HEALTH CARE FINANCING AND AFFORDABILITY IN THE EMERGING GLOBAL MARKETS

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HEALTH CARE FINANCING AND AFFORDABILITY IN THE EMERGING GLOBAL MARKETS

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During the recent few decades, global economic growth has been driven largely by developing world economies. The ones with the most intensive pace of development were marked as "emerging" markets led by so called BRICS and N-11 countries. Such changes inevitably reflected the global health arena. A number of issues previously limited to established high-income economies became popularly discussed topics on the agendas of public health policy makers across these regions. Major challenges remain population aging, rising incidence of prosperity diseases, lack of universal insurance coverage and particularly provision of just and equitable access to medical care among the poor both in urban and rural communities. A significant part of the difficulties faced by these societies are attributed to inefficient resource allocation strategies in health care and unsatisfactory funding strategies.

This Research Topic was created in order to address the core challenges of medical care financing and its affordability across the emerging global markets. Contributions of both undergoing or finished original research as well as review style papers are welcomed. All submitted manuscripts should deal with issues relevant to health care economics and policy in recognized global emerging markets. Outside the aforementioned key markets (BRICS- Brazil, Russia, India, China, South Africa; Next 11- Bangladesh, Egypt, Indonesia, Iran, South Korea, Mexico, Nigeria, Pakistan, the Philippines, Turkey and Vietnam) submissions referring to any of the dynamically developing Asian, Latin America, Eastern Europe or MENA countries are encouraged.

In addition to a variety of health-economic evaluations and health policy analysis, methodological and resource use studies are within the Topic scope. Health policy considerations should be primarily focused on financing mechanisms and affordability of health care although other surrounding issues such as health insurance, reimbursement and cost-containment strategies will be considered.

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Editorial: Health Care Financing and Affordability in the Emerging Global Markets

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The Editorial on the Research Topic

Health Care Financing and Affordability in the Emerging Global Markets

During recent decades, global economic growth has been mostly driven by developing world economies. The ones with the most intensive pace of development were marked by Goldman Sachs as top-tier "emerging" markets led by BRICS (1) (Brazil, Russia, India, China, and South Africa) and N-11 (2) (Bangladesh, Egypt, Indonesia, Iran, South Korea, Mexico, Nigeria, Pakistan, the Philippines, Turkey, and Vietnam) countries. Compared to the past few centuries, the substantial novelty of world economic history is the bold surge in global South–South Cooperation and trade (3). Such changes inevitably reflect the global health arena (4). A number of issues previously limited to the established high-income economies became hot topics on the agendas of public health policy makers across these regions (Laaser). Major challenges continue to be population aging (5), rising incidence of prosperity diseases, lack of universal insurance coverage (6), and provision of just and equitable access to medical care among the poor, both in urban and rural communities (7). A large part of the difficulties faced by these societies can be attributed to inefficient resource allocation strategies in health care and unsatisfactory funding strategies (8).

The Frontiers research topic entitled "Health Care Financing and Affordability in the Emerging Global Markets" was created in order to tackle these core challenges across emerging global markets (Jakovljevic et al.). Outside of the BRICS markets, there were successful submissions referring to other dynamically developing Eastern European countries (Poland, Hungary, Czech Republic, and Ukraine), Balkan countries (Serbia, Albania, Republic of Srpska, Poland, and Bulgaria), Papua New Guinea representing Southeast Asia as well as ones in established OECD market economies, such as the USA, Japan, and Greece. Besides the two original research articles, the majority of published opinion style articles deal with crucial health economics and health policy challenges within the topic scope. Health policy considerations primarily focused on financing mechanisms and affordability of health care with a strong emphasis on cost-sharing mechanisms (Tambor et al.) and out-of-pocket payments (Atanasova et al.).

One of the two papers on BRICS reflected on the huge burden of non-communicable diseases in these countries and effectively associated with joint burden of communicable, infectious diseases in younger age groups (Jakovljevic and Milovanovic). Another one referred to the surprisingly sudden enlargement of BRICS' share of global health spending (Jakovljevic). With regard to individual nations, health insurance coverage was challenged in a paper depicting contemporary momentum in rural India (Barik and Thorat).

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A variety of articles dealt with issues on the health-care systems of the Balkans. Serbia, Greece, Republic of Srpska, Albania, and Bulgaria were serving as regional examples of the effects of transitional health reforms to neonatal care (Velickovic et al.), affordability of medicines (Petrusic and Jakovljevic), pharmaceutical marketing (Dickov), population aging (Stojkovic and Milovanovic), dentistry care (Kanjevac), burden of major prosperity illnesses such as COPD (Cupurdija), risk-sharing agreements for innovative therapies (Iskrov and Stefanov), effects of global recession to the pharmaceutical expenditure reduction (Souliotis et al.), social protection of vulnerable population groups (Arsenijevic et al.), and successes of WHO introduction of national health accounts system (Gajic-Stevanovic).

There were several articles describing developments on patient cost sharing and out-of-pocket payments in Central and Eastern European region (Tomini et al.). Although starting from different observation angles, authors ultimately arrive to the similar conclusion that growing income inequality and informal payments (Stepurko et al.) pose long-term challenges to the effective provision of medical services.

Evolution of Hungarian national efforts to eradicate informal payments was brought to us by Baji et al. Health expenditure landscape evolved alongside transitional reforms accordingly (Rancic et al). Distinguished contribution by Yamada et al. was dealing with effects of income and education on health-care disparity based on historical experience outsourcing from the US federal health system (Yamada et al.). Pioneering work in Papua New Guinea as the only Asian health system depicted in this topic was provided courtesy of Tsukahara et al. It gives a valuable insight into internal difficulties of this Southeast Asian country striving to achieve universal health coverage. The case of community health workers attempting to provide relief in childhood febrile episodes was used as an example of local difficulties (Tsukahara et al.).

In conclusion, editors would like to point out satisfactory response by broad professional audience worldwide. Topic impact and readership appears to be truly global, encompassing 15,150+ readers affiliated to the academia, industry, and regulatory authorities in all major world regions. Many of the articles have already attracted citations even before the topic closure. One of the major weaknesses in our attempt to foster strong professional discussion were relatively few contributions by the experts based in leading African and Latin American nations. Regardless of its undisputed success, our topic remains heavily dominated by Eastern European authors dealing with issues relevant primarily to this world region. Although we believe that we succeeded to spark a debate, further similar attempts in health economics of the emerging markets should focus on other key global regions. The Asian continent and People's Republic of China, in particular, should be the main target of health financing and affordability research in years to come.

AUTHOR CONTRIBUTIONS

This editorial is committed to the final closure of research topic entitled Health Care Financing and Affordability in the Emerging Global Markets. MJ, WG, and KS have jointly and equally contributed to drafting manuscript and describing contributions out of which this research topic consisted. All authors deserve fully their authorship based on the intellectual content they provided and joint workflow during the topic development.

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BRIC's growing share of global health spending and their diverging pathways

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Keywords: BRICS, health expenditures, long term, global health, trends, health care reform

BRIC's Growing Share in Global Wealth

Post-cold war developments and accelerated pace of globalization among many changes led to the creation of so called emerging markets. These classical national economies represent few among large number of developing world countries, which are distinguished by their exceptionally strong promise of rapid and long-term stable growth of gross domestic product. Either we assess it on nominal or purchase power parity (PPP) terms, four distinct economies obviously lay ahead all other rapidly developing global markets. Acronym BRIC (Brazil, Russia, India, China) forged to describe these countries brought glory to its creator Jim O'Neil, Goldman Sachs' economist of the time (1). Since his first insight back in 2001 global recession (2) and ongoing developments were changing prospects for all four individual markets. Nevertheless, strong positive growth trend remained their common feature although with quite substantial differences in pace and balance of overall economy development (3). BRIC's share in global wealth grew tremendously effectively quadrupling itself over past decade (4). Joint growth of this group of countries, heavily dominated by China, will remain long-term trend with clear forecasts at least up to the middle of twenty-first century (5).

Consequences for National Health Systems of these Nations

Each one of BRICs countries enjoyed prolonged period of geopolitical stability. Local governments via different mechanisms succeeded to use welfare of the society to improve access and quality of health care (6). Rising middle classes contributed to the higher demand for pharmaceuticals and novel medical technologies, particularly in developed urban cores. Long-term neglect of rural populations, many of them living close to poverty line, finally led to more decisive polices to tackle these issues. Health insurance coverage recorded its first serious improvements in these regions (7). Affordability of medical care to ordinary citizens was spreading although not sufficiently to follow-up disproportionate rapid growth of out of pocket spending (8). This effectively meant some serious setbacks affecting health care access to the poor (9). Many of such issues remain high on local health policy agendas and unresolved so far. Another important obstacle in mammoth sized health sectors of these nations is delivery of cutting edge treatment options to the citizens. Local innovation rate remains quite modest compared to huge research and development investment particularly characteristic of People's Republic of China (10). Promising signs are rapidly growing frequency of scientific publications in medicine, technology patents, and strengthening of local research capabilities in terms of human resources, institutional commitment, and capital investment into equipment. Although similar positive changes are clear in all four countries, China is once again surpassing all other BRIC members with its capacity and output (11).

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Total Health Expenditures Among BRICs in Nominal and Purchase Power Parity Terms

Global health expenditure database (GHED) relying on national health accounts (NHA) system to track financial flows within national health systems of all World Health Organization (WHO) members across the globe was established since 1995 with latest official release of 2012 data (12). This is probably the most comprehensive single source allowing for international comparability of data. Observing these 18 years we might come to terms with many fine hidden patterns of health spending transformation that occurred worldwide and among the BRIC themselves. Global share of BRIC nations in total health expenditure (THE) grew from 4% ($108,938) to 12% ($858,193) in nominal terms ($USD) while change from 9% ($220,650) to 16% ($1,289,861) was even more profound in PPP terms. Joint health expenditure by BRIC nations succeeded to raise sixfold in less than two decades. Calculations of global health spending refer to 193 countries or political entities for whom complete records are available within GHED registry. Most surprising evidence comes from internal THE relationships among Brazil, India, Russian Federation, and China (**Figure 1**). Back in 1995, THE composition of BRICs in nominal terms was dominated by Brazil (31%) followed by China (29%) and approximately equal shares of Russia and India of 20%. Recent 2012 data point out to entirely different nominal THE landscape heavily dominated by China with 52%, followed by Brazil (17%), Russia (16%), and India (15%) all three very close to each other. THE expressed in $PPP reveals quite different picture. In 1995, Brazil held even 47% of joint spending while it was followed by China (24%), Russia (15%), and India (14%). If we observe percentage of gross domestic product (GDP) spent on health by individual countries it is easy to notice that only India remained at 4% level. Each of other three countries gained momentum of higher GDP proportion dedicated to health care today compared to situation 20 years ago. Such capital investment was led by Brazil (2.7% increase) followed by China (1.9) and Russia (0.9).

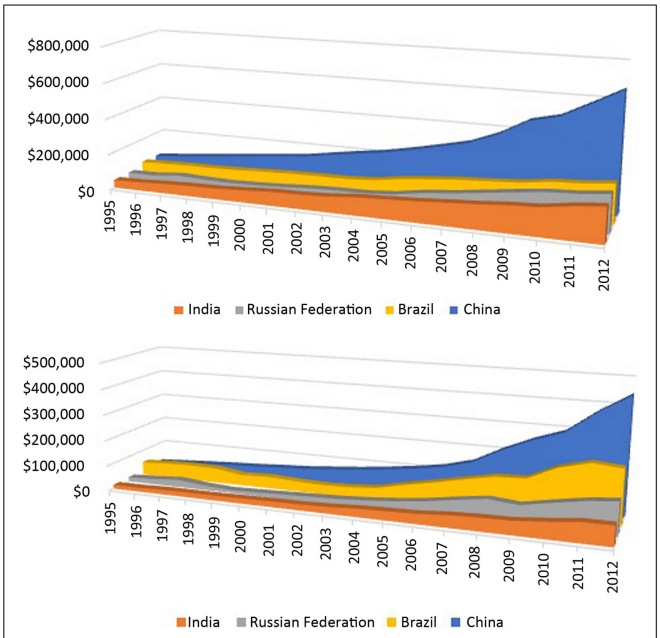

FIGURE 1 | Long-term trend on total national – level expenditure on health (THE) 1995–2012; Above: THE expressed in million current international $PPP (purchase power parity value); Beneath: THE expressed in million current US $ (nominal value); Source: Global Health Expenditure Database.

Prospects of Retaining Long-Term Growth in Health Spending Among the BRICs

All aforementioned data point out to the several important facts. In the beginning of observation period, Brazil was dominating the BRICs landscape both in terms of nominal and PPP and percentage of gross domestic product health spending (13). Over the course of years, Brazil remained on the lead only in terms of last one (14). It is THE expressed as percentage of GDP reached 9.31% topping the list with both scale of increased and its absolute value. India, regardless of huge increase in national welfare and economic output decided to forcibly maintain its expenditure at 4% of GDP (15). Respective amount available for various health programs became much larger anyway, so it recorded successes in expanding health insurance coverage and access to medical services (16). One important advantage of India compared to its three remaining counterparts is far younger population due to delayed population aging process in this large nation. Therefore, the burden of major prosperity diseases and elderly age remains significantly easier to cope with (17). Although India's share in BRIC's joint THE fell significantly in percentage terms we should not forget that scope of financial means disposable for health care actually quadrupled in same period in both nominal and PPP terms. Russian Federation recorded growth of THE in all terms over past two decades but its share of BRIC's joint THE remained at the same level (18). Nevertheless, systemic health reforms and overall economic performance were developing in the last BRIC's member faster than anywhere else (19). The BRIC's composition of THE observed as national level spending from year to year becomes more and more dominated by China. This is still not the case with per capita spending where Russia's THE per capita exceeds Chines three times ($1,474 PPP in 2012) and Brazilian ($1,109 PPP in 2012) more than twice. Many of microeconomic indicators and identified health system weaknesses point out that there is long ahead of Chinese health reforms (20). Regardless of some setbacks global multinational industry of pharmaceuticals and medicinal devices will target and support largest global markets (21). The potential of all BRIC nations, led by People's Republic of China to absorb new medical technologies and further raise demand for medical goods and services will most likely remain high in the long run (22).

BRIC's vs. OECD's Health Expenditures

Many forecasts actually point out to the growing competitiveness of BRICs compared to major OECD markets. OECD's joint share of global health expenditure still far exceeds the one of BRICs although OECD/BRICs ratio of joint THE fell from 22 times

in nominal terms in 1995 to 7 times in 2012. This same ratio expressed in PPP terms felt from ninefold larger THE in favor of OECD in 1995 to only fourfold larger THE in 2012. OECD's proportion of global health spending fell from 91 to 81% in nominal terms and from 82 to 72% in PPP terms. The global trend of gains and losses in health spending clearly went in favor of largest emerging markets at the expense of mature, traditional high-income OECD economies (23). We should not forget that BRIC's growth alone is not sufficient to explain existing differences. Significant part of these gains in national health budgets should be attributed to smaller N-11 emerging markets, South Africa and large number of middle- and low-income countries mostly situated in Asia, Eastern Europe, Latin America, and Africa (24). The global landscape of health care spending has clearly changed more in recent past than for the most of twentieth century (25).

Beyond Tomorrow?

Health policy makers are aware they should stay precautious about newly built socioeconomic welfare of many developing countries. Their national capacities to direct investment and growing capacities into the most rewarding, evidence based and cost-effective medical procedures and drugs remain very limited. Knowledge-based resource allocation still has to make roots in health policy traditions of BRICs and other emerging nations (26). Health outcomes offer final judgment on success of health care delivery to the patients in needs. Longevity gains were indeed substantial while fall in neonatal, maternal mortality, and incidence rates of communicable diseases records continuous success in these countries (27). Nevertheless, life expectancy at birth and likelihood of healthy aging remain by far higher in high-income economies with Japan topping the list (28). Facing the upcoming burden of accelerated population aging will be particularly challenging in the emerging markets where such demographic transition was far more rapid compared to most of developed societies. Official UN forecasts tell us that China will be the fastest aging among large nations for many upcoming decades (29). Very similar changes, at slightly slower pace began happening much earlier in Russia followed by Brazil. Morbidity structure of BRICs, with partial exception of India, has already changed toward the one dominated by non-communicable prosperity diseases. All of BRICs share another important geographic determinant. They do have very uneven population distribution with exceptionally large rural areas remote to most specialty hospitals and university clinics. Development of rural network of medical facilities although traditionally stronger in Russia (30), presents particular challenge to China, India, and Brazil (31). Lack of willingness in local physicians and nurses to get employed in the country side far away from more attractive career prospects in large cities, presents another obstacle leading to effective shortages of professional staff (32). Common citizens inhabiting these areas usually earn less income than those living in rich industrial cities (33). Vulnerability to catastrophic household expenditure due to illness of family member is high (34). In line with these facts, out of pocket expenditure grew tremendously in all of BRICs from $67 PPP on average in 1995 to $276 PPP in 2012. Among several causes, widespread informal payments remain significant cost driver for ordinary people (35). Faced with so many ongoing challenges it would be very hard to present any reliable future forecasts for health care affordability and sustainable financing in BRICs (36). Whether their impressive long-term efforts will bring worthy fruits in population health will probably be fully visible in the second half of twenty-first century.

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OPINION
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Issues of unequal access to public health in India

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INTRODUCTION

Health in India is a state subject. Although the central government shares a significant part in establishing health care infrastructure, each of the Indian states determines their priorities for health care financing, and provides services to the population. India's 12th plan document[1] promises to build upon the initiatives that were taken in the 11th plan and expand the reach and coverage of health care to achieve the long-term objective of "universal health care."

Irrespective of the ability to pay, people in India increasingly seek private health care even for minor illnesses like cold, fever, and diarrhea. Private health care in India, however, is not only expensive but also suffers severely from a lack of trained and skilled manpower as compared to the public sector (2). Access to health care facilities is significantly urban biased. So, people living in the rural areas face the additional handicap of such a situation and they form a disproportionately larger share of the unhealthy population.

With respect to access to health care, the 12th plan document states that "Barriers to access would be recognized and overcome especially for the disadvantaged and those living far from facilities." The document goes on to mention that "… the SC and ST,[2] the particularly vulnerable tribal groups, the de-notified[3] and nomadic tribes, the Musahars[4] and the internally displaced must be given special attention while making provisions for, setting up and renovating sub-centers and anganwadis[5]."

These groups need special attention as they not only suffer from unequal and lower access but also produce the worst health outcomes in the country. This is primarily because these groups have been traditionally excluded and discriminated, and therefore suffer from high incidences of poverty and low levels of education (health care awareness), among other disadvantages, which have made their access to public health care tougher. While the public health care system required to have ensured better care and treatment for these marginalized communities, evidence shows that access remains the lowest among these population group.

In this paper, we focus on the issues of unequal access to health care in India by rural–urban residence, economic status, and caste/religion identity.

ACCESS TO HEALTH CARE

Poor housing condition, unsafe drinking water, lack of sanitation, use of biomass fuels, exposure to environmental odds as a part of the livelihood among the marginal population group often increase the risk of numerous health problems. Desai et al. (3) noted a very high prevalence of minor ailments like cough, fever, diarrhea. (124 per 1,000 individuals) among Indian population. The minor illnesses

[1] Every 5 years, the Planning Commission (1) of India brings out a Plan document, detailing the budget outlays for and the areas of focus across various sectors of the economy. It is a development priority and direction road map.

[2] SC are those castes, which are part of the legislatively drawn schedule (Scheduled Castes), which in India benefit form reserved seats in public educational institutes, post schooling as well as in public jobs. Similarly, the ST (scheduled tribes) is a list of all those tribal groups, which are extended the same benefits.

[3] De-notified tribal groups are those which under the British occupation were legally termed as criminal tribes and were subsequently "de-notified" as non-criminal. They however continue to be associated with their past identity and face discrimination.

[4] Musahar is a low cast community who are extremely deprived and socially excluded and live on the margins of society.

[5] 12th plan document, Chapter 2, p. 10.

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despite being short term in nature cause substantial time loss from usual activities. The prevalence of these minor ailments is seen to vary substantially by socio-economic conditions of households. These are more prevalent among the poor and the uneducated population and those who belong to the scheduled tribe community. The prevalence seems to reduce with the improvement in living conditions. However, everybody benefits from living in a metro city, regardless of their social position.

Treatment rates across groups do not show much variation for minor illnesses. Minor illnesses do not require much laboratory test and people in rural areas prefer to go to a private provider for such types of illnesses due to easy availability and greater convenience. The major share of the cost of minor illnesses is the doctors' fees and medicine. But, disparity in health care seeking between various socio-economic groups becomes prominent in case of major illnesses like hypertension, heart diseases, diabetes etc. Major illnesses are long term in nature and subject to a number of diagnostic tests. A sizeable proportion of major illnesses in rural areas remain untreated mainly due to unavailability of diagnostic facilities in the local vicinity. Desai et al. (3) have shown that only 3% of the major illnesses in metro areas remain untreated, whereas 12% of the same remain untreated in the less developed villages. Again, one-fifth of the diagnosed major illness among the scheduled tribes remain untreated. The tribal households are usually located in places, which have fewer health facilities and still rely on the traditional healers. A majority of these long-term major illnesses also remain undiagnosed amongst them. They need to go out of the villages, which are often isolated to avail treatment.

Access to health care is very much asymmetric between rural and urban India. While urban residents have a choice between public or private providers, the rural residents face far fewer choices. India has a very vast public health network with sub-centers working at the community level. The health sub-centers are manned mainly by bare foot health workers and work as a bridge between community and the primary health centers (PHC). PHC is the first contact point between village community and medical officer; meant to provide an integrated curative and preventive health care to the rural population with emphasis on preventive and promotive aspects of health care. Community health centers (CHC) are more equipped and acts mainly as a first referral unit with diagnostic facilities and a bunch of specialists. Since the recommendations of the Bhore Committee in 1946, a lot of emphasis has been put on the door step delivery of the health services. But, availability of any health facilities does not seem enough to attract people to the government facilities. Desai et al. (3) further noted that the possibility of visiting a government facility for minor illnesses reduce in the presence of any private facilities in the locality, but the reduction is much lesser for larger health care units like the CHC than the sub-centers.

COST OF TREATMENT FOR MAJOR AND MINOR ILLNESSES

The envisioned universal access to health care is far from achieving its goals. Over time, a lot of emphasis has been placed on the doorstep delivery of health services. However, the scheme-wise expenditure on India's National Rural Health Mission (NRHM) during 11th Plan (2007–2012) on public health care expenditure reveals that a major share of the allocated resource on health was spent on family welfare program (90%), leaving a small segment (7.7%) for disease control (4).

Though investment in family welfare program is necessary, investment in disease control program cannot be ignored. Limited public health spending and higher emphasis on family planning services over time has resulted into a huge scarcity of resources to be spent on general health. A lot of public health facilities have been initiated in the outreach areas in the last decade, but due to unavailability of quality doctors and diagnostic facilities, people rush to the equally poor private facilities and end up spending more, almost all of which is out-of-pocket (OOP) expense.

IMPACT OF MEDICAL EXPENDITURE ON HOUSEHOLD WELL-BEING

Does the health expenditure cost the same to each household? This remains a major policy concern in many of the developing countries including India, where household OOP payment for health care is a significant part of the total health expenditure. The high OOP spending on health often leads to catastrophic level of spending for healthcare to many households and push them into poverty (5–7). The proportion of households facing catastrophic OOP health payments during 2004–2005, as measured by Ghosh (7) was 15.4% and the range varies as less as 3.5% in Assam to 32.4% in Kerala. Barik and Desai (8) measured the expenditure ratio (health expenditure as a percentage of income) on health care in India as 6% of the monthly average income, which is higher than the common benchmark of affordability (5%) in developing countries (9, 10). Moreover, this health burden is disproportionately distributed among various socio-economic groups. Poor households spent nearly 15% of their monthly income on healthcare compared to the richest households, who spend <1% of their income (**Table 1**).

As discussed above, the income share of the cost of treatment appears much higher on the socially and economically disadvantageous households. These higher health care cost often discourages them to avail treatment as reflected in case of major illnesses. More than two-thirds of the total health expenditure in India is met through household *OOP*. The coverage of health insurance is also very low among the Indians. Social insurance schemes contribute only 1.13% of the total health expenditure (11).

Besides availability and affordability, as discussed above, acceptability and adequacy are the two other important aspects of access to health care (12). A persistent negative attitude toward public health facilities in India has been recorded in a number of studies (13, 14). Das and Hammer (13) evaluated the quality of medical practices as a function of doctor's competence in terms of knowledge of diseases and the practice of existing knowledge. They found that doctors in the public facilities are more qualified than the private doctors, but they use their knowledge less than what they should do in practice. Again, few studies have pointed out doctor's absenteeism as the leading cause of people's avoidance to government health facilities (15, 16). Complaints regarding long waiting hours, lack of privacy in the consultation room etc. are some common supply side constraints of public health system in developing countries including India (17, 18).

TABLE 1 | Share of total household income spend on health care in India, 2004–2005.

	Health care spending (%) on monthly household income		
	Any morbidity	**Short term**	**Long term**
All India	6.02	4.43	1.59
Place of residence			
Metro	1.13	0.67	0.46
Other urban	3.57	2.42	1.15
More developed village	7.73	5.72	2.01
Less developed village	6.87	5.18	1.69
Income			
Lowest quintile	14.53	11.15	3.38
Second quintile	4.53	3.27	1.26
Thirrd quintile	2.44	1.74	0.7
Fourth quintile	1.44	1.02	0.42
Top quintile	0.65	0.37	0.28
Social groups			
High caste Hindu	5.13	3.65	1.48
OBC	7.59	5.66	1.93
Dalit	5.32	4.06	1.26
Adivasi	3.88	2.78	1.1
Muslim	4.84	3.88	0.96
Other religion	9.19	4.36	4.83

Barik and Desai (8), p. 57.

DISCUSSION

Even after more than 50 years of independence, health in India remains a luxury and only the rich can afford it. People visit equally poor private practitioners, ignoring the available public health units, and pay beyond their capacity. Quality health services, either public or private, with some government regulation, can help to improve the present scenario. The adivasi and the dalits are still away from the health equity and face more challenges than the others. Well-equipped health facilities in the vicinity and knowledge of disease conditions can improve the access of public health services. Rather than focusing on the doorstep services, well-equipped PHCs even can do better. A recent study by Goel and Khera (16) noted that provision of free medicine and diagnostic facilities have impacted positively on the patient utilization rate in the state of Rajasthan. Increased coverage of health insurance can add an extra protection from the health risks and early detection of disease conditions may help in achieving good health and lower treatment cost. On the eve of the epidemiological transition, rising share of non-communicable diseases will demand for facilities with diagnostic services (19, 20). So, time has come to change a move from quantity to quality.

AUTHOR CONTRIBUTIONS

Dr. DB is the main author responsible for the facts and figures. Dr. AT has assisted on shaping the ideas.

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The Choice of Healthcare Providers for Febrile Children after Introducing Non-professional Health Workers in a Malaria Endemic Area in Papua New Guinea

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Background: Disease burden of malaria in Papua New Guinea (PNG) is the highest in Asia and the Pacific, and prompt access to effective drugs is the key strategy for controlling malaria. Despite the rapid economic growth, primary healthcare services have deteriorated in rural areas; the introduction of non-professional health workers [village health volunteers (VHVs)] is expected to improve antimalarial drug deliveries. Previous studies on PNG suggested that distance from households negatively affected the utilization of health services; however, price effect on healthcare demand decisions has not been explored. Empirical studies on household's affordability as well as accessibility of healthcare services contribute to policy implications, such as efficient introduction of out-of-pocket costs and effective allocation of health facilities. Therefore, we investigate price responsiveness and other determinants of healthcare provider choice for febrile children in a malaria endemic rural area wherein VHVs were introduced.

Methods: Cross-sectional surveys were conducted using a structured questionnaire distributed in a health center's catchment area of East Sepik Province in the 2011/2012 rainy seasons. Caretakers were interviewed and data on fever episodes of their children in the preceding 2 weeks were collected. Mixed logit model was employed to estimate the determinants of healthcare provider choice.

Results: Among 257 fever episodes reported, the main choices of healthcare providers were limited to self-care, VHV, and a health center. Direct cost and walking distance negatively affected the choice of a VHV and the health center. An increase of VHV's direct cost or walking distance did not much affect predicted probability of the health center, but rather that of self-care, while drug availability and illness severity increased the choice probability of a VHV and the health center.

Conclusion: The results suggest that the net healthcare demand increases with the introduction of a VHV. Allocations from the government's budget are required to sustain VHV activities because the introduction of a small user fee could impede the utilization of a VHV. A large travel cost related to the choice of the health center suggests that resource allocation is required for the expansion of formal healthcare providers to adequately operate a referral system.

Keywords: healthcare utilization, malaria, community health workers, health services demand, health-seeking behavior

INTRODUCTION

In Papua New Guinea (PNG), malaria is the leading cause of outpatient visits, the second leading cause of hospital admissions, and the fourth leading cause of hospital deaths (1). Children are the most vulnerable to malaria infection, illness, and death. The disease burden of malaria in PNG, which is the highest in Asia and the Pacific, was estimated to be 17.6 disability-adjusted life years per 1,000 capita per year in 2010.[1] Along with improvements in vector control using a long-lasting insecticidal net, maximizing access to prompt quality diagnoses and appropriate treatment for malaria are key to reducing malaria-related morbidity and mortality, as proclaimed by the PNG National Health Plan 2011–2020 (2). Improving service delivery in rural regions wherein the majority (89%) of the population lives is the top health priority for achieving the key strategy for malaria control (2).

Papua New Guinea, a lower middle-income country, has shown rapid economic growth. PNG's sustained positive gross domestic product (GDP) growth has been more than 5% since 2007 and is expected to reach 16% in 2015.[2] Accordingly, the total health expenditure per capita at purchasing power parity (NCU per USD) has sharply increased from 67.2 in 2006 to 115.2 in 2011.[3] However, expenditure for operational costs for rural health services was only 13.5% of the total health expenditures (2).

In urban PNG, people have numerous choices of health providers. Formal health services are provided by the government, church agencies, and a few private clinics and doctors. People are also able to seek treatment from informal sectors, such as traditional healers and neighbors. Western drugs are available from pharmacies, general shops, and street traders. However, the choice of healthcare providers is limited for rural majority because primary healthcare services in rural regions have deteriorated. The number of aid posts is insufficient and 29% of them did not operate in 2010 (1). A need exists to expand health services to the community level, particularly in areas wherein aid posts are not functioning (3).

Recently, non-governmental organizations have promoted and trained village health volunteers (VHVs) for improving mother and child health in PNG (4, 5). VHVs are key players for a strategy on a worldwide scale known as home-based management of malaria (HMM) to improve access to antimalarial drugs (6). This strategy aimed to provide prompt and adequate access to prepacked quality antimalarial drugs through a network of community resource individuals. Numerous interventional trials have confirmed the effectiveness of HMM (7–9); however, no study has estimated healthcare demand of non-professional community workers using a discrete choice model in routine clinical settings of malaria endemic regions.

