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EDITORIAL

Resource allocation strategies in Southeastern European health policy

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Abstract The past 23 years of post-socialist restructuring of health system funding and management patterns has brought many changes to small Balkan markets, putting them under increasing pressure to keep pace with advancing globalization. Socioeconomic inequalities in healthcare access are still growing across the region. This uneven development is marked by the substantial difficulties encountered by local governments in delivering medical services to broad sectors of the population. This paper presents the results of a systematic review of the following evidence: published reports on health system reforms in the region commissioned by WHO, IMF, World Bank, OECD, European Commission; all available published evidence on health economics, funding, reimbursement in world/local languages since 1989 indexed at Medline, Excerpta Medica and Google Scholar; in depth analysis of official website data on medical care financing related legislation among key public institutions such as national Ministries of health, Health Insurance Funds, Professional Associations were applicable, in local languages; correspondence with key opinion leaders in the field in their respective communities. Contributors were asked to answer a particular set of questions related to the issue, thus enlightening fresh legislative developments and hidden patterns of policy maker's behavior. Cost awareness is slowly expanding in regional management, academic and industrial establishment. The study provides an exact and comprehensive description of its current extent and legislative framework. Western Balkans policy makers would profit substantially from health-economics-based decision-making to cope with increasing difficulties in funding and delivering medical care in emerging markets with a rapidly growing demand for health services.

Keywords Health economics · Southeastern Europe · Western Balkans · Resource allocation · Cost containment · Policy

Pace of health care reforms among unique Southeastern European markets

Southeastern Europe, recognized more widely as The Balkans peninsula, consists of a mosaic of small post-socialist middle-income markets. They share a common historical legacy in health care planning and policy. Unlike Albania, Yugoslavia resided outside the Iron Curtain and was atypical among surrounding socialist countries for its highly decentralized, municipally funded health care [1]. Governmental policy makers in the Balkans once considered health care as a consuming sector rather than as a sector producing health for the nation; the positive impact of health investment to working productivity was largely ignored [2]. In the turbulent 1990s, health funding almost collapsed. Since then,

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these countries have undergone transition with individual success rates. Contemporary momentum in these markets, with public health gains and losses, and the current difficulties in medical care provision and financing, are the outcomes of that process, and are the consequences of the complex and unique path followed by each particular nation.

In the postwar decades, local governments strove to deliver equity of health care access for broad poor layers of the population. Most governments adopted the Semashko model of funding with its reliance on central planing, which essentially leant heavily towards hospital care rather than primary care [3]. Finally, the aim of delivering basic care was achieved, infant mortality rates decreased substantially and life expectancy at birth increased. Some of the health policy strategies used to achieve these goals were rising standards of health professionals' education and proliferation of large secondary and tertiary care hospitals. Soon, the average numbers of physicians and hospital beds per head of population were among the world's highest. Even today, the frequency and length of hospital admissions in the Balkans are significantly higher than the EU average. In the long run, the core weaknesses of old funding pattern and the unsustainability of centrally managed large health systems became obvious [4].

The 1990s were marked by civil wars and the break up of Yugoslavia (1991–1999), and severe civil unrest in Albania in 1991 and 1997. These events left almost one-third of the health facilities, particularly in Bosnia, Kosovo and Albania, either severely damaged or looted while the "brain drain" of health care professionals from the region to the West was explosive. Financing of all seven health systems was brought to the verge of collapse and recovery was bound to take time. The first decade of the twenty-first century was marked mostly by peace, economic growth and the final shaping of transitional health system reform.

The post-recessional years of 2010–2012 brought severe instability to pharmaceutical markets in Southeastern Europe. Accumulated local government debt towards the pharmaceutical industry led to severe shortages in market supplies. In such circumstances, the issue of cost-effective prescribing of medical procedures became increasingly important. Policy makers soon realized that some of the key contributing factors causing financial losses were prescribing patterns and clinician behavior [5]. Adherence to guidelines had to be improved, and procedures recommended to patients needed to be more evidence-based and less costly. Up-to-date resource allocation strategies and cost containment policies will be analyzed using the example of regional markets. Geographically, these economies belong to the Western Balkans and, although politically still residing outside EU, they are deeply involved in the EU accession process, with four out of seven members having obtained EU Candidate status.

