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Genc Burazeri, Ulrich Laaser,
Jose M. Martin-Moreno, Peter Schröder Bäck

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EDITORIAL

E-health and m-health: Great potentials for health and wellbeing, butalso for harmonization and European integration inhealth

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Health has never been an European Union (EU) priority like agriculture, research, ecology or food safety and still remains to be first of all, if not exclusively, the responsibility of member states (MS). From the EU perspective, health is the crosscutting policy sector dominated by many other policies, especially by the ―hard law‖ regulations of the Internal Market. In the preceding two volumes, the South Eastern European Journal of Public Health (SEEJPH) published an admirable lengthy article by Hans Stein and equally splendid supplemented commentary by Bernard Merkel recounting and evaluating developments of the EU's health policy from the 1992 Maastricht Treaty (and even from earlier) to the present-day state and future perspectives (1,2). Although health still has very weak basis in the EU legislation, it has evolved from ―non-topic‖ into a key area of the EU economic policy (1), but despite a growing competence ―*the unfinished story of the EU health policy"* is slowly moving from declarative to operational phase in developing framework for circulation of health goods and related items within Europe and beyond (2).

In his commentary, Dr Merkel has summarized changes in treaties and other regulations from 1971 (Directive on pharmaceuticals and Regulation on coordination of social security systems providing rights to health care to workers in other EC countries) through the following milestones: (i) the Article 129 of the Maastricht Treaty that for the first time introduced health although in a very weak manner; (ii) the 1997 Treaty of Amsterdam that extended the public health article and introduced the new one (Article 152) including for the first time a few specific areas related to blood and organs, some veterinary and phytosanitary areas and other things, and; (iii) finally, the 2007 Lisbon Treaty with inclusion of medicinal products and medical devices but also incorporating the Charter of Fundamental Rights of the EU including the right to access health care (preventive and curative, Article 35 of the Charter)(3).

Having in mind also the common currency introduced and spreading since 1999, the conclusion that Single Market will finally have an impact on health and health policy stands up. On the other hand, Charter of Fundamental Rights of the EU (proclaimed in the year 2000 but being put in the new legal environment since it became formally binding by the Lisbon Treaty in 2009) has declared in its Article 35 in addition that ―*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*‖ prior than this principle became known as Health in All Policies (HiAP) during the Finish EU presidency in 2006.

According to what has been mentioned above, population health and organization of health system (including health insurance) has always been and remains a national responsibility. At the same time, the EU member states (as well as accession candidates and potential candidates) were shaping their health policies, implementing activities and monitoring systems directed by recognized international organizations such as WHO and OECD (and, more recently, the EU) and also used their support in responding to health threats from communicable diseases and disasters, as well as in combating the growing burden of non-communicablediseases.

Finally, Single Market principles are going to enter health sector somehow through ―back-door‖ via instruments such as Directive 2011/24/EU on the application of patients' rights in cross-border healthcare that came into force on 25th October 2013 (4), up to now without a great success, but with potential to improve access to healthcare services and harmonize their quality within the EU member states and push them to cooperate closer in establishing of health networks in order to meet patients' expectations.

Another very important opportunity for European integration is influencing and penetrating health sector from a much broader perspective of fast developing communication technologies.

A Digital Agenda for Europe Initiative was selected as one of the seven flagship initiatives supposed to be crucial for obtaining the targets of Europe 2020 strategy for smart, sustainable and inclusive growth (5). The adoption of EUROPE 2020 strategy in 2010 was followed by ―E-Health Action Plan 2012-2020‖ (6), a new one after the previous adopted in 2004 (7), and ―A Digital Single Market Strategy‖ for Europe which was adopted in May 2015 after the new European Commission elected in 2014 set up ten priority policy areas in its Agenda for Jobs, Growth, Fairness and Democratic Change including the priority to create ―a connected digital single market‖ listed as No. 2 priority by Jean-Claude Juncker in his Opening Statement speech before the European Parliament delivered on the 15th of July 2014 (8,9). It is expected that the creation of digital single market will enable the creation of new jobs, notably for younger job-seekers, and a vibrant knowledge-based society. Enhancement of the use of digital technologies and online services was proclaimed as a horizontal policy, covering all sectors of the economy, as well as the public sector including health, and common European data protection rules were seen as a necessary prerequisite.

Facts about the ―Digital Agenda for Europe Initiative and Digital Single Market (DSM) Strategy‖ are available at the respective web-site (10), where we can also find new information and follow developments and public consultations on selected topics ofinterest.

The ―Digital Agenda for Europe Initiative‖ proposes to better exploit the potential of Information and Communication Technologies (ICTs) in order to foster innovation, economic growth and progress. It consists of the following sevenpillars:

i. Digital Single Market
ii. Interoperability & Standards
iii. Trust & Security
iv. Fast and ultra-fast Internetaccess
v. Research and innovation
vi. Enhancing digital literacy, skills andinclusion
vii. ICT-enabled benefits for EU society

A ―Digital Single Market‖ (DSM) is one in which the free movement of persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place ofresidence.

At (10) we can find definitions of e-Health and m-Health as well as information on what is going on in digital society including the public consultations launched on respectivetopics.

Information and Communication Technology for health and wellbeing (e-health) is becoming increasingly important to deliver top-quality care to European citizens and includes informatisation of health care systems at all levels (from local through institutional and regional to European and global level including use of tele-consultations and telemedicine. Mobile Health (m-health) is a sub-segment of e-health and covers medical and public health practice supported by mobile devices. It especially includes the use of mobile communication devices for health and wellbeing services and information purposes, as well as mobile health applications. Particularly important are policies for healthy and active ageing with help of ICT and use of mobile applications for health and wellbeing including home care monitoring devices (wired and mobile). There are already more than 100,000 applications for health, fitness and wellbeing obtainable for different mobile platforms, the majority of which are designed for Apple IOS and Android smart phones.

The European Commission often consults with stakeholders on a number of subjects and such consultations can be found on the pages of Digital Agenda for Europe (10). The Commission launched a public consultation on the Green Paper on mobile health (11) on 10th of April2014.

The Green paper on mobile health covered broad scope of m-health potential for both, healthcare and market. Main potential for healthcare are seen in (i) increased prevention and quality of life approach, (ii) more efficient and sustainable healthcare, and (iii) more empowered patients.

Having in mind that the healthcare systems‘ organization is a national competence Green paper focused on cross-border European-wide issues and on possible coordinated actions at EU level that could contribute to the scale-up of m-health in Europe by putting 11 issues atstake:

1. Data protection, including security of healthdata
2. Big data
3. State of play on the applicable EU legal framework
4. Patient safety and transparency ofinformation
5. m-health role in healthcare systems and equalaccess
6. Interoperability
7. Reimbursement models
8. Liability
9. Research and innovation in m-health
10. International cooperation
11. Access of web entrepreneurs to the m-healthmarket

The Commission also published a staff working document on the existing EU legal framework applicable to lifestyle and wellbeing apps, aiming at providing simple guidance to application developers on EU legislation in the field (12) and invited the views of stakeholderslike:

- regional and national authorities e.g. health ministries, authorities dealing withmedical devices/data protection
- health professionals, carers, health practitioners, medicalassociations
- consumers, users of m-health apps, patients and theirassociations
- web entrepreneurs
- app developers and app stores
- manufacturers of mobile devices
- insurance agencies
- sports centres, health clubs, and the like.

Consultation was open for more than three months during which stakeholders responded to 23 questions on a wide range of themes: data protection, legal framework, patient safety and transparency of information, m-health role in healthcare systems and equal access, interoperability, reimbursement models, liability, research & innovation, international cooperation and web entrepreneurs‘ market access. A total of 211 responses were received and summarized in the published report (13).

Besides the great potential for health and wellbeing, there are some concerns, as well. The safety of mobile health solutions (and of some lifestyle and wellbeing applications, too) is a main cause for concern, explaining the potential lack of trust. There are reports pointing out that some solutions do not function as expected, and may not have been properly tested or in some cases may even endanger people‘s safety. That is why on both sides of the Atlantic, regulations for medical devices including software applications are established and continuously updated (14-16). It is beyond the scope of this article to discuss the importance

and the need of certification of e-health and m-health devices and software, but health professionals must carefully take this issue into account and stick to guidelines and recommendations issued by regulatory agencies and bodies as thosecited.

Undoubtedly, e-health and m-health have a large potential for health and wellbeing through empowering of patients and enabling them to take responsibility for their own health while reducing the ever-growing healthcare costs. At the same time, health professionals and students need to be educated and trained to evaluate such applications or at least to take into account their limitations. My personal experience has shown that medical students are capable to test m-health applications and understand the need for validation and certification of such applications. They successfully prepared a seminar in Medical Informatics using their own smart phones. Within the same course students received assignments to read, understand and present EU directives, charters and other documents (e.g. 3,4,6,11,14,16) in order to become acquainted with the European integration in health.

Health systems in the EU are facing the common challenge of a rise in chronic diseases as a consequence of our increasingly ageing population. Vytenis Andriukaitis, the EU Commissioner for Health and Food Safety, entitled his column in August 2015 issue of the European Journal of Public Health ―How the eHealth can help with Europe‘s chronic diseases epidemic‖ (17). Quotes from this article are presented below:

―*As a former medical doctor, I am fascinated with innovative solutions that are part of today"s medical toolbox. I would like to highlight eHealth in particular. The more I learn about eHealth, the more convinced I am that it can enable better health, better and safer care for citizens and more efficient and sustainable healthcare systems. eHealth and mHealth can deliver more tailormade, „citizen-centric" care, more targeted and effective therapies, andhelp reduce medical errors."*

Good to hear that eHealth Network has adopted the guidelines on electronic prescriptions needed for their cross-border exchange and progress ininteroperability:

"Although the deployment of eHealth is the responsibility of Member States, the EU adds value in many ways. The eHealth Network set up under the cross-border health care Directive provides a forum for cooperation, support and guidance for speeding up the broad use of eHealth services and solutions. Facilitating interoperability and safe and efficient handling of electronic health data across national and organizational boundaries is a key issue. The eHealth Network has already adopted Guidelines on cross-border exchange of Patient Summaries and prescriptions. These Guidelines encourage the adoption of eHealth applications at national level."

Guidelines on ePrescriptions dataset adopted by eHealth Network (18) are intended to be complementary to the Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the validation of medical prescriptions issued in another Member State (19), but also as another document for implementation in the nearfuture.

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Wenzel H, Bjegovic-Mikanovic V, Laaser U. Piloting an advanced methodology to analyse health care policy networks: The example of Belgrade, Serbia (Original research). SEEJPH 2015, posted: 27 July 2015. DOI 10.12908/SEEJPH-2014-52

ORIGINAL RESEARCH

Piloting an advanced methodology to analyse health care policynetworks: The example of Belgrade, Serbia

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Abstract

Aim: Political decisions usually emerge from the competing interests of politicians, voters, and special interest groups. We investigated the applicability of an advanced methodological concept to determine whether certain institutional positions in a cooperating network have influence on the decision-making procedures. To that end, we made use of the institutional network of relevant health care and health governance institutions, concentrated in Belgrade, Serbia.

Methods: We used a Principal Component Analysis (PCA) based on a combination of measures for centrality in order to evaluate the positions of 25 players in Belgrade‟s institutional network. Their directed links were determined by a simulated position approach employing the authors‟ long-term involvement. Software packages used consisted of *Visone 2.9*, *UCINET 6*, and *KeyPlayer 1.44*.

Results: In our analysis, the network density score in Belgrade was 71%. The PCA revealed two dimensions: *control* and *attractiveness*. The Ministry of Health exerted the highest level of control but displayed a low attractiveness in terms of receiving links from important players. The National Health Insurance Fund had less control capacity but a high attractiveness. The National Institute of Public Health‟s position was characterized by a low control capacity and high attractiveness, whereas the National Drug Agency, the National Health Council, and Non-Governmental Organisations were no prominentplayers.

Conclusions: The advanced methodologies used here to analyse the health care policy network in Belgrade provided consistent results indicating that the intended decentralization of the health care network in Belgrade may be incomplete, still with low participation of civil society representatives. With the present study we set the stage for a broad-range survey-based data collection applying the methodology piloted inBelgrade.

Keywords: Belgrade‟s health care policy network, policy analysis, Serbia, social network analysis, sources of power.

Conflicts of interest: None.

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Introduction

Political decisions are not primarily the result of scientific (rational) problem solving - like e.g. the illustration of the policy cycle suggests (1,2). The decisions usually will emerge from the competing interests of politicians, voters, and special interest groups. The policy literature considers this issue and suggests a variety of frameworks and analytic models for policy analysis (3). The spectrum ranges from the rather normative scientific problem solving approach to a more „incrementalistic" way (4). Lindblom even calls it „muddling through" (5) - and finally to the paradigm of „bounded rationality" (6,7). Analyzing decision outcomes (policies) has to consider the specific organisational structure (policy) and the initiated processes (politics), comparable to Donabedian"s concept of structure and process as a prerequisite of outcome quality (8). Related questions are: How will political decision processes possibly influence policy-making (6)? Do certain individual or institutional positions in a cooperating network have more or less influence on the decision-makingprocedures?

To explore the complex governmental portfolio of resources, Hood et al. (9,10) propose a classification scheme, which gets to the point with only four important sources of power: *Nodality, Authority, Treasure and Organisation*. They state that *nodality* denotes the property of being in the middle of an information or social network (10). A high degree of nodality gives a player a strategic position from which he allocates information, and which enables him to draw in information. *Authority* is the formal and legitimate official power (11). That is the formal power to demand, forbid, guarantee, and arbitrate. *Treasure* gives the government the ability to exchange goods, using the coin of money or something that has a money-like property. Finally, *organisation* gives to a government the physical ability to act directly, using its own forces (10).

With the Serbian Health Insurance Act of 2005 (12) the Serbian government aimed at reorienting the health care system and transform it into a more decentralised organisation. These changes would hopefully offer to the insured population an opportunity for a greater self-management. As most of the relevant institutions are concentrated in the Serbian capital Belgrade, we used this example to investigate the applicability of the aforementioned methodological concept. With the disclosure of the players" nodalities that make up Belgrade"s health care policy network, we envisaged to analyse to which degree the decentralisation of decision making has progressed since the legislation of 2005, extending our preliminary analysis (13). With the present step we focus on institutional players and their nodality only, without consideration of potentially influential individual players. The analysis of Belgrade"s health policy network is a pilot project appropriate for testing the feasibility of a countrywide survey. This analysis was based on a questionnairesurvey.

Methods

To break down the abstract notion of power and influence, different paradigms were used in sociology and political science: reputation approach, decision approach, or position approach (14). For a critical review of the approaches see Domhoff (14). In our understanding, influential actors can be best described by the position approach, i.e. a policy network. A policy network is described by its various players - public as well as non-governmental - their formal and informal connections and the specific boundary of the network under consideration. The links between the players are likely to be understood as communication channels for the exchange of information, expertise, trust and other policy resources (15). Depending on the scientific disciplines, e.g. coming from *community power research* (14), or *systems thinking* (16,17), various technical approaches and measures have been used to identify, describe and

analyse formal or informal networks within organisations. Necessary data can be collected by means of survey (questionnaires, interviews), observations, or by analysing secondary data. For economic reasons, a heuristic procedure as outlined e.g. by Vester (16) or Bryson (18) was applied and possible actors [so-called boundary specification (19, p. 77)] were enumerated in a brainstorming session listed in a ―cross-impact matrix‖ of influences (16, p. 188). Finally, the strength and direction of their connections was estimated (16, p. 188) by the authors for the purpose of this methodological study. These are ―soft data‖ (16, p. 22), but nevertheless they are based on experience, knowledge of the health care system and observations. As Newman points out, collecting data by directly questioning participants (or, players) does not necessarily provide a higher accuracy and is also a laborious endeavour (20). For visualisation of the network and a more in-depth analysis, we recurred to the analytic tools of Social Network Analysis (SNA). The concept of nodality corresponds well with the measures used in SNA and, basically, two viewpoints are possible: primarily focusing on a specific player (ego-centred) only, and analysing and evaluating the network as a whole, taking all connections and all players into account (socio-centred)(13).

On a *socio-centred level*, the network structure can be described by measuring density and centralization. *Centralization is defined as the variation in the centrality scores* of the nodes or players in the network. This variation shows the extent to which there is a centre - i.e., very central players - and a periphery - i.e., players with very low centrality scores (21). *Density is a basic network property* that reflects the overall intensity of the connected players: the more connected the network, the greater its density. A dense network is one where a lot of activity or a large number of strong ties exist among its members (22). On an *ego-centred (individual) level*, we focused on the players‟ importance. Importance reflects the visibility to other network members (23) and is broken down into indices like influence andprestige.

Measures of centrality

The concept of centrality is a crucial aspect when representing policy networks (24). Centrality measures will identify the most prominent players. These are the players who are extensively involved in relationships with other network members (25) without necessarily discriminating between formal or informal links (depending on the data collection approach). The most frequently centrality measures used include degree centrality, betweenness centrality, and closeness centrality. They reflect the view that information is transferred along the shortest pathways (26).

Degree centrality is an indicator of expertise and is measured by the sum of all other players who are directly connected to a specific player (25). Asymmetric networks are particular in that the distinction between *indegree-centrality* and *outdegree-centrality* has to be taken into account (13). Players receiving many ties (*indegree*) have a high prestige (23). Players with a high flow of outgoing connections (*outdegree*) are able to exchange with many others, or - at least - make others aware of their views (13). This means that players with a high outdegree centrality are said to be influential players(27).

Betweenness centrality counts how many times a player connects other players, who otherwise would not be able to reach one-another (25). It measures the potential for control, because a player who shows a high betweenness degree will be able to operate as a gatekeeper by controlling the flow of resources between the other nodes that are connected through him (25) - on shortest paths (28).

Closeness centrality is based on the concept of distance. A player who is close to all others in the network, e.g. having a distance of no more than one, is not dependent on any other to reach everyone in the network (25). Closeness centrality measures independence or efficiency (25). In the context of SNA, efficiency means that the higher the closeness centrality of a node, the shorter is its average distance to any other node, thus indicating a better position for spreading information (29).

Further centrality measures are hub function and authority. In directed networks, players that have important resources should get a high centrality score too. Newman defines it as follows: *"Authorities are nodes that contain useful information on a topic of interest; hubs are nodes that tell us where the best authorities are to be found"* (30, p. 179). In the framework of SNA, formal authority has to be differentiated from informal authority (11). Hubs are enablers of effective knowledge transfer (31, p. 225). A high hub player points to many important authorities (high outdegree) whereas a high authority player receives ties from many important hubs (high outdegree). They can effectively connect different sub-groups of the network and facilitate knowledge flows; removing them from the network can lead to its fragmentation (31, p. 225).

Study setting

For investigating the applicability of the methodological concept we chose a position approach as it best describes the potential of power and influence, combined with a heuristic data collection. To that end, the authors - all well informed about the Serbian health care system and the situation in Belgrade - listed 25 players, identified the links between the players and the perceived strength of their relationship together in an open process. As pointed out earlier (13), the links can point in one direction only (unidirectional), or include both directions (bidirectional). The strength of the relationship was rated on a scale ranging from 0 to 4. Very weak links with a value of 1 were put on a level with 0 for ―no link‖ (13). The rating of the links reflects the averaged assessment of the authors. The resulting ―cross-impact matrix‖ was exported to *Visone 2.9* (15) for further analysis. In some cases where the analytic toolset of *Visone 2.9* did not provide the calculation of specific indices, we used *UCINET 6* (32), and *KeyPlayer1.44* (33) instead.

