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From the past to the future!

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Editorial

Albania has been forced to follow a long and winding road from the Ottoman Empire through war and dictatorship to the open horizon of today with the perspective of accession to the European Union. Those who had like me the pleasure to work in Albania and enjoy the unbeatable hospitality of our Albanian colleagues, observe with great admiration their devotion to relieve the country from a darker past.

When the editors-in-chief invited me to write an editorial for the new English edition of the Albanian Medical Journal (AMJ), I was deeply moved passing in my memory the last decade of work: It was in May 2002 that the 3rd Conference on Public Health Training and Research has been organised in Tirana by our network of academic institutions in South Eastern Europe. It may be worthwhile to enlist the cities represented: Athens, Belgrade, Bielefeld, Bucharest, Chisinau, Ljubljana, Novi Sad, Podgorica, Prishtina, Sarajevo, Skopje, Sofia, Tirana, Varna, Zagreb (1).

At that time it was not at all self-understandable that colleagues from Serbia met with their colleagues from Albania, Croatia or Slovenia in Tirana. Many fears were to be suppressed - but Public Health proved its capability and also mission to bridge the abysses the Balkan wars had left in the nineties. The more surprising it was that a formal Agreement on Collaboration could be

preliminarily signed (formally executed a few months later at the Opening session of the 24th Annual ASPHER Conference in Zagreb), recognizing the need for sustainable collaboration and strongly supporting the reconstruction of postgraduate public health training and research based on regional specificities and following international standards in public health education.

Only four years later, in 2006, our Albanian colleagues went a step further organising one of the first summer schools of the Forum for Public Health Training and Research in South Eastern Europe (FPH-SEE) in Saranda, southern Albania. Again, 33 colleagues came from all over the region to study the "Scientific Basis of Public Health". The faculty consisted of

Prof. Bajram Hysa, Tirana, Albania; Prof. Vesna Bjegovic, Belgrade, Serbia; Dr. Gabriela Scintee, Romania; myself and two young doctors, two of the AMJ editors of today, Enver Roshi and Genc Burazeri, in the meantime regular professors at the Medical Faculty of Tirana. There was one presentation which is really memorable when Professor Bjegovic from Serbia presented a SWOT analysis of an Evidence-Based Public Health Policy in Albania. Only a few years ago this would have been unthinkable.

In the following years up to now, six volumes with 249 teaching modules on public health topics have been published (full text available at: http://www.snz.unizg.hr/ph-see/publications.htm) [2], the lecturers in the new under- and postgraduate programmes being the main target group (3). As a most strategic result of the decade of togetherness new Schools of Public Health have been established in Albania, Bulgaria, Macedonia, Moldova, Romania, and Serbia in addition to the long standing Andrija Stampar School of Public Health in Zagreb, Croatia.

All of them became members of the Association of Schools of Public Health in the European Region (ASPHER) and thus the network is literally paving the path especially of the Yugoslavian successor states to European integration.

Where to go from here?

One most important recent development is the new strategy Health 2020 of the European Office of the World Health Organisation and the corresponding European Action Plan for Strengthening Public Health Capacities and Services, adopted a few months ago at the Regional Committee for Europe in September 2012 (4). These two very important documents are grounded on the European agreement about ten Essential Public Health Operations (EPHOs), which underline the central role of Public Health. I may cite EPHO four on "Health Promotion, including action to address social determinants and health inequity" and especially EPHO seven on "Assuring a sufficient and competent public health workforce", together with EPHO ten "Advancing public health research to inform policy and practice". EPHO seven covers the adequacy of schools of public health and all three cycles of the Bologna agreements as well as it underlines the growing importance of Continuing Professional Development (CPD), especially as far distance on-line training is concerned. In the recently published ASPHER survey on profiles and programmes of Schools and Departments of Public Health in Europe (SDPH) [5] we found that there are only 23 or 35% of all participating institutions offering short courses, modules or summer schools, mainly in Public Health and/ or Health Management. Meeting the future challenges in our Century, however, implies profound changes for the public health sciences in terms of continuing inter-professional training (6). The new Schools of Public Health like the one in Tirana can frog-leap to the top of the queue if they take up these latest avenues towards modernity. CPD is supposed to enhance working together, implement multi-professionality in public health practice, and inter-disciplinarity in public health research. But, the capacity of public health institutions in Europe, even adding up Schools and Institutes of Public Health together, is very limited. The median Full Time Equivalent of teaching staff adding up all part-timers does not exceed 20 positions. Vis-a-vis the variation of public health services and professional qualification in the European Region it is certainly difficult to quantify the need for public health professionals. A rough estimate makes use of analyses from the United States (7): Bjegovic-Mikanovic et al. estimate that for the entire European Region, 783 SDPH of average size are needed if to become comparable to aspired US levels. Adequate capacity to offer CPD would require 182 institutions with an output of 121certified graduates in average. In other words, national governments and the European Union in particular should take the chance to invest massively into public health. This would also be in line with the global Non-Communicable Disease Strategy of the United Nations (8) with its focus on an integrated preventive/ curative approach to be implemented at the frontline of primary health care, embedded in the community.

For the countries of South Eastern Europe it seems that the 2010s offer a quite straightforward highway for improving population health remarkably. The stage is set - it is up to the public health professionals in Albania and the government to take the chances.

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Teaching to learn from each other

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Editorial

In Europe we have more than four dozen countries and many different health systems. To look across borders and to see how public health and health care is organized in our neighbour countries and what policies and interventions they employ can be a worthwhile exercise. Maybe our neighbours have already found a solution for a pressing health issue we still do not have any idea how to tackle.

Learning from one's neighbours asks for many things. First, one needs a certain mind-set: One has to understand and be aware that one is someone among others, that one might have developed approaches, knowledge and skills that can be exemplary – but also to be humble enough to recognize that one can learn from others who have established good practices. Second, however, one also needs methodological knowledge. One needs to be aware that not just any solution for a problem that works in one country or region can simply be transferred to another setting and adopted there. Structural or even only cultural aspects could prevent a successful transfer of a good practice from place A to place B. Thus, one also needs to know under what conditions learning from each other can be successful and what it takes to successfully implement practices that are considered to be good in other settings.

At the Faculty for Health, Medicine and Life Sciences at Maastricht University, the Netherlands, we work with the "problem based learning approach": every week students meet in groups of up to a dozen. Students work on cases or 'problems', as we call it. In these tutorials, which students chair themselves under supervision of a staff tutor, they have to define their own learning goals. These learning goals they develop by drawing on "crowd knowledge": What do we already know about this problem, what do we need to know, how can we share research tasks to efficiently get the knowledge we need? Then, students go home or to the library, study for some days and come back together to share what they have learned about the goals they set themselves. By this approach, we want to teach an attitude of lifelong and mutual learning: Students learn to learn together and from each other. Thus, they learn to be equipped for the professional world while acquiring an attitude of lifelong learning that shall be beneficial in their future jobs (1).

In the Master of Science in European Public Health programme we take this perspective even one step further to the health systems level: In this programme we teach how one can learn from one another in health systems: The mission of this master programme is to help students obtain the skills and knowledge necessary to comparehealth and healthcare in various settings, to search for and identify good practices, to foster the transfer of good and best practices, and to implement and

monitor good practices in new situations (2).
Let us conclude, we can learn from our neighbours – in the classroom and in Europe, maybe even worldwide. Of course, we have to keep issues of transferability in mind – not all data, not all evidence, not all systems, not all interventions, not all policies that function well in country A can without further modifications be adopted in country B. Yet, we should start creating the mind-set of mutual learning in our future public health professionals: that learning from each other is possible in principle and can be very effective and efficient. We do not have to reinvent the wheel and always learn solitarily from scratch. Let's join forces – in classrooms and across Europe.

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The quality of infant and perinatal mortality statistical data in Albania for the period 2000-2010

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Abstract

Aim: Albania's infant and perinatal health has improved significantly over the past twenty years. Nevertheless, relatively high mortality rates across the country remain a primary health concern and in need of ongoing attention. This study aims to assess the quality of the country's infant and perinatal health reporting system, both internally and in comparison to international standards, in order to ultimately provide recommendations based on the findings.
Methods: The study consisted in the collection of infant and perinatal mortality data for the period 2000-2010, from national institutions and hospital facilities in Albania, during a research project between the Berlin School of Public Health and The National Institute of Public Health of Tirana, Albania. The data collected was utilized as a primary tool for conducting a comprehensive quality assessment of the health data.
Results: The quality assessment of infant and perinatal mortality data highlights certain inefficiencies with regard to the internal and external comparability of the data. The discrepancy in the collection and reporting of infant and perinatal mortality data in Albania, when compared to international standards, as well as possible gaps in the internal and external data flow, were identified as the key barriers for ensuring the overall quality of the health data generated.
Conclusions: Based on findings from this study, ten country-specific recommendations were proposed. The objective of these recommendations is to improve the quality of infant and perinatal mortality reporting in Albania and ensuring both an internal and international comparability of the data.
Keywords: Albania, data quality, health-reporting, infant mortality, perinatal mortality.

Introduction

Infant and maternal health in Albania has improved significantly over the past decades. Nevertheless, national mortality rates remain high, particularly in comparison to Western Europe. In 2010, for example, the national infant mortality rate in Albania was reported as 9.7 deaths per 1000 live births (1), compared to the EU average of 5.93 deaths for the same year (2).

Infant and perinatal mortality rates are vital indicators of both quality and availability of healthcare services provided to mothers and their newborns (3), and are key indices to monitoring and assessing current health trends and driving the necessary policy and investment decisions (4). Possible inefficiencies within a health-reporting system can compromise the quality of health data and the accuracy with which assessments are conducted.

The purpose of this study is to identify prominent discrepancies in regards to the collection, calculation and reporting of infant and perinatal mortality in Albania, particularly when compared to current international standards. This assessment will serve as a basis in providing recommendations for improving the quality of the collection and reporting of health data and data flow, where deemed most appropriate.

Research questions

1. Are the current definitions and methods of calculation and reporting proposed by the World Health Organization (WHO), currently the ones being used by Albania?
2. What are the main gaps or inefficiencies associated with the reporting of perinatal and stillborn deaths in Albania?
3. What problems can be identified within the data flow process occurring in Albania?

Methods

Data collection

Two separate visits to Albania, one during the project period of mid-April to mid-May and a second in late September 2012, provided the opportunity to collect infant and perinatal mortality data for the years 2000 to 2010 on the field. The health data was collected directly and indirectly from the Statistics Sector of the Ministry of Health (MoH), The National Institute of Statistics (INSTAT), The National Public Health Institute (NPHI), the "Koço Gliozheni" and Lezhë Maternity hospitals, and the "Njësia Bashkiake" Civil Status Office (CSO) in Tirana.

Study Design

The study design is a data quality assessment, a suitable approach for identifying and assessing potential errors or inaccuracies in the generation of data (5). One component of the assessment compares current definitions and methods of calculation of infant and perinatal mortality rates used in Albania to those proposed internationally using the WHO International Classification of Diseases (ICD-10 Volume 2) as the global standard. Additionally, current methods of health data collection and reporting methods in Albania (specific to infant and perinatal data) were evaluated in comparison to international reporting criteria standards recommended by the WHO. The data used to conduct this assessment included hospital form sheets and national table designs.

A second component of the study focused on assessing the current quality of Albania's internal and external data flow. To conduct this assessment, data collected from hospitals and CSOs, along with nationally published data obtained from both the MoH and INSTAT, was utilized. Specific to the external data flow, the WHO Health for All Database (WHO HFA-DB), an international health database for the European region, was used to assess the quality and completeness of data transferred by Albania to international organizations. Based on study results, a list of recommendations was presented to improve the overall comparability of data.

Results

Definition and calculation of health indicators

The infant and neonatal mortality definitions currently used by Albania's MoH are a translated version of those published by the WHO ICD-9 Volume 2 and are ultimately also in line with current WHO ICD-10 Volume 2 definitions, as confirms the national table designs published by the Statistics Sector of the MoH (Table 1). INSTAT, Albania's statistical reporting institution, also currently follows the international definition for infant mortality rates,

Table 1. Infant mortality rates in Albania for the period 2000-2010

Indicator	Year										
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Number of Live births	53833	52888	42315	45132	40866	38789	35816	34383	33368	34044	33856
Number of deaths	864	924	730	701	617	569	466	411	372	352	328
Infant mortality (per 1000 live births)	16.0	17.5	17.3	15.5	15.1	14.7	13.0	11.9	11.1	10.3	9.7
Perinatal deaths(per 1000 live births)	13.1	13.4	11.4	12.7	13.1	12.1	12.9	11.7	12.7	10.7	11.4
Neonatal deaths (per1000 live births)	8.9	10.4	8.4	9.8	9.5	10.20	9.10	8.69	8.30	7.40	6.80

Source: Statistics Sector, MoH Albania, 2011a.

citing it in its online definition catalogues as "the number of deaths per year occurring to 1.000 infants (less than one year old) born alive" (6).

With regard to the perinatal mortality indicator, experts confirm Albania's adherence to the WHO definition of the indicator as being "the sum of fetal deaths and early neonatal deaths" (E. Kakarriqi, August 15, 2012). A set of unpublished data used internally by MoH underlines how the institution currently computes perinatal mortality rates as the *sum* of all 'ante partum' (prior to delivery), 'intra partum' (during delivery) and 'post-partum' deaths (early neonatal period). The data however does not confirm the specific time period from which the 'ante-partum' deaths are recorded, and thus it can only be assumed that the term comprises all fetal deaths occurring after the 22nd completed week of gestation. Contrary to WHO recommendations, the MoH currently does not provide a separate calculation of stillborn death rates within the table designs.

An analysis of Albania's primary level perinatal death data, within healthcare facilities, was conducted using unpublished form sheets from the "Koço Gliozheni" Maternity Hospital of Tirana, along with information gathered from the Lezhë Maternity Hospital. Form sheets from the "Koço Gliozheni" hospital define and report perinatal deaths as the sum of all deaths occurring in the facility during the *antepartum*, *intra-partum* and *post partum* period (Table 2). While not explicit within the national table designs, hospital form sheets, on the contrary, were found to include a detailed reporting of perinatal deaths according to both the weight and weeks of gestation of the dead fetus or newborn. While hospital forms include a detailed collection and reporting of perinatal deaths, there are inconsistencies in how the rates are calculated. Hospital statistical departments calculate deaths as *percentages* (Table 2), as opposed to the internationally recommended calculation of rates as per 1000 births, creating a concern as to how these rates are then adapted at the national level.

Table 2. Perinatal mortality data collection by "Koço Gliozheni" Maternity, 2005

		Perinatal Deaths Year 2005
Born	3108	ANTEPARTUM 41 = 1.31%
501> 22 weeks		+INTRAPARTUM 0 = 0%
		+POSTPARTUM 39 = 1.25%
		=PERINATAL 80 = 2.55%
Born	3108	ANTEPARTUM 30% = .96%
1001> 28 weeks		+INTRAPARTUM 0% = 0%
		+POSTPARTUM 27 = 0.86%
		=PERINATAL 60 = 1.83%

Internal and external comparability of the collection and reporting of data

Hospital form sheets provide essential evidence as to how healthcare facilities collect and report deaths. "Koço Gliozheni" hospital form sheets underscore a comprehensive and detailed procedure for collecting and reporting infant deaths. As one

example of this, form sheets show a registration of neonatal deaths according to duration of life (0-6 days, 7-28 days, and over 28 days), as well as according to weight groups (Table 3).

Table 3. Infant deaths by days and weight, "Koço Gliozheni" Maternity Hospital, 2009

Infant deaths grouped by day for the year 2009					
Day	**0-6**	**7-28**	**Over 28**	**VD-AL**	**Total**
City	11	4	0	2	17
Town	7	5	0	0	12
District	14	5	0	9	28
R-Village	6	6	0	0	11
Total	37	20	0	11	68

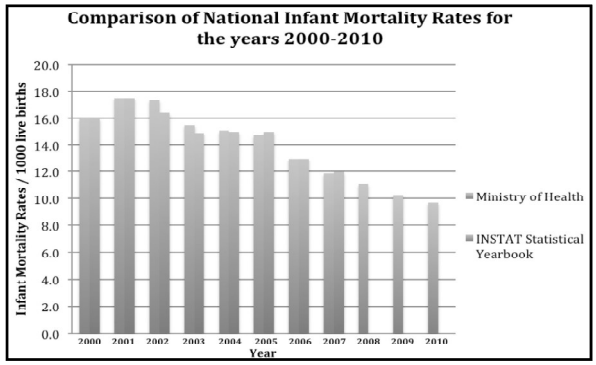
Infant deaths grouped by weight for the year 2009								
Weight	**500-1000**	**Weight**	**1001-1500 g.**	**1501-2000 g.**	**2001-2500 g.**	**>2500 g.**	**Total**	
City	2	**City**	4	3	3	5	17	15
Town	2	**Town**	4	2	1	3	12	10
District	8	**District**	5	3	3	9	28	20
R-Village	6	**R-Village**	4	1	0	0	11	5
Total	18	**Total**	17	9	7	17	68	50

Courtesy of the "Koço Gliozehni" Maternity Hospital in Tirana, 2009a (unpublished raw data).

The quality of data collection and reporting procedures at the national level is influenced by the quality of the process at the primary level. As demonstrated in Table 1, Albania's MoH is currently publishing national infant and neonatal mortality rates as per international standards, however there was found to be no reporting of deaths according to the different neonatal periods (early, late, post) within these tables, as per international recommendations. With regard to the stillborn death indicator, hospital facilities generally report the occurrence of a fetal death as *feto morto*.

As evidenced by Figure 1, fetal deaths are reported in hospitals according to the weight categories of 501g or more, and 1001g or more, slightly diverging from the WHO recommendation of 500g or more (for national data) and 1000 g. or more (for international data) (7). "Koço Gliozheni" form sheets further demonstrate a reporting of antepartum deaths according to weeks of gestation (22-27 weeks, 28-36 weeks, 37-41 weeks, and over 42 weeks) and according to birth weights (500-1000 g., 1001-1500 g., 1501-2000 g., 2001-2500 g., and over 2500g). While the stratification of weight and weeks diverge slightly from WHO standards, hospital data remains the most detailed and comprehensive health data available in the country. At the national level, the MoH and INSTAT do report perinatal mortality rates within their table designs, however, and of most concern, is the fact that stillborn deaths are omitted completely from these tables (Table 1).

Figure 1. Comparison of infant mortality rates for the period 200-2010



Source: Statistics Sector, MoH Albania, 2011a & the INSTAT Statistical Yearbook, 2009: Graph created by Eleonora Kinniautt.

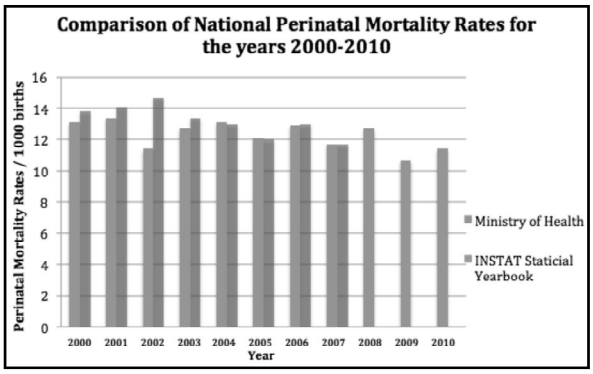
Internal data flow assessment

The MoH collects and compiles data from health care and hospital facilities, while INSTAT operates using a "dual system" of data flow, utilizing both civil registration data deriving from CSOs and health data deriving from hospitals and primary healthcare facilities (8). Albania's current birth registration forms requests information regarding length of pregnancy, description of delivery and whether the child is born alive or not. The death of a child, born in Albania

or to Albanian parents, should, according to the law, be reported in the CSO of residence of the mother. Nevertheless, if the death occurs outside Albania, it is oftentimes difficult to guarantee a registration of the event in the CSO of the mother's residences, as it remains difficult to monitor vital events occurring outside the country ("Njësia Bashkiake", May 2, 2012). INSTAT's demographic health indicators are an important reflection of the population's health status, and are vital tools for monitoring the quality of healthcare provided (8). Today, Albania is witnessing a new migration trend characterized by pregnant women deciding to temporarily leave Albania to give birth abroad. These women however are required by law to return to Albania within three months after giving birth to register their child in their CSO of residence ("Njësia Bashkiake", May 2, 2012). While these births or deaths will be recorded within the national civil registration system, they will be missing from national hospital data, opening up the possibility for an overall discrepancy in health data between hospitals and CSOs.

To further investigate a possible discrepancy in data, national infant and perinatal mortality rates published in the last ten years by the MoH and INSTAT were compared. As is evidenced by Figure 1 and Figure 2, there is currently a difference in the rates being published by the institutions for the same years, a possible cause of the current inefficiencies in Albania's internal data flow.

Figure 2. Comparison of perinatal mortality rates for the period 200-2010



Source: Statistics Sector, MoH Albania, 2011a & the INSTAT Statistical Yearbook, 2009: Graph created by Eleonora Kinniautt.

External data flow assessment

The quality of the external flow of health data is critical to ensuring international comparability. The WHO HFA-DB currently publishes a set of core health indicators from all countries in the WHO European Region, and in order to assess the quality of external data flow, infant and perinatal mortality data for Albania (2000-2010) were searched within the database (9). The search resulted in a set of incomplete data, offering only infant and neonatal mortality data for the years 2000–2004, and no data on perinatal mortality rates for Albania. Inefficiencies in the internal and external data flow are underlined by the WHO HFA-DB, stating that: *"Particularly high levels of mortality under- registration are observed in countries of central Asia and Caucasus, Albania* […]" (10).

Discussion

Quality and comparability of health data

The collection and reporting procedures of infant mortality data within hospitals was found, overall, to be in line with international standards; evidenced by the inclusion of neonatal deaths according to duration of life (despite a minor divergence in late neonatal deaths as 7-28 days as opposed to 7-27 days). As the primary national health reporting institution, the MoH currently receives *all* hospital data, however, due to an aggregation of the data; it currently only publishes *total* neonatal mortality rates (Table 1). The omission of deaths according to neonatal periods within national table designs contradicts WHO recommendation that underline the different neonatal periods as important indicators of the quality of antenatal care, care during delivery and postnatal care (11). It is therefore important that Albania prioritize the national reporting of detailed neonatal mortality data, necessary for conducting newborn health evaluations.

While Albanian law currently defines stillborn deaths in accordance with WHO standards, as the death of the fetus weighing 500g or more (E. Kakarriqi, August 15, 2012), there was no identification of a written and translated definition available in the country. Within INSTAT's online catalogue, the sole definition identified was that of *prenatal death,* defined as 'the death of a fetus or child occurring before the delivery, during the delivery and death from 24 hours till 108 hours (seven days) from the delivery of a child born alive' (6). This indicator however remains incomparable to perinatal and stillborn deaths, and also presents a calculation error in that 108 hours is only equivalent to four and half days

and not seven days.

Study results highlight ongoing challenges faced by Albania's health-reporting system in guaranteeing a standardized method of stillbirth reporting across all levels of the healthcare system (E. Kakarriqi, May 3, 2012). The terms *fetal* or *antepartum* death, utilized most often within Albania's hospital forms, lack any indication as to the weeks of gestation or weight of the fetus at the time of death, vital information when coding and reporting stillborn deaths. The complete omission of the stillborn death indicator within national table designs, despite WHO recommendations to do so, further affects the quality of perinatal mortality data, hindering an accurate evaluation of maternal and perinatal health in Albania (12).

Quality of data flow

A comprehensive assessment of Albania's demographic data flow could not be conducted due to limited time and resources; nevertheless, a number of possible concerns in the quality of internal data flow were acknowledged. A primary concern over the quality of data flow to INSTAT is in regards to currently high rates of population movement and recognized underreporting of births and deaths in Albania (10). The unquantifiable rate of Albanian women giving birth abroad implies the loss of health data within Albanian hospitals and an ultimate divergence with civil registration data (as births or deaths will be registered in CSO of mother's residence upon return to Albania) ("Njësia Bashkiake", May 2, 2012). The questionable reliability of internal data flow to INSTAT can distort population statistics and directly affect the computation of demographic health indicators produced, including infant and perinatal mortality rates (13).

An internal comparison of infant and perinatal data, conducted specifically for the study, highlights a divergence in mortality rates published by the MoH and INSTAT (Figure 3 & 4). The observed discrepancy may be at least partially caused by inefficiencies in Albania's internal data flow. An underreporting of births and deaths was a factor raised by numerous experts in Albania as a possible reason for the observed divergence in rates between two national institutions (E. Buzali, September 25, 2012). Inefficiencies in the internal data flow were found to ultimately compromise the quality of external data flow, as evidenced by a lack of available health data for Albania within the WHO HFA-DB.

Country recommendation proposals

While Albania's health system, like many others, continues to face challenges, the country has already made unquestionable progress, underlining both the ability and concerted effort being made towards responding to the health needs of its population. The findings from this data quality assessment are intended to provide support during this important phase of progress by proposing a number of recommendations:

a) Albania should adopt all current international definitions for the reporting of infant and perinatal mortality indicators, in line with the WHO ICD-10 Volume 2, across all levels of the system, with a particular focus on standardizing the coding and reporting of stillborn deaths.

b) Albania should adopt new form sheets and table designs across all levels of its health-reporting system. A reform in data collection will ensure both the internal and external comparability and validity of the health data, necessary for conducting health evaluations at the regional and global level.

c) It is recommended that Albania include an accurate stratification of deaths according to the duration of life, accordance with international standards. Within hospital forms *and* national table designs, deaths occurring during the early neonatal (0-6 days), late neonatal (7-27 days) and post neonatal (28-364 days) periods should be reported separately (7).

d) Albania is advised to report the weights of births and deaths according to international recommendations; using the following categories proposed by the WHO ICD-10 Volume 2: *Low birth weight* (up to and including 2499 g.), *Very low birth weight* (up to and including 1499 g.) and *Extremely low birth weight* (up to and including 999 g.) (7).

e) It is recommended that Albania implement a perinatal death certificate that includes information o the cause of death of the fetus or newborn along with the conditions of the mother. The data registered on this death certificate will provide more detailed information on the perinatal health situation.

f) To ensure an *internal validation* of data, Albania is advised to implement a protocol procedure for

internal flow of data. A standard protocol will ensure the quality and completeness of health data generated and used for internal and external assessments.

g) To ensure an *external validation* of data, it is advised that Albania implement a data management system that defines who is responsible for the external delivery of data and for assuring that the quality and completeness of data are in line with international protocols.

h) It is recommended that Albania prioritize its civil registration data of births and deaths as the primary or "official" set of data. The recommended reform aims to address the inefficiencies identified within the current "dual system" of data flow to INSTAT from CSOs and hospitals.

i) It is recommended that INSTAT guarantee a yearly publication of demographic data either through its online database or as a statistical demographic yearbook. Additionally, the country should aim to publish yearly health reports, produced by the NPHI, to assess current epidemiological trends, population health status and public health services across the country.

j) The implementation of national training programs, both in data collection and in statistical training is recommended. These efforts will require particular focus on the training of staff and personnel within government institutions, particularly if there is to be the eventual adoption of the WHO ICD-Volume 2. Training programs should be complemented by the formation of special commission groups, necessary for monitoring infant and maternal health at the district level.

