.

Keywords: Health technology assessment, Health policy, Health financing

Since 1995, when the Dayton Peace Agreement has been signed, Bosnia and Herzegovina as a former Yugoslavian country became a highly decentralized state. Administrative organization is based on several levels: state/national level, two entities: (i) the Federation of Bosnia and Herzegovina (FBH), consisted of 10 cantons as sub-administrative units and (ii) the Republic of Srpska (RS) and Brcko district (1). This administrative organization is reflected on the healthcare system as well. The Ministry of Civil Affairs on the state level, deals with the health sector in terms of coordination between entities and international relationships (2). It is also responsible for establishing the Agency for Medicines and Medical Devices of Bosnia and Herzegovina (ALIMS). This institution unified the pharmaceutical market in terms of marketing authorization approvals. In addition, the intention of ALIMS is to introduce a medicines price control mechanism through a referral pricing system.

According to the annual report of ALIMS, pharmaceutical expenditure in Bosnia and Herzegovina has constantly been growing in the past 5 years as it is presented in Figure 1, meaning that serious reforms should be introduced to control it. Introduction of an HTA system is one of the measures to contribute rational decisions on financing medicines, as well as on financing other health services. A similar situation is noted when it comes to public healthcare and pharmaceutical expenditures based on Health Insurance Funds (HIFs) of the Federation of Bosnia and Herzegovina and RS official annual reports, presented in Figure 1.

A detailed explanation of the healthcare system and financing will be provided below, focusing on two major entities with graphical representation of key stake holders as shown in Figure 2. We will also explain the legal framework and preconditions for HTA developments and implementation of HTA principles in practice.

METHODS

We have analyzed current legislation covering healthcare financing and drug reimbursement in Bosnia and Herzegovina. All documents have been found at the official Internet sites of Ministries of Health (MoHs), HIFs, and Official Gazettes in Bosnia and Herzegovina. All these documents are published in one of the languages spoken in Bosnia and Herzegovina (Bosnian, Croatian, and Serbian).

We have also conducted a short review of published literature by searching the PubMed database and using key words, such as “health technology assessment in Bosnia and

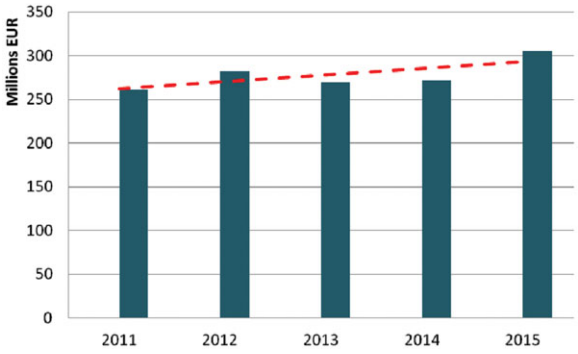

Figure 1. Pharmaceutical expenditure in Bosnia and Herzegovina 2011–2015.

Herzegovina", "health financing in Bosnia and Herzegovina", "reimbursement in Bosnia and Herzegovina", "health policy in Bosnia and Herzegovina". After revising abstracts, we have excluded articles that are not dealing with HTA and policy.

FEDERATION OF BOSNIA AND HERZEGOVINA

The Federation of Bosnia and Herzegovina has eleven MoHs: one at the Federation level and one in each of the ten cantons. The Federation level officials/organizations have virtually no authority over the ten cantonal operations. According to law, responsibility vested at the Federation level for health matters is limited to functions that cannot be executed at the cantonal level, such as border/customs inspections and operations, and legislation development. The authority over health sector operations resides with the cantonal authorities, including service delivery, revenue/insurance collections, expenditures, policy, planning, etc. Each canton operates its own HIF, and its own healthcare facilities, including hospitals. Despite the autonomy of cantonal ministries who are HIF budget holders, they often have limited budgets and capacity (due to small staff consisting of only one or two members). In the health system, they represent small populations, with the limited leverage to exercise real control over their cantonal health systems (3).

Health care is mainly financed by funds coming from a health insurance scheme within the ten cantonal HIFs and one Federal HIF (FMoH). In January 2002, within the FMoH, the Federal Solidarity Fund was established, aiming to reduce the duplication of services at cantonal and Federal level. In such circumstances, the movement of patients from one location to another for receiving needed health services was enabled. In practical terms, it means that lower income cantons can equally benefit from expensive interventions that could not be afforded before establishment of the Solidarity Fund.