Serbia

As the historical core of Yugoslavia, Serbia followed the democratic changes occurring in the surrounding area at a slower pace. The transitional process here begun to enroll the wider sociopolitical establishment after 2000. All the historical circumstances heavily influenced the evolution of the health care system itself. Later, dynamic economic development enabled Serbia to rank among upper-middle income economies. National health care expenditure consequently increased. As elsewhere in the region, there is only one core Republican Health Insurance Fund in Serbia in charge of all public and most private health care funding. As a non-profit state-owned institution, this core funder does not fulfill the basic criteria of a classical social health insurance model of an independent non-governmental funding source. Such a fund leans towards generating significant financial losses [6] by contracting with medical care providers based on estimated costs rather than number of consumers. The Serbian health system has thus experienced severe difficulties in achieving a sustainable funding model [7].

During the past decade, significant health policy changes have occurred in terms of recognizing the need for evidence-based decision making. The World Bank (WB) has financed efforts to establish a formal Health Technology Assessment (HTA) agency (2005–2008). Heavy budget funding of large research projects on health economics (2006–2014) and publishing of local guidelines on pharmacoeconomic evaluations in Serbia are some of the most visible landmarks of such developments [8]. There are only a few distinctive university degree level courses in the field. In 2002, one-semester evidence-based medicine and pharmacoeconomics courses were introduced at the University of Kragujevac—the historical bedrock of Serbian higher education. Postgraduate specialty training in pharmaceutical policy and pharmacoeconomics is offered by the Faculty of Pharmacy University of Belgrade. Some positive developments in the field are a requirement for pharmacoeconomic data to justify particular drug usage in industrial reimbursement submissions. Committee members concentrate mostly on drug budget impact and do not include the cost-effectiveness analysis (CEA) considerations adopted in most high-income societies. With a decade of HTA development behind us, awareness of the necessity for cost containment policies still needs time to mature and obtain full practical implementation.

Croatia

The most western of the countries considered, Croatia has experienced more rapid economic development, placing it among high-income non-OECD economies. A

substantial effort was made to introduce evidence-based decision-making in health care. To date, it is the only country in the region to have a formal HTA agency. Its health care funding experienced the pattern seen throughout Eastern Europe—a shifting of health expenditure from public to out-of-pocket citizens' contributions in order to cover financial deficits [9]. Since 2002, significant attention has been paid to diversification of the basis of revenue collection, although payroll taxes remain the biggest single contributor. Striving to achieve sustainable financing, local authorities will be forced to decrease another side of the equation—consumer spending and rising demand for health services in an aging population [10]. According to current national legislative on pharmaceutical reimbursement, evidence on cost/effectiveness trials with 7- point submissions are recommended for industrial applications on new drugs. A particularly promising sign was certainly the recent development and adoption of a local HTA guidelines document in February 2011. Systematic health economic evidence estimates as an official approach to resource allocation is slowly but steadily taking roots among Croatian policy makers.

Bosnia and Herzegovina

Consisting of two political entities—The Republic of Srpska and Federation of Bosnia and Herzegovina (BiH)—this country's transitional development in terms of health care funding and policy has been uneven [11]. The BiH Federation's legislative framework has predicted mandatory submission of cost-effectiveness and local budget impact evidence for reimbursement of expensive drugs. Unfortunately, this requirement has not been put into practice so far. Commonly applied criteria are based on lower price industrial offers for the domestic market [12]. The unique pharmaceutical market of the Republic of Srpska has a significantly lower rate of prescribed drugs per patient [13]. Higher overall drug expenditure in the BiH Federation can be explained by higher consumption and higher drug prices in this entity. Good news is that a new legal Act on reimbursement procedure was introduced in the BiH Federation in April 2011, proposing submission of budget impact, CEA and modelling studies as part of the decision-making process. Bosnia and Herzegovina, as a whole, has established neither a formal nor informal HTA assessment body. The introductory process in terms of capacity building is still ongoing, with a long road ahead. It will take time before systematic health economics (HE) evidence assessment becomes an institutional approach to health care considerations within the national health system.

