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EDITORIAL

Growing up the South Eastern European Journal of Public Health

Genc Burazeri[1,2], Ulrich Laaser[3], Jose M. Martin-Moreno[4,5], Peter Schröder-Bäck[2,6]

[1] School of Public Health, University of Medicine, Tirana, Albania;
[2] Department of International Health, School for Public Health and Primary Care (CAPHRI), Faculty of Health, Medicine and Life Science, Maastricht University, Maastricht, The Netherlands;
[3] Faculty of Health Sciences, University of Bielefeld, Bielefeld, Germany;
[4] Department of Preventive Medicine and Public Health, University of Valencia, Spain;
[5] INCLIVA Research Institute, University of Valencia Clinical Hospital, Valencia, Spain;
[6] Faculty of Human and Health Sciences, University of Bremen, Bremen, Germany.

Corresponding author: Genc Burazeri, MD, PhD;
Address: Rr. "Dibres", No. 371, Tirana, Albania;
E-mail: Genc.Burazeri@maastrichtuniversity.nl

Conflicts of interest: None.

The South Eastern European Journal of Public Health (SEEJPH) is an online, open-access, international, peer-reviewed journal, which was launched in 2013 (1). It covers all areas of health sciences, with a main focus on public health. SEEJPH is a journal originating from the ten years of the Stability Pact for South Eastern Europe (2001-2011), but aiming to provide a forum for all countries in transition worldwide, whose research work would otherwise be hardly visible. From this point of view, this journal strives to promote particularly an area referred to as *"Health Transition Research"* (1).

Time is passing, though, and our "baby", the SEEJPH, is already two years old by now, or more precisely four volumes "old" – volumes with excellent peer-reviewed contributions from many parts of the world and fascinating discussions e.g. on a view back to the Maastricht Treaty on European Union by the leading negotiators of the time (2); "endorsement" of a public health profession (3); the South East European Health Network (SEEHN) (4); the European public health education accreditation system (5); public health ethics (6); as well as several other outstanding original research and review articles tackling a wide range of public health issues.

Time to prepare for preschool furtherance? Yes, indeed! We moved to the Open Journal System (OJS), kindly hosted by the University of Bielefeld in Germany. OJS provides all the necessary technical facilities including online submission and review process. But, not only that! In addition, we are now registered in Index Copernicus and are currently under consideration by several other electronic databases.

Our executive editorship remains in Tirana, Albania, but we are happy to have engaged now regional editors covering the globe:

- Samir N. Banoob, President, Intenational Health Mangement, Tampa, Florida, USA, for the Middle East.
- Evelyne de Leeuw, Editor-in-Chief of Health Promotion International, , Sydney, Australia, for the Western Pacific Region.
- Damen Haile Mariam, University of Addis Ababa, Ethiopia, for the African Region.
- Charles Surjadi, Faculty of Medicine, Atmajaya University, Jakarta, Indonesia, for the South East Asian Region.
- Laura Magana Valladares, Secretaria Académica, Instituto Nacional de Salud Pública, Mexico, Mexico, for Latin America.

However, the journal will grow only upon a firm and long-term commitment of experts and researchers worldwide who believe in the pprofessionalisation of public health in order to advance public health education, training, research and practice.

We learned from many sides that SEEJPH is considered a valuable contribution to Public Health in South Eastern Europe and transitional countries worldwide. We look forward to applying for an impact factor as soon as it looks promising. Your high level contributions will help a lot. Thus, no time to celebrate but to grow up our little child to adolescence and adulthood!

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Thomas-Reilly RG, Tozija F, Soltan V, Nikovska DG, Crudu V, Atun R, McKee M. Multidrug-resistant tuberculosis in Moldova and the Former Yugoslav Republic of Macedonia: The importance of the overall governance of the health systems (Original research). SEEJPH 2016, posted: 11 January 2016. DOI 10.4119/UNIBI/SEEJPH-2016-85

ORIGINAL RESEARCH

Multidrug-resistant tuberculosis in Moldova and the Former Yugoslav Republic of Macedonia: The importance of health system governance

R. Gregory Thomas-Reilly[1], Fimka Tozija[2], Viorel Soltan[3], Dance G. Nikovska[2,4], Valeriu Crudu[3,5], Rifat Atun[6], Martin McKee[1]

[1] London School of Hygiene & Tropical Medicine, London, United Kingdom;
[2] Ss. Cyril & Methodius University, Skopje, The Former Yugoslav Republic of Macedonia;
[3] Center for Health Policies & Studies, Chisinau, Moldova;
[4] Ministry of Health, Republic of Macedonia;
[5] Phthisiopneumology Institute, Chisinau, Moldova;
[6] Harvard University, Cambridge MA, USA.

Corresponding author: R. Gregory Thomas-Reilly BA, BScN, MScPPH, PGDip, PhD;
Address: 331 St. Patrick Street, Ottawa, Ontario, Canada, K1N 5K6;
Telephone: +1613-315-0900 ; Email: greg.thomas-reilly@lshtm.ac.uk

Thomas-Reilly RG, Tozija F, Soltan V, Nikovska DG, Crudu V, Atun R, McKee M. Multidrug-resistant tuberculosis in Moldova and the Former Yugoslav Republic of Macedonia: The importance of the overall governance of the health systems (Original research). SEEJPH 2016, posted: 11 January 2016. DOI 10.4119/UNIBI/SEEJPH-2016-85

Abstract

Aim: Multidrug-resistant tuberculosis (MDR-TB) arises where treatment is interrupted or inadequate, when patients are treated inappropriately, or when an individual has impaired immune function, which can lead to a rapid progression from infection with an MDR-strain to disease. This study examines the role of health systems in amplifying or preventing the development of MDR-TB.
Methods: We present two comparative studies, which were undertaken in The Former Yugoslav Republic of Macedonia (TFYR Macedonia) and Moldova.
Results: The findings reveal several health systems-level factors that contribute to the different rates of MDR-TB observed in these two countries, including: pre-existing burden of disease; organization of the health system, with the existence of parallel systems; power dynamics among policy makers and disease programmes; and the accountability & effectiveness of programme oversight.
Conclusions: The findings do not offer a universal template for health system reform but do identify specific factors that may be contributing to the epidemic and are worthy of further attention in the two countries.

Keywords: drug-resistance, Europe, health systems, MDR-TB, Moldova, The Former Yugoslav Republic of Macedonia, tuberculosis.

Conflicts of interest: None.

Acknowledgements: This study was funded by the Global Fund to Fight AIDS, TB and Malaria. RGT-R was supported by a Graduate Teaching fellowship from the London School of Hygiene and Tropical Medicine.

Introduction

Multi-drug resistant tuberculosis (MDR-TB) is now a major problem in parts of Europe (1). Resistance arises when treatment regimens are interrupted or inadequate or when treatment is blind to the sensitivity of infecting organisms, allowing bacilli resistant to a single drug to reproduce. These conditions are most often found where health systems are weak (2) or inappropriately designed (3), providing some treatment, but not in a way that ensures that it is taken appropriately.

In this study we use a comparative case design to gain insights into why two otherwise similar countries, Moldova and TFYR Macedonia, differ significantly in their burdens of TB and patterns of drug-resistance (Table 1).

Table 1. Surveillance data from Macedonia, Moldova, and the European region in 2013 (*source:* European Center for Disease Prevention and Control)

INDICATOR		Macedonia	Moldova	Non EU/EEA Europe
New TB cases		346	4,203	194,913
	Success n (%)	298 (86.1)	3,205 (76.3)	146,404 (75.1)
	Died n (%)	28 (8.1)	418 (9.9)	14,203 (7.3)
	Failed n (%)	3 (0.9)	125 (3.0)	12,312 (6.3)
	Lost to follow up n (%)	16 (4.6)	331 (7.9)	12,843 (6.6)
	Not evaluated n (%)	1 (0.3)	124 (3.0)	9,151 (4.7)
Laboratory confirmed		188	2,695	117,802
Drug sensitivity testing n (% of those confirmed)		179 (95.2)	2,317 (86.0)	108,746 (92.3)
MDR-TB n (% of those confirmed)		1 (0.5)	912 (33.8)	33,686 (30.9)
XDR-TB n (% of those confirmed)		0	35 (1.2)	393 (0.3)
TB case notification rate / 100,000 population		15.3	144.8	12.7

The notification rate in Moldova per 100,000 population is almost ten times higher than in Macedonia, where it is only slightly higher than the non-EU/EEA countries of Europe. The treatment success rate is about ten percentage points higher in Macedonia than Moldova. A third of laboratory confirmed infections in Moldova (n=912) in 2013 were multi-drug resistant (MDR), with only one case in Macedonia. In the same year Moldova had 35 cases that were extensively drug resistant (XDR), while Macedonia had none.

Methods

We undertook an in-depth comparative case study (4). Data were triangulated from a range of sources including documentary evidence, such as statistical reports, action plans, and activity reports, and interviews with key informants. Key informants were identified using theoretical and snowball sampling to obtain a broad range of insights and perspectives (5). Interviews were semi-structured, including open-ended questions, and were recorded, with contemporaneous notes taken. Interviews continued until data saturation was achieved. Field notes were kept throughout the research.

Letters were sent to key informants outlining the purpose of the research. This sought to ensure "buy-in", both at individual and organizational levels. An initial conceptual framework, based on a literature review, was developed to identify systems-level drivers of MDR-TB but then refined during the interviews.

We interviewed 23 (100% response) informants in Macedonia, and 20 (55.6% response, 11% declined or cancelled, 33% did not respond) in Moldova. Details of those interviewed are presented in Table 2. However, data saturation was achieved in both countries, with no new

themes arising after about 15 interviews, although further clarification and factual information was obtained in subsequent interviews. The participants were equally open, reflective and critical in both countries.

Table 2. Characteristics of those interviewed

CATEGORY	Macedonia (n=23)	Moldova (n=20)
Stewardship ***(Leadership responsibilities within the health system)***	Senior managers within the TB system	Vice-minister of health
	Senior managers & directors from the Ministry of Health	Hospital directors
	Former Deputy Minister of Health	Senior administrators in the penitentiary health sector
	National Health Insurance Fund	Government administrators / managers
	n= 10	*n=10*
Service delivery ***(Responsibility for service provision within the health system)***	TB physicians	TB physicians
	HIV/AIDS physicians	General physicians
	TB patronage & public health nurses	TB patronage & public health nurses
	Prison health care staff	Pharmacists
	n= 10	*n=6*
Non-government (Representatives from various non-government organisations, with a defined focus, work or interest in TB issues)	Non-governmental organization working with vulnerable populations	Community agencies working with prisoners
	Global Fund country office	WHO country representative
	National physicians association	Academic specialist in public health
	n= 3	*n=4*

This study received approval from the ethics committee of the London School of Hygiene & Tropical Medicine and from corresponding ethics committees in each country. Informed consent was obtained from each participant, prior to the initiation of data collection. All information was made available to participants in their language of choice.

Results

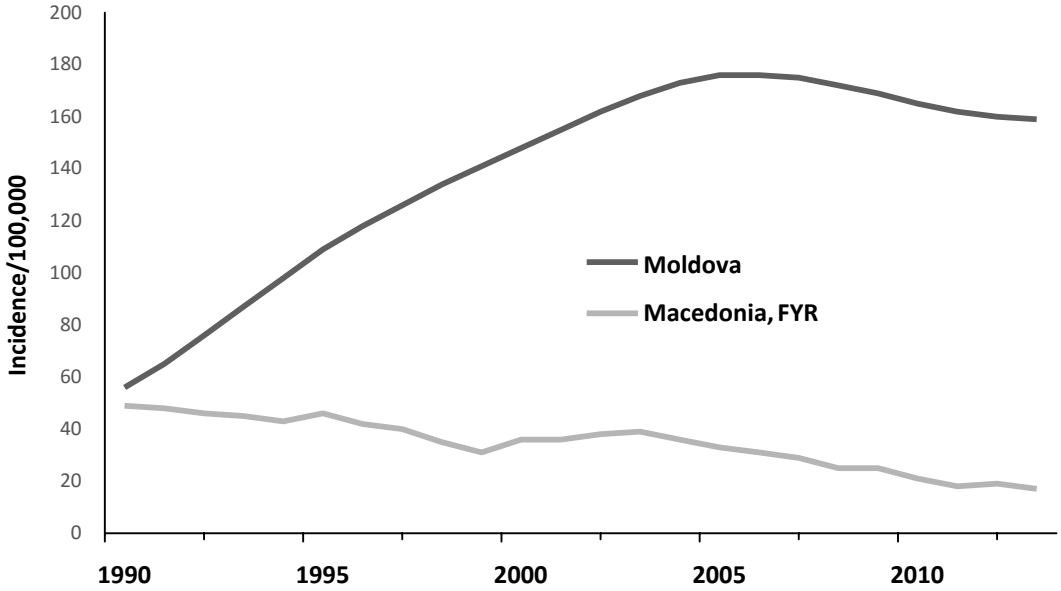
The results from each country were categorised into primary and secondary themes, according to the consistency with which respondents presented topics, the emphasis that they placed on them, and the differences observed between the two countries. The primary (emerging) themes were: (i) pre-existing burden of (TB) disease; (ii) organisation of the health system; (iii) existence of parallel health systems; (iv) degree of accountability and oversight exercised within the system; and (v) power and relationships.

Pre-existing burden of disease

Respondents felt strongly that the pre-existing burden of disease contributed to the current epidemiology. However, in the early 1990s, when each country achieved independence, incidence rates were very similar (6) (Figure 1). Another aspect related to disease burden, raised by some informants in Moldova but not in TFYR Macedonia, was migration. Moldova has experienced large-scale labour migration to Western Europe and the former USSR. Precise data are difficult to obtain because many Moldovans are entitled to, or hold, either Romanian, and hence European Union nationality, or Russian or Ukrainian nationality. However, it is estimated that t he number of Moldovan citizens living abroad is between 11 and 17% of those living in the country (7), but the figure is about a third for those of working

age (8). The challenges of controlling TB where there is large-scale labour migration, are well recognised (9,10).

Figure 1. Trends in TB incidence in Moldova and Macedonia (*source*: World Development Indicators)



Health system organisation

We define organisation as being related to the structure of health systems, from its leadership downwards. Macedonia has a national health insurance system, overseen by the Health Insurance Fund (HIF). In recent years primary health care delivery has been privatized, and general practitioners are paid by a blended model of capitation and incentive payments (i.e. completing specified health examinations). General practitioners act as gate-keepers to the health system, and have become more important, particularly as the number of acute care beds has decreased (11). The National TB Programme (NTP) in TFYR Macedonia is coordinated centrally from the National TB Institute. The NTP is the sole provider of TB services in the country, working through the National Institute in the capital, Skopje, but with affiliated regional hospitals and community dispensaries. The NTP also employs community nurses with responsibilities for directly observed community-based therapy.

Moldova also has a national health insurance programme. While less well established than in Macedonia, Moldova has moved toward a family practitioner model of primary health care. This said, a large stock of hospital beds remains (12), and hospital physicians exercise considerable influence on the health system. Tuberculosis care in Moldova is provided in several systems (e.g. prison, military and general health systems), although points of connection exist throughout. The NTP is coordinated by a manager at the Phthisiopneumology Institute in Chisinau, the capital. Services are delivered through municipal and national hospitals, along with local specialists and family physicians in the more rural parts of the country.

In Macedonia informants spoke positively of the structure, management and clinicians within the NTP, while counterparts in Moldova were critical, specifically of the structure and management of the NTP. Those in Moldova raised particular concerns about the current and future capacity of the NTP, given challenges experienced in recruiting and retaining qualified staff. As TB care is a separate specialty, informants felt that it is not attractive to new clinicians, given the inherent risks to practitioners and the confined scope of practice. This is in contrast to Macedonia, where those providing TB care have transitioned to a broader medical specialization of respiratory medicine.

As both countries have similarly structured NTPs, criticisms raised in Moldova would seem to reflect how the structure translates into service. On closer examination, informants in Macedonia tended to personalise their praise of individuals within the NTP. In Moldova, there was less personification and more reflection on the frequent transitions of individuals. Moldovan informants also reflected on a disconnection between the NTP leadership and local practices and realities, particularly in rural areas. Although informants framed their reflection as an organisational critique, what they were in reality commenting on was the capacity of individuals within the system to deliver the leadership and outcomes desired.

Parallel health systems

There was a consistent narrative in both countries about challenges associated with parallel health systems. In Macedonia these had been addressed by having all TB services provided through a single NTP, including those in the prison system, with prisoners referred to the general health system for treatment. In contrast, Moldova has dedicated prison-based facilities for the treatment of TB, which fall within the prison directorate. While informants highlighted significant advances within the Moldovan prison system, specifically in regard to the treatment of TB, there were concerns about the risk of losing individuals as they transfer into, or out of parallel systems.

Accountability and oversight

In Macedonia, informants felt that service providers were accountable for their actions, supported by training and oversight from the NTP managers. Informants described substantial uniformity in care provided across the country, which they associated with the good outcomes observed. In Moldova there was conflict between the hospital and community service providers. Those in the acute care sector blamed the community service providers for lax practices, whilst their counterparts in the community highlighted a lack of awareness of the realities in communities, particularly in rural settings. Those who are responsible for oversight of the NTP described limited capacity for monitoring and enforcing practice standards, which they believed contribute to variations in practice.

Power and relationships

Power dynamics are an important theme, although this emerged implicitly from the interviews rather than being raised explicitly. Those in Moldova described a persistent tension between acute care institutions and emerging community care service providers. They also spoke about the lack of consistent leadership, which arose from frequent leadership transitions, often due to changing political fortunes. In Macedonia informants also described frequent political transitions, but these spared the management of the NTP, enabling institutional stability. Macedonian informants further described cordial, if not pleasant working relations and communications with many of their colleagues across the country.

Secondary themes

In addition to the primary themes, several secondary ones were identified, which, while not necessarily differentiating the two countries, emerged from the literature as being of potential relevance and, in some cases, offered additional nuanced insights to their performance (Table 3). These will be discussed briefly.

Table 3. Case study themes

THEME	Macedonia	Moldova
Major themes		
Organisation	✓	X
Pre-existing burden of disease	✓	X
Parallel health systems	✓	X
Power	✓	X
Accountability & oversight	✓	X
Secondary themes		
Political Commitment	✓	✓
Infrastructure	X	☑
Historical trajectory	X	X
Institutional memory	☑	X
✓ Positive factor ☑ Mixed x Challenges		

Political commitment: in both countries informants described a high degree of political commitment to tackling TB but, perhaps surprisingly, none believed that this had any influence on the TB programme. It could be that this was taken for granted and it would have attracted more comment if it had been lacking. However, there was also a degree of cynicism as many felt that the commitment was because of the external funding attached to it, as both countries were recipients of Global Fund grants at the time of the study.

Infrastructure: Moldovan informants highlighted particular challenges in instituting uniform practices and standards in rural settings where there are difficulties recruiting and retaining health workers and where clinicians are overworked and largely disconnected from the broader health system, with its focus on larger policlinics and hospitals (13). From our observations, it was apparent that Moldova was well-equipped in respect to the diagnostic capacity available, particularly in the reference laboratories. This is the direct result of capacity building funds offered by the Global Fund to Fight AIDS, Tuberculosis and Malaria; United States Agency for International Development (USAID); World Bank, and other donors. In contrast, Macedonia did not have in-house access to high-technology equipment (e.g. Polymerase Chain Reaction or PCR), but this seemed to have little impact on the overall system of care. This observation strengthens our initial hypothesis, in that the systems of care have a greater impact on outcomes than does technology.

Historical trajectory: One phenomenon that characterised Moldova post-independence years was the growth of social inequality and breakdown of health services (14,15). This was exacerbated by a lack of management capacity in all post-Soviet republics outside Russia, in part consequent on the previously centralised system in the USSR (16). It

is plausible that some differences between former Soviet and former Yugoslav republics can be accounted for by the long history of decentralization in the latter (17,18).

Institutional memory: A loss of institutional memory may have played a role in Moldova, with frequent leadership changes in the political realm impacting substantially on the NTP. This has ripple effects on the continuity of policy, programmes and funding, as staff operate within an environment facing continual change (19,20).

Discussion

This study points to the importance of tackling not just the immediate causes of infection and resistance, but also the upstream factors, related to the way in which the health system is governed and organised. Key factors emerging from this research are congruent with those reported from other countries, including the challenges when patients cross boundaries between parallel health systems, or from a well-developed acute care sector to the community (21-23); a lack of accountability and oversight for TB treatment (14,23); the challenges arising from a strong centralized hospital sector, with consequent power imbalances (14,24-26); and the challenges of recruiting and retaining health staff in rural areas (16).

Consistent with the now extensive body of research on how some countries achieve good outcomes at low cost (27), we see that there is no single reason why Macedonia gets better outcomes than Moldova. These other studies have failed to find a single „magic bull‟e,tbut have identified several factors that increase the likelihood of success, such as effective governance systems and institutional continuity, both present in Macedonia, but weak in Moldova. Informants praised leaders in Macedonia, but those in Moldova were seen as weak, and afflicted by frequent changes. Fragmentation was a key issue, with Moldova unable to integrate prison care, contrary to what was done in Macedonia. This creates inevitable problems as there are well known challenges in enforcing uniform standards across multiple systems of care (28). The risk of losing patients to follow-up in such circumstances, particularly for people who are vulnerable or marginalized, is ever present (29). Prison health systems are a neglected political priority globally, and often provide substandard care compared with mainstream health systems (30). This being said, the Moldovan prison system is not entirely separate, maintaining some connections, as is usual in countries with parallel systems (31). Weak governance can also be inferred from the problematic relationships between different providers in Moldova.

This study has a number of limitations. The most obvious is attribution. While it is possible to infer certain relationships between observed characteristics of the two health systems and health outcomes, it is not possible, in a non-experimental study, to determine cause and effect. However, the associations observed, with weak governance, lack of institutional stability, and the existence of parallel health systems being seen in the country with the higher burden, and not in the one with less MDR-TB, is both plausible and consistent with the evidence on health systems performance more generally. The second is that, although the two countries have many similarities, they are not identical and have different historical legacies, and policies take place in different political, social, and economic contexts. These are likely, at least to some extent, to explain the differences in governance systems.

Notwithstanding these limitations, this study does add to the sparse literature on the association between health systems and the development of MDR-TB and points to the need to address the overall governance of the health system, as well as more downstream measures such as the promotion of rational prescribing.

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Nubani-Husseini M, Berry E, Abdeen Z, Donchin M. Dietary patterns and physical activity among Palestinian female schoolchildren in East Jerusalem (Original research). SEEJPH 2016, posted:15 February 2016. DOI 10.4119/UNIBI/SEEJPH-2016-92

ORIGINAL RESEARCH

Dietary patterns and physical activity among Palestinian female schoolchildren in East Jerusalem

Maha Nubani-Husseini[1,2], Elliot Berry[1], Ziad Abdeen[3], Milka Donchin[1]

[1] Braun School of Public Health, Hadassah & the Hebrew University-Hadassah Medical School, Jerusalem, Israel;
[2] Faculty of Public Health, Al-Quds University, Palestine;
[3] Nutrition and Health Research Institute, Faculty of Medicine, Al-Quds University, Jerusalem, Palestine.

Corresponding author: Maha Nubani-Husseini Maha, Braun School of Public Health, Hebrew University-Hadassah Medical School;
Address: P.O.Box 19746, East Jerusalem, Israel;
Telephone: +972522520104; Email: maha.husseini@mail.huji.ac.il.

Abstract

Aim: This study aims to assess the Palestinian girls' dietary habits and physical activity patterns as a baseline for intervention.
Methods: A cross-sectional study of grade 4 and 5 pupils (mean age: 11 years) in 14 all-girl schools in East Jerusalem, of four different types of school ownership (overall N=897), was conducted, using self-administered questionnaires and height and weight measurements. Logistic regressions were conducted to determine predictors of healthy behaviours.
Results: Only 36.6% of the pupils reported eating breakfast daily, with UNRWA schools having the highest rate of daily breakfast consumption (42.6%). About 28% reported eating the recommended daily quantity of five portions of fruits and vegetables. Only 15% of the pupils reported being active at least five days a week and more than one third of the schoolchildren viewed TV for ≥4 hours a day. The prevalence of overweight and obesity was 22.2% and 7.6%, respectively, with private schools having the highest rates, 29.6% and 12.8% respectively (P=0.001). Additional predictors of overweight and obesity were: being the first child in the family, watching TV for more than four hours a day, always eating while watching TV and being physically active less than five days a week.
Conclusions: Most Palestinian pupils miss breakfast, eat less fruits and vegetables than recommended and have sedentary behaviours. These findings raise serious concerns and point to the urgent need for tailored interventions.

Keywords: dietary and physical activity behaviour, obesity, Palestinian female schoolchildren.

Conflicts of interest: None.

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Introduction

Healthy nutrition and physical activity are the key factors in preventing and reducing obesity in children (1). Additionally, adapting such a healthy lifestyle throughout one's life span is essential for optimal physical growth and intellectual development (1). Obesity is known to be a significant risk factor for chronic diseases including type II diabetes mellitus, cardiovascular disease and certain types of cancer (2,3), and imposes a substantial economic burden (4). The obesity trend is especially alarming considering the increasing prevalence in children and adolescents. The need for effective preventive measures to control obesity has therefore become a major public health issue.

In Palestine, rapid urbanization, modernization and sedentary lifestyle have contributed to the increasing prevalence of overweight and obesity in all age groups (5). However, there are few local studies focusing on eating habits and physical activity patterns. One study was part of the Health Behaviour School Children survey (HBSC) conducted in 2004 in the West Bank and Gaza strip. This survey acknowledged problems such as skipping breakfast particularly among girls, low consumption of vegetables and fruits and low intake of milk (6). Such data is lacking for female schoolchildren from East Jerusalem. The current study is done to fill this gap and is part of a baseline study of a school-based intervention programme in East Jerusalem to promote healthy eating and physical activity among schoolchildren, their mothers and teachers.

The purpose of this paper is to describe nutritional and physical activity habits and their socio-demographic determinants among Palestinian girls in East Jerusalem schools of different types of ownerships.

Methods

Study design and population

A cross-sectional study was performed in April-June 2011 to provide the baseline data in a randomized controlled programme trial, before allocating schools into intervention and control groups. The primary target population was girls in grades 4 and 5, as those elementary schoolchildren are old enough to be able to answer the questions, however, they are not yet close to puberty when hormonal changes could have altered the results.