Previous studies have indicated that determinants of the choices of healthcare providers can be supply-side factors (e.g., choice set of health services, price, time cost, and quality) (10–16) individual/household factors (e.g., income and/or assets, age, gender, education level, and type and severity of illness) (10, 11, 13–17), and social and geographical factors (e.g., ethnicity, infrastructure, and access) (13–15, 17). Previous epidemiological studies on PNG have suggested that the utilization of health facilities declined with distance (18, 19) and increased with male and infant patients (19) based on attendance records. However, these studies did not include socioeconomic factors. Only one report exists on the choice of healthcare providers in PNG for malaria treatment using a discrete choice model (20). However, the study did not consider commonly used determinants, such as cost for health facilities, economic status of a household, and health status of a patient. These exclusions make it difficult to compare the results with those of other countries and/or settings.

Therefore, this study uses discrete choice models to investigate households' affordability and accessibility of healthcare providers for malaria treatment after the introduction of a VHV program[4] and to contribute to policymaking for efficient introduction of out-of-pocket costs and effective allocation of health facilities.

MATERIALS AND METHODS

Study Area and Target Population

We conducted our study in the rural region of East Sepik Province, PNG. The study site was a catchment area of a health center located 56 km by road from the provincial capital of Wewak. The area was situated in a lowland swamp along the coast and experienced hyperendemic malaria throughout the year. All caretakers with children aged <5 years who were living in villages in the study area were included as the target population. Among the 23 villages at the site, we excluded two villages from the target population because of the difficulty in accessing it by car and one

[1] http://vizhub.healthdata.org/irank/heat.php

[2] http://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG/countries/

[3] http://hiip.wpro.who.int/portal/DataAnalytics/AccessDataBySource.aspx

[4] Part of the results using the same data set has been presented at the ninth annual meeting of the Japanese Health Economics Association on September 6, 2014 (in Japanese). A preliminary abstract written in Japanese is available at http://www.ihep.jp/jhea/convention/list.html.

more village as it was an uncooperative village. Consequently, 20 villages were involved in the study. According to the 2011 National Census (21), the total population of the 20 villages was 8,035 people in 1,415 households.

Questionnaire Survey

We developed a structured questionnaire and conducted cross-sectional interview surveys in the rainy seasons (February 2011 and 2012) when malaria morbidity was relatively high in the study site. The survey was conducted only once in 18 villages and twice – 2011 and 2012 – in two villages closest to the health center. In the preceding 2 weeks of the interview, we collected data on the fever episodes of children, treatment choices, and caretaker and patient characteristics. Trained field assistants in the study area interviewed caretakers who were primarily their mothers, otherwise, adult household members who mainly took care of them, such as their fathers, aunts, or grandmothers. We also obtained information on the characteristics of the health facility from direct observation or interviews with health workers. In the study settings, patients with fever or a history of fever were diagnosed and treated as having malaria because of lack of diagnosis tools. Therefore, fever was considered as presumed malaria.

The caretaker's choice of treatment was defined as "a treatment that a caretaker has selected as the initial action following the last onset of an acute fever in a child." If caretakers give treatment only within their own households or simply monitor the child's condition over time and do not provide medical treatment throughout the fever episode, we defined the treatment choice as "self-care."

Treatment Choice Alternatives in the Study Area

Caretakers were able to use informal health services within their own communities, such as self-care, seeking healthcare from neighbors, traditional health practitioners, VHVs, and/or general shops. We observed self-care treatments, such as taking a cold bath or herbal sweating bath, drinking herbal hot water, and/or using leftover western drugs. Caretakers rarely received western drugs from neighbors. Traditional health practitioners who treated patients with traditional herbal medicine and/or spiritual magic were present in most communities (17 out of 20). Each community assigned one VHV, who provided essential drugs, such as antimalarial drugs and antibiotics, for patients in the community after completing 1 month initial training. Unlike African and Asian countries, over-the-counter (OTC) drugs were not popular in the study area. Villagers did not have access to antimalarial drugs and antibiotics as OTC drugs. Acetaminophens were available in some general shops in several communities.

In rural PNG, health centers, sub-health centers, and aid posts provided formal health services. One health center and three aid posts were in the study and the surrounding areas. The health center was operated by the Catholic Church, with a nursing officer as the head and 11 health workers. The health center, a key health facility in the area, was open 24 h and covered a broad range of work, such as ambulatory practice, hospitalized care, delivery care, outreach public health activities, and supervision of VHVs. Antimalarial drugs and antibiotics were always available during the study period.

Antimalarial drugs and antibiotics were also available in three aid posts (two governmental facilities and one Catholic-run facility). In each, one health worker provided outpatient care during the daytime. Residents of the study site had to drive 50–100 km to the town of Wewak to gain access to healthcare services in a general hospital, their two clinics, or their three pharmacies. Neither public nor community-based health insurance was introduced in the study area.

Discrete Choice Models

We apply the mixed logit model with random coefficients, which relaxes the independence of the irrelevant alternative assumption for discrete choice models with three or more alternatives. Following the notation described by Cameron and Trivedi (22), the utility associated with the alternative j selected by individual i is represented as

$$\begin{aligned} U_{ij} &= x'_{ij}\beta_i + z'_i\gamma_{ji} + \varepsilon_{ij} \\ &= x'_{ij}\beta + z'_i\gamma_j + x'_{ij}v_i + z'_i w_{ji} + \varepsilon_{ij} \end{aligned} \quad (1)$$

where x_{ij} is an alternative-specific variable, z_i is an individual-specific variable, and ϵ_{ij} is the error term. In Eq. 1, $\beta_i = \beta + v_i$ and $\gamma_{ji} = \gamma_i + w_{ji}$, where v_i and w_{ji} are random terms of the coefficients. Individual i selects alternative y_i from m alternatives to maximize the utility. Assuming that the error term ϵ_{ij} distributes an extreme value distribution, the logit probability of the alternative j selected by individual i is given as

$$P_{ij} \mid v_i, w_{ji} = \frac{\exp(x'_{ij}\beta + z'_i\gamma_j + x'_{ij}v_i + z'_i w_{ji})}{\sum_{l=1}^{J}\exp(x'_{il}\beta + z'_i\gamma_l + x'_{ij}v_i + z'_i w_{ji})}, \quad j = 1,\ldots,J. \quad (2)$$

The choice probability of the mixed logit model is the integral of the logit probability over a density function of β_i and γ_{ji}. The distribution for the density of the coefficients is commonly specified to be normal or lognormal. The lognormal distribution is used when the coefficient is expected to be the same sign for every individual (23). We use the simulation methods with 500 Halton draws to approximate the maximum log likelihood function. Arc elasticity was calculated as the percentage change of choice probability divided by the percent change of a unit of a variable. We calculated the percentage change from point 1 to 2 using the midpoint. Stata13 (StataCorp, TX, USA) and the user-written command *mixlogit* (24) were used for statistical analysis and model estimation.

Outcome and Explanatory Variables

The outcome variable is caretakers' initial choice for their child's fever among the possible treatment choice alternatives. The explanatory variables are divided into two categories: alternative-specific and individual-specific variables. Alternative-specific variables represent direct costs, distance from house to the health providers, and drug availability of the health providers. Individual-specific variables represent a household's assets, a patient's gender, a patient's age, severity of the illness as perceived by the caretaker, and the caretaker's education. It is not practical for a mixed logit model to include a full set of random coefficients

when the sample size is limited. Thus, we establish the model with random coefficients of four variables – direct costs, distance, drug availability, and assets – which we believe are more interesting from the perspective of affordability, accessibility, and availability of healthcare services.

Direct costs were defined as the sum of the examination fee, treatment costs, and travel costs. We estimated the direct cost for the choice alternatives that were not selected. Both treatment and travel costs in a household were 0 even when the other alternatives were selected. Generally, a patient was not charged for a VHV, but VHVs were allowed to demand a small amount. In the study period, eight VHVs charged Kina 1 (USD 0.48) for medical care. The travel costs for a VHV were also 0 because the treatment was done in the patient's community or a neighboring community that was within walking distance. In contrast, a patient's fee for the health center was Kina 1 (USD 0.48) in 2011 and Kina 3 (USD 1.43) in 2012. This fee included the examination, a prescription, drugs, and revisit costs. People living in communities near the health center or with inconvenience of public transportation were observed to travel on foot, resulting in free travel costs. A public transport vehicle to the health center was used for the other 14 communities. The one-way travel cost was Kina 3 (USD 1.43) or 7 (USD 3.33) depending on the distance from the health center. A one-way trip on a private transport vehicle to the health center cost K 100 (USD 47.62), but this use was not observed in this study. Since the coefficient of the direct cost is expected to have the negative sign for every individual, it was assumed to have lognormal distribution.

Distance to healthcare providers – a proxy for accessibility – is another important determinant of healthcare choice. We define the self-care distance in a household as 0. As previously mentioned, VHV was located within walking distance to a house. The distance from the house to VHV was calculated as a direct linear distance using both geographic positioning system (GPS) data that were manually collected using GPS devices and a digital map of the area (Pasco Satellite Ortho, Pasco Corporation, Japan). To calculate the distance to health providers beyond the normal walking distance at which people commonly use a public transport vehicle, we distinguish walking distance from transportation distance using a vehicle because the physical and time costs are viewed as different. Walking distance was calculated as the direct distance from a house to the nearest roadside. Transportation distance was measured as the road distance from the nearest roadside to a health facility. Since the coefficient of the distance is expected to have a negative sign for every individual, it was assumed to have a lognormal distribution.

We assume that the availability of antimalarial drugs is a proxy for the quality of healthcare providers because a better drug supply is expected to increase utilization by patients. In the study period, first-line antimalarial drugs included a combination of amodiaquine (AQ) or chloroquine (CQ) plus sulfadoxine-pyrimethamine (SP) for uncomplicated malaria and artesunate plus SP for severe malaria. We set the value of dummy variable for "drugs are available" equal to 1 when at least two drugs enabling the combination therapy were in stock. Otherwise, the dummy variable was set equal to 0, i.e., "drugs are not available." In the health center, drugs were always available in the study period. However, we observed that some VHVs did not have drug stock. Drugs were to be supplied to the health center every 3 months in response to a VHV's order. At their own expense, VHVs had to travel to the health center to collect drugs. Drug delivery from the provincial capital's storage of medical goods to the health center was often delayed in the first quarter of the fiscal year, i.e., from January to March. In the study period, 14 communities were assigned as "drugs are available" and eight communities were categorized as "drugs are not available." We did not have data on drug availability in a household. However, observations revealed no accessibility to OTC drugs in the area (as defined above), no possibility to have leftover SP, a single-dose therapy given at health facilities, and no use of combination drugs in observed self-care episodes. Therefore, we considered self-care in each household as "drugs are not available." Since the coefficient of the drug availability is also expected to have the negative sign for every individual, it was assumed to have a lognormal distribution.

Income and expenditures in rural areas of developing countries fluctuate widely because many individuals are small farmers, and few workers earning wages exist. Therefore, using cross-sectional data to estimate annual income and/or expenditures is susceptible to error. In contrast, because assets are more precisely measured even in developing countries, they were used as a proxy variable for long-term economic status by constructing a linear index of asset ownership and housing characteristics using principle component analysis (25). Some individuals with high economic status may make more use of healthcare providers to keep higher health status. Others may make less use of healthcare service due to higher opportunity cost. Therefore, we assume the coefficient of the assets as having normal distribution.

Individual (i.e., patient) gender and age were included as explanatory variables because biological and cultural inequalities of gender and/or age may affect the demand for healthcare. Most econometric studies of healthcare demand included the health status of a patient as an explanatory variable because an individual with a lower health status is expected to seek more healthcare services. In econometric studies of healthcare demand, type of illness symptoms (10, 26, 27), severity of illness (13, 14), number of health days in the reference period (10, 13, 15), and duration of illness or inability to work (11, 28, 29) were used as proxies for health status. The number of health days and/or the duration of the illness or being unable to work may be endogenous to the choice of healthcare provider because the provider's choice could influence these variables. To avoid this problem, we adopted perceived illness severity by caretakers at the onset of acute fever as a proxy for health status. We categorized the severity dummy as mild symptom equaled 0 and moderate or severe symptom equaled 1.

Caretaker education level is expected to increase healthcare demand because more educated individuals understand the benefits of healthcare in improving one's health status. The educational structure system of PNG comprises 3 years of elementary, 6 years of primary, 2 years of lower secondary, and 2 years of upper secondary courses before tertiary (university and college) education. The study area had six primary schools and one lower secondary school. In this study, education level was defined by the total number of years of schooling.

Ethical Clearance

Ethical clearance for the study was obtained from the Medical Research Advisory Committee of the Papua New Guinea National Department of Health (No. 09.26) and the Tokyo Women's Medical University Ethical Committee (No. 1744). This study was conducted in accordance with the Declaration of Helsinki and the recommendations of those committees with written informed consent from all participants.

RESULTS

Basic Statistics

Caretakers in 736 households with 1,012 children, or 86.5% of the target population, were interviewed. Out of this group, 257 children from 195 households were reported to have a fever episode. Among eight choice alternative sets selected, self-care was the most common (40.9% of the total episodes), followed by the VHV (31.5%) and the health center (20.6%). Some people asked for treatment at an aid post (2.7%), a pharmacy (2.0%), from neighbors (1.2%), our study team (0.8%), and a clinic (0.4%). We found that no one visited a hospital, a shop, or a traditional practitioner for the initial treatment. For further analysis on provider choice, we included the top three alternatives because they constituted 93.0% of the total episodes, and the characteristics of each of the other alternatives were too different to merge into one category.

Table 1 presents descriptive statistics of the outcome and explanatory variables used for discrete choice models. High correlation between the direct cost and transportation distance was found (0.98). We excluded the variable "transportation distance" from the final model estimation to avoid multicollinearity. The mean of the observed direct cost of the VHV (mean: 0.286; SD: 0.450) significantly differed from that of the health center (mean: 2.189; SD: 2.140; $t = -7.76$, df = 132, $p < 0.0001$) and of self-care (mean: 0; SD: 0; $t = -6.53$, df = 184, $p < 0.0001$).

Since theoretical and empirical evidences have indicated returns to investment in education (30), the education level is expected to correlate with economic status. In our study, however, correlation between the education of caretakers and economic status of their household was not very high (0.15). Therefore, we included both in the model estimation.

To estimate an asset index using principle component analysis to weigh the factor score of the first principal component, we selected seven dummy variables: own mobile phone (holding ratio; 81.8%), own radio or stereo (49.2%), own house with tin roof (24.6%), own generator (18.6%), own rainwater tank for drinking (12.0%), own western-style house (5.4%), and own car or outboard motorboat (4.2%). The eigenvalue of the first principal component was 1.88, and the ratio of valiance explained was 0.27. Since the distribution of the asset index was biased toward <0 with high frequencies at −1.6, −1.0, and −0.2 (**Figure 1**), we categorized the asset index into economic status tertiles: high, middle, and low. We included 210 observations to estimate the discrete choice models because of missing data on walking distance, illness severity, education level, and/or asset index. The observed choice ratios of self-care, VHV, and the health center were 0.429, 0.367, and 0.205, respectively.

TABLE 1 | Descriptive statistics.

Outcome variables	Obs	%				
Self-care	105	43.93				
Village health volunteer (VHV)	81	33.89				
Health center	53	22.18				
Total	239	100.00				
Explanatory variables	**Obs**	**Mean**	**SD**	**Min**	**Max**	**Median**
Direct cost for self-care (Kina[a])	239	0	0	0	0	0
Direct cost for VHV (Kina[a])	239	0.319	0.465	0	2	0
Direct cost for health center (Kina[a])	239	8.033	6.479	0	17	7
Walking distance to self-care (km)	239	0	0	0	0	0
Walking distance to VHV (km)	236	0.928	0.913	0	3.4	0.6
Walking distance to health center (km)	236	3.205	3.902	0	12.8	1.8
Transportation distance to self-care (km)[b]	239	0	0	0	0	0
Transportation distance to VHV (km)[b]	239	0	0	0	0	0
Transportation distance to health center (km)[b]	239	10.380	12.523	0	30.3	0
Antimalarial drug availability at self-care (no = 0/yes = 1)	239	0	0	0	0	0
Antimalarial drug availability at VHV (no = 0/yes = 1)	239	0.720	0.450	0	1	1
Antimalarial drug availability at health center (no = 0/yes = 1)	239	1	1	1	1	1
Gender of patient (female = 0/male = 1)	239	0.544	0.499	0	1	1
Age of patient (year)	239	2.096	1.373	0	4	2
Illness severity perceived by caretaker (mild = 0/moderate or severe = 1)	222	0.342	0.476	0	1	0
Education of caretaker (year)	232	6.586	2.635	0	14	6
Asset index	237	0.000	1.371	−1.699	6.355	−0.200

[a]*Kina 1 = USD 0.48 in 2011.*

[b]*Excluded from the final model.*

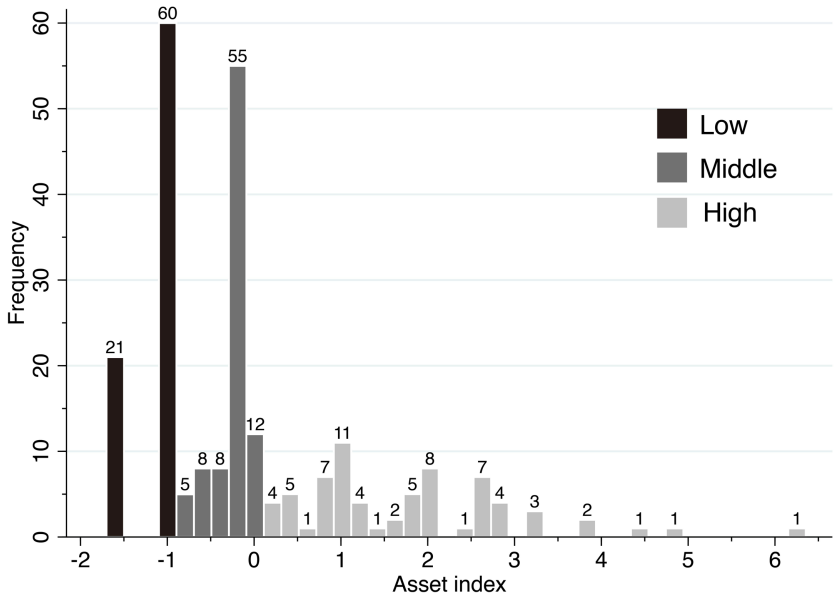

FIGURE 1 | Frequency distribution of asset indices. Each bar chart represents frequencies in intervals of 0.2 of the asset index.

Model Estimation

We employed a mixed model to estimate healthcare providers for childhood fever with self-care as the base alternative. The average predicted probabilities of self-care, VHV, and the health center were 0.428, 0.366, and 0.207, respectively. As expected, direct cost and walking distance significantly decreased the choice probability of health providers, in contrast with a positive significant effect of drug availability on their choice probability (**Table 2**). The estimated SD of direct cost and walking distance was not significant and was small in magnitude. These results indicate that every individual is likely to have the same preference in response to a change in the value of these variables. The estimated SD of antimalarial drug availability was relatively high but not significant. This result may be attributable to the small sample size; however, 96% of individuals prefer "drugs are available" even if its SD was significant. These results reveal that the preferences for direct cost, walking distance, and drug availability regarding the choice of healthcare providers are not different among each person, which justifies the use of the lognormal distribution of the three variables.

In contrast, the effect of economic status on the choice of healthcare providers was complex. Individuals with a middle economic status had a positive but not significant effect on the choice probability of VHV or the health center. Moreover, a significant difference in the individual preference of VHV choice was found: 37% of individuals disliked VHV and 63% favored VHV. In contrast, a high economic status had a negative but not significant effect on the choice of the health center. A difference in the individual preference for a health center was found but was not significant (82%: dislike; 18%: like).

Of the other variables with fixed coefficients, the sign of the effects on the choice of VHV was the same as that observed for the choice of the health center. Gender, age, and education had a negative effect, and severe illness had a positive effect. Besides the magnitude of the effect on education, the magnitude of the effect of the health center was larger than that of the VHV. These effects were significant except for the effect of age on the choice of the VHV and the effect of education on the choice of the health center.

Choice Probabilities Regarding Changes in Direct Cost, Walking Distance, Drug Availability, or Illness Severity

We calculated the average predicted probabilities of the choice alternatives regarding changes in the direct cost or walking distance of a VHV or the health center (**Figures 2A–D**). With no direct cost of the VHV, the probability of the VHV choice slightly increased to 0.422 compared with the average choice probability calculated from the sample enumeration (0.366). The probabilities rapidly declined to 0.269, 0.154, and 0.081 as the direct cost changed by Kina 1 (USD 0.48), 2 and 3, respectively (**Figure 2A**). When its direct cost was more than Kina 5.7, the probability declined to <0.01. As the direct cost of VHV increased, the choice probability of self-care increased strikingly from 0.374 to 0.733. Meanwhile, an increase in the VHV direct cost slightly increased the choice probability of the health center from 0.204 to 0.267. Then, we calculated price arc elasticities given a change in the VHV direct cost from 0 to Kina 5 (**Table 3**). The own arc elasticity of VHV demand was −1.836, and the cross arc elasticities of self-care and the health center were 0.627 and 0.264, respectively.

With no direct cost related to the health center, the probability of choosing the health center dramatically increased to

TABLE 2 | Estimation results of the mixed logit model.

		VHV	Health center
MEAN			
Direct cost (Kina; Kina 1 = USD 0.48)		−1.2977*** (0.408)	
Walking distance (km)		−0.6843*** (0.198)	
Antimalarial drug availability (no = 0/yes = 1)		2.0290*** (0.742)	
Gender of patient (female = 0/male = 1)		−1.0621** (0.514)	−1.8564** (0.862)
Age of patient (year)		−0.2646 (0.178)	−0.7626** (0.311)
Illness severity (mild = 0/moderate or severe = 1)		1.4926** (0.602)	3.4261*** (1.191)
Education of caretaker (year)		−0.2177** (0.102)	−0.1925 (0.214)
Economic status (low = base)	Middle	0.835 (0.672)	0.1147 (0.779)
	High	0.6924 (0.594)	−3.9198 (2.586)
Constant		0.9367 (0.981)	6.6108*** (2.508)
SD			
Direct cost		0.0039 (0.291)	
Walking distance		0.0039 (0.181)	
Antimalarial drug availability		1.1833 (1.358)	
Economic status	Middle	2.5479* (1.543)	0.0603 (1.964)
	High	0.0170 (2.680)	4.2573 (2.903)
Sample size		210	
Log likelihood		−148.98	
Pseudo R2		0.3280	

Self-care is the base alternative. Numbers in parentheses are SEs.
*Direct cost includes treatment cost and travel cost. Economic status is categorized into three based on asset index (see **Figure 1**).*
VHV, village health volunteer.
****p < 0.01.*
***p < 0.05.*
**p < 0.1.*

0.664 from the average choice probability calculated from the sample enumeration (0.207). The probabilities rapidly declined to 0.442, 0.322, 0.215, and 0.132 as the direct cost changed by Kina 2, 3, 4, and 5, respectively (**Figure 2B**). The probability declined to <0.01 when its direct cost was higher than Kina 8.5. Given an increase in the direct cost of the health center, both the choice probability of self-care and that of VHV considerably increased from 0.181 to 0.541 and from 0.155 to 0.459, respectively. Thus, given a change in the direct cost of the health center from 0 to Kina 5, the own arc elasticity was −1.339 and the cross arc elasticities of self-care and VHV were 0.895 and 0.872, respectively (**Table 3**).

As the walking distance to VHV increased, the choice probability of the VHV declined (**Figure 2C**). The probability was 0.448 with no walking distance and decreased to 0.358 at 1 km, 0.278 at 2 km, 0.209 at 3 km, and 0.109 at 5 km. The probability was <0.01 for distances longer than 10.9 km. Given an increase in the walking distance to the VHV, the choice probability of self-care substantially increased from 0.357 to 0.733, but the choice probability of the health center slightly increased from 0.195 to 0.267. Consequently, given a change in the walking distance from 0 to 5 km, the own arc elasticity of VHV was −1.217 and the cross arc elasticities of self-care and the health center were 0.563 and 0.263, respectively (**Table 3**).

As shown in **Figure 2D**, the choice probability of the health center declined as the walking distance from the health center increased. This probability was 0.432 with no distance and decreased to 0.357 at 2 km, 0.219 at 5 km, and 0.100 at 8 km. The probability declined to <0.01 for distances longer than 13.8 km. As the walking distance to the health center increased, the choice probability of self-care and VHV increased from 0.295 to 0.541 and from 0.273 to 0.459, respectively. Given a change in the walking distance from 0 to 5 km, the own arc elasticity of the health center was −0.655 and the cross arc elasticities of self-care and VHV were 0.348 and 0.281, respectively (**Table 3**).

Given a sufficiently large value of direct cost of VHV or walking distance of VHV, we can consider that all VHVs are neither affordable nor accessible. At that time, the average choice probabilities of self-care and the health center were 0.733 and 0.267, respectively (**Figures 2A,C**).

We calculated the average choice probabilities of a change in two dummy variables: antimalarial drug availability and illness severity (**Table 4**). The probability of VHV choice slightly increased to 0.427 when drugs were available at all VHVs. Instead, the choice probability of VHV markedly decreased to 0.188 when no drugs were available at all VHVs. Given a change in the drug availability of VHV, the choice probability of self-care and the health center increased from 0.390 to 0.575 and from 0.183 to 0.237, respectively. When no drugs were available at the health center, the choice probability of the health center decreased to 0.100, and that of self-care and VHV increased to 0.485 and 0.415, respectively.

When all patients had a mild symptom, the choice probabilities of self-care, VHV, and the health center were 0.510, 0.334, and 0.156, respectively. In contrast, the choice probabilities of self-care, VHV, and the health center changed to 0.265, 0.425, and 0.311, respectively, when all individuals were moderate or severe patients.

DISCUSSION

This study had the following four main findings related to choosing healthcare providers for febrile children. (a) Direct cost was a negative significant determinant of the choice of both a VHV and the health center, (b) the choice probability of both a VHV and the health center significantly declined as the walking distance from them increased, (c) drug availability significantly increased the probability of VHV utilization, and (d) illness severity was another significant determinant of the choice of both a VHV and the health center.

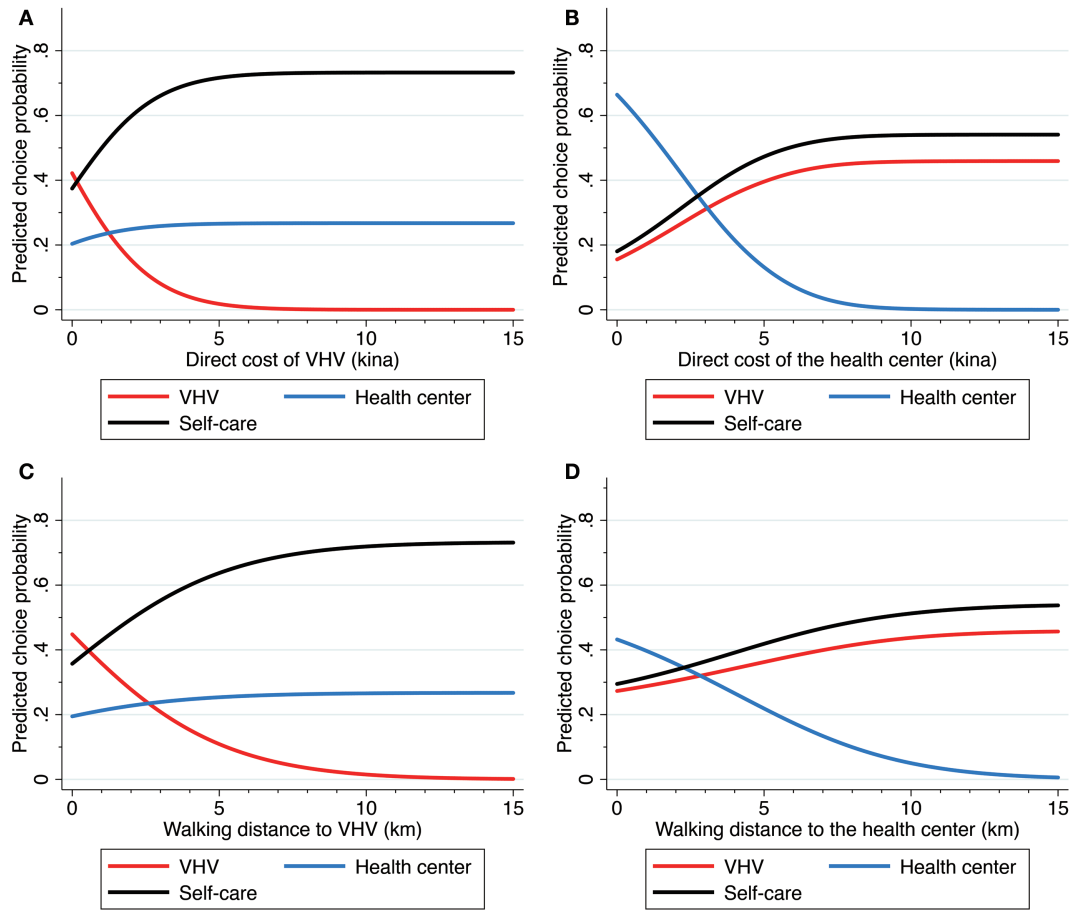

FIGURE 2 | (A) shows the choice probabilities of the three alternatives for a change in the direct cost of village health volunteer (VHV). **(B)** shows the choice probabilities of the three alternatives for a change in the direct cost of the health center. **(C)** shows the choice probabilities of the three alternatives for a change in the walking distance to VHV. **(D)** shows the choice probabilities of the three alternatives for a change in the walking distance to the health center. Direct cost includes treatment cost and travel cost. The unit of direct cost is in Papua New Guinean Kina (Kina 1 = USD 0.48 in 2011).

TABLE 3 | Arc elasticities of healthcare provider choice.

Variable changed	Arc elasticity		
	Self-care	VHV	Health center
Direct cost of VHV (0–Kina 5)	0.627	−1.836	0.264
Direct cost of health center (0–Kina 5)	0.895	0.872	−1.339
Walking distance of VHV (0–5 km)	0.563	−1.217	0.263
Walking distance of health center (0–5 km)	0.348	0.281	−0.655

Values in parentheses are a unit of a variable changed. Direct cost includes treatment cost and travel cost. Kina 1 = USD 0.48 in 2011.
VHV, village health volunteer.

TABLE 4 | Predicted probabilities of healthcare provider choice regarding a change of antimalarial drug availability or illness severity.

	Predicted probability		
	Self-care	VHV	Health center
Average (sample enumeration)	0.428	0.366	0.207
Antimalarial drug availability			
Not available at all the VHVs	0.575	0.188	0.237
Available at all the VHVs	0.390	0.427	0.183
Not available at the health center	0.485	0.415	0.100
Illness severity			
Mild for all the patients	0.510	0.334	0.156
Moderate or severe for all the patients	0.265	0.425	0.311

VHV, village health volunteer.

Previous studies have used subgroup analysis to indicate that the price elasticity of healthcare demand for children is higher than that for adults (11, 16, 27). Some studies have also indicated high price elasticities of demand for child healthcare (11, 16), a finding that is compatible with our finding of the negative effect of direct cost on demand for healthcare for febrile children.