Limitations

Study limitations included the inability to collect all necessary data for the years 2000-2010, making more difficult the ability to conduct assessments and comparisons. A limited number of English publications, specific to Albania's infant and perinatal health situation, proved to be another constraint to the study, as there was less evidence available to support certain findings. Lastly, while personal communication with experts proved to be an invaluable asset, the diverse areas of expertise resulted, in certain instances, in a divergence of information gathered. The subjectivity of some information meant that it could not be included.

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Cross-cultural adaptation of a questionnaire about competencies of family physicians in Kosovo from practitioners' and policymakers' perspective

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Abstract

Aim: Our aim was to validate an international instrument measuring abilities, skills and competencies of family physicians from practitioners' and policymakers' perspective in Kosovo.
Methods: A sample of 20 family physicians in primary health care services and 20 policymakers in the health sector was interviewed in December 2012 and subsequently re-interviewed in January 2013. A structured questionnaire, administered and subsequently re-administered after two weeks (test-retest) to all participants, assessed physicians' level of abilities, skills and competencies regarding different domains of quality of health care. The questionnaire included 37 items grouped into 6 subscales/domains. Answers for each item of the instrument ranged from one ("novice" physicians) to five ("expert" physicians). An overall summary score (range: 37-185) and a subscale score for each domain were calculated for the test and retest procedures. Cronbach's alpha was employed to assess the reliability (internal consistency) for both the test and the retest procedures, whereas Spearman's rho was used to assess the test-retest reliability (stability over time) of the tool.
Results: Among policymakers, the instrument exhibited a higher internal consistency (Cronbach's alpha was 0.97 for the test and 0.96 for the retest procedure) compared to family physicians (0.89 and 0.88, respectively). Subscale coefficients, however, were not very different in each group. In particular, the "patient care and safety" domain behaved similarly in both groups for the test and the retest procedure. Overall, stability over time of the instrument was slightly higher among policymakers (Spearman's rho: 0.87, P<0.01) compared to practitioners (Spearman's rho: 0.83, P<0.01). Except the "continuing professional development" domain, for all the other subscales, the test-retest reliability coefficients were higher among policymakers than practitioners.
Conclusion: Our findings point to an adequate internal consistency (for both the test and retest procedures) and stability over time (test-retest reliability) in this sample of family physicians and policymakers in Kosovo. From this perspective, this validation study provides useful evidence on cross-cultural adaptation of an international instrument measuring the level of competencies of family physicians in Kosovo. Seemingly, the instrument indicates a good potential for wide scale application to policymakers and especially to nationally representative samples of family physicians in transitional Kosovo.

Keywords: competencies, cross-cultural adaptation, family physician, general practitioner, Kosovo, policymakers, primary health care, quality of care, validation.

Introduction

In the past decade, there has been published a considerable amount of literature aiming to conceptualize, operationalize and define the quality of health care (1). Thus, quality of care, in general, is defined as *"….the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"* (1). From this point of view, quality of health care must be in line with the public expectations which certainly relate to a good quality of health care services. This is especially true for the expectations and demands of the clinically-ill patients – salient features which put pressure upon health care professionals at all levels and require them to provide high quality health care services (2). This is particularly relevant for general practitioners and family physicians who, in most countries, serve as gatekeepers and exercise a multitude of functions related to health care service provision at a population level. For this very reason, quality improvement and performance evaluation have become core issues in health care practice, especially in industrialized countries. In order to deal with quality improvement, however, a basic prerequisite would be to include various topics pertinent to quality of health care services in different levels and layers of the medical curricula (2). From this standpoint, quality improvement topics should be included at all levels and aspects of medical education implying that medical students and practitioners should not only receive medical knowledge in the course of their studies and training, but should additionally acquire abilities, skills and competencies in the areas of quality improvement and quality assurance at large (2,3).

It has been convincingly argued that in general practice/ family medicine, quality of health care includes different aspects of health care services and covers a wide range of practitioners' scope of work referred to as "comprehensive/ holistic approach to health care provision" (2,4). Besides the traditional features, this wide array of scope of work of family physicians includes also management skills, community orientation, and various complex problem-solving skills and abilities to effectively and efficiently handle different tasks and duties pertinent to provision of high quality health care services (2,4). Consequently, it is generally recognized that attitudes, abilities and competencies in quality improvement are vital for family physicians/ general practitioners in order to improve particularly patient care, but also health care services at a population level (2). Hence, different attempts have been established and undertaken aiming to design precise and detailed tasks, duties, roles, abilities, skills and competencies for medical doctors including also continuous professional development (which in the medical field is referred to as "continuous medical education") [5]. Such tasks, duties and roles including specific competences are grouped into various frameworks (6-9). Models and frameworks of attitudes, abilities, skills and competencies are also considered as a useful instrument for self-assessment of primary health care physicians and practitioners committed to improve the quality of health care services they provide by integrating knowledge gained into their daily (routine) health care practice (10,11).

Yet, little evidence is available with regard to efforts, programs and activities aiming to improve the teaching quality and standards of medical curricula in European countries including also the transitional countries of the Western Balkans. In particular, there is scant evidence about the topics pertinent to teaching quality improvement, reflected in the structure, content and outcomes of both undergraduate and postgraduate medical curricula, as well as continuous medical education.

The information is especially scarce for Kosovo, a country which is currently undergoing a very difficult period of transition following a decade of war with Serbia. In this context, the aim of this cross-cultural adaptation survey was to validate an international instrument (developed with the support of the European Community Lifelong Learning Program) regarding self-perceived level of skills, abilities and competencies of family physicians from both practitioners' and policymakers' perspective in post-war Kosovo.

Methods

A sample of 20 family physicians operating in primary health care services and 20 policymakers in the health care sector was interviewed in December 2012 *(test)* and subsequently re-interviewed in January 2013 *(retest)*.

A structured questionnaire, administered and subsequently re-administered after two weeks (test-retest) to all participants, assessed family physicians' level of abilities, skills and competencies regarding different domains of quality of health care from the perspective of practitioners and policymakers, respectively. More specifically, family physicians were asked to *self-assess* their level of skills, abilities and competencies regarding the described domains of primary health care. Conversely, policymakers were asked to rate, from their perspective, the *required/ desirable* level of skills, abilities and competencies of family physicians regarding the same domains of quality of care.

The questionnaire included 37 items grouped into the following six subscales/ domains of the quality of care: "patient care and safety" (eight items); "effectiveness and efficiency" (seven items); "equity and ethical practice" (eight items); "methods and tools" (five items); "leadership and management" (four items), and; "continuing professional development" (five items).

Answers for each item of each subscale ranged from *one* ("novice"= physicians have little or no knowledge/ ability, or no previous experience of the competency described and need close supervision or instruction) to *five* ("expert"= physicians are the primary sources of knowledge and information in the medical field).

An overall summary score (range: 37-185) and a subscale score for each domain were calculated for the test and the retest procedures.

Along with demographic information, data on job position and function (for policymakers), work experience (for both groups), specialization and involvement in teaching and training activities (for family physicians) were also collected.

Cronbach's alpha was employed to assess the reliability (internal consistency) for both the test and the retest procedures, whereas Spearman's rho was used to assess the test-retest reliability (stability over time) of the tool.

Results

Table 1 presents the distribution of demographic factors and work characteristics in this study sample in Kosovo including 20 family physicians and 20 policymakers in the health care sector. Among policymakers (12 men and 8 women), median age was 44.5 years (interquartile range: 42.0-47.5 years). Among family physicians, (12 men and 8 women), median age was 49.0 years (interquartile range: 37.0-58.8 years). Forty percent of policymakers hold a working position in Pristine, whereas 60% operated in other regions of Kosovo. For family physicians, these figures were 30% and 70%, respectively. The median of working experience for family physicians was 19.0 years (interquartile range: 12.0-28.5 years),

Table 1. Distribution of demographic factors and work characteristics in a sample of family physicians and policymakers in the health sector, Kosovo, 2012-2013

Characteristics	Policymakers (N=20)	Family physicians (N=20)
Age (years)	44.5 (42.0-47.5)*	49.0 (37.0-58.8)*
Sex:		
Men	12 (60.0)†	12 (60.0)†
Women	8 (40.0)	8 (40.0)
Region:		
Pristine	8 (40.0)†	6 (30.0)†
Other regions	12 (60.0)	14 (70.0)
Years of practice/position	7.0 (3.3-8.0)*	19.0 (12.0-28.5)*
Specialization:		
General practitioner	-	13 (65.0)†
Specialist		7 (35.0)
Position/function:		
Director of health center	4 (20.0)†	
Coordinator of health programs	6 (30.0)	-
Family medicine trainer/educator	3 (15.0)	
Other	7 (35.0)	
Involvement in training activities:		
No	-	15 (75.0)†
Yes		5 (25.0)

* *Median values and interquartile ranges (in parentheses).*

† *Numbers and column percentages (in parentheses).*

whereas for policymakers it was 7.0 years (3.3-8.0 years). Among family physicians, 35% were specialized, whereas 65% were general practitioners. validation study. Among policymakers, the instrument exhibited a higher internal consistency (Cronbach's alpha was 0.97 for the test and 0.96 for the retest procedure) compared to family physicians (0.89 and 0.88, respectively). Subscale coefficients, however, were not very different in each group. In particular, the "patient care and safety" domain behaved similarly in both groups for the test and the retest procedure (Table 2).

Table 2. Internal consistency of each domain (subscale) of the instrument for the test and the retest application in a sample of family physicians and policymakers in Kosovo

Domain (subscale)	Policymakers (N=20)		Family physicians (N=20)	
	Test	Retest	Test	Retest
Overall scale *(37 items)*	0.97*	0.96	0.89*	0.88
Patient care and safety *(8 items)*	0.89	0.89	0.88	0.87
Effectiveness and efficiency *(7 items)*	0.90	0.82	0.91	0.92
Equity and ethical practice *(8 items)*	0.96	0.91	0.92	0.90
Methods and tools *(5 items)*	0.89	0.91	0.87	0.91
Leadership and management *(4 items)*	0.89	0.78	0.77	0.81
Continuing professional development *(5 items)*	0.94	0.88	0.83	0.79

* *Cronbach's alpha.*

Table 3 presents the test-retest reliability (stability over time) for each subscale of the instrument. Overall, stability over time of the instrument was slightly higher among policymakers (Spearman's rho: 0.87, $P<0.01$) compared to practitioners (Spearman's rho: 0.83, $P<0.01$). Except the "continuing professional development" domain, for all the other subscales, the test-retest reliability coefficients were higher among policymakers than practitioners (Table 3).

Table 3. Test-retest reliability (stability over time) for each subscale of the instrument

Domain (subscale)	Policymakers (N=20)		Family physicians (N=20)	
	Spearman's rho	P-value	Spearman's rho	P-value
Overall scale *(37 items)*	0.87	<0.01	0.83	<0.01
Patient care and safety *(8 items)*	0.95	<0.01	0.92	<0.01
Effectiveness and efficiency *(7 items)*	0.85	<0.01	0.81	<0.01
Equity and ethical practice *(8 items)*	0.83	<0.01	0.77	<0.01
Methods and tools *(5 items)*	0.79	<0.01	0.74	<0.01
Leadership and management *(4 items)*	0.73	<0.01	0.69	<0.01
Continuing professional development *(5 items)*	0.80	<0.01	0.82	<0.01

Discussion

This validation study provides valuable evidence about cross-cultural adaptation of an international instrument (questionnaire) measuring the level of skills, abilities and competencies of family physicians from both practitioners' and policymakers' perspective in the transitional population of Kosovo. As described previously, the design and development of this questionnaire on self-assessment level of skills, abilities and competencies of family physicians was aligned with the Quality Improvement Competency Framework (QICF) [2,10]. It must be pointed out that the QICF was developed in the course of a robust and methodical expert study involving European primary care experts interested or specializing in the area of quality improvement (2,10).

Overall, the international tool employed in this validation exercise exhibited a good internal consistency for both the test and the retest procedures in both samples included in the survey namely family physicians and policymakers of the health care sector. Particularly for the policymakers, the tool showed a very high internal consistency in both rounds of application. Nevertheless, among the policymakers, there were discrepancies in the reliability coefficients for the "effectiveness and efficiency" subscale (0.90 vs. 0.82 for the test and the retest procedures, respectively), "leadership and management" domain (0.89 vs. 0.78, respectively) and "continuing professional development" subscale (0.94 vs. 0.88, respectively). On the other hand, among family physicians, there were fewer discrepancies between the test and the retest procedures compared with the policymakers, notwithstanding the overall lower reliability coefficient (Cronbach's alpha).

In both study groups, in general, the questionnaire showed a good stability over time, as indicated by the test-retest reliability coefficients. Compared with the sample of family physicians, Spearman's correlation coefficients (a measure of stability over time of the instrument) were higher among policymakers for all the subscales, except for the "continuing professional development" domain.

The overall internal consistency of the instrument in this Kosovo sample of family physicians was comparable with a fairly recent study from Albania, which reported a similar cross-cultural adaptation process of the same instrument in a representative sample of family physicians operating in primary health care services in Tirana, the Albanian capital (2). Our study expands further the evidence of validation of this international instrument in Albanian settings. It is appealing for future studies to pre-test (alias validate) this instrument also in Albanian speaking regions of Macedonia.

In conclusion, in the Kosovo context, we validated a useful tool measuring family physicians' level of abilities, skills and competencies regarding different domains of health care services from both practitioners' and policymakers' perspective. Our findings point to an adequate internal consistency (for both the test and the retest procedures) and stability over time (test-retest reliability) in this sample of family physicians and policymakers in Kosovo. From this perspective, this validation study provides useful evidence about cross-cultural adaptation of an international instrument measuring the level of competencies of family physicians in Kosovo. On the face of it, this international instrument indicates a good potential for wide scale application to policymakers and especially to nationally representative samples of family physicians in transitional Kosovo.

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Iodine status among primary school children in Albania

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Abstract

Aim: Iodine deficiency disorders (IDDs) currently constitute a major global public health problem. IDDs remain a public health concern in Albania too. We undertook this survey in Albania to determine median urinary iodine concentration in a sample of school children, and asses the level of iodine in salt samples at the household level.
Methods: A nationwide cross-sectional study was conducted in Albania in 2012 including a representative sample of 1027 school children aged 6-13 years. Urine and salt samples were examined for iodine concentration.
Results: The median urinary iodine concentration was 100.4 µg/l, indicating no iodine shortage. Conversely, 49.6% of the examined urine samples indicated iodine deficiency. Iodine content was found to be adequate in 62.1% of salt samples. The median iodine concentration of salt samples was 18.5 mg/kg.
Conclusion: Our findings indicate that IDDs are still an important public health problem in Albania. These results point to the need for strengthening the national IDD Control Program in Albania, and the need to ban production, trading and use of the non-iodized salt.

***Keywords**: Albania, iodine deficiency disorders, median iodine concentration, school children.*

Introduction

Iodine is an essential element for human survival. It is needed for growth and development, even before birth. Although iodine is an important micronutrient, it is needed only in very small quantities. In order to prevent deficiency, a person needs only 150 µg of iodine per day, and over a lifetime, the total quantity of iodine needed is only one teaspoonful of iodine. Healthy humans require iodine, which is an essential component of the thyroid hormones. Failure to have adequate iodine leads to insufficient production of these hormones, which affect many different parts of the body, resulting in a number of pathologic conditions known as the Iodine Deficiency Disorders (IDDs). Iodine deficiency continues to be a significant public health problem in many countries. Their effect is hidden and profound affecting the quality of life (1). Globally, 2.2 billion people live in areas with iodine deficiency and are at risk for IDD-related complications (2). Iodine deficiency not only causes goitre, but it may

also result in abortion, stillbirth, mental retardation, growth retardation, irreversible brain damage and retarded psychomotor development in the fetus, infant and the child. It also affects reproductive functions and impedes children's learning abilities. Iodine deficiency is currently recognized as the most common preventable cause of brain damage at a global level. Therefore, IDDs are currently one of the major worldwide public health problems.

Albania is a country with limited environmental resources of iodine. Traditionally, IDD has been a major public health problem. The levels of iodine are very low in drinking water and food. This fact is strongly correlated with IDDs in Albania. The prevalence of IDD among children aged 7-14 years in areas with iodine-free water is 78%-92% whereas, in areas where the iodine content of the water is 8.95mg/l, the prevalence of goitre is only 15.25% (3). In the recent past, Albania had severe IDDs, as shown in several studies. Thus, a study conducted in March 2003 among 826 school children in 7 schools in Korçë, South Albania, reported a median UIE of 45mg/ L and 17mg/ L for urban and rural children respectively (4). Following the examples of many countries, public health decision-makers in Albania employed an effective policy of IDD elimination based on the exclusive supply of iodized salt, and a massive public awareness campaign was launched to promote a rapid increase in acceptance of the consequent exclusive iodized salt consumption. A population-representative survey conducted in the fall of 2006 showed that 6% of the consumers' salt was not iodized at that time and that 60% of the households were already using adequately iodized salt (5). Albanian Demographic and Health Survey (ADHS) data 2008-9 indicate that 76% of families use adequately iodized salt (6). The use of adequately iodized salt in the cities was higher than in rural households.

Notwithstanding the considerable progress in Albania regarding the universal salt iodization strategy, the median urinary iodine concentrations in school-aged children and pregnant women in the same survey indicated that the iodine status in the population remains marginal.

The data of the 2006 survey were encouraging and showed a good progress, but nevertheless Albanian population is still iodine insufficient. Therefore, there is a clear case for continuation of the proposed measures and undertaking different activities and programs to eliminate IDDs in Albania.

On the other hand, there is a need for documenting and monitoring systematically the IDD prevention through epidemiological studies. The basics are in place, and the current study aims to contribute a further step in this process. Thus, the objective of this study was to provide operational data on iodine status in the Albanian population at national level and evaluate the progress towards achievement of IDD elimination in Albania.

In this framework, a survey was carried out during the period September-December 2012 to determine median urine iodine concentration in a representative sample of school children, and assess the level of iodine in salt samples at household level.

Methods

A nationwide cross-sectional survey was conducted in Albania including a representative sample of school children. Data were collected from September to December 2012. Sampling method used was the *"multistage cluster sampling with probability proportionate to size"*, recommended by WHO, UNICEF and ICCIDD (7, 8).

Albanian primary schoolchildren were the primary sampling units. The children from the first to the seventh grade were targeted for inclusion in the current survey.

The sampling frame, therefore, consisted of a list of all primary schools categorized into regional areas. Four regional areas in Albania, supposedly homogenous, were designated (9). For every regional area, 30 clusters were drawn to insure a valid estimation of the IDD prevalence (10). The division board between coastal region and internal region traverses the schools of these districts: Shkoder, Lezhe, Kurbin, Durres, Kavaje, Lushnje, Fier, Vlore and Sarande (the districts mentioned above represent the coastal area).

The total number of children selected from all schools was 1060 children. The expected prevalence of goitre was anticipated at 45% with a precision of 10%. The schools were selected randomly with replacement and with a probability proportional to size (i.e. proportional to the number of children in each school).

All families and teachers from the selected schools

gave their oral consent for participation in the current survey.

Data collection consisted of two main components:
i. For determination of urinary iodine concentration, the casual urine was taken from the children included in the survey. Samples of urine, collected in sealed plastic containers (about 8 ml urine for each person), were transported to the Institute of Public Health Urinary Laboratory for analysis. The Laboratory participates at the EQUIP Program (Ensuring the Quality of Urinary Iodine Procedures) of the CDC (Center for Disease Control and Prevention), Atlanta, USA.

ii. For determination of iodine in the salt, there were drawn samples of salt used in the children's households. Children brought the samples at their respective schools. Salt samples, collected in plastic glasses (about 20 g. of salt for each person), were analyzed at the Food Chemistry Laboratory of the Institute of Public Health.

Results

Urinary excretion of iodine

A total of 1027 urine samples were tested for median iodine concentration. The median iodine concentration was 100.4 mg/L, indicating no iodine deficiency. Median iodine concentration showed mild deficiency in rural areas of both internal and coastal regions included in the survey (Table 1).

Table 1. Median concentration of urinary iodine in a nationwide representative sample of Albanian school children by region

Geographical region	Median concentration of urinary iodine (in μg/L)
Coastal region / rural	84.8
Internal region / rural	91.6
Coastal region / urban	111.7
Internal region / urban	137.5
National level	100.4

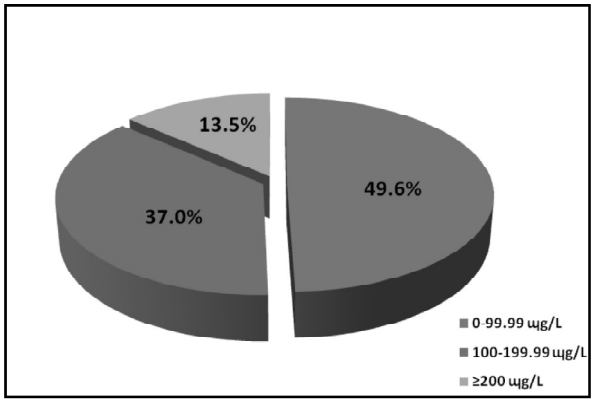
Range of normal values: 100-199 μg/l.

Overall, 49.6% of the examined urine samples showed iodine insufficiency, 37.0% of children had sufficient intake of iodine and 13.5% had excessive intake of iodine.
Overall, iodine concentration in the urine samples ranged from a severe iodine deficiency (<20mg/L) to excessive iodine (e"300 mg/ L), where 33.7% of the examined children had a concentration level of urinary iodine between 50 and 99μg/ L – indicating *mild iodine deficiency* level; 13.4% had a concentration level of urinary iodine between 20 and 49μg/ L – displaying *moderate iodine deficiency* level, and; 2.4% of the children had concentration levels of <20 μg/ L – indicating *severe iodine deficiency* level (Table 2 and Figure 1).
Compared with the distribution of urinary iodine from the study conducted in 2006, there is evidence of an improvement of the IDDs situation in the Albanian population (Figure 2).

Table 2. Distribution of iodine deficiency in Albania based on urinary iodine content (mg/L)

Urinary iodine (in μg/L)	Number	Percentage	Cumulative percentage
0-19.99	25	2.4	2.4
20-49.99	138	13.4	15.9
50-99.99	346	33.7	49.6
100-199.99	380	37.0	86.6
200-299.99	86	8.4	94.9
300+	52	5.1	100.0
Total	**1027**	100.0	

Figure 1. Distribution of iodine intake among Albanian school children (percentages) based on urinary excretion of iodine



Iodine in the salt

A total of 1027 salt samples were tested for median iodine concentration. The median iodine concentration was 18.5 mg/ L (mean value: 21.0 mg/ L).
In the coastal region, median salt iodine was 19.0 mg/ kg, whereas in the internal region it was 18.0 mg/ kg (Table 3). In the rural areas of the internal region, there was evidence of the lowest salt iodine concentration (15.9 mg/ kg) followed by the rural areas in the coastal region (16.9 mg/ kg). This difference in median salt iodine concentrations may

be explained by the fact that individuals in rural areas are reluctant to use the iodized salt due to their necessity to preserve food products for the winter season.

On the other hand, about 62% of the samples had the iodine content of e"15 ppm (i.e. iodized in accordance with WHO/ ICCIDD recommended values), whereas 38% of the samples contained no iodine or, less than 15ppm.

Coastal region displayed a higher consumption of iodized salt (66.3%) compared with the internal region. Conversely, the highest prevalence of non-iodized and/ or insufficiently iodized salt (d"15 ppm) was evident in the internal region (41.7%).

The difference in iodized salt consumption between urban areas and rural areas was considerable (75.3% vs. 58.1%) and statistically significant ($P < 0.01$). Furthermore, there was evidence of a statistically significant correlation between iodized salt consumption and urinary iodine concentration level ($P < 0.01$) [data not shown].

Discussion

The main findings of this survey, which included a nationwide representative sample of school children in Albania, point to a further improvement of the IDDs' situation in Albania compared with the previous study conducted in 2006. Thus, in 2006, Albania had an IDD prevalence of 55.6 %, with 6.8% of the population exhibiting a *severe iodine deficiency* status, 19.9% showing a *moderate deficiency* status, and 28.9 % displaying a *mild deficiency* status (5). Conversely, 44.4% of the population did not exhibit any iodine deficiency (5). In our study, the prevalence of iodine deficiency was 49.6%, whereas the prevalence of severe iodine deficiency was 2.4%.

A further improvement was also evident for dietary intake of iodine in the current study sample: in 2006, median urinary iodine was 86.2 mg/ L (5), whereas in our study median urinary iodine increased up to 100.4 mg/L.

As for the trend in iodized salt consumption, there is evidence of a slight increase at the national level compared with the previous report pertinent to the year 2006 (5). Regarding regional differences, there is a decreasing trend of iodized salt consumption in the internal region of Albania from 63.1% in 2006 (5) to 58.3% in the current survey, but an increase of almost 10% in the coastal region.

Data on urinary iodine reflect the consumption of iodized salt in each region. Thus, in urban areas of both regions (which exhibit a higher median of urinary iodine), there is also a higher median of urinary iodine.

Therefore, prevention of IDDs through employment of iodized salt is demonstrated as a rather effective approach.

In conclusion, in spite of the improvement of iodine intake of the Albanian population, this study showed that IDDs constitute still an important public health problem in Albania. Our findings, therefore, point to the need for strengthening the National IDD Control Program, and the need to ban production, trading and use of the non-iodized salt in Albania.