All schoolgirls from the different types of ownership in East Jerusalem were eligible for the study. This included 31 Jerusalem Municipality (JM) schools with 2,759 students, 23 Palestinian Authority (PA) schools with 2167 students, 40 Private schools with 820 students and eight United Nation Relief and Works Agency (UNRWA) schools with 1218 students. Average number of students per class is 34, with different numbers according to school type of ownership.

Sampling was done in two stages: i) stratified sampling of schools according to their ownership; ii) a random selection of classes (by lottery). All students in the selected classes were included.

Sample size calculation was based on the estimated prevalence of healthy behaviours relating to physical activity (>5 days per week), which was estimated at 25% among girls in grade 6 in the HBSC study (6). Assuming that this behaviour will increase among the intervention schools to 40%, and will remain at 25% in the control group, with a significance level of 5%, a power of 90%, intra-class correlation of 0.001 and a cluster size of 34, a sample of 14 schools was needed in order to provide 13% of the eligible population (952/6962). A random sample of schools was drawn in each of the four strata. This corresponded to six schools from the Jerusalem Municipality, four PA, two Private and two UNRWA schools, with 28 classes

and 935 students.

Data collection

A structured self-administered anonymous questionnaire was given to the pupils based on the HBSC questionnaire (6),which in turn was based on the WHO format (7). It focused on dietary assessment (eating breakfast, drinking before leaving for school, consumption of fruit and vegetables, milk consumption), physical activity (mode of transport to and from school, days per week active in sport for at least one hour per day), physical inactivity (watching TV) and knowledge (recommended daily consumption of fruits and vegetables).

The class teacher supervised filling the questionnaire by reading out aloud each question and then asking for an immediate response. The main researcher (MH) was present during administration of the questionnaires to clarify questions if required.

Respondents were informed that answering was voluntary and that information would be treated confidentially.

The height and weight of each student were measured after they completed the questionnaire, Students' weights were measured in their lightweight clothes (schools' uniform with no jackets) and without shoes before 10 o'clock break according to a standard protocol and instrument. Care was taken to ensure that the measurements were done sensitively and separately in a private room with the presence of the class teacher's supervisor.

Mothers' level of education and occupation was based on the mothers' self reported questionnaire and school files of the children for missing data.

Measures

Eating breakfast was assessed based on the question *"Do you always eat breakfast before you leave for school?"* with response options (1) yes, every day, (2) yes, sometimes, (3) never. Whereas drinking in the morning: (1) yes, always, (2) yes, sometimes, (3) never. Next, both questions were categorized into Yes (yes, every day) or No (sometimes or never). Daily consumption and quantity of fruits and vegetables were calculated and converted to two categories <5 serving per day ≥5 servings per day. Physical activity assessment was categorized into: (1) physical activity >5 days a week; (2)≤5 days a week. BMI -for-age was computed for each child using the WHO software AnthroPlus 2007 program. This program deduced z-score and percentiles using the exact age in days (8). Overweight was determined if a child's z-score fell between ≤ + 1SD and +2 SD (85th percentile). Obesity was determined if the child's z-score fell above and equal 2 SD (97th percentile), while underweight was determined if z-score fell below minus 2 SD (3rd percentile). Mothers' education was divided into three categories; (1) less than secondary, (2) secondary, (3) diploma and higher. Employment was divided into two categories; (1) yes, (2) no. Crowding index (the ratio between number of residents at home and number of rooms) was used as a proxy for socio-economic status and divided into (1) less than one; (2) 1-2, (3) more than 2.

Statistical analysis

Data analysis was performed using SPSS version 20. Chi-square tests were used to calculate associations between categorical variables by school ownership, grade, socio-demographic/economic variables. A stepwise forward logistic regression model was built for identifying independent predictors of eating breakfast daily, eating the recommended quantity of fruits and vegetables, physical activity and overweight and obesity. The variables in the final model of the stepwise forward logistic regression were tested again by entering them into the logistic regression models.

Ethical considerations

Approval from the Israeli Ministry of Education, Palestinian Ministry of Education, UNRWA Office of Education Department and private school principals was obtained. The research program was approved by the Hebrew University of Jerusalem/Authority for Research Students Committee.

Results

Sample characteristics

All 14 selected schools agreed to participate in the study. Of the 935 eligible schoolchildren, 897 (95.9%) participated (49.9% children were from grade 4 and 50.1% were from grade 5). Non-response was due to absence from school on the day of data collection. Table 1 presents the socio-demographic characteristics of the study population by school ownership.

Table 1. Socio-demographic characteristics of the study population by school ownership

Variable	School Type				
	Municipality (n=400)	**PA (n=236)**	**UNRWA (n=136)**	**Private (n=125)**	**Total (n=897)**
Grade (%):					
4th Grade	49.8	50.0	49.3	51.2	49.9
5th Grade	50.3	50.0	50.7	48.8	50.1
Age:					
Mean	11.02	11.00	11.10	10.98	11.02
SD	0.70	0.78	0.87	0.71	0.71
Order in the family (%):					
1	19.2	19.1	16.9	29.6	20.6
2-3	39.0	30.9	37.5	51.2	38.4
4	15.6	16.1	15.4	9.6	15.2
≥5	24.8	33.9	30.1	9.6	25.9
Sibling (%):					
0-2	14.5	6.8	5.9	43.2	15.2
3-4	44.8	42.4	38.2	46.4	43.4
≥5	40.8	50.4	55.9	10.4	41.4
Crowding index (%):					
<1	9.0	6.4	8.1	17.6	9.4
1-2	54.5	66.1	51.5	62.4	58.3
>2	36.5	27.1	40.4	20.0	32.3
Religion (%):					
Muslim	100.0	100.0	100.0	59.2	94.3
Christian	0.0	0.0	0.0	40.8	5.7
Mother education (%):					
Less than secondary	45.6	49.0	52.7	7.1	42.2
Secondary	40.0	34.3	36.4	38.1	37.7
Diploma & higher	14.4	16.7	10.9	54.9	20.1
Mother employment (%):					
Yes	16.6	15.9	14.5	33.9	18.5
No	83.4	84.1	85.0	66.1	81.5

The age of students ranged between 9-14 years (mean: 11.02, SD±0.71). About 94% were Muslims and 6% were Christians, all attending private schools. The mean family size was

7.1; Schoolchildren from Municipality, P.A and UNRWA had more siblings compared to those in Private schools. Schoolchildren from Municipality and UNRWA schools lived in higher crowding index (residents per room) compared to PA and Private Schools. About 81% of the mothers did not work and 20% had a diploma or higher education.

Dietary habits

The percent of schoolchildren who reported having breakfast was 36.6%. There was a significant difference between school ownership with UNRWA schools having the highest rate of daily breakfast consumption (42.6%), compared to Municipality, PA and Private (P=0.032) (Table 2). More Muslim schoolchildren (29.7%) consumed breakfast compared to Christian schoolchildren (25.5%) in Private schools.

Table 2. Dietary pattern, physical activity, knowledge perception, overweight and obesity (%) by school type and crowding index

BEHAVIOURAL CHARACTERISTICS	School ownership				Crowding index		
	JM N=400	PA N=236	UNRWA N=136	Private N=125	<1 (n=84)	1-2 (n=522)	>2 (n=290)
Dietary pattern							
Always eating breakfast	38.3	34.7	42.6	28.0*	56.0	33.3	33.6†
Always drinking in the morning	46.0	42.0	51.5	47.0	52.2	48.8	45.2
Always eating vegetable at 10 o'clock break	18.3	8.5	22.8	16.0‡	23.8	15.7	14.5
Always eating fruits at 10 o'clock break	18.3	11.4	20.6	16.1	16.7	15.9	17.6
Eating ≥5 serving of vegetables and fruits/day	35.8	22.1	14.0	27.2‡	29.8	27.2	27.2
Eating vegetables once or more per day	21.3	27.5	13.2	23.2*	26.2	21.5	21.4
Eating fruits once or more per day	23.3	19.6	16.9	23.2	29.8	22.2	17.0*
When thirsty water is the most used drink	69.5	90.3	79.0	68.0‡	78.6	74.7	78.3
Drinking milk every day	43.3	40.7	27.2	52.0‡	59.5	41.8	35.5‡
Lunch is the main meal at home	74.2	77.5	61.0	77.6*	76.2	73.9	72.3*
Eating with family or at least one parents	79.5	77.0	77.2	72.8	77.4	78.1	76.6
Eating while watching TV	27.0	21.7	20.6	32.0‡	28.6	24.9	25.3
Eating while using computer	5.3	1.70	8.1	4.80†	3.6	4.6	5.2
Eating when bored/angry/stressed/frustrated	6.5	4.2	4.4	1.6†	4.8	5.2	4.5
Physical activity pattern							
Walking to school in the morning	65.3	71.6	93.4	39.2‡	57.1	64.4	76.2‡
Walking back after school	73.3	76.3	97.1	40.0‡	61.9	70.3	80.7†
Physically active ≥5 days a week	16.8	13.6	8.1	16.0	20.2	16.5	9.30
Sedentary behaviours							
Using computer >4 hours	20.0	14.0	7.4	17.6†	22.6	14.9	16.2
TV viewing ≥4	33.0	36.0	38.2	38.0‡	33.3	33.5	34.5
Knowledge							
Acknowledge importance of breakfast	91.7	94.5	94.0	94.4	94.0	93.7	92.0
Acknowledge importance of fruits & vegetables	97.7	97.0	95.6	100.0	96.4	98.1	96.9
Acknowledge importance of water	98.0	95.8	100.0	99.2*	97.6	98.1	97.9
Know recommended serving vegetables/fruits	12.5	12.0	10.3	14.4	25.0	21.3	23.5
BMI							
Overweight	24.8	14.4	21.3	29.6	29.8	19.3	25.2
Obese	7.5	3.4	10.3	12.8‡	7.1	8.4	6.2

* P<0.05; † P<0.01; ‡ P<0.001.

Eating breakfast daily was associated with the socio-economic status of the family, measured by crowding index. Those living in a house with fewer than one person per room had a 2.4-

fold increase in the likelihood of eating breakfast (OR=2.38, 95%CI=1.36-4.18), controlling for school type (logistic regression, Table 3). UNRWA schoolchildren were more likely to eat breakfast (OR=1.75, 95%CI=1.07-2.88) compared to other school types of ownership. If mothers always prepared breakfast for their daughters, there was a 4-fold increase in the likelihood of the child eating breakfast (OR=3.83, 95%CI=0.82-17.96), although this finding was not statistically significant. These three determinants contributed independently to having breakfast daily (logistic regression, Table 3). The mother's level of education and employment status, beliefs, and knowledge regarding the importance of breakfast meals and birth order were found to have no effect on eating daily breakfast. "Not feeling hungry" was the main reason for skipping breakfast (78.6%).

Table 3. Determinants of eating breakfast – logistic regression models[*]

Variable	Number	OR	P-value	95%CI
Crowding index:			**<0.001 (2)[†]**	
<1	73	2.38	0.003	1.36-4.18
1-2	432	0.75	0.099	0.53-1.06
>2	230	1.00	-	reference
School ownership:			**0.004 (3)**	
JM	341	1.00	0.640	0.62-1.34
PA	193	0.91	0.030	1.07-2.88
UNRWA	86	1.75	0.018	0.34-0.90
Private	115	0.55	-	reference
Mother preparing breakfast to her daughter:			**<0.001 (2)**	
Never	13	1.00	-	reference
Sometimes	235	1.41	0.67	0.29-6.76
Always	487	3.83	0.089	0.82-17.96

[*] The last variables left of the stepwise forward logistic regression were entered into the logistic regression model.

[†] Overall p-value and degrees of freedom (in parentheses).

The most commonly consumed food for breakfast was za'ater and oil with bread. This choice varied widely between school ownership type (P<0.001), where UNRWA schoolchildren consumed the most (61.6%). Other relevant variables were Muslim religion (P<0.001) and mothers who had not attained secondary education (P<0.001).

The proportion of schoolchildren who reported drinking in the morning before leaving for school was 46.2%. This was not found to be associated with school ownership, grade, or with socio-economic variables.

About 28% of the schoolchildren reported consuming the recommended number of daily servings of fruits and vegetables (five servings a day), with a significant difference between school types of ownership (P<0.001) and the mother's level of education (P=0.01). Only 12.3% of schoolchildren reported the correct answer for the daily recommended consumption of fruits and vegetables. Children of mothers with a diploma or higher level of education had a higher proportion of consuming the recommended number of servings (47.9%). School type of ownership and the mother's level of education remained statistically significant in the final multilevel logistic regression model. Being in a JM school increased the probability of consuming the recommended quantity of vegetables and fruit by 1.55 times (OR=1.53, 95%CI=0.76-1.96). Having a mother with a diploma or higher education increased it by 1.8

times (OR=1.80, 95%CI=1.25-2.60). The mother's employment status, religion, and crowding index were found to have no effect.

School ownership had a significant effect (P<0.001) on daily milk consumption, with private schools having the highest consumption (52%). Another predictor was the crowding index, which was inversely associated (P<0.001).

Most of the schoolchildren had lunch as the main meal which they ate with at least one parent.

Physical activity

The majority of schoolchildren reported walking to and from the school (67.6% and 72.9%, respectively). There was a significant difference between school ownership type (Table2), with UNRWA schools having the highest level (93.4% and 97.1%, respectively, P<0.001).

The overall reported physical activity in schoolchildren showed that pupils were only slightly active in sport. About 14% of schoolchildren reported being active at least five days a week (Table 2). This proportion was significantly inversely associated with the crowding index (20.2%, 16.5%, and 16.5% for up to one, between 1-2, and more than two, respectively, P=0.006). A positive significant association was also found with mothers' level of education (12.9%, 13.4% and 21.5% for less than secondary, secondary and diploma or higher education, respectively, P=0.027). No other tested variables were associated with physical activity.

Sedentary behaviours

One-third of the students (33.9%) viewed TV for ≥4 hours a day and this was significantly associated with the school ownership (P<0.001). The highest percentages reporting viewing television were found in UNRWA and Private Schools (38.2% and 38.0%, respectively). (Table 2). Sedentary behaviour was not associated with the crowding index, mothers' education or employment. No correlation was found between television viewing and being physically active.

Body weight

The overall prevalence of overweight and obesity was 22.2% and 7.6%, respectively. The difference between school ownership types was statistically significant (P<0.001), where the highest proportion was among Private schoolchildren (42.4%). More Christian schoolchildren in the private schools (47.1%) were overweight and obese compared to Muslim schoolchildren (39.2%). About 1% of schoolchildren were underweight, with highest rates among PA schoolchildren (3%) (Table 2). A significant higher prevalence of overweight and obesity was noticed with the first child in the family. The other independent determinants of overweight and obesity (logistic regression) were: watching TV more than four hours a day (OR=4.13, 95%CI=2.93-5.82); being physically inactive (less than five days a week) (OR=1.95, 95%CI=1.17-3.24) and always eating while watching TV (OR=3.42, 95%CI=2.27-5.13) (Table 4).

No association was found with crowding index, mothers' level of education or employment. About 75% of overweight/obese children considered their weight as normal, whereas 66% of those who perceived themselves as "high weight for their age" were actually overweight/obese children (data not shown).

Table 4. Determinants of overweight and obesity – logistic regression models[*]

Variable	Number	OR	P-value	95%CI
Family order:			**0.003 (3)[†]**	
1	185	1.00	-	reference
2-3	343	0.48	0.001	0.31-0.74
4	136	0.91	0.74	0.54-1.56
≥5	231	0.57	0.024	0.35-0.93
School ownership:			**<0.001 (3)**	
JM	399	1.00	-	reference
PA	235	0.38	<0.001	0.24-0.59
UNRWA	136	0.90	0.660	0.56-1.45
Private	125	1.71	0.026	1.07-2.75
Physical activity:				
<5 days/week	761	1.95	0.010	1.17-3.24
≥5 days/week	135	1.00		Reference
TV viewing:				
≤4 hours/day	597	1.00	<0.001	2.93-5.82
>4 hours/day	299	4.13		Reference
Eating while watching TV:			**<0.001 (2)**	
Never	315	1.00	-	reference
Several times a week	534	0.71	0.010	0.48-1.07
Every day	266	3.42	<0.001	2.27-5.13

[*] Overweight and obesity were combined. The last variables left of the stepwise forward logistic regression were entered into the logistic regression model.

[†] Overall p-value and degrees of freedom (in parentheses).

Discussion

The aim of this study was to provide baseline information of schoolchildren living in East Jerusalem as the first stage of a randomized controlled intervention programme. The results showed that most children fail to meet the international dietary and physical activity recommendations. There was a significant independent difference between school ownership and socio-economic groups, measured by the crowding index, but no significant difference was observed between grades for all the studied variables.

Approximately one third (36.6%) of female schoolchildren ate breakfast before school. This finding is consistent with the finding of dietary habits among Palestinian adolescents where 34.7% ate breakfast (9). Most of the schoolchildren reported "not feeling hungry" as the main reason for skipping breakfast, which is a growing concern worldwide, especially among females (10). In private schools, although the pupils come from higher social classes and are assumed to be in a better position to provide good food for their children, the level of skipping breakfast was the highest.

Za'ater and olive oil with bread is the most commonly consumed breakfast meal. This could be because of its prominent role in cultural heritage, due to the widely held belief that za'ater helps to keep mind alert especially prior to exams or school. Olive oil is known to be a main component of the Mediterranean diet, a rich source of monounsaturated fatty acids and an antioxidant agent, which has several beneficial biological functions for health (11). Studies also have proved that olive oil intake is associated with the reduced risk of cardiovascular disease and mortality in individuals at high risk (12).

Drinking milk was reported only by 40% of schoolchildren. Adequate calcium intake for children is essential for the development of bone mass and mineral density (13) and in the maintenance of health and prevention of chronic diseases (14). Strategies to encourage milk consumption by schoolchildren need special attention.

The reported fruit and vegetable intake was lower in our study than that found in the 2004 Palestinian HBSC survey (6). This could be due to rapid and progressive shifting among Palestinian adults to Western-style food patterns (9). Less than one third of schoolchildren reached the recommended daily dietary intake of five servings of fruits and vegetables (1). This means that these children may fail to obtain appropriate nutritional intakes of vitamins, mineral and fiber to protect them from diet-related chronic diseases (15), including overweight and obesity (16,17), despite the fact that Palestinian markets have a wide variety of vegetables and fruits at low prices. Therefore, the need to promote the consumption of more vegetables and fruits is viable and a public health priority.

Regular physical activity plays an important role in improving the quality of life. Although more than two thirds of schoolchildren reported walking in the morning to and from school, respondents did not engage in regular sport and physical activity in leisure time. Therefore, they do not achieve the recommended level of being one hour or more physically active per day (18). In Arab countries, including Palestine, women are prohibited by the socio-cultural norms from participation in outdoor sports activities. Therefore, there is a need to develop good physical education practices (e.g. skipping, which can be performed at home) to increase physical activities among girls.

In parallel, there is an increase in sedentary behaviours among schoolchildren, which is due mainly to time spent watching television, as in many other countries (15). This is because television is so accessible and available. Current recommendations are that children should spend no more than two hours watching television a day (19).

The problem of obesity

The prevalence of overweight and obesity is high among Palestinian schoolchildren, associated with lack of physical activity and increased sedentary behaviours. Childhood obesity is an increasingly worldwide problem. This study found that the prevalence of overweight is 22.2% and obesity is 7.6% which is higher than adolescents in the Gaza strip (17.0% and 5.45%, respectively) (20), Ramallah (18.9% and 3.3%, respectively), Hebron (14.9% and 2.0%, respectively) (9), but slightly lower than a previous study conducted in East Jerusalem in 2002 (24.3% and 9.9%, respectively) (21).

The overweight/obese schoolchildren were found more likely to watch television for more than four hours. This is in accordance with several cross-sectional and longitudinal studies showing very strong associations between television viewing and childhood obesity (22,23). Significant positive associations were found between eating while watching television and the risk of becoming overweight/obese. Watching television for many hours may lead to a snacking while watching (24), which is independently associated with overweight/obesity among children (25).

Schoolchildren in private schools have higher standards of living. Several studies have demonstrated that socioeconomic status is directly related to childhood obesity in developing countries (26), which is higher in urban areas (27,28). The discussed culture restrictions placed on girls which results in their staying at home with easy access to food, contribute to their increased risk of overweight and obesity. Evidence suggests that measures should be introduced as early as possible, so that healthy lifestyle habits are learnt from childhood (29).

Study limitations

The study involved a cross-sectional design, and therefore cannot address causality. Another limitation is using a self-reported questionnaire from schoolchildren in grades 4 and 5 which could have influenced its validity and reliability. However, studies show that results from self-administered questionnaires tend to minimize social desirability bias compared to interviewer-administered questionnaires (30).

Conclusion

This study shows that Palestinian girls miss breakfast, eat less fruits and vegetables than the recommended requirements, and have sedentary behaviours, which is associated with high prevalence of overweight and obesity. There is a need for developing effective intervention programmes to promote healthy eating and physical activity among Palestinian schoolchildren.

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ORIGINAL RESEARCH

Concurrent validity of radiography and ultrasound examination for the diagnosis of aortic aneurisms in Albanian patients

Ilirian Laci[1], Alketa Spahiu[2]

[1] Radiology and Nuclear Medicine Service, University Hospital Center "Mother Teresa", Tirana, Albania;

[2] Statistics Service, University Hospital Center "Mother Teresa", Tirana, Albania.

Corresponding author: Dr. Ilirian Laci
Address: Rr. "Dibres", No. 370, Tirana, Albania;
Telephone: +355672072668; E-mail: ilirianlaci@yahoo.com

Abstract

Aim: The aim of our study was to assess the concurrent validity of radiography and ultrasound examination among patients diagnosed with aortic aneurisms in Albania, a transitional country in South Eastern Europe.

Methods: This study included 75 consecutive patients diagnosed with aortic aneurisms (thoracic and/or abdominal) admitted at the University Hospital Centre "Mother Teresa" in Tirana during 2012-2014 (56 men and 19 women). For each patient, computerized tomography (CT) scan with contrast was used to confirm the diagnosis of aortic aneurisms. In addition to the CT scan ("gold standard" for the diagnosis of aneurisms), in 37 patients, radiography and ultrasound examination were simultaneously performed in order to assess the validity of these techniques. Furthermore, demographic data and other relevant clinical information were collected for each study participant.

Results: In 18 patients with thoracic aneurisms pertinent to ascendant aorta where radiography and ultrasound were simultaneously performed, ultrasound was able to diagnose 5 (27.8%) cases which were not detected through radiography (P=0.038). Conversely, in 16 patients with abdominal aneurisms where radiography and ultrasound were simultaneously performed, ultrasound was able to diagnose 4 (25.0%) cases which were not detected through radiography (P=0.034). The remaining three patients diagnosed with thoracic-abdominal aneurisms were not detected either by ultrasound examination or radiography.

Conclusions: In this sample of Albanian patients diagnosed with aortic aneurisms (N=75), overall, 9 (24.3%) subjects were detected through ultrasound examination but not radiography (P<0.001). Findings from this study provide valuable clues about the concurrent validity and predictive value of these two key examinations for the diagnosis of aortic aneurisms.

Keywords: Albania, aneurism, CT scan, predictive value, radiography, ultrasonography, ultrasound, validity.

Conflicts of interest: None.

Introduction

Aortic aneurysms are defined as enlargements (dilations) of the aorta which is caused by a chronic weakness (thinness) of the arterial wall. Under these conditions, there is a high risk for ruptures, as well as for other unfavourable cardiovascular events in subjects with aortic aneurisms (1-3).

In the United Kingdom, in patients with aortic aneurisms of a size about 40-55 mm, only 16% of deaths have been linked to surgical interventions or ruptures, whereas 50% of deaths have been linked to other cardiovascular events including myocardial infarction and stroke (4).

Aortic aneurisms affect about 8% of men aged 65 years and above, but the occurrence of this condition is increasing in women too (5,6). Data available from the Centre for Disease Control and Prevention (CDC) in USA indicate that aortic aneurisms constitute the fifteenth leading cause of death in American men and women aged 60-84 years old (7).

As aortic aneurisms remain one of the major causes of morbidity and mortality especially among older men, its prevalence is expected to increase gradually in parallel with population aging in most countries of the world. Aortic aneurisms are usually asymptomatic and are often detected upon radiological examinations performed for other reasons. Based on the radiological evidence, surgical or endovascular interventions are performed. Especially under emergency conditions, radiography and ultrasound examinations are very important in order to identify aortic aneurisms and aortic dissections (8). In principle, however, the diagnosis of aortic aneurisms is made through the following techniques: ultrasound, CT scan without contrast and/or with intravenous contrast (CTA), radiography, angiography (aortography) and magnetic resonance imaging (MRI) (8). The risk for rupture of aneurisms is related to the level of dilation. Several studies have convincingly argued that ultrasound may be a suitable method for the diagnosis of aortic aneurisms given the fact that it is a non-invasive technique, without radiation and relatively cheap (8). The sensitivity and specificity of ultrasound examination for detection of aortic aneurisms have been estimated at 87.4%-98.9% and 99.9%, respectively (9). Nevertheless, the accuracy of ultrasound examination may be far lower in obese individuals and in those with intestinal meteorism (9). As a matter of fact, it is possible to assess only the ascendant thoracic aorta through trans-thoracic ultrasound examination, whereas assessment of the descendent thoracic aorta is possible only through trans-oesophageal ultrasound (10).

In post-communist Albania, there has been an increase in cardiovascular diseases in the past two decades (11). In particular, the death rate from ischemic heart disease in Albania is the highest in South Eastern Europe (11), in line with the rapid changes in dietary patterns characterized by an increase in processed foods and an increase in the prevalence of smoking (12). In addition, Albania is the only country in South Eastern Europe which has experienced an increase in the mortality rate from ischemic heart disease and cerebrovascular diseases in the past two decades (11,12). However, specific information about the frequency and distribution of aortic aneurisms in the Albanian population is scant.

In this framework, the aim of this study was to assess the concurrent validity of radiography and ultrasound examination among patients diagnosed with aortic aneurisms in Albania, a transitional country in South Eastern Europe which, among other reforms, is also undergoing a deep reform in the health care sector.

Methods

This study included 75 consecutive patients diagnosed with aortic aneurisms (thoracic and/or abdominal) admitted at the University Hospital Centre “Mother Teresa” in Tirana (the only tertiary care facility in Albania) for the period from January 2012 to December 2014 (56 men and 19 women).

For each patient, computerized tomography (CT) scan with contrast was used to confirm the diagnosis of aortic aneurisms.
In addition to the CT scan (which is considered as the "gold standard" for the diagnosis of aneurisms), radiography was performed in 56 (74.7%) patients, whereas ultrasound examination was conducted in 45 (60.0%) patients (Table 1).