Our study using adequate econometric model with well-controlled variables confirmed the importance of the effect of walking distance on healthcare demand suggested by previous

studies in PNG (18–20). We also show that the effect of direct cost as well as walking distance on utilization of VHV is larger than that of the health center based on the magnitude of own elasticities (**Table 3**).

Regarding an increase in the VHV user fee, demand for the health center does not increase much compared with the significant increase in demand for self-care (**Figure 2A**). Instead, given an increase in the direct cost of the health center, the cross elasticity of VHV is similar to that of self-care (**Figure 2B**, **Table 3**). In addition, a similar substitutional relationship was found between self-care choice and VHV use when walking distance changed (**Figures 2C,D**). These results suggest that a higher substitutability exists between VHV and self-care than between VHV and the health center given a change in the direct cost or walking distance. Thus, the introduction of a VHV can draw substantial demand shift from self-care to VHV, but lead to slight reduction of the health center demand. We estimated VHV demand under the condition of unaffordability or inaccessibility, which may be considered as approximative conditions of the pre-introduction of VHV. In this case, the predicted probabilities of self-care and the health center are estimated to decrease from 0.733 to 0.428 and from 0.267 to 0.207 before and after the introduction of a VHV. Consequently, we speculate that the introduction of a VHV leads to incremental healthcare demand, which is equivalent to the decrease in the self-care probability (0.305), by drawing on the demand shift from self-care to VHV.

Caretakers with a child suffering from a more severe illness are expected to seek higher quality health services. As expected, the more severe the condition of the child as perceived by caretakers, the more frequently they visited healthcare providers, a finding that is in line with that of previous studies (13, 14). The anticipated association between drug availability from the VHV and utilization of a VHV concurs with previous reports (12, 31).

A previous study in Kenya reported negative effect of antimalarial drug availability on health demand (32). They speculated that the lack of antimalarial drugs may be evidence of high demand of health facilities. Another empirical study found positive association between drug availability and health demand (33). Our study suggests that drug availability positively impacts the choice of healthcare provider.

If healthcare provider choice is wealth elastic, rich caretakers are expected to be more likely to use the health center because its average direct cost is the highest among the three alternatives. In contrast, the study result indicates that higher economic status decreases the use of the health center. This phenomenon occurs partly because the significant determinant of the choice of the health could not be the direct cost but time cost for individuals with higher economic status. Additionally, children with higher economic status may have better general health status (34), suggesting that their caretakers are not motivated to use healthcare that has a high time cost.

A caretaker with a higher education was more likely to treat a child with self-care. This result is in accordance with that reported by Levin et al. (35) – who believe that with regard to self-care, educated caretakers are more confident than less educated ones. Another possibility is that the positive association between parental educational level and health status of children (34, 36) may relate to a lower need to use health facilities by children of highly educated parents.

In some developing countries, the female gender has fewer possibilities of obtaining health services, which is considered to be due to a reflection of gender inequalities (37–39). Similarly, qualitative research on PNG reveals that adult females are less likely to access health services because of gender discrimination (40). In contrast to these studies, our result that caretakers made fewer visits to health facilities for male children is in accordance with the result from a study on outpatient demand (41). A study in PNG using household expenditure data reported gender disparity in children, i.e., a preference for boys (42). Insufficient care for female children may lead to a lower health status of female children, including high risk of malnutrition, which is reported to occur in PNG (43). Therefore, caretakers may understand that a female's vulnerability is derived from a lower health status, causing greater use of healthcare providers when female children are ill, as speculated in a previous study (41).

Direct cost of a VHV equaled to its user treatment fee because its travel cost was free in the study area. As shown in **Figure 2A**, even a small amount of use fee, such as USD 1, can considerably decrease the chance of VHV utilization. Since the introduction of a user fee seems questionable, allocations from the government's budget are required to sustain VHV activities. We believe that an appropriate drug supply is significant to the choice of VHV. In addition, constructing a referral system is important for the management of severe illness as well as treatment for prevention of *vivax* malaria – i.e., administration of primaquine, which is prohibited for the VHV in PNG. The government should attempt to expand referral health facilities to reduce travel cost for communities far from an existing health center to overcome the barrier of access to a referral health facility. Reactivating closed aid posts could be a solution.

Our study has several limitations. First, the external validity of this study was limited because it was conducted in a catchment area of a health center with a limited number of illness episodes. The results cannot be generalized to other areas in which VHVs were introduced. The second problem is an omitted variable. Transportation distance, a proxy of the time cost of transportation, could not be included in the model because of the high correlation between direct cost and transportation distance. Considering the fact that a vital portion of the direct cost of the health center is transportation, the estimated high price sensitivity regarding the choice of the health center is overestimated, and we should interpret the value as the effect of a mix of the price and the time cost of transportation. Third, we must consider that caretakers may not receive proper information on drug availability, although we used actual drug availability data of the VHV and assumed that caretakers had information on the true availability of drugs. This uncertainty of the information that caretakers did or did not have could bias the results. Fourth, self-reported episodes could be subject to a recall bias, though we used shorter 2-week recall period compared to a 4-week recall period used in the previous study in PNG (20).

Despite these limitations, to our knowledge, this is the first study to explore households' affordability as well as accessibility

of healthcare services in PNG and develop a discrete choice model including an alternative for a VHV, a non-professional health worker for distributing essential drugs. Unlike many African and Southeast Asian countries where OTC drugs for fever treatment are commonly available, possible alternatives were limited in our setting, permitting a simple estimation of models and an interpretation of the results. We hope that further investigation will be performed under the setting with non-professional health workers in other areas with adequate econometric models.

AUTHOR CONTRIBUTIONS

TT conceived the study, designed the study, conducted the data collection, performed the econometric analysis, wrote the first draft of the manuscript, and completed the final version. HE participated in the study design. MS, TF, NK, TM, and FH participated in the study design and conducted the data collection. SO and TS interpreted the data and revised the draft. All authors read and approved the final draft.

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Growing burden of non-communicable diseases in the emerging health markets: the case of BRICS

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Historical Perspective on Non-Communicable Diseases Worldwide

The blooming of incidence and prevalence of "prosperity diseases" among the broad layers of modern day populations is rather novel phenomenon in demographic history of the human race (1). Illnesses such as obesity (2), diabetes mellitus, hypertension, cerebrovascular and cardiovascular consequences of atherosclerosis, renal insufficiency, mental disorders, and even cancer are closely related to the increased longevity of most contemporary societies (3). In previous centuries, they were mostly reserved for elite social groups enjoying rather luxurious life style. Vast majority of citizens of the time were living in rural communities on the verge of poverty. Their structure of morbidity even in Europe until late 19th century was dominated by burden of infectious diseases and injury while neonatal and maternal mortality rates were huge. Industrial revolution led to the growth of living standards, invention of vaccines, and antibiotics, and ultimately development of organized publicly funded health systems. The prominent European health policy makers in the 19th century properly believed that effective public health measures will diminish huge burden of infectious diseases. Consecutively, they expected that overall costs of medical care provision should decrease substantially and ultimately reach plateau level. This second step turned out to be a great miscalculation and a surprise. Like no time in written past, people began living longer and healthier lives. But it happened at the cost. Simultaneously, from many industrialized nations, evidence were accumulating of accelerated occurrence of non-communicable diseases. Accomplishment of evidence-based medicine succeeded to control many of these initially incurable diseases, thereby transforming them into life time disorders as in the typical cases of diabetes and terminal renal insufficiency. Acute bacterial infections, dominating morbidity in the old days, were usually successfully treated within few weeks. Unlike these, chronic illnesses were bringing long-term burden for both the patients and the society. Malignant disorders with its complex treatment strategies present particularly demanding medical conditions. Cancer leaves permanent footprint in a life of a patient in terms of poor survival rates, decreased life quality, and working ability.

Non-Communicable Diseases Expansion in Developing Countries

The ultimate demographic transition consisting of ascending portion of elderly, falling fertility rates, and bold growth of median age within contemporary nations became broadly recognized as population aging (4). Most of this transformation of morbidity and mortality structure happened

in rich industrial countries of Western Europe, North America, and Japan many decades ago. The same pattern of population aging associated with huge incidence and prevalence rates of major non-communicable diseases repeated on wider scale much later in developing countries. The worldwide transformation of public health landscape to the large extent is attributable to the accelerated pace of globalization after the end of Cold War era (5). Particularly interesting, current developments belong to the economies responsible for most of global growth that are recognized as the emerging markets. The countries whose reshaped structure of morbidity is most likely to affect global health in the future are definitely the BRICS [Brazil (6), Russia, India, China, South Africa] (7). BRICS's far extended long-term influence in health arena worldwide will be related to their mammoth sized populations. Their increased domestic demand for medical technologies and medicines is already shaping investment strategies of major pharmaceutical and medicinal device industries. Another significant issue is their bold foreign medical assistance programs particularly targeted for emerging markets of Sudanese Africa, Latin America, Central and South East Asia (8). These leading countries are closely followed by a set of smaller scale economies mostly marked as N-11 (Bangladesh, Egypt, Indonesia, Iran, South Korea, Mexico, Nigeria, Pakistan, the Philippines, Turkey, and Vietnam) (9). Very similar process is simultaneously taking place in dynamically developing Southern (10) and South-East Asian (11), Latin American, Eastern European (12), and Arab speaking MENA region (13). Eradication of poverty currently taking place in these regions is coupled with changed dietary habits (14) (higher salt and fat and lower carbohydrate intake), wide spread tobacco abuse, and sedentary life styles (15). The mentioned factors contributing to the growing burden of non-communicable diseases. It became obvious that contribution of emerging markets and Third World countries to the global economic burden of NCDs will grow further. It will, highly, likely, soon have greater share than the one of established mature market economies (16). As basic assumption of most forecasts remains the fact that such growth will be dominated by developments in China (17) and India (18). High toll of this unfortunate change for developing countries is coupled impact of communicable and non-communicable diseases (19). At the same time, many national health systems throughout Asia and beyond expose poor responsiveness to the NCDs related population needs. There seems to be serious barriers in access to medical care and its affordability to the ordinary citizens.

The increasing awareness on approaching of almost unbearable burden of NCDs (20) led to the high profile United Nations meeting on the subject in 2011 (21). Such UN gatherings are so uncommon on health related topics that it happened only once in past due to AIDS. NCDs recognized as the core global health challenges were cardiovascular disorders, cancer, diabetes, and chronic respiratory illness. These changes are beginning to profoundly change the landscape of even the poorest countries around the globe. So far, NCDs have already overarched burden of infectious diseases and injury in terms of disability adjusted life years, as well as work load and economic burden to the most national health sectors (22).

Promising Cost-Effective Solutions for the Future

The blossoming of prosperity disease did not happen suddenly. It was a consequence of long chain of evolutionary events in civil society development. We will mention only some of them such as technological revolution, improved housing conditions, sanitation and sewage disposal, public health successes in eradication of major infectious diseases, policy efforts to tackle hunger and starvation among the world's poor, and ultimately tobacco (23) and alcohol abuse (24). As its preconditions took so long to be created, it is unlikely that we shall be able to tackle NCD's burden effectively in near future. Rich countries as well as developing ones concluded that orchestrated efforts will be needed in the international arena. World Health Organization has adopted a package of measures, whose implementation and progress are being monitored (25), broadly known as "Global coordination mechanisms on NCDs" (26). As most cost-effective and feasible measures were identified, control of tobacco consumption to the targeted 5% consumers worldwide until 2025 and reduction of salt intake by general populations of at least 15% in the order of significance. These interventions that were named "best buy" solutions offering best attainable compromise between the need for investment and outcomes that will be gained (27). Promotion of active life style and healthy diet, as well as other preventive and screening measures, comes at the second place. If such efforts are followed closely by national authorities, WHO expects that these measures should achieve 25% reduction of NCD attributable premature mortality until 2025 (28). Many of the proposed strategies were previously tested within a sound methodological framework applied on a second largest emerging market of the America, Mexico (29).

The most challenging issue for the emerging markets' health systems appears to be universal health coverage (30). These systems were built up on diverse historical legacies and should find each one its own way to handle the upcoming pressure of prosperity diseases coupled with accelerated population aging. Profound transformation of current network of medical facilities in Third World countries, as well as human capacity building, will be forced to move priority from acute care toward complex, chronic illnesses (31).

Growing Burden of NCDs Coincided with Increasing Health Expenditures

As witnessed by current WHO estimates given in **Table 1**, we may see that overall burden of non-communicable disease has consolidated in some countries such as Russia recording even slight decrease over the past decade. Nevertheless, leading emerging markets of China and India followed by a large distance in absolute terms by Brazil and South Africa exhibited clear pattern of increasing burden of NCDs expressed in terms of Years of Life Lost, Years Lost due to Disability, and Disability-Adjusted Life Year (DALY). According to WHO, NCDs attributable mortality increased substantially among the same four countries with notable promising exception of Russia. Russian partial success

TABLE 1 | Non-communicable diseases burden-related indicators; WHO estimates for BRICS in 2000 and 2012; total health expenditure and out-of-pocket health expenditure in terms of current international $ purchase power parity basis (source: Global Health Expenditure Database).

	Brazil		Russian federation		India		China		South Africa	
	2000	2012	2000	2012	2000	2012	2000	2012	2000	2012
Population (millions)	174.5	198.6	146.8	143.2	1,042.3	1,236.7	1,287.7	1,384.8	44.8	52.4
Years of Life Lost [YLL (′000)]*	22,532	24,915	44,566	40,597	150,751	175,435	165,905	186,591	5,534	7,398
Years Lost due to Disability [YLD (′000)]**	14,600	18,077	16,586	16,206	78,150	96,886	84,450	99,877	3,436	4,233
Disability-Adjusted Life Year [DALY (′000)]***	37,132	42,992	61,152	56,803	228,901	272,321	250,355	286,468	8,970	11,631
Estimated deaths (′000) NCDs caused, both sexes	777	978	1,819	1,801	4,579	5,869	6,839	8,577	176	264
Total expenditure on health (in million current $ PPP)	$87,681	$220,240	$54,200	$211,008	$68,816	$193,969	$138,131	$664,644	$24,728	$51,458
Out of pocket expenditure (in million current $PPP)	$33,277	$68,168	$16,242	$72,417	$46,771	$111,673	$81,469	$228,245	$3,227	$3,695

**WHO estimated Years of Life Lost (YLL) due to premature mortality NCDs caused, both sexes (′000).*
***WHO estimated Years Lost due to Disability (YLD) for people living with NCDs or its consequences (′000).*
****WHO estimated Disability-Adjusted Life Year (DALY) NCDs caused, both sexes (′000).*

in containing but not decreasing toll of prosperity diseases over 2000–2012 observation period might be attributable to the strong public health legacy of Soviet era as well as reform policies implemented in recent past (32). The rates of hospital discharges increased substantially in the emerging markets across the globe following the increased presence of NCDs in the overall morbidity and mortality structure. This was mainly the case with clinical admissions that could be attributed to the malignant disorders (33) and circulatory diseases (34), followed by chronic obstructive pulmonary diseases (35) and diabetes (36). National level spending on medicines indicated to treat these conditions followed at the same pace, so entire regional pharmaceutical markets adjusted to these changes as was the case in South Eastern Europe (37). Extensive presence of chronic prosperity illnesses supported stronger demand for medical imaging (38), laboratory testing (39), outpatient visits, prescription and dispensing of novel pharmaceuticals (40), surgical, radiation oncology (41), and rehabilitation services. These phenomena were relying on strengthened civil expectations for advanced medical technologies supported by growing living standards and domestic consumption in BRICS markets. If we take into account serious challenge of home-based care for the disabled and growing portion of elderly citizens with special needs, bold growth of national health expenditures should have been predicted (42). China is absolutely leading in terms of purchase power parity of its health spending. Huge lag of all other major emerging economies behind People's Republic of China is most obvious when compared to the India, rapidly developing nation of a similar population size.

Catastrophic household expenditure presents particularly crucial issue throughout the countries of Sudanese Africa with very low incomes, whose medical care is dominantly supported by out-of-pocket spending (43). This happens due to absence of strong national health insurance funds whose revenues would come out of mandatory taxation supported by governmental and external financial sources. Huge, occasionally sevenfold growth of out-of-patient expenditure is clearly visible among the top BRICS markets. Such socioeconomic vulnerability seriously affects the poor members of the community. This might be the crucial issue for long-term affordability (44) of medical care to the ordinary citizens because almost all of the emerging markets own massive rural populations. Urbanization process, which began in Europe in 18th century, is still rapidly evolving throughout Asia, Africa, and Latin America (45). Extensive development of medical facilities network covering remote areas will remain one of the key difficulties for national governments. This is worsened by inevitable concentration of most professional staff in large cities with much more rewarding personal career opportunities. The primary goal for the future of these health systems wiil be provision of accessible medical care. It should have decent quality supported by universal health insurance coverage and full reimbursement of at least essential medicines. The speed of economic growth, political stability, and effectiveness of health reforms remain highly diverse among the top 20 emerging markets. Some global forecasting agencies as well as international financial organizations were pointing out that some smaller scale N-11 economies were top performers on some criteria. Nevertheless, the prevailing consensus is that BRICS (46) health care markets will inevitably outpace all others and remain well ahead of their competition shaping the global health challenges in the first half of 21st century.

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Estimating the fiscal effects of public pharmaceutical expenditure reduction in Greece

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The purpose of the present study is to estimate the impact of pharmaceutical spending reduction on public revenue, based on data from the national health accounts as well as on reports of Greece's organizations. The methodology of the analysis is structured in two basic parts. The first part presents the urgency for rapid cutbacks on public pharmaceutical costs due to the financial crisis and provides a conceptual framework for the contribution of the Greek pharmaceutical branch to the country's economy. In the second part, we perform a quantitative analysis for the estimation of multiplier effects of public pharmaceutical expenditure reduction on main revenue sources, such as taxes and social contributions. We also fit projection models with multipliers as regressands for the evaluation of the efficiency of the particular fiscal measure in the short run. According to the results, nearly half of the gains from the measure's application is offset by financially equivalent decreases in the government's revenue, i.e., losses in tax revenues and social security contributions alone, not considering any other direct or indirect costs. The findings of multipliers' high value and increasing short-term trend imply the measure's inefficiency henceforward and signal the risk of vicious circles that will provoke the economy's deprivation of useful resources.

Keywords: public pharmaceutical expenditure, fiscal consolidation, multipliers, unemployment, Greece, revenue

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Introduction

Detecting sources of vulnerability in the economy timely, especially in unstable financial conditions, is a rational act keyed to the design of sound government fiscal policies on the basis of well-reasoned decisions. The process of dissolving uncertainty requires the analytical study of national account data and economic flows and can be strengthened through the use of fiscal statistics tools [see Government Finance Statistics Manual 2001 (1)].

Abbreviations: DT, direct taxes; PPE, public pharmaceutical expenditure; PR, revenue; RL, revenue losses, SSC, social security contributions; TRL, total revenue losses; UB, unemployment benefits; VATL, value added tax losses.

The Greek Government, in order to deal with the dramatic economic fluctuations caused by the global financial crisis (2), proceeded to a great number of fiscal policies in comparison with the other European Union (EU) member states (3). The drastic adjustment of Greece's economy to the macroeconomic fluctuations and stresses was designed with a view to cutting public spending, rather than raising revenues (4, 5) and, as in many EU countries, hinged to a great extent on reforms of the health sector (6–8). Thus, a series of measures were implemented, including, among others, health workforce downsizing, the reduction in fees paid to health providers, the lowering of pharmaceutical prices, and the setting of pharmaceutical budget equal to a fixed share of the gross domestic product (GDP) (as presented in paragraph 2.1.1.2).

The impact of many of these interventions on the real Greek economy remains unexplored, forming a novel field of applied fiscal statistics which the present work attempts to deal with. It focuses on a pharmaceutical policy intervention with tangible accounting outcomes and *de jure* dependence on economic growth indices (as explained in the following paragraphs), aiming to address a particular angle of the sensitive topic of restrictive healthcare policies' financial effects on the real economy's flows.

Materials and Methods

Problem Formulation: Conceptual Framework

Curtailing Public Pharmaceutical Expenditure in Greece: A Fiscal Consolidation Strategy

Urgency of measures

Upon the advent of the financial crisis in 2008, Greece was already placed at a disadvantaged financial situation due to its high general government gross debt, the highest among EU countries[1]. From 2008 to 2013, the Greek economy suffered a sharp shrinkage: the GDP with a year-on-year fall of up to 7% (**Figure 1**) fell by 22% over the same period (in per capita terms)[2] and about one-fifth of the aggregate production was lost [reaching even 2/3 in specific economy sectors, such as the Structure (9)]. Private investments and consumption were reduced by €27.4 and €16.3 bn (or 17.6 and 9.1%), respectively (9), whereas unemployment climbed to 27.4% (first quarter of 2013) from 7.6%, affecting mostly young people and women. The prolonged election period (May–June 2012) deteriorated further the business expectations and consumers' confidence (10, 11).

In Greece, small deviations from the bottom of the recession were observed from the fourth quarter of 2012 onward, driven mostly by the negotiation with the European Commission (EC), the European Central Bank (ECB) and the International Monetary Fund (IMF), the materialization of commitments on the basis of the Memorandum of Understanding (MoU) and the Memorandum of Economic and Financial Policies, and the withdrawal of €34.4 bn from the support mechanism (10).

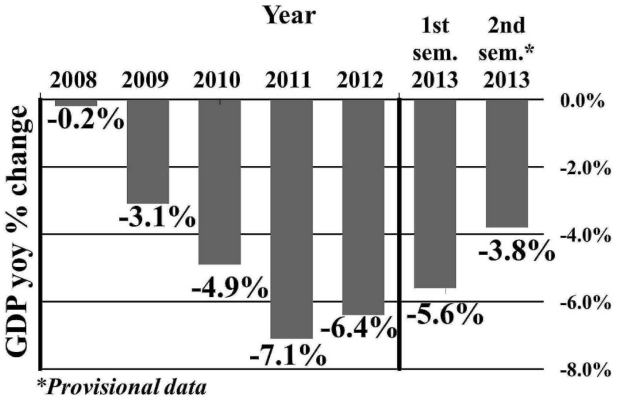

FIGURE 1 | GDP year-on-year changes in Greece (2008–2013).

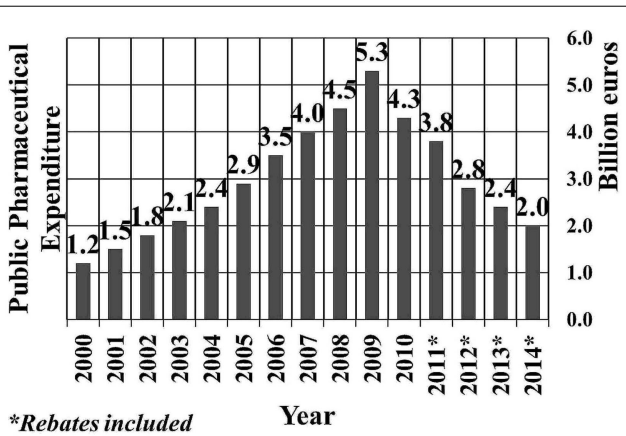

FIGURE 2 | Public pharmaceutical expenditure of Greece (2000–2014).

The fiscal consolidation strategy of 2014 entailed the application of measures for debt reduction to 174.8%, for primary surplus 1.6%, and for growth 0.6% of the GDP[3].

All economies deal with finite resources, the allocation of which determines the selection among competing strategies and interventions (12). However in the case of Greece, under the IMF loan conditions (13) and according to the MoU, specific economic sectors, such as healthcare, were identified early on, as fields of immediate intervention for fiscal consolidation (14, 15). Public pharmaceutical expenditure (PPE) in particular, having exhibited a sharp expansion in the pre-crisis period (**Figure 2**), became the capping stone of the country's effort for a rapid cost-containment in healthcare.

Regulatory framework

Since 2010, a significant number of measures have been implemented for the restriction of excess public pharmaceutical expenditure which stemmed from the over-prescription of branded

[1]Eurostat. General government gross debt – annual data. Available from: http://ec.europa.eu/eurostat/tgm/refreshTableAction.do?tab=table&plugin=1&pcode=teina225&language=en. Accessed 22 February 2015.

[2]Based on the authors' calculations. Source of data: Eurostat. Available from: http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tec00114&plugin=1. Accessed 16 June 2015.

[3]Source: Ministry of Finance, State Budget 2014. Available from: http://www.minfin.gr/?q=el/content/%CE%BA%CF%81%CE%B1%CF%84%CE%B9%CE%BA%CF%8C%CF%82-%CF%80%CF%81%CE%BF%CF%8B%CF%80%CE%BF%CE%BB%CE%BF%CE%B3%CE%B9%CF%83%CE%BC%CF%8C%CF%82-2014-0

drugs (16). These measures focused on the demand (e.g., generics prescribing, development of therapeutic protocols, etc.) or the supply side (e.g., reimbursement lists for pharmaceuticals, external reference pricing, etc.) of the pharmaceutical market (17).

In 2012, a mechanism referred to as *clawback,* for the automatic refund of amounts that excess the state's public pharmaceutical expenditure budget is instituted by law (laws 4052 and 4093, g.g. A41 and A222, respectively[4]). Following a ministerial decree (g.g. B2243/2014[4]), the ceiling for pubic pharmaceutical expenditure is specified at 1% of the country's GDP, which is applicable as from 2014.

Accounting and employment outcomes

Over the years 2009–2013, public pharmaceutical expenditure has been reduced by €2.7 bn (or 50%) (**Figure 2**), which corresponds to 11% of the total amount of reduction of aggregate public expenditure (that is, €24.9 bn) (18). At the same time, according to the Vocational Insurance Fund of pharmaceutical corporations' employees, the workforce of the medicine branch (corporations and pharmacies) was reduced from 31,100 to 21,500, that is, by 30.9%, yielding a loss of 3.5 job positions for each million cut [i.e., (21,500–31,100)/2,740].

Contribution of the Pharmaceutical Branch to the Greek Economy

The present section draws on published data of Greek organizations offering an overview of the pharmaceutical sector[5].

Public pharmaceutical expenditure (PPE) is a basic component of the country's economy. In per capita terms, it consists around 44% of the public health expenditure[6] and 1.9% of GDP (2011) (19).

Considering production value, extroversion, and impact on other sectors of the economy (externalities), the pharmaceutical sector, represents one of the most dynamic sectors of the Greek economy, including 421 pharmaceutical marketing authorization holders, 124 pharmaceutical wholesalers, and 11,315 pharmacies.

In terms of gross value added, the pharmaceutical sector has followed an upward trend in the past decade, reaching 9.6% of total manufacturing production, which represents one of the highest rates in the EU, after Slovenia (12.7%) and Denmark (10.4%). Indeed, during the period 2000–2010, the industry not only increased the percentage of manufacturing production in Greece, but also presented the highest average annual increase in the gross value added among EU countries (by about 7%, from 2.7% in 2000 to 9.6% in 2010). In 2010, the production and marketing of pharmaceutical products contributed to the Greek economy by €7.5 bn which corresponds to 3.4% of the GDP. Furthermore, the industry has invested significant amounts on research and development over time (for instance, €85 and €88 million in 2011 and 2012, respectively).

In terms of employment, only within a year (2010), 132,787 jobs were offered, while total tax revenues from the pharmaceutical sector amounted to €400.9 million. Exports of pharmaceutical products had the fourth largest share in total manufacture exports (6% on average over the years 2000–2010), with the largest percentage of exports being directed to the EU member states. High levels of demand have also been generated on behalf of South Africa, Turkey, Switzerland, and Brazil.

Another area of contribution of the pharmaceutical sector to the Greek economy is that of public debt management, through the settlement of outstanding debts via the bond market and the maturity of public obligations toward pharmaceutical companies (law 4046, g.g. A28/2012 and article 12 of law 4052, g.g. A41/2012 as revised by law 4093, g.g. A222/2012[7]).

The pharmaceutical sector has additionally exerted a considerable impact on the function of other sectors, such as Advertising, which in recent years has suffered a sharp decline of its total turnover. Total advertising costs of the pharmaceutical sector are estimated at €35–€41 million (data on 2012 and 2011, respectively).

Scope

Objectives

Considering the economy's ongoing shrinkage due to the economic crisis, the issue of applying a health measure that depends on the GDP is challenging. In this respect, the present study attempts to assess the impact of setting public pharmaceutical economy equal to a small share of the (gradually diminishing) GDP on the Greek economy.

In particular, the impact is assessed in terms of the losses in taxes and social security contributions that derive from the reduction of turnover and the increase of unemployment in the pharmaceutical industry and pharmacies. It is worth noting herein that only the direct budgetary impact of reducing public pharmaceutical expenditure is investigated, without considering the potential impact on other sectors or economic consequences, such as the problematic access to treatments due to the ongoing shrinkage of the market (20) and the delays in reimbursement for retail pharmacies (21) as well as the consequent productivity losses related to increase in the length of hospitalization (22, 23) and job absenteeism (24).

Working Assumption

In the context of the present analysis we made the working assumption that as pharmaceutical expenditure decreases, the (negative) impact on public revenue is expected to grow, because, in the early years of the measure's application, the decreases will primarily relate to waste and unnecessary spending.

Quantitative Analysis

We took into consideration the vulnerability of two categories of economic flows. The first corresponds to the annual public cost that is generated by the provision of pharmaceutical care in Greece. The second refers to the net worth resulting from tax collection as dominant share of revenue for government (1), as well as the compulsory transfer of social security contributions.

We developed a calculus for measuring the lost governmental revenues due to the reduction in private and corporate tax

[4]Source: http://www.et.gr. Accessed 16 June 2015.

[5]Institute of Social and Preventive Medicine of Greece (IKPI). The impact of Pharmaceutical Expenditure Reduction on Public Revenues Athens, April 2014

[6]Calculation of the authors. Source: http://dx.doi.org/10.1787/health-data-en; WHO Global Health Expenditure Database data-en.

[7]Source: http://www.et.gr. Accessed 12 April 2015.

amounts and social security contributions [formulas (1)–(1.3)]. Only the direct budgetary impact of the measure is investigated, not taking into consideration the putative impact on other production sectors, as specified earlier.

For the estimation of the effect of the fiscal policy under analysis (namely the PPE curtailment to 1% of the GDP) on the economy, multipliers are used as common quantitative tools. The multiplier is computed dividing cumulative losses of revenues by the observed reduction in the PPE in the time domain 2009–2013 [formula (2)].

We also perform sensitivity analysis for the values of the multipliers. Thresholds of the multiplier are derived by simply leaving indirect taxes (VAT amounts) and unemployment benefits out of the total loss equation [formula (1)].