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Psychosocial determinants of health: A pilot study in Kosovo

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Abstract

Aim: In industrialized countries, psychosocial factors have been linked to morbidity and mortality outcomes. The aim of this pilot study was to pre-test a questionnaire related to psychosocial determinants of health in the transitional population of Kosovo.
Methods: A representative sample of 87 primary health care users aged e"18 years (41 men, 46 women) was interviewed in Kosovo in November-December 2012. A structured questionnaire was administered to all participants including information on self-reported health status, psychosocial factors (hostility, reaction to transition and stress level), lifestyle/behavioral characteristics and demographic and socioeconomic factors. Binary logistic regression was used to assess the association of psychosocial factors with self-reported health status.
Results: 37% of men and 46% of women reported poor health. Hostile behavior was reported in 24% of participants, a pessimistic reaction to transition was evident in about 55% of participants, whereas about 56% of individuals reported a high level of stress. In multivariable-adjusted models, there was evidence of a positive and statistically significant association between poor self-reported health status and stress (OR=1.82, 95%CI=1.00-3.34). Conversely, the relationships of health status with hostility and reaction to transition were weak and not statistically significant.
Conclusion: Findings from this pilot study in Kosovo confirm the deleterious health effects of psychosocial factors, which is in line with previous reports from the western countries. However, the relationship of health status with psychosocial factors should be explored in more detail in future large-scale studies in Kosovo and other transitional settings.

Keywords: *health status, hostility, Kosovo, pilot study, primary health care, psychosocial determinants, reaction to transition, stress, validation.*

Introduction

In industrialized countries, psychosocial factors have been linked to several morbidity and mortality outcomes. Thus, hostility has been reported as a predisposing factor which leads to coronary heart disease (1). As a matter of fact, many studies have shown hostility, a stable personality trait (2,3), to be associated with increased risk of cardiovascular outcomes and all-cause mortality (1,4-8). Similar

evidence was also obtained from a study conducted recently in Albania (9). Another psychosocial factor namely attitudes towards the socioeconomic and political reforms have been linked to poor self-rated health in Russia (10,11) and more recently in Albania (12). Overall stress, in turn, has been arguably and consistently linked to unfavourable health outcomes in western countries (13), but also in former communist countries (14).

The evidence from Kosovo is scant. Five years ago, Kosovo emerged as an independent state after a long and devastating war with Serbia. The transition towards a new political and economic system, however, is rather difficult and poses serious challenges. Actually, Kosovo remains one of the poorest countries in Europe. Particularly, the health care system in Kosovo suffers severe problems including the lack of a social health insurance scheme. Health effects of the rapid transition have not been well-documented in Kosovo. Yet, the available evidence suggests an increase in cardiovascular morbidity and mortality.

In this context, the aim of the current pilot study was to pre-test a questionnaire related to psycho-social determinants of health in the transitional population of Kosovo.

Methods

A representative sample of 87 primary health care users aged e"18 years (41 men, 46 women) was interviewed in Kosovo in November-December 2012.

A structured questionnaire was administered to all participants including information on self-reported health status, psychosocial factors (hostility, reaction to transition and stress level), lifestyle/ behavioral characteristics and demographic and socioeconomic factors.

Participants were asked to rate their health status in the past 12 months in a scale from 1 (very poor health) to 5 (good health). In the analysis, self-reported health status was dichotomized into: *poor health* vs. *good health*.

Hostility was measured by the eight-item Cynical Distrust Scale (1,15) that was systematically derived from the Cook-Medley Hostility Scale (1,16). Response options consisted of a 4-point Likert Scale. A summary score was calculated for each participant ranging from 0 (complete absence of hostile behaviour) to 24 (highest level of hostility/ cynical distrust). In this pilot study including a small yet representative sample of primary health care users in Kosovo, Cronbach's alpha of the eight-item scale was 0.73 in men and 0.81 in women, which is higher than a prior report from Albania (9). In the analysis, hostility was dichotomized into: *hostile* behaviour (high summary score) vs. *non-hostile* behaviour (low-moderate summary score).

Reaction to political and socioeconomic aspects of transition was assessed by a three-item scale which was adapted from an instrument used in Russia (10,11) and also employed in a study conducted in Albania (12). Participants were asked to rate their agreement/ disagreement about three statements related to the current political and socioeconomic transition in Kosovo. A summary score was calculated for each individual (referred to as *overall reaction to transition*) ranging from 0 (most positive attitudes towards socioeconomic aspects of transition, alias *optimistic* approach) to 9 (most negative attitudes – *pessimistic* approach). Cronbach's alpha of the three-item scale in this pilot study in Kosovo was 0.94. In the analyses, the summary score of reaction to transition was dichotomized into: *optimistic-neutral* vs. *pessimistic* reaction to transition.

Level of stress was measured by a series of questions related to economic/ financial stress, as well as psychosocial stress. Each item consisted of a 4-point Likert Scale. A summary score was calculated for each participant ranging from 0 (no stress at all) to 15 (maximal stress). In the statistical analysis, based on the overall summary score of the stress level, each participant was classified into one of the following two categories: *stressed* (high summary score) vs. *not stressed* (low-moderate summary score).

Lifestyle/ behavioral characteristics consisted of smoking (dichotomized into: yes vs. no), alcohol consumption (also, dichotomized into: yes vs. no) and physical activity (dichotomized into: moderate-active vs. sedentary). In addition, data on demographic factors (age, sex and marital status) and socioeconomic characteristics (educational attainment, employment status and income level) were collected for each participant.

Binary logistic regression was used to assess the association of psychosocial factors (independent variables) namely hostility, reaction to transition and

stress with self-reported health status (outcome variable). Crude (unadjusted) and multivariable-adjusted odds ratios (ORs) and their respective 95% confidence intervals (CIs) were calculated. SPSS version 19.0 was used for all the statistical analyses.

Results

Table 1 presents the distribution of demographic and socioeconomic characteristics in the study sample. Overall, mean age (± SD) of study participants (47.1% men; 52.9% women) was 49.3± 13.1 years. Mean (± SD) years of education were 9.2± 4.3 years; about 78% of individuals were currently married; about 32% were unemployed, and; 31% of participants reported a low income level (Table 1).

In men, 37% (n= 15) reported a poor health status compared with 63% (n= 26) who reported a good health status. In women, these figures were 46% (n= 21) and 54% (n= 25), respectively (Figure 1).

Table 1. Distribution of demographic and socioeconomic characteristics in a sample of primary health care users in Kosovo

Demographic and socioeconomic factors	N=87
Age (years)	49.3±13.1*
Sex:	
Men	41 (47.1)†
Women	46 (52.9)
Educational level (years)	9.2±4.3*
Marital status:	
Married	68 (78.2)†
Single/divorced/widowed	19 (21.8)
Income level:	
Low	27 (31.0)†
Middle	49 (56.3)
High	11 (12.6)
Employment status:	
Unemployed	28 (32.2)†
Employed/students/retired	59 (67.8)

* *Mean values ± standard deviations.*

† *Numbers and column percentages (in parentheses).*

Figure 1. Self-reported health status in a representative sample (N=87) of primary health care users in Kosovo by sex

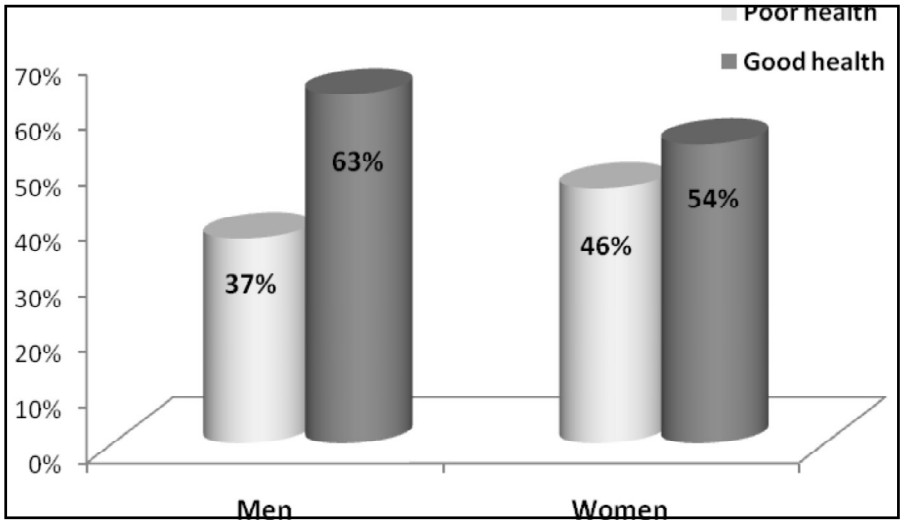

Table 2 displays the distribution of lifestyle/ behavioral characteristics and psychosocial factors among study participants. Overall, the prevalence of smoking was 30%, whereas the prevalence of alcohol consumption was 15%. About 38% of individuals reported a sedentary lifestyle. Hostile behavior was reported in 24% of participants. A pessimistic reaction to transition was evident in about 55% of participants. Finally, about 56% of individuals reported a high level of stress (Table 2).

Table 2. Distribution of lifestyle characteristics and psychosocial factors in a sample of primary health care users in Kosovo

Lifestyle and psychosocial factors	N=87
Smoking:	
Yes	26 (29.9)*
No	61 (70.1)
Alcohol consumption:	
Yes	13 (14.9)
No	74 (85.1)
Physical activity:	
Moderate-active	54 (62.1)
Sedentary	33 (37.9)
Hostility:	
Hostile behavior	21 (24.1)
Non-hostile behavior	66 (75.9)
Reaction to transition:	
Optimistic-neutral	39 (44.8)
Pessimistic	48 (55.2)
Stress level:	
Stressed (high summary score)	49 (56.3)
Not stressed (low-moderate summary score)	38 (43.7)

* *Numbers and column percentages (in parentheses).*

Table 3. Association of psychosocial factors with self-reported health status; odds ratios (ORs) from binary logistic regression

Psychosocial factors	Unadjusted models		Multivariable-adjusted models†	
	OR (95%CI)*	P	OR (95%CI)*	P
Hostility:				
Non-hostile behavior	1.00 (reference)	0.03	1.00 (reference)	0.17
Hostile behavior	1.61 (1.04-2.47)		1.38 (0.78-2.42)	
Reaction to transition:				
Optimistic-neutral	1.00 (reference)	0.09	1.00 (reference)	0.21
Pessimistic	1.57 (0.96-3.51)		1.36 (0.72-2.96)	
Stress level:				
Not stressed	1.00 (reference)	0.04	1.00 (reference)	0.05
Stressed	2.17 (1.19-3.67)		1.82 (1.00-3.34)	

* *Odds ratios (OR: poor health vs. good health) and 95% confidence intervals (in parentheses).*

† *Adjusted simultaneously for: age, sex, marital status, educational attainment, employment status, income level, smoking, alcohol consumption and physical activity.*

Table 3 presents the association of psychosocial factors with self-reported health status (dichotomized into: poor vs. good health). In crude/ unadjusted models, hostile behavior, pessimistic reaction to transition and especially stress were all associated with poor health (OR=1.61, 95%CI-=1.04-2.47; OR=1.57, 95%CI=0.96-3.51; OR=2.17, 95%CI=1.19-3.67, respectively).

Nevertheless, the association with reaction to transition was not statistically significant (P=0.09). In multivariable-adjusted models, the association with self-reported health status was attenuated and was not statistically significant for both the hostile behavior (OR= 1.38, 95%CI= 0.78-2.42) and a pessimistic reaction to transition (OR= 1.36, 95%CI=0.72-2.96). Conversely, the relationship with stress persisted strongly (albeit it was slightly attenuated) and remained statistically significant (OR= 1.82, 95%CI= 1.00-3.34) [Table 3].

Discussion

The main finding of this pilot study was the positive association of poor self-reported health status with hostility, negative reaction to transition and especially with the overall stress. Although this was a small-scale pilot study only, our findings are generally in line with the international literature pertinent to health effects of psychosocial factors.

Thus, hostility, which is characterized by negative attitudes towards others, has been shown to be associated with increased risk of cardiovascular outcomes in particular, and all-cause mortality in general (1,4-8). Upon multivariable adjustment for socioeconomic characteristics and behavioral factors, our findings related to hostile behavior were not statistically significant possibly due to the small sample included in the study. Yet, in both crude and multivariable-adjusted logistic models, notwithstanding the lack of statistical significance, hostile behavior was positively associated with poor self-reported health status.

Reaction to transition, in turn, was similarly related to self-reported health status in our study sample. Thus, individuals who displayed negative attitudes towards socioeconomic and political transition (pessimistic approach) reported a poorer health status compared with individuals who had a neutral and/ or an optimistic approach/ attitude towards transition in Kosovo. Although not statistically significant, this finding is compatible with a recent study from Albania which reported deleterious effects of pessimistic attitudes towards transition on coronary health (12). Nevertheless, underlying mechanisms of this psychosocial construct related to pessimism, remain to be investigated in more robust study designs.

On the other hand, the negative health effects of the overall stress have been arguable and consistently reported in the international literature including also the former communist countries in Europe (13,14). In this pilot study, which employed a composite construct for measurement of the overall stress, we obtained similar evidence with regard to deleterious health effects of stress. Furthermore, the positive association of the overall stress with poor self-reported health status was strong and statistically significant even after adjustment for a whole array of demographic factors (including age, sex and marital status), socioeconomic characteristics (including education, employment and income level) and behavioral/ lifestyle factors (including smoking, alcohol consumption and physical exercise).

Our study has several limitations since this was only a pilot study aiming mainly to validate a questionnaire related to health effects of selected psychosocial factors. Yet, on the face of it, the instrument operated well in this Kosovo sample.

In conclusion, our findings from this pilot study suggest a deleterious effect of psychosocial factors on self-reported health status, possibly exacerbated by the difficult circumstances of transitional Kosovo. However, the relationship of health status with psychosocial factors should be explored in more detail in future large-scale studies in Kosovo and other transitional settings.

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The establishment of congenital malformations surveillance system in Albania – A national necessity

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Abstract

Background: Congenital malformations (CMs) represent an important public health problem worldwide. Until now, only spina bifida and congenital hip dislocation were officially reported to the Ministry of Health (MoH). Poor health statistics, lack of a CMs' national registry and surveillance system as well as relying only on hospital data have contributed to systematically underestimated prevalence of CMs in Albania. Our aim was to establish the congenital malformation surveillance system in order to highlight the detailed structure of CMs in Albania and to identify their potential risk factors.
Methods: In 2009, a multi-disciplinary team under the leadership of the Institute of Public Health worked for the conception of a new official reporting form and national registry of CMs. All related health professionals were trained on the necessity to report CMs and how to fill in the official form.
Results: The new reporting form is now made obligatory for both public and private system clinics through a dedicated MoH order. Two years after these efforts, around 80% of districts are using the new reporting form whereas 50% report electronically to IPH. The information on CMs can now be classified according to various diagnoses and national and regional analyses by the type of system affected and socio-demographic characteristics are possible.
Conclusion: The establishment of the new surveillance system of CMs in Albania shows very promising and will contribute to highlight the structure and risk factors of CMs, a very under researched area in this Eastern European country.

Keywords: *Congenital malformations, Albania, Surveillance, Epidemiology.*

Background

Worldwide situation

Congenital malformations (CMs) are a diverse group of disorders of prenatal origin which can be caused by single gene defects, chromosomal disorders, multifactorial inheritance, environmental teratogens and micronutrient deficiencies. Even though there are currently no sound estimates of the number of children born with serious congenital disorder(s) attributable to genetic or environmental

causes (1,2) some risk factors have been studied extensively. For example, maternal infectious diseases such as syphilis and rubella are a significant cause of CMs in low and middle income countries. Maternal illnesses like diabetes mellitus, conditions such as iodine and folic acid deficiency, exposure to medicines and recreational drugs including alcohol and tobacco, certain environmental chemicals, and high doses of radiation are other independent risk factors for CMs (2).

CMs represent an increasing public health concern (1). As stated in the "Global Report on Birth Defects 2006" issued by the March of Dimes (MOD), every year there are 7.9 million children born with a serious birth defect of genetic or partially genetic origin accounting for 6% of all births worldwide (1). CMs can cause spontaneous abortions and stillbirths and are a significant but under recognized cause of mortality and disability among infants and children under five years of age. They can be life-threatening, result in long-term disability or cause mental, physical, auditory and/or visual impairment, and negatively affect individuals, families, health-care systems and societies(2)- Worldwide, at least 3.3 million children up to five years of age die from birth defects each year and an additional 3.2 million experience different permanent degrees of disabilities (1). While birth defects are recognized as a global problem (1-7), it is an especially challenging problem for the developing countries where more than 94% of serious birth defects and 95% of deaths from such defects occur (1). However, CMs are most prominent as a cause of death in settings where overall mortality rates are lower, for example in the European Region, where as many as 25% of neonatal deaths are due to congenital malformations (2,8,9).

The most common serious birth defects worldwide were: congenital heart defects, neural tube defects, hemoglobin disorders (thalassemia and sickle cell disease), Down syndrome and glucose-6-phosphate dehydrogenase deficiency (1). In many cases, genes and environment contribute together to cause a birth defect (3,5,10). There is little doubt that birth defects can cause enormous harm where elevated risk factors are present and health care is limited (11). Today, there are many opportunities to prevent a large number of birth defects and to reduce their negative consequences for the individual and the society. This can be done at a reasonable cost by simple public health methods and interventions (11).

Situation in Albania and the previous CMs reporting way

According to March of Dimes, from 192 countries included in the global report on birth defects, Albania ranks among the countries with a high prevalence of congenital malformations - 52.9/ 1000 live births (1). Among all diagnosed congenital malformations, District Public Health Directories (DPHD) report to the Ministry of Health (MoH) only spina bifida (8.52/1000 live births in 2006) and hip dislocation (1.23 /1000 live births in 2006). Until 2009 there was no information about major or minor congenital malformations of genetic or partially genetic origin (12,13). According to the International Classification of Diseases, 9th revision (ICD-9), the doctors and/ or nurses that assist in deliveries performed in all maternity wards and homes of Albania are requested to record all congenital malformations among *live born and dead born babies*. This is a mandatory process according to the Law of Statistic No. 7687 date 16.03.1993. Every DPHD in Albania routinely collects these data from the respective maternity wards and home deliveries. As mentioned, the DPHDs report every six months to MoH the total number of congenital malformations, the total numbers of spina bifida malformations and hip dislocations (among all other congenital malformations identified). They report these data as an aggregate number (including other data) by two official reporting forms, namely "Form 4/ Sh" and "Form 12/ Sh/ 1". The Form 4/ Sh includes data on obstetrical activity in all health institutions and delivery homes (if any). This form is reported to MoH every six months. The Form 12/Sh/1 includes data on infant mortality (less than 1 year of age) and it is reported on monthly basis to the MoH (12). Every child born alive with a congenital malformation has his/ her own clinical card kept in the statistical office of the maternity hospital. For the children with congenital malformations born dead or that die during the first year of life because of a congenital malformation, the death certificate is compiled. Congenital malformations are registered using these clinical cards and death certificates using ICD-9 codes by doctors or midwifes in all the maternity wards of the country.

However, without any obvious reason, the DPHDs detail on and report only spina bifida and hip dislocation among all malformations identified in Albania (12), since the two reporting forms require only these two categories and the total number of CMs. There was no information if the private clinics diagnosed any congenital malformations or recorded the diagnosed ones, nor did they report such information to the MoH. This way only the public sector reports them (12).

Rationale for the establishment of the CMs surveillance system

Constrained diagnostic capability, poor health statistics, lack of CMs surveillance and registries have led to a systematic underestimation of the incidence rates of congenital malformations in Albania.

This situation consequently raised the necessity of building up the congenital malformation surveillance system (CMSS). The aim of CMSS is the recording and reporting of CMs, through a newly conceived official reporting form, diagnosed during pregnancy, pregnancy interruption, births, fetal deaths and up to 2 years of age, in order to highlight the situation of congenital malformations in our country, to identify risk factors of genetic and/ or non-genetic origin and help policy makers to investigate and implement appropriate CMs' preventive policies. The new and improved way of reporting would, more specifically serve the following array of objectives (14,15):

- produce data for planning, advocacy, education and prevention;
- determine the annual prevalence of congenital malformations among all live births;
- determine the major congenital malformations diagnosed in our country according to geographical distribution and demographic characteristics of parents;
- investigate the increase in the prevalence of congenital malformations;
- conduct epidemiological studies on specific congenital malformations;
- provide useful information for maternal and child health programs;
- evaluate the effectiveness of various congenital malformations prevention programs;
- respond to the medical requirements related to congenital malformations;
- collaborate with other institutions that provide services for children living with congenital malformations.

Pathway for the establishment of the CM surveillance system

In 2009, the Institute of Public Health (IPH) in collaboration with MoH and with the support of UNFPA started the implementation of the CMSS as a first step towards identification of major birth defects in Albania and identifying potential genetic, environmental, nutritional and other factors potentially associated with congenital malformations. In early 2009, was established the Order of the Ministry of Health (dt.05. 03. 2009, NO. 157) on compulsory reporting of CMs identified in pregnancy, induced abortions, birth, fetal deaths and up to 2 years of age in public and private sectors of our country. This Ministerial Order outlines clear directives for a number of stakeholders in the process. The reporting centers comprise all maternity hospitals/pediatric wards and the primary health care centers in all districts and private hospitals licensed by the Ministry of Health that provide pediatric and obstetric-gynecological services. Each congenital malformation diagnosed is now reported through the newly conceived confidential official form (individual form 4/ 1/ ID-SH). Following these efforts, all obstetrician-gynecologists, neonatologists and pediatricians were trained on CMs reporting details, and also all reporting health institutions in the country were supplied with the registry of congenital malformations. All reporting centers are legally obliged to send the reporting forms to the DPHDs on monthly basis. The Reproductive Health Inspector of each DPHD is responsible for organizing, coordinating the work in that district for gathering CMs individual forms in public and private health institutions and subsequently for sending these reporting forms to the IPH every three months (12,13).

The IPH is the final center where the reporting forms are collected, analyzed and reports and recommendations are issued. It reports periodically to MoH.

Core elements of the new CM surveillance system

The three key aspects of the CMSS are: 1) case identification and ascertainment; 2) data collection;

and 3) data use and surveillance's evaluation (14,16). Regarding *the first key element*, criteria for CMs case ascertainment were established and agreed upon. Congenital malformations can be defined as structural or functional abnormalities, including metabolic disorders, which are present from birth. Therefore, specific health diagnoses (congenital malformations, deformations and chromosomal abnormalities) that fall under the chapter XIV of ICD-9 system, are going to be reported. All congenital malformations identified during pregnancy, induced abortions, birth, fetal deaths and up to 2 years of age in public and private sectors of the country shall be registered and reported (12,13). Congenital malformations like inborn errors of metabolism and blood disorders of prenatal origin that appear in other chapters of ICD-9 will not be part of CMSS. Regarding *the second key element* of CMSS, it was established that the reporting form would collect basic demographic and epidemiologic information on mother, father and fetus/ infant/ child with congenital malformations. Obstetrician-gynecologists, neonatologists and pediatricians shall fill in the individual reporting forms for each diagnosed case and then the reproductive health inspector of each public health district directory shall collect the reporting forms in each reporting center every three months and send them to IPH (12,13). Regarding *the third core element*, using CMSS data will be very important and beneficial for a range of stakeholders: public health experts, health professionals, policy makers and the public in order to fulfill all of its objectives and to inform on many of the issues described previously. The evaluation of CMSS is fundamental and needs to show improvement of currently available information on congenital malformations as well as improvements in the quantity and quality of data collected. It ensures that birth defect case reporting is complete, accurate, appropriate, and within the guidelines for timely reporting (14).

Results of the intervention

Now, in Albania all obstetrician-gynecologists, neonatologists and pediatricians (of all maternity wards, pediatric wards and obstetric-gynecologic wards) are trained for reporting congenital malformations by the official reporting form. All the congenital malformations reporting health centers in the country have the Congenital Malformation Registry. All reporting centers report congenital malformations forms to DPHDs. The results of such training are as follows: there are 354 medical doctors (pediatricians, neonatologists, obstetricians and gynecologists) trained for registering and reporting congenital malformations through the individual reporting form. There are 37 persons of the DPHDs' staff (reproductive health inspectors and other) trained for reporting the individual reporting form and monitoring the whole process. After two years into these efforts, around 80% of country districts are using the reporting system and in 50% of them the electronic way of reporting has been installed (13).

Now, the IPH is the final center which monitors the progress of the CMSS. It also collects the reporting forms, analyzes the data, produces reports and disseminates findings. The IPH in collaboration with the MoH provides appropriate recommendations for congenital malformations control, care and prevention.

Discussion

Congenital malformations are an important and very sensitive public health problem with a tremendous emotional and psychological impact on families. A number of risk factors for congenital malformations have been identified, including low socioeconomic status, advanced maternal age; however the factors that contribute to congenital malformations remain unknown. The CMSS activities have the potential to inform, complement and enhance existing mother and child health programs. Services and interventions for the prevention and care of birth defects should be part of existing health-care services, in particular those concerned with maternal and child health. They should combine the best possible patient care with a preventive strategy encompassing education, preconception care, population screening, genetic counseling, and the availability of diagnostic services (2,16). Effective delivery of services for the prevention and care of birth defects depends on the availability of a range of specialist clinical and diagnostic services, and a primary health-care system that is able to use them. Conventional laboratory services (hematological, microbiological, and biochemical) need to be supplemented with

cytogenetic and DNA-based diagnostic services (2,15). Even though the reporting rate is at 80% there are still problems regarding the certainty of the diagnosis (suspect/ confirmed), filling the forms and reporting them, and also there is need for continuous training of the public health district directories staff due to the quick replacement of the staff from their job positions. Up to now, the major challenge of CMSS properly functioning is to convince medical specialists to fill in the reporting forms of congenital malformations (13), as they often are "too busy" to do that by themselves and leave this responsibility to nurses or statistical office employers

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Patent Ductus Arteriosus at low birth weight preterm infants and perinatal infection

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Abstract

Aims: The aim of this study was to compare the efficacy and safety of oral versus intravenous ibuprofen for the pharmacological closure of patent ductus arteriosus (PDA) in low birth weight (LBW) preterm infants and assess the impact of perinatal infection to pharmacological closure of PDA in LBW preterm infants.
Methods: A randomized, single-blinded, clinical trial included 68 premature infants with significant PDA confirmed through cardiac ultrasound at the "Koço Gliozheni" maternity hospital in Tirana, Albania, during January 2010-December 2012. Infants were randomly assigned to receive either intravenous (n=32) or oral ibuprofen (n=36) at an initial dose of 10 mg/kg, followed by 5 mg/kg after 24 hours and after 48 hours. The rate of ductal closure, reopening, the need for surgical ligation, and the patients' clinical course were recorded.
Results: After the first treatment cycle, the PDA closed in 83.3% of the patients receiving oral vs. 71.8% of those receiving intravenous ibuprofen. 16.6% of the patients in the oral group required a second cycle of treatment, compared with 28.1% in the intravenous group; all these cases had clinical signs of infection and positive bloodculture. No reopening of the ductus after its closure was noticed. Furthermore, there were no patients with oliguria.
Conclusions: Oral ibruprofen showed a similar rate of ductal closure and renal tolerance, but fewer adverse effects compared to intravenous ibuprofen. Association of PDA with perinatal infection has a negative impact in pharmacological closure of the ductus, increasing the need for a second treatment cycle and surgical ligation. Larger comparative studies are needed to replicate these findings.