Table 1. Examinations performed in a sample of Albanian patients diagnosed with aortic aneurisms during 2012-2014 (N=75)

Radiography		Ultrasound		CT scan with contrast	
Number	**Percent**	**Number**	**Percent**	**Number**	**Percent**
56	74.7%	45	60.0%	75	100.0%

On the other hand, in 37 patients, radiography and ultrasound examination were simultaneously performed in order to assess the validity of these techniques. In principle, radiography and ultrasound examination were performed in patients admitted at the emergency unit who were residents in Tirana. Ultrasound in emergency conditions consisted of trans-thoracic or trans-abdominal examination, but not trans-oesophageal examination, because such a procedure involves a careful preparation and is not recommended under emergency conditions. On the other hand, patients from other districts of Albania for whom there was prior suspicion for aneurisms underwent directly CT scan examination.
Furthermore, other relevant clinical information and demographic data were collected for each study participant.
Mann-Whitney U-test was used to compare mean age and mean duration of hospitalization between male and female participants. On the other hand, Fisher's exact test was used to compare the proportions of place of residence, smoking, hypertension and other chronic diseases between men and women. Conversely, Cramer's V test (a measure of association between two nominal variables) was used to compare the concurrent validity of radiography and ultrasound examination. In all cases, a p-value of$\leq$0.05 was considered as statistically significant. Statistical Package for Social Sciences (SPSS, version 19.0) was used for the data analysis.

Results

This study involved 75 patients with a confirmed diagnosis of aortic aneurism according to CT scan with contrast ("gold standard"). Demographic characteristics and clinical data of the patients included in this study are presented in Table 2.
Overall, 56 (74.7%) patients were men and 19 (25.3%) were women (male-to-female ratio about 3/1). Mean age in women was higher than in men, a difference which nevertheless was not statistically significant (62.5±13.8 vs. 58.0±15.7 years, respectively, P=0.41). On the whole, 31 patients were residents in Tirana compared with 44 patients who were residents in other districts of Albania. Mean duration of hospitalization was 7.4±8.9 days, with no statistically significant sex-difference (P=0.261), notwithstanding a longer duration in men (10.3±9.5) compared to women (6.4±8.6). The overall prevalence of smoking was 32/75=43%; it was considerably higher in men than in women (52% vs. 16%, respectively, P=0.007). The overall prevalence of hypertension was 55/75=73%, with no significant difference between men and women (P=0.249). Overall, 60% (45 out 75) of the patients had other pre-existing chronic conditions, which were evenly distributed between men and women (Table 2).

Table 2. Demographic data and clinical characteristics of the patients diagnosed with aortic aneurisms

CHARACTERISTIC	WOMEN (N=19)	MEN (N=56)	TOTAL (N=75)
Age *(years)*	58.0±15.7*	62.5±13.8	59.1±15.3
Place of residence:			
Tirana	8 (25.8)†	23 (74.2)	31 (100.0)
Other districts	11 (25.0)	33 (75.0)	44 (100.0)
Total	*19 (25.3)*	*56 (74.7)*	*75 (100.0)*
Length of hospitalization *(days)*	6.4±8.6	10.3±9.5	7.4±8.9
Smoking:			
Yes	3 (9.4)	29 (90.6)	32 (100.0)
No	16 (37.2)	27 (62.8)	43 (100.0)
Hypertension:			
Yes	16 (29.1)	39 (70.9)	55 (100.0)
No	3 (15.0)	17 (85.0)	20 (100.0)
Other chronic diseases:			
Yes	11 (24.4)	34 (75.6)	45 (100.0)
No	8 (26.7)	22 (73.3)	30 (100.0)

* Mean ± standard deviation.

† Number and row percentages (in parenthesis)

Radiography was able to detect 20 patients with a confirmed diagnosis of aortic aneurism. Hence, 35.7% of suspected cases (20 out of 56 patients who underwent this procedure) were detected through radiography. It should be noted that radiography played a major role in thoracic aortic aneurisms, but less so for abdominal aortic aneurisms, except for old abdominal aneurisms with wall calcifications which enabled a prompt diagnosis upon radiography.

Conversely, trans-thoracic and trans-abdominal ultrasound examination was able to detect 36 patients with a confirmed diagnosis of aortic aneurism. Thus, 80.0% of suspected cases (36 out of 45 patients who underwent this procedure) were detected through ultrasound examination (data not shown in the tables).

It should be emphasized that complications such as ruptures, dissections, hematomas, or clots could not be detected either through radiography or by ultrasound examination.

Table 3 presents findings from radiography and ultrasound examination performed simultaneously in a sub-sample of 37 patients. In this sub-sample of patients diagnosed with aortic aneurisms (N=37), overall, 9 subjects (or, 24.3% of them) were detected through ultrasound examination but not radiography (Cramer's V=0.609, P<0.001).

Table 3. Findings from radiography and ultrasound examination performed simultaneously in a sub-sample of 37 patients

RADIOGRAPHY	ULTRASOUND		TOTAL
	Yes	No	
Yes	14 (100.0%)	0 (0%)	14 (100.0%)
No	9 (39.1%)	14 (60.9%)	23 (100.0%)
Total	23 (62.2%)	14 (37.8%)	37 (100.0%)

Overall, 23 (or, 62.2%) of the cases in this sub-sample (N=37) were detected by one of the two examination methods (radiography or ultrasound). Conversely, 14 (37.8%) of the cases in this-sample were not detected either by radiography or ultrasound examination (Table 2).
In 18 patients with thoracic aneurisms pertinent to ascendant aorta where radiography and ultrasound were simultaneously performed, ultrasound was able to diagnose 5 (27.8%) cases which were not detected through radiography (P=0.038) (not shown in the tables). Conversely, in 16 patients with abdominal aneurisms where radiography and ultrasound were simultaneously performed, ultrasound was able to diagnose 4 (25.0%) cases which were not detected through radiography (P=0.034). The remaining three patients diagnosed with thoracic-abdominal aneurisms were not detected either by ultrasound examination or radiography.

Discussion

This may be the first report from Albania informing about clinical characteristics of a consecutive sample of patients diagnosed with aortic aneurisms according to CT scan with contrast examination which is regarded as the gold standard for the confirmation of the diagnosis of this condition. Main findings of this study include a higher sensitivity of ultrasound examination compared to radiography. Hence, of the 37 patients who underwent both of these procedures, 9 (24.3%) subjects were detected through ultrasound examination but not radiography (P<0.001).
Radiography in emergency conditions is feasible and is considered as a straightforward procedure (8). In our study, radiography was able to detect about 36% (20/56) of the cases with aortic aneurisms. In particular, radiography played a major role for detection of thoracic aortic aneurisms, whereas in cases of abdominal aortic aneurisms it was less effective (valid).
Similarly, trans-thoracic and trans-abdominal ultrasound examination is also feasible in emergency conditions (8,9). In our study, ultrasound examination was able to detect 80% (36/45) of the cases with aortic aneurisms. The remaining 9 (or, 20%) of the cases were not detected through ultrasound probably due to the inability of the examiners (lack of proper training) involved in this procedure.
Notwithstanding the higher detection rate of ultrasound examination compared to radiography, it was not possible in our study to assess the complications of aneurisms such as dissections, ruptures, fistulisation with other organs, involvement of blood vessels stemming from the respective aneurisms, or calcifications. On the other hand, in our study, hematomas were partly assessed through ultrasound examination.
Our findings related to radiography are generally in line with previous reports from the international literature (13). Hence, according to a previous study, aortic aneurisms were confirmed in about 50% of the cases (13). In any case, it is argued that chest radiography has a limited value for the diagnosis of aortic aneurisms (8,13). Radiography plays an important role only in cases of aortic aneurisms with wall calcifications. In all suspected cases of aortic aneurisms though, CT scan with intravenous contrast should be promptly conducted (8,13).
This study may have several limitations. Our study included all consecutive patients diagnosed with aortic aneurisms over a three-year period at the University Hospital Centre "Mother Teresa", which is the only tertiary care facility in Albania. Based on this recruitment approach, our study population involved an all-inclusive sample for the three-year period under investigation. Furthermore, the diagnosis of aortic aneurisms was based on the state-of-the-art clinical protocols and up-to-date examination techniques employed in similar studies conducted in other countries. In any case, the self-reported information which was collected through semi-structured interviews may have been prone to different types of information

bias. This may have been the case of self-reported smoking, hypertension and other pre-existing conditions.

In conclusion, this study provides useful evidence about the detection rate of radiography and ultrasound examination among patients diagnosed with aortic aneurisms in Albania, a transitional country in South Eastern Europe. Findings from this study provide valuable clues about the concurrent validity and predictive value of these two key examinations for the diagnosis of aortic aneurisms.

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ORIGINAL RESEARCH

Influence of a six-month strengthening programme on HbA1c, cholesterol and triglycerides in type II diabetics: A pilot study

Helmut Wenzel[1], Edgar Unger[1]

[1] Bodensee Campus GmbH, Kostanz, Germany;

Corresponding author: Helmut Wenzel, M.A.S.
Address: D- 78464 Konstanz, Germany;
E-mail: HKWen@aol.com

Abstract

Aim: To assess the feasibility and effectiveness of resistance training on glycaemic control in adults with type 2 diabetes, the additional risk factors including low physical activity, measured by HbA1c, body weight, cholesterol and triglycerides.

Methods: We conducted a pilot study as a pre-and-post study with no control group. Participants had to meet the following inclusion criteria: type 2 diabetic person, 45-75 years old, duration of diabetes <10 years, no experience with resistance training within the last ten years, willingness to attend regularly the training sessions (two training units per week, with 45 minutes of duration each). Furthermore, a certificate from the treating physician (diabetologist) was requested, testifying that there were no medical reasons against participation. Patients with severe accompanying diseases, high blood pressure, heart failure (NYHA III), or retinopathy were excluded. Eighteen persons (10 men, 8 women), aged 46-71 years could be included. Due to dropouts, the pre-post-evaluation was based on 13 individuals only. Mean age of this group (6 men, 7 women) was 63.6±5.5 years. Mean body mass index at the beginning was 29.8±4.9. Mean HbA1c was 7.5%±0.6%; the triglycerides were in the range between 134 mg/dl and 335 mg/dl with an average value of 195.8±50.9 mg/dl. Cholesterol level was between 149 mg/dl and 262 mg/dl, which corresponded to an average of 206.6±34.8 mg/dl. The training took place in a fitness centre under the supervision of a certified sports scientist between April 2010 and October 2010 for 28 weeks. During the training period, the patients were asked to report whether they changed their level of general physical activity during this period, as a potential confounder. Possible treatment adaptations had to be recorded.

Results: At the end of the study, the average HbA1c dropped from 7.5%±0.6% to 7.1%±0.8%. Mean cholesterol level dropped from 206.6±34.8 mg/dl to 191.3± 30.85 mg/dl. Mean triglycerides were lowered from 195.8±50.9 mg/dl to 144±30 mg/dl. These changes were all statistically significant ($P<0.05$). The dose-response curve was not significant, probably due to the small number of participants.

Conclusions: There is now suggestive evidence supporting the use of resistance training for improving glycaemic control and insulin sensitivity in type 2 diabetes. However, this has not been perceived clearly enough to date. It is also not in the focus of economic evaluations of diabetes preventing strategies. Activating diabetic patients to perform resistance training is an effective and efficient way to reduce the burden of diabetes and, even more, to prevent this disease.

Keywords: cholesterol, HbA1c, pilot study, triglycerides, type II diabetes.

Conflicts of interest: None.

Introduction

Diabetes affects patients and their families, health insurance and society. Diabetes lowers average life expectancy of the patient increasing cardiovascular disease risk two to four fold, and is the leading cause of kidney failure, lower limb amputations, and adult-onset blindness. The disease puts a significant economic burden on society and healthcare programmes (1) and leads to considerable stagnation of national economies. The costs of caring for patients that are suffering the consequence of complications are four times higher than those without complications (2). As the International Diabetes Federation emphasizes, complications due to diabetes are a major cause of disability, reduced quality of life and death(3).

Just over 8.3% of the global population between 20 and 79 years has diabetes, which was about 415 million in 2015; by 2040, this figure will rise to 642 million (4). The number of people with diabetes in 2013 in Europe was estimated at 56.3 million, which is 8.5% of the adult population. Turkey has the highest prevalence (14.8%) and the Russian Federation has the greatest number of people with diabetes (10.9 million). By contrast, Azerbaijan has an estimated prevalence of diabetes of just 2.4%. After Turkey, the countries with the highest prevalence are Montenegro (10.1%), Macedonia (10.0%), Serbia (9.9%), and Bosnia and Herzegovina (9.7%) (3).

Diabetes imposes a large economic burden on individuals and families, national health systems, and countries. According to a report of the International Diabetes Federation (3), health spending on diabetes accounted for 10.8% of total health expenditure worldwide in 2013. Most of the money has to be spent for treating the complications. It is not diabetes or its management that causes most costs; rather, it is the consequences of the complications (4,5).

At present, type 1 diabetes cannot be prevented. The environmental triggers that are thought to generate the process that results in the destruction of the body's insulin-producing cells are still under investigation. But, there is significant evidence that lifestyle changes (achieving a healthy body weight and moderate physical activity) can help prevent the development of type 2 diabetes (6). Obesity, particularly abdominal obesity, is linked to the development of type 2 diabetes. Weight loss improves insulin resistance and reduces hypertension. People who are overweight or obese should therefore be encouraged to achieve and maintain a healthy body weight (6,7). A reduced capability of insulin to boost muscle blood flow is typical for insulin-resistant obese individuals and individuals with type 2 diabetes. Exercise training, however, has been found to help improve this problem, and substantially improve the control of insulin over blood glucose (8,9).

Implementing inexpensive, easy-to-use interventions can reduce the huge economic burden of diabetes. Many of these interventions are cost-effective and/or cost saving, even in developing countries. Vijgen et al. (10) provide a detailed overview on various approaches in primary, secondary and tertiary prevention.

Prospective studies and clinical trials have shown that moderate to high levels of physical activity and an increase in physical activity levels can prevent type 2 diabetes (11), or at least - after onset - slow down progression (12). Consequently, diabetologists and others recommend physical activity (13-15). Interestingly, the plea for physical activities in the treatment of persons with diabetes is not quite new. The importance of physical activity was already recognised at the beginning of the 20th century. Allen (16, p. 495) very early became aware of the possible impact of physical activity on the glucose metabolism. Recent research shows the favourable impact of resistance training and/or aerobic training (17-22). There are also studies that show how type 2 diabetes can cause bone dysfunction and how resistance training positively impacts bone functioning (23).

In this context the purpose of this pilot study was to determine the feasibility and effectiveness of resistance training on glycaemic control in adults with type 2 diabetes, the additional risk factors including low physical activity, measured by HbA1c, body weight, cholesterol and triglycerides.

Methods

We conducted a pilot study as a pre-and-post study with no control group. Four diabetologists/internists were asked to name eligible participants from their patients. The participants had to meet the following inclusion criteria: type 2 diabetic person (T2D), 45-75 years old, duration of diabetes less than 10 years, no experience with resistance training within the last ten years, willingness to attend regularly the training sessions (two training units per week, with 45 minutes of duration each). Furthermore, a certificate from the treating physician (diabetologist) was requested, testifying that there was no medical reason against participation. Patients with severe accompanying diseases, high blood pressure, heart failure (NYHA III), or retinopathy were excluded.

Eighteen persons (10 men, 8 women), in the age between 46 and 71 years, could be included. Due to dropouts, the pre-and-post evaluation was based on 13 persons, only. The average age of this group (6 men, 7 women) was 63.6 (SD 5.5) years. Mean body mass index (BMI) at the beginning was 29.8±4.9; the range was between 22.5 and 41.4. Mean HbA1c level was 7.5%±0.6%, ranging from 6.2% to 8.6%; the triglycerides were in the range between 134 mg/dl and 335 mg/dl, with an average value of 195.8±50.9 mg/dl. Cholesterol level was between 149 mg/dl and 262 mg/dl, which corresponded to an average level of 206.6±34.8 mg/dl. According to the current guidelines, this group was likely to fall into the category "high risk" (24,25).

The training took place in a fitness centre under the supervision of a certified sports scientist for 28 weeks. During the training period, the patients were asked to report whether they changed their level of general physical activity during this period, as a potential confounder. Possible treatment adaptations had to be recorded.

Intervention

The circuit programme consisted of two sessions per week. Each session lasted 45 minutes, and was executed at eight different stations. The level of difficulty and the progression were determined individually with the intention not to surpass 60% of the maximum possible intensity of an untrained person. Intensity was defined as a combination of weight moved, the number of repetitions, and the duration of the workout. Twenty repetitions are approximately 60% of maximum intensity (26, p 229); depending on the individual situation of the test, person eighteen to twenty repetitions were carried out. This graduation was set because the study population was in relatively poor health and had to be protected against overloading. The workload was increased by 2.5 kg every two weeks until the final maximum possible capacity was reached. The only exception was the leg press where, for technical reasons, the increase steps were 5 kg.

Furthermore, the exercises were planned in such a way that both agonists and antagonists were trained likewise. The training started with a warm-up exercise on a stationary bicycle ergometer for 10 minutes. The strength training was made up of the following exercises: vertical traction, shoulder press, leg press, abductor training, low row, chest press, lower back and abdominal crunch. Two cycles per machine and up to 20 repetitions were applied. The performance of the exercises was recorded with the help of a "training key" (i.e. workload), number of repetitions, speed, and extend of the movements.

We measured weight, height, HbA1c, cholesterol, and triglycerides at baseline and weight, HbA1c cholesterol, and triglycerides at the end of the intervention.

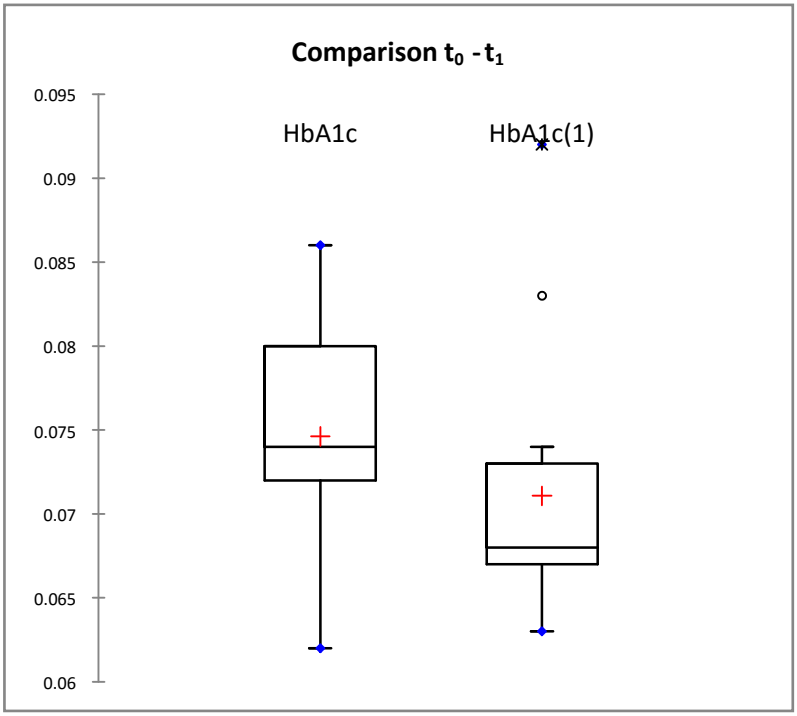
Statistical analysis

For statistical analysis, we used the Wilcoxon Matched Pairs Test. The Wilcoxon Matched Pairs Test is a nonparametric alternative to the t-test for dependent samples, which fits with the pre-and-post comparison design (i.e., repeated observations of the same person). The application does not require a Gaussian distribution of data. The variables must be measured in such a way that will allow the rank ordering of the observations (ordinal scale). We considered a p-value below 0.05 to be statistically significant (two-tailed test). Statistics were calculated with XLSTAT 2009, Version 4.07.

Results

At the end of the study, mean HbA1c dropped from 7.5%± 0.6% to 7.1%±0.8%. Figure 1 and Figure 2 provide overviews and show also the minimal and maximal values.

Figure 1. Comparison of HbA1c*

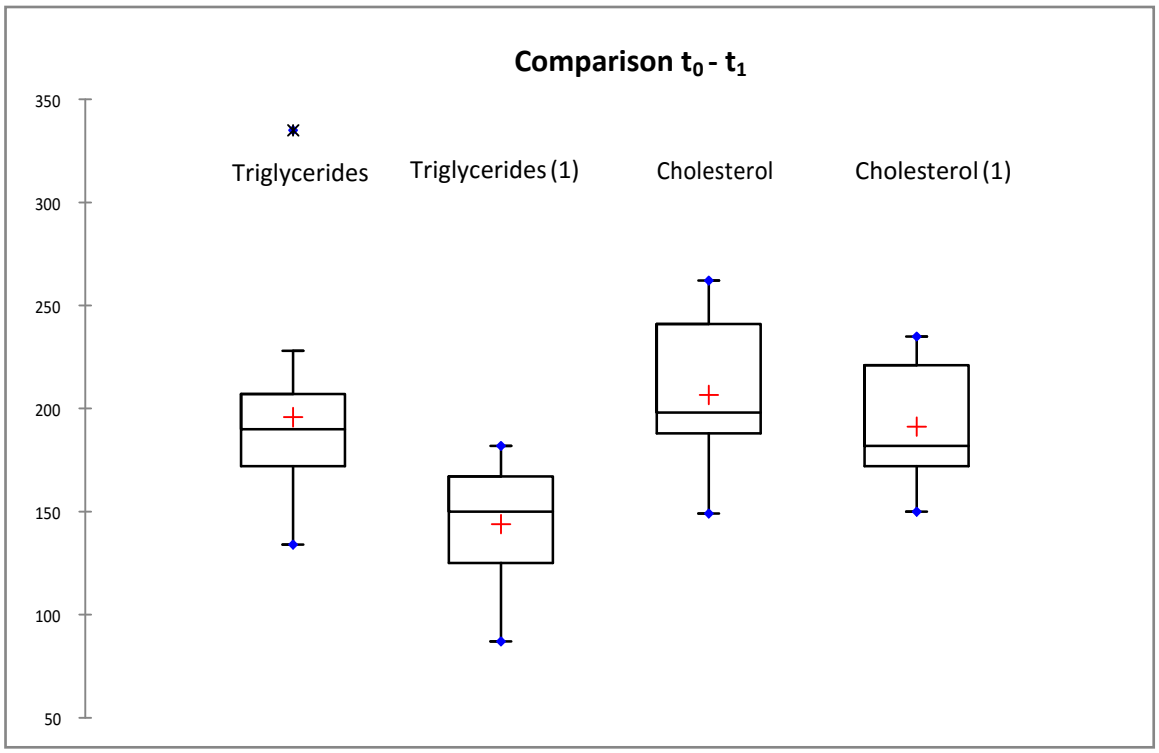


* The red cross represents the mean, the box stands for the 1st and 3rd quintile, the line in the middle is the median. The whiskers represent the minimum and maximum value, the asterisks symbolize outliers. The height of the box is the interquartile range. The differences were significant (P<0.05);n=13.

For type 2 diabetic patients the target range of HbA1c is currently set between 6.5% and 7.5%; hence, participants were close to treatment recommendations. The average cholesterol level dropped from 206.6±34.8 mg/dl to 191.3±30.85 mg/dl, ranging from 150 mg/dl to 230 mg/dl. Mean triglycerides were lowered from 195.8±50.9mg/dl to 144±30 mg/dl, with a maximum value of 182 mg/dl and a minimum of 87 mg/dl. These changes were all significant (P<0.05). Figure 1 and 2 indicate that in the case of HbA1c and total cholesterol, the interquartile range (height of the boxes) after intervention was lower than that of the initial

starting point. This means that the data are less widely spread; the minimum and maximum values are also closer to the box.

Figure 2. Comparison of triglycerides and total cholesterol*



* The red cross represents the mean, the box stands for the 1st and 3rd quintile, the line in the middle is the median. The whiskers represent the minimum and maximum value, the asterisks symbolize outliers. The height of the box is the interquartile range. The differences were significant ($P<0.05$); $n=13$.

Dose-response

Smidt Hansen and colleagues pointed out that there must be a dose-response relationship between physical activity and glucose metabolism (27). This means that, the higher the workload, the higher the reduction of HbA1c. We therefore compared the cumulated size of the weight that was moved during the training period by all participants with the corresponding changes in HbA1c achieved. We expected, in accordance with the principle of *"diminishing marginal returns in production curves"* (28), a rather s-shaped curve. The fitted curve of our data showed the expected incremental effect. The curve starts with a steep incline at the beginning and flattens towards the end. This is in accordance with the law of diminishing marginal returns. However, due to the small number of participants the explained variance was only 18%. Therefore, it was not possible to identify the optimum of the dose-response relationship.

Discussion

We started the training with a relatively low workload despite the recommendations how to prevent, delay, or reverse the process of losing muscle power (29-31). To increase musclemass a training intensity of 60% to 85% of the individual maximum possible intensity

is proposed, and for forcing the muscle development Mayer et al. even advise more than 85% of maximum intensity (30). To influence sarcopenia, i.e. the age-related loss of muscle mass and function (32), this will be appropriate in a non-diabetic elderly population. To our knowledge, we have currently no training plans that are specially adapted to the needs of diabetic patients. It is also still under discussion whether it is more effective to increase the workload or the number of repetitions, mainly in the case of diabetic patients at higher ages. To determine the maximum possible intensity, the "one repetition maximum strength test [1-R]" is used mostly (30). Applying a [1-RM] strength test is somewhat critical *"because of the high stress on the musculoskeletal system and the high injury risk, especially for sportspersons involved in recreational sport"* (33, p 1). This is even more valid for our study population. Moreover, studies allow the assumption that the [1-RM] test is inappropriate for intensity control. Compared with the "multiple repetition maximum test [M-RM]", its reliability is questionable (33,34). Therefore, we applied our multiple repetition test.

Persons with diabetes are at a higher risk to develop sarcopenia. Among other things, decreased physical activity is also complemented by metabolic impairment (35); possible interactions are quite complex, and the underlying mechanism between sarcopenia and type 2 diabetes mellitus have not been clarified completely [36]. However, the Baltimore Longitudinal Study of Aging showed that hyperglycaemia is associated with lower muscle strength (37). With our restraint, we took into account that our participants were untrained for many years and that they even manifested sarcopenia in advanced stages, also in combination with obesity (39% of participants were obese). Insofar, the effectiveness of our training concept might be at the lower end of a possible dose-response relationship. On the other hand, our results are consistent with the findings of Healy and colleagues, who show that even small increments in physical activities are associated with improved metabolic control (38). Smidt Hansen and colleagues conclude that *"for persons, increasing the amount of light physical activity might be a more realistic approach rather than increasing physical activity of moderate-to-vigorous character"* (27).