Albania

Albania developed a health care organization pattern according to the eastern Semashko model [14]. In the 1990s its health system deteriorated due to the decreasing role of the state, the rise in poverty and economic inequalities, and the bouts of social unrest in 1991 and 1997 [15]. The system was financed predominantly from the state budget, encompassing taxation that was unreliable due to the huge informal sector and difficulties in collecting taxes. During the past decade, the health system has made bold steps forward with a number of foreign assistance programmes being aimed at health care access and delivery issues. Unlike the rest of the region, the Albanian community is characterized by a young population, healthier life style and lower rates of prosperity diseases. Using as key indicators of total health system efficiency, some authors concluded that Albania was one of transitional "winners", performing better than most ex-Semashko systems [16]. Since 2008, the government has initiated an ambitious Albanian health system modernization program, through which a number of medical professionals received HTA training, which is likely to bear fruit in the future. The issue of sustainable health care funding and providing access to the broad poor layers of the population remains high on the political agenda. The overall level of health economics development still lags far behind that of Serbia and Croatia and substantial investment in capacity building is needed.

Former Yugoslav Republic of Macedonia

After peaceful secession from Yugoslavia and independence in 1991, for a number of years Macedonia followed a highly centralized socialist model of health care provision and funding [17]. There were numerous efforts aimed at raising standards and quality of care [18]. Even today, there are marked differences in the accessibility of the primary care facilities network throughout the country, with a certain neglect of rural and mountainous areas [19]. The first wave of early transitional reforms during the 1990s succeeded in improving legal framework but failed to control over-utilization of hospital care and expand reimbursement of private sector services to the citizens. HTA and evidence-based thinking among local policy makers will need time to take place. On the other hand, some promising developments have come from the local International Society for Pharmacoeconomics and Outcomes Research (ISPOR) chapter in 2011–2012. Among activities currently conducted are development of Macedonian guidelines for pharmacoeconomic analysis, HTA education for regulatory bodies employees and a proposed public debate on the role

of pharmacoeconomics in the national health care system. All of these small steps forward in the southernmost country of the region, supported by broad positive trends in the surrounding countries, are expected to bring likely benefit in future.

Kosovo (*under UN resolution 1244)

In socialist Yugoslavia, Kosovo was one of the poorest regions and republics invested heavily in its development. The dynamic socioeconomic changes after the civil war and secession in 1999 brought substantial foreign investment to Kosovo's health sector. One of the unfavorable consequences of Serb retrieval was the resulting shortage of experienced managerial staff [20]. European Union administrative assistance was essential in terms of developing a legislative and financial framework for medical care provision in Kosovo. WB field assessments claim Kosovo to have the youngest population in Europe but key health outcomes, such as life expectancy and infant mortality, rank significantly worse than the rest of the Balkans. Being the only regional economy without a health insurance fund, public healthcare is still financed from the government budget [21]. Both gross domestic product and per capita expenditure on health are significantly lower than in neighboring economies. The local list of fully reimbursed essential drugs is quite limited compared to that of neighboring states, leading to narrow treatment choices. Under these circumstances, citizens' out-of-pocket costs for health care are estimated at as much as 40 % of total expenses. Much of these come in the form of informal payments, which is a widely recognized pattern in many transitional economies. Additional obstacles to effective health care access and satisfactory equity is uneven income distribution and poor infrastructure in rural mountainous regions. Kosovo's officially planned mid-term health reform adopted principles of cost-effectiveness [20], but real application of a "value for money" way of thinking among policy makers still needs to take place.

Sustainable health system financing will be a long-term challenge. In this sense, serious human resource investment in the fields of health policy, economics and technology assessment is needed. When choosing between competing medical interventions, economic considerations bear particular weight in a low income economy. The government assigns particular amounts to health facilities in a per capita-based equation, neglecting the performance and value of the services provided. An overall trend is heavy underutilization in terms of clinical visits and admissions compared to neighboring countries, and an unsuitable structure of medical spending [22]. A wiser, long-term health policy, grounded in planning and careful allocation of scarce resources, would certainly contribute to maximizing health gains, in particular for vulnerable populations and the poor.