This fund mainly covers costs for expensive therapeutics (oncology, biologicals, HIV treatment) and procedures (hemodialysis, transplantation, etc.). The FMoH publishes the list of medicines that can be funded by the Solidarity Fund with submission criteria for the reimbursement dossier including pharmacoeconomic (PE) analysis (mainly budget impact and cost-effectiveness) based on local data (4). The latest version of this list is available at the Federal HIF Web site and it is published in the Official Gazette (5).

After the list is approved, the Fund announces tender to purchase medicines included into the list and the lowest offered price/supplier is accepted. This tender is announced each year, after the list has been revised.

According to the 1997 Law on Health Insurance, insurance is "obligatory in the territory of the Canton" (Article 1) (6). The current average contribution rate of 18 percent of salary consists of 13 percent payment made by the employee and 5 percent payment by the employer. The ten cantonal funds then administer their money and allocate resources to the providers. Cantons may also autonomously introduce the so-called "extended health insurance" to extend coverage for services that are not covered under the entity's compulsory health insurance system. The shortage of cantonal funds, combined with the uneven population distribution among the cantons, means that the amount of pooled risk is often too small (7).

The main problem of this type of the health system financing and coverage is huge differences in access to medicines and services among the cantons, which is the consequence of different abilities to cover and finance such activities, which depend on cantonal budgets.

To establish unified access to medicines, the FMoH has provided the document (Ordinance) consisting of criteria for introduction of medicines to the list. The general concept is that there are two reimbursement lists in the Federation. List A is obligatory for all cantonal HIFs and prices of drugs set on the list during the negotiation process with FMoH must be paid 100 percent by the cantonal HIF. List B consists of medicines that are recommended for reimbursement at the cantonal level with different co-payment levels. This depends on cantonal budgets, and the list can be decreased or expanded with additional drugs depending on cantonal funds. Reimbursed medicines are prescribed at the primary care level by family physicians and prescription is dispensed at pharmacies with or without co-payment by a patient, depending on which list the drug is included (A or B). For fully reimbursed drugs, patients do not pay any costs, because it is paid directly to the dispensing pharmacy by HIF on a monthly basis.

Each year, the Federal list is revised, causing price decreases of drugs included into the list (on average −10 percent to −15 percent), as it is shown in Table 1 (3). Prices are set by a negotiation process between the MoH and the pharmaceutical industry, because pricing rules are still not implemented. Submission and introduction of new drugs require a PE part of the reimbursement dossier, including budget impact analysis and cost-effectiveness analysis (3;8).

As the FMoH does not have jurisdiction to force implementation of the proposed list, each canton decides which drugs on the list will be reimbursed.

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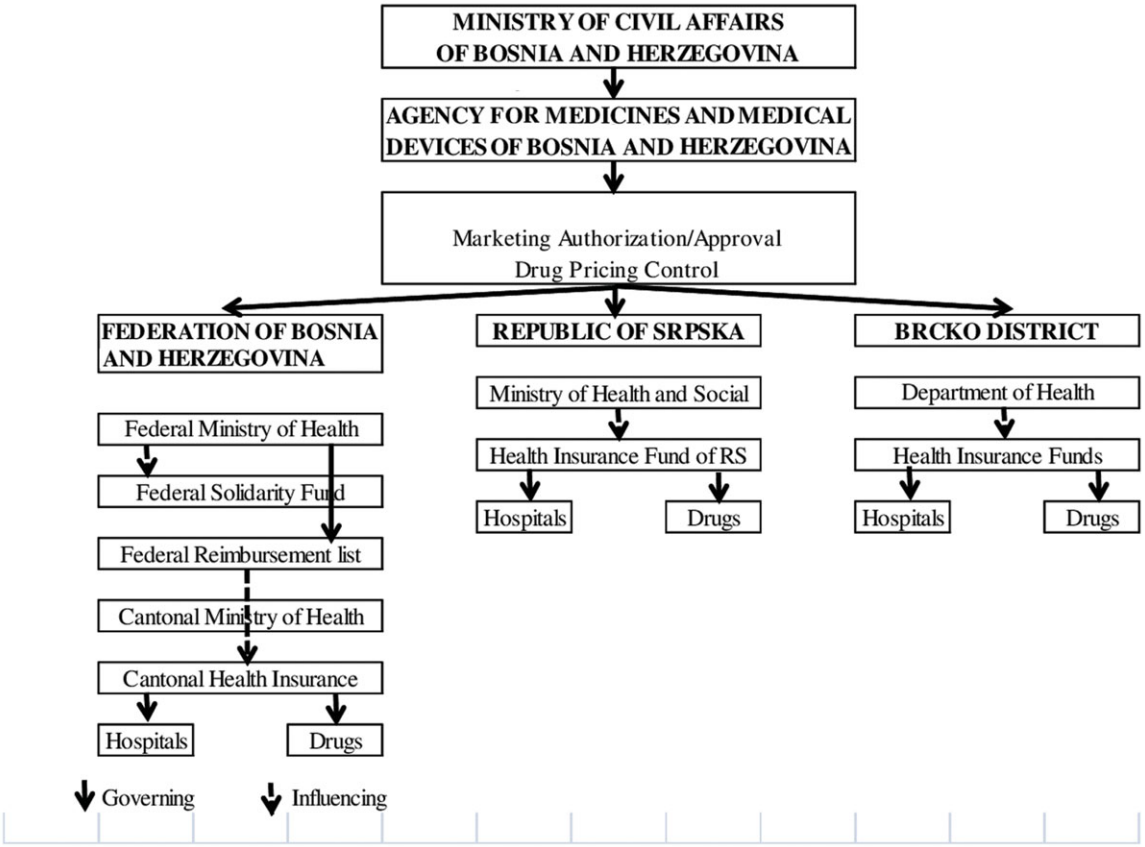