According to the UKPDS and the DCCT studies, improving the HbA1c by 1% of a person with type 1 or type 2 diabetes reduces the risk of microvascular complications by 25% (39). The changes of the other risk factors are also substantial. The investigation was planned as a pilot study; nevertheless, the improvement of HbA1c found here is compatible with the outcomes of other studies (21,40). According to König et al. (40), meta-analyses show average changes of HbA1c between 0.5 percentage points and 0.6 percentage points; mean changes in our study were 0.35 percentage points (SD: 0.4). Sigal et al. report changes of 0.38 percentage points when applying resistance training alone (21). Depending on the composition of the sample under examination and the training scheme, HbA1c changes of >1 percentage points were also reported – actually, 18 percentage points in the case of a progressive resistance training over 10 weeks (41, p 5).

Cauza (42) observed a 28% reduction of cholesterol. Baseline levels of total cholesterol significantly decreased in the training group from 205.5±14.1 mg/dl to 177.5±13.3 mg/dl. In our study, the average value dropped from 206.6±9.7 mg/dl to 191.3±8.6 mg/dl. In their strength training group, the triglyceride levels were reduced from 229±25 mg/dl to 150±15 mg/dl (42). Our respective data showed a reduction from 188.8±14.12 mg/dl to 145.7±8.6 mg/dl.

Previous analyses have demonstrated that structured supervised training is more effective than unsupervised training at home (43-45). In a new meta-analysis, randomised studies with supervised training were analysed which directly compared aerobic training, resistance training and a combination of both. Combination training (CT) led to a 0.6 percentage points

improvement of HbA1c compared to resistance training. Similarly, beneficial results were found for fasting glucose, triglycerides and systolic blood pressure (43). Schwingshackel and colleagues conclude that CT might be the most effective exercise modality to improve glycaemic control and blood lipids (44). Nevertheless, they recommend cautious interpretation, due to limited information on adverse outcomes of exercise.

The outcomes of our pilot are statistically significant. However, are they significant from a medical/epidemiological viewpoint too? To assess further the health effect of the training and to evaluate the relevance of the changes, it would be worthwhile to extrapolate the changes of the risk factors to events like myocardial infarction and/or stroke. There are several risk functions available, for example the EURO Score (46), or the Framingham risk function (47) and the like. The algorithms are mostly based on blood pressure, cholesterol, LDL, HDL and triglycerides. Diabetes is coded as "yes/no" only. Therefore, as a compromise, we used the Framingham risk function to estimate in an exemplary manner the cardiovascular risk and its reduction. One of the participants in the age of 68 years with cholesterol level of 188 mg/dl, and an HbA1c of 8%, reduced the total cholesterol level to 153 mg/dl and the HbA1c level to 7.4%. If we assume that, the blood pressure (conservative) is at 140 mm Hg and HDL at 40 mg/dl (also conservative), the 10 years risk of general cardiovascular events is about 24.22%. The reduction in cholesterol reduces his risk to 19.44%. If we further could assume here that the reduction of HbA1c from 8% to 7.4% is equivalent to "no diabetes" coding, then the new 10-year risk would be 10.26%. Looking at all 13 patients, the cholesterol dropped from 206.6 mg/dl on average to 191.3 mg/dl. Based on the conservative assumptions on blood pressure and HDL, the risk would drop from 23.65% to 11.59%.

Admittedly, these calculations can only give a rough estimate of the training's health impacts, especially because the improvement of HbA1c can be modelled insufficiently only. However, the benefits for various stakeholders are obvious. The patient improves his quality of life and life expectancy, the health insurance saves money, employers have less sick days, and so on. At a first glance, it looks like a win-win situation. Unfortunately, the "investment" has to be done by the individual. It is not only expenditures, but it is also the "cost of motivation". To keep diabetic patients at it, sophisticated measures have to be introduced. They have to be based on a concept of motivation and identified barriers, which in turn possibly impede maintenance of training (48). Special attention must be given to the peculiarities and possible differences in T2D and T1D (49).

This pilot study, regardless of the small study population, is compatible with the respective literature. Nevertheless, there are some weaknesses. First of all, the pre-and-post design cannot provide "class one evidence"; controlling for confounders was difficult. Secondly, the small number of participants does not yield a high statistical power. On the other hand, there are many other studies involving small numbers too (41,50). Thirdly, more sophisticated statistical analysis is not possible due to the small number of participants. A study with more participants and the collection of all health parameters that are needed to calculate health outcomes would be required.

Conclusions

There is evidence supporting the use of resistance training for improving glycaemic control and insulin sensitivity in type 2 diabetes. However, this has not been perceived clearly enough to date. It is also not in the focus of economic evaluations of diabetes preventing strategies, i.e., lifestyle changes that were economically assed did not include resistance training. The fact that in many studies the participants had individually supervised training sessions requires larger, population-based (effectiveness) studies to ensure that these findings can be generalised. Also, further research is needed to identify the efficiency of dose-response

relationship by describing frequency and intensity of training and the sustainability of the effects, i.e. the duration of acute and chronic improvements. Activating diabetic patients to perform resistance training is an effective and efficient way to reduce the burden of diabetes, and, even more, to prevent diabetes.

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ORIGINAL RESEARCH

Pharmaceutical expenditure changes in Serbia and Greece during the global economic recession

Mihajlo B. Jakovljevic[1], Kyriakos Souliotis[2,3]

[1] Health Economics and Pharmacoeconomics, Faculty of Medical Sciences, University of Kragujevac, Kragujevac, Serbia;

[2] University of Peloponnese, Corinth, Greece;

[3] The Centre for Health Services Research, Medical School, University of Athens, Greece.

Corresponding author: Mihajlo (Michael) Jakovljevic, MD, PhD, Head of Graduate Health Economics & Pharmacoeconomics Curricula, Faculty of Medical Sciences, University of Kragujevac;
Address: Svetozara Markovica 69, 34000 Kragujevac, Serbia;
Telephone: +38134306800 (ext. 223); Email: sidartagothama@gmail.com

Abstract

Aim: Clarity on health expenditures is essential for the timely identification of risks that jeopardize the democratic provision of health services and the credibility of health insurance systems. Furthermore, observing health outcomes with geographical scope is essential for making multilateral associations. This study aimed at conveying information on the variability of important economic parameters of the health sector of Serbia and Greece from 2007 to 2012, when the most serious financial crisis in the post-war economic history hit the global economy.
Methods: Exchange rates, purchase-power-parities (PPP) and price indices were used for the bilateral review of health and pharmaceutical expenditure dynamics during 2007-2012. Prescription and dispensing changes were also studied taking into account the anatomical therapeutic chemical (ATC) structure of drugs consumed.
Results: Greece was forced to cut down its total health care and pharmaceutical expenditure and mainly its out-of-pocket payments were more seriously affected by the recession. Surprisingly, emerging market of Serbia, although severely damaged by global recession, succeeded to maintain 19% growth of its per capita health expenditure and even 25% increase of its per capita spending on pharmaceuticals. Innovative pharmaceuticals showed an upward trend in both countries.
Conclusions: These two countries might serve as an example of two distinct pathways of mature and emerging health care markets during financial constraints caused by global recession. Our findings show that producing disease-based feedback, in the long run, may empower the assessment of the return on investment on medical technology and healthcare systems' cost-effectiveness.

Keywords: economic crisis, expenditure, Greece, pharmaceutical global recession, Serbia.

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Introduction

Studying the cost of services in healthcare over multiple periods is a challenging task taking into account the coalescence of explicit and implicit parameters of change in the service products provided; namely, the changes in the commodities' price and quality (1). Pharmaceutical care is, *'par excellence'*, a dynamic part of health sector. Firstly, pharmaceutical products are dominated by continual change due to the unstoppable technological improvement; secondly, the public sector has a role of payer and hence the power to regulate market prices. Financial fluctuations can thus act as tidal waves affecting providers, users and, ultimately, the population's health. The following paragraphs attempt to delineate key changes in the Serbian and Greek healthcare sector covering the period from 2007 onwards, when the global economy was hit by the most serious financial crisis in the post-war economic history (2).

Serbia, the largest market of the Western Balkans region, has experienced bold growth of domestic public and private health care sector. Its total health expenditure grew from 7.7% of GDP in 2000 to 10.5% in 2009, well above the EU average. Its total public health expenditure increased enormously (from €1,175 million in 2004 to €1,847 million in 2012). At the same time, public spending on pharmaceuticals doubled, reaching a level of €742 million (3). Unfortunately, like all the surrounding Balkan and Eastern European transitional post-socialist markets, the Serbian health system suffered heavily from several consecutive waves of global recession. After sustaining these impacts and introducing severe cost-cutting policies (some of which introduced only recently in 2014), the national market of Serbia began its slow recovery.

The Greek health sector experienced a period of significant growth during the first decade of the millennium, with a total health expenditure rising from 8.7% of GDP in 2003 to 10% in 2009, which was above the EU average (4). This growth was very pronounced particularly in the pharmaceutical sector where total expenditure more than doubled during the same period (from €3.2 billion in 2003 to €6.6 in 2009), rising from 1.9% to 2.8% of the GDP, with more than 78% being public expenditure (5). Specifically, public pharmaceutical expenditure increased by €0.5 billion per year between 2004 and 2009, reaching €5.2 billion in 2009 (4). Yet, following the signing of the Memorandum of Understanding (MoU) (6) in 2010, a series of extraordinary cost-containment measures and structural reforms were imposed on the Greek health sector, and on the pharmaceutical sector in particular, a sector regarded as a major contributor to both the deficit and the public debt due to the excessive public spending resulting from lack of control over both volume and cost of prescribing. Thus, since May 2010, the pharmaceutical sector has been placed at the centre of fiscal consolidation, becoming one of the key areas of intervention in order to reduce public pharmaceutical expenditure to 1% of GDP, thereby approaching the European average (7). As a result, public pharmaceutical expenditure has dropped by 44% between 2009 and 2012, reaching €2.8 billion and corresponding to 1.5% of the GDP in 2012 (IOBE, 2014).

Methods

Setting

Serbian and Greek national pharmaceutical sectors assessments grounded in official data released by the respective national medicines' agencies and national health insurance funds.

Study design consisted of a retrospective database analysis conducted from the First Party Payer's perspective with a six-year long time horizon.
Health outcomes regarding values, prices and the quality of the services provided were observed for Serbia and Greece. The time domain of the analysis covers the time interval 2007-2012. Any information fissures caused by lack of data in health accounts are glossed over by more recent data.
Differences in price levels between the two countries are measured with the official exchange rates into US dollars. The purchasing power parity (PPP) was additionally used as a real expenditure change survey tool (8). The presented PPPs are in 2011 US dollars (9). The price index of the comparative price level (CPL) was also computed according to the algebraic expression shown below (10):

$$CPL = \frac{PPP}{Exchange \quad Rate}$$

The relevant outcomes are presented in Table 1. Other measures of bilateral comparability are also included in Table 1, such as the GDP and the GDP per capita which are based on PPPs in US dollars. Population magnitudes as the size of the population, the percentage of people aged 65 and over, and the crude birth and death rates per 1000 people are also appended.

Table 1. Basic macroeconomic and demographic magnitudes in Serbia and Greece in 2012/2013

ECONOMY	SERBIA	GREECE
Gross national income (PPP billions US$, 2012)	82.6	290.3
Gross national income per capita (PPP US$, 2012)	11 430	26 170
Indices		
PPP* (1 US$=1.000)	37.29	0.69
Exchange rate (1 US$=1.000)	73.34	0.72
CPL price index (US prices=100)	16.22	37.00
Demographics		
Resident population (millions, 2013)	7.3	11.3
Population ≥65 years (%, 2013)	14	20
Crude death rate per 1000 people (2012)	14	11
Crude birth rate per 1000 people (2012)	9	9
Unemployment % of total labour force (2008-2012)	24	24

* Sources: 2014 World Development Indicators. 2014 International Bank for Reconstruction and Development, The World Bank Purchasing Power Parities and the Real Size of World Economies. A Comprehensive Report of the 2011 International Comparison Program. 2015 International Bank for Reconstruction and Development, The World Bank.

Table 2 includes health expenditure values and changes based on PPPs. Annual percentage changes depicted in the last column of the table are yielded according to the harmonic mean of annual changes within the period 2007-2012.
National total and pharmaceutical health expenditure per capita trends in Serbia and Greece during 2007-2012 are analytically presented (in PPP$ values) in Figure 1.

National health expenditures as percentage of GDP in Serbia and Greece during the period 2007-2012 are also depicted in Figure 2.

Table 2. Health expenditure values and their increase: Serbia and Greece, 2007-2012

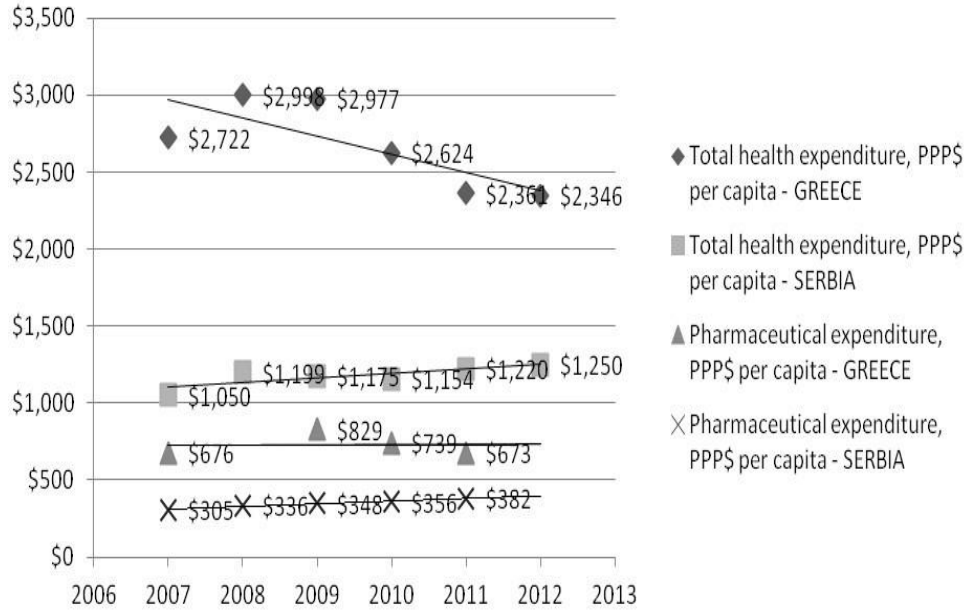
HEALTHCARE OUTCOME	2007	2012	Change (%)	Annual change (%)
Health expenditure per capita, PPP$ - Serbia	1 047	1 250	19.39	3.44
Health expenditure per capita, PPP$ - Greece	2 727	2 346	-13.95	-3.28
Health expenditure, private (% of GDP) - Serbia	4	4	1.62	0.28
Health expenditure, private (% of GDP) - Greece	4	3	-16.39	-3.88
Health expenditure, private (% of total health expenditure -THE) - Serbia	39	39	0.55	0.10
Health expenditure, private (% of total health expenditure-THE) - Greece	37	32	-11.53	-2.84
Health expenditure, public (% of GDP) - Serbia	6	6	0.72	0.12
Health expenditure, public (% of GDP) - Greece	6	6	7.09	1.06
Health expenditure, public (% of government expenditure) - Serbia	14	13	-3.37	-0.72
Health expenditure, public (% of government expenditure) - Greece	12	11	-7.10	-1.56
Health expenditure, public (% of total health expenditure) - Serbia	61	61	-0.34	-0.07
Health expenditure, public (% of total health expenditure) - Greece	60	68	13.32	2.42
Health expenditure, total (% of GDP) - Serbia	10	10	1.07	0.19
Health expenditure, total (% of GDP) - Greece	10	9	-5.50	-1.20
Health expenditure, total (current US$, millions) - Serbia	4 035	4 030	-0.13	-1.00
Health expenditure, total (current US$) - Greece	29 964	23 080	-22.97	-5.58
Pharmaceutical expenditure per capita, PPP$ - Serbia	305	382*	25.25	0.64
Pharmaceutical expenditure per capita, PPP$ - Greece	676	673*	-0.44	-1.16

* Sources: Data from database: Health Nutrition and Population Statistics. The World Bank. 2011. WHO Global Health Expenditure Database 2007–2012 and European Health for All Database (HFA-DB) 2007–2012.

Tables 3 and 4 illustrate respectively the maximum and minimum absolute changes in the available outcomes of the two countries' pharmaceutical sector, classified according to the ATC4 level of the anatomical therapeutic chemical classification system of drugs (11).
Direct bilateral PPP comparisons were conducted for the GDP per capita and the pharmaceutical expenditure per capita, simplifying the Paasche price index. In the algebraic expression (2), Serbia is the base country and the P_{GS} expresses Greece's "p" values (i.e., the p.c. GDP or the p.c. pharmaceutical expenditure) in Serbian terms. "S" and "G" initials denote "Serbia" and "Greece", respectively, and "q" is the general population ofGreece.

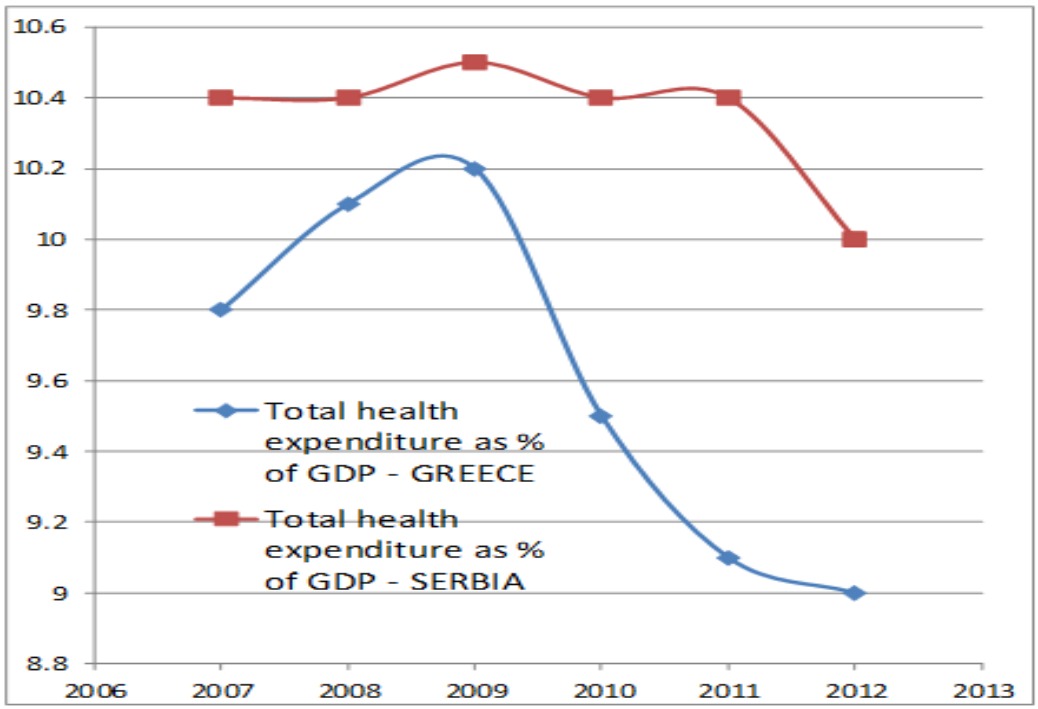
$$P_{GS} = \Sigma p_G q_G / \Sigma p_S q_G \quad (2)$$

Figure 1. National total and pharmaceutical health expenditure trends in Serbia and Greece during the period 2007-2012 (expressed in current PPP $ per capita)



* Source: WHO Global Health Expenditure Database 2007-2012 and European Health for All Database (HFA-DB) 2007-2012.

Figure 2. National health expenditure trends in Serbia and Greece during the period 2007-2012 (expressed as a percentage of disposable Gross Domestic Product, GDP*)



Source: WHO Global Health Expenditure Database 2007-2012 and European Health for All Database (HFA-DB) 2007-2012.

Table 3. Top 20 ATC drug classes based on turnover growth, 2007-2012

ATC classes	Serbia*	ATC classes	Greece†
C09BA ACE inhibitors and diuretics	€ 2 246 511	L01XC Monoclonal antibodies	€ 11 287 179
L01XC Monoclonal antibodies	€ 1 890 961	L01XE Protein kinase inhibitors	€ 9 001 287
B01AC Platelet aggregation inhibitors excluding heparin	€ 1 662 525	L04AB Tumor necrosis factor alpha (TNF-α) inhibitors	€ 8 711 090
C10AA HMG CoA reductase inhibitors	€ 1 560 979	L04AA Selective immunosuppressants	€ 4 954 700
R03AK Adrenergics in combination with corticosteroids or other drugs, excl. Anticholinergics	€ 1 430 330	L02BX Other hormone antagonists and related agents	€ 4 405 048
C09CA Angiotensin II antagonists, plain	€ 1 180 464	L04AX Other immunosuppressants	€ 4 155 810
L01XE Protein kinase inhibitors	€ 1 000 095	S01LA Antineovascularisation agents	€ 3 530 581
A10AD Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting	€ 863 908	L04AC Interleukin inhibitors	€ 2 756 671
C07AB Beta blocking agents, selective	€ 789 919	A16AB Enzymes	€ 2 440 854
V08AB Water-soluble, nephrotropic, low osmolar X-ray contrast media	€ 635 129	J05AB Nucleosides and nucleotides excluding reverse transcriptase inhibitors	€ 2 396 560
N04BC Dopamine agonists	€ 600 260	B03XA Other antianemic preparations	€ 2 354 249
G04CA Alpha-adrenoreceptor antagonists	€ 589 965	C01EB Other cardiac preparations	€ 2 238 049
J05AR Antivirals for treatment of HIV infections, combinations	€ 581 846	C09DX Angiotensin II antagonists, other combinations	€ 2 001 835
N02BE Anilides	€ 562 326	A10BD Combinations of oral blood glucose lowering drugs	€ 1 902 922
C05BA Heparins or heparinoids for topical use	€ 541 038	R03DX Other systemic drugs for obstructive airway diseases	€ 1 760 418
L01CD Taxanes	€ 493 830	L01XX Other antineoplastic agents	€ 1 758 626
N06DA Anticholinesterases	€ 438 968	B01AE Direct thrombin inhibitors	€ 1 606 684
G04BE Drugs used in erectile dysfunction	€ 432 442	L01BA Folic acid analogues	€ 1 597 243
R01AA Sympathomimetics, plain	€ 418 995	L03AA Colony stimulating factors	€ 1 411 531
A10BA Biguanides	€ 415 132	L01BC Pyrimidine analogues	€ 1 368 591

* Sources: medicines and Medicinal Device Agency of Serbia annual reports on turnover and consumption of pharmaceuticals; National Health Insurance Fund of Serbia Greek National Organisation for Health Care Services Provision-EOPYY

Table 4. Bottom 20 ATC drug classes based on turnover growth 2007-2012

ATC classes	Serbia*	ATC classes	Greece†
C09AA ACE inhibitors, plain	-€ 1 643 854	C10AA HMG CoA reductase inhibitors	-€ 31 679 014
G03GA Gonadotropins	-€ 1 330 919	C09DA Angiotensin II antagonists and diuretics	-€ 13 420 269
J01FA Macrolides	-€ 1 197 082	B01AC Platelet aggregation inhibitors excluding heparin	-€ 8 526 396
J01DD Third-generation cephalosporins	-€ 1 059 188	C09CA Angiotensin II antagonists, plain	-€ 7 929 987
M01AB Acetic acid derivatives and related substances	-€ 1 040 177	N03AX Other antiepileptics	-€ 7 071 604
C01DA Organic nitrates	-€ 935 780	A02BC Proton pump inhibitors	-€ 6 745 836
A02BA H2-receptor antagonists	-€ 896 631	N06AB Selective serotonin reuptake inhibitors	-€ 6 399 987
M01AE Propionic acid derivatives	-€ 846 670	N06DA Anticholinesterases	-€ 5 199 056
J01DB First-generation cephalosporins	-€ 691 096	N05AX Other antipsychotics	-€ 5 119 251
L01CB Podophyllotoxin derivatives	-€ 577 411	M05BA Bisphosphonates	-€ 4 794 650
B03XA Other antianemic preparations	-€ 566 477	C08CA Dihydropyridine derivatives	-€ 4 165 272
C04AD Purine derivatives	-€ 563 692	N06AX Other antidepressants	-€ 3 810 668
L04AA Selective immunosuppressants	-€ 438 147	C09AA ACE inhibitors, plain	-€ 3 275 530
J01CA Penicillins with extended spectrum	-€ 433 257	R03DC Leukotriene receptor antagonists	-€ 3 182 560
J01DC Second-generation cephalosporins	-€ 417 805	N05AH Diazepines, oxazepines, thiazepines and oxepines	-€ 2 894 838
B05BA Solutions for parenteral nutrition	-€ 390 852	A10BG Thiazolidinediones	-€ 2 860 150
R03AC Selective beta-2-adrenoreceptor agonists	-€ 376 303	R03BA Glucocorticoids	-€ 2 455 708
J01CR Combinations of penicillins, including beta-lactamase inhibitors	-€ 374 335	C09BA ACE inhibitors and diuretics	-€ 2 195 843
R03DA Xanthines	-€ 340 329	A10BB Sulfonamides, urea derivatives	-€ 2 137 085
B05AA Blood substitutes and plasma protein fractions	-€ 328 794	L02BG Aromatase inhibitors	-€ 2 007 464

* Sources: medicines and Medicinal Device Agency of Serbia annual reports on turnover and consumption of pharmaceuticals; National Health Insurance Fund of Serbia. Greek National Organisation for Health Care Services Provision-EOPYY (estimations based on 2010-2012 data)

Results

Aside from minor differences in their aging populations, Serbia and Greece were spending similar amounts on health as percentage of the GDP, in the beginning of the recession. The recession, however, resulted in decreases in the amounts allocated for health in both countries, with Greece reducing mainly its private expenditure on health (from 37% to 32% of THE). In per capita terms, pharmaceutical expenditure recorded bold 25% growth in Serbia, whereas marginal decreases (0.4%) were jotted down for Greece, during the recession.