Keywords: *intravenous ibuprofen, oral ibuprofen, patent ductus arteriosus, perinatal infection, prematurity.*

Introduction

Patent ductus arteriosus (PDA) is extremely common in very premature infants and untreated symptomatic PDA may be associated with chronic lung disease (1). Clinical and epidemiological data strongly suggest that infections, either prenatal or nosocomial, and the presence of a patent ductus arteriosus (PDA) play a major role in the neonatal mortality and morbidity (2-4). For this reason, efforts to prevent this complication in low birth weight infants should include an aggressive approach to the prevention and treatment of prenatal and neonatal infections and an early closure of the PDA. Pharmacological closure of PDA with indomethacin or ibuprofen, which are both prostaglandin inhibitors, has remained the mainstay of treatment in premature infants over the last three decades (5,6). In search of an explanation for the interaction between neonatal infection and PDA, it was observed that the presence of a systemic infection in the premature infant adversely affects permanent closure of the ductus, often inducing ductal opening after the first week of life and failure to respond to medical treatment with indomethacin (7). A likely explanation for this interaction is the elevated serum levels of prostaglandins and tumor necrosis factor (TNF) observed in infants with infections. In addition, infants with serious infections frequently have complications that prevent or delay the medical or surgical treatment of the PDA. As a result, the ductus remains open for prolonged periods of time, maintaining an increased pulmonary blood flow, high capillary pressure, and increased lung fluid. Furthermore, when both complications (infection and PDA) occurred at the same time, they produced a synergistic interaction, further increasing the risk for developing chronic lung disease (CLD). As a consequence of the left-to-right shunting through the PDA, pulmonary blood flow and lung fluid increases, negatively affecting lung function and gas exchange, and thereby increasing the risk for CLD. The presence of a PDA has also been associated with elevated concentrations of myeloperoidase in the tracheobronchial fluid, suggesting that the increased pulmonary blood flow may result in damage of the pulmonary endothelium and adhesion and migration of polymorphonuclear cells (PMNs) into the lung tissue (7,8). Sepsis is reported to increase the risk of late ductal reopening, and failure of PDA closure probably relates to the associated increased levels of prostaglandin and tumour necrosis factor á (9). Concerns have been raised that indometacin may predispose very low birth weight neonates to sepsis (10). Considerable biological plausibility thus exists to explain the influence of significant PDA and sepsis on feed tolerance in preterm neonates. PDA and sepsis are possibly markers of prematurity, and a prolonged interval between starting feed and full enteral feed simply reflects the reluctance to start or continue feeds in the presence of such perceived risk factors for feed intolerance and necrotising enterocolitis (NEC) (11,12). A temporary closure and reopening of the duct has been reported as being associated with severe infection and sepsis (5).

Methods

The study was designed as a prospective, randomized, single blinded, study. The study was conducted in the neonatal intensive care unit (NICU) of the University Hospital for Obstetrics and Gynecology "Koço Gliozheni" in Tirana, Albania, from January 2010 to December 2012. This study was approved by the Faculty of Medicine and the Neonatology Department.

The study enrolled preterm infants with a gestational age 28-32 weeks, birth-weight d"2000g, postnatal age 48-96 hours, RDS treated with mechanical ventilation [CPAP or intermittent positive pressure ventilation (IPPV)] with additional oxygen requirements above 30% and one of the following echocardiographic criteria of a duct size >1.5 mm: a left atrium-to-aorta ratio >1.5, left-to-right shunting of blood in addition to signs of PDA.

GA was assessed by obstetrical dating criteria or, when obstetrical data was inadequate, by Ballard examination.

Exclusion criteria were major congenital abnormalities, right-to-left ductal shunting, life-threatening infection, grade 3 or 4 intraventricular hemorrhage, oliguria of less than 1 ml /kg /h during the preceding eight hours, serum creatinine concentration in excess of 1.6 mg/ dl, blood urea nitrogen in excess of 60 mg/ dl, thrombocyte count of less than 60 000/mm^3, clinical bleeding tendency as revealed by haematuria, blood in the gastric aspirate or in the stools, blood in the endotracheal tube aspirate, oozing from venous or capillary

puncture sites, hyperbilirubinemia for which exchange transfusion was required and pulmonary hypertension.

All infants who met the entry criteria first underwent echocardiography and cranial ultrasonography, after which they were treated with oral ibuprofen (Brufen, Abbot S.r.l, Italy Algofren) at 10 mg/ kg dose via an orogastric tube, which was flushed with 1 mL of sterile water to ensure delivery of the drug, or intravenous ibuprofen (Pedea, Orphan Europe; a vial of 2 mL containing 10 mg of ibuprofen) which was infused over a 15-minute period with a syringe pump, the line was subsequently being flushed with saline.

The two imaging procedures were again performed 24 hours after each ibuprofen dose. When the PDA was still hemodynamically significant, as demonstrated by echocardiography, and there was no evidence of deterioration in brain ultrasonography, a second dose of ibuprofen 5 mg/ kg was administered. A third equivalent dose was given after another 24 hours if deemed necessary. Cranial ultrasound was repeated 1 week after the last ibuprofen dose and again before discharge from the ward. Hematochemical analyses were preformed daily in the unit during the first days of life.

RDS was treated with respiratory support (CPAP,intermittent mechanical ventilation or high-frequency ventilation), oxygen supplements, and surfactant (Curosurf, Chiesi, Italy; a vial of 1.5 mL containing 120 mg) was administered intratracheally at the dosage of 100 to 200 mg/ kg. Prophylactic antibiotics were started on admission and stopped after 5 days if blood cultures were negative. Birth weight, gestational age, and clinical outcomes were recorded prospectively.

Occurrence of any of the following conditions was enough to discontinue treatment: IVH grade 3–4, renal failure, NEC, and gastrointestinal bleeding (GEB).

The color Doppler echocardiografi was conducted by a pediatric-cardiologist who was not awere to the child's name and the treatment being given. PDA was considered echocardiographically significant when the ductal size was >1.5 mm or the left atrial-to-aortic root ratio was >1.4. We evaluated these parameters before the first dose and 24 hours after each dose of ibuprofen, never exceeding 3 doses in total. One day after the third treatment, an echocardiographic evaluation was performed by the same pediatric- cardiologist to determine the success of the treatment and the need for a second course via the same route.

Before and 24 hours after treatment, all patients were evaluated with a complete blood count, renal function tests (serum creatinine level, blood urea nitrogen and urine output), cranial ultrasonography, and echocardiography. All infants continued their current enteral feeding during the treatment.

Sample size and statistical analysis

We calculated that a study group of 68 patients would be necessary for detection of a difference of at least 25 percentage points in the closure rate between the oral ibuprofen and intravenous ibuprofen groups, assuming a closure rate of 70% with intravenous ibuprofen, with a P value of 0.05 and a study power of 85%.

SPSS for Windows (SPSS version 19.0, Chicago, IL), and Minitab (Minitab version 15.0, State College, PA) were used to conduct the statistical analyses.

The data are presented as means ± standard deviations (numerical variables), or frequencies (absolute number and their respective percentages – categorical variables).

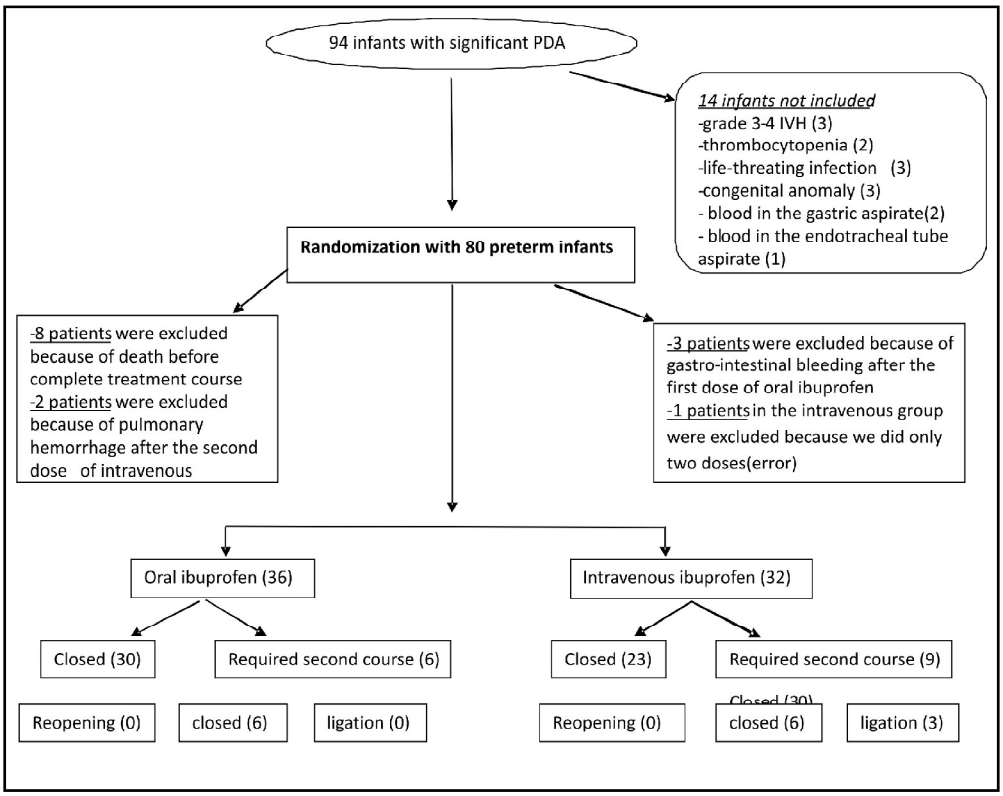
Paired-samples *t*-test and independent-samples *t*-test were used for continuous variables. Conversely, chi-square test was used to compare the proportion of patients experiencing the secondary outcomes of PDA closure. In all cases, a p-value of d"0.05 was considered statistically significant.

Results

A total of 168 premature infants at gestational age <32 weeks and birth weight d"2000 g and SDR were admitted to our NICU, from January 2010 to December 2012 and underwent an echo-cardiografic Doppler ultrasound evaluation at the age of 48-96 hours. The entire study protocol was completed for 80 patients because of exclusion for various reasons (Figure 1).

Baseline characteristics were similar between the two groups in the first 96 hours (Table 1).

Figure 1. Study design



After the first course of the treatment, the PDA closed in 30 (83.3%) of the patients assigned to the oral
ibuprofen group versus 23 (71.8%) of those enrolled in the intravenous ibuprofen group. Six patients (16.6%) in the oral ibuprofen group required a second course of drug therapy, compared with 9 (28.1%) in the intravenous ibuprofen group. There was no reopening of the ductus after closure was achieved. The cumulative closure rates were higher in both groups, and only three patients (9.3%) in the intravenous ibuprofen group had surgical ligation.

Table 1. Baseline characteristics of study participants

Variable	Oral group (n=36)	Intravenous group (n=32)
Gestational age, weeks		
28.1-30.0 weeks	19 (52.7%) *	18 (56.2%)
30.1-32.0 weeks	17 (47.2%)	14 (43.7%)
Birth weight (in grams)		
<750g	2 (5.5%)	0 (0%)
751 -1000g	7 (19.4%)	6 (18.7%)
1001 -1500g	15 (41.6%)	19 (59.3%)
1501-2000g	12 (33.3%)	7 (21.8%)
Gender		
Male	22 (61.1%)	15 (46.8%)
Female	14 (38.8%)	17 (53.1%)
Delivery by cesarean section	20 (55.5%)	14 (43.7%)
Antenatal indomethacin	0 (0%)	0 (0%)
Antenatal glucocorticoid	28 (77.7%)	18 (56.2%)
Mean ductal diameter (mm)	2.1	1.9

* *Absolute numbers and percentages (in parenthesis) within the respective groups.*

In the evaluation of renal tolerance, none of the patients had oliguria. The serum creatinine levels and plasma blood urea nitrogen after the treatment did not differ significantly between the groups. Renal function test results before and after the second course of each drug did not differ significantly within or between the groups (Table 2).

Table 2. Renal function results among the study participants

Parameter	Oral group (n=36)	Intravenous group (n=32)	P
Plasma blood urea nitrogen(mg/dl)			
Day 1	30.7 ± 14.8 *	30.4 ± 13.7	0.900
Day 2	30.3± 14.2	30.6 ± 14.0	0.890
Mean plasma creatinine (mg/dL)			
Day 1	1.07 ± 0.24 *	1.09 ± 0.24	0.060
Day2	1.20 ± 0.95	0.97±0.45	0.070
Oligoanuria (ml/kg/h)			
Day1	0 (0%) †	0 (0%)	
Day2	0 (0%)	0 (0%)	
Infection			
Need for a second treatment course	6 (16.6%) †	9 (28.1%)	
Need for surgical ligation	0 (0%)	3 (9.3%)	

* *Mean value ± standard deviation.*

† *Absolute number and percentage within the respective group (in parenthesis)*

15 patiens needed a second treatment course and they were all(100%) with clinical signs of infection and positive bloodculture and the same result was for the 3 (9%) patients who needed surgical ligation.

Discussion

Intravenous ibuprofen is not available in most countries (and in our country to), and is more expensive than the oral form. If oral ibuprofen were as efficient as intravenous ibuprofen with no greater adverse effects, its simple administration and lower cost would be important advantages. Our study was designed with sufficient power for determining whether oral and intravenous ibuprofen treatments are equally efficacious and safe in PDA closure in premature infants with respiratory distress syndrome (RDS). Our results showed oral ibuprofen to be effective and safe in PDA closure, with 30 of our 36 (83.3%) study infants achieving a successful outcome. The rate of closure in the group assigned to intravenous ibuprofen was similar to rates previously reported (4,11). Some trials on the use of oral ibuprofen for closure of PDA have been recently published (13-15). All studies had small sample sizes. Aly (16) in a randomized pilot study, reported that PDA was closed in 7 of 9 premature infants (d"35 weeks) given oral ibuprofen and in 10 of 12 premature infants given intravenous indomethacin (P = 0.75). Fakhraee, (17) in a randomized study, reported that PDA was closed in all of 18 premature infants (d"34 weeks) given oral ibuprofen and in 15 of 18 premature infants given oral indomethacin (P > .05). Efficacy of oral ibuprofen compared with intravenous indomethacin, was reported by Supapannachart et al. (18) and Chotigeat et al. (19) as well. In nonrandomized open trials, Heyman et al. (20) and Cherif et al. (21) reported a ductal closure with oral ibuprofen respectively in 21 (95.4%) of 22 patients, 38 (95%) of 40 patients, and in 11 (84.6%) of 13 patients. The authors concluded that oral ibuprofen might constitute a feasible alternative in the treatment of PDA. Another study investigated the efficacy of indomethacin and ibuprofen given to larger premature infants (d"32 weeks) at the age of 2-4 days. They reported that the closure rate was similar (66% and 70%, respectively) after the first course and that there was no significant difference in side effects, although ibuprofen was associated with significantly less impairment of renal function (11). The previous study comparing oral and intravenous ibuprofen enrolled 64 preterm infants. That trial

demonstrated that the rate of ductal closure tended to be higher in the oral group (84% versus 62%). This study was not powered to detect differences in complications (20). Two studies increase the number of infants randomized and expand the information about the safety and efficacy of oral ibuprofen in more mature very LBW infants (22,23). We hope that our study will give its contribution in this regard too.

Since renal tolerability of ibuprofen on renal function in the neonate is a major argument in favour of its use in the treatment of PDA (22,23), our study expands our information about the safety and efficacy of oral ibuprofen in more mature VLBW infants.

Serum creatinine levels and uremia in our patients were within normal range at all times, so there was no contraindication for a second dose of ibuprofen when it was needed. This might be an explanation for the higher rate of pharmacologic ductal closure observed in our study.

There are several limitations to our study. This was an open-label, one-arm study, and the physicians and nurses were aware of the nature of the study, although the cardiologist who supervised the echocardiographic studies was blind to the status of the infants and whether they were treated with oral ibuprofen or intravenous ibuprofen. This is the first experience that we have with ibuprofen (oral or intravenous) for treatment of PDA in preterm infants.

Conclusion

Our data indicate that, for preterm infants especially for LBW infants, the rate of early ductal closure was comparable and the adverse effects were fewer with oral ibuprofen in comparison to the intravenous route. Association of PDA with perinatal infection has a negative impact in pharmacological closure of the ductus, increasing need for a second course and for surgical ligation. The oral form was as safe as the intravenous form in terms of renal tolerance. Larger comparative studies are needed to replicate these findings.

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Evaluation of communication channels about sexually transmitted infections among Tirana University students

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Abstract

Aims: Different communication channels as interpersonal communication, the transmission channels (radio, television, and internet) and printed materials must be considered for influencing knowledge, attitudes and practices about health. Our aim was to assess the communication channels about sexually transmitted infections at Tirana University students in order to identify appropriate channels to deliver health-related messages.
Methods: A structured self-administered questionnaire was used to collect information from a representative sample of 557 students, representing 27646 students at Tirana University.
Results: Discussion on issues related to sexuality (including STIs) remains still taboo for young people. Thus, students reported that they have discussed more with peers, 49.9%, followed by partner 31.8%, mother 27.5%, siblings 26.8%, health personnel 13.1%, teachers 12.9% and fathers 5.2%. The internet was a main source of information of our respondents, reported by 66.4% of them, followed by television (63.7%), newspapers/books/brochures (55.1%), friends (42.7%), teachers (41.5%), parents (41.3 %), health personnel (26.9%), partner (23.7%), and social worker/psychologist (14.7%).
Conclusions: Television and internet are the two most followed and preferred media by students and should be used in promotional campaigns for conveying health messages. Selection of specific media, based on the audience and the peak hours, must be considered for delivering health-related key messages.

Key words: *communication channels, Internet, sexually transmitted infections, students, television.*

Introduction

Health communication channels are different: interpersonal communication channels, which are good to give credibility to the message, the transmission channels such as radio, television, the internet, offering wide coverage and reaching a large number of audience quickly and print materials such as leaflets, brochures, posters, etc., which provide a timely reminder messages.

Media is an important ally of public health with its role as a source of accurate information, and an advocate for fair health behaviors. Local and national media play a vital role as a link between health personnel and the general public. Health authorities should educate media with substantial and scientific health information, which then must be passed to the public in the appropriate form and through a variety of channels (1).

During the work with media, the following factors should be carefully considered: a) the channels through which messages are forwarded, b) audience to which is attributed the message, c) how the audience responses, d) selecting messages with greater impact. These considerations reflect the essential components of the communication process: communication channel, the source, the message and the receiver of the message (2).

In the field of public health has been given more importance to the use of media (radio, TV, newspapers, books, brochures) to modify the attitudes and practices to persuade audiences to protect their health. Today, internet is a competitive media that is moving faster (3). With the popularity of the internet as an innovation, more and more young people are using it to get health information. Peers are also an important communication channel, based on the idea that they have a strong influence to each other's behavior (4).

The purpose of this study is to assess the communication channels of Tirana University students about sexually transmitted infections, in order to find the most appropriate channels for conveying health messages to this target group.

Methodology

The collection of the information was done from a sample of 557 students, representative of 27646 students (20028 females [72.5%] and 7618 males [27.5%]), selected randomly and proportional to size (5,6) from the number of University students (stratified by faculties). Data on the number of students by faculty was pulled from official statistics of the Ministry of Education. The proportion of the students in each University and Faculty was determined and then, in each University the students were randomly selected proportional to size. For example, if the University of Tirana comprised 40% of all university students, then 40% of our sample would also be selected from the Tirana University. Power of the study was set at 80% whereas the significance level (type 1 or alpha error) was set at 5 % (0.05). Based conservative assumptions, it resulted that the minimum sample size to detect the differences was 470. We decided to interview more students in order to increase the study power. Data collection instrument was a self-structured questionnaire, which was previously pretested with a similar group of 50 students (5). Data entry and data analysis was done in SPSS format, version16.0.

Results and Discussion

We analyzed a total number of 557 questionnaires, 404 of which were females and 153 were males. Some of the main results obtained from the data analysis of these questionnaires are as follows:

The students were specifically asked to report if they had discussion on the STIs. The analysis of data on this issue concluded that they discuss very often with peers (friends) which occupied the highest percentage of cases 49.9%. Respondents then reported partner by 31.8%, mother 27.5%, sister / brother 26.8%, health personnel 13.1%, teachers 12.9%, psychologist / social worker 7.5% and father only 5.2%. As in other studies conducted among youths, peers are more reliable group than other to discuss such issues related to sexuality, including STIs. On the other hand, the medical staff was less preferred to discuss these issues with them, compared with other groups, Table 1.

Table 1. With whom do you discuss about STIs?

Do you discuss about STIs with:	Yes, often	Yes, rarely	No
Your mother?	153 (27.5)*	164 (29.4)	240 (43.1)
Your father?	29 (5.2)	88 (15.8)	440 (79.0)
Your partner?	177 (31.8)	114 (20.4)	266 (47.8)
Your friend?	278 (49.9)	188 (33.8)	91 (16.3)
Health personnel?	73 (13.1)	126 (22.6)	358 (64.3)
Your teacher?	72 (12.9)	248 (44.5)	237 (42.5)
Psichologist/social worker?	42 (7.5)	90 (16.2)	425 (76.3)

* *Absolute numbers and row percentages (in parenthesis).*

In response to a question on learning at school on STIs only 8.1% of participants responded negatively, while 87.6% of them report that they have been talking and discussing about it at school. But, on the other hand, 32.5% of them say that have been talking only for HIV/ AIDS as one of STIs.

Another question that students were asked was if they watch the television, listen to the radio, read newspapers/ magazines or uses the internet. They reported that the internet is the media more used from them with 97.3% positive responses (66.8% use often and 30.5% use occasionally or rarely) [Table 2].

Table 2. Do you use the Internet to get health information**?**

Do you use the Internet to get health information?	Number	Percentage
Yes	372	66.8
No	15	2.7
Occasionally	154	27.6
Very rarely	16	2.9
Total	*557*	*100.0*

A significant number of respondents, 93.9%, reported television (81.0% often and 12.9% rare) as the media followed by them (Table 3). More of half of them 57.3% read newspapers or magazines and 56.6% listen to the radio (38.6% often and 18% often).

Table 3. Do you use television to get health information?

Do you use television to get health information?	Number	Percentage
Yes	451	81.0
No	34	6.1
Yes, rarely	72	12.9

The data above go in the same line with the answers below given by students regarding the source of information on STIs.

So, the largest source of information on sexually transmitted infections (STIs), for our students has been the internet, which responded positively to the 66.4% of respondents, followed by television (63.7%) newspapers/ books/ brochures (55.1%), friend (42,7%), teacher (41.5%), parents (41.3%), health personnel (26.9%), partner/wife (23.7%) and the social worker/psychologist (14.7%). Data above noted that the Internet is being used increasingly by our students and health staff is estimated to be a poor source of information on STIs. Also, from the analysis of the data found a positive correlation between parental education and the level of discussion with them about STIs.

Regarding the media that the students would prefer to receive information on STIs, television was ranked first with 65.5%, of the respondents followed by the Internet with 59.8%, books 50.6%, magazines 27.3%, schools 7.7 %, health personnel

7%, parents 1.8% and psychologist 0.4%. Consistently, health personnel again remain less preferred to receive information on STIs.

Conclusions and recommendations

This study confirmed results of previous investigations that discussion on issues related to sexuality including STIs remains still taboo for young people in Albania. Also, the findings indicate the importance of peer-educator methods and parental involvement in implementing various educational programs for health communication regarding this target group.

Internet as an innovation is being used increasingly by our students. Television and the Internet are the two more followed and preferred media to obtain health information, followed by newspapers, magazines and radio. These media should be widely used in various campaigns to monitor the health messages. Selecting specific media based on the students' audience and the peak hours pursued by them, are two other important aspects that must be considered when selecting these media as channels for the transmission of messages related to sexuality and STIs.

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Incidence and case-notification rate of tuberculosis in Kosovo for the period 2000-2010

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Abstract

Aim: At a global level, there has been a significant progress towards reduction of tuberculosis morbidity and mortality in the past decades. Our objective was to describe the incidence and case notification rate of tuberculosis in Kosovo for the period 2000-2010.
Methods: Data about all new cases of tuberculosis, incidence rate and case notification rate for the period 2000-2010 were obtained from the National Tuberculosis Control Program in Kosovo. Furthermore, selected indicators of tuberculosis in Kosovo were retrieved from the World Health Organization Global Tuberculosis Report 2012.
Results: In the past decade, there has been a significant decrease in the incidence rate of tuberculosis in Kosovo. More specifically, the incidence of tuberculosis declined twice in the period 2000-2010: it was 89.9 per 100,000 population in 2000 vs. 43.7 per 100,000 population in 2010 (linear trend: $P<0.01$). Similarly, case notification rate declined from 78.2 per 100,000 population in 2001 to 43.7 per 100,000 population in 2010 (linear trend: $P<0.01$).
Conclusion: Official statistics for Kosovo indicate a downward trend in tuberculosis incidence and case notification rate in the past decade. Nevertheless, the most significant decrease concerns the period from the year 2000 to the year 2003. Afterwards, there has been a fluctuation in the incidence rate and the case notification rate.