Finally, three naïve estimating models for the multipliers are fitted to the data, a linear (Eq. 3), an exponential growth (Eq. 4) and a quadratic trend (Eq. 5). Projections on 2015 are performed, using the statistical software Minitab Release 14. The following relationships hold.

$$TRL_{t_n} \equiv \sum_{i=1}^{n} RL_{t_i} = dPR_n + \sum_{i=1}^{n} UB_{t_i} \quad (1)$$

$$dPR_n = PR_{t_0} - PR_{t_n} \quad (1.1)$$

where TRL_{t_n} is the total losses in public revenue between years t_0 and t_n, with $t_n - t_0 = n$, RL_{t_i} is the loss of government revenue in the year t_i, $i = 1, 2, \ldots, n$ from the previous year, UB_{t_i} is the unemployment benefits in year t_i, $i = 1, 2, \ldots, n$, and PR_k is the revenue in the t_k year, $k = 0, 1, 2, \ldots, n$, defined as follows:

$$PR = DT + VATL + SSC \quad (1.2)$$

$$DT = DT_1 + DT_2 \quad (1.3)$$

where DT is the direct taxes, DT_1 is the losses in personal income taxes in year t, DT_2 is the losses in corporate income taxes in year t, VATL is the value added tax losses, i.e., losses in indirect taxes in year t, and SSC is the social security contributions.

$$m_t = \frac{TRL_t}{dPPE_1} \quad (2)$$

where m_t is the value of the multiplier in the year t, TRL_t is the total estimated revenues loss in the year t, and $dPPE_1$ is the size of annual cutting down on PPE between two consecutive years.

$$\hat{m}_t = a + b * t \quad (3)$$

$$\hat{m}_t = c * d^t \quad (4)$$

$$\hat{m}_t = e + f * t + g * t^2 \quad (5)$$

where $\hat{m}_t$ is the estimated value of the multiplier in the year t, and a, b, c, d, e, f, g coefficients with a, b, c, e, f, g $\in R$, d $\in R_+^*$.

Results

Total Losses

Table 1 presents the estimated annual losses in public revenues that are caused by the downsizing of the pharmaceutical market.

Total losses of revenues equal €453 million. Nearly half (41.6%) of these losses are observed in the period 2012–2013.

Since $dPPE_{2013}$ equals €400 million (**Figure 2**) and TRL_{2013} equals €188.5 million (**Table 1**), the multiplier is estimated at 0.47 for the year 2013. Based on this estimation, €100 million of PPE curtailments are expected to generate losses of €47 million in public revenues.

Figure 3 depicts estimations of the multiplier for the period 2009–2013 and combines it with information on public pharmaceutical expenditure and losses in public revenues for the same period.

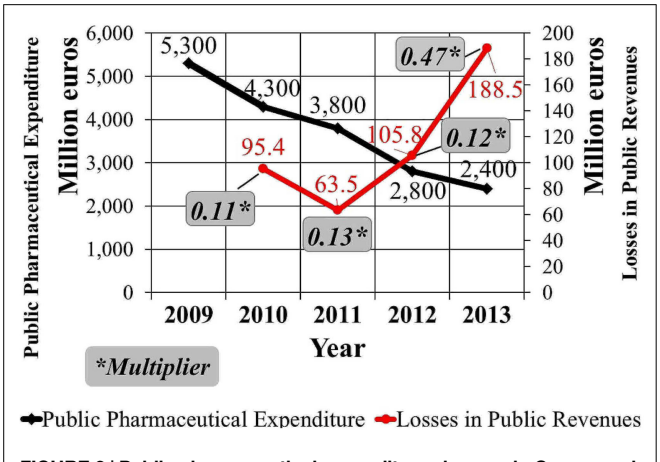

FIGURE 3 | Public pharmaceutical expenditure changes in Greece and the multiplier (2009–2013).

TABLE 1 | Losses per year in government revenues due to the public pharmaceutical expenditure curtailment (2009–2013).

Revenue loss category	Absolute change (in € million)				
	2010–2009	2011–2010	2012–2011	2013–2012	2013–2009
Direct taxes (DT)	73.78	37.68	77.15	75.37	263.98
Indirect taxes (VATL)	2.50	5.27	4.26	17.75	29.79
Social security contributions (SSC)	9.50	20.05	16.21	67.55	113.31
Subtotal-RL	85.78	63.00	97.63	160.67	407.08
Unemployment benefits (UB)	9.58	0.48	8.14	27.78	45.98
Total-TRL	95.36	63.48	105.77	188.45	453.06

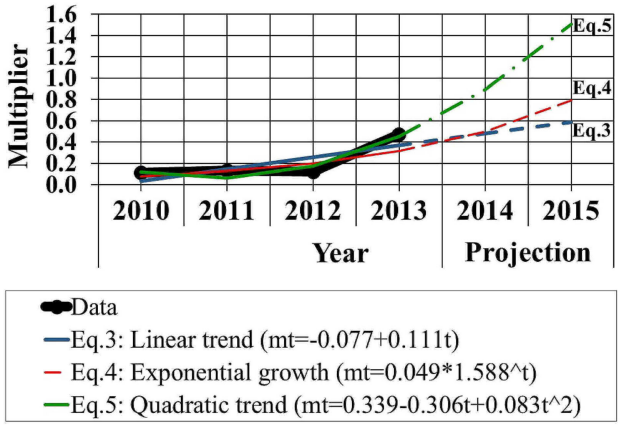

FIGURE 4 | Projection of the multiplier based on linear trend, exponential growth curve, and quadratic trend models.

Sensitivity Analysis

The derived threshold for the estimated multiplier is 0.35 in 2013 meaning that for every €100 million of reduction in the PPE, the losses in public revenues are anticipated to be €35 million at least.

Projections

Results based on Eqs 3–5 are depicted in **Figure 4**. According to the linear and exponential growth trends, the multiplier exceeds 0.5 in 2015, which implies the counterbalance of PPE curtailment by 50% at least. With the quadratic model, the multiplier reaches and exceeds the value 1.0 in 2014 and 2015, respectively.

Discussion

Contribution of the Analysis

Analysts in Greece have substantiated the pharmaceutical sector's contribution to the Greek economy on the basis of its high partial multipliers on GDP (2.43), gross value added (2.56), employment (2.48), as well as tax revenues (1.55), compared to other sectors, such as tourism and shipping[8]. In the context of this analysis, we strengthen the existing theoretical framework focusing on an intervention which was adopted as a suppressive measure of excess public pharmaceutical spending. Instead of studying the gains earned from the pharmaceutical sector, we reverse the problem, by assessing the losses stemming from its exhaustion, which to the notion of the authors is an original approach in the field of pharmaceutical policy.

Analytically, this study deployed a simplistic multiplier-based tool for evaluating the impact of a fiscal measure in the time domain 2010–2013 and further, for estimating its dynamics in the near future. This period is short, yet it isolates the crucial historical (i.e., political and institutional) events that are instrumental for the evolution of public pharmaceutical expenditure, namely the MoU and the country's major healthcare reform (that established electronic prescribing in 2010[9] and integrated the health branches of social security funds into a single health care provider in 2011[10]).

Key Findings

In the present analysis, we highlighted the weaknesses and short-term risks that accompany the restrictions imposed on the state's expenditures for pharmaceutical care. Based on the calculated values of the multiplier, a considerable share (35–47%) of the outcome of pharmaceutical spending cutback is expected to be counterbalanced by the yielded losses in public revenues (taxes and contributions). The multiplier increases sharply to 0.47 in 2013, complying with the working assumption that the application of a restrictive pharmaceutical policy is expected to have a bounded period of efficiency, after which further reductions in PPE shall have repercussions on public revenues and the economy as a whole.

The projection procedure indicated that the effects of the applied measure on the GDP are sizeable enough to make the intervention obsolete in the near future. The linear and the exponential growth approach yielded more conservative and similar results. On the contrary, the quadratic trend model generated a sharp projection beyond the value "1," from 2014 onward. This outcome could be thought of as extreme, yet it is compatible with similar assessments from the literature, regarding government spending multipliers' propensity to increase, reach or exceed the value "1," under certain circumstances, in economic downturns (25).

Conclusion

The pharmaceutical market, an already regulated sector due to the existing external reference pricing system (26), is important for yielding net worth in the Greek economy. Unambiguously, pharmaceutical policies have so far enabled the rationalization of public health expenditures. However, the activation of the clawback mechanism as explained herewith has important side effects, such as the increase of unemployment and the reduction in main sources of public revenue, which undermine the values of solidarity in financing, equity of access, and the provision of high-quality health care (27).

Prospects of Further Analysis

The compilation of healthcare data and the subsequent broadening of time series will allow further development of estimation and forecasting tools. In this context, applying multiplier-based analyses to other areas of health policy intervention is considered a reliable methodological vehicle for taking policy-makers a step forward in evidence-based healthcare decision making.

[8]Foundation for Economic and Industrial Research (IOBE). Economic footprint of production and distribution of pharmaceutical products in the Greek economy. Athens, January 2013.

[9]Law 3982 "Electronic recording and processing of prescriptions and medical examinations," g.g. 189/2010. Available from: http://www.et.gr. Accessed 10 June 2015.

[10]National Organisation for Health Care Services Provision (EOPYY). Law 3918 "Structural reforms of the health system and other provisions," g.g. A31/2011. Available from: http://www.et.gr. Accessed 10 June 2015.

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Changing healthcare policies: implications for income, education, and health disparity

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Introduction

The economic pie has seen growth, despite the recessions of the past decade, and has resulted in an increase in the total income level. At the same time, increasing national healthcare spending due to the high costs of medical research and development paired with a growing and aging population has become prevalent in most nations. Healthcare costs (HCs) are a significant factor that influences the current and future government budget allocations. These HCs are generating major problems for welfare systems in both the short and long term.

Income disparity has become a major issue in the past decade (1–3). Ettner (4) shows that increased income levels improve mental and physical health, and Wildman (5) theoretically proves the relationship between the income differential and health disparity (4, 5). Also, Liu et al. (6) document the health inequality implications of the increasing gap in income and healthcare utilization (6). Apart from income, education also has a positive effect on healthcare consumption and health status (7). Literature shows that increase in education enhances health capital. However, there is no clear discussion on the systematic relationship between the health educational differential and income level with health disparity (8).

This paper demonstrates how health education and income differentials affect health status thus creating health disparity.

Healthcare

Under the government health insurance programs: Medicare, Medicaid, and State Child Health Insurance (SCHIP), which are designed to ameliorate unequal access to healthcare services caused by income inequality, governments tried to initiate programs that caped rising healthcare expenditures. The government partially implemented a policy change that switched from a cost-based reimbursement system, the fee-for-service system (FFS), to a capitation scheme (CS). In the US, there was a private and government oriented mixed financing system that caused the emergence of managed care plans, e.g., HMO, PPO, POS, etc. The policies addressed the efficiency of resource allocation and have decreased expenditures without affecting healthcare services utilization. The FFS payments include co-insurance with deductibles, exclusions and limits on covered benefits, and lifetime spending caps. The CS generally includes co-payments, sometimes with deductibles, and/or spending utilization caps.

The recent economic downturn has caused a sharp decrease in employer-provided health insurance benefits. The U.S. has a mixed healthcare system that has left a large portion of the population uninsured or underinsured. This leads to racial and socioeconomic driven healthcare

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access disparities, which are strongly associated with health outcome inequalities (2). As discussed earlier, the U.S. implements a mixed healthcare system where citizens can receive insurance privately or from the government. Medicaid is provided for low-income individuals by state governments, and Medicare is made available to retired citizens and is financed by the federal government. There are two parts to Medicare benefits: (1) a hospital insurance plan and (2) a physician insurance plan. State governments also fund the SCHIP, which was designed to reduce the number of children without adequate health insurance coverage for low-income families that do not qualify to receive Medicaid.

Theoretical Framework: Diagrammatic Presentation

Assume that a society consists of two identical individuals. One individual's preferences or consumption does not enter another individual's utility function and preferences are not necessarily homothetic. Their demand functions are homogeneous of the degree 0 in income and prices. The relative prices of goods affect their consumption combination through changes in the production mix. The general increase in price level does not change the consumption bundle because of relative pricing. Both individuals produce health and a composite good, and both their income levels vary by health status. The efficient production set is non-linear, and their capital–labor ratios are different. Health as a good is relatively more capital intensive than composite goods. Also, there are no externalities in production.

Focusing on Quadrant I in **Figure 1**, the H(ED1) curve is derived from the marginal rates of transformation of the efficient production sets of Health (H) and composite goods (O), given the level of resources and technology (H/O). Both production functions H and O have constant returns but different capital–labor ratios along a non-linear efficient production set. A relative price of both goods rises along H(ED1) such that the unique price ratio of goods H and O equals the marginal rate of substitution. The H curve becomes vertical at the maximum level of relative consumption of H/O; it is steeper with a larger production of Health relative to the composite good due to the initial capital endowment.

We assume that as a function of H/O, the demand or choice of the combination of health and composite goods in the private sector is affected by a change in the relative prices. For healthcare production efficiency on the EF curve in Quadrant IV, there are two ways to evaluate efficiency: efficient resource allocation and efficiency of technological development to deliver healthcare services. The EF line shows that a decrease in health status, which moves health status from HS2 toward the origin (HS3) on Health Status horizontal line, increases HCs from HC2, HC1 to HC3. Efficiency of healthcare service production in Quadrant IV (EF line), which shows a negative and non-linear relationship between health status (HS) and HCs, does not affect the H/O level.

An increase in health education shifts the H line from H(ED1) to H(ED2) and raises health status from HS1 to HS2. The health educational effect goes from Quadrant VI through to Quadrant III. An increase in health status reduces HCs from HC1 to HC2 and reduces the government subsidy for an individual from GS1

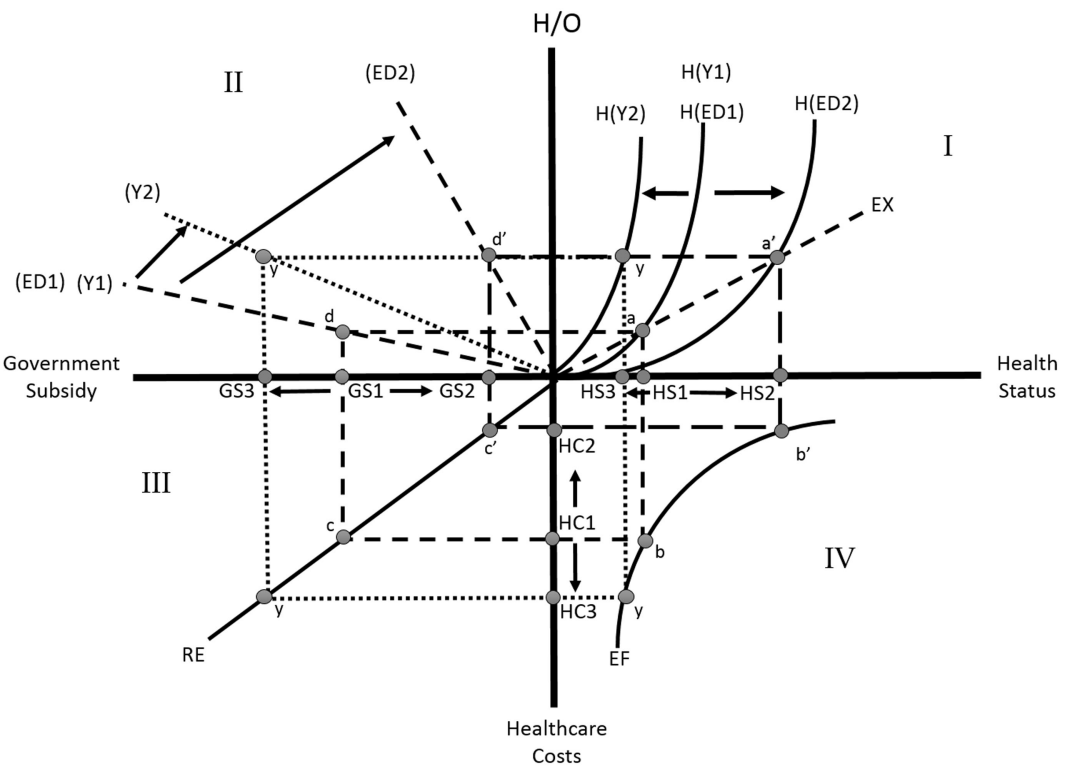

FIGURE 1 | Graphical representation of the effect of income and education on various health disparity indicators.

to GS2 in Quadrant III through the RE. The RE in this quadrant indicates the reimbursement rate of the government to healthcare service providers. A rise in RE rotates this line toward the HC axes thus making it a steeper line.

Quadrant II shows that a more health-educated individual needs less government subsidy. The subsidy correspondingly declines from GS1 to GS2, because people with a higher level of education tend to lead healthier life styles. Better health-educated people utilize health and other market inputs, and their own time to produce a greater health output. An increase in health education, coupled with the improvement in health status and human capital, positively impacts the H/O level from d to d′ in Quadrant II. This increase would greatly benefit the society.

Another critical rationale on **Figure 1**, a decrease in income level would pivot the health status curve H from H(Y1) to H(Y2). Opposite results can be drawn for the EF and RE curves, in Quadrants IV and III, respectively. At the lower health level H(S3) due to a decrease in income H/O will be at y, implying that lower income will induce a lower level of health status. The reduction in income level will tend to decrease the availability/accessibility of healthcare services and in turn lower health stock. Thus, HCs inefficiently rise from HC1 to HC3 along the axis in Quadrant IV, and the government subsidy would rise from G(S1) to G(S3) with given y level of H/O. This situation is analogous to an increase in income tax.

Results and Discussion

The data used in this study are sourced from the Behavioral Risk Factor Surveillance System (BRFSS) of 2013, a collaborative survey administered by every state in the United States. The BRFSS, an ongoing surveillance system designed to measure behavioral risk factors for the non-institutionalized population, is overseen and supported by the Center for Disease Control and Prevention (CDC). Some of the factors tracked by the BRFSS include substance abuse, HIV/AIDS prevention, physical activity, immunization, health status, preventive care, sleep, cholesterol and hypertension awareness and prevention, fruit and vegetable consumption, as well as various socioeconomic information. The original sample contained ~500,000 observations. After careful cleaning and application of age constraints (e.g., 18–64 years old), 24,300 observations remained.

The previous discussion in Theoretical Framework: Diagrammatic Presentation implies an increase in education or health education raises general health, namely health stock, in the long run. This shift in health stock will decrease the use of healthcare services, thus reducing healthcare costs. We used statistics method of ordinary least squares and paired its results with the elasticity concept in health economic theory. We found that a 1% increase in health education will lead to a certain percent increase in healthy days. Our estimation shows a 10% increase in education corresponds to a decrease in poor healthy physical and mental days by 24.3% ($\approx -2.64 \times 4.85/5.27$)10, which is {[coefficient of education × (mean of education/mean of poor healthy days)] × 10}. This shift from HS1 to HS2 is visually depicted in Quadrant I of **Figure 1**. We also evaluated the effect of education on physician visits. An increase in education by 10% lowers physician visits per year by 3.60% ($\approx -8.32 \times 0.22/5.08$)10, which is {[coefficient of physician visits × (mean of education/mean of physician visits)] × 10}. This decrease in physician visits decreases overall HCs, the shift from HC1 to HC2 is shown in Quadrant IV of **Figure 1**.

Both general and health education increases a person's ability to read health information and understand preventative measures, thus increasing health stock (9). The results are consistent with our theoretical hypothesis, which is presented in **Figure 1**. In addition to education, income plays a role in a person's general health. For example in Quadrant I, our study illustrates that a decrease in income by a 10% causes a decrease in mental and physical healthy days from HS1 to HS3 by 13.0% ($\approx -1.23 \times 5.59/5.27$)10, which is {[coefficient of healthy days × (mean of income/mean of healthy days)] × 10}. This income decrease also increases the number of physician visits per year by 12.3% ($\approx 0.112 \times 5.59/5.08$)10, which is {[coefficient of income × (mean of income/mean of physician visits)] × 10}, and is shown in the movement from HC1 to HC3 in Quadrant IV. Estimates show that, in an optimal case, a healthy person visits their physician once or twice per year.

The concentration index [CI] is implemented in this study to measure health inequality (10). The index ranges between 0 and 1. A low index indicates more equality or equal distribution, while a high index indicates more disparity or unequal distribution. Our results show that the financial burden of healthcare falls disproportionately on the unhealthy segment of the population, i.e., health disparity (CI = 0.48). This can be explained by the fact that people with poor health also excessively visit the doctor, as shown in CI of the physician visit sector (CI = 0.26).

As stated previously, health education increases a person's ability to obtain, process, and understand the basic health knowledge and information needed to make appropriate health decisions. Limited health knowledge is an enormous cost burden on government healthcare systems and increases the risk of errors in medication, patient compliance, and treatment.

Healthcare financing has a significant impact on health inequality. Healthcare costs/expenses are major obstacles for healthcare accessibility. It is imperative to develop a public healthcare financing system for the population that promotes equality. A recent increase in healthcare costs can be traced to an increase in access disparity. It is already known that worsening economic factors such as decreasing income are debilitating for the health of population.

The education variable in this study supports the hypothesis that formal and informal health education will lead to a more healthy population in the long run. In the short run, government led preventive care is a viable option that should be explored. It is essential for policy makers to make healthcare more affordable and accessible in order to reduce general healthcare inequality and lessen the overall healthcare-cost burden.

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Can European countries improve sustainability of health care financing through patient cost-sharing?

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Introduction

Rising health care cost and resource constraints confront policy makers with the challenge to ensure the financial sustainability of health care systems, without jeopardizing the main health system objectives. To respond to this challenge, many European countries have introduced patient payments for publicly financed health care services (patient cost-sharing) (1–4). The potential of patient cost-sharing to contribute to the sustainability of the health care system relies on two elements. First, cost-sharing generates additional sources of funding. Hence, through cost-sharing, some of the health care cost might be shifted from public budgets to patients. Second, cost-sharing has the potential to improve efficiency in publicly financed health care, as it is expected that patients, when faced with the price of health care services, reduce the utilization of unnecessary and low-value health care (5, 6). It is also expected that this could slow the growth of health care costs. However, opponents of cost-sharing question the potential of cost-sharing to improve efficiency and instead point to its potentially negative effects on equity in health care. This is documented by evidence, among them the best known is the RAND health insurance experiment (7, 8).

Whether the potential of cost-sharing can be realized without threatening equity and consumers financial protection depends on various context-specific factors as well as on the design of the cost-sharing systems applied by European countries.

Patient Cost-Sharing and Resources Generation

The ability of cost-sharing to generate revenues for the health sector is of particular interest to policy makers in countries with a poorly financed health care systems, where the lack of sufficient resources impedes the provision of health care services with an adequate quality and access. The evidence indicates that in many Central and Eastern European (CEE) countries, cost-sharing is seen primarily as a measure to reduce existing deficits in the underfinanced health care systems (9).

Designing a cost-sharing system, which raises substantial resources, is not a straightforward process and requires data on how consumers react to the change in the price of health care services. Higher charges might provide a greater potential for revenues. Yet, if demand is price sensitive, such cost-sharing system might substantially reduce the utilization of health care services. This limits the revenues generated, and also might adversely affect the population's health status (if consumers forego the use of necessary care). For this reason, policy makers rather opt for cost-sharing to be sufficiently low to assure that the majority of consumers are able to pay the fees while offering even lower or no charges for those who cannot pay or who use health care frequently (10). A review of cost-sharing arrangements for health care services in European countries (1) shows that

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in CEE countries, co-payments (a flat fee) for out-patient visit ranges from approximately 1€ (Bulgaria, Czech Republic) to approximately 3€ (Latvia Estonia for a visit to specialist) (data for 2008–2009). In Western European countries, the fees are higher, yet their contribution to health care financing is still rather marginal, e.g., in Germany, a 10€ charge per first patient visit to the medical doctor in each calendar quarter, which existed till 2013, generated a net revenues of about two billion Euros a year (approximately 1% of public health insurance expenditure) (11). In some European countries (e.g., France, Slovenia), where cost-sharing takes the form of co-insurance and patients pay a percentage of health care cost, a private complementary health insurance, frequently purchased by consumers, takes over the responsibility and covers patients' cost-sharing obligations.

The revenues from cost-sharing might be substantially restricted because of exemptions or compensations for selected population groups and payment limits, which are broadly applied in European countries. For example, in Latvia, due to exemptions (approximately one third of the population is exempted) and payments caps, the revenues from cost-sharing are reduced by half and accounted for 7% of total providers' revenues (12). Although the presence of protection mechanisms, which are intended to diminish adverse equity effects of cost-sharing, deserves credit, their design, and applications leave much to be desired. The evidence indicates that the exemption/reduction mechanisms applied by European countries are not always well-targeted to those who need protection, for example, the criteria for the exemption/reduction includes occupation (e.g., medical professionals or war veterans are entitled) (13). In addition to an inadequate design of protection measures, their implementation sometimes fails in practice, for example, due to a problematic identification of vulnerable groups (e.g., low income individuals) or the complexity of the protection system, which is not transparent for patients and health care providers (14).

Patient Cost-Sharing and Efficiency Improvements

In the well-funded health care systems of Western European countries, patient cost-sharing is often implemented as a measure to increase patient responsibility and thus, for a more efficient use of health care resources. Economic theory provides the rationale for the application of patient cost-sharing for the purpose of efficiency improvement. Since the price is a major determinant of the quantities of goods or services demanded, providing health care free-of-charge at the point of use (as it is in case of pure public financing) increases the quantity demanded (15–17). Part of this demand is considered to be excess demand since the marginal benefits of the consumption of these additional units of health care are lower than the marginal costs of their provision. From an economic point of view, efficiency then deteriorates as the best value for resources spent is not obtained (18). Thus, economic theory predicts that if consumers have to pay, they become more cost-conscious, i.e., they evaluate the expected benefits before the actual service use and utilize only those services whose benefits exceed the cost for them (5, 19). Imposing prices on the use of health care services is expected to affect also other forms of health-related behavior of health care consumers, i.e., provide incentives for a healthier lifestyle and prevention, which also might lead to efficiency gains in health care (20).

Nevertheless, the potential of cost-sharing to improve efficiency and further contain costs relies on the assumptions that the demand for health care is price sensitive and the decision on the use of services is made by consumers. Moreover, when making decisions, consumers are able to adequately value the services, i.e., estimate short- and long-term clinical benefits from the service consumption and the consequences of their behavior (21). While the first assumption is typically met, i.e., the quantity demanded for most health care services reacts to changes in price (the exemption can be, for example, lifesaving surgical procedures), the other assumptions are more doubtful (22).

First, the decision to use health care services is often not a patients' choice but rather a physician's decision and in such case implementing prices on services cannot be expected to change the quantity demanded. The evidence from the USA indicates that even if cost-sharing reduces the number of patient visits, the intensity of services provided remains unchanged, as it is largely driven by the providers (23). Therefore, cost-sharing alone without adequate supply-side measures, i.e., incentives for health care providers, has poor effectiveness in controlling the cost of health care (24). The importance of supply-side measures to improve efficiency and control cost of health care is well-recognized in Europe. Yet, more effort should be made to align demand- and supply-side measures for better performances of the health care systems.

Second, given the existing information issues (consumers' insufficient medical knowledge, uncertainty), it is questionable whether consumers are able to adequately value the services and distinguish between low- and high-value services. Particularly, in case of services with positive externalities or merit goods (e.g., preventive services), it is well-recognized that individual or social benefits from their consumption are not fully recognized and considered by individual consumers (25). Hence, for a cost-sharing system to be able to enhance efficiency, it should give price signals to help consumers to discriminate between low- and high-value services. However, in European countries, the amounts of patient payments are generally not aligned with the values of the services for patients. Most countries apply uniform co-payments for broad categories of services (visit to a GP/specialists, hospitalization day) and few countries base the payment amounts on the actual service cost (co-insurance, deductibles) (1). Such "one size fits all" cost-sharing does not adequately moderate the utilization of services and is likely to reduce both essential and non-essential services, limiting the efficiency gain (26). This was confirmed in various studies, including the RAND Health Insurance Experiments conducted in the 1970s and more recent studies, which showed that an increase in patient cost-sharing results in the reduction of not only ineffective care but also of medically appropriate and essential care, and the low income and chronically sick are disproportionally affected by cost-sharing (7, 27–31). The evidence on the effects of cost-sharing policy in few European countries where such analyses have been performed, also confirms the adverse equity effects of cost-sharing (32–34). For example, the results of the study by Lostao et al. (32) indicate that patient

cost-sharing in France reduces the frequency of physician visits and that this decrease is greater for persons from the lower socio-economic groups. Similarly, Rückert et al. (34) concluded that co-payments in Germany detained socially deprived patients from visiting a physician.

A Step Forward

Despite the policy expectations for enhancing the sustainability of health care financing, the cost-sharing solutions applied by European countries have limited potential to improve efficiency or to generate additional resources. To better contribute to the sustainability of health care systems, cost-sharing arrangements in European countries should be reconsidered. The need to amend cost-sharing policies has been already put forward in health care debates. A new approach to cost-sharing called value-based cost-sharing (value-based insurance design) has been proposed (35). In this system, fees for health care services are differentiated based on their cost-effectiveness or on the health benefits they provide; health care services or goods, which are proven to be cost-effective are provided with no charges, particularly for patients who can benefit the most from their consumption (19, 36). Value-based cost-sharing has been increasingly applied for pharmaceuticals. In the area of health care services, it has been less common. Only some attempts to relate the level of fees to the value of services can be observed in European countries. For example, a review of cost-sharing arrangements for health care services in 27 EU countries (1) indicates that in a majority of these countries maternity and preventive services are excluded from the cost-sharing obligation. An interesting example comes from the Netherlands, where some insurers offer an option for their enrollees to be exempted from obligatory deductibles, if one uses services of preferred providers (i.e., providers who adhere to price and quality agreements) (37, 38). A common European countries' practice of reducing fees for chronically ill should be also considered as a step toward value-based cost-sharing.

The main barrier to the implementation of value-based cost-sharing is the lack of data on the health benefits or cost-effectiveness of health care interventions and the high-administrative costs of such system. Nevertheless, European countries should consider a broader use of value-based cost-sharing in the future. This system could complement supply-side measures to improve quality and efficiency in health care, such as paying-for-performance and paying-for-coordination (39, 40). Furthermore, the fiscal efficiency of cost-sharing systems should be measured and should constitute important evaluation criteria of cost-sharing policy, particularly in countries, which aim to generate additional resources for health care through patient payments.

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Making patients pay: informal patient payments in Central and Eastern European Countries

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Informal patient payments are a key characteristic of nearly all Central and Eastern European health care systems (1–3). Apart from formal patient payments, which are regulated by national legislation (4) and quasi-formal charges, which are set by the health care provider in the absence of clear government regulations (5–7), there are also informal payments (also known as "under-the-table" or "envelope" payments), which comprise the unregistered patient payments for publicly funded health care services (7–9). In addition to this, there are also quasi-informal payments for goods that should be provided free of charge to the patient by the health care establishment but that patients are asked to purchase outside and bring for the treatment. Indeed, out-of-pocket patient payments are a major source of health care funding in Central and Eastern European countries (10).

Informal patient payments warrant special attention as ignoring these payments causes an underestimation of total health expenditure and their hidden nature imposes a great challenge to the health care provision in terms of accessibility as well as accountability and transparency (2, 11–13). Informal payments constitute about 1.5–4.6% of total expenditure on health in Hungary, about 0.3–0.5% in Poland, and about 2% in Bulgaria (14). Furthermore, a few decades ago, informal patient payments were considered mostly as "gratitude money," or a socio-cultural phenomenon (5). Currently, multi-dimensional explanations, such as insufficient resources (low income of physicians) and inadequate governance (poor political-regulatory context) combined with the socio-cultural reasons prevail in the literature (15–17). These three dimensions are rather interwoven leading jointly to the existence of a specific pattern of informal patient payments in a country.