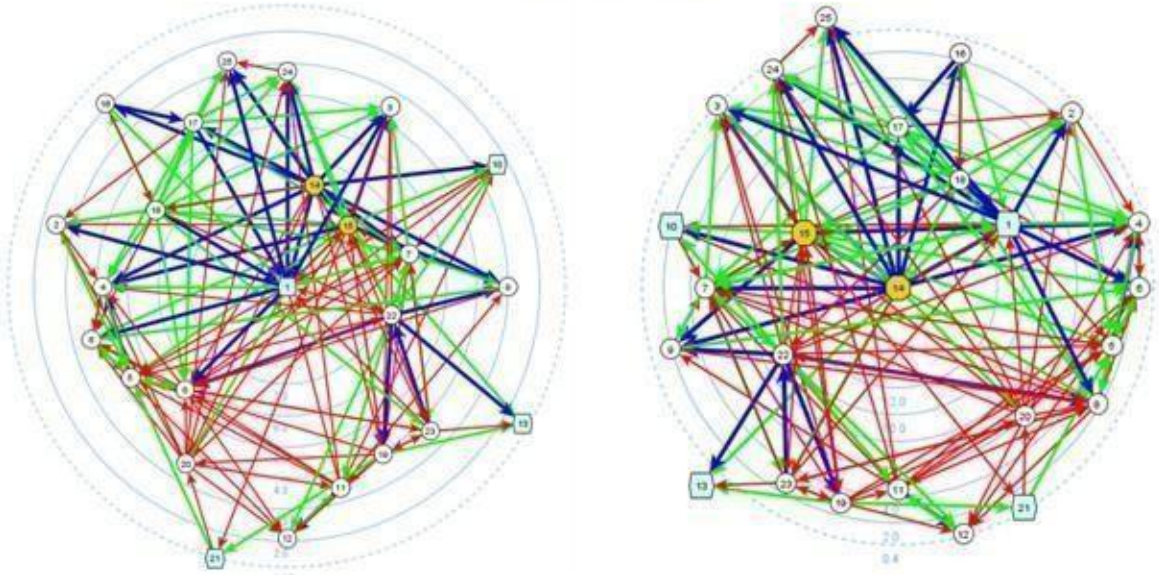
To visualise the analytical findings in an easily understandable format, we chose the design of a target diagram, which is also a built-in feature of *Visone 2.9*. In this diagram, the 25 players (nodes) are placed according to their scores. This means that the player with the highest score is positioned in the centre of the diagram; the others, according to their decreasing scores, are moved toward the periphery of the structure, correspondingly. To ensure a largely undisturbed view, the authors of *Visone 2.9* applied a specialized layout algorithm that aims at minimizing entanglement by reducing the number of crossing lines and occlusions determine the angular location. The different score levels are displayed as thin concentric circles. This allows comparing the scores of the players easily, without looking at the output table (15, p. 17). Brandes et al. (15) successfully used these diagrams to analyse local health policies and the underlying structure of the various players, e.g. to disclose the differences in the local drug policy of two German municipalities and the networks of players that form the basis of the policy making. Furthermore, to facilitate an overall perspective (holistic view) of the indices applied, we merged the results with the help of a Principle Component Analysis (PCA) diagram. PCA is a multivariate data analysis method which is used to reduce complexity by transforming a set of possibly correlated variables into a set of uncorrelated variables,

., principal components (34,35). This approach explains best the variance of data and helps to reveal the internal structure of the data.

Results

The network matrix was composed by 25 players and 158 directed and valued links or connections as determined - for the purpose of this methodological study - by the authors. The network density was calculated as 71% realized links out of all possible ones. A density greater than 50% is considered high (36). Therefore, we assumed here that the players in Belgrade were well connected. For valued networks (see Figure 1), the centralization score has to be calculated separately for outdegree and indegree centrality. The outdegree score here was 46.3% of all possible connections, whereas the indegree score was 19.1% (calculated with *UCINET 6*). This would disclose a distinct centralisation. However, the range of outdegree scores was larger than that of indegree scores, and the players showed a higher variability. The coefficient of variation was 93% for outdegree and 54% for indegree centrality, indicating that the network was less homogeneous with regard to outdegree centrality, or influence (27). The possible influence of the players in the network varied largely, i.e., the positional advantages were rather unequallydistributed.

Figure 1: Target Diagram of Belgrade's Health Care Network with respect to 'Degree Centrality' and 'Hub Function'



1 a: Degree Centrality *1 b: Hub Function*

The colours describe the strength of the links. Red colour corresponds to number 2, green colour to number 3 and blue colour to number 4. The hexagon symbols show the players that are indicators for a more decentralized system; the octagon symbols represent the Ministry of Health [15] and the National Government [14]. For the numeric codes see Table 3 in the annex.

The most important players – identified in terms of degree centrality (Figure 1a and Table 1) - were the National Health Insurance Fund [1], the Ministry of Health [15], the National Government [14], and the Medical Faculty, Belgrade [22]. The Health Insurance Fund [1] received most of the strongest [blue] links. The players with the highest indegree centrality or

prestige were the Clinical Hospital Centres, Belgrade [8], the Institute of Public Health, Belgrade [4], the National Health Insurance Fund [1], and the Clinical Hospital Centre of the Republic [7]. Players with the highest outdegree centrality or influence were the National Government [14], the Ministry of Health [15], the Medical Faculty, Belgrade [22], the State Revisor [18], and the National Health Insurance Fund [1].

Table 1. Ranking of players by centralityindices
(based on percentages – for the numeric codes, see Table 3 in theannex)

INDICES OF CENTRALITY						
Degree centrality	**Indegree centrality**	**Outdegree centrality**	**Betweenness**	**Closeness**	**Hub function**	**Authority**
1	8	14	8	14	14	3
15	4	15	15	15	15	8
14	1	22	22	18	18	4
22	7	18	7	22	1	7
7	3	1	19	19	22	23
8	5	17	1	7	17	1
18	6	7	20	1	20	25
5	23	20	11	20	7	9
4	25	19	23	23	11	2
17	9	11	5	17	19	10
19	15	23	6	11	5	15
20	23	8	9	16	23	6
23	2	5	23	8	8	23
6	10	16	18	10	10	5
11	22	9	12	3	9	13
3	12	6	17	9	16	17
23	19	10	3	23	6	16
9	13	4	4	21	2	19
25	17	2	10	12	4	12
2	11	12	2	5	23	22
10	20	21	14	6	21	20
12	16	23	16	2	12	11
16	21	3	21	4	3	21
13	18	25	25	25	25	18
21	14	13	13	13	13	14

With respect to the betweenness centrality, the Clinical Hospital Centres, Belgrade [8] were the most central players. The Ministry of Health [15], the Medical Faculty, Belgrade [22], the Clinical Hospital Centre of Serbia [7], and the Serbian Physicians Society [19] seemed to be very close to each-other, but located more to the margin. Players with a high degree of closeness were the National Government [14], the Ministry of Health [15], the State Revisor [18], the Medical Faculty, Belgrade [22], and the Serbian Physicians Society [19]. The picture changed when we looked at hub functions. As pointed out, hubs are enablers of effective knowledge transfer, they can effectively connect different sub-groups of the network and facilitate knowledge flows; removing them from the network can lead to its fragmentation (31, p. 225). Considering the hub function, the National Government [14] was in the most

favourable position (see figure 1b), followed by the Ministry of Health [15]. The National Health Insurance Fund [1] moved more to the periphery indicating a loss of importance for knowledge transfer. The State Revisor [18] and the MOF Budget Inspection [17] also moved more to the centre of the diagram.

As Hannemann and Riddle note, the question of how structural positioning implicates power is still a matter of research and debate (34). To reduce the complexity, eventually sort out redundant information and get an integral view, we applied PCA which is displayed in Table 2 and Figure 2.

Table 2. Contribution of centrality measures to the dimensions of the PCA (percentages)

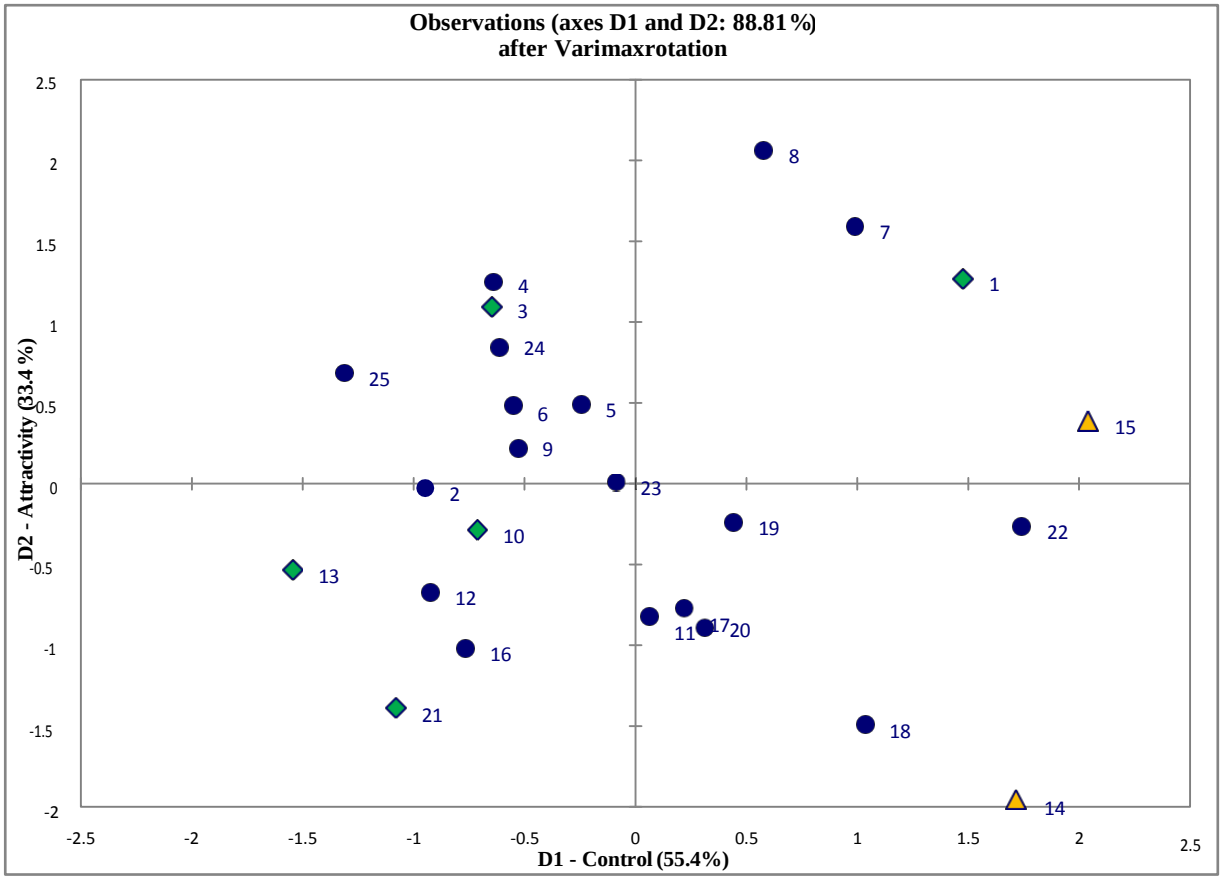
CENTRALITY MEASURES	D1 (Control)	D2 (Attractiveness)
Degree	**22.645**	3.186
Indegree	0.159	**40.837**
Outdegree	**22.820**	3.876
betweenness	12.246	7.907
closeness	**19.822**	3.205
Hub function	**21.654**	3.607
authority	0.654	**37.381**

The PCA provides evidence of two dimensions (Figure 2); they explain 88.81% of the data. The first dimension consists of degree, outdegree, closeness, and hub function. The second dimension consists of indegree and authority. The first dimension D1 represents the capacity for ―Control‖; the second dimension D2 depicts what we called ―Attractiveness‖.

The main players: The Ministry of Health [15] - apart from the formal aspect i.e. legal authority and organisation - was highly ranked on the first dimension of control. On the second dimension of attractiveness, it was ranked just above the average. This picture was confirmed in the classification by hub function and authority. The Ministry of Health was a hub as well as an authority in this analysis, whereas the hub feature was more pronounced. This would mean that it was connected to many popular players and received links from important players. The National Government [14] was likewise highly ranked on the first dimension, but showed the lowest score on the second dimension. This means that control was high but the attractiveness was low. On the other hand, the National Government [14] was also a hub, which means that it was connected to many very important players, and its influence might be based on this feature, primarily. The National Health Insurance Fund [1] showed less potential of control [first dimension] than the Ministry of Health [15], but had a higher score on the attractiveness axis [second dimension]. The National Health Insurance Fund [1] was a hub and an authority too. The hub score was lower than that of the Ministry of Health or the National Government, but its authority score was very pronounced. This means, its authority feature - receiving links from important players – in our pilot study was moreimportant.

According to this analysis, effective decentralisation would require more autonomy for institutions like the National Institute of Public Health [3], the National Drug Agency [10], the National Health Council [13], and Non-Governmental Organisations [21], all ranking with the exception of the National Institute of Public Health [3] towards the end in Table 1 and low on both dimensions in Figure 2. But, also the Chambers of Health Professionals [11, 12] could play a more important role as well as the trade unions [20] and the branches of the National Health Insurance Fund [2].

Figure 2. The position of players by twodimensions



Legend: The yellow triangles mark the National Government and the Ministry of Health; the green diamonds signify the players focussed in the analysis; the blue circles represent the remaining players. For the numeric codes, see Table 3 in theannex.

The National Institute of Public Health [3] ranked below average on the first dimension (control) and was positioned above average on the second dimension (attractiveness) that is players were seeking contact. Its high authority score confirmed this, but as a hub it ranked very low (Table 1). According to Borgatti, such players are primarily mediators(37).

Discussion

It is a widespread view in the literature that no single or generally accepted method for measuring decentralization exists (38); there are many different definitions, understandings of the concepts and diverse measurement instruments (39). Thus, measuring centralization or decentralization is mostly based on analyzing the financial autonomy or regulatory mechanisms (39,40). Independent of the underlying ―intellectual tradition‖ (41), disciplinary and language differences, and the way the various indices were constructed, these approaches focus on formal aspects. Informal ways of influence and power are not taken into account. However, these informal relationships may superimpose the formal balance of power, supporting or even hindering structural changes or specific policy-making, and possibly will underestimate the real balance of power. The concept of nodalities, used here, is based on relationships (links). These links cannot only indicate subordination but can also stand for information

channels. Insofar, mapping the nodalities, is complementary to the approaches mentioned above and will round off the picture.

Compared to other European countries, Serbia is among the most centralized systems (42). It ranks second on a list of thirteen countries (38). The analysis of the degree and appropriateness of decentralization, however, is not an end in itself. It is a means to achieve a broader spectrum of goals (43) or, more generally speaking, it is an important component of good governance (38). Very often it is emphasized that decentralization is a very significant step in promoting democracy (44,45). With decentralization essential goals should be achieved, such as effectiveness and efficiency, fairness, quality, financial responsibility, and respect for local preferences (43,45). Decentralization is one of the most important issues on the agenda of health care reform in many countries. However, there is little information from research that can show the likely correlation between the degree of centralization and health outcomes, i.e. the health of the population (40). Furthermore, observations and case studies indicate that, if inadequately planned, and implemented, i.e. too rapidly or inconsistently, decentralization can have serious consequences on the provision of health services to the population (43). For that reason, appropriate planning, and considering corresponding experiences in other countries, may prevent disappointment and slow-down of processes. Decentralization also will shift the role of the Ministry of Health, from direct management and decision making toward formulating health care policies, technical counselling and assistance, as well as monitoring and evaluation of programmes andactivities.

Decentralization represents the transfer of authority and responsibility for public functions from the central to subordinate levels and/or to the private sector (43,45). The essential task, then, is to define the adequate level of decentralization (45) by entities, i.e., regions, districts, and municipalities, and by appropriate forms of bureaucratic autonomy, i.e. deconcentration, delegation, and devolution. Any consideration on whether decentralization is necessary and how much will be feasible has to undergo a detailed examination in the context of a (rational) organisational structure (46); this is very often perceived a common place, and ignored with associated consequences. Certain aspects of decentralization deserve closer attention. For example, the possibility of local authorities to adapt to local conditions should be carefully balanced against a common vision and the goals of the health care system (4). For this reason, the policy of decentralization should include mechanisms of coordination, since the local political interests grow as more responsibilities are transferred to that level (47). Furthermore, decentralization bears the risk of fragmenting responsibility for different types of health care (specialist hospitals, general hospitals, primary care etc.) between the levels of regional and municipal government (43). In this context, it is indicative that the coordinative and integrative potential of the National Health Council of Serbia [13] seemingly is not used. This body could include Non-Governmental Organisations [21] in the field of health, as well as trade union representatives from the most important health institutions.

The limitations of our approach relate to its validity and reliability. A valid model has to be isomorphic, thus representing a true picture of the system to be modelled. The level of isomorphism can be disclosed in analogy to the revision of „validity of structure and processes" (48), or „expert concurrence" (49). However, in this study the boundaries and the linksremain to be crosschecked as a next research step, especially as the present dataset relies only on the author"s evaluation of the situation. Missing data, i.e., the absence of players and/or links can also have an important impact (50,51) on the „application validity". Another criticism that raised concerns relates to the shortest paths-based measures as they do not take intoaccount

diffusion along non-shortest paths (52). However, the modelling algorithms used here are consistent with validated standard computersoftware.

In order to challenge the appropriate level and structure of a health care system and to control any process of reorganisation, it is essential to be fully familiar with the positive interaction of the various players. In this context, it is an important cornerstone to know the nodality of the health care network, in our example that of Belgrade hosting most of the national health institutions. The network depicted would also provide a basis for what-if-scenarios to anticipate the likely effects of intended changes. Furthermore, the methodology used for the network and its description, which examines the system from a relatively high level (bird‟s eye view), can be adapted to specific decision-making situations, and tailored to support specific planning processes.

Conclusion

The advanced methodologies used here to analyse the health care policy network in Belgrade deliver consistent results indicating that the intended decentralization of the health care network in Belgrade may be incomplete, still with low participation of civil society representatives. With the present study we hope to prepare for a broad-range survey-based data collection and to apply the methodology piloted in Belgrade.

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ANNEX

Table 3. List of Players and their correspondingcodes

Work Code	Full name
1	National Health Insurance Fund
2	NHIF, Belgrade Branch
3	National Institute of PublicHealth
4	Institute of Public Health, Belgrade
5	Secretary for Health, Belgrade
6	Primary Health Care Centres (17), Belgrade
7	Clinical Hospital Centre of Serbia
8	Clinical Hospital Centres (4), Belgrade
9	National AccreditationAgency
10	National Drug Agency
11	National Chambers of HealthProfessionals
12	Chambers of Health Professionals, BelgradeBranches
13	National Health Council
14	National Government
15	Ministry of Health
16	Ministry of Finance
17	MOF Budget Inspection
18	State Revisor
19	Serbian Physicians Society
20	Trade Unions
21	Non-Governmental Organisations
22	Medical Faculty, Belgrade
23	Council of the Medical Faculty, Belgrade
24	Special Hospitals, Belgrade
25	Tertiary Medical Institutes, Belgrade

ORIGINAL RESEARCH

Estimating health impacts and economic costs of air pollutioninthe Republic of Macedonia

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Abstract

Aim: This paper assesses the magnitude of health impacts and economic costs of fine particulate matter (PM) air pollution in the Republic of Macedonia.

Methods: Ambient PM_{10} and $PM_{2.5}$ monitoring data were combined with population characteristics and exposure-response functions to calculate the incidence of several health end-points known to be highly influenced by air pollution. Health impacts were converted to Disability-Adjusted Life Years (DALYs) and then translated into economic terms using three valuation approaches to form lower and higher bounds: the (adjusted) Human Capital Approach (HCA), Value of a Statistical Life (VSL) and the COI (cost ofillness).

Results: Fine particulate matter frequently exceeds daily and annual limit values and influences a person‟s day-to-day health and their ability to work. Converting lost years of life and disabilities into DALYs - these health effects represent an annual economic cost of approximately €253 million or 3.2% of GDP (midpoint estimate). Premature death accounts for over 90% of the total health burden since this represents a loss of total life-long income. A reduction of even $1\mu g/m^3$ in ambient PM_{10} or $PM_{2.5}$ would imply 195 fewer deaths and represent an economic savings of €34 million per year in reduced health costs.

Conclusion: Interventions that reduce ambient PM_{10} or $PM_{2.5}$ have significant economic savings in both the short and long run. Currently, these benefits (costs) are „hidden‟ due to the lack of information linking air quality and health outcomes and translating this into economic terms. Policymakers seeking ways to improve the public‟s health and lessen the burden on the health system could focus on a narrow set of air pollution sources to achieve these goals.

Keywords: air pollution, health and economic costs, particulatematter.

Conflicts of interest: None.

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Introduction

According to the Global Burden of Disease (2010) estimates (1), the crude mortality rate from ambient particulate matter (PM) pollution in Macedonia was 80.6 deaths per 100,000 in 2010. In comparable neighboring states such as Serbia, it was 71.8 deaths per 100,000; in Croatia it was 69.4 per 100,000; in Hungary 92.0 per 100,000; and 70 per 100,000 in Slovakia. The total Disability-Adjusted Life Years (DALYs) attributable to PM were about 1,480 per 100,000 in Macedonia (but, up to 1,600 in Hungary) (1).