Greece's more intense recession effects on the pharmaceutical sector were also reflected on the values of the P_{GS} price index. Greece's p.c. GDP in PPP$ was 2.29 times the p.c. GDP of Serbia in 2012 (P_{GS} = 26,170/11,430). Similarly, the pharmaceutical expenditure per capita of Greece was 2.22 times the pharmaceutical expenditure per capita of Serbia in 2007 (P_{GS} = 676/305), whereas in 2012 it reduced to 1.76 (P_{GS} = 673/382).

The pharmaceutical market internal structure of prescription and sales has in some cases moved in the same direction in the two countries. Specifically, within some therapeutic categories, pharmaceutical expenditure continued to grow despite the depression. These categories included the L01XC monoclonal antibodies, the L01XE protein-kinase inhibitors, the A10B blood glucose lowering drugs, excluding insulins and the J05A direct acting antiviral drugs. Continuing rise of share of innovative biological medicines is evident despite the financial constraints.

Few important differences in adaptive responses to the economic crisis induced weaknesses were noticed between emerging and mature health market. While health expenditure per capita (PPP$) in Serbia still succeeded to grow for 19.4%, the Greek one felt almost 14% during these six years. The total health expenditure (THE) in Serbia decreased marginally by 0.13%, whereas during the same time, the Greek THE fell abruptly by even 23%. Health expenditure percentage of GDP in Serbia grew 1% while Greek one decreased almost 5.5%. A similar pattern was noticed with private health care expenditure expressed either as percentage of THE or GDP: the Greek one decreased by 16.4% and 12% respectively, while Serbian private health expenditure recorded minor growth in crisis' years. Governmental share of health expenditure has fallen dramatically in both countries although more prominently in Greece. Opposed to all the aforementioned recessional changes, public health expenditure was rising much faster in Greece compared to Serbia both on grounds of GDP proportion and THE proportion which reached 13.3% increase. At the same time, in Serbia, these values were slightly up and down, but only marginally (see Table 2).

Discussion

To date, all countries of the broader South Eastern Europe have found themselves in different stages of profound demographic transition outsourcing from increased longevity and falling fertility rates (12). Greece's population is ageing faster considering its lower crude death rates and its higher proportion of old ages in the general population. Population aging in Serbia has deep historical roots and is likely to pose severe challenge on the national health system financing in the upcoming decades (13). This inevitable demographic change will be shaping growing needs for pharmaceuticals and the landscape of their consumption in both countries in the long run.

Observing much shorter time horizon of six recent years of global economic recession, emerging Serbian pharmaceutical market has undergone complex changes in terms of value-based medicines prescription and dispensing. Regardless of significant difficulties and slower growth, national public expenditure on pharmaceuticals has doubled since 2004. Innovative cardiovascular, anti-diabetic agents, combined adrenergic and corticosteroid preparations and targeted immunotherapies dominated the landscape. Economic crisis induced package of policy measures provided temporary relief for the ongoing financial difficulties.

Nevertheless, shortages of pharmaceuticals continued to occur more frequently compared to the period before 2008. These shortages occasionally refer even to the essential medicines and are primarily caused by the substantial public debt toward major multinational pharma companies supplying the Eastern European markets. Contemporary market access and reimbursement policies by regional authorities in most of Balkans peninsula limit patient access to the expensive innovative medicines to narrowly defined diagnoses related groups (14). It is essential to be aware of the boomerang effect created by these restrictive policies. Individuals, who are denied primary care preventive or screening services, ultimately end up in late severe stages of illness requiring expensive and complex inpatient treatment. A higher presence of clinically evolved conditions in transitional Eastern European countries has already been proven in the case of COPD (15), alcohol abuse (16) and cancer (17). These health system inefficiencies inherited from the socialist era create significant costs to the system, as well as worse health outcomes. High consumption of medicines indicated to treat some of key "prosperity" diseases such as diabetes (18), COPD, risky pregnancies (19,20), addiction disorders, hepatitis (21) and cancer (22) serves as the evidence of such vulnerabilities within the system (20). These major illnesses should also present core targets for more responsible, evidence-based national resource allocation strategies (23).

In Greece, the pharmaceutical industry has traditionally represented an important sector of the economy and has been a major employer in the production, research and development, as well as distribution wholesale and retail. However, the Greek pharmaceutical market has been long characterized by significant overspending (24), with public pharmaceutical expenditure reaching unprecedented levels in 2009 and thus being blamed as one of the main contributors of public deficit and debt.

Between 1990 and 2010, the applied pharmaceutical policy has focused mostly on price regulations in order to control expenditure, while no real effort was made to contain the volume of prescribed medicines, determined by the prescribing habits of physicians and by patients' demand (25,26). As a result, public pharmaceutical expenditure continued to rise during this period, while the introduction of measures such as pharmaceutical pricing according to the lowest ex-factory European price and the positive list, had only a temporary effect on reducing expenditure, ultimately leading to the replacement of old products with new, more expensive ones and to the switching to more expensive medicines of the same therapeutic category (27,28).

In light of the above and in the context of fiscal consolidation, a comprehensive health care reform was implemented after the signing of the MoU in 2010 and is still on-going, aiming, among other things, to reduce waste, control expenditure and increase the accountability and efficiency of the Greek pharmaceutical sector. The MoU defined a number of cost-containment measures that had to be implemented within very tight timelines, targeting the reduction of both cost and volume of prescribed medicines. These measures included interim flat decreases of pharmaceutical prices, a new pharmaceutical pricing system according to

which prices are determined based on the average of the three lowest prices in the EU-27, introduction of positive, negative and over-the- counter (OTC) medication lists, reduction in the profit margins of pharmacists and wholesalers, collection of rebate and claw-back from pharmaceutical companies, changes in the distribution of high-cost medicines, increase in the use of generics in the national health system, introduction of electronic prescriptions for medicines, publication of clinical guidelines and prescribing protocols, as well as monitoring of physicians' prescribing habits (29).

Following the implementation of the MoU, the Greek government has primarily focused on applying cost-containment measures such as flat decreases of pharmaceutical prices and the collection of the rebates from pharmaceutical companies in order to achieve a fast reduction of pharmaceutical expenditure, while the measures and structural reforms aiming at the rationalization of the prescribing behaviour of physicians, such as e-prescribing and monitoring of physicians' behaviour progressed at a slower pace. By 2012, public pharmaceutical expenditure shrunk by 44% since 2009, reaching 1.5% of GDP, while in 2013 it was reduced to €2.4 billion (53% decrease).

The recent changes in pharmaceutical policy which have been implemented in Greece in the context of its economic adjustment program have created turmoil in the pharmaceutical sector challenging its growth prospects and its long-term sustainability, thus resulting in instability in the market. This led to temporary drug shortages, hampering access to timely and effective therapy for the patients (30). At the same time, the policy of continuous reductions in pharmaceutical expenditure after a certain level and the substantial downsizing of the market, led to significant losses in public income resulting from the layoffs in the pharmaceutical sector and the subsequent lost of tax revenues and social contributions from pharmaceutical companies and pharmacies. The above demonstrate that even though in 2010 there was a real, urgent need for rationalization of the Greek pharmaceutical market and for the implementation of a number of structural reforms, currently, several years after the eruption of the fiscal crisis and while the health care reform is still on-going, there is a need to adopt a more multi-factorial approach in policy-making, i.e., an approach which will account for the potential impact of applied policies on: i) patient access; ii) insurance contributions, employment and GDP, as well as; iii) the benefits brought by the strengthening of scientific research and development, when estimating the net financial result of these policies.

Conclusions

These two countries might serve as an example of two distinct pathways of mature and emerging health care markets during financial constraints caused by global recession. Apart from the ostensible differences in their composition of health and pharmaceutical expenditure, Serbia and Greece both cut down on their pharmaceutical expenditure during the financial crisis, even though Greece was more seriously affected by the recession. Surprisingly, the emerging market of Serbia, although severely damaged by the global recession, succeeded to maintain 19% growth of its per capita health expenditure and even 25% increase of its per capita spending on pharmaceuticals.

The recession left unaffected certain pharmaceutical expenditure trends in both countries dictating inelastic areas in the curve of pharmaceutical needs. Specifically, an increasing expenditure was documented for the L01XC monoclonal antibodies, the L01XE protein-kinase inhibitors, the A10B Blood glucose lowering drugs, excluding insulins and the J05A direct acting antiviral drugs.

The current results show that studies in the direction of producing disease-based feedback could empower the assessment of return on investment on medical technology, enhance the process of pharmaceutical expenditure estimations, predictions and projections and, in the long run, increase health outcomes' predictability and the European healthcare systems' cost-effectiveness.

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SHORT REPORT

Towards a Code of Conduct for the European Public Health Profession!

Ulrich Laaser[1], Peter Schröder-Bäck[2,3]

[1] Faculty of Health Sciences, University of Bielefeld, Bielefeld, Germany;
[2] Department of International Health, School for Public Health and Primary Care (CAPHRI), Faculty of Health, Medicine and Life Science, Maastricht University, Maastricht, The Netherlands;
[3] Faculty of Human and Health Sciences, University of Bremen, Bremen, Germany.

Corresponding author: Dr. Peter Schröder-Bäck
Address: Postbus 616, 6200 MD Maastricht, The Netherlands
E-mail: Peter.Schroder@maastrichtuniversity.nl

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Introduction

Is the group of public health professionals consistent of other professions such as physicians, nurses, social workers and the like, or should public health professionals define themselves as a distinct profession in their own rights? As of today, in Europe, public health professionals do not build an own profession. Czabanowska et al. (1) define and promote in this journal the formalization of the public health profession, based on the criteria which – following Macdonald (2) – differentiate a profession from an occupation. These criteria include adherence to a code of conduct and altruistic service. From an ethical point of view, both elements are essentially related and both are reflected in the most famous example of a code for a health profession: the ancient Hippocratic Oath (3). For a public health profession we can draw only partly on the Oath as public health deals with populations – not with individual patients – and, therefore, requires population ethics, not medical or bio-ethics, the latter well accepted since the 1980s at least (4).

Population ethics

What is particularly relevant when we take a social or population ethics point of view? Following e.g. Laaser (5) financial means are in principle never sufficient because the health of population groups is always subject to potential improvement. Therefore, efficiency or cost-effectiveness of interventions gains ethical relevance as resources can be spent only once, and are then not available for alternative use. For this reason, population ethics often adhere to the utilitarian principle. However, it is normatively important to amend the utilitarian calculus, namely that the 'pursuit of happiness' for the greatest number must not be achieved by reducing the benefit of any single individual (6). Given the specific prevailing European value tradition of Solidarity (7), an additional amendment may be considered namely, that differences between population groups should not increase by any public health measure but be minimized wherever possible. Another deontological limitation of the utilitarian principle is the respect for the autonomy of persons and their rights (8). In addition, a fundamental moral issue remains in that all decisions on population health level are based on probabilities and statistical lives (9), making possible technologies of assessing interventions – and promoting the giving or withholding of interventions – based on utilitarian cost-effectiveness rationales (10). The utilitarian principle, its ethical limitations and practicability for public health decision-making requires a continuous public health ethics discourse (11).

Which principles could nevertheless be identified guiding a public health profession in its decisions on the population's health? Summarising the ethical literature, Schröder-Bäck et al. (12) proposed seven mid-level principles to be considered: maleficence, beneficence, health maximisation, efficiency, respect for autonomy, justice, and proportionality. Laaser et al. (13) proposed with reference to a specific European heritage the following principles: solidarity, efficiency, participation, equity, subsidiarity, sustainability, reconciliation, and evidence, underlining in addition the component of empathy/altruism which is of essential relevance in the individual physician-patient relationship, as well as in the professional-population realm. With regard to a European dimension, the European Commission published Council Conclusions (14) manifesting four overarching principles: equity, universality, access to good quality of care, and solidarity – critically discussed by Schröder-Bäck et al. (15).

From this short account it seems that, in spite of different terminologies used, the following four values can be considered as core for a European framework: solidarity, equity, efficiency and respect for autonomy. The access to good quality of care describes only one of the preconditions of health and can be hardly considered as an ethical principle.

A professional code?

Can we build a professional code on this value account? Various aspects are published in volume 36 of the Public Health Reviews (16). In its Recommendation on good governance in health systems (17) in 2010, the Council of Europe promotes codes of conduct for stakeholders in the health sector including effective mechanisms for enforcement and specific clauses on conflict of interest. In 2002, the American Public Health Leadership Society published twelve Principles of the Ethical Practice of Public Health (18) [Table 1].

Table 1. Principles of the ethical practice of Public Health

No.	PRINCIPLE
1	Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.
2	Public health should achieve community health in a way that respects the rights of individuals in the community.
3	Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
4	Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
5	Public health should seek the information needed to implement effective policies and programs that protect and promote health.
6	Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
7	Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
8	Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in thecommunity.
9	Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.
10	Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.
11	Public health institutions should ensure the professional competence of their employees.
12	Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

Even though the values we mentioned and affirmed above are somewhat reflected in the Code of the Leadership Society, values that seem particularly important for a European perspective on public health – namely solidarity and equity – are not explicitly mentioned. According to Prainsack & Buyx (19), often they are even referred to as opposed to the American thinking. Prainsack & Buyx define solidarity as shared practices reflecting a collective commitment to carry costs (financial, social, emotional, or otherwise) to assist others. Also, the term equity has a long European tradition and has likewise a moral dimension. Inequity refers to differences which are unnecessary and avoidable but, in addition, are also considered unfair and unjust (20).

We propose herewith that solidarity and equity are core values that have to be reflected in a European version of a Code of Conduct for public health professionals, operating in a

framework that is also guided by the principles of efficiency and respect for autonomy. With a transnational perspective, Verkerk & Lindemann (21) call in addition for more justice of resource sharing on a global scale, whereas Stapleton et al. (22) talk already about a global ethics.

These values would reflect a specific European value dimension in public health conduct. But, what does this mean? If we assume – what we do – that a Code of Conduct is important to function as an explicit normative compass for public health and to help building the public health profession for Europe, then such a Code of Conduct should be formulated and it will help to further professionalization of public health.

Professionalization of public health is important to advance public health education, training, and practice. In our opinion, there is no contradiction that the profession of public health consists of members of different other professions – which also have their own values and conducts. Yet, if professions work under the roof of public health, the pillars – the core values – of the house that is built are the common denominators. Making the guiding norms and values explicit is important for the self-definition of the professional field/profession and giving guidance in pursuing a fair and respectful improvement of population health.

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REVIEW ARTICLE

Ten years onwards: Comparison of the South Eastern European regional public health strategy 2004 and the South Eastern European 2020 strategy

Christiane Wiskow[1], Maria Ruseva[2], Ulrich Laaser[3]

[1] Sectoral Policies Department, International Labour Office, Geneva, Switzerland;
[2] Executive Committee, South Eastern Europe Health Network, Skopje, FYR Macedonia (Republic of Macedonia) and Management Board, International Health Partnerships Association, Sofia, Bulgaria;
[3] Section of International Public Health, Faculty of Health Sciences, University of Bielefeld, Bielefeld, Germany and member, International Health Partnerships Association, Sofia, Bulgaria.

Corresponding author: Maria Ruseva, MD, International Expert, Public Health Member, Executive Committee, SEE Health Network (SEEHN) and Founding member, International Health Partnerships Association (IHPA);
Address: Bellmansgade 23, 7 tv. 2100 Copenhagen Ø, Denmark;
Telephone: +4539186929; E-mail: rusevamaria33@gmail.com

Abstract

Aim: Regional collaboration has continuously contributed to the development of public health in the South Eastern Europe (SEE) region since 2000 when the Public Health Collaboration in SEE (PH-SEE) was initiated. This article looks into two frameworks for regional collaboration in the area of public health: a framework developed in 2004 by a network of public health professionals and academics, and another one developed by the SEE Health Network as integral part of the SEE 2020 strategy on *Jobs and Prosperity in a European Perspective*, adopted in 2013. It compares the commonalities and differences of the two frameworks; considers what is still valid and relevant after ten years and which new features have emerged in the new strategy.
Methods: A literature review was carried out and a qualitative analysis was applied for the comparison of the two frameworks.
Results: Notwithstanding the time gap of nearly ten years, the commonalities between the two regional health strategies are significant. Major consistent goals include: improving equity in health; strengthening human resources for health; improving intersectoral cooperation and governance. The differences between the two regional strategies, including issues around social participation and regional health information systems, are partially due to their different development context. Cross-border policies and quality management have emerged as new or more pronounced topics in the SEE 2020 strategy's health dimension.
Conclusions: Many aspects addressed in the 2004 framework are pertinent with regard to the SEE 2020 health dimension and remain relevant in the current context. The integration of health as part of the economic SEE 2020 strategy reflects a significant paradigm shift and important step forward for public health.

Keywords: public health strategy, regional collaboration, socioeconomic development.

Conflicts of interest: None.

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Introduction

In November 2013, Ministers of Economy of seven South Eastern European (SEE) transition economies signed the SEE 2020 strategy on *Jobs and Prosperity in a European Perspective* (hereafter SEE 2020 strategy, or strategy). The SEE 2020 strategy aims at socio-economic growth and underlines the importance of the European Union (EU) perspective for the SEE region. It provides a framework for regional cooperation in specific political and economic areas with the purpose to assist governments in the achievement of common national goals. The development of the strategy has revealed a high level between regional and national agendas (1,2).

While the focus of the strategy is primarily on advancing the economic development of its members, health constitutes an integral part of this strategy. As highlighted by the SEE Health Network (SEEHN), this is an innovative aspect reflecting a paradigm shift in recognizing that health contributes to socioeconomic growth rather than constituting just a burdening cost factor (3,4). The SEEHN has been mandated to assist in the implementation of the health dimension of the SEE 2020 strategy (5).

In the context of another network, the Public Health Collaboration in SEE (PH-SEE), a Framework for a Regional Public Health Strategy had been developed and suggested as early as in 2004 (6).

This article looks into two frameworks for regional collaboration in the area of public health: one framework developed in 2004 by public health professionals and academics, and another one developed by the SEEHN as integral part of the SEE 2020 strategy. It compares the commonalities and differences of the two frameworks; considers what is still valid and relevant after ten years and which new features emerged in the new strategy. It is based on a literature review and applied qualitative analysis for the comparison.

Background information

During the past three decades, the SEE countries have experienced dramatic changes through the disintegration of the communist systems and the subsequent rapid transition to market-oriented economies. This shift had social and cultural implications for the societies, marked by increasing poverty, high unemployment, massive emigration, and financial downturn, further aggravated by a devastating war. As a consequence, the burden of disease in many SEE countries has been – and continues to be – higher than in Western European high-income countries despite varieties in the region (7-9).

The EU-initiated Stability Pact for the SEE (1999-2008)[1] included two major health programmes under the Social Cohesion pillar that resulted in two distinct public health networks, operating at political and professional levels:

- The SEE Health Network (SEEHN), established in 2001, brought together the Ministries of Health of nine SEE countries[2] and other experts, and has since acted as an intergovernmental forum and legal platform implementing regional collaboration on health systems and public health at political level. In 2010, the SEE Health Network took ownership for the regional collaboration on health and development under the Regional

[1]The EU was the main initiator of the Stability Pact for the SEE. Over 60 partners provided funding for the activities and programmes under the Stability Pact, including the WB, EBRD, CEB, CoE, all UN Organizations and many bilateral donor countries. All health actions were financially and technically supported by ten bilateral donor countries, CoE, CEB and WHO Europe.

[2]Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the former Yugoslav Republic (FYR) of Macedonia (Republic of Macedonia), Republic of Moldova, Montenegro, Romania and the Republic of Serbia. Israel joined SEEHN in 2011 as the tenth Member Country.

Cooperation Council (10), the successor of the Stability Pact since 2008 (11). Its institutions include regional health development centres in each of its ten Member States and a network of over 300 experts, with a secretariat based in Skopje, FYR Macedonia (12). It is one of the over 60 SEE regional initiatives under the broad political framework of the SEE Regional Cooperation Process and the Regional Cooperation Council.

- At the academic and technical level, the Public Health Collaboration in SEE (PH-SEE), funded by the German Stability Pact (2000-2008), brought together universities and Institutes of Public Health of SEE countries and partner universities from European countries to develop Programmes for Training and Research in Public Health and assist in the establishment of Schools of Public Health. Following the end of the Stability Pact, in 2008, PH-SEE transformed into the Forum for Public Health in SEE (FPH-SEE), a non-governmental and non-profit consortium of public health institutions in the SEE region. As an affiliate of the European Public Health Association (EUPHA) it aims at exchange of experience, mutual support, and common activities for a New Public Health(13).

Both networks continue to be active; it is noteworthy that they share the vision and mission to promote peace, reconciliation, and health through regional collaboration in public health. As pointed out by Ruseva et al. (14), both networks together enhanced public health as a common denominator of both a political and an academic movement to improve the health and wellbeing of the SEE populations. The SEEHN achievements are numerous with significant impact on health policies, spanning the areas of mental health, non-communicable and communicable diseases, healthy aging, antibiotic resistance, organ donor and transplant medicine, blood safety, accreditation and quality improvement of health services, health workforce, and public health services. At the academic level, the PH-SEE by 2008 had produced six volumes of teaching materials (3500 pages), a shortlist of health indicators; organized more than 25 conferences and summer schools; and had assisted in the establishment of new schools of public health in Belgrade, Bucharest, Chisinau, Novi Sad, Pleven, Skopje, Sofia, Tirana, and Varna. As a lesson learnt from the SEEHN, Ruseva et al. conclude that a network approach constitutes an added value for the region with view to the small size of most of SEE countries. The regional collaboration network amplifies their influence and power at international levels, as they speak with one voice; moreover, collaboration between various stakeholders has enabled the countries to rapidly resort to their respective networks to mobilize assistance in emergency events, such as the floods in 2014 (14).

Development of a Regional Public Health Strategy Framework in 2004[3]

In 2004, the Public Health Collaboration in SEE Programme (PH-SEE) (13) brought together public health professionals from seven SEE countries and other European countries[4] in a seminar that served as a forum for the development process of the regional strategy framework. The seminar built on previous work in the region and followed a participatory approach in several steps. Hence, based on the existing national health strategies at that time, the participants jointly elaborated a situation analysis with regard to public health in the SEE

[3] This section draws on reference no. 6: Framework For a Common Regional Public Health Strategy of South Eastern Europe, in: Scintee SG and Galan A (eds.). Public Health Strategies: A Tool for Regional Development – A Handbook for Teachers, Researchers and Public Health Professionals. Lage: Hans Jacobs Publishing Company, 2005.

[4] 36 public health experts from Albania; Bulgaria; Croatia; FYR Macedonia; Romania; Serbia and Montenegro; and Slovenia; five public health experts from Denmark, Germany, Switzerland and the UK.

region, selected priorities for a regional framework, formulated major goals and developed an operational action plan.

A methodological combination of the SWOT[5] analysis and the nominal group technique was selected for the framework development. Both methods are recognized in supporting decision-making and problem solving processes, by applying heuristic reasoning for advancing analysis and decision-making. Being primarily intuitive and judgemental rather than mechanistic and measurable (15), these methods nevertheless follow rigorously disciplined regulations. In regional development as well as in strategic planning, the use of heuristic reasoning is well-established.

Situation analysis of public health in the SEE region in 2004

The situation analysis using the SWOT methodology aimed at describing the external and internal environment of public health in the SEE region and facilitating the choice of strategic options.

Strengths

The countries in the SEE region could build on a strong tradition and history in public health. Namely, the management of communicable diseases in conjunction with the sanitary control of water supplies and food safety had the potential for further development at regional level. The traditional system of family physicians and the focus on maternal and child health were highly relevant with regard to international trends in health. This was backed by already existing legislation and regulations like the laws on surveillance of communicable diseases, food safety and healthy nutrition, environmental health, occupational health, school children health, immunization and the like. Routine health data collection was maintained in most countries.

The existing public health infrastructure consisting of professionals, inspectorates and National Institutes of Public Health represented a solid base both at country and regional levels. In 2004, a core group of public health professionals with international training and connections provided quality input into projects and institutions. Nearly all countries in Central and Eastern Europe had mature education and training systems (15), although the SEE region could build only on a selected number of schools of public health, such as the Andrija Stampar School in Zagreb, Croatia with its long tradition. Professional associations and non-governmental organizations (NGO) reflected the continuing cooperation and communication and represented a means for empowerment of public health. National public health associations and schools of public health had been founded in Romania, Serbia, Moldova, FYR Macedonia, Bulgaria and Albania in recent years with the support of the Open Society Foundations and the German funded Stability Pact.

Weaknesses

Weaknesses within public health in SEE countries were observed in the areas of legislation, organization, financing, health promotion, health information system, human resources, education and training, and ethical issues.

The health sector reforms during the transition period brought about rapid changes of legislation. In addition, the unstable political situation often led to the disruption of development processes in public health, and as a consequence resulted in a lack of persistent vision and policy. At the same time, the slow transition from a centralized structure to

[5] SWOT analysis is a structured planning process that assesses strengths, weaknesses, opportunities and threats with regard to the internal and external environment of a project or business.

decentralised systems reflected a form of inflexibility stemming from former systems. Additionally, poor vertical and horizontal communication impeded the advancement of new structures and initiatives. Community involvement in health development tended to be neglected.

Overall, the efficiency of the health information systems was questioned, as was the quality and the effective use of health information.

The health financing was perceived to be insufficient. Of concern were also the inappropriate allocation of funds and the low effectiveness in spending, enhanced by a lack of control mechanisms. Corruption was a significant worry, as it was contributing to increasing inequalities in health care.

Inappropriate salaries and lack of incentives were also weakening the delivery of public health services through demotivated health personnel. Furthermore, the lack of professional and social recognition and the missing formal inclusion in decision-making processes demotivated the public health professionals. At that time, a critical mass of well-trained public health professionals was not built yet and a clear shortage of management skills in public health was observed.

Opportunities

In contrast to the 1990s, in 2004, the SEE region was characterized by a climate of opening and cooperation between the countries. The Dubrovnik Pledge of 2001 (16) had marked a firm political commitment to regional health development. The political and technical cooperation had been institutionalised in the "SEE Health Network" as the main political body for providing leadership and sustaining ownership of the countries and implementing concerted action in defined areas of mutual interest.[6]There was an enhanced trend to increased professional cooperation within and between the SEE countries, facilitated and sustained by the establishment of institutionalized structures, such as the SEEHN and the PH-SEE networks.

Political changes and increasing foreign investment targeting the socio-economic development in SEE countries also opened opportunities for public health initiatives.