Keywords: *case-notification rate, Kosovo, extra-pulmonary tuberculosis, pulmonary tuberculosis.*

Introduction

As stated in the World Health Organization (WHO) Global Tuberculosis Report 2012 (1), at a global level, there has been a major progress in reduction of tuberculosis incidence and mortality rate in the past decades. Thus, incidence rates and death rates from tuberculosis have decreased in all six regions of WHO (1). However, notwithstanding the laudable progress achieved so far, WHO recognizes that the global burden of tuberculosis poses a significant problem and constitutes an enormous challenge for many countries (1).

The situation poses serious challenges in cases without treatment where mortality rates are high. Thus, in studies of the natural history of the disease among sputum smear-positive and HIV-negative cases of pulmonary tuberculosis, about 70% of cases died within 10 years, whereas among culture-positive (but smear-negative) cases, 20% died within 10 years (2). Therefore, despite the availability of treatment, tuberculosis remains a major global health problem ranking as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (1,3).

The prevalence of tuberculosis can be assessed in nationwide population-based studies, and WHO has recently published a comprehensive theoretical and practical handbook on design, implementation, analysis and report of such surveys (4). However, population-based data on the incidence and prevalence of tuberculosis in the countries of the Western Balkans including Kosovo is scant. A fairly recent study reported poor health-seeking behaviors among Kosovo patients with tuberculosis (5). Yet, the magnitude and trends of the incidence and prevalence of tuberculosis in Kosovo have not been systematically documented. In this context, the aim of this article is to describe the incidence and case notification rate of tuberculosis in Kosovo for the period 2000-2010.

Methods

Data about all new cases of tuberculosis, incidence rate and case notification rate for the period 2000-2010 were obtained from the National Tuberculosis Control Program in Kosovo. Furthermore, selected indicators of tuberculosis in Kosovo were retrieved from the WHO Global Tuberculosis Report 2012 (1). Incidence is defined as the number of new and recurrent/ relapse episodes of all forms of tuberculosis occurring in a given year. Recurrent episodes are defined as a new episode of tuberculosis in people who have had tuberculosis in the past and for whom there was bacteriological confirmation of cure and/ or documentation that treatment was completed (1).

The case notification rate refers to new and recurrent episodes of tuberculosis notified to WHO for a given year, expressed per 100,000 population (1). As described in the methods annex of the WHO Global Tuberculosis Report 2012 (see at: http:// www.who.int/ tb/ publications/ global_report/ gtbr12_annex1.pdf [6]), the case notification rate for new and recurrent tuberculosis is important in the estimation of tuberculosis incidence. However, in cases when information on treatment history is not available, recurrent cases cannot be distinguished from cases whose treatment was changed, since both are registered and reported in the category "retreatment" (1). Data for patients reported in the "unknown" category (Table 1) were assessed by WHO in collaboration with the National Tuberculosis Control Program in Kosovo to determine the proportion of such patients included in the category of recurrent cases (1).

Table 1. Tuberculosis case notifications in Kosovo for selected years *(source: WHO, Global Tuberculosis Report, 2012)*

Year	New and relapse	New		
		Smear-positive	Smear-negative/unknown	Extra-pulmonary
2005	1062	232	596	234
2009	254	254	-	-
2010	884	287	269	299
2011	875	251	349	246

Results

In the past decade, there has been a decline in the overall number of new cases of tuberculosis in Kosovo (Figure 1). Thus, the number of new cases of tuberculosis declined from 461 in 2001 to 287 in 2010 (linear trend: P< 0.01). However, the most significant decrease concerns the period from 2001 to 2003 (the number of new cases in 2003 was 292). Subsequently, there was evidence of an oscillation in the number of new cases with a rise and fall until 2010.

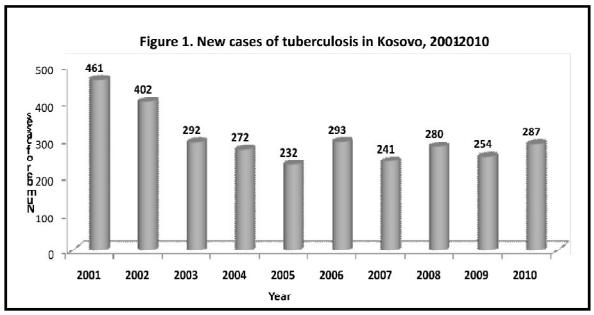
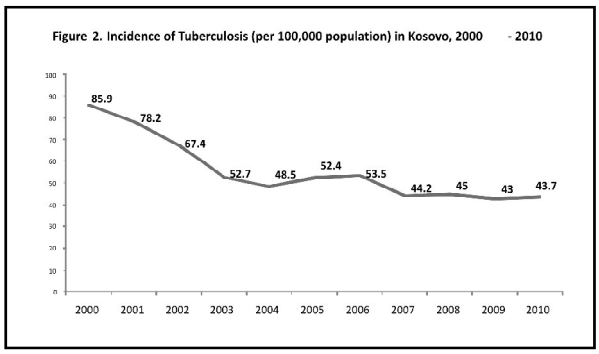


Figure 2 presents the incidence rate of tuberculosis (per 100,000 population) in Kosovo for the period 2000-2010. Overall, the incidence rate of tuberculosis in Kosovo declined twice in the period 2000-2010. In 2000, the incidence rate (per 100,000 population) was 89.9 compared with 43.7 for the year 2010 (linear trend: P< 0.01).



Similarly, the case notification rate (per 100,000 population) declined from 78.2 in 2001 to 43.7 in 2010 (linear trend: P<0.01) [Figure 3]. Nonetheless, for both the incidence and the case notification rate, a sharp decrease was evident only for the period from the year 2000 to the year 2003. Afterwards, there has been a fluctuation in the incidence rate and case notification rate with a rise and fall until 2010 (Figures 2-3).

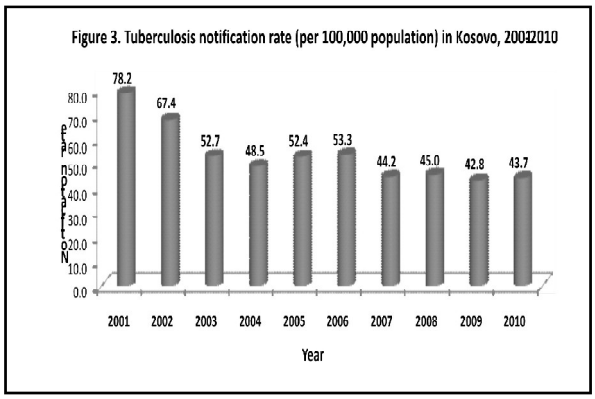


Table 1 presents tuberculosis case notifications in Kosovo for selected years (source: WHO, Global Tuberculosis Report 2012 [1]). In 2005, there were 1062 new and relapse cases of tuberculosis in Kosovo. This number declined almost four times in 2009 (n=254). One year later (in 2010), however, the number of new and relapse cases of tuberculosis increased up to 884, and in 2011 the number remained almost unchanged (n=875). Conversely, the number of smear-positive cases increased from 232 in 2005 to 254 in 2009. It further increased in 2010 (n=287), but decreased back to 251 cases in 2011. The apparent huge number of new and relapse cases of tuberculosis in 2005 reflects mainly the smear negative and/ or "unknown" cases (n=596). On the other hand, overall, the number of extra-pulmonary cases was similar in 2005 (n=234) and in 2011 (n=246) [Table 1].

Discussion

This report highlights the decreasing trends of incidence and case notification rate of tuberculosis in Kosovo in the past decade. This is compatible with worldwide trends published recently in the WHO Global Tuberculosis Report, which clearly indicated that both incidence rates and death rates from tuberculosis have decreased in all six WHO regions (1).

In line with many countries in different regions of the world, data from Kosovo indicate a downward trend in tuberculosis incidence and case notification rate for the period 2000-2010. Nevertheless, the most significant decrease concerns the period from the year 2000 to the year 2003. Afterwards, as stated earlier, there has been a fluctuation in the incidence rate and case notification rate in Kosovo. Mechanisms and determinants of such fluctuations

in the incidence and case notification rates need further investigation and elaboration. A detailed analysis should be conducted in line with WHO recommended methodology for proper definition and identification of new and recurrent (relapse) episodes of all forms of tuberculosis (6).

In Kosovo, a DOTS-based National Tuberculosis Program was established and operationalized in 1999 through a collaboration of several international partners as part of the reorganization of health services (7). Nevertheless, despite the continuous efforts, the available information on the tuberculosis notification rate in Kosovo indicate that the level remains high compared to neighboring countries such as Albania, Macedonia, Serbia and Montenegro and especially compared to Slovenia, but lower than Bosnia Herzegovina, Romania and former Russian Federation Countries (8).

A fairly recent study provided evidence on health-seeking behaviors, diagnosis and management of tuberculosis among patients in Kosovo (5). Findings from this report pointed to poor health-seeking behaviors among Kosovo patients with tuberculosis. In particular, female gender, Albanian ethnicity, urban residence and a lower income level were all associated with a longer duration of seeking medical care, notwithstanding the lack of statistical significance (5).

The Ministry of Health in Kosovo, through the Tuberculosis Global Fund Project, has established a sustainable mechanism of tuberculosis reporting to the annual WHO Global Report on Tuberculosis (8). In line with this commitment, the tuberculosis case notification and incidence rates have gradually decreased in recent years (8), as illustrated in the current report.

In conclusion, this article described the incidence rate and the case notification rate of tuberculosis in Kosovo indicating a decreasing trend in the past decade, which is in line with the declining trends of tuberculosis in all regions of the world.

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Evaluating interventions aimed at promoting social participation of older people: A review of the literature

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Abstract

As a reaction to the growing amount of academic literature on the relationship between social participation and health outcomes such as quality of life, this article intends to explain how the effectiveness of interventions aimed at promoting social participation of older people can be evaluated, in order to identify good practices which are relevant for Europe. In doing so, this article assumes a positive relationship between social participation and the health of older people. Following a model for evaluating evidence on the effectiveness of health promotion interventions, this article analyses three systematic reviews for answering the above-mentioned research question. In general, group interventions with a strong interactive character, having an educational input or offering social support, targeted at specific groups of older people and including the older people in the development and implementation of the interventions, were considered as the most effective type of interventions. The systematic reviews analysed in this article, however, suffer from several serious weaknesses, concerning credibility of the research itself, completeness of the evaluated intervention outcomes, and transferability of the research evidence. Future research should be directed to more specific types of interventions promoting social participation and specifically to European interventions.

Keywords: *older people, quality of life, social participation.*

Introduction

Public health interventions in Europe focused on health promotion for older people are often based on the WHO principle of active ageing, defined as "the process of optimizing opportunities for health, participation and security in order to enhance quality of life as people age" (1). In this way, the adjective 'active' does not merely relate to being physically active, or being active in terms of employment, but also—and perhaps foremost when taking into account the often inevitable physical impairment and retirement of older people—in terms of social participation. During the last decade, academic literature on social participation of older people seems to point in the direction of a positive relationship with a variety of health outcomes like quality of life and wellbeing (2-4).

An example of the way the EU has put social participation of older people on the agenda, was by declaring 2012 as the European Year for Active Ageing and Solidarity between Generations. The European Year aims to urge policymakers and other relevant stakeholders, like public health professionals, to take action aimed at promoting active ageing in three domains: social participation, employment and independent living.

In this article we intend to answer the following research question: "How can the effectiveness of interventions aimed at promoting social participation of older people be properly evaluated, in order to identify good practices which are relevant for Europe?" In doing so, we propose an approach for evaluating evidence on public health interventions. Interventions aimed at promoting social participation amongst older people are captured here under this broad heading of public health interventions, because social participation is considered in this article as a way of promoting health or preventing ill health in communities or populations—hereby following the definition of public health interventions as proposed by Rychetnik et al. (5). The results of three systematic reviews will be compared on the basis of this approach. Finally, we will discuss whether the current scientific literature provides us with sufficient evidence for the potential identification of good practices relevant for Europe.

Methods

Although in general the academic literature shows an increasing interest in the concept of social participation of older people, there is no consensus in the literature about the exact definition of the concept. Interestingly however, a study conducted by Levasseur et al. which aims at systematically reviewing definitions of social participation specifically targets older people. This study revealed that most of the forty-three definitions it considered are centred around the explicit notion of interaction between the respective individual and others in society, instead of mere participation in activities or being amongst others (6).

Next, in the introduction of this article, a positive relationship between social participation and health was assumed. At the same time, however, a growing part of the academic literature actually contests this relationship (2). But, only few studies appear to have examined the specific influence of sex and age on the relationship between social participation and health. A striking example is the survey conducted in South Korea by Lee et al., whose results show that the effect of social participation on self-rated health rises as age advances. As the same survey shows a negative relationship between the degree of social participation and age—due to developments typically related to age, such as physical impairments, retirement or the loss of relatives—it urges social participation to be a basic consideration in health promotion strategies for older people (3). These findings are similar to those found for the European region, in a study conducted by Sirven & Debrand (2). Defining this relationship into more detail would be beyond the scope of this article. It suffices here to state that good indications exist within the academic literature for the existence of a positive relationship between social participation and health status of older people.

When turning to interventions aimed at promoting social participation amongst older people, social participation as such does not seem to be an easy target for policy makers and public health professionals. Instead, many existing health promotion interventions geared at increasing social participation of older people do so within the context of preventing social isolation (7). In this way, social participation activities are regarded as

indicators "promoting good health by protecting against the negative effects associated with social isolation" (8). Simultaneously, the bulk of evaluative literature considers interventions aimed at reducing social isolation, instead of improving social participation (9). It is exactly for this reason that this article deals with systematic reviews of interventions aimed at reducing social isolation. These systematic reviews were chosen for the obvious reason that these were the only three systematic reviews that were found in the literature, following a simple PubMed search strategy. For analyzing the systematic reviews, we applied an approach for evaluating evidence on the effectiveness of public health interventions based on the work by Rychetnik et al. (5). According to this approach, a critical appraisal of what constitutes best evidence in evaluative research generally focuses on three key considerations. First, one should consider whether the credibility of the evaluative research itself is sufficient in order to allow for sound evidence-based decisions on public health interventions. Next, the completeness of the evaluated intervention outcomes should be critically appraised. Finally, one should consider whether the research evidence is transferable.

Results

In the remainder of this article, the three systematic reviews that are applied will be labelled A (10), B (11) and C (12), in the order of publication. Using three systematic reviews allows for interesting insights in the weaknesses of each review, and the added value of each consecutive review. Table 1 provides a, precise and literal, overview of the characteristics of the three systematic reviews.

Generalizing from the three systematic reviews, it can be said that there is agreement within the available literature on the characteristics contributing to effective health promotion interventions aimed at reducing social isolation among older people. Interventions regarded as most effective were in the first place group interventions, that is, interventions with a strong interactive character between the participants and offered outside people's own houses. Within this category, especially interventions with a clear educational character or those offering social support, appeared to be effective. Examples for the former include discussion groups dealing with health-related issues or physical activity groups, while the latter typically refers to discussion groups with a more therapeutic character. Secondly, effective interventions appear to be focused on specific groups of older people, like those that have physical impairments, male or female, those with a cognitive impairment, those that have already lost their spouse etc. Thirdly, effective appear to be those interventions that allow the older people themselves to participate in the development and implementation phases of the interventions themselves, especially those older people that have a caring attitude towards others. Least effective appear to be one-to-one interventions, offered at people's own houses, like home-visiting and home nursing care arrangements. At the same time, this same literature agrees as well on the fact that although the interventions included in the systematic reviews may contain some of these characteristics, none of them seem to comprise all of these characteristics.

After having elaborated on the results of each of the systematic reviews, their evidence can now be evaluated, hereby following the model as outlined in the previous section of this article. Concerning credibility of the research, the three systematic reviews show large similarities. Firstly, in terms of their study design, being systematic reviews primarily based on RCTs, each could be referred to as approaching top level in the so-called evidence hierarchy. Secondly, regarding methodological flaws of the research, each of the reviews suffers from a bias towards studies published in English, (too) broad inclusion criteria, high degrees of heterogeneity among the included studies, and a limited number of high quality studies. Regarding the completeness of the interventions in the evaluated studies, striking is that only review C explicitly reports on health outcomes, while the other two reviews only report on health outcomes in an indirect way. On the one hand this is peculiar, as each of the reviews embraced the existence of a positive relationship between reducing social isolation and positive health outcomes. On the other hand, one could argue that this indirect reporting is obvious, as the prime outcome measure of each of the reviews is clearly stated as 'reducing social isolation'. Next, none of the systematic reviews reported in any meaningful way on the cost-effectiveness of the interventions they evaluated. Interestingly, the

Table 1. Characteristics of selected systematic reviews

	Systematic review A [10]	*Systematic review B [11]*	*Systematic review C [12]*
Characteristics of systematic reviews themselves			
Year of publication	2003	2005	2011
Country of publication	United Kingdom	United Kingdom	United Kingdom
Inclusion criteria	Included studies that: - "related to older people"; - "considered interventions targeting social isolation and/or loneliness"; - "described interventions intended to achieve health gain"; - "recorded outcome measures"; - "were published in English"; - "were published between 1982 and 2002".	Included studies that: - "related in full or in part to older people"; - "considered interventions that were intended to prevent or alleviate social isolation and/or loneliness in full or in part"; - "described health promoting interventions that enabled older people to increase control over and to improve their health"; - "recorded some form of outcome measures with or without process measures".	Included studies that: - "related in full/part to older people"; - "considered interventions that targeted people identified as socially isolated and/or lonely, and stated a clear and plausible aim to alleviate this"; - "recorded some form of participant level outcome measure, and reported sufficient outcome data for treatment effects to be obtained"; - "used a RCT or quasi-experimental design and included an inactive control group"; - "were published in English".
Characteristics of studies included			
Number of studies included	17	30	32
Years of publication	1982-2002	1970-2002	1976-2009
Countries were studies were conducted	USA (8) Australia (3) Canada (2) The Netherlands (2) Italy (1) Sweden (1)	USA (17) Canada (3) The Netherlands (3) Sweden (2) United Kingdom (2) Denmark (2) Germany (1)	USA (17) The Netherlands (6) Canada (3) Japan (2) Sweden (2) Finland (2)
Study designs	Randomized controlled trials (6) Quasi-experimental studies (3) Non-randomized post-treatment/test survey (3) Pre-post intervention studies (2) Cross-sectional survey (1) Observational study (1) Non-randomized matched control trial (1)	Randomized controlled trials (16) Non-randomised controlled trials (10) Other (4)	Randomized controlled trials (16) Quasi-experimental studies (16)
Types of interventions	Group interventions (6) One-to-one interventions (5) Internet usage (4) Service provision (2)	Group interventions (17) One-to-one interventions (10) Service provision (3)	Group interventions (19) One-to-one interventions (11) Service provision (1) Mixed mode (1)

importance of sophisticated knowledge on the cost-effectiveness of such interventions is though widely recommended by the reviews. Finally, applicability and transferability of the research evidence seems to be of particular interest if one seeks to identify good practices for the European region. Information on applicability can only be extracted from review B. In review C, applicability appears to be captured together with transferability under the heading of generalizability. Review A does not discuss both terms at all. Nonetheless, a more detailed discussion about applicability would be desirable, as it would provide us with more detailed information on the settings of the intervention processes. Perhaps as a result of this flaw, transferability is generally considered insufficiently

proven by the systematic reviews themselves, their own main argumentation being that the majority of studies were conducted in the United States of America. A more detailed overview of the above findings is provided in Table 2.

Table 2. Evaluation of evidence of selected systematic reviews

	Systematic review A (ref. 10)	***Systematic review B (ref. 11)***	***Systematic review C (ref. 12)***
Credibility of research			
Study design	Systematic review, based to a large extent on RCTs (6/17).	Systematic review, based to a large extent on RCTs (16/30).	Systematic review, based to a large extent on RCTs (16/32).
Methodological problems	- Limited number of interventions evaluated. - Bias towards studies published in English. - Broad inclusion criteria.	- High degree of heterogeneity among evaluated interventions. - Limited number of high quality studies. - Bias towards studies published in English, despite the fact that the English language was not an inclusion criterion in this review. - Broad inclusion criteria.	- High degree of heterogeneity among evaluated interventions. - Limited number of high quality studies. - Bias towards studies published in English. - Broad inclusion criteria.
Completeness of intervention outcomes			
Information as required by stakeholders	- Only indirect reporting on health outcomes. - Recognition of limited value of results overall, due to limited number of studies included.	Only indirect reporting on health outcomes.	Clear reporting on health outcomes (social, mental and physical health).
Unanticipated results	Rejection of the broadly supported effectiveness of health promotion interventions aimed at reducing social isolation among older people.	No information on unanticipated results.	No information on unanticipated results.
Cost-effectiveness	- Reports on cost-effectiveness of two of the interventions. - Recognizes that cost-effectiveness analyses should indeed be performed before interventions are implemented.	No information provided on cost-effectiveness.	- No information provided on cost-effectiveness. - Argues that, despite growing evidence-based support for the effectiveness of health promotion interventions aimed at reducing social isolation among older people, the cost-effectiveness of successful interventions continues to be under-researched.
Transferability of research evidence			
Applicability	- No detailed information on setting of intervention process. - No discussion about applicability.	- Detailed information on setting of intervention process. - For most studies, the imprecise definition of the term 'social isolation' considered as a	- No detailed information on setting of intervention process. - No discussion about applicability.

Discussion

This article has attempted to contribute to the growing amount of literature on the effectiveness of health promotion interventions aimed at increasing social participation among older people. Social participation was considered in this regard as having a positive influence on the health status and quality of life of older people.

The strength of this article is probably foremost its reliance on three systematic reviews, which gave a comprehensive insight into the available evidence on the topic in question. Although each of the systematic reviews did not depend solely on RCTs, this does not necessarily constitute a weakness in the quality of the evidence. Indeed, the academic literature generally depicts studies that are not RCTs as having a high risk of bias. On the other hand, many authors agree that low quality RCTs might be of less value than high quality non-randomized controlled trials (13). However, due to the high degree of heterogeneity of the evaluated interventions, as well as due to a generally low quality of the studies included, each of the systematic reviews admitted the existence of a high risk of bias. Another weakness of the systematic reviews was the inappropriate range of outcomes in light of the research question of this article. On the other hand, the relative lack of in depth information on health outcomes and cost-effectiveness measures may constitute possibilities for future research. The latter is particularly true for research with a clearer focus on specific kinds of interventions. A final weakness in the systematic reviews was its predominant reliance on quantitative outcome studies for making judgments about applicability and transferability. As is proposed by Rychetnik et al., qualitative, or at least quantitative observational studies, may be required to bridge the gap between the research evidence on the one hand and the practice of a local setting on the other hand (5).

Apart from the above-mentioned methodological flaws in the applied systematic reviews as well as in the studies they included, this article itself suffers from the problem of reverse causality. For example, older people who have a bad health condition may not be able to engage in, or uphold their level of, social participation in the first place. A solution to this problem may be to draw more attention to longitudinal studies, instead of the current focus on cross-sectional studies. A second limitation stems from the fact that the available evaluative research studies on health promotion interventions primarily deal with the concept of reducing social isolation instead of increasing social participation.

Nonetheless, this observation of a gap in the available research provides opportunities for future research. It may be interesting to step aside from research that encompasses all of these more general intervention categories, like group interventions and one-to-one interventions, and instead conduct a more in depth evaluation of the category that was identified as the most effective. Moreover, taking into account the initial European focus of this article, the fact that each of the currently available systematic reviews primarily evaluated interventions conducted in North-America, and the transferability problems identified due to this latter point, further research could be specifically geared towards European interventions. However, one should also take into account that the availability of sufficient numbers of high quality studies on such interventions is limited in many European countries. Moreover, if case such studies exist, they are often not published in English. Such practical problems substantially hamper the possibility for conducting the preferred research. Therefore, one could instead consider conducting research on one specific European country, and/ or on the category that was identified as the most effective.

In summary, this category can be described as group interventions with a strong interactive character, particularly those with an educational input or offering social support. Moreover, such interventions should be focused on a specific group of older people and give these older people the opportunity to participate not only in the activities as such, but also in the development and implementation of the interventions. Certainly, the increase of social participation of socially isolated older people does not occur overnight, nor will its effects on health status and quality of life manifest itself immediately. However, referring for example to the current European Year of Active Ageing and the various local initiatives attached to it, the topic is becoming already firmly established on the policy agenda. Especially for policy makers and health

professionals it is of key importance to remember that increasing social participation of older people is a process, which cannot simply rely on one social activity once in a while.

Competing interests

The authors declare that they have no competing interests.

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Epidemiology of rheumatoid arthritis: A literature review

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Abstract

Rheumatoid arthritis is basically considered a clinical syndrome across several disease subsets characterized by systemic inflammation, persistent synovitis, and autoantibodies.

Genetic factors account for 50% of the risk of developing rheumatoid arthritis. In population-based studies in developed countries, it has been reported that rheumatoid arthritis affects 0.5%-1.0% of adults. The condition is three times more frequent in women than men. In both sexes, the prevalence increases with age. The prevalence of rheumatoid arthritis has remarkable geographical variations. The disease is more prevalent in Northern Europe and North America compared with many parts of the developing world. Nonetheless, valid and reliable data about developing countries and/or transitional societies are scarce.

The new classification criteria for rheumatoid arthritis, developed by the American College of Rheumatology and the European League Against Rheumatism, assess joint involvement, autoantibody status, and acute-phase response and symptom duration. Notwithstanding the unresolved difficulties and challenges related to management of rheumatoid arthritis, the ongoing introduction of ground-breaking treatments may turn out to be rather effective. In any case, it has been convincingly argued that the new direction of treatment and management of rheumatoid arthritis should be towards short intensive therapeutic courses that result in remission instead of the traditional approach that is long-term suppressive treatment strategies.

Keywords: arthritis, rheumatoid arthritis, rheumatic conditions, rheumatology.

Introduction

Rheumatoid arthritis is basically considered a clinical syndrome across several disease subsets (1), involving several inflammatory flows (2), leading to an ultimate common pathway in which persistent synovial inflammation and associated damage to articular cartilage and underlying bone are present (3). Classification criteria of rheumatoid arthritis

were developed about 50 years ago (4).