Figure 2. Overview of main stakeholders in healthcare system in Bosnia and Herzegovina.

Table 1. Trends in Price Decreases (Percentage) during Reimbursement List Revisions in Federation of Bosnia and Herzegovina

Reimbursed drug	2013 (EUR)	2015 (EUR)	Difference
Atorvastatin 10 mg	4.24	3.60	−15%
Atorvastatin 40 mg	8.23	6.59	−20%
Rosuvastatin 10 mg	11.33	9.84	−13%
Lisinopril 10 mg	2.81	2.43	−14%

Although PE criteria have been mentioned in the legislation as a part of reimbursement submission dossier, it is still not clear whether these data have an influence on the reimbursement decision or the reimbursement is mainly based on political decisions.

REPUBLIC OF SRPSKA

The RS is another administrative unit in Bosnia and Herzegovina. It has its own health system with complete autonomy. The health system is centralized with one MoH and one HIF. Health insurance is obligatory for all employed citizens, and it is collected from 12.5 percent of employees' salary, and 1 percent of fees that retired people receive (9).

The Health Insurance Fund of RS (HIFRS) is the only payer, buying health services, medicines, and medical material for all insured population. In these circumstances, it is estimated that approximately 80 percent of the population is insured. There are no precise data, because results of the population census are still not available.

The field of medicines is also completely covered by HIF for the insured population. HIF buys medicines for all of its insurers. There are several types of reimbursement lists (10):

1. Lists A and B cover all the medicines prescribed directly by primary care physicians and most medicines recommended by a specialist in the secondary and tertiary health care. Medicines are then bought in pharmacies. For medicines on the A list, HIFRS reimburses 90 percent of the drug price, and for medicines on the B list, that amount is 50 percent. Prices of drugs on the A list and the B list are formed according to the internal reference system by using generic name of the medicine. The fund accepts the lowest proposed price (by the manufacturer or wholesaler) for one generic medicine name (one INN). This means that the Fund reimburses to pharmacies only the accepted lowest price, and the difference between the accepted lowest price and the market price of the

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branded medicine in the pharmacy will be paid by the insured person. Therefore, insurers pay 90 percent and 50 percent of the medicines price in the pharmacies (depending on whether the medicine is on A or B list, respectively) and eventually a difference mentioned above (if there is any) (11). In the RS, physicians are obligated to prescribe medicines by their INN and writing of brand names of medicines on the prescription is forbidden.

2. The list for ambulatory healthcare medicines covers medicines that are used at the emergency departments on the primary healthcare level. They are bought by the public procurement and delivered to the primary healthcare facilities (12).

3. The hospital list includes all medicines that are used in hospitals. Medicines on this list are also bought by the public procurement and then delivered *via* distributors to the secondary and the tertiary level healthcare facilities (13).

4. Drugs which are on the list for cytotoxic and biologic drugs with oncology indications are proposed by specialists in hospitals and mainly used for in-patient conditions. Public procurement is the way of buying medicines for this list too, but it is announced every 2 years (14).

5. The drugs for the disease such as: hepatitis C virus infection, HIV, multiple sclerosis, hemophilia, Chron's disease, and ulcerous colitis and some new biologics for oncology and nononcology indications as well are included into the list of drugs with special conditions of financing. At this moment, this list is approved by the HIF Board. Drugs on this list are mainly used in tertiary level healthcare facilities and mainly cover expensive drugs.

Each of the above-mentioned lists has been approved by Committee appointed by HIF General Director. The Committee usually consists of experienced physicians and representatives from Fund (medical doctors and pharmacists). The committee's proposal for drug reimbursement is then approved by the HIF Board and the MoH. It is fully applicable 8 days after publishing in the Official Gazette.