The main sources of this ambient condition were the use of solid fuel for heating households in the winter, as well as the impact of industry and traffic. Uncontrolled urbanization is also a significant source of particulate matter. In 2009, an average annual concentration of 90μg/m^3 was registered in Skopje. Compounding the situation, poor air circulation is another reason why the capital city of Skopje has one of the worse air conditions inwinter.

Air pollution is also significant throughout the European region, with only nine of the 34 Member States reporting PM_{10} levels below the annual WHO air quality guideline (AQG) of 20μg/m^3. Almost 83% of the population in these cities is exposed to PM_{10} levels exceeding the AQG levels(2).

Results from a recent project *Improving Knowledge and Communication for Decision-making on Air Pollution and Health in Europe* (Aphekom), which uses a traditional health impact assessment method, indicated that average life expectancy in the most polluted cities could be increased by approximately 20 months if long-term $PM_{2.5}$ concentrations were reduced to WHO guidelines (3). One recent study in Macedonia found that an increase of PM_{10} by 10μg/m^3 above the daily maximum permitted level (50μg/m^3) was associated with a 12% increase in cardiovascular disease(2).

Methods

To estimate the health impacts and economic costs of air pollution, the approach required overlaying data from multiple sources. The method used ambient air quality data *[information received from the Ministry of Environment and Physical Planning (MoEPP)]* for PM_{10} and $PM_{2.5}$, health statistics – annual deaths by disease type; frequency of chronic bronchitis, asthma, infant mortality; and health cost data *(information received from the Institute of Public Health and Health Insurance Fund)*, exposure-response functions from health studies *(information from international and local literature)* and population characteristics – age groups, gender, urban/rural population *(information from the state Statistics Bureau)*. These data were combined for a municipal (city) - levelanalysis.

The approach to estimating health impacts and economic costs encompassed fivesteps:

- Collection of monitored, ambient concentration data on PM_{10} and$PM_{2.5}$
- Calculation of exposed population
- Exposure-response functions
- Calculation of physical health impacts (mortality, morbidity,DALYs)
- Monetizing health impacts

Collection of monitored data on fine particulatematter

Currently, the Ministry of Environment and Physical Planning (MoEPP) has a network of 19 Automatic Monitoring Stations: seven in Skopje, two in Bitola, two in Veles and one in Kicevo, Kumanovo, Kocani, Tetovo, Kavadarci, village Lazaropole, and two near the OKTA oil refinery (near the villages of Miladinovci and Mrsevci). Stations measure SO_2, NO_2, CO, PM_{10}, $PM_{2.5}$, ozone, benzene, toluene, ethyl benzene and BTX – although some stations do not measure all pollutants *[monitored $PM_{2.5}$ measurements began in November, 2011 in*

Karpos and Centar. In cases where $PM_{2.5}$ is not actually monitored, observed PM_{10} is adjusted by the ratio $PM_{2.5}/PM_{10}$. The ratio, based on recent observations, is estimated at in the case of Macedonia; and is within ranges found in other international studies. See Ostro (4) for a discussion]. This information is available electronically through their air quality portal (available at: http://airquality.moepp.gov.mk/?lang=en).

Calculation of exposed population

Population information for 2010 was used focusing on the working population as well as vulnerable segments of society *(for example, those under the age of five or older than 65 are considered more vulnerable to the effects of air pollution – that is more prone to develop acute or chronic respiratory ailments).*

Exposure-response functions

The selection of exposure-response functions was based on epidemiological research between PM_{10} and $PM_{2.5}$ and mortality and morbidity. For mortality, exposure-response functions for long-term exposure to $PM_{2.5}$ were (4):

Relative risks (RR) were calculatedas:

Cardiopulmonary (CP) mortality: $RR = [(X+1)/(X_0 +1)]^{0.15515}$

Lung cancer (LC) mortality: $RR = \exp[0.23218 (X-X_0)]$

ALRI mortality in under-five children: $RR = \exp[0.00166 (X-X_0)]$

with: X = current annual average $PM_{2.5}$ concentration for CP and LC among adults, and PM_{10} concentrations for ALRI among children and X_0 = target or baseline $PM_{2.5}$ concentration.

Information on the crude death rate (CDR), CP, LC and ALRI data were used to set the mortality baseline. For morbidity, exposure-response coefficients (annual cases per 100,000 population) for PM_{10} from Ostro (4,5) and Abbey *et al*. (6) were applied. Ostro (4) reflects a review of worldwide studies, and Abbey *et al*., (6) provides estimates of chronic bronchitis associated with particulates (PM_{10}).

A baseline for PM concentrations

A baseline level (natural background concentration) for $PM_{2.5}$ = 7.5 $\mu g/m^3$, as suggested by Ostro (4), was used *(some argue that the baseline should be set at zero since the literature does not support the existence of a concentration level of which there are no observable effects. However a baseline of zero is not realistic since natural background concentrations hover between 10-15 $\mu g/m^3$ in Macedonia – and one would only look at investments which could reduce ambient concentrations to this level (i.e. at least from a benefit-cost standpoint of weighing alternativeinvestments).*

Given a $PM_{2.5}/PM_{10}$ ratio of 0.71 using observations in Macedonia, the baseline level for PM_{10} is 10.6 $\mu g/m^3$. These baseline concentrations were applied to both large and medium/small urban areas.

Calculation of physical health impacts (mortality, morbidity, DALYs)

Using the population information and the exposure-response functions, mortality and morbidity impacts were calculated through the conversion of impacts to DALYs *(DALYs = sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability)*. The DALY method weights illnesses by severity: a mild illness or disability (e.g. morbidity effects) represents a small fraction of a DALY and a severe illness represents a larger fraction (e.g. mortality = 1 DALY). Weights used in this context were adapted from Larsen (7) and are presented in Table 1.

Table 1. Estimated health impacts of air pollution, urban and rural,2010
(Source: World Bank, 2012)

Health impacts	DALYs /10,000 cases
CP mortality($PM_{2.5}$)	80,000
LC mortality ($PM_{2.5}$)	80,000
ALRI mortality (PM_{10})	340,000
Chronic bronchitis (PM_{10})	22,000
Hospital admissions(PM_{10})	160
Emergency room visits (PM_{10})	45
Restricted activity days(PM_{10})	3
Lower respiratory illness in children(PM_{10})	65
Respiratory symptoms (PM_{10})	0.75
Total	

Monetizing health impacts

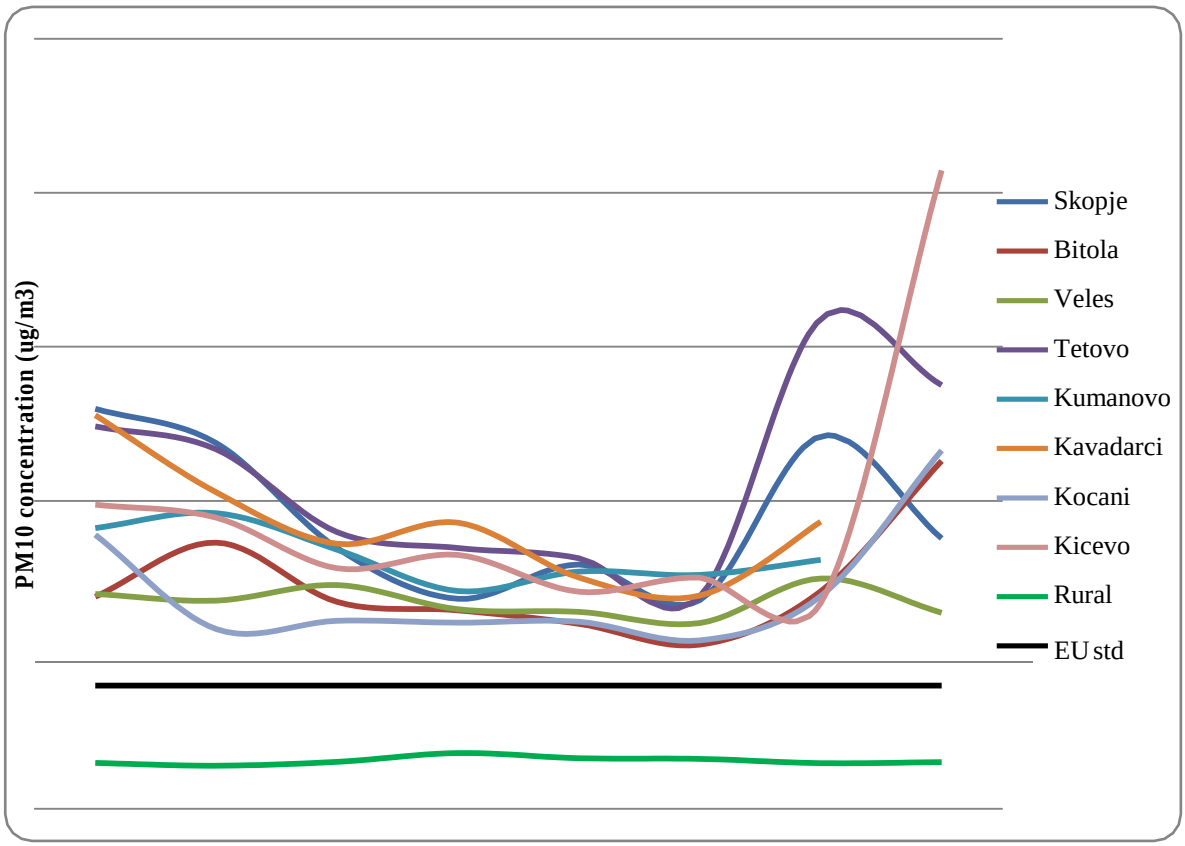
To create a set of bounds three alternative valuation approaches were used: the (adjusted) Human Capital Approach (HCA) *[the adjusted version avoids the issue of assigning a value of zero to the lives of the retired and the disabled since the traditional approach is based on foregone earnings. It avoids this issue by assigning the same value – per capita GDP – to a year of life lost by all persons, regardless of age]*, Value of a Statistical Life (VSL) and the COI (cost of illness). The HCA estimates the indirect cost of productivity loss through the value of an individual‟s future earnings. Thus, one DALY corresponds to one person‟s contribution to production, or GDP per capita. This method provides a realistic lower bound for the loss of one DALY. The VSL measures the willingness-to-pay (WTP) to avoid death – using actual behavior on the tradeoffs between risks and money. The VSL is calculated by dividing the marginal WTP to reduce the risk of death by the size of the risk reduction. Measured this way, the value of one DALY corresponds to the VSL divided by the number of discounted years lost because of death. The VSL typically forms an upper bound measure of health damages. The COI approach estimates the direct treatment costs associated to different health end-points (e.g. hospitalization, restricted activity days, and doctor visits). Mortality was valued using HCA as a lower bound and the VSL as an upper bound. For morbidity effects the COI was estimated as a lower bound and willingness-to-pay to avoid a case of illness was applied as a higher bound of cost (WTP was assumed to be two times theCOI).

Results

Air quality data support the finding that particulate matter is one of the most serious concerns in the country. Ambient PM_{10} concentrations frequently exceeded the EU standard of $40\mu g/m^3$ over the years (Figure 1).

Using information on ambient PM_{10} and $PM_{2.5}$ in conjunction with the methods outlined above, it is estimated that in Macedonia 1,350 deaths occur annually from cardiopulmonary disease and lung cancer (Table 2). These deaths are considered „premature“ in the sense that air pollution contributed to their early demise – since many factors actually influence a persons‟ lifespan (e.g. smoking, exposure to the outdoors, job, etc.). Particulate matter can also influence a person‟s day-to-day health and their ability to work. In 2011, levels of PM_{10} and $PM_{2.5}$ were primarily responsible for 485 new cases of chronic bronchitis, 770 hospital admissions, and 15,200 emergency visits.

Figure 1. Annual average PM_{10} concentration at each automatic monitoring stationin µg/m^3 *(Source: Ministry of Environment and Physical Planning,2012)*



What do these translate to in terms of a total cost to society? Converting lost years of life and disabilities to DALYs (or disability-adjusted life years) - these health effects represent an annual economic cost of €253 million or 3.2% of GDP (Table 2). Note that premature death accounts for over 90% of the total health cost since the loss of life is a loss of total (future) income. People also suffer from the day-to-day consequences of respiratory diseases. It is estimated that several thousand work-years are lost annually from chronic bronchitis, asthma, hospital admissions and days of restricted activity.

These estimates are consistent with other recent studies – such as Kosovo where annual deaths were estimated to be in the range of 805-861 from cardiovascular disease and lung cancer (8). It should be noted that our estimates are mid-points (middle) with lower and higher ranges reflecting different assumptions made on the $PM_{2.5}/PM_{10}$ ratio and the population‟s exposure to airpollution.

What are the potential benefits of reducing particulate matter? If Macedonia were to lower PM_{10} and $PM_{2.5}$ to EU limit values this would avoid over 800 deaths and thousands of days in lost productivity – representing a health cost savings of €151 million per year (Table 3). A reduction of even 1µg/m^3 in ambient PM_{10} and $PM_{2.5}$ would result in 195 fewer deaths (1,648 fewer DALYs) and imply an economic savings of €34 million per year in reduced health costs.

Table 2. Number of annual cases, DALYs per year and economic cost in millionEuros, 2011 *(Source: authors' calculations)*

Health impact	Annual cases*	Total DALYs per year	Annual economic cost (€ million)
Cardiopulmonary & lung cancer mortality($PM_{2.5}$)	1,351	10,809	232.0
ALRI† mortality(PM_{10})	1	17	0.1
Chronic bronchitis (PM_{10})	485	1,066	3.0
Hospital admissions(PM_{10})	770	12	0.4
Emergency room visits(PM_{10})	15,200	68	0.9
Restricted activity days(PM_{10})	3,213,000	964	8.6
Lower respiratory illness in children(PM_{10})	22,400	146	1.5
Respiratory symptoms(PM_{10})	10,197,000	765	6.8
Total		*13,847*	*253.3*

* Mid-point estimates using a baseline for PM_{10}= 15 µg/m^3 and $PM_{2.5}$= 7.5 µg/m^3

† ALRI: Acute Lower RespiratoryInfections.

Table 3. The potential health 'savings' associated with reductions in PM_{10} and $PM_{2.5}$ (€ million) *[Source: authors' calculations]*

Level of reduction in ambient PM_{10} and $PM_{2.5}$(µg/m^3)*	Reduced DALYs	Annual health savings (€ million)
0	0	0.0
1	1,648	34.1
5	4,894	98.9
10	6,636	133.6
15	8,059	161.5
20	9,275	184.9
EU standards met†	7,840	151.5

* Example reductions were equally applied to both PM_{10} and $PM_{2.5}$ at the same time.

† PM_{10} = 40 µg/m^3 and $PM_{2.5}$= 20 µg/m^3.

Discussion

There is significant evidence of the effects of short-term exposure to PM_{10} on respiratory health, but for mortality, and especially as a consequence of long-term exposure, $PM_{2.5}$ is a more robust risk factor than the coarse part of PM_{10} (particles in the 2.5–10 µm range). All-cause daily mortality is estimated to increase by 0.2 - 0.6% per 10 µg/m^3 of PM_{10} (9). Furthermore, it has been estimated that exposure to $PM_{2.5}$ reduces life expectancyby about months on average in the European Region. Results from the study ―Improving Knowledge and Communication for Decision-making on Air Pollution and Health in Europe‖ (Aphekom), which uses traditional health impact assessment methods, indicates that average life expectancy in the most polluted cities could increase by approximately 20 months if long- term $PM_{2.5}$ concentrations were reduced to WHO annual guidelines (10).

Monitored PM_{10} and $PM_{2.5}$ concentrations have repeatedly exceeded EU standards in Republic of Macedonia and have contributed to short-term and chronic respiratory disease. This study estimated an annual (mid-point) loss of approximately 1,350 lives with thousands of lost-productive days, indirectly costing the economy up wa rds of €253 million or 3.2% of GDP in 2011. The specific exposure-response functions used in this study were

borrowed from the international literature – however the orders of magnitude have been shown to be robust in many developing country applications after adjusting for local conditions(4,5,7,8).

From a policy standpoint, it is important to note that these estimated costs are generally ―hidden‖ since they are not normally quantified, and benchmarked to the value of economic activity that generated the pollution (i.e. GDP). Likewise the distribution of this burden is shared between the general public and the health care system – so total costs are not transparent. The results should motivate policy makers to be more focused on preventative measures, among them, local green options to reduce particulate matter including energy efficiency, fuel switching and the adoption of cleaner technologies. The benefits from such actions should find their way into the benefit-cost analysis of associated investments since the health ―savings‖ could offset theinvestment costs of greeninginterventions.

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ORIGINAL RESEARCH

Health and health status of children in Serbia and thedesired Millennium DevelopmentGoals

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Abstract

Aim: Children represent the future, and ensuring their healthy growth and development should be a prime concern of all societies. Better health for all children is one of the leading objectives of the National Plan of Action for Children and a key element of the tailored Millennium Development Goals forSerbia.
Methods: Our analysis was based on relevant literature and available information from the primary and secondary sources and databases. We analyzed health status of children that can be illustrated by indicators of child and infant mortality, morbidity, and nutritional status.
Results: There has been a significant reduction in the mortality rates at the national level, particularly with regard to infants and children under five years of age. However, the current mortality rate of Roma children is still three times as high as the Millennium Goal set at the national level for Serbia. Most deaths of children under the age of five are due to preterm birth complications, congenital anomalies, birth asphyxia and trauma, pneumonia and sepsis. The rate of malnourished children among the poor and in Roma settlements is twice as high as in the general population of Serbian children. A growing number of obese children was also noted in the Roma population.
Conclusion: Political awareness, commitment and leadership are required to ensure that child health receives receive the attention and the resources needed to accelerate the progress of Serbia.

Keywords: children, health status, Millennium Development Goals,Serbia.

Conflicts of interest: None.

Introduction

A comprehensive understanding of the children‘s and women‘s health as a state of complete physical, mental and social wellbeing (1) is essential to the health of current and future generations. Almost every culture holds that a society has a responsibility to ensure a nearly equal start in life for children, which implies developing their full health potential (2). However, there are still significant ethnical and regional differences that need to be considered while developing the global health policy framework. The differences in people health are determined by their exposures to health risks, which are, in turn, the social determinants of health (3). The prevention of disease requires overall investment in the social determinants of health and reduction of inequalities and unfairness inhealth.

The foundations for adult health and, indeed, the health of future generations are laid in early childhood and even before birth. Therefore, better health for all children is one of the leading objectives of the National Plan of Action for Children (4) and a key element of the tailored Millennium Development Goals forSerbia.

Progress in the reduction of child mortality is one of the leading public health challenges in all countries (1). Reducing child mortality is also one of the Millennium Development Goals, and the first of the total of 27 goals adopted at the World Summit for Children. It has also been incorporated into many national plans of action for children. In spite of major improvements, national reports on progress in attaining the Millennium Development Goals, even in countries in which child mortality has been reduced by two thirds on the average, highlight that the problem is still present in rural areas, among people living below the accepted poverty line and – as regards Southeastern Europe – in particular, among Roma subpopulations (1,5). Child mortality due to preventable causes is further compounded by poverty, unfavorable living conditions, low educational level of mothers, social exclusion, neglect, violence against children and insufficiently accessible antenatal and postnatal health care (6,7). Deaths among children under the age of five years represent one of the most serious challenges currently faced by the international community. To address this challenge, it is necessary to measure accurately the levels and causes of mortality among this population group (8). Major causes of under-five mortality remain the same globally; their relative importance varies across regions of the world. While in low-income countries infectious diseases account for a large proportion of under-five deaths, the main killers of children in high-income countries are non-communicable diseases such as congenital anomalies, prematurity, injuries and birth asphyxia (9). Monitoring of the nutritional status plays an important role in the analysis of the health of children, particularly when health risks and preventive actions need to be assessed and considered. Irregular and insufficient nutrition during infancy and later can significantly impair the growth and development of children and have adverse health effects (physical fitness, mental functions, immune system). At the same time, excessive food intake and an imbalanced diet may also result in obesity and negative health consequences (10).

The aim of our study was to analyze children mortality rates in Serbia, leading causes of death, differences in mortality rates between the average population of children and Roma children and diet and nutritional status of children under the age of fiveyears.