In the pathophysiology of the rheumatoid arthritis, a main inflammatory process includes overproduction of the tumor necrosis factor (3,5) which, in turn, leads to overproduction of many cytokines such as interleukin 6, which causes persistent inflammation and joint destruction (3,6).

Genetic factors account for 50% of the risk of developing rheumatoid arthritis (7,8) and are mainly associated with either autoantibody-positive disease (ACPA-positive) or ACPA-negative disease (3). ACPA-positive disease is associated with increased joint damage and low remission rates (9). Smoking, which is the most frequently studied environmental factor for rheumatoid arthritis (see below), appears to be a risk factor for ACPA-positive disease (10). In general, genetic research supports the idea that rheumatoid arthritis is a heterogeneous group of overlapping syndromes (3).

Diagnostic classification of rheumatoid arthritis

Early classification criteria for rheumatoid arthritis were designed to distinguish established rheumatoid arthritis from other types of established joint diseases (3,4). For this purpose, researchers and clinical epidemiologists conducted studies including homogeneous patients' groups; this was particularly the case in clinical trials (3).

The American College of Rheumatology criteria developed in 1987 (4) have demonstrated poor sensitivity and specificity for classification of patients with early inflammatory arthritis as having rheumatoid arthritis (11). These criteria have failed to identify individuals with very early arthritis who subsequently develop rheumatoid arthritis (12). Nowadays, effective treatment in early arthritis prevents or delays patients fulfilling the 1987 American College of Rheumatology criteria and, therefore, new classification criteria need to be endorsed.

Table 1 presents the new classification criteria for rheumatoid arthritis (3). These criteria were

Table 1. Classification criteria for rheumatoid arthritis – American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR), 2010

ACR/EULAR 2010 criteria (3,11)
1. ***Joint involvement (0–5)***
• One medium-to-large joint (0)
• Two to ten medium-to-large joints (1)
• One to three small joints (large joints not counted) (2)
• Four to ten small joints (large joints not counted) (3)
• More than ten joints (at least one small joint) (5)
2. ***Serology (0–3)***
• Negative RF and negative ACPA (0)
• Low positive RF or low positive ACPA (2)
• High positive RF or high positive ACPA (3)
3. ***Acute-phase reactants (0–1)***
• Normal CRP and normal ESR (0)
• Abnormal CRP or abnormal ESR (1)
4. ***Duration of symptoms (0–1)***
• Less than 6 weeks (0)
• Six weeks or more (1)
Points are shown in parentheses. Cut-point for rheumatoid arthritis: ≥6 points.
Patients can also be classified as having rheumatoid arthritis if they have:
a) typical erosions;
b) long-standing disease previously satisfying the classification criteria.

developed by the American College of Rheumatology and the European League Against Rheumatism to classify both early and established disease (13). These new classification criteria for arthritis assess joint involvement, autoantibody status, and acute-phase response and symptom duration (3,13). The effect on diagnosis and management of these new criteria will become clearer gradually over the next few years.

Frequency of rheumatoid arthritis

It must be noted that estimates of the frequency of rheumatoid arthritis vary depending on the methods used to determine its presence (3,14,15). In population-based studies in developed countries, it has been reported that rheumatoid arthritis affects 0.5%-1.0% of adults (3). The condition is three times more frequent in women than men (3). In both sexes, the prevalence increases with age. In women, the prevalence of rheumatoid arthritis is highest among those over 65 years, which suggests that hormonal factors could play a pathogenic role (16). Incidence of rheumatoid arthritis ranges from 5-50 per 100,000 adults in developed countries and increases with age (17). Data about developing/ transitional countries are scarce.

As for the prevalence of rheumatoid arthritis, it has remarkable geographical variations (18). The disease is more prevalent in Northern Europe and North America compared with many parts of the developing world and/or transitional countries, such as e.g. rural West Africa (19). It has been argued that these geographical variations maybe linked to different genetic predispositions, but are also related to different environmental factors which expose individuals from different regions in the world to different levels of risk for acquiring the disease (3).

Environmental risk factors of rheumatoid arthritis

Smoking is reported as the main environmental risk factor which increases twice the risk of developing rheumatoid arthritis (20). As mentioned earlier, the effect of smoking is restricted to patients with ACPA-positive disease (10). However, at a population level, the risk linked to smoking is too low to be clinically relevant notwithstanding the pathogenetic importance of this agent (3).

Other potential environmental risk factors for development of rheumatoid arthritis may include alcohol consumption, coffee intake, vitamin D status, and oral contraceptive use (3,21). Nevertheless, the evidence on the impact of these putative risk factors is controversial.

Clinical assessment of rheumatoid arthritis

The main assessment in rheumatoid arthritis pertains to joint inflammation (2), as presented in Table 2.

Table 2. Assessments in rheumatoid arthritis (source: Scott DL et al., 2010)

Assessments in rheumatoid arthritis (3)
Disease activity
Core assessments
• Joint counts (tender and swollen joint counts)
• Global assessment (doctor and patient) and pain score
• Laboratory (erythrocyte sedimentation rate and C-reactive protein)
• Disability (eg, health assessment questionnaire)
Additional assessment
• Fatigue
• Radiological damage
Combined status indices
• Disease activity score
• Simple disease activity score
• Clinical disease activity score
Change in status (trials only)
• ACR20, ACR50, and ACR70 responders

Assessments in rheumatoid arthritis (3)

Extra-articular disease

- Nodules
- Pulmonary
  - Pulmonary nodules
  - Pleural effusion
  - Fibrosing alveolitis
- Ocular
  - Keratoconjunctivitis sicca
  - Episcleritis
  - Scleritis
- Vasculitis
  - Nail fold
  - Systemic
- Cardiac
  - Pericarditis
  - Pericardial effusion
  - Valvular heart disease
  - Conduction defects
- Neurological
  - Nerve entrapment
  - Cervical myelopathy
  - Peripheral neuropathy
  - Mononeuritis multiplex
- Cutaneous
  - Palmar erythema
  - Pyoderma gangrenosum
  - Vasculitic rashes
  - Leg ulceration

Amyloidosis

Comorbidities

Cardiovascular

- Myocardial infarction
- Heart failure
- Stroke
- Peripheral vascular disease

Doctor-based reviews include overall estimates of disease activity and health status as evidenced by swollen and tender joint counts, as well as a global assessment of patient's conditions. Standard joint counts focus on 28 joints in the hands, upper limbs, and knees; joints in the feet are not included notwithstanding their clinical importance (3). Some experts prefer extended 66 and 68 joint counts including the feet. Laboratory parameters include erythrocyte sedimentation rate, C-reactive protein, or both (3).

Patient-based measures assess pain, global assessment, and disability (22), as determined through the health assessment questionnaire. Patients themselves document other relevant disease characteristics, such as fatigue and depression (3). It has been argued that patient-based measures are especially important to assess the individual's perspective of the burden of rheumatoid arthritis (3).

Management of rheumatoid arthritis

Currently, there exist several guidelines and protocols for management and treatment of rheumatoid arthritis which have been developed by the American College of Rheumatology, the European League Against Rheumatism and the UK's National Institute for Health and Clinical Excellence (3,23-25). Analgesics reduce pain, and non-steroidal anti-inflammatory drugs (NSAIDs) diminish pain and stiffness. Both groups of drugs are used widely to control symptoms of rheumatoid arthritis (3). NSAIDs have lost their traditional role as first-line treatment because of concerns about their limited effectiveness, inability to modify the long-term course of disease, and gastrointestinal and cardiac toxic effects (26).

Disease-modifying anti-rheumatic drugs (DMARDs) are used to reduce joint swelling and pain, decrease acute-phase markers, limit progressive

joint damage, and improve function (3). Methotrexate is the dominant DMARD. Sulfasalazine and leflunomide are also widely used effectively (3).

Biological agents are used when arthritis is uncontrolled or when DMARDs exhibit toxic effects (3). Tumor necrosis factor inhibitors were the first biological agents (3).

Nonetheless, the ultimate goal for management of rheumatoid arthritis would be a long-term remission induced by intensive, short-term treatment selected by biomarker profiles (3).

Conclusion

Currently, there are many unresolved difficulties for people suffering from rheumatoid arthritis. Nevertheless, the ongoing introduction of innovative and ground-breaking treatments can overcome many of these difficulties and challenges. One of the main requirements involves the characterization of disease subsets in individuals with early onset of rheumatoid arthritis in order to target intensive treatment regimens at patients who most need them and are likely to respond (3). From this point of view, it has been convincingly argued that the new direction of treatment and management of rheumatoid arthritis should be towards short intensive therapeutic courses that result in remission instead of the traditional approach that is long-term suppressive treatment strategies.

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Management of opioid tolerability and related adverse effects

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Abstract

Aims: Adverse effects associated with opioid use are numerous and can be treatment limiting, but a variety of management strategies and tactics exists. The aim of this study was to review opioid use adverse effects and their treatment options.
Methods: We reviewed the recent literature and highlighted the most common adverse effects associated with opioid use and the suggested treatment options and tactics.
Results: Adverse effects of opioids range from common ones (constipation, nausea) to the less common (hiccups, lower leg edema), from the relatively mild (dry skin, runny nose) to the severe (respiratory depression). The adverse effects of opioids may be classified into inhibitory and excitatory, although they sometimes occur simultaneously. Ultra-low doses of opioid antagonists can reduce excitatory effects which, in turn, can heighten the inhibitory response (and possibly potentiate analgesia).
Conclusions: Patients on opioid therapy may benefit from a change in drugs (ideally to a non-opioid altogether, but possibly to a lower dose or different opioid) or combination therapy. Specific medications or therapies have been shown to be effective in managing some adverse effects of opioid therapy, but there is considerable intra-patient variability. Opioid therapy confers analgesic benefits to well-selected patients, but adverse effects of this therapy are common and may require physician management.

Keywords*: Opioids, opioid adverse effects, opioid adverse events, opioid antagonists.*

Introduction

Opioid tolerance can be defined as the need to take increasing amounts of the opioid agent in order to effectively maintain the same level of analgesic relief (1). However, the relationship between opioid tolerance and addictive mechanisms is unknown. While opioid rotation can often be useful to strike this appropriate balance, the adverse effects of different opioids may create new or worsened side

effects. Opioid rotation can be limited by the fact that there is not always sufficient evidence available to guide equianalgesic ratios (2). The most straightforward approach to management of opioid-related side effects starts with dose reduction, followed by changing to a different opioid or route of administration (3,4). However, many adverse effects (AEs) are systemic and central in nature, so opioid rotation may not abate the symptoms; changing routes of administration may be impractical. Thus, prescribing additional medications to manage side effects has become common, although it often leads to patient inconvenience and potentially hazardous polypharmacy.

Classification of opioid adverse effects

Excitatory and inhibitory effects may occur simultaneously, producing bimodal action (5). Ultra-low doses of opioid antagonists block the excitatory effects, such as hyperalgesia, while potentiating the inhibitory effects, such as analgesia, and may improve the side-effect profile (6,7). A recent study of low-dose nalbuphine and morphine in humans (n= 174) found that low-dose nalbuphine with morphine in patient-controlled anesthesia reduced the rate of nausea without adversely affecting analgesic benefit (8). In the aforementioned study, 1 mg nalbuphine was added to 100 mg preservative-free morphine and saline to make a total volume of 100 mL solution for patient-controlled analgesia. Another human study of analgesia (n = 112) combined 100 ng (1 mL) of naloxone with 100 ìg of fentanyl and 34 mL of lidocaine 1.5% for the active agent arm of the study, finding that the addition of low-dose naloxone prolonged axillary brachial plexus blockade – that is, time to first postoperative pain – in patients undergoing elective forearm surgery (9).

Managing opioid-related adverse effects

Many patients who take opioids may discontinue them and restart. Tolerance to opioids can build quickly, but it is also lost quickly.

Table 1. Management of opioid-related adverse effects

1.	If possible, use non-opioids.
2.	Use combination therapy (opioid and a non-opioid pain reliever) rather than increasing the dose of the single opioid.
3.	Periodically convert to non-opioids, decrease and/or discontinue opioids to see if the patient tolerates the change.
4.	Consider opioid rotation (changing from one opioid to another opioid) if you are unable to circumvent side effects (10).
5.	Consider social and family history in relation to opioids.
6.	Exercise caution when combining opioids with other CNS depressants.
7.	If opioids are decreased or discontinued and then reintroduced, slow titration is preferred to give the body time to adjust.
8.	Watch for CYP P-450 medications interactions.

Opioid-related adverse effects

Respiratory AEs: Respiratory AEs are so important that they belong in a special category. This action decreases the brain stem's response to CO_2 and directly affects the cough center in the medulla, even at sub analgesic levels. Morphine and fentanyl have higher rates of respiratory depression than buprenorphine, which in one study was found to exhibit a plateau effect with respect to respiratory depression (11). Doubling the dose of buprenorphine increased analgesia but did not increase the rate of respiratory depression. General principles of airway management and managing inhibitory symptoms may be utilized including naloxone 0.4 mg to 2 mg intravenously in emergencies.

Intracranial AEs: All opioids, particularly short-acting opioids, are known to induce headaches in chronic headache patients. A severe headache induced immediately after opioid initiation usually subsides spontaneously and may respond, at least partially, to acetaminophen and non-steroidal anti-inflammatory drugs. Severe headaches may require discontinuation of the opioid.

Musculoskeletal AEs: Musculoskeletal AEs are mainly excitatory and may be a part of opioid-induced hyperalgesia. Muscle weakness with a decrease in deep tendon reflexes may be a result of opioid-induced central nervous system inhibition. Muscle relaxants in usual doses can be used; antispasmodic medications, including alpha blockade from tizanidine, can be beneficial in treating muscle twitching and myalgia. Dopaminergic anti-Parkinson medications, such as pramipexole dihydrochloride and ropinirole extended release, may be beneficial but must be used with caution because of their potential to depress the central nervous system. Buprenorphine has less excitatory effects on the muscles than other similar agents.

Cutaneous AEs: Cutaneous AEs are mostly excitatory in nature and include itching, flushing, sweating, rash, ecchymosis, petechiae, and facial wrinkles. Inhibitory cutaneous AEs include dry skin as well as brittle hair and nails. Hypoventilation is associated with pallor or grayish skin color and is a direct sign of developing hypoxia and encephalopathy. Some cutaneous adverse effects are related to the release of histamine and may diminish over time in chronic opioid therapy. Sweating may be treated with a variety of measures: hydroxyzine 25 mg to 100 mg every 6 to 8 hours; terazosin 2 mg to 4 mg orally per day; scopolamine patch and atropine; aluminum chloride 20% topically; calcium supplementation; and micro-doses of naltrexone. Anticholinergic biperiden also may be used, but care must be taken since anticholinergic agents may increase constipation, urinary retention, or other adverse effects. For inhibitory AEs, simple measures, such as 3 g to 6 g a day of Omega III fatty acids (fish oil, flaxseed oil) and liberal use of creams and topical ointments, may suffice.

Circulatory AEs: The inhibitory AEs associated with opioids on the circulatory system include orthostatic hypotension due to vasodilatation; a decrease in cardiac output; bradycardia or tachycardia; and QT-segment prolongation on the electrocardiogram. The excitatory AE is mainly peripheral edema, especially lower leg edema due to histamine release and cAMP induction. For inhibitory AEs, vasoconstrictors and hydration can be used. For excitatory AEs, diuretics and terazosin 1 mg to 10 mg by mouth at bedtime can be considered. Compression stockings and sequential circulation may be used in cases of lymphedema.

Visual AEs: The mechanism behind visual problems is not clearly understood, but one suggestion is that MOR-3 activation releases nitric oxide, which, in turn, causes intraocular hypertension and miosis, resulting in blurred vision (12,13). Another theory proposes even opioid-tolerant patients may have miosis with sudden or marked increases in dose. Mydriasis is more likely to occur in patients with opioid-induced hypoventilation and hypoxia. Pulsating pupils under penlight exam suggest adrenal fatigue. Visual disturbances, like other side effects, may be dose related.

Gastrointestinal AEs: When released from enteric neurons, it is likely that opioid peptides play a mediator role in the regulation of propulsion and secretion (16-20). Stool softeners are commonly used to treat opioid-induced constipation, but this is not usually as effective as a laxative or laxative-stool softener combination, since opioid-induced constipation is caused by poor gut motility. Patients who had GI spasm prior to opioid therapy will likely find their abdominal pain exacerbated by opioids. To manage excitatory GI AEs, decrease opioid dose and consider the use of promethazine, prochlorperazine, and ondansetron. Micro-doses of naltrexone can be considered as well. Inhibitory AEs, specifically constipation, are treated by laxatives (possibly in combination with a stool softener) as well as metoclopramide and dicyclomine. Methylnaltrexone 12 mg by subcutaneous injection can block opioid-inhibitory GI AEs in the gut. Erythromycin-related motilides, ghrelin analogues,

the mixed 5-HT4 receptor agonist/ 5-HT3 receptor antagonist renzapride and the CCK1 receptor antagonist dexloxiglumide represent further prokinetic drug candidates that are in clinical development (14,15).

Endocrine AEs: There is a dose-dependent relationship with respect to opioids and AEs involving the endocrine system. Curiously, there are no reports in the literature of decreases in follicular-stimulating hormones and prolactin blood levels as AEs of opioids. Thyroid-stimulating hormone (TSH) may be suppressed or stimulated by opioids and can mask hypothyroid symptoms. Hypoadrenalism is related to suppression of adrenocorticotropic hormone (ACTH), and some opioid patients may require steroid supplementation because of cortisol suppression and clinical Addison's disease. Prolactinemia has been reported, including gynecomastia, weight gain, and infertility. The use of bromocriptine 5 mg to 7.5 mg by mouth every day may be used to treat prolactinemia along with decreasing the opioid dose.

Urinary AEs: Urinary AEs are primarily excitatory and involve urinary retention caused by an increase in the sphincter's tonus. There is a higher prevalence of hypogonadism in male opioid patients than in females, which has led to the speculation that prostatic hypertrophy may owe to inhibitory effects of opioids suppressing more testosterone than estrogen. Clinical management of urinary AEs may include conservative approaches with hydration or one of the pharmacological measures, such as dicyclomine 10 mg to 20 mg up to 4 times daily, oral bethanechol 10 mg to 30 mg 2 to 4 times daily, 1 mg to 10 mg oral terazosin at bedtime, or 0.5 mg oral dulasteride daily. Meperidine, in particular, should not be used in patients where renal toxicity might be an issue.

Conclusions

Opioids represent a challenge in clinical practice due to their wide-ranging clinical, side effect, and end-organ effects. The complex properties of opioid analgesics and their potential interactions with other medications present a significant clinical challenge to even seasoned pain specialists. It is not unheard of that chronic opioid patients choose to discontinue opioid therapy (and give up pain relief) rather than endure intolerable adverse effects. Nevertheless, opioid analgesia offers tremendous benefits to well-selected chronic pain patients when resulting AEs can be managed. In addition to the previously described strategies, further research needs to be carried out to address specific opioid AE management strategies that will optimize analgesia while lessening concerns about tolerability, serious adverse events, and chronic end-organ concerns.

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Tonsillectomy in medical practice: A literature review

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Abstract

Tonsillectomy is one of the most frequently undertaken procedures in otolaryngology. Tonsillectomy is defined as a surgical procedure performed with or without adenoidectomy that completely removes the tonsil including its capsule by dissecting the peritonsillar space between the tonsil capsule and the muscular wall. The indications for tonsillectomy, however, remain controversial. Children undergo surgery primarily to reduce the frequency and severity of recurrent sore throats. A smaller number endures tonsillectomy – often with adenoidectomy – in order to provide relief of airway obstruction. Nonetheless, there is no evidence that the benefits of tonsillectomy for recurrent sore throat are prolonged beyond two years.
The main aim of this review is to provide clinicians with evidence-based guidance for identification of patients who are the best candidates for tonsillectomy. Secondary objectives include optimization of the peri-operative management of children undergoing tonsillectomy; emphasis on the need for evaluation and intervention in special populations; improvement of counseling and education of families who are considering tonsillectomy for their children; description of different procedures currently used for tonsillectomy; description of the management options for patients with modifying factors, and; reduction of inappropriate, or unnecessary variations in medical care.

Historical notes

Celsus in 'De Medicina' (14–37 AD) described 'induration' of the tonsils, which he advised could be removed by dissection with the fingernail. If this was not possible they could be grasped with a hook and pulled out with a 'bistoury' (1). Improved instrumentation – particularly the snares and 'guillotines' used by Morrel McKenzie (2) led to popularization of the operation in Victorian England. Sir Felix Semon (1849–1921) removed the tonsils from several of Queen Victoria's grand-children and the procedure became fashionable in the drawing rooms of the aristocracy (3). It was said

to cure a variety of childhood ailments (4). The criteria for offering tonsillectomy have changed significantly over the years and are now much more stringent.

The evidence-base

Despite the popularity of tonsillectomy and the enthusiasm with which it is offered and sought, high quality evidence of efficacy is sparse. A systematic review concluded that there was little evidence on the use of tonsillectomy for recurrent throat infection and a Cochrane review concludes that there is no evidence from randomized controlled trials (RCT) to guide clinicians in formulating guidelines for surgery in children or adults. There is no good evidence that any benefit from tonsillectomy for recurrent sore throat in children is sustained for more than two years after surgery.

The most celebrated trials make up the 'Paradise study' reported in 1984 (5). These randomized and nonrandomized controlled trials prospectively compared groups of children who met strict entry criteria and who received surgery (tonsillectomy with, in some circumstances, adenoidectomy) or non-surgical intervention. Participation was dependent on children having a history of seven episodes of sore throat in the year prior to the study, five or more in the preceding two years or three or more in each of the preceding three years. Well-documented clinical features had to be demonstrated to ensure eligibility. These trials showed that in such 'severely affected children' tonsillectomy was efficacious for two years, and possibly for a third year. Efficacy was measured by a reduction in the number and/ or severity of throat infections. Many of the children treated non-surgically improved spontaneously. Such benefits as there were from surgery were slight. Critics point out that the study was poorly randomized. Children randomized to the nonsurgical group proceeded to surgery at the subsequent request of the parents. Children in the control limb of the study had active therapy, which may have minimized the morbidity. Perhaps inadequate knowledge of the natural history and expected outcome of recurrent sore throats in children has bedeviled the quest for a sound evidential base for current practice. Preliminary data from a study conducted during the 'tonsillectomy embargo' in the UK in 2001, resulting from concerns about variant Creutzfeldt-Jakob disease (vCJD) transmission, suggests that spontaneous improvement is to be expected in adults (6).

Current practice

Tonsillectomy in children is one of the most frequently performed operations in the developed world. Although numbers are declining from a peak of over 200,000 annual tonsillectomies in the 1950s (UK), some 52,000 tonsillectomies were performed in England under the National Health Service in the year 2003/04. Data from the Department of Health Statistics show that around 30,000 of these were in children with an approximately equal gender ratio (www.dh.gov.uk). The majority are for recurrent sore throats with most of the remainder for airway obstruction. Parents in the UK initially present to a general practitioner. Referral patterns are dictated by thinking in primary care and many parents have firm views by the time they see an otolaryngologist. Despite the availability of guidelines and protocols in practice, a decision to undertake tonsillectomy is made by negotiation between the parent/ caregiver and the otolaryngologist.

Socio-cultural factors

There is no published evidence that the pattern of disease varies by racial, ethnic, climatic or cultural factors across the globe, but there are wide variations in the rate of tonsillectomy by geographical region (7). A quoted incidence of 6.5 per 10,000 children in the UK National Health Service contrasts with 11.5 per 10,000 in the Netherlands and 5 per 10,000 in the USA. The figures for the UK may be higher as an estimated one-sixth of otolaryngology interventions occur in private practice where figures are not as widely available. In the developing world, the incidence of surgery is much lower, related perhaps to access to health care and parental expectations and preferences. Recent work suggests that social class and parental smoking does not influence the number of reported episodes of sore throat or tonsillitis, but that a history of parental tonsillectomy and a family history of atopy have a positive association with the frequency with which children present with sore throat and tonsillitis (8). Parental enthusiasm for

surgery varies. Some of the variation may be due to differences in demand for health care. There is evidence from the North of England and Scotland Study on Tonsillectomy and Adenoidectomy in Children (NESSTAC) that girls now present much more frequently than boys (9).

Guidelines

The British Association of Otolaryngologists Head and Neck Surgeons suggest what are felt to be reasonable indications based on current level of knowledge, clinical observation in the field and the results of clinical audit of outcomes. Patients should meet all the following criteria:

- sore throats due to tonsillitis;
- five or more episodes of sore throat per year;
- symptoms for at least a year;
- episodes of disabling sore throat which prevent normal functioning.

As with any surgical procedure, the risks of surgery must be balanced against the potential benefit.

The American Academy of Otolaryngologists/Head and Neck Surgeons (AAO HNS) guidelines are widely accepted by US health care insurance companies. These guidelines suggest that tonsillectomy should be considered for children with 'three or more infections of tonsils and/ or adenoids per year despite adequate medical therapy'.

Tonsillectomy technique

'Cold steel' tonsillectomy

The most common method of 'cold steel' tonsillectomy is the dissection technique. In this, the tonsil is retracted medially, the mucosa overlying the tonsil capsule incised and the plane of loose areolar tissue between the tonsil and the pharyngeal musculature dissected with steel dissectors, gauze or cotton wool until the tonsil is fully mobilized. Blood vessels traversing the plane of dissection are dealt with either by ligature or diathermy as required.

Diathermy tonsillectomy

In recent years, the technique has evolved of using diathermy not only as an aid to haemostasis when the tonsil has been delivered, but to dissect the tonsil from its bed. This has the obvious advantage from the point of view of both operator and patient, particularly if a child, of reducing intra-operative blood loss to a minimum. Various claims and counterclaims have been made regarding the advantages and disadvantages of this technique, the most common alternative to traditional cold steel tonsillectomy.

Coblation tonsillectomy

This relies on the use of a specially designed bipolar electrical probe, which both coagulates and cuts the tissues as it develops the dissection plane between tonsil and capsule. The probes or 'wands' are single use and there is a cost consideration. The technique involves the use of the operating microscope. There are no good controlled studies comparing coblation with cold steel dissection without the addition of diathermy; current evidence is inadequate to justify its introduction in preference to cold steel dissection with ties and/ or packs.