A number of international agreements and regional declarations constituted important reference points for a regional public health strategy, including the United Nations (UN) Millennium Development Goals (MDGs) (17). The European public health policies provided a frame for harmonizing SEE approaches and alignment with the European standards, including the WHO Health 21 strategy (18); the Ljubljana Charter on Reforming Health Care, 1996 (19); and the EU public health programme (20-22). Other relevant international declarations were the WHO Ottawa Charter concerning health promotion and the Verona Initiative advocating for multi-sectoral investment in health (23).

The development of information technology (IT) offered new opportunities in terms of facilitating better access to the international body of knowledge in public health for professionals and politicians in the region, helping to exchange information and improving equal access to new databases, journals and other up-to-date information.

The emerging national public health strategies demonstrated the relevance of a regional approach as they provided evidence on the numerous common problems and challenges that

[6] In 2004, the SEE Health Network consisted of over 200 members, including representatives of nine SEE beneficiary countries, ten donor and neighbour countries and representatives of international organizations, such as WHO Regional Office for Europe, the Council of Europe (CoE) and the Council of Europe Development Bank (CEB). The political body of representatives of the Ministers of Health, called the National Health Coordinators of the SEE countries, acted as the Steering Committee for implementing the Dubrovnik Pledge.

most SEE countries faced. For addressing those, a regional framework through setting of goals of mutual interest, joining forces through cooperation and information exchange was considered beneficial for advancing public health in the SEE region.

Threats

At the same time, political, security and socioeconomic instability in the region and at country level was perceived as a major constraint on the way forward. Particularly, the political instability was of concern as every electoral mandate came along with changes in governmental strategies, institutions and agencies with effects on legislation and financing mechanisms. The lack of continuity in management, legal framework and allocation of resources throughout and across different political cycles were challenging the development of sustainable public health strategies. Competing and conflicting interests of the different political groups also meant a threat to the thorough development of a long-term public health policy.

Despite the Stability Pact efforts in the follow-up of the Dubrovnik Pledge, the SEE countries at that time felt that the international community had paid limited attention to the reform of the health systems in SEE and health had been excluded as a regional priority in the frame of the EU CARDS Programme (24).

Primary concern among the consequences of the socioeconomic instability was the high turnover of health professionals. Furthermore, the lack of recognition of public health professionals compared to clinical medical staff, in terms of identity, social status and public image, hindered the evolution of public health within the health system.

Strategic choice and recommendations

The mapping of interactions between the external and the internal environment suggested the choice of the *comparative advantage strategy* that matched the strengths in the public health field in SEE with the external opportunities. Building on the potentials did not mean losing reality out of sight: maximising the strengths implied overcoming the weaknesses for a stronger position to take opportunities offered by the external environment.

In this understanding, a set of key messages and recommendations were formulated:

- A key priority in the SEE region was the reduction of health inequalities within and between the countries with a view to further socioeconomic stabilization of the region and a better use of external opportunities.
- Improved community involvement and social participation in the decision-making process in health activities would be important with a view to meeting the expectations of the population and making the public health strategy socially and culturally acceptable.
- Intersectoral collaboration (vertical and horizontal) would be indispensable for integrating public health in the agenda of all economic sectors and overall politics. It would also help to resolve competing interests in national coalitions and international partnerships.
- The willingness of joining the EU could be the engine for economical and social development. The public health field should take advantage of the requirements to adapt to EU standards and regulations in order to improve legislation, professional regulations and harmonize public health practices.
- Regional cooperation would contribute to improving the capability of attracting international funding for multi-national projects. Joining forces in obtaining international

investments in public health research, capacity building and improving infrastructure could help to mitigate the weak financing of public health in the region.

- The sustainable development of a public health workforce was necessary to strengthen public health aspects in health reform and health policies. Capacity building should include management of health systems and better use of existing resources.
- An improved status of public health professionals would enhance their active involvement in policy development and decision making processes, thus ensuring the integration of public health knowledge and the use of data for evidence based policy-making processes. This could be operationalized in strengthening or establishing national public health associations and forming a regional umbrella organization.
- Professional collaboration in the form of networks would help in capacity building across SEE countries through mutual exchange of information and experiences and the sharing of successful national projects throughout the region.

The results of the situation analysis and the recommendations informed the priority setting process for public health goals in the region. The final priorities were formulated as goals, framing the regional public health strategy. This framework of strategic goals was translated into an action plan by setting operational objectives, specifying activities, timeframe, deliverables, outcomes, indicators, and analysing potential partners, resources and risks.

The SEE regional public health strategy framework (2004)

Five strategic goals build the overall framework for action to address public health priorities at a regional level (Box 1). An initial five-year period for implementation was established (2005-2010). The regional strategy framework aims to complement the national public health strategies. In addition to the countries' strategies, it provides a framework for addressing common health challenges in the region, contributing to the harmonization of public health policies between the countries and the approximation to European standards.

Box 1. Overview of the strategic goals and objectives of the draft of SEE regional public health strategy framework (2004) ***[Source: Scintee SG and Galan A (eds.) (2005). Public Health Strategies: A Tool for Regional Development, page 629]***

SEE regional public health strategy framework, 2005-2010

Goals and objectives

Goal 1 Improving equity in health
: Targeting vulnerable groups
: Ensuring adequate and safe living conditions Goal 2 Strengthening social participation
: Mapping social participation opportunities and initiatives
: Awareness rising and empowerment of the public
: Developing mechanisms to involve civil society in decision making processes Goal 3 Strengthening human resources in public health
: Ensuring sustainable development of human resources
: Enhancing regional professional collaboration
Goal 4 Improving regional public health information and knowledge
4.1: Establishing a regional public health information system
: Developing mechanisms for reporting and analysis at regional level
: Improving the level of public health knowledge among three key groups: the professionals, the decision-makers and the public
Goal 5 Establishing intersectoral cooperation
5.1:Establishing involvement in programmes of non-health sectors
5.2:Introducing intersectoral research

SEE 2020 strategy – the health dimension (2013)

The SEE 2020 strategy pursues a holistic approach of development (1, page 4). It features health as integral part of the overall socioeconomic development. The strategy aims to achieve three overall economic targets[7] building on a structure of five pillars (*Integrated Growth, Smart Growth, Sustainable Growth, Inclusive Growth and Governance for Growth*), with pillar specific targets and a set of 16 dimensions. Health and employment form the two priority dimensions under the pillar *Inclusive Growth* as they were identified as the most urgent topics to be addressed and there are expectations of significant return of efforts in terms of social development. The employment dimension appears more prominent compared to the health dimension, which may reflect on the importance of employment in the strategy, as well as the commitment to create one million new jobs in the SEE region by 2020. Yet, the inter-linkages of the employment and the health dimensions become apparent in two key goals of the strategy: fighting poverty through job creation and fighting health inequalities with a focus on low-income and vulnerable groups. The aim is to ensure that everybody benefits from growth through reduction of poverty, improved health and wellbeing, and greater social cohesion.

The SEE 2020 labour market policies focus on the flexicurity approach to be implemented through comprehensive lifelong learning strategies, effective active labour market policies and modern social security systems (1, pages 28 & 50). According to the European Commission, flexicurity is an integrated strategy that attempts to reconcile employers' needs for a flexible workforce (flexibility) with workers' needs for security (25). The SEE 2020 actions refer to the four components of flexicurity approaches: flexible and secure contractual arrangements and work organisations, both from the perspective of the employer and the employee; active labour market policies that help workers to cope with rapid changes, unemployment, reintegration and transitions to new jobs; lifelong learning systems to ensure the continuous adaptability and employability of all workers, and to enable firms to keep up productivity levels; and modern social security systems which provide adequate income support and facilitate labour market mobility (26).

Effective social security can be achieved through comprehensive social protection floors. This approach comprises an integrated set of social policies designed to guarantee income security and access to essential social services for all, with a focus on vulnerable groups and protecting and empowering people across the life cycle (27). Social protection floors, as defined by the International Labour Organization (ILO), are nationally defined sets of basic social security guarantees that ensure that all in need have, as a minimum, access to essential health care and to basic income security that together secure effective access to goods and social services. The concept is part of a two-dimensional strategy aimed at the rapid implementation of national social protection floors in line with the ILO Social Protection Floors Recommendation, 2012 (No. 202), and the progressive achievement of higher levels of protection within comprehensive social security systems according to the ILO Social Security (Minimum Standards) Convention, 1952 (No 102) (28). Robust social protection floors are important particularly with view to the demographic transition in the SEE region posing challenges for both the employment and the health dimension. Accelerated population aging has been observed in the region throughout the past six decades, with an increased median age, rising life expectancies and a simultaneous fall of fertility rates by more than half

[7] Short version: (I) Increase SEE average GDP per capita relative to the EU average; (II) Boost total SEE trade in goods and services; (III) Reduce SEE trade deficit (1, page 5).

(from 3.55 children per childbearing woman in 1950 to 1.49 in 2010). The percentage of population aged 65 or older has doubled in the same period (from 7 to 14 per cent) as well as the old-age dependency ratio (from 10.6 to 20.9). The effect of the demographic transition on health systems consists of an increasing demand through more old-age related health care needs; the employment dimension will have to address the increasing gaps in labour, while social security systems have to struggle with the decrease of the potential support ratio. The countries in the SEE region will have to respond to these developments with complex and integrated socioeconomic and health policies (29).

The SEE Health Network has developed the health dimension for the SEE 2020 strategy (12). This section of the SEE 2020 strategy has been based on the SEEHN policies expressed in the Skopje (2005) and Banja Luka (2011) Pledges, the findings and recommendations of four SEEHN studies (3,4,30,31), the national health and health systems policies, strategies and action plans of all SEEHN member states and, finally, on their cross-country analysis. A brief description of the situation within the SEE 2020 acknowledges the significant progress in health care in the region while pointing to several challenges. Among the common health challenges identified in the region, inequalities within and between countries are a priority concern. Health systems in the region have been described as still being inefficient with common weaknesses including the lack of effective access to health services; inadequate financing of health systems, but also inefficient use of available resources; fragmentation of health services; deficiencies in quality of care; inefficient management; low capacities of the health workforce and significant internal and international migration. In terms of public health needs, the burden of non-communicable diseases also suggests a lack of effective health promotion policies and preventive health services (1, page 27).

In order to achieve the set objective of improving health and wellbeing of all people living in the SEE region, four key strategy actions have been set:

i) Strengthen the delivery of universal and high-quality health-promoting services. Policies for improving the health status focus on low-income and vulnerable groups.
ii) Strengthen and improve the intersectoral governance of the health sector at all levels, including the health information structure and enhancing regional information exchange.
iii) Harmonise public health and public health services legislation, standards and procedures across countries in the region. This includes developing mutual recognition and trust to enable the creation of a Free Trade Area from a public health perspective.
iv) Strengthen human resources in the health sector, harmonise qualifications of health professionals in the SEE region and monitor health workforce mobility.

Table 1 summarizes the objective, key strategy actions and activities, projects or instruments for implementation of the SEE 2020 health dimension.

The responsible actors for implementation of the Health Dimension consist of the Ministries of Health at national level and the SEE Health Network at regional level.

Table 1. Overview of the SEE 2020 Strategy, Dimension Health
(Source: Regional Cooperation Council. SEE 2020 Strategy, pages 28-29 and 50-51)

Objective: Improve health and wellbeing of all those living in the SEE region	Timeframe
1. Strengthen the delivery of universal and high-quality health-promoting services at all levels of care • Adopt and implement a regional model for delivery of universal and high-quality health, promoting services at all levels of care with an emphasis on a strong primary care sector for improving the health gain in the SEE region, with a particular focus on low-income and vulnerable groups; • Develop a baseline cross-country study on the efficiency of health systems and services; • Update current health service legislation and regulations related to health care, disease prevention, health promotion and patient safety; • Develop and implement quality improvement mechanisms; • Introduce efficient monitoring and evaluation mechanisms in the region's health systems to improve transparency and accountability.	2015–16
2. Strengthen and improve the intersectoral governance of the health sector at all regional levels. Adopt regional exchange mechanism for sharing experiences and good practices • Strengthen health institutions and improve the intersectoral governance of the health sector at national, regional and community levels following the Health in All Policy (HiAP) approach; and including capacity building for health information infrastructure and introducing e-health; • Adopt a regional information exchange mechanism for sharing experiences and good practices in cross-border public health, health care and mobility of healthworkforce; • Review the current networks of health institutions and develop reformstrategies; • Review and update the existing health legislation in order to introduce HiAP and HIA; • Implement best practice from EU countries when introducing mechanisms for the intersectoral governance of health;	2015–16
3. Harmonise the cross-border public health legislation and enable a Free Trade Area from a public health perspective • Adopt multilateral and bilateral agreements to harmonise the cross-border public health and public health services legislation, standards, procedures and develop mutual recognition and trust to enable the creation of a Free Trade Area from a public healthperspective; • Develop mutually agreed regional public health cross-border standards and procedures; • Develop and launch an SEE regional information database on cross-border public health issues and best practice.	2020
4. Adopt multilateral and bilateral agreements to strengthen human resources for health, harmonise and mutually recognize health professionals' qualifications • Adopt multilateral and bilateral agreements to strengthen human resources for health, harmonise and mutually recognise health professionals' qualifications and monitor the human resources for health and their mobility; • Review the current situation on forecasting and planning in respect of the health workforce, as well as on harmonising and mutually recognising the qualifications and mobility of health professionals; • Establish a permanent SEE forum for health educationinstitutions; • Establish a regional Masters programme for public health based on EU public health curricula.	2016

Discussion

Notwithstanding the time gap of nearly ten years and the different context of their development histories, the commonalities between the two regional health strategies described above are significant. This may be owing to the common spirit in which they have been created with shared values of equity, social justice, and health as a human right as

underlying principles. Another reason emerges when comparing the two situation analyses pointing to a number of persisting common problems and weaknesses, including health inequalities within countries and across the region as a primary concern. The aim to address these problems being the basis for the selection of strategic goals and implementation action may explain some of the similarities between the two strategies.

In 2004, the experts of PH-SEE were convinced that a regional public health framework would underscore the critical role of public health for the socioeconomic development and its implementation would help enhancing social stability and peace in the region. While in 2004 it was acknowledged that the health of populations was an important factor in economic development (18,32), the potential of public health as active supporter remained underestimated. Similarly, in the context of SEE 2020, the SEEHN refers to health and wellbeing as a determinant as well as a contributor to peace and economic development (12). The integration of health as part of the economic growth strategy SEE 2020 reflects indeed an important paradigm shift towards the full recognition of health as a contributor to economic growth as highlighted by SEEHN (5).

Both regional strategies underline the commitment to EU and WHO Regional Office for Europe policies in the area of health as well as the intention to complement national health policies and support the collaboration between countries in the region to address issues of mutual interest in national health policies aiming for harmonization of policies and standards. Regardless the differences in structure and wording, both strategies are consistent in the majority of their goals and strategy actions. Major consistent objectives include:

i) Improving equity in health with a focus on vulnerable and low-income groups, hence improving health for all;
ii) Strengthening human resources for health and public health, respectively;
iii) Strengthening and improving intersectoral cooperation and governance.

Within those consistent goals, partially different priorities and approaches reflect the time-gap and the variety of contexts.

i) Improving equity in health

In 2004, reducing inequalities in health and in access to quality health care within and between the countries in the region was a top priority. At that time, political changes, economic breakdowns and war had resulted in the deterioration of the overall population health status, affecting most the vulnerable groups. A special challenge for some SEE countries in that period was the situation of internally displaced persons and refugees; those living in conflict areas under the stress of insecurity and violent threats; and those considered as ethnic minorities. These groups were considered vulnerable in terms of social exclusion and deprivation from resources influencing health such as income, education and healthy living conditions. Despite the progress made to date, health inequalities within and between the countries remain of high concern; assisting governments in reducing poverty and health inequalities is the declared aim of the SEE 2020 Inclusive Growth pillar. The health objective in this regard is to ensure universal quality health services focusing on access for vulnerable groups.

ii) Strengthening the health workforce

The concern of insufficient numbers and capacities of the health workforce has been addressed in both strategies, regardless of different perspectives. The PH-SEE framework emphasized the strengthening of the public health workforce capacities and status within the overall health workforce. In 2004, the emergence of the holistic approach to public health

was not mirrored in the public health workforce in SEE. The existing body of knowledge, institutions and professionals focused on the bio-medical aspects of public health and was complemented by the existing expertise in social medicine; however, the need for integrative approaches and inter-professional collaboration was evident. In the context of SEE 2020, low capacities of the health workforce have been indicated as one of the persisting weaknesses. Under the objective of strengthening the health workforce, the cross-border aspect is emphasized. Mobility has been mentioned in the 2004 Framework Strategy, but the emphasis of this aspect in SEE 2020 reflects the current situation characterized by significant international migration of health workers. General trends of health professional mobility flows from Eastern to Western Europe have been persisting throughout the past decade with peaks following the EU enlargement, though at more moderate levels than expected, and with varying magnitude across countries depending on their health labour markets (33,34). On the one hand, health professional mobility is being facilitated in the context of EU policies, through harmonization and mutual recognition of qualifications; on the other hand, the intention is to improve the management of the mobility through monitoring and bilateral and multi-lateral agreements to mitigate adverse effects of outflows from vulnerable health systems that already experience workforce shortages as well as protecting migrant health workers. Both regional public health strategies commonly aim for enhancing the regional professional collaboration in the area of education through harmonisation of curricula and a common forum of health education institutions. SEE 2020 further aims at establishing a regional Public Health Masters programme based on the EU public health curricula. Here is certainly an opportunity for enhanced collaboration between the two networks FPH-SEE and SEEHN as most of the SEE countries have already implemented the three cycles of the Bologna process including master programmes in public health. Both strategies focus on the qualification and performance aspects regarding the health workforce while the importance of employment opportunities and decent working conditions in the health sector have been mentioned only marginally. Yet, health provider performance and quality of care are linked with enabling and supportive work environments (35). In the context of the SEE 2020 strategy, the health sector is also economically important in terms of its potential for employment creation, with a view to the increasing demand for health services in times of demographic transition.

iii) Improving intersectoral collaboration

The progress made in the past ten years is particularly evident in the aspect of achieving the integration of health across all sectors. Intersectoral collaboration has become more commonly accepted with the appearance of the health impact assessment in the context of the health promotion movement. While the 2004 Strategy Framework (modestly) aimed at establishing the involvement of public health in the programmes of non-health sectors, the SEE 2020 aims to implement the integrative approach of "Health in All Policies" (HiAP). In 2004, there was already recognition that most of the determinants of health were outside the sphere of influence of the health sector. However, at that time, the awareness of health impact of actions undertaken in other sectors was limited and neglected in practice in the SEE region. Regular and institutionalized mechanisms of intersectoral cooperation needed to be developed and established in the region in order to promote the protection of health. Such integrative and intersectoral approach, while recognized and promoted since the Alma Ata Declaration on Primary Health Care (in 1978) has only later been labelled as "Health in All Policies" (HiAP), more specifically in the EU during the second Finnish EU Presidency in 2006 (36). In parallel, methods of Health Impact Assessment (HIA) have been developed and

implemented. Furthermore, the WHO Europe framework health policy "Health 2020" develops and recommends the whole-of-government and whole-of-society approaches that were endorsed by all ten SEEHN Members States during the WHO Europe Regional Committee Session in 2012 in Malta (37). The SEE 2020 strategy takes advantage of these developments and includes in their objectives to *"review and update the existing legislation in order to introduce HiAP and HIA"* (Table 1, action 2). HiAP and HIA reflect the important influence of health within the policies of other sectors in the overall SEE 2020 strategy and offers new opportunities for public health intersectoral collaboration. SEEHN has been mandated to monitor the health impact of the SEE 2020 implementation and has ensured that health targets and indicators incorporate prevention and health promotion within the HiAP approach, social determinants of health and inequalities (5).

In addition to the obvious commonalities, there are also apparent differences between the two strategies that are reflected in a number of objectives and issues without matching counterparts. Nevertheless, some of those aspects can be found as elements or indirect intentions in the other strategy.

- ***Social participation***

The 2004 framework for a regional public health strategy emphasized the importance of strengthening social participation in public health and in decision-making processes. It referred to the Alma Ata Declaration on Primary Health Care (PHC; 1978) and the Health For All Strategy (HFA; 1981) policies promoting public participation in health policy development. It further pointed to the responsibility and accountability of all as a prerequisite for sustainable health development, which required the involvement of all stakeholders in health policy and action, including communities. The concept of social dialogue had been suggested as a means for inclusive development processes in the health sector (38). The emphasis of social participation in the 2004 Framework Strategy may be explained by the historical context and situation at that time, influenced by the aftermaths of a war and in light of the political and socioeconomic instabilities in transition countries. Developing trust between people and nations was seen as a priority at a time when SEE countries were perceived as fragile and the rapid changes involved socio-cultural incoherence. Nevertheless, while social or community participation is not explicitly mentioned in the SEE 2020 health dimension, it emphasizes Primary Health Care and seeks to improve transparency and accountability. Both aspects take into account the community level and population interface with the health service delivery, with the aim to build up resilient communities.

- ***Regional public health information***

Improving regional public health information and knowledge was one of the priorities and strategic goals in the 2004 framework strategy as well as one of the seven objectives of the SEEHN Dubrovnik Pledge. The health information systems at that time were considered inefficient and compounded by the ineffective use of the information in shaping health policies. The set objectives included establishing a regional public health information system and developing mechanisms for reporting and analysis at regional level with a view to improving the level of public health knowledge among professionals, decision-makers and the public. The objective referred to the Dubrovnik Pledge with its commitment to *"establish regional networks and systems for the collection and exchange of social and health information"* (16). Within the SEE 2020 health dimension, information systems appear less prominently and in a different way. A reference is found under the objective of cross-border harmonization where the *"development and launch of a SEE regional information database on cross-border public health issues and best practice"* is one of the planned activities (Table

1, action 3). While the establishment of health information systems in the SEE region has advanced following the commitment of the Dubrovnik Pledge, it is still "work in progress". Thus, strengthening health information systems in the SEE region continues to be an important priority, as recognized by the Ad-hoc Meeting of the SEE Ministers of Health, 22 June 2015, in Belgrade, Serbia (39).

- ***Cross – border public health***

The SEE 2020 strategy includes cross-border public health as a new aspect that is not reflected in the 2004 framework. The strategy action aims at harmonizing cross-border public health legislation and to enable a Free Trade Area from a public health perspective (Table 1, action 3). To this end, multilateral and bilateral agreements shall help in harmonizing standards and procedures and, moreover, in the development of mutual recognition and trust to enable a public health free trade area. In 2004, the idea of a SEE regional free trade area was not foreseen given the instable situation in the region at that time.

- ***Quality improvement***

SEE 2020 explicitly addresses quality improvement of health services delivery. It aims at exploring the efficiency of health systems with a baseline study and establishing a sustainable quality management system. The aspect of quality management is missing in the 2004 strategy while it implicitly forms an underlying principle.

Conclusions

Despite the time lag of nearly ten years, the commonalities of the two strategies for regional public health collaboration are significant. Many aspects addressed in the 2004 framework are pertinent with regard to the SEE 2020 health dimension; therefore, the main parts of the 2004 framework strategy are still relevant in the current context. The differences between the two regional strategies are partially due to the different development context, not only in terms of the different situations in the SEE region in 2004 and 2013, respectively, but also in terms of different angles: the 2004 framework strategy was developed from within the health system perspective by public health professionals, whereas the SEE 2020 strategy has been developed at a political level and implies consequently a different perspective on the issues at hand.

Collaboration between the two networks FPH-SEE and SEEHN particularly in the area of public health education could be of mutual benefit, with a format still to be agreed upon though. Similarly, collaboration between the two networks could further strengthen the improvement of regional health information. The integration of health in the SEE 2020 strategy with the HiAP approach opens opportunities for health influencing socioeconomic development policies. This paradigm shift is an important step forward for public health.

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REVIEW ARTICLE

Governance and management of health care institutions in Serbia: An overview of recent developments

Vesna Bjegovic-Mikanovic[1]

[1] Faculty of Medicine, Belgrade University, Belgrade, Serbia.

Corresponding author: Prof. Vesna Bjegovic-Mikanovic, MD, MSc, PhD;
Address: Dr Subotica 15, 11000 Belgrade, Serbia;
Email: bjegov@med.bg.ac.rs

Abstract

In order to promote awareness of factors that affect social services, their quality, effectiveness and coverage, the term "governance" is frequently used. However, there is no agreement on definitions, frameworks and how it relates to the health sector.
In this overview, two interrelated processes in Serbia will be analyzed: governance and management at the macro-, meso-, and micro level.
Key messages are as follows: i) Continue decentralization and support to an effective national decision-making body (Health Council of Serbia) with all relevant stakeholders; ii) Reduce the well-known implementation gap and agree on a binding time frame for reforms, and; iii) Establish obligatory schemes for education and training of managers and support sustainability of state institutional capacity to teach, train and advise on a scientific basis.

Keywords: governance, health sector, management, Serbia.

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Introduction

Governance and management of health care institutions encompass a series of regulatory measures undertaken for planning, organizing, functioning and evaluation of all the numerous and interrelated system elements by which the set objectives are brought into effect (1). Although it is considered as a multidimensional and interdependent process, there are differences between governance and management. How to apply in particular the term "governance" to the health sector? In order to promote awareness of factors that affect social services, their quality, effectiveness and coverage, the term "governance" is frequently used. However, there is no agreement on definitions, frameworks and how it relates to the health sector (2). In general, governance relates to decisions on the framework that defines expectations, grants power, or verifies performance. The debate over this terminology began in the early nineties when the World Bank defined governance as: *"the exercise of political authority and the use of institutional resources to manage society's problems and affairs"* (3). In recent years, the avenues towards effective governance are described in more detail: good governance in health systems promotes efficient delivery of health services. Critical are appropriate *standards, incentives, information,* and *accountabilities*, which induce high *performance* from public providers (4). The United Nations led a debate on the understanding of good governance. Referring to the World Bank definition, good governance entails sound public sector management (efficiency, effectiveness, and economy), accountability, exchange and the free flow of information (transparency), and a legal framework for development (justice, respect for human rights and liberties) (5). WHO summarizes it as follows: *"The leadership and governance of health systems, also called stewardship, is arguably the most complex but critical building block of any health system. It is about the role of the government in health and its relation to other actors whose activities impact on health. This involves overseeing and guiding the whole health system, private as well as public, to protect the public interest. It requires both political and technical action because it involves reconciling competing demands for limited resources, in changing circumstances"* (6). Governance represents the owners, or the interest group of people, who represent an organization or any institution (7,8). The governing body, on the other hand, appoints personnel for the (executive) management. While governance is relevant for the vision of an organization, and translation of the vision into policy, management is related to making decisions for implementing the policies. Governance also includes the relationships among the many players involved (the stakeholders) and the corporate goals. The principal players include the shareholders, the board of directors, and the management. Other stakeholders include employees, suppliers, customers, regulators, the social environment and the community as a whole. Management comes only second to the governing body, and it is bound to strive as per the wishes of the governing body.