Montenegro

Being the smallest of the "ex-Yu" republics, Montenegro had the advantage of being able to adapt more rapidly to the changing socioeconomic landscape. Its current per capita spending for health care is among the highest in the region. However, efficiency in terms of quality assurance and accessibility of services is not following at the same pace [23]. Revenue collection as source of funding remains inefficient because of high unemployment rates in rural areas. Evidence-based thinking in clinical medicine and cost awareness are not high on the agenda among local policy makers. One of the likely reasons is the very small market size, which itself decreases the scope of difficulties present in the surrounding countries. Its mountainous geography and uneven population distribution allows for only one tertiary and ten secondary hospitals to cover most population needs. In the Ministry of Health National Strategy, adopted from 2011, HTA was proposed as one of the priorities for further development [24]. Regardless of these promising signs, it is unlikely that a "value for money" concept in delivering health care will become exploited routinely among local health professionals for many years (Table 1).

Recommendations for future implementation of health economic assessments in reimbursement of medical services

Observing the pace of the huge changes in Southeastern Europe in the past 23 years, we see an upward trend of health system reforms aimed at improving quality and accessibility of medical care [24]. Recently, a number of countries bordering the EU region have experienced severe difficulties in health care financing worsened by recession. WB economies exhibit some distinctive common weaknesses of financial sustainability in their health systems [26]. Firstly, the main source of revenue collection is payroll taxes, levied mostly equally on employees and employers. Coverage of populations remains uneven [27]. This model limits the income base to formally employed citizens, and there is a severe problem in how to encompass informal employment wages and the huge pool of unemployed, which in the Balkans ranges from 17 % to 35 % of the overall labor force. Another issue is that medical care is generally funded through different adaptations of Otto von Bismarck's universal health insurance model by a single core health insurance fund that is a not-for-profit governmental institution. The vulnerability of such

Table 1 Western Balkans countries, World Bank (WB) and World Health Organization (WHO) estimates on key parameters for 2010; additional sources: official national statistics and legislative framework in local languages

Country	SRB	CRO	BIH	ALB	MKD	KOS[a]	MNE
GDP per capita PPP 2010 (USD)	11,349	19,330	8,690	8,592	11,311	2,535/2011	12,861
Health care expenditure (% from GDP) 2010	10.4	7.8	11.1	6.5	7.1	2.3/2009	9.1
Health care expenditure (PPP) per capita 2010 (USD)	546	1,067	499	241	317	108/2009	578
Formal/informal HTA agency role	Informal Quality assurance unit, Ministry of Health Commission on pharmacoeconomics—the republic fund of health insurance Serbia	Formal Agency for quality and accreditation in health care, Department for Development, Research and Health Technology assessment Croatian Branch of the Italian Cochrane Center	Absence of HTA bodies in both entities—capacity building taking place in Federation BiH	Absence of HTA body—capacity building taking place	Absence of HTA body	Absence of HTA body	Absence of HTA body—HTA proposed in national health policy strategy
National Health Economics Associations	ISPOR, Pharmaco economics section of Serbian pharmaceutical society	ISPOR, Croatian Society for Pharmaco Economics and Health Economics (HDFEZ)	ISPOR	None	ISPOR	None	None
Cost-effectiveness evidence requirement in industrial submissions for marketing approval of new drugs/ medical technologies	Recommended	Recommended	Not requested	Not requested	Recommended	Not requested	Not requested
Health system funding pattern	Bismark	Bismark	Bismark	Bismark	Bismark	Bismark	Bismark
Budget impact analysis evidence for reimbursement decisions	Requested	Requested	Requested	Recommended	Recommended	Not requested	Requested
Cost effectiveness evidence for reimbursement deaccessions	Required as mandatory	Recommended	Not required	Not required	Recommended	Not required	Not required
Explicitly defined willingness to pay threshold or range	None	None	None	None	None	None	None
Presence of national HTA and/or pharmacoeconomics guidelines	Guidelines for pharmacoeconomic evaluation for Serbia	Croatian guideline for health technology assessment process and reporting	None	None	Pharmacoeconomics guidelines—currently under development	None	None

Countries are placed in decreasing order from left to right, according to their population size. Main source of official data: The World Bank working for a World Free of Poverty 2010 (http://data.worldbank.org/indicator), last accessed 3 July 2012. Legislative framework data source: official web sites of national Ministries of Health and Health Insurance Funds in local languages