Ultrasonic dissection

Ultrasonic dissection uses an oscillating blade, which acts as both a cutting and coagulating device. Enthusiasts for the 'harmonic scalpel' have claimed advantages over conventional techniques, in terms of reduced pain and general morbidity, but evidence remains unconvincing.

Laser tonsillectomy

With the advent of the laser as a surgical tool, the use of this method of dissecting out the tonsil has been advocated as having advantages in terms of reduction of bleeding, postoperative pain and more rapid healing. Several studies have failed to confirm these advantages. There is convincing evidence that the rate of secondary hemorrhage and late postoperative pain is significantly greater with laser (10).

'Capsulotomy' techniques

The above techniques are designed to remove the entire palatine tonsil. A preference for 'office-based' surgery particularly in the USA has led to the popularization of techniques to ablate a part of the tonsil, usually leaving the capsule intact. These 'tonsillotomy' techniques include thermal tissue ablation using radiofrequency volumetric reduction (RFVR) using a customized probe and surface laser surgery. They are widely used but have not been subject to good quality randomized controlled trials.

They may be considered when tonsillectomy is undertaken in the very young where it may be desirable to leave some functioning lymphoid tissue (11).

Morbidity of tonsillectomy

Psychosocial morbidity and pain

Morbidity from the operation is significant. It includes both the expected adverse consequences and the possible complications. Pain and dysphagia are normal in the early postoperative period. Most children require at least a week to resume normal functioning and an average return to school or work time is one to two weeks. This is mainly due to pain preventing a return to normal diet and occasionally vomiting in the early postoperative period due either to the after-effects of the anesthetic or to the effect of swallowed blood on the stomach.

Mortality

The complications of tonsillectomy may be divided into those associated with the anesthetic and those directly associated with the operation itself. As the operation is normally performed on children and young otherwise fit adults, for the majority of patients the risk of the short anesthetic required for tonsillectomy is small. There are risks inherent in anesthesia in very young children and for this reason tonsillectomy is seldom performed in children before the age of two years, even in the unlikely event of them fulfilling the above criteria for consideration for surgery. In general, tonsillectomy is not frequently indicated in children under the age of four years, the exception being children with obstructive sleep apnea syndrome. Since its instigation in 1995, the Royal College of Surgeons in England audit on surgical mortality (12) records no deaths occurring from tonsillectomy, but there were two deaths reported in the British lay press in 2001. Extrapolating from US data and from Department of Health statistics, the potential mortality from tonsillectomy has been calculated at one per 24,000 operations or one in 16,000 to one in 35,000. There were two cases reported in Albania in the last 50 years.

Peri-operative complications

Occasionally, patients may experience *temporo-mandibular joint dysfunction* due to the mouth being opened too widely with the tonsillectomy gag. Non-traumatic *atlantoaxial subluxation* (Grisel syndrome) may occur secondary to any inflammatory process in the upper neck. Treatment consists of cervical immobilization, analgesia and antibiotics to reduce the risk of neurological deficit.

The main early complication is *hemorrhage*. This is defined as primary (within the first 24 hours postoperatively) or secondary, i.e. occurring after 24 hours and during the phase of healing of the tonsil bed. Secondary hemorrhage can occur any time until the tonsil bed has healed, which may take as long as two weeks. It is attributed – on sparse evidence – to infection in the granulating tonsil bed, often with streptococcal organisms. The reasons for this wide variation in bleed rates is not clear; it may be related both to the technique used and to the experience of the operator, although in the NPTA there was no significant difference in rates between trainees and more experienced surgeons.

Postoperative 'infection' is sometimes diagnosed in primary care. The presence of severe halitosis is the most prominent feature, usually associated with fever.

Box 1: Recommendations of the National Prospective Tonsillectomy Audit, 2005 (12)

- When a patient is counseled for surgery, the risk of tonsillectomy complications, and in particular postoperative hemorrhage, should be carefully explained to the patients/parents.
- This risk should be quantified, preferably using the surgeon's own (or department's) figures.
- National figures can be used, but this should be made clear to patients.
- Surgeons using monopolar diathermy should consider using an alternative technique. There are no advantages to using this instrument over other methods.
- All trainee surgeons should become competent in cold steel dissection and haemostasis using ties, before learning other techniques in tonsillectomy.

- Emphasis must be placed on teaching the correct use of, and the potential hazards of, diathermy and other 'hot' techniques. Checks should be made of the power settings before starting the operation.
- Inexperienced trainees must be supervised by a more senior surgeon until competency has been achieved. This recommendation is in agreement with the College's Standards on Good Surgical Practice issued in 2002.
- Irrespective of seniority and experience, surgeons who wish to start using new techniques, such as coblation, should undergo appropriate training.
- All ENT departments should have regular morbidity and mortality meetings to monitor adverse incidents affecting patient outcome. For tonsillectomy, data should be presented by the surgeon, indicating the technique used for dissection and haemostasis and power settings if applicable, type of instrument used, and any difficulties encountered.
- It is the responsibility of the surgeon, and if appropriate his trainer, to follow up any identified problems appropriately.
- Use of single-use instruments should also be recorded, especially for cold steel dissection.
- There is an urgent need for new standards for diathermy machines so that the amount of power used is obvious to the user. Manufacturers of diathermy machines should be encouraged to produce machines with information on the total amount of energy delivered to patients.

Box 2. Conclusions

- Tonsillectomy is one of the most commonly performed surgical procedures in the developed world.
- The evidence-base for current practice is poor.
- Tonsillectomy rates vary considerably in different populations. These variations are not accounted for by variations in disease prevalence.
- Improvements following surgery are particularly small in less severely affected children. The morbidity of surgery usually outweighs any potential benefit in this group.
- There is no evidence that the benefits of tonsillectomy for recurrent sore throat are prolonged beyond two years.
- The operation is associated with significant morbidity, which may be minimized with careful peri-operative management.

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Validation of an instrument measuring primary health care users' opinion about abilities, skills and competencies of their family physicians in Kosovo

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Abstract

Aim: Our aim was to validate an international instrument addressing family physicians' competency level from the primary health care users' perspective in transitional Kosovo.

Methods: A sample of 98 primary health care users aged e"18 years was interviewed in Kosovo in December 2012 (42 men and 56 women; mean age: 53±11 years). Participants were asked to self-assess the level of abilities, skills and competencies of their respective family physicians regarding different domains of quality of health care. The questionnaire included 37 items pertinent to six subscales/domains. Answers for each item of the instrument ranged from one ("novice" physicians) to five ("expert" physicians). An overall summary score (range: 37-185) and a subscale summary score for each domain were calculated for all participants. Demographic and socioeconomic data were also collected. Cronbach's alpha was used to assess the internal consistency of the tool, and Mann-Whitney U test was used to compare mean scores for the overall scale and each subscale between men and women.

Results: Internal consistency of the overall scale was Cronbach's alpha=0.88; it was similar in men and women (0.88 vs. 0.89, respectively). The overall summary score of the instrument was 88.9±8.8; it was somehow higher in women than in men (90.1±9.3 vs. 87.3±7.8, respectively, P=0.069). There were no statistically significant differences in the subscale summary scores between men and women, except for the "patient care and safety" (P=0.049). There was a week inverse correlation of the overall summary score with age, but a positive correlation with educational attainment.

Conclusion: This pilot study provides useful evidence about the cross-cultural adaptation of an international instrument measuring patients' self-perceived level of skills and

competencies of their family physicians regarding important aspects of the quality of primary health care services in Kosovo.

Keywords: abilities, competencies, cross-cultural adaptation, family physician, general practitioner, Kosovo, primary health care, quality of care, skills, validation.

Introduction

It has been extensively reported that abilities, skills and competencies in quality improvement are vital for general practitioners and family physicians in order to foster and improve patient care (1). From this point of view, it has been argued that for medical doctors, precise roles, abilities, skills and competences should be defined and specifically designed at all training levels including also continuing medical education (1,2). Such roles and competences have been already classified in frameworks (CanMEDS – Canadian Medical Education Directives for Specialists Roles Framework [2,3]), Tomorrow Doctor's at the UK (4) and the six core competences identified and described by the Accreditation Council for Graduate Medical Education (ACGME competencies) [5].

As reported previously, competency models can additionally serve as a useful self-evaluation tool for general practitioners and primary care physicians committed to practice-based learning (1,6,7) who want to improve the quality of care they provide, evaluate their clinical skills and experience, with the ultimate goal of integrating and including the eventually improved knowledge and skills into their daily practice with patients (1,8).

Nevertheless, it is a crucial point to develop valid instruments aiming to assess patients' opinions and perceptions about abilities, skills and competencies of their family physicians and general practitioners (8).

Very little is known about abilities, skills and competencies of health care personnel (including family physicians) in transitional countries of the Western Balkans including Kosovo, which emerged as the newest state of Europe after ten years under United Nations' administration following a devastating war in the region. In this context, our aim was to validate an international tool (developed with the support of the European Community Lifelong Learning Program) addressing family physicians' competency level from the primary health care users' perspective in post-war Kosovo.

Methods

A convenient sample of 98 primary health care users in Kosovo aged e"18 years was interviewed in December 2012 (42 men and 56 women; mean age: 53± 11 years). Study participants were asked to assess, from their perspective, the level of abilities, skills and competencies of their respective family physicians about the following aspects (referred to as *domains*) of primary health care:

- Patient care and safety (eight items);
- Effectiveness and efficiency (seven items);
- Equity and ethical practice (eight items);
- Methods and tools (five items);
- Leadership and management (four items), and;
- Continuing professional development (five items).

Answers for each item of each subscale ranged from one ("novice"= physicians have little or no knowledge/ ability, or no previous experience of the competency described and need close supervision or instruction) to five ("expert"=physicians are the primary sources of knowledge and information in the medical field).

An overall summary score (including 37 items; range: 37-185) and a subscale summary score for each domain were calculated for all participants. Demographic and socioeconomic characteristics included age, sex and educational attainment.

Cronbach's alpha was used to assess the reliability (internal consistency) of the full scale (37 items) and each of the six subscales, separately in men and in women. Conversely, Mann-Whitney U test was used to compare the mean scores for the overall scale and each subscale between men and women.

Results

Mean age was similar in men and women who participated in the cross-cultural adaptation of this international instrument in the Kosovo setting. Furthermore, educational level was similarly distributed in both sexes (data not shown in the tables).

Reliability (the internal consistency) of the overall scale (37 items) was Cronbach's alpha= 0.88; it was similar in men and women (0.88 vs. 0.89, respectively) [Table 1]. Reliability coefficient (Cronbach's alpha) ranged from 0.82 for the "leadership and management" domain to 0.90 for the "patient care and safety" and "continuing professional development" subscales. In men, reliability (internal consistency) was the lowest for the "leadership and management" subscale (Cronbach's alpha= 0.68), and the highest for the "equity and ethical practice" domain (Cronbach's alpha= 0.91). On the other hand, in women, the lowest internal consistency (reliability coefficient) was evident for the "equity and ethical practice" subscale (Cronbach's alpha= 0.83), whereas the highest (reliability coefficient) was exhibited for "continuing professional development" domain (Cronbach's alpha= 0.94) [Table 1].

Table 1. Internal consistency of the instrument assessing primary health care users' perceptions on competencies of their family physicians in Kosovo, 2012

Domain (subscale)	Men (N=42)	Women (N=56)	Overall (N=98)
Overall scale (37 items)	0.88 (0.81-0.92)*	0.89 (0.84-0.93)	0.88 (0.85-0.91)
Patient care and safety (8 items)	0.86 (0.78-0.91)	0.92 (0.89-0.95)	0.90 (0.87-0.93)
Effectiveness and efficiency (7 items)	0.82 (0.73-0.89)	0.92 (0.88-0.95)	0.89 (0.85-0.92)
Equity and ethical practice (8 items)	0.91 (0.86-0.94)	0.83 (0.75-0.89)	0.87 (0.82-0.91)
Methods and tools (5 items)	0.82 (0.71-0.89)	0.84 (0.77-0.90)	0.83 (0.78-0.88)
Leadership and management (4 items)	0.68 (0.49-0.82)	0.87 (0.81-0.92)	0.82 (0.76-0.87)
Continuing professional development (5 items)	0.79 (0.67-0.88)	0.94 (0.92-0.96)	0.90 (0.87-0.93)

* *Cronbach's alpha and their respective 95% confidence intervals (in parentheses*

The overall summary score of the instrument was 88.9± 8.8; it was somehow higher in women than in men (90.1±9.3 vs. 87.3±7.8, respectively, P=0.069) [Table 2]. There were no statistically significant differences in the subscale summary scores between men and women, except for the "patient care and safety" where the mean score was significantly higher in men than in women (22.4± 3.0 vs. 23.2± 4.2, respectively; P= 0.049).

There was evidence for a week inverse correlation of the overall summary score with age, but a positive correlation with educational attainment (data not shown in the tables).

Discussion

We conducted a cross-cultural adaptation of an international instrument (self-administered questionnaire) for assessment of family physicians' competency level from primary health care users' perspective/ viewpoint in the context of Kosovo, a country in rapid transition towards a functional democracy.

Overall, this recently developed instrument showed a rather satisfactory reliability (internal consistency) in this convenient sample of primary health care users in Kosovo. The overall reliability of the instrument was similar in men and women, a finding which differs from a fairly recent study from Albania, where the internal consistency of the same tool was reported to be higher in women compared to men (9). In the Albanian validation study, the internal consistency of the instrument was higher for all of the subscales in women compared with men (9). In the Kosovo sample we did not obtain evidence of a clear sex difference, at least for the overall reliability coefficient (internal consistency)

Table 2. Summary score of each domain (subscale) of the measuring instrument by sex

Domain (subscale)	Overall (N=98)	Sex-specific		
		Men (N=42)	Women (N=56)	P†
Overall scale (score range: 37-185)	88.9±8.8*	87.3±7.8	90.1±9.3	0.069
Patient care and safety (score range: 8-40)	22.9±3.7	22.4±3.0	23.2±4.2	0.049
Effectiveness and efficiency (score range: 7-35)	14.3±2.7	14.2±2.3	14.5±3.0	0.240
Equity and ethical practice (score range: 8-40)	16.2±2.4	16.1±2.6	16.4±2.3	0.257
Methods and tools (score range: 5-25)	10.2±1.8	10.0±1.8	10.4±1.9	0.572
Leadership and management (score range: 4-20)	11.2±2.0	10.9±1.6	11.4±2.3	0.082
Continuing professional development (score range: 5-25)	14.0±2.6	13.8±2.1	14.2±2.9	0.144

* *Mean values ± standard deviations.*

† *P-values from Mann-Whitney U test.*

which was similar in both sexes. Nonetheless, similar to the previous report from Albania (9), there was evidence of a higher internal consistency for most of the subscales/ domains of the instrument. Conversely, the "equity and ethical practice" subscale showed a higher internal consistency in men than in women, a finding which requires caution and careful exploration in future studies involving the same measuring instrument in Kosovo settings.

In our study, interestingly, the overall summary score of the instrument was higher in women compared to men, a finding which nevertheless was borderline statistically significant. Furthermore, the inverse (negative) relationship with age should be addressed in future studies in Kosovo and similar settings.

As we have reported earlier, the current instrument assessing patients' perceptions about the level of competency and abilities of their family physicians was designed in line with the Quality Improvement Competency Framework (QICF) which has been developed in the course of a systematic consensus study carried out among European primary care experts interested or specializing in quality improvement (1,9). As stated elsewhere, the QICF involves six domains compatible with the current instrument employed in the cross-cultural adaptation exercise for assessment of patient's perceptions about the competencies of their general practitioners in Kosovo: "patient care and safety", "effectiveness and efficiency", "equity and ethical practice", "methods and tools", "leadership and management", and "continuing professional education" (1,9). Each domain in turn reflects an important area of medical care which constitutes a routine primary health care practice and requires reflexion and assessment with the ultimate goal of improving the patient care (1,9).

In conclusion, we validated a useful instrument in the Kosovo population, measuring patients self-perceived level of abilities, skills and competencies of their family physicians regarding some important domains of primary health care services.

After the pre-test phase (i.e. the validation study reported in this article), this instrument is currently being administered to a large representative sample of primary health care users in different regions of Kosovo.

Source of support

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Diagnostic utility of serum procalcitonin measurement in bacterial meningitis

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Abstract

Aims: The aim of this study was to assess the role of serum procalcitonin level in the diagnosis of bacterial meningitis and compare it against other laboratory parameters which are used in the clinical practice.

Methods: This cross-sectional study included 32 patients with bacterial and non-bacterial meningitis hospitalized at the Infectious Diseases Service of the University Hospital Center "Mother Teresa" in Tirana, Albania, during April 2010-April 2012. Bacterial meningitis was diagnosed or ruled-out using clinical history, physical examination, cerebrospinal fluid (CSF) laboratory findings, and identification of bacterial agents in CSF, gram staining and cultures. The non-parametric Mann-Whitney test was used to assess between-groups' differences.

Results: The median serum procalcitonin level was higher in patients with bacterial meningitis 22.47 ng/ml (range 2.5-100 ng/ml), while in the group with non-bacterial meningitis it was 0.83 ng/ml (range 0.25-1.46 ng/ml).

Conclusions: Procalcitonin appears to be a more reliable biomarker of bacterial meningitis diagnosis than CRP. A concentration of PCT >2 ng/ml had 100% sensitivity for bacterial meningitis.

Introduction

Acute bacterial meningitis continues to be a significant course of morbidity and mortality, despite advances in antibiotic therapy. Early diagnosis and starting immediate empirical therapy are the key factors to reduce the morbidity and mortality related to bacterial meningitis (1).

Therefore, distinguishing bacterial and aseptic meningitis in the emergency department could help to limit unnecessary antibiotic use and hospital admissions. Because the consequence of delayed diagnosis of bacterial meningitis can be severe, any proposed diagnostic parameter must achieve near 100 % sensitivity. Clinical criteria, gram staining, and bacterial antigen testing of cerebrospinal fluid (CSF) as well as the classic biological markers in the blood (c- reactive protein, white blood cells) or CSF (protein

level, glucose level, white blood cell (WBC) count and neutrophil count), do not offer near 100 % sensitivity with high specificity for distinguishing bacterial meningitis from non-bacterial meningitis (2).

To identify bacterial growth in CSF cultures need at least 2 days, whereas this period is 3-8 days for viral cultures. Lately, intensive research has been carried out to find new and rapid diagnostic parameters for differential diagnosis of bacterial and viral meningitis.

In this condition, a new marker, procalcitonin (PCT) which is a calcitonin propeptide, is supposed to be synthesized in C-cells of the thyroid gland in normal conditions and secreted from leukocytes on the peripheral blood in bacterial infections .The secretion of PCT was found to increase in the presence of bacterial lypopolisaccharides and cytokines. PCT production during inflammation depend from bacterial endotoxins and inflammatory cytokines, interleukins 6 (IL-6) and tumor necrosis factor (TNF alpha) (3,4).

The aim of our study was to assess the role of PCT in diagnosis of bacterial meningitis, and compare PCT with other laboratory standard markers: CRP (C–reactive protein), total leukocyte count, WBC and percentage of polimorphonuclears in CSF and peripheral blood, protein concentration in CSF and the ratio glucose CSF/ glucose serum.

Methods

This study included 32 patients hospitalized at the Infectious Diseases Service of the University Hospital Center "Mother Teresa" in Tirana, Albania, during a two-year period: April 2010 to April 2012. Clinical characteristics of patients were recorded upon admission. Meningitis was diagnosed according to clinical history, physical examination, CSF laboratory findings, identification of bacterial agents in CSF, gram staining and cultures.

Patients enrolled into the study were categorized in two groups:

- G 1-Bacterial meningitis (BM) including 20 patients (12 males and 8 females);
- G 2-Non-bacterial meningitis (NBM) including 12 patients (7 females and 5 males).

Meningitis was defined as bacterial if the CSF findings indicated an increased protein of >2 g/ l, decreased glucose ratio <0.4, leukocytes count >1500x10^6/ l and polymorphonuclear leukocytes domination, identification of bacterial agents in Gram staining and/ or bacterial positive cultures.

Meningitis was defined as non-bacterial meningitis if no bacteria were documented on gram stain or in bacterial culture of CSF, lymphocyte predominance of CSF cells, reduced protein level and increased glucose ratio >0.5 (5,6).

Patients exhibiting another site of infection in addition to meningitis, or who had received prior antibiotic treatment for more than two consecutive days were excluded from the study.

All patients underwent a full clinical examination and the following tests: complete blood count, C-reactive protein, serum procalcitonin and cytochemical study and bacterial culture of CSF.

Blood samples for procalcitonin were taken at the time of admission and after 72 hours, from the waste of blood taken for routine examination.

Complete blood count as part of routine laboratory test was performed by CELL-DYNE 1800 ABBOTT SYSTEM.

Serum procalcitonin was measured by electrochemiluminiscente immunoassay in COBAS INTEGRA 6000 with ELECSYS BRAHMS PCT reagent. Immunoassay for quantitative determination of PCT is a sandwich method with two antigen-specific monoclonal antibody, with a detection limit of 0.1ng/ ml and a total duration time of 18 min. PCT is stable in *vitro* and in *vivo* and only 30 microliter serum or plasma is needed for this purpose (7,8).

C-reactive protein (CRP) was measured by immunometric method in Immulite 1000.

Statistical analysis

For description of the numerical variables, the mean values and their respective standard deviations were reported. The difference between groups were assessed using the non-parametric Mann-Whitney U-test and correlation coefficients. A p-value of <0.05 was considered statistically significant in all cases.

Results

Table 1 presents the distribution of selected biochemical parameters in the study ample. As displayed in this table, the observed values for WBC,

PCT and CRP had a wide overlapping area in patients with bacterial and non-bacterial meningitis. At the moment of hospital admission, patients with bacterial meningitis had higher values of all parameters included in the study. PCT levels were statistically significantly elevated in all patients with bacterial meningitis (mean value: 22.47±28.1ng/ml) in comparison to PCT levels in patients with non-bacterial meningitis who had lower PCT levels (mean value: 0.83± 0.46 ng/ ml).

PCT, CRP and leukocyte count were all positively correlated (data not shown), but these relationships were highly significant only in the bacterial meningitis group. A PCT concentration of >2ng/ml had 100% sensitivity and negative predictive values in bacterial meningitis.

Table 1. Distribution of selected biochemical parameters in the examined patients

Parameter	Bacterial meningitis (n=20)		Non-bacterial meningitis (n=12)		P-value
	Mean value	Standard deviation	Mean value	Standard deviation	
WBC	20.1730	5.222	14.954	2.556	<0.001
PCT	22.4755	28.4098	0.8382	0.4653	<0.001
CRP	176.4625	73.8939	34.7667	22.4613	<0.001
IL-6	288.7450	351.8021	16.7583	10.7506	<0.001
TNF-alpha	162.1800	299.4984	21.1167	25.8940	<0.001

Discussion

A good marker for bacterial infection should fulfill the following criteria: early diagnostic and prognostic values and should be additionally helpful for therapeutic antimicrobial decisions (10,11).

In this study, we found that serum PCT levels are exclusively higher in patients with bacterial meningitis. Mean values in these patients were 22.4 ng/ m and lower values 2.25 ng/ ml, compared to mean values 0.83 ng/ ml and high values 1.46 ng/ ml in non-bacterial meningitis.

Our results demonstrate that, the higher value of PCT in non-bacterial meningitis is still low compared with lower value of PCT in bacterial meningitis. Even CRP and total leukocyte count are helpful to discriminate bacterial meningitis from non-bacterial meningitis, but our results indicate that concentration of CRP should be low in the first days of bacterial meningitis.

On the other hand, in non-bacterial meningitis there should be verified considerable values of CRP. High values of PCT correlate with severity of infection and the presence of the organ dysfunctions. Our results correlate with other studies that concluded that PCT and CRP had diagnostic value in diagnosis of bacterial meningitis in patients with CSF pleiocytosis, with higher sensitivity for PCT (2,3).

In conclusion, serum procalcitonin level must be used in early diagnosis of bacterial meningitis with higher sensitivity than other traditional parameters. PCT appears to be a reliable biomarker in differential diagnosis between bacterial and non-bacterial meningitis, and diminishes the value of lumbar puncture performed 48-72 hours after admission to assess treatment efficacy.

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ULTRASOUND EXAMINATION OF ANATOMICAL VARIATIONS OF THE GALL BLADDER

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Abstract

In surgical settings, it is very important to know and understand the anatomy and different types of variations of the gall bladder and the biliary tract, because these structures are in close connection with the adjoining organs and may show various anomalies and anatomic variations. There exist several variations of the normal gall bladder including duplications (ectopic cysts), septate cholecyst, agenesis and hypognesis of the gall bladder, variations of the form of the gall bladder including "Phrygian cap", Hartmann's pocket, as well as other types of anatomic variations.
In this short report, we highlight some of these anatomic variations of the gall bladder which are also examined and documented among hospitalized patients at the University Hospital Center "Mother Teresa" in Tirana and in a large and representative sample of primary health care users in Tirana municipality, the Albanian capital.

Keywords: *anatomic anomaly, anatomic variation, biliary tract, ectopic gallbladder, gall bladder, multiseptate gall bladder, Phrygian cap.*

Introduction

The gall bladder and the biliary tract are structures in close connection with the adjacent organs and may show various anomalies and anatomic variations. Therefore, in surgical settings, it is very important to know and understand the anatomy and different types of variations of the gall bladder and the biliary tract (1,2).

There exist several variations in the normal gall bladder including duplications (referred to as *ectopic cysts*), septate cholecyst, agenesis and hypognesis of the gall bladder, variations of the form of the gall bladder including "Phrygian cap", Hartmann's pocket, as well as other types of anatomic variations (1,3,4).

In this short report, we highlight some of these anatomic variations of the gall bladder which are also examined and documented among hospitalized patients at the University Hospital Center "Mother Teresa" in Tirana, and in a large and representative sample of primary health care users in Tirana municipality, the Albanian capital city. More specifically, Box 1 presents some of the major anomalies of the gall bladder which were also addressed in Tirana study through a systematic and comprehensive ultrasound examination.