Methods

This situation analysis has been done on the basis of relevant literature and available information from the following primary and secondary sources anddatabases:

- Published documents including strategies, policies, programs, plans, laws and other regulations of the Government of the Republic of Serbia, health regulations and guidelines of the Ministry of Health, published reviews, scientific and professional articles on health and health status of the Serbian population in national and international journals, national surveys and project reports of international organizations (UNICEF, WHO, EU, World Bank) that deal with issues of children‘s and women‘s health in Serbia;
- Publications in the area of routine health statistics, national e-databases (Institute of Public Health of Serbia, Dr. Milan ―Jovanović Batut‖, Statistical Office of the Republic of Serbia and international e-databases (WHO/Eurostat) for comparison purposes.

This statistical information often is only available in aggregated sets of data which do not allow for detailed analyses.

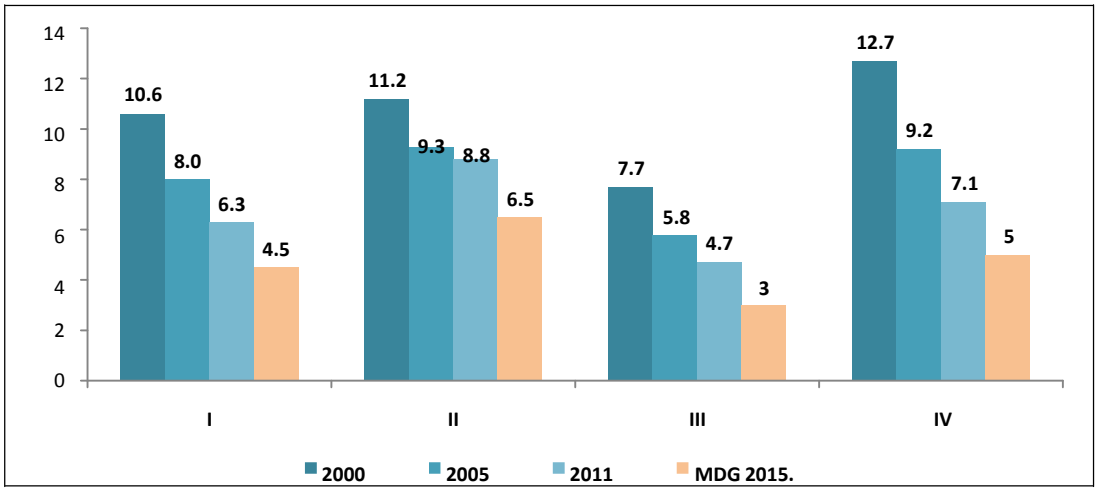
Health outcomes and health status of children are illustrated by the following indicators: infant mortality rate (deaths of children in the first year of life), perinatal mortality rate (fetal deaths from the 22nd week of gestation or achieved 1000g in intrauterine development and deaths by the seventh day of life), neonatal mortality rate (deaths in the first 27 days of life only), and morality of children under five years of age (deaths before children turn five years); morbidity, nutritional status and comparisons with relevant national and international benchmarks and objectives. A special focus was placed on disparities and social inequalities in health among population groups within Serbia, which are considered unfair, unjust, avoidable and unnecessary.

The results were presented in tables andgraphs.

Results

In Serbia, there has been a significant reduction in the mortality rates at the national level, particularly with regard to infants and children under five (Figure 1), while the reduction of the mortality rate in the prenatal period was somewhat morelimited.

Figure 1. Children mortality rates in Serbia: Situation analysis and the desired Millennium Goal by 2015



I-infant mortality rate; II-perinatal mortalityrate; III-neonatal mortalityrate; IV-children under 5-yearmortalityrate.

Mortality among Roma children remains high, the rate has almost halved over the last five years bringing the number closer to the national Millennium Goal of reducing Roma under-five child mortality to 14 and infant mortality to 12. However, the current mortality rate of Roma children is still three times as high as the Millennium Goal set at the national level for Serbia (Figure2).

Figure 2. Differences in mortality rates between the average population of childrenand Roma children in 2005 and 2010 in Serbia

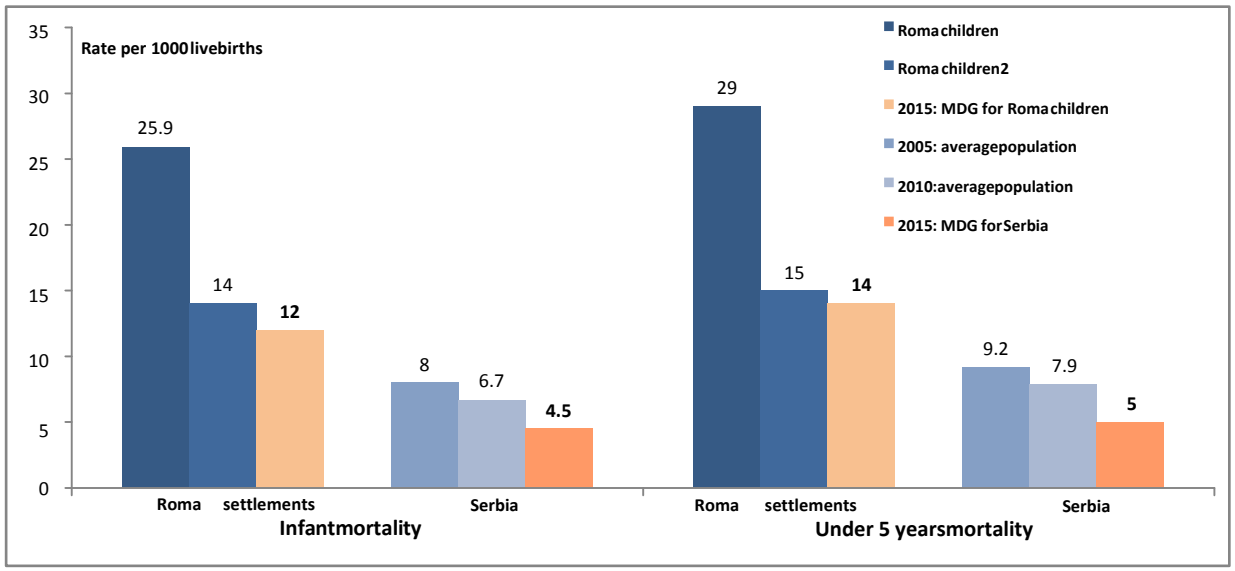
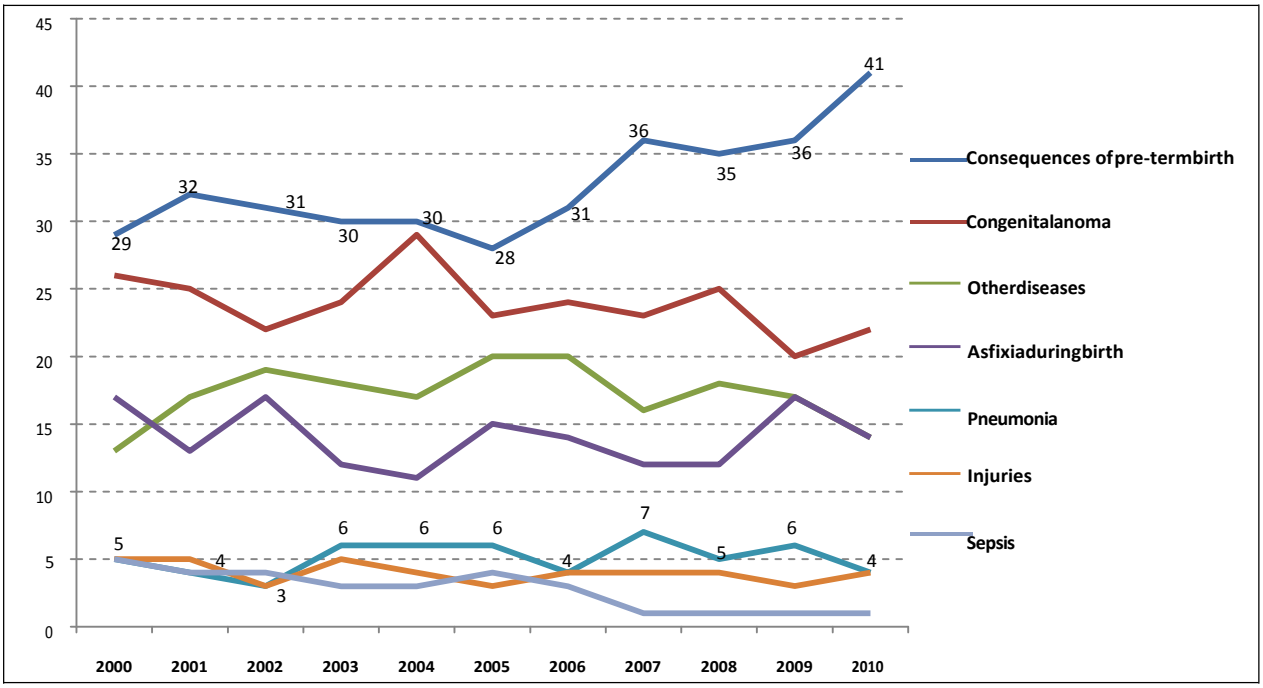


Figure 3 presents the leading causes of death in Serbian children under-five years. Most deaths of under-five children are due to preterm birth complications, congenital anomalies, birth asphyxia and trauma, pneumonia andsepsis.

Figure 3. Distribution of the leading causes of death of children under-five inSerbia



The indicators of diet and nutritional status of children under-five years of age are presented in Table 1. The rate of malnourished children among the poor and in Roma settlements is twice as high as in the general population of Serbian children. Surprisingly, a growing number of obese children were also noted in the Roma population, from 6.7% to 12.8%, which points to irregular nutrition. The corresponding Millennium Development Goal in Serbia aims to bring the share of obese children down to 9.1% by 2015. Breastfeeding habits have not substantially changed, except in the Roma population where the number of exclusive breastfeeding up to the age of six months has decreased. The rate of exclusive breastfeeding is still only half of the desired Millennium Development Goal in Serbia (30% of exclusively breastfed children from birth until the six month ofage).

Table 1. Diet and nutritional status of children under five years of age in 2005 and 2010 in Serbia

Indicator	Serbia		The poor		Roma settlements		MDG
	2005	2010	2005	2010	2005	2010	2015
Live births with low birthweight	4.9	4.8	8.6	8.3	9.3	10.2	
Percent of children first breastfed within a day after birth	68.8	61.9	71.7	69.1	72.5	70.3	
Percent of children with exclusive breastfeeding for the first sixmonth	14.9	13.7	15.4	19.5	18.0	9.1	30.0
Percent of children 6-23 months who receive the minimum number ofmeals	Na	84.3	na	80.0	na	71.9	
Prevalence of malnourishment among children under-five (body weight for the given height ≤-2SD)	3.2	2.3	3.8	5.2	4.1	5.2	
Prevalence of obesity among children under-five (body weight for the given height ≤-2SD)	15.6	12.7	15.5	12.5	6.7	12.8	9.1

Discussion

This situation analysis covers the health status of Serbian children that can be illustrated by indicators of child and infant mortality, morbidity and nutritional status which are compared with relevant national and international benchmarks and objectives. A special focus was placed on disparities and social inequalities in health among population groups within Serbia, which are considered unfair, unjust, avoidable and unnecessary since they open a systematic burden on vulnerable population groups. It is believed that the unfair differences in health of children result from social structures and political, economic and legal relations: they are derived from the system, and are result of the social system (so that they can be changed) and they are unjust (11). Marmot insists that they are not a natural phenomenon by any means; instead, they are a combination of poor conditions and low standards of living, poverty, risky life-styles, social exclusion, scarcely formulated, inappropriate health programs and sometimes toxic national and local policies(12).

Infant mortality is generally regarded as a basic indicator of population health and a measure of long-term consequences of perinatal events. This parameter is particularly

important for monitoring and assessing health outcomes in high risk groups such as pre-term children and children with developmental difficulties. Trends show that Serbia has made significant progress towards the Millennium Development Goal relating to infant mortality (13,14).

An analysis of routine statistical data, although infant mortality is still above the European Union–27 average (for example, in 2010, the EU-27 infant mortality average was 4.1 vs. 6.7 in Serbia), suggests that Serbia may achieve the proposed national Millennium Goals in 2015: an infant mortality rate of 4.5 and an under-five mortality rate of 5 per 1000 live births. Earlier comparisons of infant mortality revealed rates in Serbia two times higher than the EU rates, but this difference has been substantially reduced to date (15,16).

Recent studies conducted by UNICEF and other organizations indicate that the majority of the Roma population face social disadvantage and exclusion, and most of them live in poverty (17). Many Roma individuals are also unemployed, have limited education, as well as insufficient access to information, which combined with a lack of trust in institutions often prevent them from using healthcare services in case of need. The Multiple Indicator Cluster Surveys (MICS), which have been conducted periodically in Serbia since 1996 with the help of UNICEF, have been extremely valuable in gaining a better understanding of the challenges involved. From 2005, these surveys have provided assessments of child mortality in the Roma population using the *Brass* method for estimating child mortality taking into account the risk of death to which the children are exposed to (18). Although mortality among Roma children remains high, the rate has almost halved over the last five years bringing the number closer to the national Millennium Goal of reducing Roma under-five child mortality to 14, and infant mortality to 12. However, the current mortality rate of Roma children is still three times as high as the Millennium Goal set at the national level for Serbia (15).

According to the World Health Organization, most deaths of children under the age of five years are due to a small number of diseases and conditions. Forty-three per cent of these deaths occur among babies aged 0-28 days (newborns) and are mainly due to preterm birth complications, birth asphyxia and trauma, and sepsis. After the first 28 days until the age of five years, the majority of deaths are attributable to infectious diseases such as pneumonia (22%), diarrhoeal diseases (15%), malaria (12%) and HIV/AIDS (3%)(8,9).

While international efforts to address mortality among children under the age of five have resulted in significant reductions globally, persistent inequities between and within countries exist. These are not only driven by poverty, but are intrinsically linked to social exclusion and discrimination. Therefore, continued efforts to eliminate under-five mortality must take into consideration both direct causes and underlying determinants. This requires a comprehensive and holistic approach,which must explicitly recognize human rights‘ standards as essential and integral elements.

Also, poor nutritional status in children is strongly correlated with vulnerability to diseases, delayed physical and mental development, and an increased risk ofdying. While, between 1990 and 2011, the proportion of children under the age of five years who were underweight declined by 36%, under-nutrition is still estimated to be associated with 45% of child deaths worldwide. In 2011, there were 165 million children under the age of five years who were stunted, and 52 million who were wasted (10,19,20). Low birth weight is closely associated with increased risks of neonatal mortality, cognitive problems and chronic diseases in later life (20). Our

analysis shows that the national average share of live births with low birth weight (under 2,500 grams) has remained constant in Serbia in the last decade. The share of low birth weight is significantly higher for Roma and poorchildren.

More preventive approaches and consistent efforts for improvement are needed in Serbia, to ensure that child health receives the attention and resources needed and secure the benefits that children and familiesrequire.

Identifying the health outcomes that matter most for the children, and set out the contribution that each part of the health system needs to make in order that desired health outcomes are achieved, would be an effective way to reachprogress.

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ORIGINAL RESEARCH

Adverse effects of maternal age, weight and smoking during pregnancy in Pleven, Bulgaria

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Abstract

Aim: This paper aims to study the relationship between mothers‘ age, body mass index (BMI), gestational weight gain (GWG) and smoking and the risk for premature birth in Pleven, Bulgaria.

Methods: A case-control study was conducted in Pleven in 2007. The study was comprehensive for all premature children (N=58) and representative for full-term infants (N=192, or 10.4% of all of the 1827 full-term children) born in 2007 at the University Hospital of Pleven and resident in the city of Pleven. Retrospective data on determinants under study were collected from all the mothers included in this study(N=250).

Results: Mothers of premature children were more likely to be above 35 years old (27.6%), with a BMI ≥25 kg/m² (23.1%), GWG below the recommended value (38.5%) and to smoke during pregnancy (37.9%). The odds of being a smoker during pregnancy were five times higher among mothers with low birth weight (LBW) newborns compared with their counterparts with normal birth weight newborns (OR=5.1, 95%CI=2.4-10.6). There was a positive association between BMI and LBW in infants whose mothers were overweight (OR=2.1, 95%CI=1.0-4.0). The risk of LBW increased when GWG was less than recommended (OR=1.8, 95%CI=1.0-3.1).

Conclusion: Our results indicate that pre-pregnancy BMI ≥25 kg/m², less than recommended GWG and smoking during pregnancy are risk factors for premature birth in Pleven region. Findings from this study suggest the need for active health and educational actions by health professionals in order to avoid premature births inBulgaria.

Keywords: Bulgaria, lifestyle, Pleven, premature birth, riskfactors.

Conflicts of interest: None.

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Introduction

Premature birth (PB) is a major public health problem worldwide (1). Furthermore, PB is rated as one of the most important single causes of the global burden of diseases in neonatal period (2). It is associated with increased infant mortality, short and long-term negative effects on health and additional costly care needs(3).

The interest of researchers in personal characteristics and lifestyle factors of the mothers is due to the fact that they are modifiable and they affect the incidence of premature birth. The challenge is to accurately measure the impact of these factors because of their complexity (4). Several studies have shown young maternal age as a significant risk factor for premature birth (5,6). It has not been established with certainty yet, whether this risk is associated primarily with the biological immaturity of young mothers, or an increased incidence of certain risk factors associated with socioeconomic status such as age-appropriate educational level, parity, smoking status, prenatal care utilization and poverty status (7,8). Women over the age of 35 years are also at increased risk of pre-term birth. Astolfi and Zonta (2002) found a 64% increase in the probability of giving premature birth for women over 35 years after controlling for educational status, birth order, and sex of the newborns(9).

Low or high pre-pregnancy body mass index (BMI) and inadequate or excess gestational weight gain (GWG) are linked to an increased risk of adverse neonatal outcomes (10,11). The weight of a woman before the pregnancy is related to her diet, quantity and quality of food (4). Studies have shown that low weight of women before pregnancy is associated with an increased risk of preterm birth (12). Campbell et al. (2012) found a link between low pre-pregnancy BMI and the birth of a premature baby, with a relative risk of >2.5 (6). A study conducted in 2010 in Bulgaria on the role of some risk factors for preterm birth failed to establish a statistically significant difference in the weight of women bearing preterm children and those with to term births (13).

Smoking is defined as one of the most common and preventable causes of adverse outcomes of pregnancy (14,15). Many chemicals in maternal smoking pass from the pregnant woman to the fetus through the placenta (16). Smoking is associated with placental abruption and inadequate weight gain during pregnancy, but this relationship with the birth of a premature baby is not conclusive and is not proven in all studies. The probable reason for this is that the impact of smoking depends on its duration and intensity, and decreases in women who stop smoking at the beginning of pregnancy (17). Some studies have found a strong causal association between smoking and PB of a child (18). A large number of studies have found a moderate influence of smoking in relation to PB of a baby(14,16,17).

Bulgaria is a country that is characterized by one of the highest indicators of age-specific fertility rate (above 40 per 1000) in Europe in the age-group 15-20 years, which is a risk factor for giving birth to a premature baby (19). According to Manolova (2004), 42.3% of women in Bulgaria smoked during pregnancy (20). However, prematurity as a public health issue has not been subject to scientific inquiry in Bulgaria in the past two decades. Yet, there are a small number of scientific publications in terms of risk factors for PB in Bulgarian children (21).

In this context, there is a need to determine the lifestyle characteristics of mothers as important factors for PB in Bulgaria. This paper aims at studying the relationship between mothers‘ age, BMI, GWG and smoking during pregnancy and the risk for PB in the city of Pleven, Bulgaria. We hypothesized a positive association between PB and younger or older age and smoking habits of the mothers. Furthermore, we assumed a positive link between low BMI and low weight gain during pregnancy andPB.

Methods

Study design

A case-control study was carried out in 2007 in the city of Pleven, Bulgaria. Pleven is a typical township, located in Central North Bulgaria. At the beginning of the study (in 2007) the size of the population of the city was 139,573 people. In the same year, the birth rate was 8.96‰. Maternal care was carried out only by the University Hospital. There were 2004 children born at the University Hospital, of whom, 1981 were live births. The proportion of preterm infants among all live births was 7.7%.

Study population

The anticipated sample size for inclusion in this study consisted of 250 newborns. The study was comprehensive for all premature children (N=58) and representative for full-term infants (192, or 10.4% of all 1827 full-term children) born in 2007 at the University Hospital of Pleven and resident in the city of Pleven.

Cases: 58 premature infants weighing 2500 g or less at birth. Their gestational age was 37 weeks or less, and they resided in Pleven.