Aim of this review

In this overview, two interrelated processes in Serbia will be analyzed: governance and management. To summarize the terminology, which will be used in the overview, as an official translation from Serbian, "macro," "meso" and "micro" levels are discussed.

At the "macro" level, (usually at the state level) governance of health care system in Serbia is performed by Government, Ministry of Health and Republic Fund of Health Insurance. In addition, some governance functions in Serbia (without Kosovo and Metohija) are also at the level of (9,10):

- Autonomous Province of Vojvodina and its six cities and 39 municipalities; Governing bodies are "Province Government of Vojvodina", "Province Secretariat for Health Social Policy and Demography" and "Province Fund of Health Insurance".
- City of Belgrade and its 17 municipalities; Governing bodies are "City Council with the Mayor, Deputy Mayor and members" and "City Secretariat for Health Care", and 23 cities (including those in Vojvodina with its 28 urban municipalities) and 150 municipalities (including those in Vojvodina); Governing bodies are the city and municipality authorities.

At the "meso" level (at the facility/institutional level), governance is performed by the Managerial Board of each facility/institution (in Serbian: "Upravni odbor"). Also, some governance functions with very weakly defined ToR (terms of references) at the institutional level are performed by the Supervisory Board (in Serbian: "Nadzorni odbor"). At the "meso" level management is performed by the Director and his/her management team.
At the "micro" level, we can observe only management processes.
A framework for assessing governance and management of health institutions in Serbia is based on a set of criteria to cover assessment of institutional, financial and accountability arrangements, together with decision-making capacity and responsibility during the last decade (11,12). Besides the "macro" level determining the basic structure, organization and finance of all publicly owned health institutions in the Serbian context, this overview particularly deals with the description of the "meso" level: the functions/responsibilities of health managers at primary, secondary and tertiary care level of organization (see Figure 1). However, the "micro" level dealing with operational management of staff and services inside the organization is also highlighted. This overview is prepared based on the following sources of information (data):

- published health policy and legal documents in Serbia, health legislation and guidelines from the Ministry of Health (MoH), published papers in the Serbian and international health management literature, internationally funded project reports (EU and WB projects' reports dealing with health management, financing (capitation), quality improvement and local governance), health management conferences in the country and the region, training curricula and programmes of work;
- published general health statistics, national electronic databases and WHO/Eurostat database for comparison, and;
- results of national survey of all health institutions' directors and matron nurses done by the Health Council of Serbia in 2010 and 2011.

I. Governance and management at macro level

The essential characteristics of the external environment in which today's governance and management of health service organizations in Serbia are taking place include population aging, costly medical technologies, lifestyle intervention, and advance health promotion and prevention. Also, the health care system, as in some other transitional countries, is faced with ethical and economic crises of unpredictable outcome. Political, social and, predominantly, professional groups attempt to introduce changes in health legislation and functioning of health service organization, however, with variable success.

At the macro level of governance, the most important was the adoption of the Health Policy Document (13) by the Serbian Government. No similar document has ever been adopted in Serbia, hence the process of bringing health in Serbia closer to the relevant policy of the

European Union was at this moment initiated. The Health Policy Document defined the main directions of development of the health care system. As such, it was essential as a foundation of laws and bylaws conducive to the reforms of the health care system, including governance and management at all levels. According to this Document, the reform of the health care system in Serbia, being a continuous process of the transition of the entire socio-economic system, presupposes the implementation of the following goals of the health policy:

a) Safeguarding and improving the status of health of the population in Serbia and strengthening of the health potential of the nation;
b) A just and equal accessibility to health care for all the citizens of Serbia and improvement of the health care for vulnerable populations;
c) Putting the beneficiaries (patients) into the centre of the health care system;
d) Sustainability of the health care system while ensuring transparency and a selective decentralization in the field of resource management, and diversification of sources and methods of financing;
e) Improvement in functionality, efficiency and quality of the health care system and definition of specialized national programs to advance human resources, corporate networks, technologies, and provision of medical supplies;
f) Defining the role of private sector in provision of medical services to the population;
g) Improvement of the human resources for health care.

However, more than a decade after the adoption of this Document, achievements of the health policy proves still to be variable in the sense of governance and implementation, due to the lack of specific objectives and priorities adopted by all parties. In practice, the implementation of the proposed framework of health policy of Serbia presupposes consensus thereon of all the key actors in the health care system (beneficiaries, providers of services and mediators in the provision of health care – health insurance and ministry). Following the adoption of the new system laws in 2005 (Health Care Law and Health Insurance Law), intended decentralization has been considered to play a major role in the portfolio of possible activities to improve governance and management of health care organizations in Serbia. The actual organizational structure of the health care system in Serbia as a framework for governance and management at "macro level" is presented in Figure 1.

Serbia, as other parts of former Yugoslavia, inherited a centralized state health system financed by compulsory health insurance contributions. The system was intended to provide access to comprehensive health services for all citizens with an extensive network of health institutions. At the end of 2013, the publicly owned health care system in Serbia employed persons in a total of 354 institutions (14).

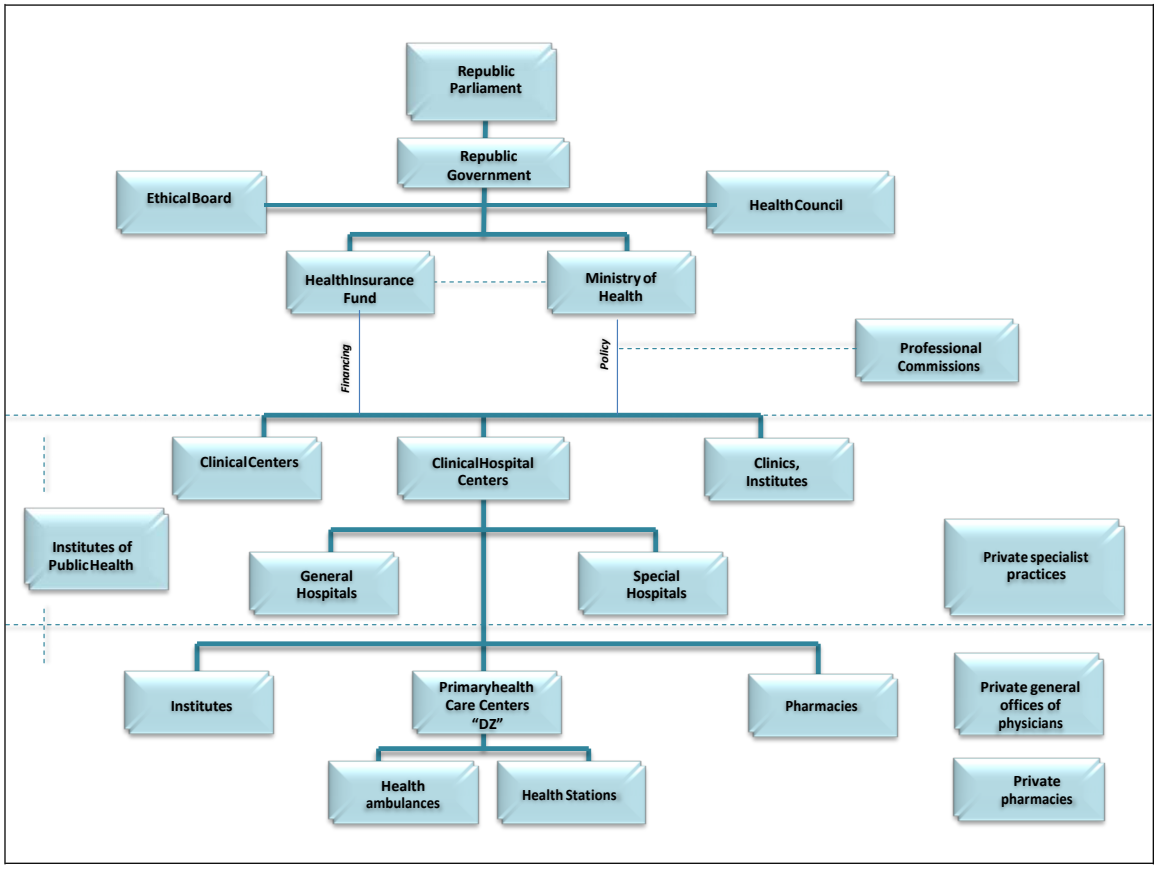
Currently, in Serbia, looking at the governance at "macro" level as the process by which authority is exercised, still many functions related to strategic directions/planning, legislation, and financing are at the national – Republic level (Ministry of Health and Health Insurance Fund, see Figure 1).

However, with the beginning of the process of decentralization, important players at "macro level" could also be seen at Vojvodina Province level, within its Provincial Secretariat for Health Care, Social Policy and Demography (15), City Belgrade Secretariat for Health Care (16), and the respective Provincial Health Insurance Agency (17). Social care for health at the level of an autonomous province, a municipality, or a city, includes measures for the provision and implementation of health care according to the interest of the citizens in the territory, as follows (Article 13 of Health Care Law) (18):

i. *Monitoring of the state of health of the population and the operation of the health service in their respective territories, as well as looking after the implementation of the established priorities in health care;*
ii. *Creating of conditions for accessibility and equal use of the primary health care in their respective territories;*
iii. *Coordination, encouraging, organization, and targeting of the implementation of health care, which is exercised by the activity of the authorities of the local self-government units, citizens, enterprises, social, educational, and other facilities and other organizations;*
iv. *Planning and implementation of own program(s) for preservation and protection of health from polluted environment, which is caused by noxious and hazardous matters in air, water, and soil, disposal of waste matters, hazardous chemicals, sources of ionizing and non-ionizing radiation, noise and vibrations in their respective territories, as well as by carrying out systematic tests of victuals, items of general use, mineral drinking waters, drinking water, and other waters used for production and processing of foodstuffs, and sanitary and hygienic and recreational requirements, for the purpose of establishing their sanitary and hygienic condition and the specified quality;*
v. *Providing of the funds for assuming of the foundation rights to the health care facilities it is the founder of in compliance with the law and with the Plan of the network of health care facilities, and which includes construction, maintenance, and equipping of health care facilities, and/or capital investment, capital-current maintenance of premises, medical and non-medical equipment and means of transport, equipment in the area of integrated healthcare information system, as well as for other liabilities specified by the law and by the articles of association;*
vi. *Cooperation with humanitarian and professional organizations, unions and partnerships, in the affairs of health care development.*

Decentralization implies a transfer of authority and competencies, as well as responsibilities from higher to lower levels. The transfer of authority from the central administration to smaller and local communities does not necessarily deprive the central government from all authority and power. The central administration should retain some control along with essential tasks in the sense of governance, such as legislative, financial, and regulatory duties. Any excess, whether it refers to total centralization or total decentralization, can harm the health care process (19). In the Health Insurance Act of 2005 (articles 208 et seq.), the Serbian Government (20) admitted that the reorganization of the Serbian Health Care System has to take into account the following key issues: *"The compulsory health insurance is provided and implemented by the Republic Fund of Health Insurance, with its official seat in Belgrade"* (article 208), and: *"The Republic Fund is managed by the insured that are equally represented in the Board of Directors of the Republic Fund in proportion to the type and number of the insured established by this act"* (article 209).
According to the Serbian legislation, health care facilities with funds in state ownership (hereinafter referred to as: state owned health care facility) are funded in accordance with the Plan of the network of health care facilities, which is adopted by the Government. Health care facilities that provide emergency medical care, supply of blood and blood derivative products, taking, keeping, and transplantation of organs and parts of human body, production of serums and vaccines and patho-anatomical and autopsy activity, as well as the healthcare activity in the area of public health, shall be funded exclusively in state ownership.

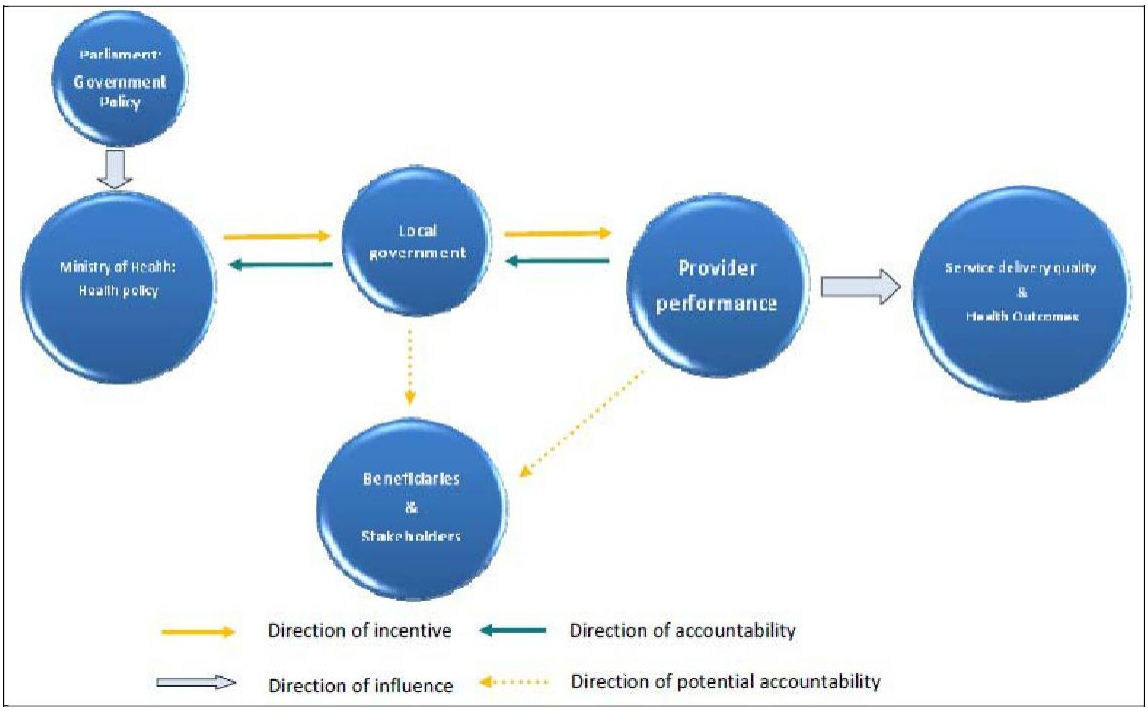
Figure 1. Organizational structure of the health care system in Serbia



Otherwise, health care facilities can be established by legal or natural persons at any level. The complex interrelationships between the macro-, meso-, and micro level are illustrated in Figures 2 and 3.

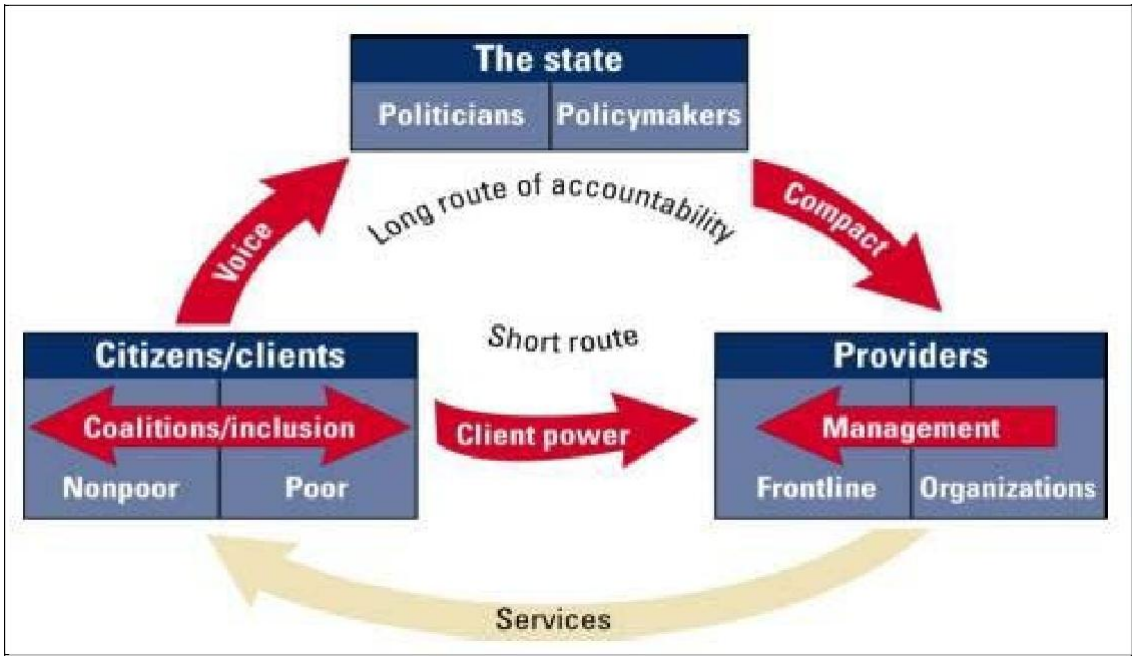
However, governance at the level of municipalities predominantly has been exercised only regarding appointments of the directors, deputy director, the members of the management board (board of directors), and the supervisory board of health care institutions, at the same time with low capacity/competencies to exercise the decision making process at the local level and use responsibilities in the decision making space. Execution of financial functions at the local/municipality level could be observed within some municipalities and their annual programme budget planning, which engages resources mainly to meet infrastructure needs of primary health care at the local level. Besides the adopted Law on Local Self-Governance (23) which is providing decision space for local authorities to exercise more responsibility in governance at the local level, decision capacity stays limited. Therefore, the main objective of the recent international projects, such as: DILS – "Delivery of Improved Local Services" [managed by ministries of health, education, labour and social policies (24)] and "Support to Local Self-government in Decentralization" [managed by Standing Conference of Towns and Municipalities (25)] are meant to increase decision capacity of multidisciplinary teams at municipality level, both in governance and management.

Figure 2. Overview of the governance process



Source: Original copy from: Lewis W, Pettersson G. Governance in Health Care Delivery: Raising Performance. Policy Research Working Paper 5074. Washington: The World Bank Development Economics Department & Human Development Department 2009 (21).

Figure 3. The long and short routes of accountability



Source: World Bank. World Development Report 2004: Making Services Work for Poor People, Washington, DC: World Bank 2004 (22).

Several factors contributed to this type of evolvement of governance at "macro" level. Firstly, Serbia is still in economic crisis, inherited from the past and aggravated by the world economic crisis. The poor performance of economy has a deep negative impact on the social sectors, including the health sector. Political involvement at almost all administrative levels has also affected in a negative way the proper governance and management of the health system. It induced changes in the human resources structure (especially top managers) affecting the continuity of governance at "macro" level and strategic thinking (26,27). Besides financial and legislative problems, many other weaknesses in the area of organization and functioning of the health care sector are present at "macro" level governance:

- rigid normative regulation of the health care system;
- centralized and bureaucratized management with limited autonomy of managers lacking necessary management skills;
- still not fully developed and operational health information system and up-to-date information as basis for decision-making processes;
- undeveloped "market" in the health sector with deprivation of private health care providers and still "passive" approach to privatization in the health care system;
- development of health facilities beyond economic possibilities, their duplication, lack of coordination of activities according to levels of health care organization, poor maintenance of equipment and buildings, lack of sufficient operational budgets;
- low professional satisfaction of health workers caused by low salaries with the consequence of bad motivation for providing efficient and quality health services;
- dehumanised relationships between medical personnel and patients followed by absence of citizens' responsibility for their own health;
- curative orientation of the health care system with priority in development of secondary (hospital) and tertiary (sub-specialized) levels of care, despite formal support to primary health care orientation;
- unrealistic objectives for prevention with formal and non-effective programs and activities in health promotion despite widespread risk behaviour and numerous environmental hazards;
- lasting postponement of implementation of legal and administrative decisions, with lack of SWAps (Sector Wide Approaches) as necessary for development and implementation of regulations connected to the authority of other ministries, such as those dealing with economic affairs and regional development.

However, certain achievements of "macro" level governance during the last decade have to be acknowledged, such as the introduction of the Health Council of Serbia as advisory body to the Ministry of Health, development of a transparent process for continuous quality improvement in health care and the agency for accreditation, trying out new payment mechanisms in primary health care ("performance-based payment" as a step towards capitation), preparation for more efficient financing of hospitals by development of a DRG system, and the like.

II. Governance and Management at meso-level

Institutional arrangements

A review of health service legislation and the regulatory environment related to governance and health management shows weak areas that should be addressed and opportunities that

exist to make governance and management the mainstay of health sector reform in Serbia. Contrary to a typical business organization, the authority structure in managing a health services organization is divided among three authority and responsibility centres: Board of Directors, Doctors, and Administration represented by the Director and his Management Team (28,29). The Managerial Board is legally responsible for the organization as a whole, including provision of health care, public relations and assistance in supply of resources for its functioning. If basic social roles of a health service are under consideration, it is the *Managerial Board* that most commonly reflects the profile of the community and its health services organization. It means that the former consists of delegates from various social groups of certain educational level and experience and in this way is executing governance at the "meso" level. *Doctors*, comprising a medical board, but others as well, have a powerful role in management, since they are hold responsible for the majority of cost rendering decisions made. *Administration*, composed of director, heads of departments and chiefs of assisting services, is the third and last authority centre in managing health services organizations, responsible for operational management.

The authority and responsibility structure in managing the health services organization in Serbia is defined in the Health Care Law and bylaws together with the role and current and expected function of health managers at "meso" level. According to the Health Care Law (Article 130), a typical health care organization in Serbia has the following management structure: the director, the managerial board (corresponding to the board of directors), and the supervisory board. It may also have a deputy director, who is appointed and relieved under the same conditions and according to the same procedure, which is specified for appointment and relieving of the director of the health care organization. The director, deputy director, the members of the management board, and the supervisory board of health care organisations are appointed and relieved by the founder. As an example, the director, deputy director, the members of the management board, and the supervisory board of an institute, clinic, institute, and clinical center, or the Health Care of Employees Institute of the Ministry of Interior Affairs, the founder of which is the Republic, are appointed and relieved by the Government. The director, deputy director, the members of the management board, and the supervisory board of health care facilities the founder of which is the Republic, except for the specifically mentioned institutions, are appointed and relieved by the Minister.

The director of a health care facility is appointed on the basis of a vacancy publicly announced by the management board of the health care organisation. The management board of a health care organization makes selection of the candidate and submits the proposal to the founder, which then makes the appointment. However, should the management board of a health care organization fail to elect the candidate for the director of the health care facility, or should the founder of a health care facility fail to appoint the director of the health care facility, in accordance with the provisions of the Law, the founder shall appoint the acting director for a period of six months. In practice, it was not unusual that "acting director" stays for couple of years; whereas the Law (article 135) also prescribed criteria for appointment, as well as conditions in which the director of a health care organization should be replaced.

Furthermore, the same Health Care Law defines responsibilities and duties of the respective managerial bodies. The director is organizing the work and managing the process of work, representing and acting as proxy of the health care facility and is responsible for the legality of work of health care facility. In this way, contrary to established theory and practice, it seems that in Serbia the director has also some governance function. If the director does not

have medical university qualifications, the deputy, or assistant director shall be responsible for the professional and medical work of the health care facility. The director shall submit to the management board a written quarterly, and/or six-monthly report about the business operations of the health care organization. The director shall attend the meetings and participate in the work of the management board, without the right to vote.

Contrary to the position of the director, the Law does not prescribe such detailed instructions as regards who should be appointed for management board and supervisory board. It is only stated (article 137) that the management board in primary health care centres - DZ, pharmacies, institutes (see Table 1 for details), and the national public health institute have five members of whom two members are from the health care organization, and three members are the representatives of the founder, whereas the management board in a hospital, clinic, institute, clinical hospital, and clinical centre has seven members of whom three members are from the health care facility, and four members are the representatives of the founder. Responsibilities of the management board are the following:

i) Adopt the articles of association of the health care organization with the approval of the founder;
ii) Adopt other bylaws of the organization in compliance with the law;
iii) Decide on the business operations of the health care organization;
iv) Adopt the program of work and development;
v) Adopt financial plan and annual statement of account of the health care organization in compliance with the law;
vi) Adopt annual report on the work and business operations of the health care organization;
vii) Decide on the use of resources of the health care organization, in compliance with the law;
viii) Announce vacancy and implement the procedure of election of the candidates for performing the function of the director;
ix) Administer other affairs specified by the law and the articles of the association.

A supervisory body as the third centre of authority is appointed in a similar way as the management board (with three members for less complex health care organizations and five for those at secondary and tertiary level of organization). Contrary to the management board, the Law does not prescribe in detail responsibilities of the supervisory board, except for the following (article 138): *"The supervisory board of health care organization shall exercise supervision over the work and business operations of a health care organization"*. In practice, such formula is producing a rather passive role for this body.

A recent survey of all directors of health care organizations conducted by the Health Council of Serbia in 2010 and 2011, pointed to some general and some specific characteristics of management at "meso-level". The study used a questionnaire designed on the basis of similar studies in Serbia, which comprises five groups of questions: general characteristics that define the manager profile, the problems of management, assessment of the importance of motivational factors, carrying out the management goals and self-evaluation of managerial skills. According to this survey, the managers of health care organizations in Serbia are mostly experienced specialists, slightly more often males than females, who usually have some form of management education (Table 1). In comparison with the period of the nineties, the structure of health organizations' managers in Serbia improved in terms of management training and gender sensitivity.

Table 1. General profile of directors of health care organizations in Serbia

CHARACTERISTICS	Directors of outpatient institutions (n=140)		Directors of hospital institutions (n=90)		P
	Number	Percent	Number	Percent	
Gender					
Male	76	54.3	61	68.5	0.032
Female	64	45.7	28	31.5	
Age (years)					
<35	3	2.1	1	1.1	
35-45	14	10	11	12.5	0.033
46-55	92	65.7	42	45.7	
56-65	31	22.1	34	38.6	
Occupation					
Physician with specialization	104	76.3	87	96.7	
Physician without specialization	6	4.3	0	0	<0.001
Dentist	8	5.7	0	0	
Pharmacists	19	13.6	1	1.1	
Economists, lawyers, other	3	2.1	2	2.2	
Working experience					
up to 15	8	5.9	7	8.1	
15-19	21	15.4	7	8.1	0.135
20-24	44	32.4	20	23.3	
25-29	38	27.9	27	31.4	
over 30	25	18.4	25	29.1	
Managerial experience (years)					
<1	21	15.2	7	8	
1-2	43	31.2	28	31.8	
3-4	25	18.1	10	11.4	0.265
5-6	18	13	14	15.9	
7-9	24	17.4	23	26.1	
over 10	7	5.1	6	6.8	
Education in management					
Yes	110	79.1	60	67.4	0.047
No	29	20.9	29	32.6	
Type of education					
Self-empowerment	13	11.2	12	18.2	0.212
Courses	73	62.9	43	65.2	
Master programmes	30	25.9	11	16.7	
Satisfaction with social status					
Very satisfied	99	70.7	65	72.2	0.959
Moderate satisfaction	35	25	21	23.3	
Not satisfied	6	4.3	4	4.4	
Member of a political party					
Yes	85	63	37	42.5	0.003
No	50	37	50	57.5	

Source: Health Council of Serbia Survey of Directors of Health Care Organizations 2010-2011 (30).