SRB Serbia, *CRO* Croatia, *BIH* Bosnia and Herzegovina, *ALB* Albania, *KOS* Kosovo, *MNE* Montenegro, *USD* United States dollars, *HTA* health technology assessment, *GDP* gross domestic product, *PPP* purchasing power parity, *ISPOR* International Society for Pharmacoeconomics and Outcomes Research

[a] Kosovo is an exception in terms of partial availability of official data due to its disputed diplomatic status—data provided originate from WB assessments in the field for 2009–2011

funds to generating significant financial losses has been exposed many times in past [25]. Another particular weakness is the recognized Eastern European pattern of filling gaps by both formal and informal out-of-pocket expenses [28]. Widespread corruption throughout the Balkans, in particular for hospital-based services, is still a large part of the landscape [29]. For ordinary citizens this simply means lower affordability and therefore decreasing demand for necessary health services [30]. To date, there have been many attempts to widen the basis of revenue collection but no efficient mechanism to resolve the issue has been proposed [31]. In a number of countries, the consequences include worsening of general population health in terms of neonatal mortality and life expectancy at birth [2]. Authorities have room to intervene and stimulate contracting between private health care facilities and these large national funds. If private health insurance companies showed an interest to enter competition at the level of the regional market place, it would help funding relief in future. The influence of traditional authorities and inefficiencies of the rigid administrative hierarchy still remain as obstacles to a more adaptive health policy.

The remaining issue is the application of an analytical framework to provide an evidence base for resource allocation in health care. Knowledge of HTA and HE methodological skills and interpretation is scarce throughout the region [32]. The very concept of incremental cost-effectiveness ratio (CER) and quality-adjusted life year (QALY) is poorly understood and mostly unexploited in public debates on the issue. Willingness-to-pay thresholds remain undefined in all countries of the region. There is some practice of interpretation of original Cochrane or NICE reports on particular technologies. However, it is widely recognized that inter-country transferability of such analysis and their conclusions is unreliable [33]. It is extremely difficult to compare microeconomic and clinical settings; these have developed under fundamentally different circumstances and labor costs are still substantially lower in the east of Europe. Local assessments or systematic adoption of strategies from more advanced but similar Eastern EU economies seem to be the most reasonable choice according to the Hungarian model [34]. To date, the key positive development in the region was the introduction of obligatory (Serbia and Croatia) local budget impact and CEA (mandatory in Serbia, recommended in Croatia) for industry after new drug/technology marketing approval and before pricing negotiations and seeking reimbursement. National capacities for reimbursement approvals of innovative drugs with extreme budget impact are in fact very low throughout the region. With the current lack of understanding of cost-utility analysis (CUA) and CEA results and consequences among board members, key features of pharmacoeconomics application rely on simplified cost-minimization judgements. An honest observer would note local economies' inability to keep pace with growing overall health care costs and, in particular, drug expenditure rising twice as fast as national GDP [35].

Local policy makers must recognize the need to raise health economic awareness and to implement capacity building measures. Relying on HTAs in pricing and reimbursement processes, would afford greater value for money for those paying for services [36]. Such a strategy would tackle not only costs but, even more importantly, would affect the other side of the equation and lead to system efficiency in delivering high-quality, evidence-based services. Wider dissemination of HE and HTA skills and methodology would contribute to more efficient prioritization and reimbursement strategies. Development of national guidelines on pharmacoeconomic and HTA assessments in local settings was a bold step forward. An even more important step would be top-down policy pressures aimed at improving adherence to good clinical practice guidelines in order to control prescription patterns and impact choices of cost-effective technologies among clinicians. By this means, more satisfactory clinical outcomes in terms of life years gained, DALYs or QALYs could be achieved by wiser prioritization of resource allocation. Substantial investment in health economics development and practical application would lead to a decrease in irrational spending and significant cost containment. These savings would allow these transitional health systems better affordability and higher equity of health care access for their vulnerable and mostly aging populations. If the proposed changes take place, it could lead to relief of the current difficulties in the provision and funding of medical care in the Balkan countries.

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