Empirical studies on informal payments are one of the main sources of evidences on this multi-faceted phenomenon; however, they comprise a variety of methodological challenges (7), including (a) the identification of a suitable sample unit (patients, citizens, providers, and/or officials), (b) a socio-culturally acceptable data collection mode (face-to face interviews or self-administrated questionnaires) (18, 19), and (c) adequate operational definitions of informal patient payments because some respondents find it difficult to distinguish between formal and informal payments (9, 20). The difficulties related to an adequate methodology design and implementation may explain the focus of most empirical studies on single countries and on the scale and determinants of these payments rather than on complex multi-country comparative studies (7). Still, a huge variety in the nature and patterns of informal patient payments is reported across countries (7). Studies provide evidence on the variation in the type of informal payments (cash or in-kind gifts given by patients or their families), timing (before, after or during service provision), subject (out- or in-patient service), purpose (obtaining better quality or access), and motivation (physician's request or patient's initiative) (1, 3, 8).

Last but not least, the key characteristics of informal patient payments studied should also include the perceptions and attitudes toward these payments, which are the most indicative in a

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cross-country comparison. Indeed, evidence on perceptions and attitudes toward informal patient payments may play an essential role in developing and implementing adequate strategies for dealing with these payments (21–23). A cross-country comparison of public attitudes, perceptions, and opinions on informal patient payments is presented in Stepurko et al. (3). In 2010, representatives of households in Bulgaria, Hungary, Lithuania, Poland, Romania, and Ukraine consistently reported negative attitudes toward informal cash payments. This suggests a prevalence of corruption connotation, which is evidence of its social undesirability. In-kind gifts are more often perceived as gratitude than informal cash payments. More positive perceptions of informal payments in general are observed among those who have ever given in-kind gifts rather than those who have ever paid informally in cash. Concerning cross-country patterns, public perceptions in some countries (especially in Poland but also in Bulgaria) are less positive about informal patient payments than in other countries (specifically in Hungary and Ukraine). In terms of policy analysis and research, it is important to distinguish truly gratitude informal payments that have practically no impact on health care service provision, from other types of informal payments (bribes) that undermine the functioning of the health care system, and attitude study provides one piece to this puzzle.

Moreover, when perceived behavior related to making informal patient payments has been studied (24), it also appears that health care users in Bulgaria and Poland are less inclined to make informal payments, while health care users in Romania and Ukraine most often report such payments. The informal payment rates for Hungary and Lithuania fall between these two groups. In all six countries, individuals who feel uncomfortable when leaving the physician's office without a gratuity and who feel unable to refuse the request of medical staff to pay informally, more often make informal payments. Additionally, it has been found that socio-demographic characteristics have lower relevance compared to perceived behavior. Indeed, the behavioral pattern of making informal patient payments is mostly associated with patient's perceptions, while socio-demographic features play a minor role in explaining this pattern. Specifically, those who feel uncomfortable to leave without a gratitude payment and who feel unable to refuse to pay informally if asked, more often report making informal payments than the rest of the respondents. The less positive attitudes and perceptions toward informal patient payments in Poland can be attributed to the successful anti-corruption policies supported by mass-media and relatively better governance in the country than in neighboring countries (3).

Public opinions and individual perceptions provide a good ground for better understanding the level and patterns of informal patient payments. Variation in informal patient payments with regards to the country and year of occurrence, type of service used, the purpose and initiator of the payment shed more light on the roots of the informal payments, and therefore strategies for their eradication (25). The results of the cross-country comparison mentioned above suggest a relatively higher prevalence of informal patient payments in Ukraine than in Bulgaria, where patients also meet formal service charges in the public sector. More than 35% of health care users in Ukraine report informal payments for physician visits during the preceding 12 months in addition to widespread quasi-formal payments (26), while in Bulgaria it is <10%. Regarding hospitalizations, the percentage of service users who report informal payments is also higher in Ukraine (more than 40%) and lower in Bulgaria (10–20%). It should be noted that in Bulgaria, the private health care sector has considerably grown during the last decades, which provides alternatives to the public health care services. This can explain to a certain extent the lower share of informal patient payments in Bulgaria as Bulgarian patients may opt for private services and avoid informal payments in the public sector.

Informal payments are more spread and higher when they are solicited or expected by providers (25). However, the relatively high prevalence of informal patient payments in Hungary does not follow this logic since informal payments in Hungary are mostly initiated by the consumers (3). This underlines the importance of country-specific strategies for dealing with informal patient payments. In Hungary, in particular, the initial objective of such strategy should be the revision of national regulations, which at this moment are supportive to informal payments (23).

Furthermore, the probability and the size of the informal payment are to a great extent determined by the type of service consumed (GP or specialist, out-patient or in-patient care) (15, 27). The trend of a higher number of users who make more expensive informal payments to specialists when compared to GPs remains noticeable. It is similar for surgery and childbirth compared to other hospital interventions. Indeed, the number of payers and the amounts paid (including informal payers) are highest for hospitalizations related to childbirth or pregnancy (25). For example, in Ukraine, about half of the in-patients report informal payments for pregnancy or delivery, although the median value of these payments is about 70–100€ while total payment is about two to three times higher.

Insufficient data on maternity care provision in Eastern European countries have drawn the attention of researchers to the qualitative aspects of the process of informal payments (28, 29). Qualitative study conducted in the capital of Ukraine shed some light on the experience of consumers and providers with informal payment for childbirth (28). The methodology of ethnographic study has enabled us to learn more about local specificity of human behavior related to the process and nature of informal patient payments for childbirth. In 2008–2009, two groups of patients in the Ukrainian maternity care ward are identified: "individual patients" and "emergency room patients." Also, push factors that lead to a search for a "personal obstetrician" in Ukraine are described as the need for 24 hours access to reliable information and the need for psychological comfort during the childbirth. Thus, gaining better "service wrapping" (reliable information, better attention, responsiveness) against the background of feelings of anxiety is seen by patients as a strategy to avoid "substandard care." The obstetricians do not conceal their experience on the redistribution of the informal payments among medical staff as well as the use of money to buy pharmaceuticals and to maintain physicians' wards. Informal payments not only add to the salary of the obstetricians but also to the salary of other staff members and to the budget of the hospital facility. In fact, the low salary of medical staff is indicated by both obstetricians and mothers as the main cause for the existence of informal payments. Thus, informal

payments remain an unregulated tool that ensures extra payments to health care providers when adequate reimbursement policies are lacking.

Variations in regulatory mechanisms, availability of alternatives to informal payments as a means for achieving better quality and access, level and sources of funding can explain the cross-country diversity (30). Meanwhile, the devotion to accepting, giving, and relying on informal patient payments observed in the region can become a great obstacle in introducing health care reforms in any of the countries. Informal patient payments affect the health care system at the macro (system) level as they impede health care reforms, and at the micro (service) level by creating barriers to adequate care (1, 30). Most important, however, informal patient payments distort equity since patients who cannot afford to pay informally might be deprived from adequate health care (31). Thus, strategies for dealing with informal patient payments and their causes are urging.

However, the ability of the government to ensure a good performance of the public sector in general and of the health care sector, in particular, is seen as a key factor for avoiding shadow practices. So far, political decision-making in Eastern Europe has been too much based on the interests of business (the medical elites in case of health care) with too little consideration of evidence-based strategies and public opinion. This impedes real positive changes in public service provision regardless of the policy goals stated by the governments. Therefore, changes in governments and international organization interventions may give a stimulus to improve governance and the culture of management of all public sectors. The ultimate challenge for policy-makers is to realize that when informal patient payments appear in health care, it also aggravates the health and wealth of the nation.

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Long-term health expenditure changes in selected Balkan countries

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Keywords: health expenditure, Balkan, gross domestic product, life expectance, medicines

Spending on health is a significant policy issue for most countries' economies of the world. Those expenditures put high pressure on public budgets, measuring government investments in health and well-being of their citizens. This task is even more challenging for most Balkan countries, embraced by the global economic crisis in the last decade and prior history of civil war for most of them.

Total health expenditure (THE), as a sum of public and private expenditure (1), expressed as percentage of gross domestic product (GDP), in the most of the selected Balkan countries, for the selected period from 1995 to 2012, showed obvious increase (**Table 1**) among majority of them. THE share of GDP among observed countries in 2012 was highest in Albania, with almost two and the half times larger share than in 1995. Romania, Serbia, and Bulgaria recorded about 1.5 fold higher share, while Greece, Bosnia, and Herzegovina and Montenegro remained at the same level as in 1995, comparing selected indicator. Exceptions were Croatia and The Former Yugoslav Republic of Macedonia (FYRM), with minor decrease. Possible explanations could be decline in the number of births, an increase in the mortality of younger aged people during the war and negative migration trends. Those could have influenced on stagnation of the growth of THE as percentage of GDP in Croatia (2), while FYRM is a country with more than 25% of the population living in poverty and with an unemployment rate in the country of over 30% (3). On the other hand, growth in health spending as a proportion of GDP contribute to the problem of economic and fiscal sustainability where health system revenue is insufficient to meet growing health obligations (4). This scenario is even more obvious in countries with shrinking economies.

Total expenditures on health per capita, in terms of current purchase power parity in international $, in all selected Balkan countries showed significant growth comparing 1995 and 2012 (**Table 1**). Reason for this, not just local phenomenon, partially would be probably due to a population aging (5), which is in the close relationship with intensive health care spending and one of the cores of a health financing problem in Balkan countries (6). Life expectancy, as one of the widely used measure of health, showed increase in all observed countries, except Montenegro (7). The most obvious increase achieved Bosnia and Herzegovina, with prolonged 8 years of life in 2012 compared to 1995, reaching 76 years. Greece and Slovenia had the highest life expectancy, with 81 and 80 years, respectively (7).

In all observed countries, general governmental and private expenditures on health per capita also showed significant and constant growth (**Table 1**). However, general governmental expenditure still remains a dominant mode of the health financing in most selected Balkan countries. The only exception is Albania, where private expenditure on health in 2012 was slightly higher than governmental. The fact that the ratio of private expenditure growth in 2012 compared to 1995 was almost sevenfold higher in Bulgaria, closely followed by Serbia, Albania, and Romania remains. The greatest share of private expenditure consists of out-of-pocket expenditure, which accounts 56% of THE in Albania, 42% in Bosnia and Herzegovina, and 22% in Serbia and Montenegro (8). It could have severe effect on household economic status of already impoverished population.

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TABLE 1 | Expenditure data across selected Balkan countries – values reported to World Health Organization by the national authorities in 1995/2012*.

Countries/year	Total health expenditure (THE)% gross domestic product (GDP)		Total expenditure on health (current PPP int. $ per capita)		General government expenditure on health (current PPP int. $ per capita)		Private expenditure on health (current PPP int. $ per capita)	
	1995	2012	1995	2012	1995	2012	1995	2012
Albania	2.52	5.97	97.59	541.38	46.91	257.70	50.68	283.68
Bosnia and Herzegovina	9.37	9.89	128.43	927.61	47.81	659.99	80.62	267.62
Bulgaria	5.23	7.42	290.21	1177.08	214.64	662.58	75.57	514.50
Croatia	6.85	6.82	546.03	1409.77	472.08	1160.54	73.95	249.23
Greece	8.59	9.27	1263.09	2346.50	644.03	1584.04	574.40	762.46
Montenegro	7.42	7.57	445.18	1018.76	311.74	608.34	133.44	410.43
Romania	3.22	5.11	183.43	872.86	136.73	678.46	46.69	194.40
Serbia	7.32	10.47	259.86	1249.78	184.32	764.41	75.53	485.37
Slovenia	7.46	8.76	969.40	2419.86	753.22	1773.55	216.18	646.31
The Former Yugoslav Republic of Macedonia	8.51	7.13	421.39	834.94	247.17	535.15	174.22	299.79

**Data source: World Health Organization National Health Accounts Global Expenditure database http://apps.who.int/nha/database/Select/Indicators/en.*

General governmental spending on health was highest in Slovenia, Greece, and Croatia, which are countries with highest total expenditure on health among all observed, as well. In Greece, private health insurance coverage remains low compared to other EU countries, despite dissatisfaction with the public system (9).

Expenditure on healthcare continues to grow, not only due to aging of populations but also due to growing public expectations on the accessibility and quality of healthcare (10). In well-developed economies, inpatient and professional services account for almost two-thirds of private health insurance spending, with pharmaceuticals share of 15% (11). Costs of increased use of technology, as well as of expensive medicines could escalate in the impending period (12). Structure of used medicines is also contributing to the healthcare costs. New brand-name drugs are often expensive, but the large number of generic drugs tends to increase the costs (13). Numerous factors may cause price increases for generic drugs: drugs shortages, supply disruptions, and consolidations within the generic drug industry (14).

We could conclude that, as countries become richer, the total amount of healthcare spending would increase. The model of health care financing mechanisms appears not to be a key driver for raising healthcare costs, as all observed countries showed similar growth in spite of relative different financing models among them.

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Does the implementation of official user charges help to eradicate informal payments – lessons to be learnt from the Hungarian experience

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Introduction – Implementation of Official User Fees to Eradicate Informal Payments

User fees for health care services are a frequently applied policy tool to improve efficiency by controlling demand and contain costs. It is also applied to increase resources for health care, especially when public resources are limited or the increase of income-related contributions is not feasible or not desirable. In addition, in Central and Eastern European (CEE) countries, where informal payments are widespread, the introduction of user fees is often promoted by politicians and policy makers as a potential policy tool to eradicate or "formalize" informal payments (1).

Informal payments are unofficial cash payments or gifts in kinds directly given to the health care personnel before or after using health care services. The literature on informal payments suggests that these payments violate the idea of transparency in health care financing and the accountability of providers, which results in an inefficient use of health care resources and inequalities in access to health care Furthermore, informal payments create adverse incentives for their beneficiaries, which can be in conflict with the government's policy objectives. (2).

Thus, in the last decades in the CEE countries, several policies have been implemented to eradicate these payments, including the introduction of official user fees for health care services. However, there is no evidence that supports this expectation. On the contrary, there is evidence to suggest that patients continue to pay informally after the introduction of user fees (3–5). In this case, user fees induce a double financial burden on patients, aggravating the existing problems caused by the informal payments. This makes user fees even more unpopular among the public.

According to the OECD Health Statistics in Hungary, the total health expenditure accounts for 8% of the GDP in 2012, with a per capita expenditure of 1,358 USD, which is lower than the OECD average. The share of out-of-pocket payments in total health expenditure has increased considerably during the last decades, and has reached 28.3% in 2012, and accounts for about 5% of the total household expenditure. This level is one of the highest among European OECD countries. Above 80% of these payments are co-payments for pharmaceuticals (80%). There are no official co-payments for health care services, however informal payments are widespread. Hungarian health care consumers have been paying informally for medical services on a routine basis, especially in in-patient care. According to a study carried out in 2010 around one-fifth of the respondents who used physician services during the last 12 months, made informal payments, on average 60 €, and almost

half of the respondents who were hospitalized during the last 12 months, paid informally on average 130 € (6). Studies suggest that the scale of these payments has not changed considerably during the last two decades. (7).

In 2007 in Hungary, official user fees were introduced for the use of health care services covered by the social health insurance. The introduction of these fees was one element of the reform package to contain health care cost. According to the documented policy objectives, it was expected that official fees will contribute to the eradication of informal payments (8).

Although the amount of user fees was relatively low (about 1 € per physician visit and per day spent in hospital), the implementation met with strong political opposition and unpopularity among the public. One year later, in April 2008, the payments were abolished as a result of a population referendum initiated by the opposition party in the parliament, where more than 80% of the voters supported the abolishment of the fees (8).

The introduction and abolishment of users fees in Hungary can be considered a natural experiment, and enable us to study the association of formal and informal charges. The aim of this paper is to summarize findings on this issue based on studies carried out to examine the Hungarian case, and draw some policy conclusions.

Unclear Equity Effects – Decrease of Informal Payments in Low-Income Households

Studying Hungarian households' expenditure on formal and informal charges during a 4-year period (2005–2008) including the implementation and abolishment of user charges, Baji et al. found, that the co-payments lead to a relatively greater burden on worse-off households. [The Kakwani-index of formal household expenditure for health care services decreased from 0 to −0.1 in 2007 (9)]. At the same time, the study suggests that the increase of formal payments was partly compensated by the decrease of informal payments, especially in low-income households.

During the 1-year period (2007) when user fees were charged for the utilization of health care services, household expenditure on informal payments decreased and became less regressive, i.e., the decrease of informal payments was higher in lower-income households (the share of informal payments decreased from 0.56 to 0.26% of the household income in the poorest quintile, and from 0.20 to 0.14% in the richest quintile). The reduction of informal payments can partly be explained by the drop in the utilization of services, which was recorded during this period. However, a higher decrease in the expenditure on informal payments among low-income households was observed, which also suggests that worse-off households tried to compensate the increase of formal payments by decreasing their expenditure on informal ones.

In another study, Baji et al., analyzed the short-term changes in the probability of paying informally for in-patient and out-patient care 2 months after the implementation of user fees. The findings suggest that the probability of paying informally decreased only for hospitalization among elderly people (10). Elderly with a lower ability to pay respond to the increased burden of formal payments with a decrease of their expenditure on informal payments, as elderly people are likely to be among lower-income households in Hungary.

Overall, the results presented above suggest that the implementation of user fees can lead to a reduction of informal payments of those health care consumers who are not able to meet the double burden. However, this finding raises questions concerning equal access to health care services. It is possible that consumers, who are not able to pay informally for health care services, may not obtain the services that other consumers obtain because they continue to pay. In this way, the reduction of informal payments can create even greater inequalities between different income groups.

Complements or Substitutes?

Nevertheless, both studies show that informal payments remain relevant. For those who are able to pay and have no budget-constraints, formal payments do not substitute for informal payments, at least at the short term, these payments rather co-exist and complement each other.

Findings from a qualitative study provide some explanation for this (11). Consumers argue that neither the measure nor the objectives, nor the beneficiary of informal payments is the same as those of user fees. Formal and informal payments serve different objectives, and consumers achieve different benefits by paying formally and informally. In Hungary, informal payments are directly pocketed by physicians (mostly by the head/manager) and contribute to their income. In this way, these payments may affect the choice of the physician, the attitude of the personnel, or in some cases, even the access to services. On the other hand, formal payments have more potential when used to improve equipment or the maintenance of health care facilities or if otherwise reinvested in health care provision. However, according to public opinion, the user fees introduced in 2007 did not contribute to the improvement of service quality (11).

Also, attributes connected to the health care personnel (i.e., the skills and reputation of the physician, as well as the attitude of the health care personnel) are more important for health care consumers than other service attributes, like the health care facility, equipment or even waiting time for the visits, or traveling time to the health care facility (12). These results indicate the importance of the patient–physician relationship. Since informal payments are a relevant element of this relationship, it is quite probable that despite the formal charges, patients continue to pay informally directly to their physician, as an expression of their gratitude or in the hope of getting extra services, better access or more personal attention. Or, they keep on paying informally, because of the fear that they do not obtain the care they need if they do not pay.

Furthermore, Hungarian health care consumers are rather tolerant toward informal payments, mainly because these payments provide additional salary to the (underpaid) health care personnel (2). Also, some population groups (e.g., elderly people and consumers from the capital) seem to prefer paying informally for health care services (6).

To summarize, health care consumers doubt that user fees in 2007 had the potential to eradicate informal payments as formal fees do not substitute for informal payments. The lack of support for the stated policy objectives makes the implementation

of these charges more unpopular and this might be one of the reasons why the fees were rejected by the population in the referendum. Findings suggest that the problem of informal payments remains relevant even after the implementation of user fees. However, if formal payments do not substitute for informal payments, user fees induce a double financial burden on health care consumers, and make official charges less acceptable to the public.

Policy Implications of the Findings

After the implementation of user fees, informal payments remain relevant and the two payments co-exist. However, the increase of formal payments may indeed lead to a decrease in informal payments, specifically among low-income households who are not able to pay for the double (formal and informal) price.

Regarding the policy implications, we can say that the reduction of informal payments is a desirable policy aim because of the adverse effect of these payments on the health care system, i.e., inefficient use of resources, barrier to access, and adverse financial incentives for beneficiaries. However, if the decrease of these payments only occurs among the lower-income households, among those who are not able to pay for the double burden, this mechanism can increase inequalities in access among households with different income. Those who are able to pay for the double burden may have better access to health care services compared to those who are not able to pay. Thus, the implementation of user fees is hardly sufficient and rather a controversial policy tool to diminish informal payments.

The Hungarian experience with the implementation of user fees confirms that public acceptance is crucial for a successful implementation of user fees. However, in Hungary the declared policy objectives of the implementation of the user fees were not supported by the public, making the implementation of these charges more unpopular.

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Health spending follows pace of population aging: challenges lying ahead of the largest Western Balkan market

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Origins of Population Aging in Serbia

Humanity has almost won its battle with many infectious diseases, thus increasing longevity, but is now confronted with challenges arising from population aging (1). A blessing turned into a curse as modern societies began struggling with prosperity diseases proliferation (2). Such obstacles are notable in the largest Western Balkan country (1). One-fifth of the Serbian population is aged 65, where that age group holds 8% globally (3). Serbia has a negative population growth and descending fertility rates, which places its population among the oldest in Europe (4). Following these trends, it is estimated that population older than 75 will make up a majority in the next two decades forming a T shaped age pyramid (5). Within the broader South East European region, population aging trend is clearly present for decades and shows clear signs of acceleration (6).

This phenomenon originated from tumultuous changes in terms of political and economic stability affecting the Balkans in past decades. During the civil war in the 1990s, there has been an exodus of refugees from former parts of Yugoslavia to Serbia. This influx of people accounted for 5% of the total Serbian population count, but left no positive mark on the overall fertility rates due to similar reproductive behavior of internally displaced people (7). Destitution caused by sanctions placed by the Security Council of the UN forced indigenous people to embark on massive emigrations toward richer and more viable economies. Additional impacts on renewal of demographic potential were "brain drain" consisting of almost 50% of skilled emigrants younger than 40 (8).

Difficulties in finding a partner of the opposite sex are also noteworthy. Even though the ratio of men and women is even at reproductive age, the proportion of each gender in rural and urban settings is significantly off-balance (9). Also, the age for women when couples decide on having their first child has shifted from 25 in 2001 to 27 in 2011 (5).

Local Health Expenditure Trends in Past Two Decades

The Serbian health care system relies financially on Republican Health Insurance Fund (10) that is supported by taxation imposed on the employed population (11). Unfortunately, it is susceptible to budget shortages caused by the growing number of pensioners (12), rise of prosperity diseases, and inefficient allocation of available financial resources for health care (13). Total expenditure on health marked a 45.5% increase for 1995–2010 (**Table 1**), and the main culprit stigmatized for devouring limited resources were prosperity diseases. Repercussions of an inadequate health care system are weighing on low-income citizens, a sicker population with greater pressure on home budget (14), as total out-of-pocket expenditure for patients rose almost seven times in the last two decades (**Table 1**).

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TABLE 1 | Core population aging indicators for Serbia and expenditure data 1995–2010.

	1995	2000	2005	2010
Population aging indicators[a]				
Total fertility rate (children per woman)	1.96	1.74	1.55	1.41
Population growth rate (average annual rate of population change, %)	1.272	−0.198	−0.625	−0.631
Median age of the total population (years)	34.0	35.2	36.1	37.8
Percentage of elderly aged 65+	11.2	12.9	14.0	13.7
Old-age dependency ratio (ratio of population aged 65+ per 100 population 15–64)	16.9	19.3	20.5	19.8
Health expenditures[b]				
Total health expenditure (THE) % Gross Domestic Product (GDP)	7	7	9	11
Total expenditure on health (current PPP int. $ per capita)	$260	$313	$771	$1,183
General government expenditure on health (current PPP int. $ per capita)	$184	$219	$509	$732
Private expenditure on health (current PPP int. $ per capita)	$76	$94	$262	$451
Out of pocket expenditure (current PPP int. $ per capita)	$64	$79	$231	$431

[a]*Data source: United Nations Department of Economic and Social Affairs Population Division.*
[b]*Data source: World Health Organization National Health Accounts Global Expenditure database.*

National Health System Preparedness to Respond to the Challenge

Serbia is not in an enviable economic position with the economy suffering, the public debt doubling, and no sustainable economic solution in the foreseeable future. Republican Health Insurance Fund should depart from previously centrally planned budget and rely on the evidence-based proposals by the academic milieu that reflects real needs at a local level (10). Global economy has exposed unpredictable downfall since 2007 with recession still taking its toll in Eastern Europe.

Serbia must not make impetuous moves in reformation when compiling with EU standards. Local evidence has shown that patient satisfaction with primary care declines in cases when health care reforms are being implemented at an accelerated pace (15). Comparably, the dentistry policy was a hasty reform adopted from patterns found in rich Western societies. Namely, all but emergency dentistry services for adult patients were paid out-of-pocket leading to diminished access of such care (16). However, one of the beneficial and voluntary actions would be implementation of an official HTA agency even though recent fruitless efforts were devoid of legislature maturity (13). Other than lessons gained from the EU, national authorities should learn from the emerging BRIC economies as they recorded some impressive successes in coping with population aging challenges (17). Japan serves as the prime example of the oldest large nation struggling with the burden of medical care for the elderly citizens. By strengthening mandatory taxation of the working age population, they are achieving a short-term solution and not addressing the impeding issue (11). In Serbia, employers and employees alike undergo mandatory taxation for provision of health insurance to the employee's family members (18). National health system capacities are not prepared for the aforementioned challenges of aging. Rural network of health care facilities suffers from chronic staff shortages. Insurance coverage of the elderly remains mostly insufficient in terms of reimbursed medicines for most chronic disorders. Affordability of home care is more of a privilege than a commonly resorted aspect of medical services. Catastrophic health expenditures due to serious illness of senior family members are frequently sinking families into poverty. These surmounting challenges will need to be addressed within the framework of national strategies tailored to major public health issues. Strengthening of the family medicine capacities and investment into the cost-effective preventive and screening medical technologies are likely an appropriate long-term solution (19). Governmental legislative support to the proliferation of a rather weak private health sector would relieve public health facilities (20). Serbia may effectively fight these challenges by increasing birth rate, thus obtaining a younger taxable working population, and ultimately supporting the health care budget.

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Prospects of risk-sharing agreements for innovative therapies in a context of deficit spending in Bulgaria

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Funding of Innovative Therapies in Bulgaria

Innovative therapies are usually defined as newly introduced or modified health technologies with unproven effect or side effect undertaken in the best interest of the patient. These therapies could be situated at any point of the continuum: from genuine innovation with no precedent, to relative innovation representing a small variation from standard therapy, or using a conventional treatment in a different context (1). While the conception of innovative health technologies is not limited by therapeutic form (drugs, devices, procedures) or disease indication, innovative therapies are generally associated with expensive original drugs (2). Inclusion and provision of these therapies tend to be one of the most resource-consuming tasks for national health systems and payers.

The above mentioned perceptions are well illustrated by the National Health Insurance Fund (NHIF) in Bulgaria and its funding activities. NHIF is an independent public entity that was established to carry out the mandatory health insurance in the country. Progress in medical science and introduction of innovative therapies, together with aging population and increased prevalence of chronic non-communicable diseases have put NIHF into a permanent situation of budget deficit. Overspending has led to concerns about the overall sustainability of NHIF and the present health insurance model in Bulgaria. Moreover, NHIF is currently lacking effective mechanisms to address this growing financial risk.

National Health Insurance Fund budget is annually set and approved through a legal act by the National Assembly of Bulgaria. Its funds that are intended to cover drug therapies are distributed between two cost items as defined by the relevant legislation – costs for outpatient drugs and costs for inpatient cancer drugs. The first category mainly includes outpatient medicinal therapies, although a limited part of these funds are earmarked to medical devices and medical foods. NHIF total drug expenditure steadily rose between 2011 and 2014 (**Figure 1**). These total costs were 268 million EUR in 2011 and were expected to reach up to 488 million EUR in 2014 (3–7). At first sight, the expansion of NHIF coverage during that period explains the significant increase of drug spending. The provision of several categories of innovative medicinal therapies (such as rare disease and some cancer drugs) was transferred from the Ministry of Health to NHIF in 2011 and 2012, respectively. Those were all included in the outpatient drug budget category, thus increasing its spending share in absolute and relative terms. Inpatient cancer drugs were also established as a separate cost item to be funded by NHIF in 2012. This budget category alone was expected to stand at up to 100 million EUR in 2014.

While nominally not all outpatient drugs paid by NHIF are innovative, Bulgarian stakeholders have generally attributed deficit spending to outpatient medicinal therapies for rare disease

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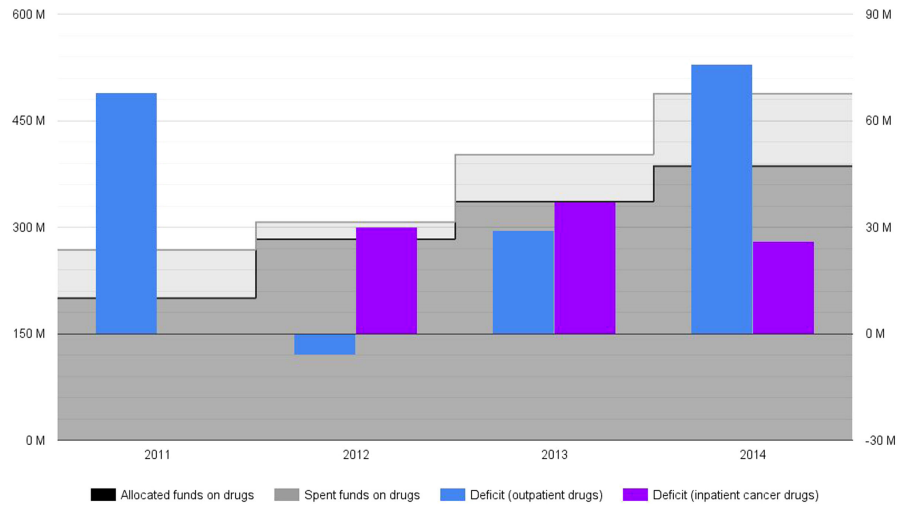

FIGURE 1 | National Health Insurance Fund drug budget deficit for 2011–2014*, (actual, non-discounted costs, reported in million EUR)**. *No actual spending on inpatient cancer drugs is reported for 2011, as these medicines were made part of (and subsequently paid by) NHIF basket in 2012. **The amount of actual spending for 2014 is based on forecasts.

and cancer. This is mostly due to the higher cost per patient and in total of those drugs. A recently published study reported important levels of cost and utilization uncertainty for some of those medicinal therapies (8). NHIF was already experiencing a budget deficit, so this insecurity of innovative therapies has contributed for the restart of the political debate in the country about NHIF expenditures.