A situation analysis performed within a recent EU project found that given the opportunity, some health workers would choose management roles in the health services. They may also choose project-based work with international organisations and NGOs, and when the funding for such projects ends may seek to return to the health services in management positions.

There are also managers in legal services, human resources, utilities management and other professional categories. The issues of general management and non-medically trained managers are complex and have not yet been addressed in Serbia as a debate about health management has only recently started. The need for new management skills is being partially met by existing institutions and universities, on the job training, projects funded by international organisations and NGOS, and, in a very limited way, education programmes by newly emerging private providers. A large boost is required to create a cadre of managers who can bring about change in the health services.

Responsibilities of managers in Serbia will request change with decentralisation, requiring more knowledge and skills at municipal level. Private/public partnerships are likely to develop within the next five years, requiring more skills in contracting out. As of now, there is no clear career structure or progression pathway for health managers. However, this is likely to be mapped out within the next five years and will increase demand for formal training and accredited courses.

It is expected that the old style bureaucratic and very hierarchical structure will change and for this managers with change management skills will be required. The following have been identified by key informants as priority areas for the introduction of change management:

- Team working will enable a more effective approach to cross-disciplinary tasks.
- Better use of information technology is likely to produce information that is more relevant to decision-making.
- Financial tracking will shift to output-based methods and efficiency will be measurable.
- Individual accountability, currently weak, will be required to increase; there will be a shift to benchmarking rather than a reliance on blame and, therefore, criteria for positive results will become more transparent and measurable.
- Transparency in decision making and better planning and consultation processes.
- Prioritizing of scarce resources while protecting access to services for the poor and uninsured.
- Project management skills will be applied within the health service.
- There will be a shift from development support from the international community towards loans and credits; managers who understand how to use such funds will be required.
- There will also be a shift towards contracting out services.
- Increased individual accountability and managers who understand client-focused services will be required.

This will require a cadre of managers with a very new set of skills. By producing large numbers of change managers it is also expected that they will be able to support each other in a system that is currently quite hostile to change. This has been a positive experience from the EAR funded and Carl Bro implemented project, where team-based working and problem solving has also provided professional support for the managers involved.

There is a frequently expressed belief in the health services that hospital management is very different to general management of other organizations. There is likely to be little acceptance of general managers in the health system; actually, this has not been tried out in Serbia to date, but it should not be excluded. There is also a practice that amongst health professionals, only senior specialist doctors have the authority required for senior management and leadership positions in the health services; again, this should be questioned and tested (27).

Financial arrangements

Besides the main financial arrangements in Serbia and implementation of ongoing changes in the financial management system, particular attention is given to the managerial aspects of decision making related to capital investment, adjustment of capital and operational expenses and ability to incur debt, sometimes considered by managers (directors and management teams) as deficit carried over from the last fiscal year and due to introduction of a new budget system for reporting based on the new Law on Budget System, which is ongoing from 2009 and adopted in the Serbian Parliament each year (31). According to real practice examples, strengths and weaknesses are obvious in planning and reporting on institutional financial flows. Typically, the managerial board ("Upravni odbor") is responsible for the adoption of financial reports and annual budget plans at the beginning of each calendar year, after which a report and a plan is processed to the Republic Fund of Health Insurance for approval and serves as a base for contracting with the health care organization. Those institutions which have also financing directly through the Republic Budget (such as Institutes of Public Health) are obliged to send their plan of activities including a budget in the foregoing calendar year for the next calendar year. Although it should be activity-based costing, very often the correlation between activities and budget lines is not clear and visible. Examples from practice indicate that the managerial board ("Upravni odbor") does not have always direct responsibilities in financial arrangements, as sometimes changes in contractual agreements with the Republic Fund of Health Insurance, as well as with the Ministry of Health during the year are reported by directors only post factum. This is also an indication of the relatively weak role (responsibility) of the managerial board within health care organizations of Serbia regarding governance.

Accountability arrangements

Health Managers are not defined as a separate profession in Serbia. Senior staff in the health services has management functions and responsibilities, and these are noted under the Health Law of 2005 and under various other procedural documents in the legislation. With very few exceptions, senior health services managers in the country are doctors, there is more variety at middle management level, although the two levels have not till now been clearly defined.

In the study of managing health services organizations in Serbia over the last decade, apart from the triple power and authority distribution between management and supervisory board, administrative director with his collegiums, workforce particularly doctors, *specific accountability and responsibilities* include the following:

- accountability and responsibility *for the patient*, above all, within the scope of modern medicine and health promotion movement, with provision of the best possible health care, with minimal costs. Only recently in Serbia - within the development of different patient NGO's;
- accountability is increasing in this regard, apart also from recently established the so-called "protector" of patients' rights in each institution. Reports about patients' complaints are regularly presented both to directors and managerial boards. However, regular monitoring during five years within the reporting about quality indicators has pointed to a low level of complaints and consequently few actions by management for corrections;
- accountability and responsibility *for the employed workforce* by recognizing their sensible requirements for safety in terms of wages, appropriate working conditions,

promotions, but also identifying their fears caused by uncertainty regarding positive effects of their work (outcomes concerning the treated patients' health). Usually, this is exercised through trade unions, sometimes several per one health care organization;
- accountability and responsibility *for a financier* and different social groups (donors, sponsors) supplying resources for functioning of the institution;
- accountability and responsibility *for the community (public)* in determining means for meeting the population health care needs, and;
- accountability and responsibility *for oneself* by making efforts to perfect one's knowledge and skills related to management as well as readiness to make effective responses under conditions of continuing changes and threats.

The national survey of directors is offering assessment of the last bullet point referring to managerial skills (Table 2). There are no differences between outpatient and hospital managers in this regard, however, this is a very subjective assessment indicating surprisingly high competences, which should be further investigated and verified.

Table 2. Self-assessment of managerial skills *(on a 5-point scale)*

SKILL	Directors of outpatient institutions (n=140)		Directors of hospital institutions (n=90)		
	Average	SD	Average	SD	P
Evidence based situation analysis	4.39	0.862	4.37	0.788	0.859
Application of SWOT analysis	3.59	1.293	3.42	1.277	0.350
Development of mission and vision	4.20	1.052	4.30	0.866	0.450
Development of flow-charts for specific work process	3.28	1.227	3.25	1.199	0.833
Development of SMART objectives	3.57	1.290	3.39	1.216	0.322
Development of diagrams	3.15	1.321	3.10	1.234	0.805
Development of WBS	3.46	1.332	3.23	1.180	0.217
Assessment of employees	4.26	0.930	4.17	0.865	0.476
Public relations skills	4.30	0.852	4.25	0.918	0.700
Change management skills	4.29	0.862	4.30	0.714	0.944
Project management skills	4.26	0.864	4.33	0.769	0.536
Conducting effective meeting	4.45	0.704	4.54	0.724	0.374
Searching through internet	4.14	0.928	4.17	0.950	0.811
Communications with employees	4.60	0.560	4.51	0.642	0.222
Fund raising and donor searching	4.10	1.046	3.84	1.127	0.087

Source: Health Council of Serbia Survey of Directors of Health Care Organizations 2010-2011 (30).

Decision-making capacity versus responsibility

This section is based mainly on the national health management survey executed among directors of health care institutions and matron nurses. There are few exclusive health service managers, as it is an insecure profession. Often doctors take up a management role but continue to wear their "clinical hats" and keep a base in their clinical work. This gives them a safety net in the event that they do not keep their management posts, the most senior of which are subject to political appointment. According to the national survey results in Serbia, priority objectives for managers are: improving health care quality, increasing patient

satisfaction and professional development, as well as improving employee satisfaction and work organization (Table 3).

Significant differences were found between managers of primary healthcare organizations and hospitals: outpatient facilities' managers are much more likely to improve in the areas of management, are significantly more often members of a political party and more frequently state that the problem of management is the lack of coordination in health care institutions. The major objectives for hospital managers are familiarizing new employees with the work process, introducing new technologies and developing scientific research.

Table 3. Assessment of importance of institutional objectives by directors *(on a 10-point scale)*

OBJECTIVE	Directors of outpatient institutions (n=140)		Directors of hospital institutions (n=90)		P
	Average	SD	Average	SD	
Improvement of work organization	73.17	26.59	78.30	21.88	0.132
Decreasing of operational costs	63.31	31.10	64.77	31.28	0.733
Increasing staff satisfaction	76.26	23.38	75.17	24.82	0.740
Increasing consumer satisfaction	79.14	22.89	80.80	24.08	0.603
Multidisciplinary team work	69.78	26.80	74.89	24.02	0.148
Empowering of newly employed staff	57.55	30.30	65.34	26.78	0.050
Continuing education	78.06	23.68	77.84	25.12	0.948
Introduction of new technologies	71.09	28.40	78.60	24.02	0.042
Research and development	52.07	33.61	68.50	32.20	0.001

Source: Health Council of Serbia Survey of Directors of Health Care Organizations 2010-2011 (30).

Considering the main player in the setting of institutional objectives, the situation is very interesting pointing to very low authority of managerial boards in this process, which is mainly governance function. According to the national survey conducted in 2010-2011, the situation is as follows:

- Ministry of Health 7.4%
- Director alone 2,6%
- Director after discussion with collaborators and staff 65,7%
- Management team and its discussion 22,6%
- Other players 0.4%
- Without answer 1,3%

Managerial problems (Table 4) are grouped into factors, based on which it is possible to define future interventions such as improvement of work organization and coordination, control systems and working discipline.

Strategic management comprises drafting, implementing, and evaluating cross-functional decisions that enable an organization to achieve its long-term objectives together with solving strategic and operational daily problems of management. In this process, a strategic plan is laid out that encompasses the organization's mission, vision, objectives, and action plans aimed at achieving these objectives.

Table 4. Assessment of management problems *(on a 4-point scale)*

Type of problems	Directors of outpatient institutions (n=140)		Directors of hospital institutions (n=90)		P
	Prosečna	SD	Prosečna vrednost	SD	
Planning	2.78	0.942	2.65	0.871	0.314
Work organization	2.79	0.832	2.72	0.750	0.514
Coordination of services	3.17	0.731	2.85	0.847	0.003
Replacement of staff	2.75	0.884	2.63	0.949	0.363
Professional development	3.06	0.923	2.93	0.997	0.329
Procurement of equipment	2.09	1.062	1.84	0.931	0.067
Keeping of equipment	2.39	1.036	2.21	0.935	0.199
Financing	1.86	0.938	1.76	0.905	0.413
System of control	2.90	0.851	2.84	0.838	0.589
Information System	2.46	0.992	2.38	1.053	0.598
Working discipline	2.96	0.734	2.80	0.733	0.108
Cooperation with Ministry of Health	2.80	1.105	2.87	1.120	0.664
Cooperation with Health Insurance Fund	2.70	1.057	2.63	1.083	0.658

Source: Health Council of Serbia Survey of Directors of Health Care Organizations 2010-2011 (30).

A recent study of 40 hospital management teams in Serbia proved capacity of managers who are trained to improve strategic management competences and accept clear responsibility in strategic management. During the workshop done with the same 40 general hospitals managers they did a SWOT analysis and possible strategic options for development of their organizations. Examples are presented in Table 5.

Continuing education on health care management is being offered in Serbia at an increasing scale, in response to the health care system's well-known deficits. Recently, at the Belgrade School of Medicine, a postgraduate Master's program in health care management was established. However, in Serbia, such programs have been evaluated very rarely if at all. Exceptions are the results of the training programme for hospital and primary health care managers, offered by the Centre School of Public Health and Management in Belgrade, with providing evidence, for the first time in Serbia, of effective support to the directing managerial teams with respect to their strategic planning abilities.

During those studies, the measurement and evaluation of hospital performance were recognized as essential, partly as a consequence of the recently established reporting system of quality indicators and partly due to recognition of the usefulness for benchmarking. Only a few stakeholders, e.g., the Ministry of Health, the Republic Health Insurance Fund, and project agencies, were considered relevant for the hospitals. Those key partners directly affect hospital services and financial flows and, therefore, were highly correlated to hospital managers' ability to plan strategically. This demonstrates that the managerial teams were predominantly oriented toward the fulfilment of legal obligations and contracts. The second independent component was a detailed analysis of the internal environment (staff, their training and development, management, information system, equipment, customers and their satisfaction, and kind and quality of health services).

The hospital's internal environment was included in the government's health reform initiatives (32). In Serbia, defining a hospital's mission, vision, action plan, and especially its

SMART objectives (33) seems to be dependent on the political environment and the existing legislation.

Table 5. Strategic management thinking in Serbian general hospitals

Example of vision and mission statement: *"We are here to provide optimal methods in health care services with respect to the demands of our patients and to apply new technological accomplishments for the faster and more efficient treatment of our customers."*	
Examples of goals: Development of quality and efficiency of health care services Establishing new diagnostic and therapeutic methods Implementation of procedures for ambulatory surgery	
Examples of strengths: Highly educated staff Introduction of clinical guidelines Renovation of some parts of our facilities Good relationship with the media	**Examples of weaknesses:** Medical staff holding second jobs in private practice Medical equipment out of date Low motivation of staff Negative financial balance
Examples of opportunities: Rationing of hospital staff and facilities Support from the local community and from NGOs Participation in international projects	**Examples of threats:** Lack of treatment standards and protocols High number of refugees and internally displaced people Lack of effective gatekeeper function in primary health care
Proposals of strategic options	
Comparative advantage (Strength/Opportunity): Widen the spectrum of services to gain additional income	**Investment/Divestment (Weakness/Opportunity):** Promotion of cooperation with local authorities
Mobilisation (Strength/Threat): Improvement of communication with customers	**Damage control (Weakness/Threat)** Note: The teams could not or did not want to imagine this scenario

Source: Workshop with 40 general hospital teams done in 2009 by the School of Public Health and Health Management University of Belgrade, within an EU project (see also Terzic-Supic et al. (32).

In order to increase further management capacity to deal with management problems, numerous training have been organized since 2007 supported by several projects which resulted in the development of strategic plans:

- "Capacity building of hospital management teams", supported by EU project (result: 40 hospitals developed strategic plans);
- "Programme for management development in primary health care institutions of Belgrade" Project funded by the City Secretariat of Health Care Belgrade, 2007-2009 (result: 14 primary health care centres in Belgrade developed strategic plans);
- Working group of Serbian Basic Health Project – Ministry of Health (WB) – education of 7 primary health care managers (result: 9 primary health care centres in Belgrade developed strategic plans);
- "Politics of Primary Health Care in Balkans", project managed by CIDA (result: 7 primary health care centres developed strategic plans);

- "Support to the implementation of capitation payment in primary health care in Serbia", EU financed and managed project (result: 29 primary health care centres developed strategic plans);
- DILS – "Delivery of Improved Local Services" (managed by PIU of ministries of health, education, labour and social policies (result: 28 primary health care centres developed strategic plans).

Looking at primary health care organizations up to 2012, in total, 78 out of 157 have developed strategic plans based on this capacity building (predominantly with the support of the School of Public Health and Management, Faculty of Medicine, University of Belgrade). In addition, strategic plans for capacity building of management teams in primary health care as support to the new method of payment of providers in primary health care are developed since 2010. It is also proven (34-37) that the training courses offered to management teams in Serbia by the Centre School of Public Health and Management in Belgrade had positive effects on the teams' ability to formulate their organizational mission and vision, strategic objectives, and action plan as learning outcomes and to implement monitoring and adjustment of their strategies. Nevertheless, the research evidences in Serbia also demonstrates that improving strategic planning practices can be effective, but many health care organizations have difficulties in translating their strategic plan into actions that result in successful performance.

III. Management at micro-level

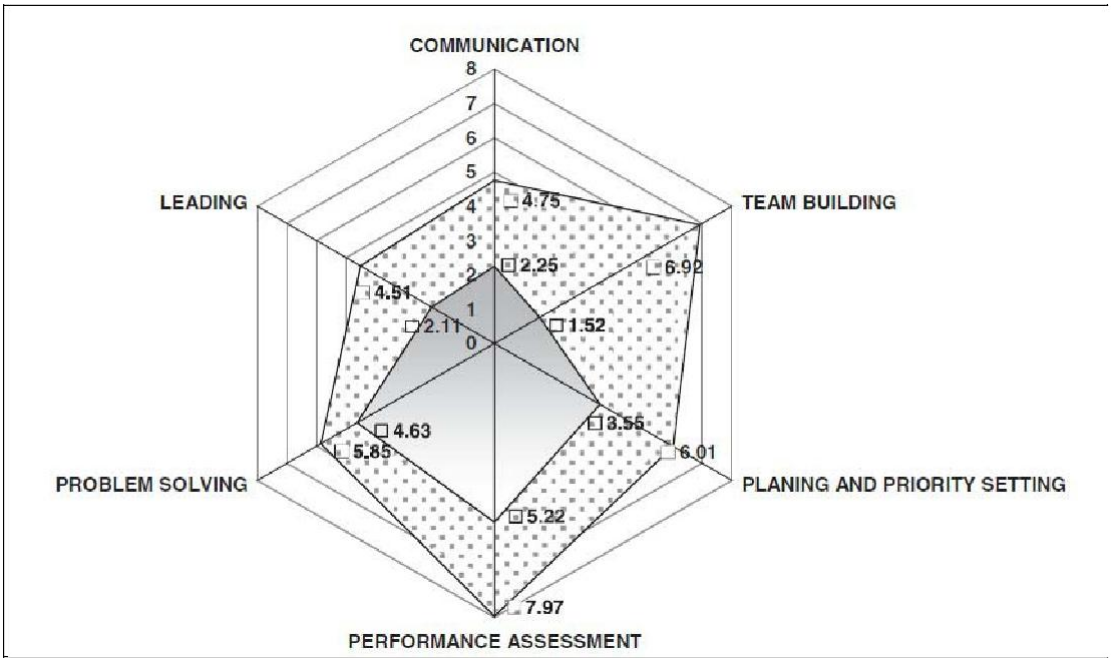
As physicians and to a lesser extend nurses regularly execute management functions at micro-level, it is of great relevance for a smooth operation of services as well as for the satisfaction of patients and staff, that these functions are not only performed with good will but also with knowledge and skills.

The example of gaps in management competence before and after training for physicians and nurses illustrated in Figures 4 and 5 highlight a key problem at the micro-level: training! Female managers in our studies, here following Santric-Milicevic (36), developed higher competency levels after training in communication skills and problem solving.

Managers rated assessing performance of higher importance, while chief nurses emphasized the importance of leading. Before training, the estimated competency gap was generally the highest in assessing performance, followed by team building and planning and priority setting.

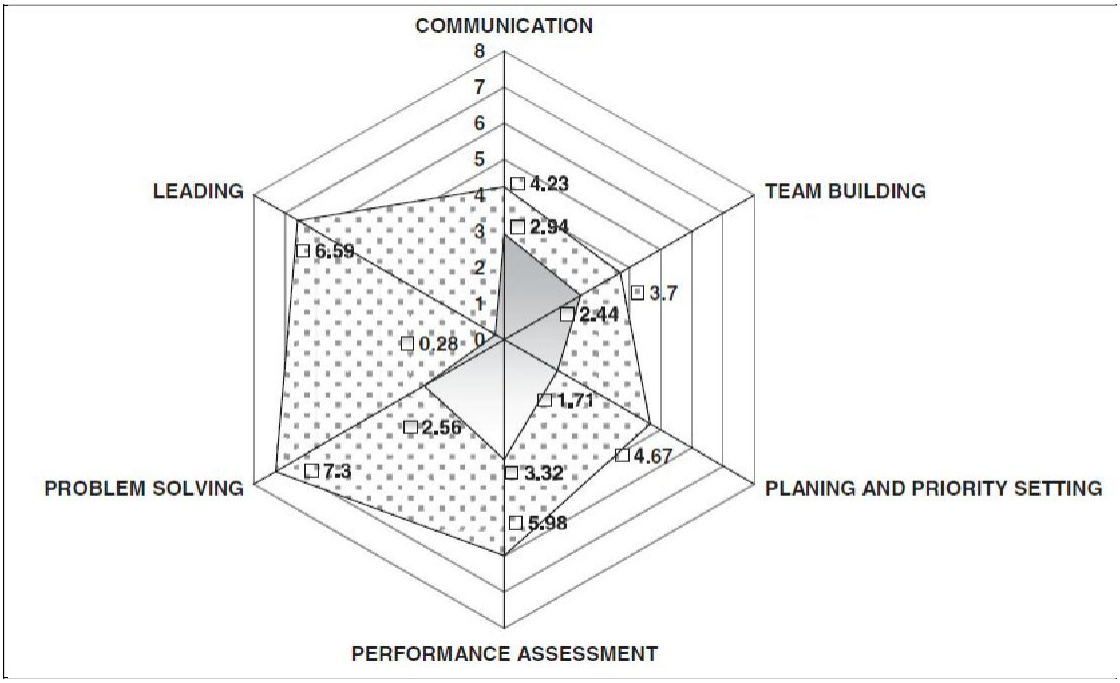
Terzic et al. (35) came to similar conclusions but added the analysis of predictors: *"The biggest improvement was in the following skills: organizing daily activities, motivating and guiding others, supervising the work of others, group discussion, and situation analysis. The least improved skills were: applying creative techniques, working well with peers, professional self-development, written communication, and operational planning. Identified predictors of improvement were: shorter years of managerial experience, type of manager, type of profession, and recognizing the importance of the managerial skills in oral communication, evidence-based decision making, and supervising the work of others."*

Figure 4. Core management competences of top managers (physicians): Competence gap before and after training *(the confetti pattern of radar indicates the area of improvement after training)*



Source: Santric Milicevic M, Bjegovic-Mikanovic V, Terzic-Supic Z, Vasic V. Competencies gap of management teams in primary health care. The European Journal of Public Health 2011; 21(2):247-53 (36).

Figure 5. Core management competences of chief nurses: Competence gap before and after training *(the confetti pattern of radar indicates the area of improvement after training)*



Source: Santric Milicevic M, Bjegovic-Mikanovic V, Terzic-Supic Z, Vasic V. Competencies gap of management teams in primary health care. The European Journal of Public Health 2011; 21(2):247-53 (36).

Challenges and recommendations for possible improvements of governance and management of health care institutions in Serbia

Challenges ahead for the governance and management of health institutions in Serbia are derived from the situation analysis and recommendations are made based on actual examples of good practices in Europe and the world and in the light of management opportunities/threats and strengths/weaknesses in Serbia.

The Serbian Health System is by tradition highly centralized. However, providing health services of high quality on a regular basis requires a high degree of complexity and interaction between various levels of management and different stakeholders. Keeping all relevant decisions at the national level and organizing complex tasks centrally cannot be perceived without establishing a highly trained, numerous and well-paid central bureaucracy. This does not seem to be a realistic option for Serbia and many other countries as well. Therefore, the issue of far reaching and effective *decentralization* is on the table which at the same time introduces a certain degree of competition between service institutions. The term *"horizontal, not vertical management"* has been introduced in this context. However, each country coming from a specific historical background has to find its own way forward.

The concept of decentralization according to Bossert (38-41) comprises three elements at the macro-level, namely allowing for "decentralist decision space", "corresponding institutional capacity", and "local accountability" (towards the community). At the managerial meso-level this has to be translated into operational planning, budgeting, human resources management, and service organization, where this last element is considered to be a matter of the micro-level.

In order to strive for the implementation of this concept in Serbia, the following activities are recommended to be carried out timely and successfully:

Macro-level:

i. The Ministry of Health should revise the valid legislation allowing for a stepwise transfer of more decision making powers within a limited time period to the "decentralist level", defined as municipality authorities.
ii. The Republic Fund of Health Insurance is to become fully independent and has likewise to defer financial powers to the lower levels – branches. However, there should be a compensation mechanism between poorer and richer municipalities in Serbia, maybe supported from tax money allocated by the budget or by the Ministry of Finance, or through the Ministry of Health.
iii. The service facilities (hospitals and others) within a district (= region = "okrug") negotiate their service profile and budget directly with the local partners – the branch of the Republic Fund of Health and municipal authority.
iv. Insured patients can select a chosen physician wherever they want.
v. In order to harmonise the various elements of the health system in terms of a horizontal management, a national decision making body composed of the HIF and the representation of the service providers together with the professional chambers should meet chaired by the Ministry of Health in order to adapt permanently the governance. The package of basic health services is to be defined at this level, as well as the care to be provided to uninsured persons.
vi. The number of institutional managers required nationwide has to be determined and trained accordingly in postgraduate programmes for Public Health and Management

(based on defined competences required to provide good performance). Otherwise, they will not be able to make use of the larger decision space provided.

vii. Likewise, short-courses in community health management for mandated civil servants and politicians at the community level should be regularly offered.

Meso-level:

i. Standard models of terms of references for all management staff categories have to be developed and harmonised to correspond to the new legislation and practice in educational sector and linked to corresponding programmes of Continuous Professional Development (CPD) offered by the four Serbian medical/health faculties in close cooperation with the faculties of management and organization.

ii. Satisfaction of patients and employees which is measured by standard instruments every year at the institutional level should be improved both in the way of assessment and tools for improvement.

iii. Development of a guideline on change management and decentralist accountability towards the local elected community representatives.

iv. Promotion of the employment of non-medical managers and managers coming from non-medical environments.

Micro-level:

i. Allowance of intra-institutional opportunities for increased decision space of staff, especially nurses, and encouragement of training options up to postgraduate levels.

ii. Regular negotiations with the trade union representatives to agree on payment schemes which correspond to the qualification and position of staff, especially nurses.

Key messages

- Continue decentralization and support to an effective national decision making body (Health Council of Serbia) with all relevant stakeholders.
- Reduce the well-known implementation gap and agree on a binding time frame for reforms.
- Establish obligatory schemes for education and training of managers and support sustainability of state institutional capacity to teach, train and advise on a scientific basis.

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