Controls: 192 term infants who were matched to premature infants by date of birth. They were selected randomly among preterm children born on the same date. They weighed more than 2500 g. Their gestational age was more than 37 weeks and they also resided inPleven.

Data collection

Document analysis: The information on birth weight, gestational age and home addresses of newborns was derived from medical records in a neonatal clinic at the University Hospital-Pleven.

Interview: The information for mother‘s age, weight of women before the pregnancy, weight gain during pregnancy and smoking habits was gathered retrospectively by interviewing mothers during home visits. Such information was not available in the records of mothers in the obstetrics ward, and not all women retained documents from antenatal visits.

Special questionnaires were designed for the purpose of the study. They were part of a larger study on risk factors for premature birth in the region of Pleven, Bulgaria. The questionnaire used for the documents‘ analysis contained 39 questions, four of which were related to demographic and socio-economic status of the mother. The questionnaire for the interview comprised 92 questions, nine of which were about the lifestyle factors of the mother. For the validation of the questionnaires, a pilot study was conducted. Before and after the pilot study questionnaires were discussed and approved by experts, pediatricians, obstetricians and public health professionals.

All included mothers answered the questionnaire in the process of an interview. All data in this study were based on women‘s reports during the surveyinterviews.

Ethical considerations

The study was conducted under the supervision of the Chair of the IRB (Institutional Review Board). The right of privacy of the studied subjects was guaranteed. Only the leading investigator had access to the identifying information. Mothers expressed their free will for participation and signed an informed consent before theinterview.

Outcomes

We studied two outcomes: preterm birth (PB<37 weeks completed gestation and birth weight <2500 g) and low birth weight (LBW: birth weight <2500g).

Determinants

Age of the mothers was determined as: ≤24 years, 25-29 years, 30-34 years and ≥35 years.
Pre-pregnancy BMI was categorized according to the World Health Organization (WHO) as either being underweight (BMI<18.5kg/m²), normal weight (18.5≤ BMI≤ 24.9), overweight (25≤BMI≤29.9), or obese(BMI≥30).
We utilized the 2009 Institute of Medicine guidelines on GWG to categorize women's weight gain for their BMI as below, within, or above the recommended value(22).
Smoking during pregnancy was determined based on the question *"Did you smoke during pregnancy?"*. Women who responded *"yes"* or *"rarely"* were categorized as ―regular smokers‖ and―occasionalsmokers‖.

Statistical analysis

The survey data was processed with the statistical software packages SPSS (Statistical Package for Social Sciences), version 11.5, STATGRAPHICS and EXCEL forWindows.
The results were described using tables. Percentages were used to report the observed distribution of age of the mothers, BMI, GWG, smoking during pregnancy and other maternal characteristics.
Parametric tests for hypotheses testing at normal and near to normal distribution of cases: T-test, ANOVA with post hoc tests (LSD, Tukey, Scheffe, Bonferroni, Newman-Keuls, Duncan) and nonparametric tests in other than normal distribution of cases Pearson χ^2-test, Mann-Whitney, Kruskal-Wallis H-test were applied. Regression models for modeling and predicting of correlations and multiple logistic regression analyses controlled for covariates estimated the odds ratios with 95% confidence intervals of PB and LBW wereused.
Using multivariable linear regression we assessed the relationships of studied determinants with outcomes (PB, LBW). Odds ratios (OR) were calculated to determine the effect of the age, weight and smoking during pregnancy, as factors for pretermbirth.
In all cases, a value of P≤0.05 was considered as statisticallysignificant.

Results

Table 1 presents the distribution of basic characteristics of the participants by PB status. The distribution of maternal characteristics varied across mothers with PB and termbirth.
Overall, 17.2% of women were above 35 years old. The share of older mothers was two times higher among those with PB compared to women with term-birth. Overall, 23.3% of women were underweight and 12.5% were either overweight or obese. The proportion of overweight was more than two times higher among mothers with PB (19.2%) compared to mothers with term-birth (9.6%). Around half (48.8%) of women gained above than the recommended weight for their BMI and a quarter (24.6%) gained less than the recommended weight. About 39% of women with PB compared to 21% of mothers with term-birth gained less than the recommended weight. Smoking was reported by 38% of women: 16% of them were regular smokers and 22% occasional smokers. The proportion of mothers with PB who smoked (38%) was about four times higher compared to smoking women with term-birth(10%).
Compared to mothers with term-born infants, mothers of premature children were more likely to be above 35 years (27.6%), have a BMI≥25 (23,1%), have a GWG below the recommended value (38.5%), smoke during pregnancy (37.9%) and deliver PB children after the third delivery (17.2%). Significant differences among mothers with PB were identified for maternal age, pre-pregnancy BMI, GWG, maternal smoking during pregnancy and birth order. Conversely, there was no significant difference between groups with regard to their income level.

Table 1. Distribution of maternalcharacteristics

Characteristics	All wome n (N=250)	Mothers with premature birth (N=58)	Mothers with term birth (N=192)	P
Maternal age				
≤24 years	25.8	10.4	30.5	0.001
25-29 years	27.4	37.9	24.2	0.049
30-34 years	29.1	24.1	30.5	NS
≥35 years	17.2	27.6	14.8	0.047
Pre-pregnancy BMI				
<18.5 kg/m^2	23.3	15.4	25.5	NS
18.5-24.9 kg/m^2	64.2	61.5	64.9	NS
25.0-29.9 kg/m^2	11.7	19.2	9.6	NS
≥30 kg/m^2	0.8	3.9	-	-
Gestational weight gain				
<recommended	24.6	38.5	20.7	0.010
= recommended	26.7	26.9	26.6	NS
> recommended	48.8	34.6	52.7	0.020
Smoking during pregnancy				
Regularly	16.1	37.9	9.5	0.001
Occasionally	21.8	10.3	25.3	0.002
No	62.1	51.8	65.2	NS
Per capita income				
Lowest (0-125 Euro)	36.0	41.4	34.4	NS
Middle (126-250 Euro)	46.4	41.4	47.9	NS
Highest (>250 Euro)	17.6	17.2	17.7	NS
Birth order				
1	52.4	41.4	55.8	0.050
2-3	41.2	41.4	41.1	NS
≥4	6.4	17.2	3.1	0.005

Table 2. Maternal characteristics correlated with normal birth-weight and lowbirth-weight(g)

Characteristics	All (n=250)		Linear regression: Low birth weight (N=58)		Linear regression: Normal birth weight (N=192)		Logistic regression: Low birth weight	P
	Mean±SE	P	Mean±SE	P	Mean±SE	P	OR (95%CI)	
Maternal age								
25-29	3120±85	-	2297±45	-	3491±46	-	Reference	-
≤24	3219±69	NS	2256±47	NS	3318±62	NS	0.22 (0.08-0.58)	0.001
30-34	3168±71	NS	2361±43	NS	3318±53	NS	0.50 (0.23-0.99)	0.048
≥35	2790±127	0.007	1876±88	0.001	3312±71	0.005	1.19 (0.54-2,65)	0.600
Pre-pregnancy BMI								
18.5-24.9	3185±59	-	2149±90	-	3427±41	-	Reference	-
<18.5	3124±72	NS	2163±72	NS	3284±56	NS	0.64 (0.27-1.48)	0.280
25.0-29.9	2844±101	0.040	2296±45	NS	3148±96	0.001	2.12 (1.02-4.03)	0.049
≥30*	2400±0	0.010	2400±0	NS	-	-	-	-
Gestational weightgain								
= recommended	3158±84	-	2300±44	-	3347±64	-	Reference	-
<recommended	2955±74	0.020	2307±40	NS	3287±61	NS	1.83 (1.04-3.08)	0.048
> recommended	3191±66	NS	1971±146	0.002	3402±46	NS	0.65 (0.30-1.41)	0.270
Smoking duringpregnancy								
No	3192±60	-	2065±92	-	3437±40	-	Reference	-
Regularly	2666±72	0.001	2328±29	0.030	3080±86	0.001	5.05 (2.41-10.58)	0.001
Occasionally	3162±66	NS	2333±58	NS	3265±58	0.001	0.52 (0.20–1.32)	0.160

* Only two children weighing 2400 g were born from mothers with BMI≥30.

Table 2 shows that maternal age at delivery, GWG and smoking during pregnancy were significantly associated with LBW.

Mothers who smoked regularly had a significant fivefold increase in LBW risk compared with nonsmoking mothers (OR=5.05, 95%CI=2.41-10.58, P=0.001). The association between BMI and LBW was evident among infants whose mothers' were overweight (OR=2.12, 95%CI=1.02=4.03, P=0.049). We did not assess obesity as a risk factor for LBW, because there were no mothers of children with normal birth weight who had a BMI≥30. The risk of LBW increased when GWG was less than the recommended value (OR=1.83, 95%CI=1.04-3.08, P=0.048).

Age of the mothers upon delivery less than 24 years (OR=0.22, 95%CI=0.08- 0.58, P=0.001) and between 30-34 years (OR=0.50, 95%CI=0.23-0.99, P=0.048) was found as a protective factor for LBW.

Table 3 shows the results of fitting a multiple linear regression model to describe the relationship between prematurity and three independent variables: pre-pregnancy BMI, GWG and maternal age. The model explains 93% of the variability in PB.

The equation of the fitted model was as follows:

PB = 87.6117*BMI + 41.0981*GWG + 9.6293*Maternal age

Table 3. Multiple regression analysis: Pre-pregnancy BMI, GWG and maternal age correlated with premature birth

Dependent variable: premature birth				
Parameter	**Estimate**	**Standard Error**	**T Statistic**	**P**
Pre-pregnancy BMI	87.6117	12.4486	7.03787	0.001
Gestational weight gain	41.0981	7.13523	5.75988	0.001
Maternal age	19.6293	8.4454	2.32426	0.021

Analysis of Variance					
Source	**Sum of Squares**	**Df**	**Mean Square**	**F-Ratio**	**P-Value**
Model	2.30485E9	3	7.68283E8		0.001
Residual	1.70403E8	235	725119.0		
Total	*2.47525E9*	*238*			

R-squared = 93.1157 %; R-squared (adjusted for d.f.) = 93.0571 %; Standard Error of Est. = 851.539; Mean absolute error = 646.141; Durbin-Watson statistic =1.04712.

Discussion

This study provides useful evidence about PB and LBW in the region of Pleven, Bulgaria. Our results indicate that pre-pregnancy BMI, GWG related with personal BMI and smoking during pregnancy are important characteristics for PB in this population.

The age of the mother is essential for normal pregnancy and delivery with a favorable outcome. From a biological point of view, the best age for childbirth is 20-29 years (8). The average age of women in our study was 26.3±5.8 years which was non-significantly lower than the average age for childbirth established in Bulgaria (27.9 years of age) (23) and also lower than that established by Yankova and Dimitrov (2010) who stated an average age of 28 years at birth (24). The results for more than a twofold increased risk of premature birth to mothers aged under 20 years were reported by Branum and Schoendorf in 2005 (25). The association between the risk of a preterm labor and mother's age is reported to be inverse (21,26), but we did not establish this. We found the age of the mothers at delivery less than 34 years as a protective factor for LBW.

We did not find a significant difference between the mean weight of mothers of premature (55 kg) and to term infants (54 kg) before pregnancy. We found a more than two times higher risk for LBW among mothers with pre-pregnancy BMI 25.0-29.9 kg/m², but there was no effect found of pre-pregnancy BMI<18.5 kg/m². The results of our study are compatible with the findings of a recent meta-analysis on the existence of a weak association or lack of association between low BMI before pregnancy and the birth of a premature baby(27).

According to our results, the probability of giving birth to a premature baby in women who have had GWG less than recommended is around two times higher compared with mothers with recommended GWG. The insufficient weight gain during pregnancy increases the risk of having a premature baby, especially amongst women with low BMI before pregnancy: RR=1.5-2.5 (27). Our results are similar to those of Schieve LA et al. (2000), who found out a three times higher risk of giving birth to a premature baby in women with a normal BMI, but not enough weight gain during pregnancy compared with women of normal weight and with adequate weight gain during pregnancy(28).

Our results concerning smoking during pregnancy (around 40% of all mothers) are close to a previous study from Bulgaria conducted by Manolova (2004), which reported that about 42% of all women smoked during the whole pregnancy (20). Yet, the proportion of smoking mothers in our study was higher than a previous study conducted in Bulgaria in 2007, which reported a prevalence of 33% (23).

Smoking is regarded as one of the most common and preventable causes of poor pregnancy outcomes (17). There is variability in the reported results for the relationship between smoking and PB, but a large number of studies establish an RR=1.2-1.5 when daily consumption of cigarettes is 10-20, and an RR=1.5-2.0 when more than 20 cigarettes are smoked per day. The same results were obtained by Andriani and Kuo for smoking mothers who lived in urban areas (17). Our survey revealed a greater than fivefold increase in the risk of LBW among mothers who smoked during pregnancy, a finding which is in line with previous reports about the influence of smoking on the PB risk(14,17).

Study limitations

This study may have several limitations. Firstly, reports of the characteristics of mothers were retrospective after the child was born. Additionally, self-reported data on BMI, GWG and smoking are highly correlated with PB and LBW, but they tend to underestimate these measures. Women who smoked were categorized into three groups based on qualitative variables, and not according to the number of cigarettes smoked per day. The dissemination of information on adverse outcomes of smoking may have discouraged some mothers from disclosing it.

Secondly, because the place of study was an urban area we did not find enough mothers less than 19 years old. The result was that we did not establish the association between young maternal age and PB.

Thirdly, we utilized the Institute of Medicine guidelines to categorize women‘s weight gain as below, within, or above recommended value (22), which maybe is not appropriate for Bulgaria, but there are no other recommendations to be used.

Finally, we excluded from the analysis some women with either missing information on the principal determinants of interest (age, BMI, GWG, smoking), or missing information on gestational age and birth weight (needed for outcome variables), but the number of missing values was small.

Obviously, there is a need for prospective studies from the registration of the pregnancy, in Pleven and in other regions of Bulgaria, in which such data should be collected in a standardized manner and the number of mothers and their children should be higher.

Conclusion

Our results confirm our research hypothesis that pre-pregnancy BMI>25 kg/m², less than recommended GWG related with their personal BMI and smoking during pregnancy arerisk factors for PB. Age of the mothers at delivery <34 years was a protective factor for LBW. This analysis was part of a study on the risk factors for PB and their impact on development and health status of children <3 years in Bulgaria. Our findings highlight the public health importance of promoting a healthy lifestyle of mothers in order to reduce the level of PB in Bulgaria.

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ORIGINAL RESEARCH

Lifestyle correlates of low bone mineral density in Albanianwomen

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Abstract

Aim: The aim of this study was to assess the association of lifestyle/behavioral factors with low bone mineral density in Albanian women, a transitional country in the WesternBalkans.
Methods: A cross-sectional study was conducted in Tirana city in 2010 including a population-based sample of 549 women aged 35 years and above (response rate: 92%). Low bone mineral density (osteopenia and/or osteoporosis defined as a bone mineral density T-score less than -1) was assessed with a bone ultrasound device which is simple and easy to use for screening of bone mineral density in population-based studies. Binary logistic regression was used to determine the relationship of low bone mineral density with behavioral factors in this studypopulation.
Results: The prevalence of low bone mineral density in this study population was 28.4% (156/549). In multivariable-adjusted logistic regression models, low bone mineral density was positively associated with smoking (OR=4.1, 95%CI=2.2-7.4) and coffee consumption (OR=2.3, 95%CI=1.3-4.1), but inversely related to overweight and obesity (OR=0.4, 95%CI=0.2-0.7 and OR=0.3, 95%CI=0.2-0.6,respectively).
Conclusion: This study offers useful evidence about the lifestyle/behavioral determinants of low bone mineral density among women in this transitional South Eastern European population. Health professionals and policymakers in Albania should be aware of the major behavioral factors which increase the risk of low bone mineral density in order to provide correct treatment and control of this condition in the generalpopulation.

Keywords: Albania, bone mineral density, bone ultrasound, bone ultrasound device, osteopenia, osteoporosis, Tirana.

Conflicts of interest: None.

Introduction

Low bone mineral density, especially osteoporosis, is characterized by excessive skeletal fragility and susceptibility to trauma fracture (1), particularly among older individuals (2,3). Conventionally, low bone mineral density includes osteopenia and osteoporosis. Osteopenia is deemed as en initial step of osteoporosis notwithstanding the fact that not every person with osteopenia may inevitably experience osteoporosis (4-6). As a rule of thumb, osteopenia is defined as a bone mineral density T-score lower than -1.0 and greater than -2.5 (7). On the other hand, osteoporosis is defined as a bone mineral density T-score of -2.5 or lower (7). It is important to note that osteopenia is an indication of normal aging, as opposed to osteoporosis which is evident in pathologic aging(1,5).

The prevalence of low mineral bone density, especially osteoporosis, increases with age (2,3,8). Furthermore, the prevalence of osteoporosis is higher in women, especially after menopause (1,8,9). In addition, unhealthy behavioral patterns consisting of smoking, excessive alcohol consumption and physical inactivity increase the risk of low bone mineral density and/or exacerbate the conditions of osteopenia and osteoporosis (5,10,11). On the other hand, body weight has been shown to exert a beneficial effect on increasing bone mass which, in turn, reduces the risk of osteoporosis (1). Furthermore, fat mass has been described as a protective factor against osteoporosis in several studies conducted worldwide (12-14). However, the findings related to excessive fat mass are not consistent and several other studies have reported that it may not protect against decreases in bone mass(15-17).

The assessment of bone mineral density is typically done with dual X-ray absorptiometry (DEXA) procedure (18). At the same time, assessment of bone mineral density can be also performed with portable scanners using ultrasound, and portable machines can measure density in the heel (19,20). As a matter of fact, quantitative ultrasound is currently used worldwide due to its low cost, simplicity of performance, mobility and due to the lack of ionizing radiation (19).

After the fall of the communist regime in 1990, Albania, a transitional country in the Western Balkans, has been characterized by a particularly difficult political and socioeconomic situation associated with periodic civil unrests and high rates of unemployment(21).

According to a recent report, the burden of musculoskeletal disorders has increased in Albania in the past two decades (22). The overall share of musculoskeletal disorders accounted for 8.5% of the total burden of disease in 1990, whereas in 2010 it amounted to 11.0% (22,23). There is evidence of a stronger increase in females than in males. In both sexes, there was a similar moderate yet steady increase from 1990-2005 (22,23). Subsequently, there was a steeper increase in females, but a smaller increase in males, which additionally accentuated the excess burden of disease explained by the musculoskeletal disorders in females compared to males (22). The burden of musculoskeletal disorders in Albania was similar to most of the countries in South Eastern European (SEE) region in both 1990 and 2010 (22,23). In 2010, the share of musculoskeletal disorders was 11.0% of the total burden of disease in several SEE countries including Albania. Essentially, musculoskeletal disorders are said to have increased in Albania probably due to a higher accessibility to the health care services in addition to the ageing pattern of the Albanian population (22).

To date though, data on the prevalence and determinants of osteopenia and osteoporosis in the Albanian population is scarce. In this framework, the aim of our study was to assess the lifestyle/behavioral correlates of low bone mineral density (osteopenia and/or osteoporosis) in Tirana city, the capital of Albania, a transitional country in the Western Balkans

characterized by an intensive process of urbanization and internal migration of the population in the past twenty five years.

Methods

A cross-sectional study was conducted in 2010 including a population-based sample of women aged 35 years and above residing in Tirana city, the capital of Albania.

Regarding the sample size, a minimum of 540 women was estimated as the minimal number required for inclusion in this study. In order to account for potential non-response, we decided to invite 600 women to participate in our study. The inclusion criteria consisted of women aged 35 years and above residing in Tirana city. Of 600 eligible individuals invited to take part in this study, 549 women agreed to participate (mean age: 55.6±9.1 years; response rate: 92%).

The bone mineral density among study participants was assessed with a bone ultrasound device which is simple and easy to use for screening of bone mineral density in population-based studies (19,20). From this point of view, ultrasound is considered as a quick, cheap and non-radiating device for assessing bone quality (19,20). Low bone mineral density was defined as a bone mineral density T-score less than -1 that is osteopenia and/or osteoporosis.

The physical examination included also measurement of height and weight for all study participants based on which body mass index (BMI) was calculated (kg/m^2) and categorized in the analysis into normal weight (BMI≤25 kg/m^2), overweight (BMI: 25.1-29.9 kg/m^2) and obesity (BMI≥30 kg/m^2).