National Health Insurance Fund deficit spending on drug therapies was expected to be around 26.6% in 2014: 488 millions EUR spent instead of 386 millions EUR initially allocated (**Figure 1**) (6, 7). Outpatient drug deficit spending was 34% in 2011: 268 million EUR spent against 200 million EUR allocated (3, 7). These numbers strongly alarmed Bulgarian health authorities who adopted legal amendments in drug pricing and reimbursement regulations (2). This new policy framework seemed successful at first – outpatient drug costs deficit was reduced in 2012 and 2013 (4, 5, 7). Nevertheless, outpatient drug deficit spending increased again in 2014, counting for an overspending of 76 million EUR (a deficit of 25%) (6, 7). From their inclusion in the mandatory health insurance, inpatient cancer drugs demonstrated consistent spending deficit too – 102% (a deficit spending of 30 million EUR) in 2012, 80% (a deficit spending of 37 million EUR) in 2013, and 35% (a deficit spending of 26 million EUR) in 2014 (3–6). These fluctuations can not be linked to changes in inflation (a relatively short period of 4 years) and/or currency exchange rate (Bulgaria has a currency board that maintains a fixed exchange rate with the euro).

Rationale of Performance-Based Reimbursement

In a context of fiscal austerity, timely access to innovative therapies has to be balanced against the priorities and resources of the health system. Epidemiological, economical, and clinical uncertainty of innovative health technologies imposes deeper reflections in the process of public health priority setting and resource allocation (9, 10). When regulating access, health authorities and payers demand evidence on the number of patients to be treated, costs, and health gains (11). For these reasons, different decision support tools are explored to maximize the health benefits of the costs incurred, while mitigating the risk of overspending.

Risk-sharing agreements (RSA) are performance-based reimbursement schemes, in which the price, level, or nature of reimbursement are tied to future performance measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life (12–15). Generation and collection of new evidence is a key component of these contracts between manufactures and payers. Real-world data on the therapy's performance subsequently assist in making informed decisions on access and coverage.

Classification of RSA relies on the type of results to be achieved: these agreements could be either health or non-health outcome-based (12). Health outcome-based RSA are linked to the achievement and/or proof of certain health benefits in a patient population for a period of time, whereas non-health outcome-based RSA are mostly tied to negotiating price and/or consumption levels. Non-health outcomes-based RSA are, however, mainly guided by financial considerations, without taking into account the health benefits at individual and population level. This practice itself does not contribute for improving the national health system's effectiveness, as well as no new evidence is generated.

Health outcomes-based RSA are often split into two main categories (12, 13): conditional coverage, where coverage is granted conditional on the initiation of a program of data collection, and performance-linked reimbursement, where reimbursement level for covered products is tied to the measure of real-world clinical outcomes. Under a conditional coverage scheme, reimbursement decision is conditioned upon the collection of additional population level evidence, from a pre-specified scientific study, to support continued, expanded, or withdrawal of coverage. The second category, performance-linked reimbursement, is characterized by

outcomes guarantees, in which the manufacturer provides rebates, refunds, or price adjustments if the product fails to meet the agreed upon outcome targets. In practice, however, RSA very often include components from both subcategories depending on the uncertainty that is being addressed.

Prospects of Risk-Sharing Agreements for Innovative Therapies in a Context of Deficit Spending in Bulgaria

Improving patients' access to new therapies is legitimate and in line with progress and innovation in medicine. Despite well documented trend to improve Bulgarian patients' access to innovative therapies, availability and accessibility of those therapies largely remain limited compared to other EU member states (8). Of course, Bulgarian national health system has to operate within largely fewer and very limited resources. Thus, any source of uncertainty that leads to significant overspending could jeopardize the overall sustainability of the local healthcare model. However, nowadays dominating concepts of health technology assessment (HTA) and evidence-based medicine focus not on patient access restrictions and cost containment, but on health outcomes surveillance and real-world evidence collection (10). As coverage policy in Bulgaria remains subject to cost-minimization, a growing number of countries switch to cost-effectiveness – to spend the available resources wisely, in a way that will generate the greatest amount of health benefits to the greatest number of people (16–18). Reference pricing, centralized tenders and budgetary constraints do lower drug expenditure indeed, but eventually they all lack the effective control of outcomes obtained. In fact, these policy tools offer a temporary solution, which ultimately does not eliminate the risk of budget deficit, as observed in Bulgaria.

When rare diseases and cancer medicinal therapies were transferred to NHIF, the payer took measures to control uncertainty in cost and utilization. NHIF determined clinical criteria to be met in order to initiate and then to continue a therapy. Coverage is renewed every 6 months upon achieving predefined clinical outcomes. This mechanism falls in the category of conditional treatment continuation, which is a standard feature in many RSA. Such scheme ensures that only patients that benefit from treatment remain on treatment (12). However, a serious shortage of the approach, currently applied by NHIF, is the lack of management of the potential overspending that may occur. Linking reimbursement status to performance does not directly address this issue. Another drawback of the present practice in Bulgaria is the evidence gap about innovative therapies. NHIF is monitoring, in fact, a basic set of surrogate outcomes in patients in order to continue reimbursement, but no efforts are made to assess and appraise these real-world data in aggregate and to use this new knowledge in policy-making. In this context, evidence collection is a prerequisite for overcoming difficulties in transparency, legitimacy, and feasibility of priority setting and resource allocation in the field of public health.

Risk-sharing agreements are conceived as a response to all the above mentioned concerns (19). We call for the legal definition and practical implementation of RSA in Bulgaria. This mechanism is essential for the sustainable access to innovative medicinal therapies in the country. A hypothetical framework of RSA should include the following elements: early dialog and fast-track first-stage evaluation, post-marketing monitoring and patient registry, independent HTA report, and final informed reimbursement decision-making. The application of RSA should begin with an initial, more implicit evaluation of innovative health technologies. The main reason is the fact that most of these therapies are often the very first therapeutic option available for the patients in question (20). RSA with mandatory post-marketing surveillance will allow patients to start therapy early, thereby avoiding clinical complications and further medical expenses. At the same time, regulators and payers can get data on the real-world effectiveness and utilization of the product (21). Last but not least, RSA should contain an agreed mechanism for reducing the risk of overspending, sharing the burden of budget deficit among payers and manufacturers.

Lack of reliable epidemiological, clinical, and economic evidence, generated in local settings, is a substantial obstacle for effective planning and management of healthcare costs in Bulgaria. Especially in the case of rare diseases, the small number of patients and the impracticability to conduct large-scale randomized controlled clinical trials call for alternative study designs to generate and collect new evidence. RSA experience demonstrates that post-marketing studies and patient registries are the most appropriate tool for streamlining the processes of HTA and reimbursement decision-making for innovative therapies. Evidence generated from such studies at national level is more consistent and reliable, because it reflects the specifics of the local population and health system (9, 10). Bulgarian health authorities should actively promote the collection of real-world evidence, which is fundamental for rigorous and objective HTA, as well as for subsequent final reimbursement-decision-making.

Conclusion

An access scheme that combines features from both health and non-health outcome-based RSA achieves two objectives simultaneously. First, it would effectively restrict the possibility of budget deficit in the healthcare system. Second and even more importantly, it would allow coverage decisions to be consistent and coherent, following a transparent procedure and clear criteria. Generation and collection of new epidemiological, clinical, and economic real-world evidence ensure that inform reimbursement decisions have been made and costs incurred have produced greatest benefits to a greatest number of people.

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Economic impact of leading prosperity diseases: COPD in South East Europe

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ECONOMIC BURDEN OF COPD

Chronic obstructive pulmonary disease is one of the leading "prosperity diseases" worldwide. Pooled global prevalence rates based on clinical assessments and spirometry ranged from 7.6 to 8.9%, reported in a sound meta-analytical study design (1). It has far reaching consequences, not only for an affected patient's health but also for the entire national health systems (2). These refer to the substantial work load for the medical facilities due to chronic clinical course of illness and modest success of available treatment approaches. COPD attributable resource utilization patterns are particularly substantial if large university tertiary care hospitals, specialist clinics, and intensive care units are observed (3). According to most of published evidence the key cost driver are periodic exacerbations followed by intensive care unit admissions and episodes of infectious complications (4). Among major cost domains, physician consultations and surgery dominate in high-income settings. Unlike in the West, within the most of South Eastern European region, COPD medical care is still dominated with acquisition costs of pharmaceuticals and oxygen (5) and imaging diagnostics (6). Outpacing of indirect productivity-related opportunity costs by the direct costs of in- and outpatient medical care is common to this region due to substantially lower wages of physicians and nursing staff (7). Apart from direct costs of COPD, mainly constituted from the resources consumed in the health care process, including costs of ambulatory care, drug treatment, hospital care, rehabilitation, and long-term home care, there are substantial indirect costs of COPD, which are incurred by productivity losses, premature retirement, and premature mortality from this disease. The indirect costs for premature mortality are being calculated through human capital approach, with the life years lost up to the age of 65 multiplied by the gross annual income. An insight into the economic reality of SEE region, particularly Serbia, with average wages significantly lower than in countries of the Western Europe, but at the same time with high unemployment rates in younger age groups, where some 50% of the working population is currently outside of the workforce (8), being in their most productive decades of life but at the same time most prevalent tobacco users, makes indirect cost of COPD in SEE region very difficult to calculate or even predict, but clearly shows significant magnitude of this burden in present years, and probable rise of these costs in the future. Intangible costs are not convertible into monetary terms and units, they are specifically related to the distress and suffering, which is caused by the disease. General lack of insight into patients' perception of the disease and limitation and incapability, which it imposes, while healthcare workers are being focused mainly on physical burden of the disease, with very few patients being provided with structurised psychosocial aid in the attempt to overcome significant yet underestimated mental and emotional burden of the disease, makes these costs impossible to predict and foresee.

AN EXAMPLE OF SERBIA'S HEALTH REFORMS

Serbia as the largest Western Balkans upper-middle income market began health reforms one decade later than most transitional countries of SEE region (9, 10). After dynamic 2000–2007 GDP increase and overall development, the issue of long-term sustainability of its health system financing became hot topic under the first strike of global recession (11). Large part of almost unbearable economic burden was attributable to the major prosperity diseases including pulmonary diseases (12). The unique common weakness revealed by all of these pioneering cost-of-illness assessments in the Balkans region was poor health system responsiveness to population needs together with overextended hospital budgets and accumulating of public depth generated by the national health insurance fund (13). An occurrence of catastrophic household expenditure triggered by severe illness, sinking entire families into poverty is still prevalent within the society (14). Expensive medical technologies, which were denied reimbursement, remained mostly unaffordable to the ordinary citizens (15).

CONSEQUENCES OF COPD RELATIVE TO POPULATION AGING AND COMORBID DISORDERS

Populations across Eastern Europe and the Balkans are aging even more rapidly than their Western European counterparts. This population aging is likely to further constrain already limited resource allocation in health care (16). This happens mostly due to dwindling base of employed tax payers in their most productive life time combined with increased proportion of the elderly. Demand for medical services by the retired citizens is significantly higher compared to working, younger age groups

and this is particularly the case within the last year of life (17). Substantial impact of age to the COPD costs of care was already claimed in literature. Clinical severity of disease according to the Global initiative for chronic Obstructive Lung Disease (GOLD) classification, clearly correlated with resource use and costs of hospital and outpatient care (18).

In an exploration of long-term pharmaceutical market transformation trends in Western Balkans, it has been observed that agents used to treat COPD exhibited prominent rise in market share during the past decade. Reported value based turnover of medicines intended to treat respiratory disorders grew from € 17,090,000 in 2004 to the € 46,500,000 in 2012 (19). It is a paradox that during same 9 years unit drug consumption in terms of defined daily doses DDD/1000 inhabitants/day actually fell from 164.55 in 2004 to 50.55 level in 2012 [according to Anatomical Therapeutic Chemical (ATC) classification ("R" ground code group)] (20). Explanation for this shift in Balkan pharmaceutical markets should be looked within stronger brand penetration and modest success of generic pharmaceuticals in many therapeutic areas (21). COPD-related prescription and dispensing of β-adrenergic preparations in combination with inhalatory corticosteroids ("R03AK" ATC code group) were reported record breaking fivefold increase from € 2,682,320 in 2004 toward € 11,761,775 in 2012 based on latest official release by the National Medicines and Medicinal Device Agency of Serbia (22). Recent dissertation conducted on health economics of community acquired pneumonia (CAP), proved clear proof of substantial COPD comorbidity impact to the overall costs of medical care. While ordinary CAP clinical cases incurred on average € 717 costs in a 1 month time horizon while the ones suffering from COPD and CAP incurred € 970 monthly costs of inpatient care (23).

PROPOSED MEASURES TO TACKLE THE CHALLENGES LYING AHEAD

Although COPD prevalence and incidence seem to be steadily slowing down in some parts of the European region, this might not be the case with mortality rates. Unfortunately, COPD will most likely be the third leading cause of death worldwide and the fifth leading cause of years lost through early mortality or handicap (disability-adjusted life years) in 2020, which is far worse landscape compared to 1990 (24). So far serious policy initiatives to combat decreased longevity and quality of life caused by COPD have been taken both by WHO and the European COPD Coalition (ECC) (25). Orchestrated supranational efforts to increase research investment in the therapeutic options for COPD were proposed within the Horizon 2020 framework as well (26).

Broad forecasts on COPD for the South Eastern European region may be significantly less optimistic compared to the traditional EU15 economies (see **Table 1**). Some underlying reasons are strong popular affection toward smoking tobacco among adolescents (27, 28) and inefficiencies of anti-tobacco public health campaigns and policies (29). Environmental pollution plays less significant role due to shutting down of most heavy industries in former socialist countries (30) due to socioeconomic transition as well as their lack of global competitiveness (31). Popular opinion on tobacco is gradually beginning to change but this is likely to be a lengthy process. Additional obstacles to this tobacco reduction process seem to be traditionally high prevalence of tobacco smoking habit in Balkan countries such as Bulgaria (32) and FYR Macedonia (33) and heavy investment of global multinational tobacco manufacturers in Serbia and Turkey in particular (34). Essential revenues provided to the local governments by taxation of tobacco sales both to the industry and the consumers is still too important to the regional economies, still outside EU, such as Western Balkans and Turkey. This fact makes tobacco control policies currently in place less successful. Opposingly, promising trend of decreasing tobacco consumption is clearly visible in the OECD economies such as Greece (35), Slovenia, Hungary, and Cyprus where smoking free legislation, higher taxes on cigarettes, and facilitated access to medicines used to treat nicotine addiction are being applied for a number of years in line with the EU health priority targets (36). According to combined tobacco control score (TCS), most countries of South Eastern European region obtained <50 grades with the exceptions of Ukraine and Turkey. Interestingly, unsatisfactory and weak tobacco control policies remain in place in a number of traditional high-income European economies.

Containing epidemiological burden of COPD in the Balkans, while providing equitable and affordable medical care for patients will demand surmounting efforts from local communities. Economic consequences in terms of illness attributed lost productivity are huge and due to ongoing upward economic developments in the area likely to increase further. Current national capacities in SEE health care provision remain insufficient, not only in terms of professional staff but also in terms of specialized clinics and rehabilitation facilities, which are still scarce across the region (37). Through the course of past decades, historical network of facilities created to combat tuberculosis was seriously downsized due to successes of innovative vaccines and antibiotics. Another important issue is strong concentration of clinical physicians and nurses in urban cores, leaving rural areas underserved (38).

Far reaching potentially successful strategy to combat COPD in South Eastern Europe would have several distinct features. Such effort should be supranational and should contain key priorities defined within common EU policy on COPD (39). It would have to include peculiarities of local public health and clinical settings, which were already proven to affect resource use and outcomes of COPD medical care (40). Major measures assume prevention of smoking among youth and controlling environmental pollution primarily in large cities. Timely detection of illness by broadly targeted diagnostic screenings could allow more efficient treatment and preserving clinical evolution in its early stages. Evidence based allocation, favoring implementation of cost-effective diagnostic and treatment protocols would help to contain cost without significant adverse influence to the quality of care. Such a complex approach could allow larger portion of local communities to be taken care for, particularly among the poor and underserved citizens.

Although the quantification of the direct health care costs of COPD as well as indirect and intangible costs in these

Table 1 | Ground indicators on respiratory disorders, tobacco consumption, and health expenditures in SEE 1980–2010.

Country	AL	BA	BG	HR	CY	GR	HU	MN	MD	RO	RS	SK	SI	MK	TR	UA
SDR, bronchitis/emphysema/asthma, all ages, per 100,000 – 1980	26.08[1987]	36.77[1985]	41.91	27.86[1985]	12.89[2004]	20.64	62.15	1.7[2000]	20.1[1981]	71.71	28.67[1998]	31.97[1986]	14.74[1985]	40.25[1991]	N/A	26.57[1981]
SDR, bronchitis/emphysema/asthma, all ages, per 100,000 – 2010	13.07[2004]	15.33[2011]	10.45	21.06	9.31	0.17	31.1	0.12[2009]	42.3	20.5	23.04	13.09	12.2	18.74	35.83	31.16[2004]
SDR, selected smoking-related causes, per 100,000 – 1980	262.81[1987]	269.46[1985]	544.43	353.88[1985]	158.33[2004]	292.22	566.24	243.38[2000]	844.85[1996]	461.93	382.43[1998]	440.38[1992]	347.76[1985]	335.44[1991]	N/A	637.25[1991]
SDR, selected smoking-related causes, per 100,000 – 2010	324.09[2004]	237.58[2011]	345.25	349.9	128.09	183.07	425.16	180.62[2009]	762.36	427.69	332.47	416.46	185.02	331.21	232.04	774.79[2004]
Hospital discharges, respiratory system diseases, per 100,000 – 1980	1954.46[1989]	850.83	2743.52	1351.22[1981]	773.5	1193.82	1854.34[1992]	1678.87[1988]	3830.1	3089.9	812.19[2000]	1958.95[1991]	1721.4	970.65[1983]	329.85	4930.78
Hospital discharges, respiratory system diseases, per 100,000 – 2010	1331.93	855.92[1989]	3098.79	998.13	599.76[2008]	1536.89[2007]	1685.35	1275.22	2467.71	2817.71	1106.06	1471.01	1410.74[2009]	1863.55	1781.6	3704.3
Prevalence of chronic obstructive pulmonary disease (%) – 1980	0.15[1994]	3.14	2.6	0.41[1981]	N/A	0.35	0.12[1988]	N/A	1.3[1991]	0.49[1989]	N/A	1.02[1994]	N/A	0.17[1983]	N/A	2.76[1996]
Prevalence of chronic obstructive pulmonary disease (%) – 2010	0.21	1.56	2.25[2000]	0.14	N/A	0.24[2008]	1.47	N/A	N/A	1.47	N/A	1.68	N/A	0.38[2007]	N/A	3.94
Number of cases of chronic obstructive pulmonary disease – 1980	4870[1994]	128449	230335	18745[1981]	N/A	34117	37278[1990]	N/A	56878[1991]	113814[1989]	N/A	54545[1994]	N/A	3359[1983]	N/A	1403640[1996]
Number of cases of chronic obstructive pulmonary disease – 2010	6874	59968	184167[2000]	6200	N/A	26595[2008]	147480	N/A	N/A	315437	N/A	91023	N/A	7737[2007]	N/A	1799851
% Of regular daily smokers in the population, age 15+ – 1980	29.5[1990]	37.6[2002]	31.4[1986]	32.6[1995]	23.9[2003]	46[1991]	44[1992]	N/A	19[2000]	25.9[1989]	33[2000]	24.4[1992]	34[1988]	N/A	44[1988]	40[1990]
% Of regular daily smokers in the population, age 15+ – 2010	39	14.3	39.7[2007]	27.4[2003]	26.5[2008]	31.9[2009]	31.4[2009]	32.7[2008]	27.1[2006]	26.7[2011]	26.2[2006]	19.4[2009]	19.2[2012]	36[1999]	25.4	23.3
Number cigarettes consumed per person per year – 1980	436.19[1996]	820.82[1997]	1880.95	2167[1992]	N/A	2271.4	2652.39	N/A	N/A	1347.07[1991]	N/A	1715.05[1993]	2500.54[1996]	2143.11[1996]	1167.44	N/A

(Continued)

Table 1 | Continued

Country	AL	BA	BG	HR	CY	GR	HU	MN	MD	RO	RS	SK	SI	MK	TR	UA
Number cigarettes consumed per person per year – 2010	744.06[2000]	1244.01[2000]	2792.6[2000]	1736.68[2000]	N/A	3200.49[2004]	2151.41[2000]	N/A	N/A	1392.63[1997]	N/A	1230.4[2000]	2232.86[2000]	1794.36[2000]	1547.84[1998]	1027[2000]
Sulfur dioxide emissions, kg per capita per year – 1980	N/A	107.19[1990]	231.34	32.72	N/A	41.48	152.46	N/A	76.78	47.52	N/A	156.49	123.41	N/A	4.59	77.14
Sulfur dioxide emissions, kg per capita per year – 2010	N/A	N/A	104.77[2000]	15.98[2000]	N/A	50.01[2000]	53.86[2000]	N/A	31.61[2000]	40.12[1994]	N/A	38.88[2000]	13.57[2000]	52.3[1998]	15.49[2000]	46.91[2000]
Average annual concentration of sulfur dioxide (SO_2) in capital, $\mu g/m^3$ – 1980	N/A	18.4[2002]	27.4[1998]	N/A	N/A	22.2[1997]	41.6[1997]	N/A	N/A	N/A	58.6[2003]	25.4[1997]	35.4[1997]	27.3[1997]	N/A	N/A
Average annual concentration of sulfur dioxide (SO_2) in capital, $\mu g/m^3$ – 2010	38.5[2009]	35.1	9.4	N/A	N/A	5.7[2008]	6.7	N/A	N/A	15	37.8	19.5	2[2008]	1.3	12.6	N/A
Average annual concentration of particulate matter $<10\,\mu m$ (PM10) in the capital, $\mu g/m^3$ – 1980	N/A	N/A	20.4[2000]	N/A	N/A	34.7[2001]	35[2003]	N/A	N/A	N/A	52.7[2004]	36.5[1999]	30.9[2002]	N/A	N/A	N/A
Average annual concentration of particulate matter $<10\,\mu m$ (PM10) in the capital, $\mu g/m^3$ – 2010	22.6[2009]	48.5	48.4	N/A	N/A	30.4[2007]	31.9	N/A	N/A	35.4	23.1	26.6	29.4[2009]	N/A	59.5	N/A
Average annual concentration of nitrogen dioxide (NO_2) in capital, $\mu g/m^3$ – 1980	N/A	27[2002]	39.7[2003]	N/A	N/A	50.8[1997]	53.2[1997]	N/A	N/A	N/A	40.2[2003]	34.3[1997]	31.6[2002]	N/A	N/A	N/A
Average annual concentration of nitrogen dioxide (NO_2) in capital, $\mu g/m^3$ – 2010	N/A	25.7	31.3	N/A	N/A	42.4[2008]	28.1	N/A	N/A	20.5[2011]	27.9	13.3	34.7	15[2009]	N/A	N/A
Average annual concentration of ozone (O_3) in the capital, $\mu g/m^3$ – 1980	N/A	68.4[2006]	4.4[1999]	N/A	N/A	75.8[1997]	69[1997]	N/A	N/A	N/A	65.4[2004]	72[1998]	66[1998]	N/A	N/A	N/A
Average annual concentration of ozone (O_3) in the capital, $\mu g/m^3$ – 2010	N/A	53.6	65.4	N/A	N/A	88.6[2008]	73.7[2009]	N/A	N/A	57.7	71.2[2011]	71.6	63.7	N/A	N/A	N/A
Total health expenditure, PPP$ per capita, WHO estimates – 1980	97.6[1995]	128.44[1955]	290.22[1995]	546.04[1995]	722.76[1995]	1263.1[1995]	656.74[1995]	445.18[1995]	115.12[1995]	183.44[1995]	259.86[1995]	503.8[1995]	969.4[1995]	421.4[1995]	174.12[1995]	246.56[1995]
Total health expenditure, PPP$ per capita, WHO estimates – 2010	481.9	833.74	1053.1	1461.7	2221.68	2584.6	1653.88	947.86	369.66	880.94	1183.44	2088.18	2366.4	772.02	1071.54	520.44

countries is very difficult, it is clear that pulmonary specialists across the South Eastern Europe region are challenged to increase their efforts to reduce the menace of smoking and to put in additional efforts in creation of new strategies aimed at early diagnostics. The estimation of total health care costs can therefore only be a first step in assessing the overall impact of COPD burden in South East Europe region. Further studies on the economic burden of COPD, including the perspective of mostly underestimated indirect and intangible costs within the region will be needed to prove and justify the prevention and early diagnostics efforts and development of new strategies of reduction of both financial and non-financial burden of disease. Many policy makers are starting to realize that a more robust evidence base is needed in order to make informed decisions on resource allocation. In light of current weaknesses of regional health financing, funding the quest for knowledge of the local cost drivers of key clinical conditions represents a valuable investment in the future of emerging markets (41).

COPD with its multimillion patient population in the SEE region should be regarded as one of the high-profile policy issues on the agenda of national health ministries and governmental agencies. Future of these patients remains particularly unpredictable among the small Western Balkan economies approaching EU membership.

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Out-of-pocket patient payments for public health care services in Bulgaria

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Prolonged Transition from a Tax-Based to Insurance-Based Health Care Provision

In Bulgaria, the democratic social and economic reforms began when the new Constitution was adopted in 1991. The communist period prior to this reform was marked by the development of the health care system within an environment of centralized management (1). Health care financing was entirely based on general taxation. Medical services were provided by the state or the municipality. All health care establishments were public institutions as private medical practices were prohibited before 1989. These establishments were allocated an earmarked budget, the size of which was mainly determined on a historical basis. The key factors that determined the allocation of funds were the number of staff and beds. Large staff and a high number of beds were rewarded, and a high level of patient admissions and long hospital stays were common. The reimbursement of health care professionals was in the form of a salary based on employment contracts (2). Health care provision was free of charge at the point of service use. There were only small charges when purchasing prescribed pharmaceuticals and devices outside the health care settings (e.g., at the pharmacy).

With the socio-political changes in 1990s, many elements of the Bulgarian health care model were discredited. A number of problems with the health and demographic status of the population became visible. The failure to cope with the inefficiencies in the health care sector, as well as the poor management and suboptimal use of resources for health care, gradually became more evident (3). The reform of the health care system was put on the government agenda. The main aims of the reforms were the restructuring of the health care financing system, strengthening primary care, and rationalizing the network of outpatient and inpatient facilities. The preparation for the introduction of the health insurance system was accompanied by the adoption of legislative acts that formed the basis for the health care reforms.

The discussion on the need to restructure the centralized tax-based health care system into a social health insurance system started in 1990s and was conducted parallel with the transformation of the country's economy from a centrally planned economy to a market-based economy (1). However, the health care system was transformed into a social health insurance system only in 2000 after the Bulgarian Parliament adopted the Health Insurance Act of 1998 (2). The reform introduced market principles, decentralization, as well as pluralism in the ownership of the health institutions and the provision of health care services.

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Out-of-Pocket Payments have Become the Main Source of Health Care Financing

The regulatory changes created three major players in the system as follows: (a) citizens as insurance buyers/consumers, (b) outpatient and hospital establishments as providers, and (c) public and private health insurance organizations as third-party payers. The Act of 1998 established the National Health Insurance Fund (NHIF) and defined the relationship between the NHIF, health care consumers and providers. The relationships between the NHIF and health care providers are based on the National Framework Contract. Based on this contract model, providers sign individual contracts with the district branches of the NHIF, namely, the 28 Regional Health Insurance Funds (RHIF). The NHIF interacts with all kinds of providers. The general practitioner (GP) is the central figure in the primary care and acts as a gatekeeper for specialized ambulatory and hospital care. Ambulatory care is provided by specialized outpatient facilities, including individual and group practices, medical and medico-dental centers, diagnostic–consultative centers, and medico-technical laboratories. Hospital care is provided by public and private health establishments divided into multi-profile and specialized hospitals (1).

The reform included the introduction of formal patient charges for public health care services. These charges take the form of co-payments and apply to all levels of medical services, except emergency care. Until 2012, the official fee for each outpatient visit to a GP and medical specialist (after a referral) was equal to 1% of the minimum monthly salary for the country. For hospitalization, fee amounts to 2% of the minimum monthly salary per day for the first 10 days of the hospital stay and it is paid once a year. Since these fees were defined as a percentage of the minimum monthly salary, their amount increased with the rise of the minimum monthly salary in the country. However, in order to reduce the financial burden of the insured people, the Council of Ministers replaced user charges set as a percentage of the minimum monthly salary by fixed co-payments in 2012 (4). The formal co-payments are collected and retained by the providers and their official objective is to improve efficiency in public health care provision (5).

Bulgaria currently has a mixed system of health care financing. Health care is financed from compulsory and voluntary health insurance contributions, taxes, out-of-pocket payments, donations, and external funding. The revenue from general taxation has gradually decreased as the compulsory health insurance revenues increased from 1999 to 2003 (6). However, the diminishing state role in the financing of the health care system has led to a significant increase in out-of-pocket payments, which became the predominant source of revenue in 2000 (1). This trend has continued and at present the main source of revenue for the health care system are out-of-pocket payments. The second largest source of revenue is the social health insurance contributions, which constitute 8% of the individual monthly income. These contributions are shared between the employee and employer at a ratio of 40:60, or are paid individually by the self-employed or unemployed. The third main source of revenue is the funds allocated to the Ministry of Health budget from the central budget. In addition to this, there are informal patient payments, which continue to exist irrespective of the formal charges (7).

The Burden of Out-of-Pocket Patient Payments is Considerable in Bulgaria

In Bulgaria, the share of out-of-pocket payments has increased substantially, which reflects a common trend in Europe. In 2008, out-of-pocket payments in Bulgaria formed 40% of total expenditure on health, compared to 16% in EU. In 2009, this ratio was 43.4% and in 2010, it was 44.2%. This share is one of the highest in Europe (8, 9). The projection for Bulgaria is that this trend will continue and the share of out-of-pocket payments on health care is expected to become as high as 48–49% of total health care expenditures in the coming years (9). Thus, out-of-pocket payments constitute a major source of health financing in Bulgaria and the role of patient payments will become even more important in the future.

A recent study among a nationally representative sample of the population in 2010 and in 2011 (10) has explored whether user fees, combined with informal payments are affordable for the population. Two indicators of inability to pay, namely, the need to borrow money to pay for health care and the need to forego health care services due to high payment requirements, are analyzed. The results show that in 2010 and 2011, 60% of users paid out-of-pocket payments for both physician services and hospitalizations. Of those who paid, about 6% borrowed money to pay for physician services in both years and more than 10% of users borrowed money to pay for hospitalization. In addition to this, 32% of the sample forewent physician visits due to the patients' inability to pay and about 6% of the sample reported foregoing hospital services. Thus, irrespective of the coping strategy (borrowing money or foregoing services) used by patients to deal with their inability to pay, the results showed that population groups with insufficient household resources (low income) and in frequent need of health care (poor health and chronic conditions) are the most vulnerable groups. The existence of an adequate exemption mechanism can only partly solve the problem of the inability to pay of vulnerable groups. This is because of the existence of informal payments in Bulgaria.