Despite that the committee mainly makes decisions based on clinical effectiveness, these decisions also depend on costs of new drugs and restricted budget. Every year, the Fund adopts a budget for the next year, and the budget for medicines is strictly determined. All new drugs must be incorporated within those budget parameters. Drug expenditure is strictly supervised by the Fund.

HTA Current Status

Health technology assessment as a term has been recognized in Health Care Law of Federation of Bosnia and Herzegovina published in 2010 (15). According to this law, the FMoH appoints a Committee for HTA with 4-year mandate and the main responsibility of this body is to evaluate different healthcare technologies and give opinion to the Minister about introduction of specific technology in the Health Care System. HTA committee has still not been appointed.

Establishment of this Committee would highly contribute to transparency and a more clear decision-making process. In the past 5 years, all activities related to evidence-based medicine and HTA in general are performed by professional associations, such as chambers and physicians and pharmacists' associations.

There is also a significant contribution by the ISPOR Bosnia and Herzegovina Regional chapter, which has organized a few scientific events and conferences to popularize HTA and engage decision makers on this issue (16).

In the RS, PE evaluation and following managed entry arrangements have been introduced recently, especially for drugs that are highly expensive. At the moment, PE studies are optional in the reimbursement request, although estimation of yearly consumption and some kind of budget impact analysis are demanded.

HTA has still not been implemented in practice, although this concept has been recognized by the law and a legal framework has been established. A few articles have been identified in PubMed dealing with this issue, mainly with theoretical aspects and possible implementation in practice. Because Bosnia and Herzegovina is not a European Union (EU) member state, EU Directive 89/105/EEC or the "transparency directive," is not recognized or included into legislation. It is expected that, during the process of accession to the EU, this issue will be raised in the future.

DISCUSSION

Due to the decentralized system and multiple decision makers in Bosnia and Herzegovina, financing and decision making need transparency as well as rational use of scarce resources in the healthcare sector. Even HTA and criteria for reimbursement of drugs are included into legislation; full implementation is still not provided due to different reasons. First, there is a huge political impact in the decision-making process, and current legislation has not defined decision criteria which should be clear. Additionally, decentralized budgets complicate these processes. A survey conducted in 2011 on HTA understanding and implementation among key stakeholders in Bosnia and Herzegovina showed that main decision criteria for introducing a new technology or drug into reimbursement was the price of the drug (17). This survey showed that reimbursement decisions are mainly based on expert opinion, which is at the lowest level of the evidence-based medicine scale. Analysis of the Federal list of reimbursed drugs published in 2015 showed that there was no sufficient evidence or previously conducted HTA reports to justify the reimbursement decision for the majority of included drugs (18).

Besides political will, the main obstacle for implementation of PE criteria and HTA in the decision-making process is

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a lack of human resources and professionals that are educated in this field (19). Some authors propose that HTA reports in Balkan countries, including Bosnia and Herzegovina, should use HTA just in case of expensive drugs in the initial phase, and later expand it to broader area (20). This concept could be applicable in Bosnia and Herzegovina, because new expensive medicines are mainly delayed in reimbursement due to the budget impact and lack of broader analysis of such drugs by local decision makers.

HTA should use evidence-based data in decision making and also use experiences and previously performed HTA reports from other countries with similar socio-economic characteristics. Some studies showed that there was a significant interest and need to educate future professionals who would be able to participate actively in HTA process establishment in Bosnia and Herzegovina (21;22). Croatia, as a neighboring country of Bosnia and Herzegovina, which shares similar organization of the healthcare system, has made major progress in introducing HTA to the system as a part of Agency for accreditation and quality in health care (23). These experiences should be considered when establishing a similar body in Bosnia and Herzegovina, as it has been proposed by some authors from Bosnia and Herzegovina (24). Introduction and implementation of HTA around the world have a positive impact on rational resource use and appropriate allocation in the health system, as is the case of Austria (25) and some other countries. The positive impact is seen not only in the domain of drugs but other health technologies also (26;27).

CONCLUSIONS

Health technology assessment in Bosnia and Herzegovina is a relatively new concept recognized by the current legislation. It is still not incorporated into the decision-making process due to high decentralization and lack of political will, but also due to lack of experts in this field. Because resources in health care are scarce, we can expect that this concept will be more and more popular. Experiences from developed and neighboring countries should be evaluated, and the first step of introduction of HTA should be applied to expensive medicines. This is necessary to ensure their access to patients and to develop innovative concepts of financing medicines through different entry agreements.

CONFLICTS OF INTEREST

The authors have no conflict of interest to disclose.

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