The other lifestyle/behavioral factors were assessed through an interviewer-administered structured questionnaire including information on smoking habits (dichotomized in the analysis into: yes vs. no), alcohol intake (yes vs. no), coffee consumption (yes vs. no) and tea consumption (yes vs. no).

Demographic and socioeconomic data (age, marital status, educational level and employment status of study participants) were also collected for all women included in thisstudy.

Binary logistic regression was used to assess the association of low bone mineral density (outcome variable) with lifestyle/behavioral factors (independent variables). Initially, crude (unadjusted) odds ratios (ORs) and their respective 95% confidence intervals (95%CIs) were calculated. Next, all the lifestyle factors (smoking, alcohol intake, coffee and tea consumption and BMI) together with demographic and socioeconomic characteristics (age, marital status, educational level and employment status) were entered simultaneously into the logistic regression models. Multivariable-adjusted ORs and their respective 95%CIs were calculated. In all cases, a p-value of ≤0.05 was considered as statistically significant. Statistical Package for Social Sciences (SPSS, version 15.0) was used for all the statisticalanalyses.

Results

The prevalence of low bone mineral density (osteopenia and/or osteoporosis) in this study population was 156/549=28.4% (Table 1). The prevalence of smoking was significantly higher in women with low bone mineral density compared with those with normal bone mineral density (25.6% vs. 8.7%, respectively; P<0.001). There were no differences regarding the prevalence of alcoholintake.

The prevalence of both coffee consumption and tea consumption was significantly higher in women with low bone mineral density than in those with normal bone mineral density (83.3% vs. 68.2%, P<0.001 and 53.8% vs. 41.2%, P=0.005, respectively).

On the other hand, the prevalence of both overweight and obesity was significantly lower in women with low bone mineral density compared with women with normal bone mineral density (30.8% vs. 40.2% and 23.7% vs. 32.2%, respectively; overall P<0.001) (Table1).

Table 1. Distribution of lifestyle/behavioral factors in a sample of Albanian womenby bone mineral densitystatus

Variable	Total (N=549)	Normal bone mineral density (N=393)	Low bone mineral density (N=156)	†
Smoking:				
No	475 (86.5)*	359 (91.3)	116 (74.4)	<0.001
Yes	74 (13.5)	34 (8.7)	40 (25.6)	
Alcohol intake:				
No	514 (93.8)	369 (93.9)	145 (93.5)	0.508
Yes	34 (6.2)	24 (6.1)	10 (6.5)	
Coffee consumption:				
No	151 (27.5)	125 (31.8)	26 (16.7)	<0.001
Yes	398 (72.5)	268 (68.2)	130 (83.3)	
Tea consumption:				
No	303 (55.2)	231 (58.8)	72 (46.2)	0.005
Yes	246 (44.8)	162 (41.2)	84 (53.8)	
BMI:				
Normal weight	179 (32.7)	108 (27.6)	71 (45.5)	
Overweight	205 (37.5)	157 (40.2)	48 (30.8)	
Obesity	163 (29.8)	126 (32.2)	37 (23.7)	

* Absolute numbers and their respective *column* percentages (in parentheses).

† P-values from Fisher's exact test.

Table 2 presents the association of low bone mineral density with lifestyle factors of the women included in this study.

In crude (unadjusted) logistic regression models, there was evidence of a strong and statistically significant association of low bone mineral density with smoking (OR=3.6, 95%CI=2.2-6.0), but not alcohol intake (OR=1.1, 95%CI=0.5-2.3). On the other hand, there was a strong association of low bone mineral density with coffee consumption (OR=2.3, 95%CI=1.5-3.7) and tea consumption (OR=1.7, 95%CI=1.2-2.4). On the contrary, the odds of overweight and obesity were lower among women with a low bone mineral density compared with their counterparts with normal bone mineral density (OR=0.5, 95%CI=0.3-0.7 and OR=0.4, 95%CI=0.3-0.7, respectively).

In multivariable-adjusted logistic regression models, low bone mineral density was positively associated with smoking (OR=4.1, 95%CI=2.2-7.4), coffee consumption (OR=2.3, 95%CI=1.3-4.1) and (non-significantly) with tea consumption (OR=1.4, 95%CI=0.9-2.2), but inversely related to overweight and obesity (OR=0.4, 95%CI=0.2-0.7 and OR=0.3, 95%CI=0.2-0.6, respectively) (Table 2).

Table 2. Association of low bone mineral density with lifestyle/behavioral factorsamong women in Tirana, Albania

Variable	Crude (unadjusted models)		Multivariable-adjustedmodels	
	OR (95%CI)*	P*	OR (95%CI)*	P*
Smoking:				
No	1.00 (reference)	<0.001	1.00 (reference)	<0.001
Yes	3.64 (2.20-6.02)		4.07 (2.23-7.40)	
Alcohol intake:				
No	1.00 (reference)	0.880	1.00 (reference)	0.478
Yes	1.06 (0.49-2.27)		0.73 (0.30-1.75)	
Coffee consumption:				
No	1.00 (reference)	<0.001	1.00 (reference)	0.003
Yes	2.33 (1.46-3.74)		2.33 (1.34-4.07)	
Tea consumption:				
No	1.00 (reference)	0.008	1.00 (reference)	0.134
Yes	1.66 (1.15-2.42)		1.40 (0.90-2.16)	
BMI:		**<0.001 (2)†**		**<0.001 (2)†**
Normal weight	1.00 (reference)	-	1.00 (reference)	-
Overweight	0.47 (0.30-0.72)	0.001	0.39 (0.23-0.65)	<0.001
Obesity	0.45 (0.28-0.72)	0.001	0.32 (0.18-0.55)	<0.001

* Odds ratios (OR: low bone mineral density vs. normal bone mineral density), 95% confidence intervals (95%CIs) and p-values from binary logistic regression. Besides the variables presented in the table, multivariable-adjusted models were additionally controlled for age, marital status, employment status and educationallevel.

† Overall p-value and degrees of freedom (inparentheses).

Discussion

This study including a representative sample of women residing in Tirana – the capital city of transitional Albania which was the most isolated country in Europe during the communist regime – offers useful evidence about selected lifestyle/behavioral predictors of low bone mineral density (osteopenia and osteoporosis) in the adult female population. Smoking and coffee consumption were positively associated, whereas overweight and obesity were inversely related to osteopenia and osteoporosis in this sample of Albanian women, after controlling for other lifestyle factors and several demographic and socioeconomic characteristics.

Our findings related to a positive association between low bone mineral density with smoking and coffee consumption are in line with previous reports from the international literature (5). In our study, the association of osteopenia and osteoporosis with coffee consumption was strong and remained unaffected upon simultaneous adjustment for a wide array of covariates including alcohol intake and tea consumption. Furthermore, the positive relationship with smoking was even stronger after multivariable adjustment for other behavioral characteristics.

In our study, overweight and obesity were strong correlates of osteopenia and osteoporosis. The negative association of overweight and obesity with low bone mineral density was accentuated in multivariable-adjusted logistic regression models. Our findings regarding body mass are compatible with several reports from the international literature (1,24). From this point of view, higher body weight or higher BMI is known to be a protective factor against bone loss in both men and women worldwide (1,24-26). Nevertheless, overweight and

obesity are related to a gain in fat mass as well as an increase in lean mass. Therefore, identification of the specific roles that fat mass itself plays in bone mass regulation is important to establish the clinical implications of osteoporosis (24). Several studies have indicated that both fat mass and lean mass can lead to an increase in bone mass which, in turn, reduces the risk of osteoporosis (13,24). On the other hand, according to some other studies, fat mass has a negative effect on bone mass after controlling for body weight (1,27). Importantly, regarding total fat mass, subcutaneous fat has been reported to be beneficial for bone mass, whereas visceral fat has negative effects(24,28).

This study may have some limitations. Notwithstanding the representativeness of the sample of women included in this study, the possibility of selection bias, at least to some extent, may be an issue which cannot be completely excluded. In any case, Tirana women are not assumed to represent the overall Albanian women and, hence, findings from this study cannot be generalized to the overall female population in Albania. In our survey, we employed a standardized and internationally valid instrument for assessment of low bone mineral density in population-based studies. Furthermore, findings from the quantitative ultrasound measurements of bone mineral density correlate well with the dual energy X-ray absorptiometry (DXA) (19), which is one of the most widely validated tools for measurement of BMD in clinical practice (18). On the other hand, the lifestyle/behavioral data collected through the interview may have been subject to information bias. This may be the case of smoking, alcohol intake, as well as coffee and tea consumption. Seemingly though, there is no plausible explanation of a differential reporting of lifestyle factors between women distinguished by the presence of osteopenia and/or osteoporosis in our study. Conversely, measurement of height and weight provides little grounds for biased estimates of overweight and obesity in our study sample.

In conclusion, our study provides important evidence about the lifestyle/behavioral determinants of low bone mineral density in Tirana, the capital city of Albania. Smoking and coffee consumption were significant predictors of low bone mineral density (osteopenia and osteoporosis) in this study sample of Tirana women. Future studies in Albania should assess the magnitude and distribution of osteopenia and osteoporosis in population-based samples of the general population.

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ORIGINAL RESEARCH

Public expenditure and drug policies in Bulgaria in2014

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Abstract

Aim: The objective of this study was to provide an analysis of the factors which have a significant impact on the growth of public expenditure on medical products inBulgaria.
Methods: This research work consists of a critical analysis of the data reported by the National Health Insurance Fund in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for2014.
Results: The results from the current analysis indicate that the growth of public expenditure is directly proportional to the number of reimbursed medical products and that the pattern of prescriptions including the innovative medical products mainly for the treatment of oncological and rare diseases has a significant impact onit.
Conclusion: The reasons for the increase of public expenditure in Bulgaria include the non-transparent decisions in pricing and reimbursement of the products, the lack of guidelines for presenting pharmacological evidence and the lack of legislatively-defined drug policies for the management and control of the patterns of medicalprescriptions.

Key words: Bulgaria, drug policies, reimbursement, publicexpenditure.

Conflicts of interest: None.

Introduction

Healthcare in the European Union (EU) countries including Bulgaria is funded by the healthcare systems and/or through general taxation. The main objective of the healthcare systems is the protection of public health, based on the principles of solidarity and universal access. The drug policy in every country is part of the healthcare policy and adopts the same objectives and principles (1). The expenses on medical products are an important component of the healthcare budgets of all the EU member states. There is an increasing necessity to limit the escalating expenses on healthcare including those on medical products, as well as the effective spending of the financial resources (2).

The good European practice on drug policy implies the determining of Positive Drug Lists (PDL) provided by the healthcare system, and the regulation of the drug prices in a certain order.

The main focus of the approaches to drug policies includes the rational use of medical products, which contributes to the control of public expenditure (3). Considering the fiscal impact of the economical and financial crisis, as well as the expected healthcare expenses for the aging population, these policies are of an increasing interest to the institutions which pay for the public expenses in healthcare (4).

The contemporary views of the European healthcare policies are that through the correct regulation of the pharmaceutical markets economies can be achieved, without having an impact on the provision of care (5).

The drug policy in Bulgaria is legally established by the Ministry of Health and practically applied by the National Council on Prices and Reimbursement of Medical Products (NCPRMP). This is the authority which regulates the prices and makes decisions regarding the reimbursement of the medical products with public funds. The control on prices is based on external and internal reference pricing and regressive margins for distributors and pharmacies. The reimbursing decisions are formally based on pharmaco-economic valuations, but the experts‘ reports are not available to the public and the objectivity of these decisions cannot be established.

In this context, the aim of this study was to analyze the public fund expenses on medical products in Bulgaria in 2014 in order to determine the impact of the legislative approaches to drug policies and their possible impact on public health.

Methods

This article is a critical analysis of data from the report of the National Health Insurance Fund (NHIF) in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for 2014 (6). A commentary is provided concerning the existing prescribing patterns, national policies for the inclusion of medical products in PDL and their impact on the increasing public expenses. A detailed analysis of the expenses by disease groups and the pattern for the prescription of medicines is also provided.

All graphs and tables included in this article are created on the basis of the data derived from the report of the NHIF in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for the year 2014 (6).

The difference of costs and amount of reimbursed products in the PDL for the period under investigation is presented as a percentage and is calculated with a mathematical method based on the determination of proportionalitycoefficients.

When trying to predict the future value, one follows the following basicidea:

future value = present value + change

From this idea, we obtain a differential, or a difference equation by notingthat:

change = future value – present value

The growth of public expenses is influenced by a number of factors discussed in the report of the NHIF in Bulgaria on the stability of the healthcare insurance model and the implementation of the budget for 2014 (6).

All prices are given in BGN with current exchange rates of: 1.95583 BGN = 1EUR.

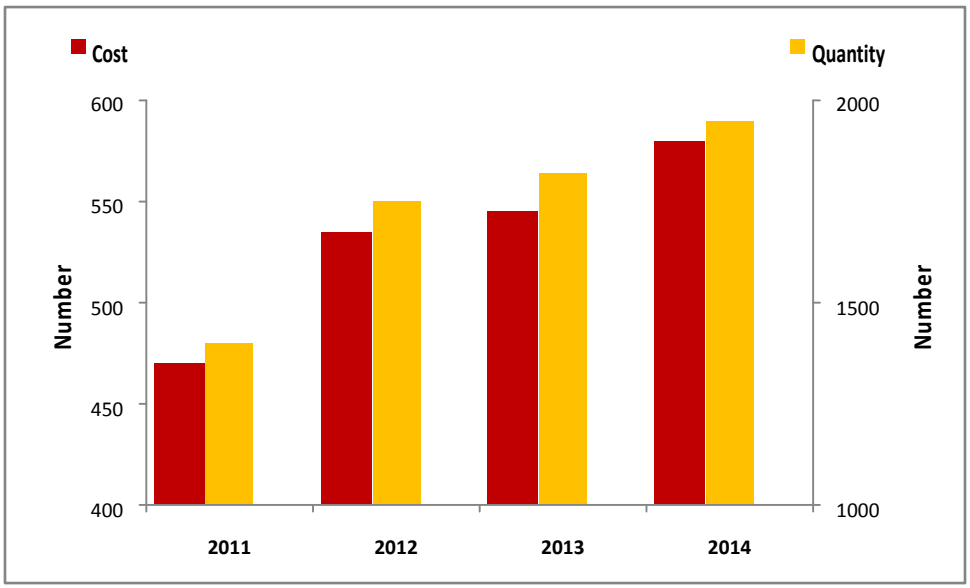
Results

The review of the development of the PDL in Bulgaria in the past three years (2011-2014) from the viewpoint of quantitative indicators shows a big volume (1997 medical products) and a list with frequent changes (every 15 days).

In 2011, the PDL included 1382 medical products, in 2012 it included 1673 products, and in 2014 there were 1997 products. During this three-year period, the number of reimbursed medical products increased by 45%.

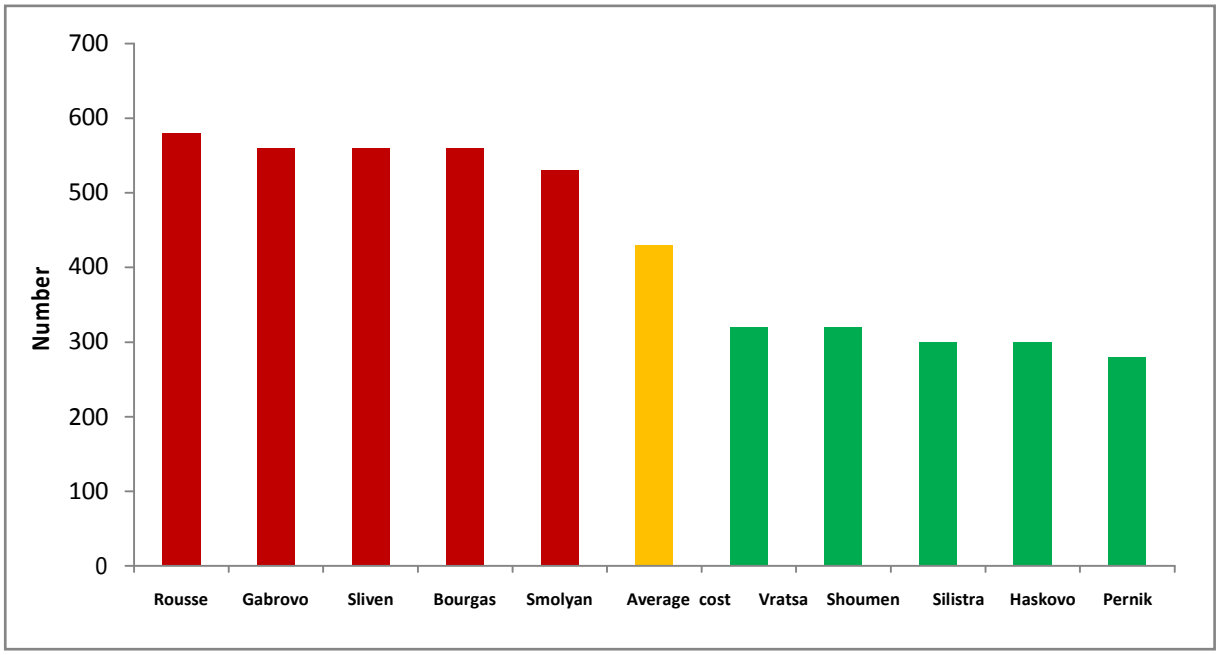
The proportion of public expenditure and the number of reimbursed medical products is presented in Figure 1. The established relationship is directly proportional, whereas the cost of public expenses increased by 25%.

Figure 1. Reimbursed medicines for home treatment and the cost of public expenses (bothin BGN) in Bulgaria; data for 2014 consists of estimates *(Source: NHIF Report for June 2014)*



The other factor which has a marked impact on public expenditure is the pattern of prescription of the medical products. The presented results (Figure 2) of the average cost of public expenditure for the treatment of non-insulin diabetes in 2013 are indicative – the cost of the expense differs doubly in the various regions, considering that the list of the medical products, their prices and the reimbursed amounts are the same for all the regions of Bulgaria. The different cost of public expenses in the various regions of Bulgaria directly depends on the level of prescribing of DPP-4 inhibitors and GLP-1 receptor antagonists. These are the two groups of innovative medical products for the oral therapy of diabetes, which are rather recommended as a second and a third line of treatment, due to unclear data for the long-term cost effectiveness and doubts about the safety profile(7).

Figure 2. Average cost per patient (in BGN) for the treatment of non-insulindependentdiabetes in Bulgaria in 2013 *(Source: NHIF Report for June2014)*



The analysis of public expenses by groups of diseases outlines the clear tendencies for an abrupt increase in the expenses for the treatment of rare diseases and oncologicaldiseases.
The expenses for the treatment of rare diseases increased by 36% in 2013 compared to 2012 and reached 59 million BGN, which constitutes 10.7% of all public expenses for medical products (Table 1). This points to a pronounced imbalance of solidarity in the insurance system, because these public costs are absorbed by only 0.15% of the insured individuals. At the same time, public expenses for socially significant diseases such as the cardiovascular disease, diseases of the neural system and diseases of other systems are decreasing (6). These results are an expression of the flaws in the drug policy, part of which are the application of internal reference pricing without a system for the control of medical prescriptions (8), the lack of transparency in the decisions on pricing and reimbursement, based on an expert evaluation of pharmaco-economical evidence, the lack of a defined limit of public expenses for one gained Quality-Adjusted Life Year (QALY), and the like(9).

Table 1. Expenses for the treatment of rare diseases in2013
(Source: NHIF Report for June 2014)

Disease	Public expense	Average annual cost per patient in BGN	Number of patients
Haemophilus	20 009 544	5290	3783
Beta-thalassemia	8 323 230	3692	2254
Gaucher disease	8 196 183	32 795	250
Blonhopulmonal Dysplasia	4 245 087	2828	1501
Mukopolizaharoidosis	3 294 574	68 637	48
Hereditary amyloidosis with neuropathy	1 625 885	27 098	60
Pompe disease	477 953	47 795	10

The analysis of the expenses on the medical therapy for oncological diseases, paid outside the cost of clinical pathways emphasizes several mainfacts:

- The expanding of the indications for innovative medicines, mainly for monoclonal antibodies and tyrosine kinase inhibitors. However, there is no data on the evaluation of the efficacy, benefits and costs of the newindications.
- The addition of monoclonal antibodies to the target therapies, which increases the cost of the therapy more than 30 times, while the benefits, expressed as final health outcomes, are minimal. The willingness of society to pay such a high price for the gain of a QALY remainsuncertain.
- The inclusion of new international non-proprietary names in the PDL without a clear evaluation of their differential cost-effectiveness as compared to the existing therapies.