Informal Payments for Health Care Services Continue to Exist in Bulgaria

Informal payments (both cash and in-kind informal payments) for health care services have a long tradition in Bulgaria (11–13). After the implementation of social health insurance, informal payments continued to exist despite the formal co-payments for services under the insurance scheme. Before the political changes in 1989, almost all informal payments were gifts in-kind. Informal cash payments emerged during the transition period and became rather widespread in the period before the social health insurance reform. The recent study conducted in Bulgaria in 2010 and 2011 (7) indicates the experience with informal payments after 10 years of official co-payments. The results show that in 2010, around 13% of the respondents who used outpatient services during the last 12 months,

made informal payments (on average 45 EUR per year), and in 2011, around 10% of users report informal payments (on average 23 EUR per year). In 2010, approximately one-third of the respondents who were hospitalized during the last 12 months paid informally (on average 85 EUR per year), and in 2011, 18% of users made such payments (on average 108 EUR per year). Another study conducted in Bulgaria in 2010 (14) also confirms that about 10% of respondents have paid physicians informally in cash. Thus, the incidence of about 10–12% of the patients making informal payments has remained relatively constant during the years.

Tolerance Toward in-Kind Gifts for Health Care Services

Some studies conducted in Bulgaria before and after the reform analyze the attitudes and perceptions toward informal payments. The findings suggest the tolerance and acceptance of in-kind gifts. There are different expert opinions regarding the factors influencing the decision of patients to pay informally (15, 16). Taking into account, the three models proposed in the literature (17, 18), which explain the causes of informal payments by the joint effects of cultural perceptions, quality of governance, and the economic situation, we have put the emphasis on the cultural model to explain the high level of tolerance toward in-kind gifts. This model considers informal payments as a particular type of behavior of care seekers who express their gratitude in the form of gifts. The value of gifts is negligible and depends on the wealth of the patient. Thankful patient give in-kind gifts without any request or hint by the medical staff and in order to be truly a gift, it should be given after the service and not before. Therefore, a true expression of gratitude does not put a sizeable burden on patients and a necessary condition should be also that it is a voluntary act. Thus, the cultural model may be used to explain the positive attitude toward gifts in-kind observed in Bulgaria.

In contrast to in-kind gifts, informal payments in cash can have serious negative consequences. They may hinder access, create problems of the affordability to pay, may result in a refusal of treatment in the absence of payments, and lead to unnecessary medical interventions (19). The attention of policy-makers should be directed to the implementation of effective measures for their elimination, as well as the elimination of sizable in-kind gifts even though initiated by patients. In contrast to informal cash payments and sizable in-kind gifts, a true gratitude payment does not violate patient's rights and dignity. The freedom of patients to give small in-kind gifts does not make them vulnerable. Therefore, this type of payment is difficult to eliminate. However, there should be clear regulations on what a thankful patient can give to medical personnel after the service provision (20).

Conclusion

The parallel existence of formal and informal payments in Bulgaria has led to high out-of-pocket payments. Hence, there is a need to eliminate the existence of informal patient payments, which induce additional payment obligations for health care users. These payments are used by patients and health care providers as a means to overcome the poor service quality, to compensate the low remuneration of health care personnel, and to receive proper attention. However, the fight against these payments requires a set of different measures, persistency and strict control, and regular government investments in the improvement of service quality.

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Dental services funding and affordability in Serbia – decade-long perspective

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Demand for Dental Care Services

Global awareness of growing demand for oral health care services became prominent over past several decades (1). Far reaching consequences of clinical dentistry for overall societal welfare were more obvious to the governing health authorities in mature market economies at first (2). Eastern European and Balkan health systems suffered from serious development setbacks during painful transitional health reforms taking place in the region since 1989 (3). Some of the core challenges across the region were temporary worsened insurance coverage in most countries of the region and huge contribution of out-of-pocket payments by ordinary citizens (4). As in so many areas of curative medicine, dental care was undergoing the same evolution. The early stages of this process were quite challenging for the regional health sector, and successful adaptation to the increasingly globalized health care market took many years to happen (5). Peculiarity of dental medicine is reflected in strong demand for frequent services, initiated by common acute disorders and adverse consequences of treatment procedures (6). Preventive and conservative dentistry in pediatric populations has significant long-term impact to the dental expenditure across the region (7). In some other areas, such as restorative dentistry, these issues are particularly prominent (8). In many transitional health systems, financial constraints worsened by global economic recession reflected heavily on dental care, imposing further narrowing of existing reimbursement practices as it happened in Bulgaria (9).

The Case of Serbia

Serbia, as the largest successor state of former Yugoslavia, has its health system legacy in many ways different from Post-Semashko systems of other South East European countries (10). It is funded through one core state-owned health insurance fund (11) whose revenues mostly come from mandatory taxation of employers and employees (12). This transitional health system is currently undergoing significant reform from massive, hospital-based, supply-oriented one toward more responsive, lighter primary care-oriented system (13). Regardless of many successes, substantial challenges remain and these are reflected in evolving structure of national health care spending over past two decades (14). As in most of remaining European nations, work load to the entire health system and expenditures are dominated by accelerated population aging (15, 16) and prosperity diseases (17). So far, there are diverse difficulties related to inefficient funding mechanisms (18) and poor access and affordability of medical care (19) to the vast population of poor citizens and those residing in rural areas (20). Dental services remain seriously underfunded from public resources and this issue shapes the related to oral health of the nation (21). There are very few published local estimates on budget impact of clinical dentistry in the Balkans and related cost-of-illness studies. One of the few promising signs of growing awareness among policy makers is prioritizing oral health in some long-term national public health strategies (22).

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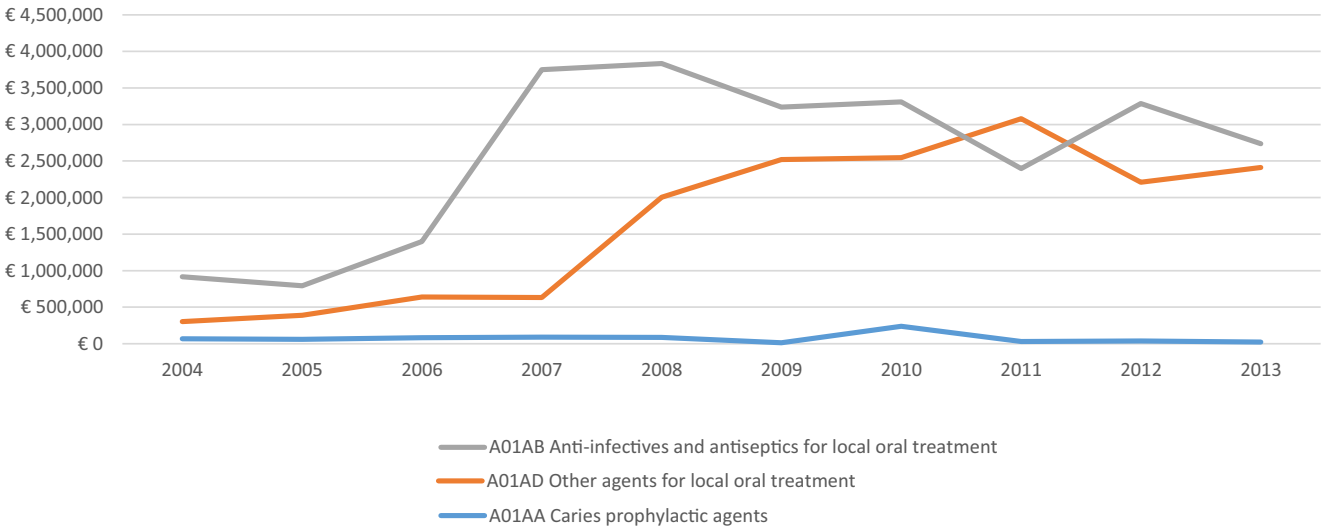

FIGURE 1 | Value-based turnover of publicly financed consumption of dental medicines presented across ground ATC medicines classes according to 2004–2013 growth in value-based turnover.

Public Spending for Dental Care and Medicines Over the Last Decade

Since 2004, National Agency for Medicines and Medical Devices of Serbia (ALIMS) issue commercially available periodic reports on precise structure of prescription dispensing and value of sales of all pharmaceuticals within the publicly funded health care facilities, pharmacies, and wholesalers. Recent research of trends over past decade has shown bold growth in local market size (23) dominated by biologicals (24) and oncology-related treatment options (25). These same sources offer us best attainable insight into the structure of Serbian market of dental medicines classified within broadly recognized Anatomical–Technological–Chemical classification system (ATC). Data presented in **Figure 1** point out the falling prescription and dispensing of "Caries prophylactic agents" (A01AA code) whose value-based turnover decreased from € 66,704 in 2004 to € 21,397 in 2013 (actual peak value in the observed period was € 238,397 back in 2010). At the same time, sales of "Other agents for local oral treatment" (A01AD code) grew eightfold from € 302,608 in 2004 to € 2,413,302 in 2013 (actual peak value in the observed period was € 3,079,162 back in 2011). Slightly slower increase but the one dominating the market was the one of "Anti-infectives and antiseptics for local oral treatment" (A01AB code) rising from € 917,894 in 2004 to € 2,736,887 in 2013 (actual peak value in the observed period was € 3,833,995 back in 2008). Combined market size of all these three major groups of drugs used in various branches of dental medicine grew from € 1,287,207 in 2004 to € 5,171,585 in 2013. It is important to emphasize that entire national consumption of stomatological preparations actually contracted due to global economic recession and value of spending was exceeding € 6,000,000 back in 2010. The strong impact of economic crisis on Balkan pharmaceutical markets was noticed across the region with surprisingly better performance of transitional economies compared to OECD ones (26). Size of targeted public spending for oral health inclusive of capital investment, staff salaries, utilities, consumables, and other costs by far exceeds drug acquisition costs. According to the first officially available data, Republican Health Insurance Fund of Serbia (RFZO) has devoted € 51,131,383 in 2007 while over 21% less only 7 years after in 2013 (€ 40,351,340). Referring to the entire public health spending in the country funded by RFZO that this effectively meant percentage point decrease of governmental resources assigned for oral health programs from 2.82% in 2007 to 2.12% in 2013. These facts make de-investment into the clinical dentistry a rare exception compared to the many areas or clinical medicine regardless of crisis induced budget constraint (27). Such reimbursement policy imposed by local authorities effectively shifted financial burden of primary dentistry care to the ordinary citizens. Government legislature confirms that mandatory health insurance premiums were not inclusive of adult dentistry care unless in case of emergencies (28). Unlike among high-income EU economies, such policy in Serbia led to strong fall of demand for dental services motivated by simple lack of affordability rather than clinical need (29). Bureaucratic obstacles to the provision of dentist services contributed to the aforementioned phenomenon as well. Poor access to these medical services ultimately exposed well-known boomerang effect. Patients who were denied right to treatment in the early stages of their illness much later must be treated for severe form of neglected illness, which is much more expensive to treat. Outcomes of such delayed care are much less favorable and predictable and these interventions lose their cost-effectiveness when applied in clinically advanced cases (30).

Core Future Challenges of Dental Services Provision and Financing

Dental medicine is one of the rare examples of flourishing of private-owned clinical facilities rising from historical legacy of

state-owned health care in the region. Nevertheless, due to several core weaknesses, pace of contemporary Serbian oral health efforts seems to be insufficient to cover long-term population needs. Surprisingly, strong development of pharmaceutical market in other areas of clinical medicine occasionally reaches several fold annual growth. Due to public funding limitations, such setting creates significant pressures against financing of dental services. Accumulated public debt toward multinational industries of pharmaceuticals and medicinal devices will most likely continue to grow further (31). Some of the possible escape strategies should be rooted in evidence-based resource allocation policies. Regional efforts to establish feasible local health technology assessment agencies might be very rewarding in the long run. Throughout most of Western Balkans, cost-effectiveness estimates are not even mandatory condition for marketing approval of novel medicines. The core challenge lying ahead of more effective dental care provision in Serbia remains lack of insurance coverage and too high out-of-pocket payments by citizens. Bold growth of out-of-pocket health care spending is unfortunately evident in most globally leading emerging markets, which severely affects affordability of medical care to the poor (32). Demand for dentist's services remains much higher than in most other clinical disciplines. Serbia's dental healthcare market will probably achieve further growth in the upcoming years but mostly within its already conceived private sector. Decreasing public expenditure on oral health poses an unpleasant setback, which might be corrected after consolidation of economic growth (33). If national authorities commit themselves to prioritizing preventive dentistry (34), such move could yield significant gains (35). Unpredictable financial sustainability of existing health insurance systems in the Balkans will demand long-term efforts targeted to achieve accessible dental care for local communities in future.

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Social protection in health care and vulnerable population groups in Serbia

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Social Protection and the Health Care System in Serbia

Social protection refers to a set of policy measures to protect individuals, especially the critically poor, from financial losses due to high-risk events, such as natural disasters, social risks like unemployment, war or unexpected financial shocks, and political risks like discrimination of minorities in conflict zones (1–3). In terms of health, social protection includes protection against health risks, to ensure good quality of care and financial protection that aims to protect people from unexpected health care shocks (4). One way to assure financial protection in the health care sector is to introduce universal social health insurance (5). However, when universal health insurance cannot provide financial sustainability of the health care system, patient charges are necessary. With patient payments social protection can be achieved by the implementation of an exemption mechanism (5). In this paper, we focus on financial protection in health care in Serbia.

Serbia is a middle income country with long-term tradition in social protection related to health, inherited from the period of the former Yugoslavia (6–11). The health care system of Yugoslavia was known as a Swedish model in the Balkan (12). However, during the period 1991–2000, Serbia faced a civil war combined with a severe economic crisis (13). The crisis was followed by impoverishment among the citizens and the collapse of the existing health care system. Impoverishment was not the only consequence of the civil war. Like in many other post-conflict and transitional societies, corruption became a *modus vivendi* in the public sector in Serbia (14). The widespread corruption had a direct effect on health care consumers as well. Different types of informal (under the table) patient payments become common practice in the health care system (15).

After a major political change in 2000, the Serbian government introduced health care reforms. The main objective was to improve efficiency, service quality, and equity in health care (16). As part of the health care reforms, in 2002, the Serbian government introduced official co-payments for services covered by the compulsory health insurance to improve the financial situation of the public health care system. The introduction of official co-payments was accompanied with an exemption mechanism (7, 17).

To What Extent does the Exemption Mechanism Protect Vulnerable Groups?

In Serbia, various population groups are exempted from paying for health care: children younger than 15 years, pregnant women, persons older than 65 years, disabled persons, HIV-infected persons, monks, people with low-family income, unemployed, chronically ill people, military service servants, people registered as refugees, and the Roma population (6). The government motivated the high number of exempted population groups by arguing that it reflected a long tradition of solidarity

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and equity in Serbia (18). However, recent studies show that the exemption mechanisms in Serbia are not effective (19). Two main reasons for the failure of exemption mechanisms are the design of the exemption mechanisms and the implementation of the exemption mechanisms. People with low income, although exempted, often report high amounts of payments (19). They are usually unaware of their rights. On the other side, some population groups with chronic conditions are not exempted or just partially exempted and they experience the burden provoked by patient payments. The implementation of the exemption mechanism also has weaknesses. Since the guidelines are not clear and written in law-centered language, it is very confusing for patients and health care providers to understand for which services the (partial) exemption mechanisms should be applied (20). Another obstacle in the implementation of the exemption mechanism is related to the procedure to obtain the exempted status. The procedure is administratively difficult and time consuming (21). At the same time, some population groups, even if they are not in need, are still exempted. These include military civil servants and monks, all people older than 65, and all children younger than 15. Those subpopulation groups were exempted during the civil war when the government of Slobodan Milosevic used the health care system as a political tool to buy social peace (22). However, not all people older than 65 and not all children younger than 15 are in financial need to be exempted. The payments for health care services for children are made by their parents. Not all parents are unable to pay for health care services. A better policy approach would be to use parents income as an indicator for exemption, instead of exempting all children younger than 15. Those examples confirm that the high number of exempted groups influence the financial sustainability of the health care system in Serbia. In the period 2003–2008, there were some attempts to reduce the number of health services that were included in the insurance package, but there was no attempt to decrease the number of exempted groups. During the parliamentary elections in 2004, 2008, and 2012, the main political parties emphasized that health care should remain free of charge for vulnerable population groups (23). The attempts of the previous Minister of Economy to simplify the exemption procedure and to decrease the number of exempted individuals led to his resignation (24). The Serbian case shows that when exemption mechanisms are not well designed and well implemented, vulnerable population groups may stay unprotected.

To What Extent are Pregnant Women Protected Within the Health Care System in Serbia?

In Serbia, maternity care is formally free of charge. All Serbian governments from 1991 to 2014 wanted to encourage women to have more children (25). In a country which is in a difficult politic and economy situation, a full exemption of pregnant women in maternity wards from official co-payments was one of the first financial protection measures taken. Financial protection also included prenatal and postnatal health services. Although exempted from official co-payments, many women report informal patient payments and quasi-formal patient payments (official charges set by the facility but not regulated by the government) (26). Quasi-formal payments are charged by hospitals for services that should be provided for free (e.g., epidural analgesia). Regarding the informal payments, the main reason for paying informally is to obtain better quality of care and safety for the new born child (27). However, recent studies show that informal patient payments do not guarantee better quality of care (26). Even though some women report informal patient payments, they still experience inconveniences related to quality of care, namely, problems with equipment and obligatory but non-necessary procedures during the admission. They also report poor bedside manners and derogative communications from the side of medical staff (26). Those inconveniences are related to psychological and social accessibility to health services and violate the official social protection measures. In order to avoid such inconveniences many women call upon "special connections." "Special connections" are described as friends or relatives who work in the hospital and who can ensure a special treatment and adequate care. "Special connections" represent someone whom the pregnant woman can trust (26). In a certain way, they also represent a non-monetary way to buy compassion during the process of delivery. In this way, special connections represent a type of informal social protection. It means that pregnant women in Serbia are aware that formal social protection will not ensure adequate care in maternity wards. The existence of "special connections" also emphasizes that formal financial protection in Serbia is a necessary but not sufficient way to ensure adequate care.

Perspectives for the Future

The examples presented above show that an adequate social protection policy for vulnerable population groups in health care should be based on different dimensions. Financial protection is one of these dimensions. Exemption mechanisms as a tool to achieve financial protection should be clearly designed and available for patients. A broad scope of exempted groups does not guarantee that the social protection policy is adequate and effective, especially in countries where the financial sustainability of health care systems is fragile. Instead of including a large number of population groups (such as in Serbia), attention should be paid to the adequate targeting of eligible groups (for example, using the already existing insurance system) and the adequate provision of health care services for those who are exempted. A good social protection policy should not only be more pro-poor oriented but also take in account health status. For example, the current policy could emphasize the importance of prevention of chronic diseases (28). People who are already diagnosed with a chronic disease are faced with the financial burden of using health care. Also, the example of maternity wards in Serbia shows that financial protection is a precursor but it is not enough to secure adequate social protection. Quality of care is another dimension of an adequate social protection policy. Within the maternity wards in Serbia, a lot is still left to be desired regarding the quality of care provided (29–32). Although recent studies show that physician's

skills are not perceived as bad, their communication skills are (26). In order to provide good services in maternity wards, the Serbian government should take women's preferences into account. The government should also educate physicians to respect women's preferences. This means that good physicians' skills are a necessary but not a sufficient condition for providing good quality care (31, 33). The current system of medical education in Serbia is mainly focused on the technical skills of future physicians. Patients' needs are not recognized as important for the curative process. Physicians in Serbia need to become aware that the satisfaction of patient needs contributes to more effective curative outcomes (34).

Despite the efforts of policy makers in Serbia to provide generous social protection policy, vulnerable population groups are still non-protected. Serbia shows that social protection policy in countries with limited financial resources should not be overgenerous. An adequate policy should focus on better targeting of those in need. Furthermore, social protection policy is related to official co-payments neglecting the existence of informal patient payments. More attention should be paid to prevent informal and quasi-informal patient payments. Also, future policy should recognize the importance of patient preferences.

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Improvements in neonatal and childhood medical care – perspective from the Balkans

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Traditional Childhood Medical Care Provision – Legacy of Former Yugoslavia

Health services covering needs of pregnant women, newborns, infants, and preschool and school-age children in Serbia, are provided according to the plan of the compulsory health insurance (1). Such insurance premiums include the implementation of organized screening in health institutions of secondary and tertiary levels (prenatal examinations, mandatory screening for phenylketonuria and hypothyroidism, audiometric screening, ophthalmologic screening for retinopathy of prematurity, ultrasound screening for developmental dysplasia of the hip, central nervous system, etc.).

Within the primary health care of newborn infants and infants, regular visits of the attending nurse are mandatory after discharge from the maternity ward. In later period, the chosen doctor does systematic and regular check-ups [complete blood count (CBC) in the age of 6 months, 2 years, and 4 years] and follows the growth and psychomotor development of the child. In preschool and school, medical examinations are performed in dispensary (every other year). Chosen physician is obliged to refer to the additional examinations (speech therapist, dentist, physiatrists, ophthalmologist, and otolaryngologist) in the age of 4 years and before school enrollment. These screenings are used for early detection of functional disorders, in order to carry out structural analysis and preventive interventions to preserve the health of the youngest population in Serbia.

At the same time, the protection from infectious diseases is carried out by vaccination, according to mandatory immunization calendar by age groups. This procedure is consistent with the recommendations of the Republic Institute for Health Insurance and European regional strategy "Health for All." National public health strategy to cope with communicable diseases is funded by the Republic Institute for Health Insurance (2).

Pregnant women and children in Serbia have the right to regular dental care from the compulsory health insurance ("health booklet"), within the framework of primary health care – the principle of the chosen dentist (3). In the preschools and schools, preventive dental examinations are periodically carried out, with immediate health and educational work with children. The aim is to adopt healthy eating habits, improving oral hygiene, and early caries prophylaxis (i.e., application of fluoride, sealants, etc.).

Transitional Success Story – Improved Outcomes in Neonatal Care Since the End of 1990s

In the last 15 years, in Serbia, the number of children born in a marriage, properly declines, while their number is in inverse relation to the age of mothers, more exactly, the number of women who

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TABLE 1 | Selected demographic, child health indicators and fertility-related health care resources (midwife capacity) in Serbia in 1998 and 2012 (HFA-DB).*

	1998 or closest year available	2012 or closest year available
Contraceptive use among currently married women aged 15–49 (%), any method	58.7[2000]	60.8[2010]
Midwives (PP) per 100 000	35.53[2003]	36.17
Number of midwives (PP)	2658[2003]	2604
Proportion (%) of births attended by skilled health personnel	98.1[2002]	99.7[2010]
% of all live births to mothers aged under 20 years	12.8	5.59
% of all live births to mothers aged 35+ years	12.72	14.07
% of live births weighing 2500 g or more	95	94
Cesarean sections per 1000 live births	79.81[2000]	267.78
Congenital anomalies per 100 000 live births	2449.4[2006]	5584.55
Births with Down's syndrome per 100 000 live births	54.93[2006]	31.22
Fetal deaths per 1000 births	5.58	5.47
Perinatal deaths per 1000 births	12.44	6.62
Abortions per 1000 live births	573.75[2000]	302.35
Abortions per 1000 live births, age under 20 years	189.66[2000]	222.75
Abortions per 1000 live births, age 35+ years	2429.72[2000]	746.99

**Data Source: European health for all database (HFA-DB) released by World Health Organization Regional Office for Europe.*

give birth after 35 years has been rising (4) (see **Table 1**). Mostly, that is the case of highly educated women, whose postponing of motherhood is justified by progress in their careers and late finding of adequate partner. Also, the number of single mothers grows, due to the increased number of divorces and poor socio-economic situation in Serbia (5).

On the contrary, the number of abortions in the subpopulation of women over 35 years is in significant decline [almost three times lower compared to 1998 (**Table 1**)], probably as a result of improved popular education concerning contraception, in relation to underage pregnant women. Although according to the National Institute for Public Health "Dr. Milan Jovanovic Batut," the number of adolescent pregnancies declined starting from 2009, the number of teenage abortions according to data from 2012 is still alarming (about 223 per year) (6).

These data suggest that the level of sexual culture among teenagers in Serbia remains low, due to lack of awareness about safe methods of contraception and fear that contraception will cause health endanger (real risk of thromboembolic complications at pregnant women under 20 years is decently low), high cost of some contraceptive methods, shame, etc. Encouraging sign is the reduction of perinatal mortality in recent years (**Table 1**). This data cannot be explained by increasing qualified health personnel capacity (for about 1.6:100,000, according to data from **Table 1**), but rather with increasing frequency of cesarean section.

Empirically, we know that after prematurity, the leading reasons for perinatal morbidity and mortality are asphyxia and systemic infections. Having in mind that obstetric interventions (forceps and vacuum extraction) are often followed by such complications, we believe that more frequent cesarean section surgery would contribute to significantly reduced overall perinatal mortality (7).

Better prevention of prematurity and treatment of respiratory diseases is mostly attributable to the prenatal application of glucocorticoids, postnatal surfactant application, and less invasive high frequency ventilation devices. The mortality caused by serious grade respiratory distress syndrome (RDS), as the leading risk in premature infants, has been reduced.

Besides, fetal mortality in Serbia still exists (**Table 1**) and for worrying is the fact that the number of newborn children with congenital anomalies in 2012 was doubled compared to 1998. This can be explained by increased number of older pregnant women (8). On the other hand, after latency period of two decades since the civil wars of Yugoslavia and depleted uranium bombings, population is faced with susceptible consequences of environmental pollution (9, 10).

Taking into consideration the aforementioned facts, we can conclude that pregnant women and children remain particularly vulnerable group. This is reflected in currently endangered population health status in Serbia, primarily indicated by growing impact of malignant diseases among younger age groups (11).

It is interesting, that despite the current trend of giving birth in late ages, there is a certain decrease in the birth of children with Down syndrome. These results suggest that early use of screening tests ("double," "triple" test, amniocentesis, cordocentesis, fetal ultrasound expert, etc.), especially in women after 35 years, can contribute to the reduction of such perinatal morbidity and perinatal mortality rate. Therefore, we believe that more substantial financial resources should be directed toward improving cost-effective prenatal Down syndrome screening (12).

Vulnerabilities of Contemporary Early Childhood Medical Care in Serbia

Despite obvious progress in the provision of medical care services within the national health system of Serbia, there are still some ongoing challenges (13). Among high-income European countries, primary health care establishments resolve at least 75% of health problems, such as 84% reported in the United Kingdom (14). In the former Yugoslavia, the same proportion rarely exceeded 50%, which resulted in redirection of significant number of adults and pediatric patients alike to the polyclinic and hospital health care (15).

Very often, waiting time for specialist examinations or necessary radiology diagnostics (16) and therapeutic procedures could range from several weeks up to few months (17). So, the patients are often forced to carry them out-of-pocket in private health institutions (18). Thus, health care costs are increasing and occasionally does not seem to provide adequate gains visible in key population health indicators. This public perception is present in most of the countries originating from the former Yugoslavia (19).

As the published evidence suggests, on the cost of insurance, residents in Serbia may have lower affordability of novel medicines

compared to the patients in the surrounding countries (20). The positive list of publicly reimbursed medicines, there are significantly less innovative medicaments (21, 22). Budget share of pharmaceuticals in Serbia was ∼742 million € in 2012 out of 1847 million € total public health expenditure available (23). At the same time, few other countries of the South East Europe region (SEE) succeeded to allocate significantly higher amount (24).

In juvenile gynecology, currently topical issue is the unavailability of many modern methods of contraception (such as progestin pills, depot injections, implants, etc.), or their relative high price. Also, sex education is not adequately adapted to the age of teenagers, medically based, or psychologically supported. Therefore, the number of teenage abortions in Serbia, compared to the countries in the region, continues to be comparably high.

According to the European Health for All Database latest 2013 official release (25), neonatal mortality in Western European countries is only 2:1000 live births (Austria and Belgium). In Serbia, perinatal mortality is still high and approximately corresponds to data from Albania (7:1000) and Bulgaria (6:1000). At the same time, the health care staff capacity in Serbia is similar to in the one of Bosnia and Bulgaria (≈100:100,000) (26).

As for the immunoprophylaxis program, according to the Institute for Public Health "Dr. Milan Jovanovic Batut," the number of vaccinated children in the first and second year of life in 2012 was below target of 95%, except for BCG and DTP3. Such result is probably the lowest one in the last 20 years. Interruptions in the continuity of immunization implementation in 2012, due to vaccines market shortages and weaker response of parents due to insufficient information, jeopardized the sustainability of the achieved outcomes.

Core Opportunities for Further Build-Up of Neonatal Care Capacities

In order to prevent unwanted teenage pregnancies in Serbia, the introduction of sex education in teaching units might have very important role, having in mind that according to polls, less than 5% of teenage girls use contraception (27). By reducing the number of unwanted pregnancies at teenage girls, their reproductive health would be preserved and the number of live born children would be increased.

On the other hand, if the trend of giving birth in later living period continues, we can expect growth *in vitro* fertilization, high-risk pregnancies, premature births, and fetal mortality, as well. In order to achieve further decrease of perinatal morbidity and mortality, it is necessary to improve access to the novel medical technologies. It must be simultaneously accompanied by stronger investment into health personnel education, acquisition of medical equipment and more effective management of hospital facilities. Continuing professional training of health neonatal intensive care professionals bears particular significance. Capital investment in the equipment for neonatology centers that could be transferred "toward the patient" to provide emergency care is essential. It assumes procurement of portable incubators, monitors, infusion pumps, portable respirators, and associated intensive care appliances (28).

Another, perhaps more realistic option would be the training of staff in local maternity hospitals to carry out an adequate short-term patient transfer to the specialized referral facilities, and thereby reduce unnecessary engagement of highly educated personnel, out of neonatal units. Unfortunately, the current situation shows that most countries in the SEE region allocate more money for health care then Serbia. Density of clinical physicians in Serbia is still below the European average. On the other hand, there are approximately 2000 physicians, 1200 dentists, 400 pharmacists, and almost 15,000 secondary vocational staff, currently unemployed.

Probably the most cost-effective and feasible solutions to improve neonatal care quality and outcomes in Serbia would be faster pace of replacement of senior staff approaching retirement with younger residency training and specialist physicians, expanded health insurance coverage, wiser resource allocation as well as strengthening of private-owned medical care facilities network. Whether complex transitional health care reform going on over two decades in the region shall make a success story or a lost historical opportunity remains to be seen.

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Paying out-of-pocket and informally for health care in Albania: the impoverishing effect on households

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The health care system in Albania, as in all other ex-communist countries of Central and Eastern Europe (CEE), is rooted in the Soviet "Semashko" model. The legacies of the Semashko system still remain visible especially in the state ownership of public healthcare institutions, public provision of the services, as well as the funding from the general tax base (especially for secondary and tertiary care) (1). WHO data show that in 2013, the total health care expenditure for the country amounted to 5.9% of its GDP (2). This is relatively high compared to other former communist CEE or Former Soviet Union (FSU) countries, but still much lower than the average 8.5% for the EU15 countries (2). However, only about 48.4% of the total health care spending in Albania comes from the general state budget (2), and the share of private expenditures and out-of-pocket expenditures is relatively high (3). The utilization of health insurance in Albania remains low (4). In addition to this, almost 19% of all patients visiting outpatient services and almost 44% of patients visiting inpatient services in 2008 pay informally as well (5). But, are out-of-pocket and informal payments in Albania catastrophic to households' budgets? If yes, what are their effects on poverty? And more importantly, what are the main policy implications for a fast-developing country like Albania?