As a result of all these factors, the public expenditure on oncological medical products significantlyexceeded the settled budgets for the past years, as indicated in Table 2.

Table 2. Expenses of the medical therapy for oncological diseases, paid outside the costs of clinical pathways *(Source: Report on the implementation of the budget of NHIF,2013-2014)*

YEAR	YEAR	
	2013	**2014**
Budget in BGN	90 000 000	145 000 000
Public expenditure in BGN	172 443 480	203 472 732*
Relative share of the overspending (%)	91,60	40,30

* Data for 2014 consists of estimates.

Discussion

Several main factors have been identified which have an impact on the annuallyincreasing public expenses on medical products inBulgaria:

- *Non-transparent decisions for the inclusion of medical products in the PDL with unclear cost-effectiveness compared to the existing drug alternatives.* There is no data on the recommendations of NCPRMP for the pharmaceutical industry and set out denials for reimbursement justified by the lack of sufficient evidence of effectiveness and/or high prices. The practice in the economically developed countries is different. For example, the Committee for the Evaluation of Medicinal Products in Canada refused to reimburse Pemetrexed for the treatment of malignant pleural mesothelioma, because the product does not provide added value for the price difference compared to the existing alternatives (10).

  Another Canadian solution sets to reimburse Sunitinib for the treatment of metastatic renal cell carcinoma only after negotiating the price because of poor cost-effectiveness, despite the improved efficacy over the existing therapeutic alternatives. Many similar negative decisions regarding the reimbursement of medical products for a specific diagnosis can be found in the scientific literature. Their aim is both to facilitate the access of patients to therapies which give them additional therapeutic value and use, as well as to protect patients from health risks connected to severe adverse drug reactions (11,12).

- *The lack of legally defined public expenditure related to one gained QALY.* This is a widely used instrument for limiting public expenditure and for the control of the innovative medical therapies (13).
- *Lack of legal control on the patterns of prescribing medicines.* The EU states have a number of measures in working order for improving the patterns of prescribing medicines. Most often they entail the monitoring of the prescriptions, recommendations and guidelines of advisory/obligatory nature regarding the prescriptions, including the requirements to prescribe an international non-proprietary name, a maximum limit on the prescribed medicines, prescription quotas, financial incentives, as well as educational and informational approaches(14-16).

The aim of all enumerated policies is to promote the rational use of medical products for the benefit of public health. The combinations of diverse measures, as electronic monitoring in prescription and in guidelines, connected with electronic systems which support the process of decision-making and give feedback to the physician, are an effective way to improve the patterns in prescribing medicines (17). In addition, educational and informational instruments should be activated.

The prescription of international non-proprietary names and prescription quotas, if possible in combination with target budgets and financial incentives, seem to be effective tools for the purpose of regulating public expenditure.

Conclusion

The effectiveness of public expenditure in Bulgaria will improve when it becomes the main objective in medical policy, i.e., when medical therapies are evaluated in a real and transparent way as a ratio of expenses and use as compared to the existing alternatives. It is necessary that the first steps are aimed at developing a control system of the prescription and evaluation of medicines‘ pharmaco-economical evidence, as well as determining public expenditure of the medical therapy at the level of one gainedQALY.

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ORIGINAL RESEARCH

Reaction to political and socioeconomic transition and self-perceived health status in the adult population of Gjilan region,Kosovo

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Abstract

Aim: The objective of our study was to assess the association of reaction to political and socioeconomic transition with self-perceived general health status in adult men and women in a region of Kosovo, a post-war country in the Western Balkans which has proclaimed independence in 2008.

Methods: This was a cross-sectional study carried out in Gjilan region of Kosovo in 2014, including a representative sample of 867 primary health care users aged ≥35 years (419 men aged 54.3±10.9 years and 448 women aged 54.0±10.1 years; overall response rate: 87%). Reaction to political and socioeconomic aspects of transition was assessed by a three-item scale (trichotomized in the analysis into *positive* attitude, *intermediate* attitude, and *negative* attitude towards transition), which was previously used in the neighbouring Albania. Self-reported health status was measured on a 5-point scale which was dichotomized in the analysis into ―good‖ vs. ―poor‖ health. Demographic and socioeconomic data were also collected. Binary logistic regression was used to assess the association of reaction to transition with self-rated health status.

Results: In crude/unadjusted models, negative attitude to transition was a ―strong‖ predictor of poor self-perceived health (OR=2.5, 95%CI=1.7-3.8). Upon multivariable adjustment for all the demographic factors and socioeconomic characteristics, the association was attenuated and was only borderline statistically significant (OR=1.6, 95%CI=1.0-2.6,P=0.07).

Conclusion: Our findings indicate an important association between reaction to transition and self-perceived health status in the adult population of the newly independent Kosovo. Policymakers and decision-makers in post-war countries such as Kosovo should be aware of the health effects of attitudes towards political and socioeconomic aspects of transition, which is seemingly an important psychosocialfactor.

Keywords: attitude to transition, Gjilan, Kosovo, psychosocial factors, reaction to transition, self-perceived health, self-ratedhealth.

Conflicts of interest: None.

Introduction

In several post-communist countries including Russia, negative attitudes towards the political transition and socioeconomic reforms have been linked to poor self-perceived health among adult men and women (1,2). Similarly, a negative or a pessimistic reaction to transition has been more recently linked to development of acute coronary syndrome in Albania (3), a country which shares the same language and culture with the nowadays Republic of Kosovo. According to this previous study conducted in Albania, a plausible mechanism linking pessimism, or negative attitude with excess coronary risk was deemed the stressor effect of inadequate coping with change in this transitional society(3).

Nonetheless, the evidence from many former communist countries of Southeast Europe, including Kosovo, is scarce. After a long war against Serbia and its proclaimed independence in 2008, Kosovo has been undergoing a very difficult process of political and socioeconomic transition (4) associated with a particularly high unemployment rate and a rather poor socioeconomic situation of the general population (5), which leads to an intensive process of emigration to different European Union countries and beyond (6). Given this particularly difficult socioeconomic situation, the attitudes and perceptions of the adult population in Kosovo towards the political reforms and socioeconomic aspects of transition are considered to have been negatively affected notwithstanding the lack of systematic documentation (6). As a matter of fact, regardless of its natural resources, Kosovo is one of the poorest countries in Europe (4-6). Current evidence suggests an increase in the morbidity and mortality rates from non-communicable diseases in adult men and women in Kosovo (7,8), which is explained by an increase in unhealthy behaviours (9) and presumably psychosocial factors (9). According to a recent review, alongside with unhealthy lifestyle including dietary patterns and physical inactivity, unfavourable socioeconomic and psychosocial conditions are considered as important determinants of the excess morbidity and mortality from chronic diseases in Kosovo including diabetes and cardiovascular diseases (9). Notably, it has been argued that changes in behavioural patterns may have unevenly affected different population subgroups, especially the vulnerable and the marginalized categories who are unable to cope with the dramatic changes of the rapid transition occurring in post-communist societies including Kosovo (6,9,10). Nonetheless, the negative health effects of psychosocial factors in the adult population of Kosovo have not been scientifically documented todate.

In this context, our aim was to determine the association of reaction to political and socioeconomic aspects of transition with self-perceived general health status among adult men and women in a region of post-war Kosovo. Based on a previous report from Albania (3), we hypothesized a negative health effect of pessimistic attitudes towards transition, suggesting inadequate coping with change, independent of (or, mediated through) demographic factors and socioeconomic characteristics.

Methods

This was a cross-sectional study which was carried out in Gjilan region, Kosovo, in2014.

Study population

This study included a representative sample of primary health care users of both sexes aged 35 years and above. A minimum of 740 individuals was required for participation in this study, based on the initial sample size calculations. Nevertheless, it was decided to invite 1000 individuals in order to increase the study power accounting also for non-response. Therefore, 1000 consecutive primary health care users aged 35 years and above who were resident in Gjilan region were invited to participate in thisstudy.

Of 1000 individuals who were invited to participate, 62 primary health care users were ineligible (individuals aged <35 years and/or very sick to participate), whereas 71 individuals refused to participate. Hence, the final study population included 867 individuals (419 men and 448 women) with an overall mean age of 54.2±10.5 years (54.3±10.9 years in men and 54.0±10.1 years in women). The overall response rate in this study was:867/1000=87%.

Data collection

A structured questionnaire was administered to all participants including information on demographic and socioeconomic characteristics, reaction to political and socioeconomic transition in Kosovo and self-perceived healthstatus.

Reaction to political and socioeconomic aspects of transition among study participants was assessed by a three-item scale which was previously used in the neighbouring Albania (3). This scale employed in Albania was adapted from an instrument originally used in Russia (1,2,11). In the current study conducted in Kosovo, all participants were asked to rate their agreement/disagreement about the following three statements: a) *"Overall, the current economic system in Kosovo is better than the old system"* [range from 0 (strongly agree) to 3 (strongly disagree)]; b) *"The transition toward the new system in Kosovo is difficult; however, it's worthwhile in view of the forthcoming prosperity"* [range from 0 (strongly agree) to 3 (strongly disagree)], and; c) *"Compared with the previous system, most of the people in Kosovo are poorer now"* [range from 0 (strongly disagree) to 3 (strongly agree)]. A summary score was calculated for each individual (referred to as ―overall reaction to transition‖) ranging from 0 (most positive or optimistic attitude towards political and socioeconomic aspects of transition) to 9 (most negative or pessimistic reaction to transition). Cronbach's alpha of the three-item scale in our study conducted in Kosovo was 0.94, which was slightly lower than a previous study conducted in Albania (3). In the statistical analysis, the summary score of attitudes to transition was categorized into three groups [*positive* attitude (score: 0-3), *intermediate* attitude (score: 4-6), and *negative* attitude (score:7-9)].

In addition, all participants were asked to rate their general health status: *"Overall, during the past year, how would you rate your general health status: excellent, very good, good, poor, or very poor?"*. In the analysis, the self-perceived health status was dichotomized into: ‖good‖ vs. ‖poor‖.

Demographic factors included age of study participants (in the analysis grouped into: 35-44 years, 45-54 years, 55-64 years and ≥65 years), sex and marital status (in the analysis, dichotomized into: married vs. not married), whereas socioeconomic characteristics consisted of educational attainment (categorized into: low, middle and high), employment status (trichotomized into: employed, unemployed and retired), income level (categorized into: low, middle and high) and social status (similarly trichotomized into: low, middle andhigh).

Statistical analysis

Measures of central tendency [mean values (± standard deviations) and median values (with their respective interquartile ranges - IQR)] were used to describe the distribution of reaction to transition scores separately in male and female study participants. On the other hand, the distribution of different categories of the reaction to transition scores (positive, intermediate and negative) was expressed in absolute numbers together with their respective percentages separately in men and in women.

Chi-square test was used to assess the crude (unadjusted) association of reaction to transition scores (trichotomized into: positive, intermediate, negative) with the socio-demographic characteristics and self-perceived health status of studyparticipants.

Conversely, binary logistic regression was used to assess the crude (unadjusted) and subsequently the multivariable-adjusted associations of self-reported health status (outcome variable dichotomized into: ―good‖ vs. ―poor‖ health status) and reaction to transition (independent variable) of study participants. Initially, crude (unadjusted) odds ratios (ORs) and their respective 95% confidence intervals (95%CIs) were calculated. Next, the logistic regression models were adjusted for age of participants. Subsequently, the other demographic factors (sex and marital status) were entered simultaneously into the logistic regression models. Finally, socioeconomic characteristics (educational attainment, employment status, income level and social status) were entered simultaneously into the logistic regression models. In all logistic regression models, the self-perceived health status was the outcome variable and reaction to transition (introduced in three categories: positive, intermediate and negative) was the main independent variable. Multivariable-adjusted ORs and their respective 95%CIs were calculated. Hosmer-Lemeshow test was used to assess the overall goodness-of-fit of the logistic regression models (12). In all cases, a p-value of ≤ 0.05 was considered as statistical significant. Statistical package for Social Sciences (SPSS, version 17.0) was used for all the statisticalanalyses.

Results

Overall mean (SD) summary score of reaction to transition was 4.2±2.8 (4.1±2.8 in men and 4.2±2.7 in women) [Table 1]. Furthermore, median (IQR) was quite similar in men and in women [sex-pooled median (IQR): 3.0 (3.0)]. Overall, 494 (57%) of participants reported a positive attitude towards the political and socioeconomic transition in Kosovo, as opposed to 181 (21%) of individuals who had a negative reaction to transition. The negative attitude to transition was higher in men than in women (23% vs. 19%, respectively) [Table 1].

Table 1. Distribution of reaction to political and socioeconomic transition scores ina representative sample of primary health care users in Gjilan region, Kosovo, in2014

Reaction to transitionscore	Men (N=419)	Women (N=448)	Total (N=867)
Mean (standard deviation)	4.1±2.8	4.2±2.7	4.2±2.8
Median (interquartilerange)	3.0 (4.0)	3.0 (3.0)	3.0 (3.0)
Positive (score: 0-3)	243 (58.0)	251 (56.0)	494 (57.0)
Intermediate (score: 4-6)	79 (18.9)	113 (25.2)	192 (22.1)
Negative (score: 7-9)	97 (23.2)	84 (18.8)	181 (20.9)

Table 2 presents the distribution of demographic factors, socioeconomic characteristics and self-perceived health status by reaction to transition scores (trichotomized into: positive, intermediate and negative scores) among study participants. As noted above, the prevalence of negative attitudes to transition was significantly higher in men compared to women (P=0.05). Furthermore, older individuals (65 years and above) displayed the most negative (pessimistic) attitudes to transition compared with their younger counterparts (P<0.001). Similarly, the prevalence of a negative reaction to transition was the highest among the retirees (P<0.001), given the aging of this population subgroup. There was no significant association with marital status. Remarkably, low-educated participants had a significantly higher prevalence of negative attitudes to transition compared with their highly educated counterparts (40% vs. 7%, respectively, P<0.001). Likewise, albeit with smaller differences, low-income individuals and those with a lower social status displayed a higher prevalence of negative reaction to transition compared to high-income participants (33% vs. 18%,

respectively, P<0.001), and individuals with a higher social status (29% vs. 12%, respectively, P<0.001). Participants with a poor self-perceived health status had a significantly higher prevalence of negative reaction to political and socioeconomic transition compared with individuals who reported a good health status (34% vs. 18%, respectively, P<0.001) [Table 2].

It should be noted that, on the whole, there were 696 (80.5%) participants who reported a ―good‖ health status compared with 169 (19.5%) individuals who perceived their health status as ―poor‖.

Table 2. Distribution of socio-demographic characteristics and self-perceived health statusby reaction to transition scores in the study population(N=867)

Variable	Positive (score: 0-3) [N=494]	Intermediate (score: 4-6) [N=192]	Negative (score 7-9) [N=181]	P†
Sex:				
Men	243 (58.0)*	79 (18.9)	97 (23.2)	
Women	251 (56.0)	113 (25.2)	84 (18.8)	
Age-group:				
35-44 years	132 (69.8)	37 (19.6)	20 (10.6)	
45-54 years	171 (68.7)	56 (22.5)	22 (8.8)	<0.001
55-64 years	131 (52.8)	59 (23.8)	58 (23.4)	
≥65 years	60 (33.1)	40 (22.1)	81 (44.8)	
Employment:				
Employed	272 (71.0)	78 (20.4)	33 (8.6)	
Unemployed	129 (62.0)	52 (25.0)	27 (13.0)	
Retired	93 (33.8)	62 (22.5)	120 (43.6)	
Marital status:				
Not married	63 (49.2)	31 (24.2)	34 (26.6)	
Married	431 (58.4)	161 (21.8)	146 (19.8)	
Educational level:				
Low	101 (30.5)	96 (29.0)	134 (40.5)	
Middle	246 (69.9)	73 (20.7)	33 (9.4)	
High	145 (80.1)	23 (12.7)	13 (7.2)	
Income level:				
Low	46 (35.7)	40 (31.0)	43 (33.3)	
Middle	118 (47.0)	85 (33.9)	48 (19.1)	
High	330 (68.2)	66 (13.6)	88 (18.2)	
Social status:				
Low	40 (40.0)	31 (31.0)	29 (29.0)	
Middle	318 (55.4)	128 (22.3)	128 (22.3)	
High	136 (71.6)	32 (16.8)	22 (11.6)	
Self-perceived health:				
Good	416 (59.8)	158 (22.7)	122 (17.5)	
Poor	78 (46.2)	33 (19.5)	58 (34.3)	

* Absolute numbers and their respective *row* percentages (in parentheses). Discrepancies in the totals are due to the missingvalues.

† P-values from the chi-squaretest.

Table 3 presents the association of reaction to transition with self-perceived health status of study participants. In crude (unadjusted) logistic regression models (model 1), there was

evidence of a strong positive association between negative reaction to transition and poor self-rated health: OR(negative vs. positive scores)=2.5, 95%CI=1.7-3.8. Adjustment for age (model 2) attenuated the findings (OR=1.8, 95%CI=1.2-2.8). Additional adjustment for sex and marital status (model 3) did not affect the findings (OR=1.8, 95%CI=1.2-2.8). Further adjustment for socioeconomic characteristics including education, employment, income level and social status (model 4) attenuated the strength of the association which, in fully-adjusted models, was only borderline statistically significant (OR=1.6, 95%CI=1.0-2.6,P=0.07).
On the other hand, there was no difference in the odds of self-perceived health status between participants with intermediate scores and those with positive scores of reaction to transition, even in crude (unadjusted) logistic regression models (Table 3, models 1-4).

Table 3. Association of reaction to transition with self-perceived health status in a representative sample of primary health care users in Gjilan region,Kosovo

Model	OR*	95%CI*	P*
Model 1†			**<0.001 (2)‡**
Positive attitude (score:0-3)	1.00	reference	-
Intermediate attitude (score:4-6)	1.11	0.71-1.74	0.636
Negative attitude (score:7-9)	2.54	1.71-3.76	<0.001
Model 2¶			**0.014 (2)**
Positive attitude (score:0-3)	1.00	reference	-
Intermediate attitude (score:4-6)	0.99	0.63-1.56	0.958
Negative attitude (score:7-9)	1.81	1.18-2.78	0.007
Model 3§			**0.011 (2)**
Positive attitude (score:0-3)	1.00	reference	-
Intermediate attitude (score:4-6)	0.97	0.62-1.53	0.897
Negative attitude (score:7-9)	1.84	1.20-2.83	0.005
Model 4**			**0.079 (2)**
Positive attitude (score:0-3)	1.00	reference	-
Intermediate attitude (score:4-6)	0.88	0.54-1.43	0.605
Negative attitude (score:7-9)	1.58	0.96-2.61	0.072

* Oddsratios (OR: ―poor health‖ vs. ―good health‖), 95% confidence intervals (95%CIs) and p-values from binary logisticregression.

† Model 1: crude (unadjusted).

‡ Overall p-value and degrees of freedom(inparentheses).

¶ Model 2: adjusted for age (35-44 years, 45-54 years, 55-64 years and ≥65 years).

§ Model 3: adjusted for age, sex (men vs. women) and marital status (married vs. unmarried).

** Model 4: adjusted for age, sex, marital status, educational level (low, middle, high), employment status (employed, unemployed, retired), income level (low, middle, high) and social status (low, middle, high).

Discussion

The main finding of this study consists of a positive association of pessimistic reaction towards political reforms and socioeconomic transition with poor self-rated health among adult men and women in post-war Kosovo, a country characterized by dramatic and rapid changes in the past few years. The association of poor self-perceived health with negative reaction to transition was strong, but upon multivariable adjustment for a wide array of demographic and socioeconomic characteristics the relationship was only borderline

statistically significant. Our findings are largely compatible with previous reports from former communist countries including Russia (1,2,11) and Albania(3).

Overall, the prevalence of negative reaction (score 0-3) towards socioeconomic aspects of transition in our study population was 21%, which is higher than a previous study carried out in Albania which reported a sex-pooled prevalence of 13% (3). Nevertheless, the prevalence of pessimistic reaction in our sample is much lower than in Russia, where 49% of a representative sample of the adult population reported a nostalgic reaction to political and socioeconomic changes (disapproving the new system and approving the old system) according to a previous study (2). It should be pointed out that, in Russia, it was considered that the attitudes towards the political and socioeconomic reforms in 1990s were significantly more negative than in other post-communist countries in Europe(2,3).