The Health System in Albania

The Albanian health sector during the communist period was underfinanced, and the investments in health technology were very low. The extensive web of primary health care (PHC) posts and centers and the large number of local and regional hospitals had out-dated equipment and were overstaffed (6). After the change of regime, the main reforms were focused in PHC and have sought to transfer the financing of the sector to the Health Insurance Institute (HII), which was established in 1994. The HII covers the costs of PHC visits, reimburses (part) of the drugs' prices for drugs in the reimbursement list, as well as covers some costs of secondary and tertiary care. Ministry of Health (MoH) remains the owner and administrator of all public hospitals (4). During the past years, interventions in the hospital sector were mainly targeted to infrastructure and technology improvements and little has been done in terms of reforming the financing of providers.

Although the funding of PHC is through the HII, the sector is still dependent on subsidies from the general state budget. In 2013, about 74.1% of total public expenditure on health came from social health insurance funds while the rest came from general taxes [WHO (2)]. The health insurance contribution consists of a flat rate of 3.4% of gross salaries. However, numbers of contributors are still low due to the (still large) informal sector of the economy.

Since 2008, patients are required to pay a small fixed co-payment per visit for PHC visits or specialized treatment in hospital care (7). Despite the fact that by law all citizens should be covered by health insurance, surveys show that about 40–45% of the population declares to have a health insurance booklet (5). Previous studies have indicated that catastrophic health care payments remain high in the country (4). In fact, three main conditions are supposed to increase the incidence of catastrophic payments in health care: (i) the existence/availability of health care services requiring out-of-pocket payments, (ii) low capability from the public to pay for health care, and (iii) lack or inefficiency of the health care insurance (8). All these conditions seem to hold in Albania given that: (i) patients visiting public health centers are still required to pay out-of-pocket for many services and drugs that otherwise would be free-of-charge (5), (ii) poverty seem to be a constant concern during the last decades (9), and (iii) public health insurance is still not able to cover for all health care expenditures incurred in the public facilities (2).

Formal and Informal Payments in Albania

Albania's limited public spending on the health care sector (as compared to other Balkan or Eastern European countries) (10) has resulted in an increased reliance on out-of-pocket payments for both inpatient and outpatient care. Survey data report that for the lowest income quintile, the share of total out-of-pocket spending in inpatient services has gone up to 60% of the total monthly household expenditure (4). These vulnerable or poor groups of the society lack protection against out-of-pocket spending and this may contribute to increased inequalities but also to barriers to access (11). Although inpatient care is almost free for all those in possession of a health insurance booklet (except for some co-payments for high-cost diagnostic tests), in reality, most of the people visiting this service report to have paid substantial amounts of out-of-pocket payments (4). Out-of-pocket payments consist mainly of fees for services received, money to buy medicines, payments for laboratory work, transport expenditures, as well as money paid informally to medical staff. Expenses on medicines are the highest in outpatient care (12).

In general, there is a lack of clarity between formal and informal payments in Albania (4). The changes in legislation in early transition years imposed co-payments for users of PHC. Albanian health care seekers are therefore confronted with other formal out-of-pocket payments for laboratory tests, medicines, and transportation costs. However, it is not always clear whether such payments are paid formally or informally (13). As the Albanian legislation prohibits direct payments to medical staff, most of the informal payments studies focus exclusively on payments paid to medical staff. The amount paid informally to medical staff also differs (14). The main factors of this relate to attributes of patients (i.e., economic status, residence in the same locality, personal relations, and societal/political position) attributes of providers (specialists vs. general practitioners, highly specialized medical staff, and availability), the type of services (inpatient/outpatient, locality, specialty, complexity of treatment, and technology involved), and other contextual factors (like urbanization of the locality, social norms, etc) (5, 14). Payment mechanisms also tend to differ and are complex. Despite the illegal nature of such payments, they are reported to take place in the open and are often not something that is hidden. Patients may gather information from social networks but in many cases the nurses or physicians directly induce the payments. Some of these strategies involve talking about the low salaries, leaving money on the table (to show that others have also paid), requesting them from patients or relatives accompanying the patient, acting unfriendly, or delaying care (14). The impact of these payments on patient's welfare has proven to be quite substantial and the situation is particularly dramatic for people in the lowest quintile of the expenditure distribution (15).

Are Out-of-Pocket Payments in Albania Catastrophic for Households' Budgets?

Out-of-pocket expenditures for health care can be a heavy burden on household's expenditures. If they are too high, they can also hinder household's long-term income generating capabilities. Out-of-pocket expenditures for health care are considered catastrophic when they force individuals or households to significantly decrease their standard of living now or in the future (16). This pushes them not only into a closed circle of inter-generational transmission of poverty (17) but may also prevent them from getting necessary health care treatment.

A recent study (4) shows that payments per health care episode constitute a substantive share of total monthly per capita expenditures. When looking at the share of out-of-pocket expenditures over total non-health expenditures and using a 10% threshold to define a catastrophic health care payment for that household, almost 22.6% of the population had catastrophic out-of-pocket payments in 2002, while this incidence declined in 2005 and 2008 to, 17.6 and 13.3%, respectively. Despite this decrease, the incidence of catastrophic out-of-pocket payments remains high, and moreover, this is higher for vulnerable groups of the population. Evidence from the same study (4) shows that for the lowest quintile, this incidence declined by a lower extent for the poorest quintile, i.e., from 29.9% in 2002 to 28.7% in 2005 and 20% in 2008.

In fact, the effect of catastrophic out-of-pocket payments is most worrying if it pushes households in poverty. The pre-payment and post-payment poverty headcount rates can tell about this effect. Jan Pen's parade of "dwarfs and a few giants" (18) depicts total household expenditures with and without (gross and net) of total out-of-pocket payments and helps to visualize this (see **Figure 1**).

The graphs show clearly that the effect of out-of-pocket payments may be catastrophic (i.e., push households below the food poverty line of 2 US$ a day) and that this is not only observed for the poorest quintiles. The graphs show also clearly that an increase in formal or informal payments can be problematic even for the highest quintiles in the absence of insurance to compensate for the financial losses.

Limitations to Studying Catastrophic Impact of Out-of-Pocket Payments

One of the main limitations in studying the impoverishing effect of out-of-pocket and informal payments is the lack of information

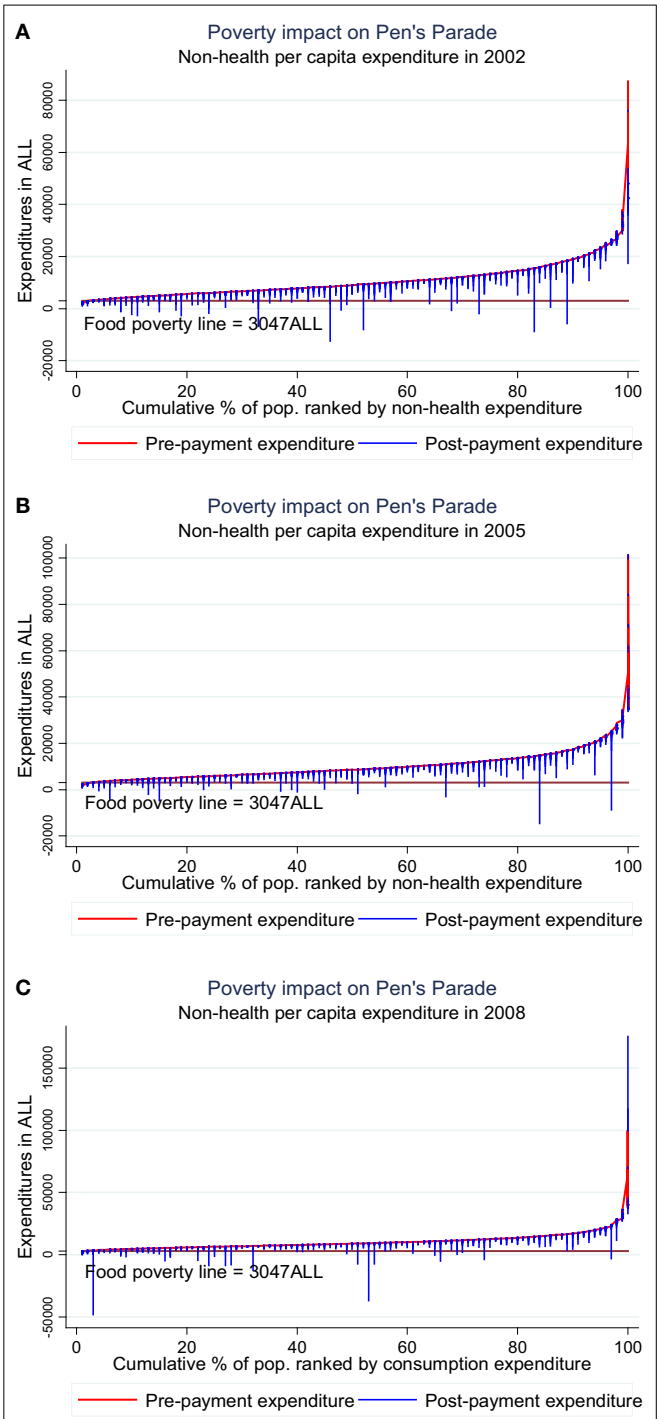

FIGURE 1 | Poverty impact of health expenditure on the distribution of non-health expenditure. **(A)** Year 2002, **(B)** year 2005, and **(C)** year 2008. Source: Tomini et al. (4).

on those patients that needed health care but could not afford it. Survey data give information only on patients that have sought health care and do not allow estimating the gap that needs to be filled in order to ensure equal access for everyone. Other limitations relate to the most likely underestimated effect of informal payments. Survey data for Albania allow distinguishing only the part of informal payments paid as "gifts" to medical staff. Other definitions of informal payments may include more types of informal payments. Additional data (allowing for a more comprehensive definition of informal payments) may provide more insights on the overall causes of informal payments and the burden imposed on households. Also household surveys are not necessarily randomized based on health and health care-related information. This may lead to an underrepresentation of certain groups (especially high utilization groups like the elderly or chronically ill) and therefore underestimate the effect of out-of-pocket payments for such groups.

Policy Implications

The existence of catastrophic health care expenditures raises concern. Catastrophic health care expenditures do not only impose a higher poverty risk for people seeking health care but may also impose barriers to access for them (19). The Albanian authorities should seriously consider the reduction of total out-of-pocket payments, which amount to almost 60% of total expenditures for health care in the country. This is best achieved through ensuring the effectiveness and attractiveness of formal mechanisms of health care financing (i.e., general tax revenues and health care insurance). While improving the effectiveness of such mechanisms requires a better coordination and allocation of resources, the attractiveness could be raised by adopting the structure of contributions and co-payments so that they better reflect the income distribution. Measures like fee exemptions or price subsidies for vulnerable groups have already proven effective in reducing catastrophic payments in other countries (20).

Other measures like subsidized transportation for the poor or a better distribution of health care centers would also help in this regard. But, on the other side, any policy reform aiming to increase health care utilization of the poor should evaluate the effect on catastrophic payments, especially for the poor and the vulnerable. Previous research has warned that focusing only on the availability of health services can indeed contribute to improving health of the poor but it may also increase the proportion of poor households facing catastrophic expenditures (8).

Further research should be focused on identifying the effect of out-of-pocket and informal payments on people who cannot afford such payments and are therefore denied access to health care. In fact, previous research has shown that more that from the effect of catastrophic health care expenditures, the poor suffers the catastrophic effect of illness given the barriers to access and the consequences on the uninsured shocks on prospective incomes from employment (19). Another interesting aspect for future research is also the investigation of the effectiveness of policy measures, like fee exemptions and price subsidies, in reducing the risk of falling in poverty among particular health care seekers addressed by these policies.

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Budget impact of publicly reimbursed prescription medicines in the Republic of Srpska

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Health Care Funding and Provision of the Republic of Srpska

Health Care Services in the Republic of Srpska are provided through the primary, secondary, and tertiary care levels. Primary medical services provision happens throughout the network of 53 primary health care facilities and 1 family medicine polyclinic (1). There are approximately 500 pharmacies (2). Secondary and tertiary health care services are provided in two university hospitals, nine regional hospitals, three health centers, two specialized psychiatric clinics, and two specialized medical rehabilitation facilities (3). Insured citizens use health care services in public health care institutions and private institutions who have signed the contract with the Health Insurance Fund. Health care financing is mostly provided by the Health Insurance Fund, out of the mandatory taxes imposed to the employers and employees alike. Coverage for unemployed population is extended from the employed family member premiums (4). Fund is a legal entity established and owned by the State (5). The Ministry of Health and Social Welfare conducts the supervision of the Fund (6). One of the main functions of the Health Insurance Fund is collection of contributions for health insurance and contracting of health services. Complementary direct payment of contributions is made to the Pension and Disability Insurance Fund (7). The health care system in the Republic of Srpska is centralized with the overall power trusted to the Ministry of Health and Social Welfare, the Institute of Public Health, and the Health Insurance Fund. Employee pool in the health care system of the Republic of Srpska consists of approximately 2,400 clinical physicians, 200 dentists, 100 pharmacists, 6,500 nursing staff, and 4,000 administrative and technical staff (1). Gross National Income per capita increased from 8,770 to 9,820 US$ during 2009–2013 span. Total expenditure on health, as a percentage of gross domestic product, was 9.9% in 2012 (last official release) (8). The Republic of Srpska has around a population of 1,327,000 (9), and health expenditure per capita in 2009 amounted to €389 while in 2013 it reached €397 (10). Private and public expenditure on health care has increased in total from 2009 to 2012, and the public share of spending grew from 68.81 to 70.33% (11).

Official Records on Prescription Medicines

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina issues annual reports on utilization of pharmaceuticals nationwide. These annual reports are commercially available since 2009 (12). This source contains data on medicines prescription, dispensing, and sales provided directly by the pharmaceutical multinationals and domestic manufacturers. Wholesalers are required to provide data on the number of packages of drugs that are imported and wholesale price. This price usually consists of manufacturer's price plus customs, incremental costs, and the wholesale markup. Domestic producers were required to provide data on the number of packages of

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drugs that are produced and released into the market with wholesale price (manufacturer's price plus the wholesale markup). Costs are expressed in Bosnia and Herzegovina's local currency – convertible mark (BAM). Data are ordered in ATC (Anatomical–Therapeutical–Chemical) codes on first, second, third, fourth, and fifth level of classification (13). Latest report has been made in 2014 for the year 2013. Total of 39 wholesalers provided data. The ratio of domestic and foreign manufacturers of medicines in the total turnover of pharmaceuticals in 2013 was 17 vs. 83% (14). Population health official estimate is being issued annually by the Public Health Institute of the Republic of Srpska (15). It provides us with exact data with regard to health facilities, staffing, and the structure of spending (public and private expenditure). Third source of data supporting these claims was the Agency for Statistics' publications on gross domestic product and National Health Accounts Statistics for the period from 2009 to 2013 (16).

Ongoing Pharmaceutical Market Transformation 2009–2013

Observing 5-year time horizon (2009–2013), we see that moderate growth of pharmaceutical market took place. Some ATC code groups recorded far more substantial market changes than others. Thus, systemic hormonal preparations, excluding sex hormones, and insulin value-based turnover increased for 92%, and antiparasitic products, insecticides, and repellents spending decreased for 63%. Changes were also significant in the indication field of blood and blood-forming organs reporting 36% growth, as well as antineoplastic and immunomodulating agents, sensory organs, respiratory system, and alimentary tract and metabolism drugs which increased their sales volume around 30% each. Top 10 ATC second-level code groups in 2009 and 2013 have been renin–angiotensin system agents, antibacterials for systemic use, antineoplastic agents, psycholeptics, drugs used in diabetes, drugs for acid-related disorders, analgesics, calcium channel blockers, anti-inflammatory and antirheumatic products, beta blocking agent, and antithrombotic agents. Consumption of preparations for wounds and ulcers treatment has increased three times. Nasal preparations, digestives, including enzymes, pituitary and hypothalamic hormones, and prescribing antigout preparations have also increased twofold (**Table 1**).

Differences in certain ATC drug group consumption are reflecting the changes that have been happening in the national health system. Prices have been reduced, especially for generic drugs where patent protection has expired. A lot of effort has been invested in the implementation of good clinical practice guidelines. That is the reason for reducing antibiotics consumption outsourcing from decreased frequency of nosocomial infections and overprescribing by general practice physicians. Development of novel targeted antineoplastic medicines, primarily the biologicals, as well as increased incidence of malignant diseases influenced constant growth of utilization. The level of obesity is increasing and so is antidiabetics consumption as well as pharmaceuticals indicated in cardiovascular and associated diseases.

TABLE 1 | Top 10 ATC second- and third-level drug code groups ranked in 2009 and 2013 according to value-based turnover of dispensed medicines and its growth ratio 2013/2009[a].

Top 10 ATC second-level code groups in 2009 and 2013 (hierarchy from 2009 applied in descending order of appearance)	Value of prescriptions dispensed in 2009 (million €)	Value of prescriptions dispensed in 2013 (million €)	Growth ratio 2013/2009	Total increase 2009–2013 (million €)
C09 agents acting on the renin–angiotensin system	25.9	26.8	1.03	0.9
J01 antibacterials for systemic use	21.8	16.2	0.74	5.6
L01 antineoplastic agents	16.1	21.4	1.33	5.3
N05 psycholeptics	13	10.1	0.78	2.9
A10 drugs used in diabetes	12.5	23.1	1.85	10.6
A02 drugs for acid-related disorders	10.5	10.3	0.98	0.2
N02 analgesics	9.6	9.1	0.95	0.5
C08 calcium channel blockers	7.4	5.4	0.73	2
M01 anti-inflammatory and antirheumatic products	7.4	8.9	1.21	1.5
C07 beta blocking agent	6.9	8.1	1.18	1.2
B01 antithrombotic agents	6.8	10.6	1.56	3.8
Top 10 ATC third-level code groups according to 2013/2009 growth ratio	**Value of prescriptions dispensed in 2009 (thousand €)**	**Value of prescriptions dispensed in 2013 (thousand €)**	**Growth ratio 2013/2009**	**Total increase 2009–2013 (thousand €)**
C01C cardiac stimulants excluding cardiac glycosides	7.6	122	16.07	114.5
S03A anti-infectives	3.8	36	9.47	32.2
M03A muscle relaxants, peripherally acting agents	37.1	347.6	9.37	310.5
C09D angiotensin II antagonists, combinations	511	2993.1	5.86	2482.1
S01B Anti-inflammatory agents	17.8	99.5	5.59	81.7
R01B nasal decongestants for systemic use	484.6	2350.1	4.85	1865.5
D03A cicatrizants	43.3	169	3.90	125.7
L01A alkylating agents	238.6	876.8	3.67	638.2
V03A all other therapeutic products	53	189.2	3.57	136.2
G02B contraceptives for topical use	19.9	70.5	3.54	50.6

[a] *Latest Republic of Srpska's official release available [publicly reimbursed prescription medicines only; over-the-counter (OTC) and out-of-pocket citizen payments excluded].*

Forecasts of Future Changes

Although there are some promising developments, local pharmaceutical market structure and dynamics is still far from the one responsive to population needs. In the country still recovering from unstable political situation over the last few decades, a lot of progress has been made. The Health Insurance Fund is consistently negotiating with pharmaceutical companies imposing price caps and generic substitution wherever possible. Thus, Fund created more room for innovative therapies reimbursement. That is why authorities are considering marketing approvals of novel drugs indicated in hepatitis, diabetes, targeted antineoplastic agents (17), as well as immunotherapy, which we expect to be available to the patients over the next 5–10 years.

Western Balkan countries share post-socialist legacy of former Yugoslavia in health care management and financing patterns (18). Quite similar but faster development in a large-scale population could be observed in neighboring Serbia (19). This country suffered as well from seriously constrained resource allocation for medicines during global economic recession (20). Signs of early recovery are now clearly present particularly in the oncology indication field (21). Accessibility and affordability of innovative therapies gradually became reality for even the poorest citizens (22).

The Republic of Srpska due to its smaller population size might have more convenient opportunity for sustainable health policy solutions learning from painful lessons of other South-East European transitional health reforms (23). Current developments nationwide present a promise of more responsive pharmaceutical market. The country is likely to be capable of providing more affordable, mostly generic medicines in the upcoming years.

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Serbian experience with national health accounts

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Serbia, as many countries in Eastern Europe, is in the process of reforming its health system in an effort to improve the efficiency and efficacy of health services and to achieve equal distribution of health resources.

Representatives of Ministry of Health (MOH), Health Insurance Fund (HIF), and Institute of Public Health (IPH) articulated an overall health vision for the health sector in Serbia in August 2002.

In order to get reliable information on financial resources used for health, their sources, and the way they were used, policy-makers realized that they needed a tool that clearly illustrates the flow of funds through the health system. National health accounts (NHA) (1–4), as such a tool, provides a basis for monitoring different health care activities and trends in health spending for all sectors – public and private, providers, diseases, population groups, and regions in country, so Serbian Government have decided to implement the NHA.

Work on development, implementation, and institutionalization of NHA started at the end of 2004, under "Serbia health project," financed by the World Bank (WB).

The conception of the NHA project was divided in two phases, with following achievements:

In phase I: creation and training of a country team who led the work on the NHA and development of a work plan based on detailed analysis of the situation and assessment of existing data. First NHA have been produced at the beginning of 2006.
In phase II: development of the second round of NHA at the end of 2007 and increased awareness on NHA with eight workshops for different interested structures: policy and decision makers and for institutional experts.

The formation of a new department for NHA production in the Republican Institute of Public Health represents a major accomplishment for the year 2008, after WB project was finished.

National health accounts became an assigned programmatic job of MOH, with the new established financial line for NHA production. Country office of the World Health Organization (WHO) with Dorit Nitzan helped with the implementation process significantly, together with Pia Schneider from WB.

Presenting capability to work on NHA and keep the step with more experienced countries, Serbia has been included in the joint WHO, European Statistics (EUROSTAT), and Organization for Economic Country Development (OECD) work on "A System of Health Accounts (SHA)" version 1.0 into version 11.0 methodology changes. Serbia became participant at OECD, EUROSTAT, and WHO teleconferences, workshops, and OECD internet forum.

From 2008, third and fourth NHA exercises have been accomplished, along with a revision of all previous years' results, as MOH survey identified discrepancies with Republican Statistical office data on out of pocket payment for health.

Once finished, NHA have produced evidence to help policy makers and health managers to understand health system in Serbia, improve its performance, and better manage health resources (5–13).

Since the first time NHA have been produced, information received was frequently used by Ministry of Health Sector for EU integrations and international Cooperation as a basis for project planning and grants proposals, applications for some study research, presentation of Serbian health system, in country and abroad, like on *Health Policy* Forum *meeting* in Brussels, 2009 along with other types of communication with European commission.

Also, information has been used for:

- Health reform planning, as NHA indicators provide MOH with information needed to review overall health expenditures patterns. In Serbia, NHA revealed that more than 35% of health spending actually came from households, what significantly differed from government official's perception;
- Assessment of reform achievements, the positive changes are observed like more finances allocation to providers of ambulatory health care, as it was strategically planned;
- Institute of Public Health research purposes, such as analysis of primary health care, cost of illness analysis, assessment of private health sector, Assessment of financial flow in the health system of Serbia in a period 2003–2006, NHA policy impact from 2004 to 2008, etc;
- For development of national strategies, called "Strategy to fight HIV-AIDS from 2011 to 2015";
- Helping HIV office with UNGASS report;
- Comparison with other countries.

but still poorly used for Ministry of Finance financial projections of a country's health system requirements.

In 2014, new Health evidence low with specific NHA policy (14) was adopted, as well as Memorandum of understanding

between IPH of Serbia, MOH, Ministry of Finance, Republican Statistical Office, and Republican Health Insurance Fund.

National health accounts results are still used mostly for MOH purposes, without broad awareness of NHA existence among Government, civil society, and private sector, presumably as a consequence of lack of financial sources for adequate results dissemination.

CONCLUSION AND RECOMMENDATION

Conclusion and recommendation would be that respective national or international donors should continue to support further work on NHA results dissemination and strategic implementation in some legal document in Serbia at one side, and work with policy makers and managers on use of NHA data on the other side.

Also, the country should work on connection between newly established Central Health Information System and health accounts information.

According to Serbian experience, the biggest reasons for successful NHA implementation and later use of data in the country are the presence of political demand, aid of some donors, and determination of the team who is responsible for NHA institutionalization.

Regional communication and cooperation through workshops and other forms of regional gathering could be the most effective actions in supporting some country in the effort to institutionalize NHA and then communicate NHA results with other countries in region.

National health accounts is expected to be a useful tool for tracing the funds' flow, for estimating the "health outcome" produced by these funds, and thus for providing detailed input for political decision-taking not only in some region but also all over the world.

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Peculiarity of pharmaceutical marketing in Serbia

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Keywords: pharmaceutical market, pharmaceutical industry, pricing regulations, strategic analysis

Major challenge for the Western Balkan pharmaceutical markets remains legal enforcement of measurable tender criteria (1) when submitting offers for supplying large healthcare centers. All of regional economies increased health spending rapidly over past two and a half decades. Nevertheless, constrained national drug budgets have led to the development of diverse resource allocation strategies (2). Public debate has created an impression that there is room for more active inclusion of marketing in generating strategic decisions at the company level (3). Focus on operative, daily duties may also be the result of the complex and difficult conditions in which the pharmaceutical industry functions in Serbia (4). This market is characterized by modest size, decent growth rates, and heavy domination of generics as compared to other Eastern European countries (5). Local industry balances between imposed legislative limitations, its own orientation to generating profit, and *de facto* present social and ethical factor. Value creation in domestic market is unified in synergetic effect of the product, pricing, distribution, and promotion (6). A superior competitive strategy must be sought at the enhanced product level, i.e., in the concept of value added, where companies on the market of Serbia are only making their first steps (7).

A networked environment may serve as a useful framework for a brand new view of the roles of individual stakeholders, once again with the aim to maximize the outputs of healthcare system. There is also the traditional lag existing in the arrival of innovation to the market of Serbia. It is not characteristic of the pharmaceutical industry, but rather results from the fact that recent years have seen an evident lag of Serbian economy behind global trends, manifested in the delayed effect of the global economic crisis (8). Suppliers on the Serbian market argue that patient education is the responsibility of the healthcare system. The practices of pharmaceutical companies in the markets of developed countries testify to a new, more active role of the pharmaceutical industry in this education (9). Opinions on direct promotion speak that originators of supply on the Serbian market do not see patients as "legitimate target" of the industry's marketing effort, which is in accordance with the marketing practices elsewhere in liberal, less regulated, high-income markets (10).

Based on published evidence, it can be concluded that there is a significant potential for improving the marketing function, its place and role, and the resulting marketing activities (11). As cited, contemporary research included 30 companies on the territory of the Europe, the problems faced, and conclusions presented correspond closely to the results of qualitative research conducted on 10 participants on the pharmaceutical market of Serbia (12).The common premise is that the European market is far more developed and matured in terms of the application of marketing. Government regulations on pricing and the objective permanence of distribution channels prevent pharmaceutical companies from viewing them as active marketing mix elements. The socio-political element is especially manifested in the domain of price control (13). Formalized process of adopting marketing strategies may be potentially successful in certain market conditions and specific corporate culture. Change in conditions may valorize different approaches to planning and implementing marketing strategies. It appears that different degrees of formalization of adopting marketing strategies and a different position and role of marketing within an organization may result in equally successful pharmaceutical companies. Companies that participated in the research in Serbia achieved their

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leading position through successful adaptation to changed conditions. Nevertheless, the process of transformation in the environment and the organization is permanent (14). Some of the respondents very objectively assessed that changes in the business conditions and organization also imply new behavior patterns in order to accomplish the objectives (15). Further acceleration of population aging and growth of global emerging markets reshaping health care landscape worldwide will give the long-term imprint to the pharmaceutical markets evolution in small nations bordering EU's economic zone (16).

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A plea for good global governance

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We are facing a rapid globalization in the twenty-first century. This sharpens our view on this one planet (1) traveling through space, the Spaceship Earth. It is largely in our hands as a human race whether this journey is a safe one. However, we can summarize the global threats endangering us – the passengers – as shown in **Figure 1**.

All five threats affect our health but cannot be controlled at the national level. They are the consequence of ineffective, failing, or even totally missing global governance. Certainly, the millennium development goals (MDGs) are partly successful in a global scale due mainly to the overachievement of China (2); however, many of the poorest countries are left out and the Ebola crisis developed not by chance in Sierra Leone and Liberia, countries torn by civil war, leaving the health services destructed (3).

Do we at least speak the same professional language? The answer is NO. Even the most basic so-called "Essential Public Health Functions" vary between WHO regions (2) as do the definitions of public health or population health. Recently, at the 14th World Congress of Public Health in Kolkata, India a first serious effort has been made to agree on common global public health functions (GPHF) (4) as there are three overlapping areas for action, namely, health promotion and protection together with prevention are embraced by four enabling and supporting functions, namely information, governance, advocacy, and capacity. A main purpose is to scale up workforce development in public health and to advance the investment case for public health promotion, protection, and prevention.

FIGURE 1 | Core global threats of twenty-first century.

Is good global governance for health in reach? As it seems the answer is NO again. The main obstacle securing equitable "Health for All" today is posed by the five threats listed in **Figure 1**, not by any of the vertical disease programs competing globally for resources. A typical example of this is the much praised HIV/AIDS programs, which succeed to a large degree by draining the regular health services from the top staff by considerably higher remuneration.

The global government we need also cannot be based on a multiplicity of around 40 United Nations organizations and 25 development banks. Worse do the fragmentation and the lack of coordination and accountability in the sector of Non-Governmental Organizations (NGOs), comprising thousands of organizations, which represent about a quarter of total development assistance for health (DAH). Obligatory accreditation for NGOs therefore has been argued for (2).

So in conclusion: what to do? A global government will be there – 1 day. Hopefully, not too late! An interim step could be to further strengthen regional collaboration not only on a fragile voluntary basis but also organized as long-term binding agreements (5). Examples of a successful regionalization of transnational governance including the health sector are given by the European Union and ASEAN. Beyond that some key areas for advancing global governance can be identified (5):

(1) The mandate of the World Health Organization needs to be reconsidered in terms of an umbrella to include and coordinate all actions necessary to deal with the health consequences of the five global failures listed above.
(2) An enlarged mandate of WHO needs to be based on the inclusion of all stakeholders, private or public, beyond the present restriction to national governments.
(3) A systematic follow-up on the Monterrey and the Paris/Accra/Busan criteria, making development cooperation more effective.
(4) Consider proposals to improve national coordination by sector-wide approaches (SWAp).
(5) Transform innovative health and social care practices to education and training. Achieving a transformation of

health systems that impact directly and effectively on the health and well-being globally depends on broadening opportunities for learning at all societal levels and across all nations.

Many questions wait for an answer from the global community, especially on a more democratic, effective, and efficient global governance for health or in other words: what global, regional, national and local structures, organizational principles, and mechanisms should ideally evolve in the early decades of this century to improve and sustain global health and well-being, including universal health coverage.

However, what is the likelihood that recommendations will be implemented successfully and impact positively and ethically on people's lives? Progress has been slow and agonizingly much too late in many instances and calls for a new type of leadership, which transcends self-interests, is informed by long-term global people and planetary perspectives, and strives to make the quality of life and well-being of all people the top priority for public health.

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