In our study, there was no evidence of a graded relationship with pessimistic or negative attitudes to transition. Hence, the association was evident only between negative vs. positive attitude groups, with no differences between neutral (intermediate) and positive attitude categories (Table 3). On the other hand, a previous study conducted in Albania reported a graded relationship between acute coronary syndrome and negative attitudes towards socioeconomic transition consistent in both sexes and irrespective of demographic and socioeconomic characteristics and a wide range of conventional risk factors(3).

Potential mechanisms of psychosocial factors including reaction towards political and socioeconomic aspects of transition have been suggested to operate either directly through the neuro-endocrine system (13), or indirectly through induction of unhealthy behaviour such as smoking, excessive alcohol consumption, unhealthy diet and sedentary lifestyle (3,13). Furthermore, regarding the negative effect of psychosocial factors on cardiovascular risk, it has been suggested that psychological distress may act chronically through pathological modifications of the cardiovascular system, such as changes in lipid profile and elevation of arterial blood pressure (3,14). In our study, the mechanism of excess self-perceived poor health among pessimists may be related to poor adaptation to critical circumstances associated with the particularly rapid transition in Kosovo, as suggested by previous research on this field (3), where obvious differences in coping strategies between optimists and pessimists have been convincingly demonstrated (3,15,16). Conversely, negative reaction towards political and socioeconomic aspects of transition may also serve as a marker of depression (17,18), which may lead to poor health status ingeneral.

This study may suffer from several limitations including its design, representativeness of the study population and the possibility of information bias. Firstly, findings from cross-sectional studies do not imply causality and, therefore, future prospective studies should robustly assess and establish the directionality of the relationship between self-reported health status and attitudes to political and socioeconomic transition in Kosovo and other transitional settings. Secondly, we cannot exclude the possibility of selection bias in our study sample notwithstanding the inclusion of a fairly large sample of consecutive primary health care users of both sexes in Gjilan region. In addition, we obtained a very high response rate (87%), which is reassuring. Yet, we cannot generalize our findings to the general adult population of Gjilan region given the fact that our study population was confined merely to primary health users. More importantly, findings from this study cannot be generalized to the overall adult population of Kosovo, as our survey was conducted only in Gjilan region. Thirdly, the instrument used for measurement of reaction to transition may be subject to information bias, regardless of the fact that this tool was previously validated in Albania (3). In our study population, the measuring instrument of reaction to transition exhibited a very

high internal consistency and discriminated well between population subgroups distinguished in their educational attainment, income level and social status – similar to previous reports including the neighbouring Albania(3).

In conclusion, regardless of these potential limitations, our findings indicate an important association between reaction to transition and self-perceived health status in the adult men and women of post-war Kosovo. Health professionals and policymakers in developing countries and transitional populations should be aware of the negative health effects of psychosocial factors including also the general attitude towards political and socioeconomic aspects of transition, as evidenced in the current study conducted in Kosovo.

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Merkel B. A growing competence: The unfinished story of the European Union healthpolicy (Commentary). SEEJPH 2015, posted: 15 June 2015. DOI 10.12908/SEEJPH-2014-49

COMMENTARY

A growing competence: The unfinished story of the European Unionhealth policy

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A few months ago, the South Eastern European Journal of Public Health (SEEJPH) published a lengthy article by Hans Stein on the importance of the Maastricht Treaty of 1992 and how the European Union (EU) health policy has developed since then (1). Undoubtedly, Dr. Stein made a major contribution to this story himself and in his paper he sets out his own viewpoint on key events and trends, offering us a wealth of historical detail and many real insights. But, like all good commentators who try to condense and make sense of a tortuous and convoluted sequence of events spanning more than two decades and involving very many players, he inevitably omits parts of the story, and his interpretations can sometimes give rise to more questions than answers.

In this review, I will entirely leave aside his general discussion of the overall evolution of the EU and its future prospects, and instead concentrate on a few specific points about the development of EU health policy to date.

It is a truism, and the beginning of perceived wisdom on the history of EU Health policy, that the Maastricht Treaty introduced the first explicit EC (European Community) legal competence for public health, devoting an Article to it (Article 129). It is also true, as Dr. Stein mentions, that there was much health-related activity in the EC well before the advent of the Maastricht Treaty. Such actions, in fact, go back many years. For instance, there was an EC Directive on pharmaceuticals in 1971 and in the same year a Regulation on coordination of social security systems providing rights to health care to workers in other EC countries. Moreover, various public health programmes on cancer, AIDS and drugs also predate Maastricht. Yet, Article 129 represented the first explicit framework for public health.

However, Dr Stein makes the more interesting point that this competence was *"often but never substantially changed in the subsequent treaties"*. And, again, *"The main components of Article 129 were slightly reworded in the following treaties, but essentially are still valid"*. In saying this he is implying that it was and remains after several treaty changes, a very weak competence which results from the *"defensive and negative position of MS"* (EU Member States) and reflects their position *"to keep the EU as far away as possible from influencing their health policy"*.

There is no doubt that the health ministries of the older MS, and most, if not all, of the newer ones, have never wanted the EU to tell them how to run their healthcare systems, or to subsume their health policies into an EU-wide policy as has been done in areas such as trade or agriculture. And it is certainly the case, as Dr. Stein emphasizes, that the Article 129 competence is a weak one – as well as being veryill-defined.

But, this raises some furtherissues.

As he says, it was MS, not the Commission or the European Parliament, that dominated the process of negotiating and agreeing the Maastricht Treaty. The question then must arise of why did these very MS decide to put into the Treaty a new competence in public health at all if they did not want the EC (EU as it has become) to do anything of significance in this field?

Later in his paper, Dr. Stein quotes approvingly from an article by Scott Greer who says that Article 129 *"was the harbinger of more effective promotion of health issues within EU policy-making. In time, however, the Internal Market and the single currency have had the biggest health consequences"*. And then, Dr. Stein adds the interesting comment that: *"This was not really what the MS had in mind when they established a specific EU Public Health Mandate"*. Of course, in 1992, the MS could not really have been thinking about the impact of the single currency which was not introduced until 1999! It is true that the Treaty did set out some clear steps towards achieving an economic and monetary union. But, it seems far-

fetched, to say the least, to suppose that those involved in designing a new public health competence would have given any thought to the potential impact on health of such a theoretical eventuality.

Similarly, how likely is it that many of them were envisaging the creation of some kind of protective instrument to counter the single market‘s potential impact on public health? This may have been on the mind of one influential player: Hans Stein, at least according to what he wrote in an article some years later (2). In this he states that: *“Single market regulations are sure to have an impact on health and health policy.....The full consequences of the internal market in the field of health and health care are as yet unknown. To analyse, to support or to counteract them can be done effectively only on an EUscale”*.

But, it is doubtful that others were so far-sighted. Moreover, if MS had really wanted to establish a health competence that could act as a bastion to promote and defend the interests of public health against the possible negative consequences of the single market, why did they make the public health competence so feeble that it _is the weakest legal base possible‘?

What seems more plausible is that MS (most of them in any case) saw some advantages in European cooperation in some health areas either where they faced common health problems such as AIDS, and tobacco, and on some apparently non-contentious topics, such as improving health information, and health education, where they could exchange experience and expertise. In doing so it is arguable that they were trying to achieve two objectives: first to show that the EC was not just about markets and economics but could play a valuable role in other policy spheres. This indeed was a general underlying thread of the Maastricht Treaty. It is noteworthy in this context that Article 129 is sandwiched by two rather similar Articles, 128 on Culture, and 129a on Consumer Protection. The second aim could be seen as being perhaps a more cynical one: it was to give the EC a formal competence to take some actions in health, which they had in any case been doing for some time in fields such as cancer,AIDS and drugs, while reducing the potential for any future action in areas where MS did not wish to see EC involvement by defining the scope of the EC‘s public health activities and explicitly limiting its competence in this field. This view was common among Commission officials involved in health policy, including this reviewer, who expressed it in an article in 1995 (3).

A second contestable point is the claim that the treaty competence on public health has remained essentially the same over the last two decades. On the face of it, this cannot really be the case. Indeed what is particularly striking about this competence is how greatly the legal provisions have changed from treaty to treaty. Unlike many other policy areas where the treaty provisions have remained largely unchanged, the wording about health has been greatly amended and the provisions have become more and moredetailed.

In the Treaty of Amsterdam of 1997, for example, the public health article (Article 129 of the Maastricht Treaty) was significantly lengthened and the new article (Article 152), among other things, included for the first time the power to make binding EU legislation in a few specific areas, in relation to blood and organs, and in some veterinary and phytosanitary areas.

A quick look at the current health article, (Article 168 of the Lisbon Treaty) will show that it is again substantially different from the ones agreed in previous treaties, as well as being very much longer. The areas of binding legislative powers introduced in 1997 are retained and there is a further one: medicinal products and medical devices, Additionally, the scope for taking legal measures is increased, and now also includes cross-border threats tohealth,

tobacco and alcohol; and the article includes soft law provisions similar to those of the so-called _open method of coordination‘ used in social and employment policy.

The Article also concedes for the first time that the EU in the framework of its public health competence may have a role in relation to health services, saying that the EU: *“shall in particular encourage co-operation between the MS to improve the complementarity of their health services in cross-border areas”*.

Finally, of course, in addition to Article 168, the Treaty of Lisbon also incorporates the Charter of Fundamental Rights of the EU. Article 35 of this promulgates a right in respect of Health care: *“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union’s policies and activities”*.

Hence, clearly, the EU‘s legal competence has considerably evolved since the Maastricht Treaty. But perhaps Dr. Stein is making a deeper point, that regardless of the specific textual amendments in successive treaties, the underlying scope of and limitations on the EU‘s public health competence have not fundamentally changed. There is some strength in this argument. But the position is not as clear-cut as he maintains.

The first point to be considered is similar to the one we have made in connection with the Article 129 of the Maastricht Treaty. If MS wanted to preserve the EU‘s public health power weak and nebulous, why did they not simply keep it as it was? Why did they keep changing it (and adding to it!) in each Treaty revision? We can advance several reasons. First, there was never unanimity among the MS about the extent of the EU‘s role in public health, and in fact a diminishing degree of consensus as more MS joined the EU. Some of them, notably the newer MS, actively welcomed a greater EU involvement not only in developing national public health policies but even in respect of the functioning of their healthsystems.

Second, the Treaty reformulations represent (to some extent) responses to developments in Europe and beyond. Gradually, even against their basic instincts, most, if not all, MS came to appreciate that the EU could be of use in helping tackle some health problems that would be difficult to deal with by individual countries acting separately. These include forexample

- responding effectively to health threats from communicable diseases and man-made and natural disasters,
- tackling various health determinants,
- developing a framework for regulating health goods and related items that circulatein Europe, and
- responding to global health problems.

Thirdly, the MS were not negotiating in a vacuum; they had to take into account public opinion and, in particular, the views of the other EU Institutions, notably the European Parliament (EP) and the Commission which both pressed at various points for the EU to be given additional powers in particular health fields. In relation to the Maastricht Treaty, for example, the Commission may have had a limited role in the actual negotiations, but it made proposals for what it wanted to see, it liaised with MS about how texts were worded and certainly followed the negotiations extremely closely. The final draft of the new public health article therefore came as no surprise to the Commission. And directly after the Treaty had been ratified on 1 November 1993, it published a detailed communication setting out how it intended to implement the new provisions (4). Similarly the EP played a very forceful role in the BSE crisis which led both to a substantial shake–up in the organization of the Commission services to separate agriculture from food safety and also to pressure to

strengthen the Treaty provisions on the protection of public health. This resulted in the inclusion in Article 152 of the Amsterdam Treaty of provisions allowing for binding measures to be taken in the veterinary and phytosanitary fields in relation to public health, and the extension of the overall scope of EC public health action to *"preventing human illness and diseases, and obviating sources of danger to human health"*.

Certainly, Dr. Stein is right in his contention that the health ministries of many MS have never been the warmest advocates of increasing EU competence in health. Yet despite this the fact remains that it has increased, is increasing and seems likely to continue to increase. Paradoxically, it is arguable that the prime movers of this growth in EU power have not generally been those in the health field, but rather those in charge of other policy areas who have never been so zealous about national prerogatives in relation to health. Decades ago it was heads of government who pushed for action on the single market which led ultimately led to EU action on pharmaceuticals, mutual recognition of health professionals and reciprocity of health insurance coverage. Later those same heads of government called for EU action on cancer and AIDS. In the last few years it has again been heads of government and finance ministers who have set up a new EU system of economic governance which has led to direct interventions in MS's budgetary and economic policies and through those means intrusion into their national health care policies. Today, as part of this system, we have an EU instrument, the semester, which enables the EU to give every MS specific (non-binding but very influential) recommendations on the main issues confronting their healthcare systems, their health spending and the reforms they shouldmake.

We have obviously travelled a very long way indeed from the arguments about whether the EU had a significant role in public health policy, let alone that it could have anything to do with the functioning of national health systems. Dr. Stein has written a thought-provoking article which helps us to trace the path that has been followed and offers us some pointers to what may come in the future for European Health Policy. As he wrote in 1995: *—It may take some time, but I have little doubt that when the range of possibilities inherent in the new treaty provisions are really used, their impact on public health will be greater than anybody expects today"* (5). Now, twenty years and several treaties later, we can see just how prescient he was.

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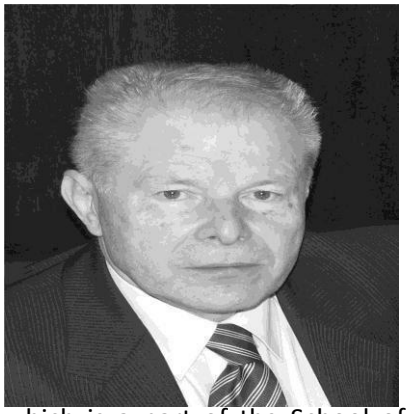
Obituary Luka Kovacic

The Editors of the South Eastern European Journal of Public Health express their deepest sorrow about the death of one of our most prominent members of the Editorial Board, Professor Luka Kovačic, founder of the Stability Pact's Forum for Public Health in South Eastern Europe (FPH-SEE) in 2000/2001 and strong supporter of the creation of this journal.

Genc Burazeri (Tirana, Albania and Maastricht, The Netherlands)
Ulrich Laaser (Bielefeld, Germany)
Jose Martin-Moreno (Valencia, Spain)
Peter Schröder-Bäck (Maastricht, The Netherlands)

Obituary Professor Luka Kovačic, MD, PhD



Professor Luka Kovačic, MD, PhD, specialist in social medicine and organization of health care, retired full professor of the School of Medicine, University of Zagreb, passed away on 21 April 2015 fatigued by incurable malignant disease.

Luka Kovačic was born on 13 October 1940 in a small town Đurđevac some 100 km north of Zagreb in the area called Podravina, where he attended primary school and finished gymnasium in Koprivnica. He graduated from the School of Medicine in Zagreb in 1965, and after a few years of medical practice he joined the Andrija Štampar School of Public Health which is a part of the School of Medicine, University of Zagreb. There he spent practically his entire working lifetime. He earned both, MSc and PhD degrees from the University of Zagreb, School of Medicine in 1972 and 1983. In his academic career he advanced from the assistant position at the Chair for Hygiene, Social Medicine, and Epidemiology through positions as assistant professor (1984) and associate professor (1988) to full professorship (2003). He completed the specialization in social medicine and organization of health care successfully in 1974. He was also trained in Sweden (1964), Scotland (1966), USA (1968 and 1971, when he was trained in Public Health, Epidemiology and Research Methods at the Johns Hopkins School of Hygiene and Public Health in Baltimore), Finland (University of Kuopio, 1977) and Alma-Ata (WHO training in Planning and Management in 1985). He paid study visits or served as a consultant in the UK, the USSR, Kazakhstan, Sudan, Cameroon, India, Iran (UNDP), Nigeria (WHO) and elsewhere.

At the Andrija Štampar School of Public Health he used to held numerous posts and responsibilities: he was a head of the Department for Hygiene, Social Medicine and Epidemiology 1993-1997 and after its dissolution in three smaller departments in 1997 he continued to chair the Department for Social Medicine and Organization of Health Care; he was deputy coordinator from 1984 and coordinator 1997-2000 of the WHO Collaborating Centre for Primary Health Care. He served as an assistant to the director and deputy director (1984-2004) and finally as the director of the School from 2004 till his retirement in 2006.

He served firstly as the coordinator and later as director (1990-1996) of the International 9-week course "Planning and management of primary health care in developing countries" which was

held 16 times between 1978 and 1996 at the Andrija Štampar School of Public Health with the support of the Government of The Netherlands and had altogether more than 350 participants coming from 66 countries. Luka Kovacic was active member of the Croatian Medical Association, president of its Section for Social Medicine and Organization of Health Care (1978-1986). Later the section changed its name into the Society for Public Health with him as president (1986-1999). His activities and duties were so numerous, both within his institution and in the broader Croatian and international context, that we mentioned only those mostly pronounced or internationally visible.

Luka was a gifted and dedicated teacher, mentor of six MSc theses and one PhD dissertation as well as altogether more than 200 diploma works for medical and nursing students at the School of Medicine and School of Applied Health Sciences. He was principal investigator in many domestic projects and played a leading role in several international projects and networks. He actively participated in the work of the European network of districts "Tipping the Balance Toward Primary Health Care" (TTB) from 1987, being also its Chairman of the Board and President of the Assembly from 1997 to 2005, and the coordinator of the whole network and the project "TTB Second Decennial Survey of the Health Needs and Health Care for Older People in Europe", which was implemented in five European countries including Croatia in 2005-2006. He was also a member of the European Society for Public Health and its Scientific Committee since2000.

The cooperation between the School of Public Health, University of Bielefeld and public health academic institutions in ten South Eastern European (SEE) countries started in the year 2000 under his able leadership together with professor Ulrich Laaser, supported by the Stability Pact for South Eastern Europe. Professor Luka Kovačic contributed enormously to the establishment of the Forum for Public Health in South Eastern Europe (FPH-SEE) as a network of academic institutions, aiming at the reestablishment of professional cooperation between public health teachers and professionals in SEE. As the result of this cooperation six book volumes were prepared and published between 2004 and 2010 encompassing altogether more than 4300 pages, containing some 250 teaching modules authored by more than 200 authors. Among them professor Kovačič co-edited the volume “Management in Health Care Practice” and authored four modulestherein.

Luka Kovačic was retired less than 9 years ago but he continued to be active and involved in teaching, especially in postgraduate specialist programmes and the PhD programme "Medicine and Health Sciences" where he coordinated courses in Research Methods in Public Health Also at the School of Applied Health Sciences in Zagreb he taught several subjects and mentored diploma works. He was a full member of the Croatian Academy of Medical Sciences where he chaired the College of Public Health and participated in the work of the Committee for food and the Committee for telemedicine to which he was previously president during two terms.

Professor Luka Kovačic has published almost 200 scientific and professional articles and edited several books, among them also a textbook in Social Medicine. He coordinated a number of national and international projects and networks, and has organized numerous national and international conferences in the field of public health and health careorganization.

Condolence arrived to family Kovačic and his colleagues from many institutions and individuals not only from Croatia but also from abroad, especially from colleagues from the South Eastern European countries. Their words once again proved not only how much professor Kovačic was respected as an expert, but also how he was appreciated and loved as a co-worker, colleague and teacher.
Professor Luka Kovačic will remain in our memory forever as a creative and responsible teacher, an excellent organizer, a competent expert, but above all as a colleague and a friend alwaysready

to assume obligations and help others, a modest and friendly man. A number of colleagues, former students, associates and friends from all over Croatia together with those coming from neighbouring countries joined his beloved ones, his wife Marija, sons Mladen and Damir, brother, daughters in law and four lovely grandchildren at his funeral as well as at the commemoration held in the Andrija Štampar School of Public Health on May 12 to pay a tribute to a conscientious and gifted teacher, diligent and organized scientists but above all to the dear colleague, a man who did not have and could not have enemies, because he was gentle and always ready to help, both students and colleagues.

Only ten days after Luka passed away the Global Public Health Curriculum was published in the South Eastern European Journal of Public Health (SEEJPH) including two modules (2.1 and 2.8) he authored. So it happened that his last two teaching texts appeared in SEEJPH,

Let there be glory and praises to LukaKovačic!

May he rest in peace!

On behalf of the Andrija Štampar School of Public Health, School of Medicine, University of Zagreb
Prof. Jadranka Bozikov

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