Phrygian cap

It has been well-documented that the gall bladder often folds on itself, at the junction of the fundus with body, which may result in a normal anatomical variation referred to as the "Phrygian cap" gall bladder (5). This appearance sometimes can be erroneously labeled as a "septate gall bladder" by the ultrasound examiners. It should be pointed out that the commonest cause for the "septate" appearance of the gall bladder is the Phrygian cap anatomical variation (5). Nevertheless, the ultrasound examination sometimes fails to detect the Phrygian cap variation of the gall bladder, because this assessment depends on the discretion/ judgment of the examiner (operator) [5]. Therefore, magnetic resonance cholangiopancreatography (MRCP) examination is considered a more objective means of diagnosis of this anatomic variation of the gall bladder as compared to the "subjective" ultrasound examination (5). Furthermore, ultrasound examination may also fail to detect the recurrent pyogenic cholangitis (RPC), a condition which is characterized by recurrent inflammation of the bile ducts (5,6), because echography can merely evaluate the dilatation of the biliary tree and not the inflammatory response of the biliary tree wall (7,8), which is best distinguished by contrast enhancement, such as the case of the MRCP examination (5). Thus, the delayed phase contrast enhances imaging on MRI, which can portray the RPC (5).

In our study in Tirana, including hospitalized patients at tertiary level as well as primary health care users, the frequency of Phrygian cap was evident in about 1%-6% of the examined individuals. Details on the main findings of this study are under review elsewhere, but can be made available upon request (email: afrim_pirraci@yahoo.com).

Multiseptate gall bladder

Multiseptate gall bladder is a rare variance which was first described in 1963 by Simon and Tandon (9). This condition is considered as a consequence of an incomplete cavitation of the developing gall bladder bud (10-12). Since 1960s, over 30 cases with this anomaly have been reported in detail in the international literature (10). Thus, a few cases of multiseptate gall bladder have been reported to be associated with cholelithiasis, with choledochal cyst, or with primary biliary cirrhosis (10). Furthermore, in some other cases, the gall bladder turned out to be hypoplastic (10). Multiseptate gall bladder is a condition that may exist as an isolated variation or may coexist with other biliary system anomalies such as e.g. hypoplasia (10,13), or a choledochal cyst (10,12).

Diagnostic imaging means for multiseptate gall bladder include oral cholecystography, intravenous cholecystography, sonography, CT, endoscopic retrograde cholangiopancreaticography, and MRCP (10,14). It has been demonstrated that the MRCP provides more constant visualization of biliary abnormalities (10). However, availability of this examination procedure and its related cost are major limitations of MRCP compared with sonography. Therefore, it has been suggested that the primary imaging means for gall bladder abnormalities should consist of sonography (10).

Ectopic gall bladder locations

Ectopic gall bladder locations include intrahepatic, left-sided within the lesser omentum, within the falciform ligament, suprahepatic, retrohepatic, retroperitoneal, retroduodenal, retropancreatic, and within the abdominal wall (15). As for the diagnostic imaging means, both sonography and MRCP may be helpful for demonstration of ectopic gall bladders. Nonetheless, it has been argued that the MRCP may be more informative because it enables a clearer visualization of the relationship between the cystic duct, ectopic gall bladder, and common hepatic duct (10).

Congenital malformations of the gall bladder

Congenital malformations of the gall bladder can be categorized by their location, size, number, and shape. The most common congenital anomaly of the gallbladder is variation in its location. Agenesis and duplication of the gallbladder are less common. Multiseptate gallbladder, an anomaly of shape, is extremely rare. It may exist as an isolated anomaly or coexist with other biliary system anomalies such as hypoplasia (10,13), or choledochal cyst (10,12).

Study about anatomic variations of the gall bladder in Tirana, Albania

A study was conducted in Tirana in 2011-2012 including about 6300 hospitalized patients at the University Hospital Center "Mother Teresa" – the only tertiary level facility in Albania – and a representative sample of about 3100 primary health care users in Tirana city. Both study groups (hospitalized patients and primary health care users) underwent an ultrasound examination for assessment of anatomic variations of the gall bladder. The aim of this study was to assess the overall prevalence of anatomic variations of the gall bladder. Furthermore, among individuals with anatomic variations of the gall bladder, a secondary objective was to describe the distribution of the major types of anatomic variations of the gall bladder. In addition, an important objective of this study was to assess the association of the anatomic variations of the gall bladder with demographic characteristics (including sex and age of the examined individuals). Findings from this study are currently under review in another scientific journal.

Box 1. Selected anatomic variations of the gall bladder

- Duplications (*ectopic cysts*)
- Septate cholecyst
- Agenesis / Hypognesis
- Variations of the form of the gall bladder
- Hartmann's pocket
- Phrygian Cap
- Biliary porcelanosa

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Potentially inappropriate prescribing among older people in Kosovo: A study protocol

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Abstract

Inappropriate prescribing in older people is a common and serious healthcare problem in most of the countries, but especially in transitional countries of the Western Balkans including Kosovo where there are no clear and strict regulations related to prescriptions or use of medications. Thus, similar to other countries, the *polypharmacy* phenomenon is supposedly linked to an increased risk of adverse drug reactions and inappropriate prescribing in Kosovo too. However, population-based data on drug use and misuse, or potentially inappropriate prescription rates are scarce.
In the framework of information scarcity related to surveys and other studies focusing on potentially inappropriate prescribing among older people in Kosovo, we propose a study protocol to assess the magnitude and determinants of inappropriate prescribing among men and women aged e"65 years in Kosovo using standardized and internationally validated instruments. More specifically, this proposed protocol aims to assess the prevalence and predictors of potentially inappropriate prescribing among older people admitted to the hospital, but also among older people attending primary health care centers in Gjilan region, in Kosovo.

Keywords: *Beers' Criteria, inappropriate prescribing, Inappropriate Prescribing in the Elderly Tool (IPET), older people, polypharmacy.*

Older people in Kosovo

In Kosovo, older people (individuals aged e"65 years) are at greater risk of poverty and ill-health conditions compared to the general population. According to 2008 estimates, the expected life expectancy at birth in Kosovo was 67 years for males and 71 years for females in 2008 (1). Notwithstanding the fact that Kosovo consists of the youngest European population, it is inevitably akin to the global trend of aging reflected by a steady decrease of the growth rate of the population (2). Such a trend points to a gradual increase of the older segment of the population which is due to an increase in life expectancy coupled with a decrease in fertility rate. Thus, the share of

older people (individuals aged e"65 years) is currently estimated at 7% (1).

Older people in Kosovo face serious socio-economic and financial difficulties (3). Furthermore, current national programs, strategies and policies do not sufficiently address socioeconomic needs and health problems of older people in Kosovo. To date, there is no social health insurance scheme in place for the population of Kosovo. This poses serious challenges for the older segment of the population which is a vulnerable and marginalized subgroup in need of many health care services. As a matter of fact, the lack of health insurance scheme in Kosovo is reflected in the health status of the population, particularly of the older people.

Thus, a fairly recent report from Kosovo indicated remarkable health problems and challenges pertinent to individuals aged e"65 years of both sexes (4). According to the findings of this recent study including a nationwide representative and large sample of older people in Kosovo (1890 individuals aged e"65 years: 949 men and 941 women), 42% of older people were unable to access medical care, of whom 88% due to unaffordable costs (4). Furthermore, more than half of the older people in this survey perceived their health status as poor. As for the prevalence of chronic conditions, about 83% of older men and women reported at least one chronic condition (63% cardiovascular diseases), and 45% reported at least two chronic diseases. Women were particularly vulnerable as the prevalence of chronic morbidity and poor self-rated health was significantly higher than in men. Also, the very old individuals had a remarkably higher prevalence of multi-morbidity and poor self-perceived health status. Finally, poverty (including its related inability to access medical care) was a strong predictor of poor self-reported health and the presence of chronic conditions (4).

Potentially inappropriate prescribing among older people

Older people often experience multiple diseases and, therefore, this is inevitably associated with multiple drug use. This phenomenon, being referred to as *polypharmacy* (5), is related to the concurrent use of at least five different medications. Such multiple use of medications may lead to inappropriate prescribing and a decrease in the therapeutic response (5-7). According to the international literature, potentially inappropriate prescribing in older people are considered those drugs which do not have evidence-based indications for use, those which bear a high risk for side effects in older people compared with younger adults, or those drugs which have not been shown to be cost-effective in clinical settings, but particularly in population-based studies (8).

From this point of view, inappropriate prescribing in older people is a common and serious healthcare problem in most of the countries, but especially in transitional countries of the Western Balkans including Kosovo where there are no clear and strict regulations related to prescriptions of medications. Thus, similar to other countries, the *polypharmacy* phenomenon is supposedly linked to an increased risk of adverse drug reactions and inappropriate prescribing in Kosovo too.

It must be pointed out that, notwithstanding the fact that inappropriate prescribing is a vast phenomenon in many countries, this condition is almost fully preventable and, for this very reason, there have been developed specific screening instruments for inappropriate prescriptions including Beers' Criteria and the Inappropriate Prescribing in the Elderly Tool (IPET) [8]. Such instruments are envisaged for testing and use in our Kosovo study.

In the international literature, Beers' Criteria consist of the most frequently reported screening instrument for inappropriate prescribing notwithstanding some major criticism which has been evoked mostly due to the fact that several drugs are rarely prescribed currently, there exists a lack of structure in the presentation of the criteria and omission of several important and common inappropriate prescribing instances (8).

Suggested study protocol for potentially inappropriate prescribing in Kosovo elderly

The rapid socioeconomic and political transition in the past two decades including the devastating war with Serbia have further marginalized the older people in Kosovo. As a matter of fact, the World Bank reports that Kosovo is among the poorest countries in Europe with older people being at a particularly risk of poverty (9). The economic hardship is also reflected in the poor health indicators of older people. However, population-based data on drug use and misuse, or potentially inappropriate

prescription rates are scarce.

Therefore, in the framework of information scarcity related to surveys and other studies focusing on potentially inappropriate prescribing among older people in Kosovo, we propose a study protocol to assess the magnitude and determinants of inappropriate prescribing among men and women aged e"65 years in Kosovo using standardized and internationally validated instruments. More specifically, this proposed protocol aims to assess the prevalence and predictors of potentially inappropriate prescribing among older people admitted to the hospital, but also among older people attending primary health care centers in Gjilan region, in Kosovo. Findings of this study will be reported in detail elsewhere.

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Evaluation of functional health literacy among primary health care users in Kosovo: a cross-sectional study

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Abstract

Aim: Adequate functional health literacy is critical for the appropriate function of individuals in health settings. The aim of this study was to assess the functional health literacy of adult primary care patients in Kosovo.
Methods: This cross sectional study included 1035 primary health care patients aged e"18 years old during November 2012-February 2013 in the Principal Family Medicine Centers of Prishtina, Gjakova and Prizren municipalities in Kosovo (response rate: 86.3%). Functional health literacy of the participants was measured via the validated Albanian long version of TOFHLA test, an instrument used to assess reading comprehension and numerical abilities. TOFHLA scores range between 0-100 with higher scores implying better functional health literacy. Cronbach's alpha was used to estimate the internal consistency of the instrument. Mean values of TOFHLA were reported. One way ANOVA test was used to assess differences in mean TOFHLA scores according to demographic and socioeconomic characteristics of the subjects.
Results: Mean age of participants was 44.3 years and 60% of them were females. Cronbach's alpha internal consistency coefficient was 0.88. Mean functional health literacy was significantly higher among younger participants, men, highly educated individuals and those with better self-reported economic conditions.
Conclusions: The validated Albanian version of TOFHLA showed good internal consistency when applied in large-scale settings. Specific groups of primary care patients in Kosovo experience lower functional health literacy skills and might be more exposed to adverse health outcomes this situation entails.

Keywords: *functional health literacy, health literacy, Kosovo, TOFHLA.*

Introduction

Health literacy entails the ability to obtain, understand and process basic information which enables the individuals to make appropriate health decisions (1). Although the term has gained increasing attention in the international arena, still there is no single definition of health literacy (1-5). Regardless of how health literacy is measured and the different tools used for assessing it in various studies, evidence suggests that inappropriate or limited health literacy might be associated with poorer health outcomes, increasing use of health care services and health care costs, worse management of chronic diseases, added difficulty to orient oneself in the health system and lower participation in screening programs (5). One of the most frequently used tools for the assessment of health literacy among patients is the test of functional health literacy in adults (TOFHLA) which focuses on the numerical skills and reading comprehension capabilities (6). These skills are supposed to be fundamental for the appropriate function and orientation of the single patient in the health care environment. Patients need to understand oral and written health information and to follow certain written and numerical instructions in order for the treatment or management of health conditions to succeed (6).

Information regarding health literacy levels of primary health care patients in Kosovo is scarce. This transitional country is undergoing deep reforms which have also affected the health sector. The perplexity of the situation requires primary care patients to adapt to the changing environment. Recently, the long version of TOFHLA test has been validated in a limited sample of primary care users in Kosovo (7), thus creating the opportunity to use it on a larger scale for evaluating functional health literacy. In this context, the aim of this study was to assess functional health literacy in a representative sample of adult primary care patients in Kosovo using the validated TOFHLA instrument.

Methods

This is a cross-sectional study conducted in three main regions of Kosovo and namely Prishtina (the capital), Gjakova and Prizren during November 2012-February 2013.

According to the 2011 Census, Kosovo has a total population of 1739825 inhabitants and it is divided in 37 municipalities. The selected municipalities represent around 27.1% of the total population (8). Each municipality has a Principal Family Medicine Center (PFMC), which is a primary health care center (9). Our study was conducted in the three PFMCs of these municipalities. Adopting conservative assumptions, with power of the study set at 80%, the sample size resulted in 1200 individuals using WINPEPI software. We included only patients aged 18 years or older. Also, not cooperating individuals, those unable to see, read, comprehend and too sick to participate were excluded from the study. Of the 1200 enrolled individuals, 165 refused to participate. Thus, the response rate was 86.3% (1035/ 1200).

To assess functional health literacy of primary care patients we used the long version of TOFHLA test in the Albanian language. The validation procedures of TOFHLA in Kosovo have been described elsewhere (7). In brief, the instrument was translated and back-translated by two professional experts and cultural contextual changes were applied. Then, it was administered to a quota sample of primary care patients in Pristina PFMC. The Albanian version of TOFHLA reported good total internal consistency (Cronbach's alfa = 0.94) (7).

The score of the long version of TOFHLA ranges from 0-100. This enabled us to calculate the mean score of functional health literacy.

We also collected data about demographic and socioeconomic characteristics of the participants, including age, sex, level of education and self-rated economic situation.

Mean values and standard deviation of health literacy score by demographic and socioeconomic variables were reported. ANOVA test was used to assess the differences in mean TOFHLA scores by these variables. In addition, Cronbach's alpha and test-retest procedure reporting was used to assess the internal consistency of the Albanian version of TOHLA applied in full scale study. These figures were than compared with those reported by the validation study.

All analysis was carried out using the Statistical Package for Social Sciences (SPSS) software, version 17.0.

Results

The mean age of participants was 44.3 years ± 17.0

years ranging from 18 years old to 92 years old. Three out of five participants (60%) were females. On average, the subjects had 11.3 years of formal education ± 3.5 years. Regarding the economic conditions, 8% reported to be in a good economic situation, 77.9% and 14% reported an average and bad economic situation.

The overall internal consistency as measured by Cronbach's alpha was 0.88. The test-retest consis)-tency as measured by the Guttman Split-Half coefficient was 0.78.

The mean TOFHLA score in this sample of adults aged e" 18 years old was 61.8 ± 14.8. The mean TOFHLA scores by demographic and socio-economic characteristics are presented in the following Figures.

Figure 1. Mean TOFHLA score by age and gender

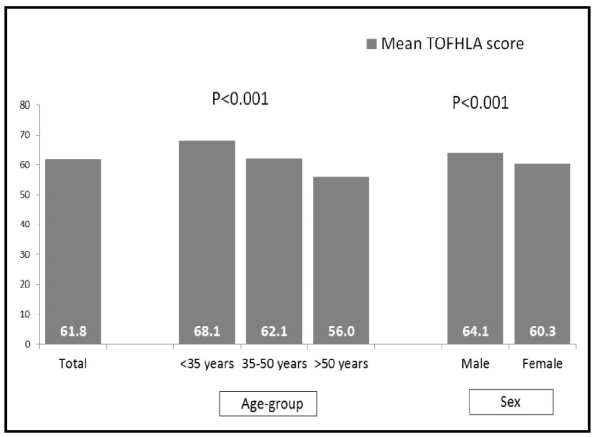
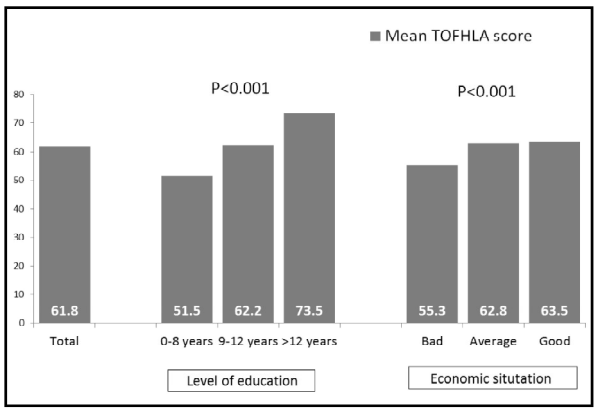


Figure 2. Mean TOFHLA score by education level and economic situation



Mean TOFHLA scores were statistically higher among younger persons, males, those individuals highly educated and those perceiving themselves as being in a good economic situation (P< 0.001 in all cases).

Discussion

The present study assessed the functional health literacy in a sample of adult primary care patients in Kosovo. To our knowledge, this is the first time the TOFHLA test was used in a full scale popula-tion-based study in this country. The instrument showed good overall and test-retest consistency. Mean functional health literacy scores varied significantly according to demographic and socioeconomic characteristics of the participants.

The internal consistency of the instrument applied in the large scale was comparable to that reported by the validation study of TOFHLA in Kosovo (7). This suggests that it might be used as a reliable tool within the Albanian settings. However, the validation exercise warrants extreme caution as the adaptation of the instruments to the local cultural context may be a complicated process (10).

Similar to the findings reported by studies in the region and beyond, functional health literacy level in our study was associated with individual charac-teristics of primary health care patients. For example, a study among primary care patients in Serbia (11) reported a higher mean TOFHLA score among males than females (79.9 vs. 66.1, respecti-vely) whereas these figures in Kosovo were 64.1 and 60.3, respectively. In addition, the mean TOFHLA score among those highly educated in Serbia was 77.9 vs. 73.5 reported in our study. Furthermore, the associations between health literacy with demographic and socioeconomic factors reported in our study are in accordance with results published in the international arena as well (12-14). Patients with limited health literacy are common in health care settings (15). Since low health literacy is associated with a whole range of adverse health outcomes, higher system resources' utilization and less adherence to medical and health instructions then it is important to detect those patients most at risk and who could benefit more if the appropriate measures are taken.

In conclusion, the Albanian version of the validated TOFHLA instrument yielded comparable results in this sample of primary care patients in Kosovo. The findings suggest that certain groups of patients in Kosovo might experience lower health literacy levels thus making them less compatible with the health care environment and potentially more prone to adverse health events associated with this situation.

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Carotid artery dissection following posterior neck trauma

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Abstract

Introduction: Dissection of the carotid arteries can occur in the general population as a result of blunt trauma to the neck, such as a car accident or a fall, or from hyperextension of the neck in sports or exercise. According to recent studies, the incidence of carotid artery dissection as a result of blunt injuries (mainly high-speed motor vehicle accidents) ranges from less than 1% to 3%.
Methods: We present a case of dissection of the right common carotid artery in a 25 years old patient after blunt neck trauma at the workplace.
Results: The patient complained of neck pain. The radiologic exam revealed a dissection of the right CCA associated with the stenosis of the lumen up to 75 – 78 %. The angiosurgeon of the case confirmed the radiologic diagnosis.
Conclusion: During the traumas of the neck region, performing the right protocol of examinations will improve treatment and prognosis.

Key words: Common Carotid artery dissection, neck trauma, Doppler ultrasound, Angio CT.

Introduction

Carotid artery dissection begins as a tear in one of the carotid arteries of the neck, which allows blood under arterial pressure to enter the wall of the artery and split its layers. The result is either an intramural hematoma or an aneurismatic dilatation, which can be both a source of micro emboli, with the latter causing also a mass effect upon the surrounding structures. Dissection of the internal carotid artery can occur intracranially or extracranially, with the latter being more frequent (1). Internal carotid artery dissection can be caused by major or minor trauma, or it can be spontaneous, in which case, genetic, familiar, or inherited disorders are likely etiologies (2). The actual incidence may be higher; some dissections are asymptomatic or cause only minor transient symptoms and remain undiagnosed (3,4). The cause of Carotid Artery Disease (CAD) is usually a form of trauma, possibly superimposed

upon a predisposing condition such as fibromuscular dysplasia (5). The trauma, which is often the immediate cause, may be major or minor. Traumatic events which have been reported to precede CAD include sport injuries, road accidents (including deceleration trauma from airbags (6), etc. The diagnosis should be suspected in any individual who presents with transient unilateral weakness or transient unilateral blurred vision that occurs after direct trauma or hyperextension of the neck. Workplace activities that might give rise or have risk to cause CAD can be roughly divided into two: those that involve acute traumatic events and delayed traumas. Most acute traumatic events have a sudden and unexpected character — a quick blow to the neck or an abrupt turning of the head with lateral flexion of the neck, which may be enough to compress the internal carotid artery against the transverse process of one of the upper cervical vertebra, causing the initial intimal tear in an otherwise healthy vessel. Perhaps, of more relevance in the workplace are the manifold situations in daily life that involve forced neck positions that might lead to CAD.

Aim

Our objective is to highlight the role of performing the correct protocol of examinations in the case of traumas as a basic step and as a major role in the treatment and prognosis of disease.

Case report

The patient, P.M. 25 years old, presented initially at the ER of University Trauma Hospital in Tirana, after a marble tile fall on the neck at the workplace. The patient's conditions were stable, without motor and sensor deficits, without neurological problems, only with presence of subcutaneous emphysema on the right cervical region. In these conditions was performed an urgent CT scan of the chest, which revealed no rupture of the bronchi, no sign of lung collapse, neither esophageal rupture. After that, the ENT specialist excluded the injury of trachea and oropharynx. Further diagnostic examinations were performed. Doppler ultrasound of the neck revealed a right common carotid artery (CCA) dissection, with 75-78% stenosis of the lumen. AngioCT scan of the neck revealed rupture of the intima in the right CCA, with significant stenosis of the lumen, without having the possibility of measuring the extension of the dissection. The intracranial arteries were within the normal limits and flow voids.

Carotid Doppler sonography examination showed right CCA, with Dmax 7 mm. A dilatation was noted 3 cm from the bifurcation, extending up to 9.7 mm, continuing with a dissection of the intima and presence of a false lumen. The lumen below the dissection was D_{max} 7.2 mm.

The real lumen was D_{max} 3.8 mm. At the level of the stenosis the flow velocity was 220 cm/ sec, (Figure 1).

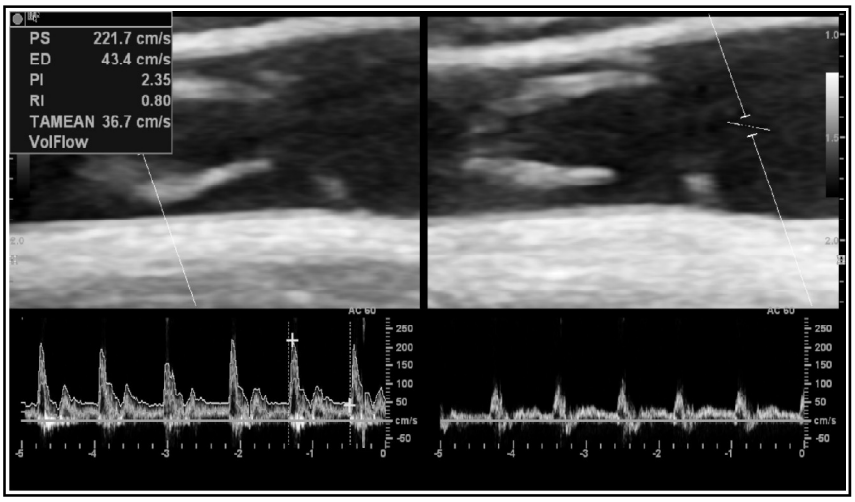

Figure 1 . Spectral analisys of the right CCA and speed velocity differences in the false and real lumen

The dissection caused a stenose of about 75 – 78 % (Figure 2).

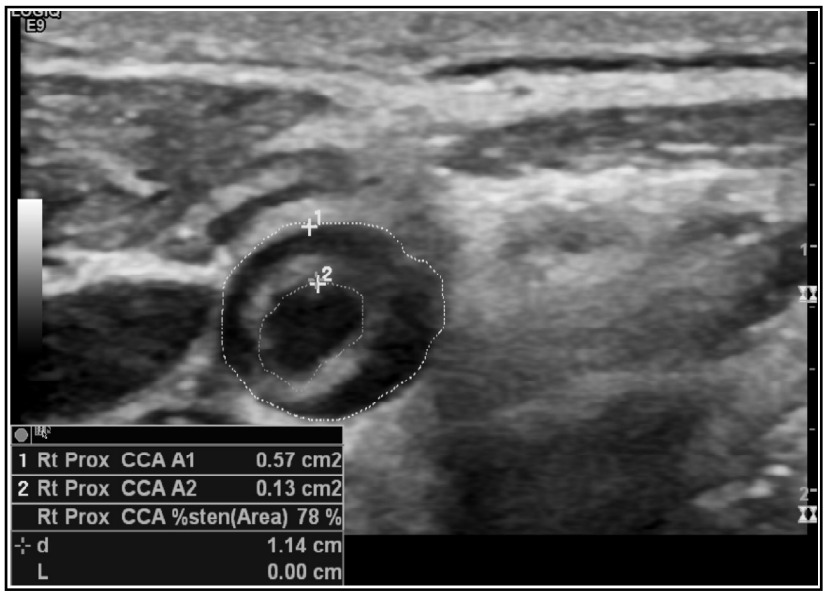

Figure 2. Right CCA stenosis of about 78 %

AngioCT of the neck and head confirmed the rupture of the intima in the right CCA associated with significant stenosis **(Figure 3**).

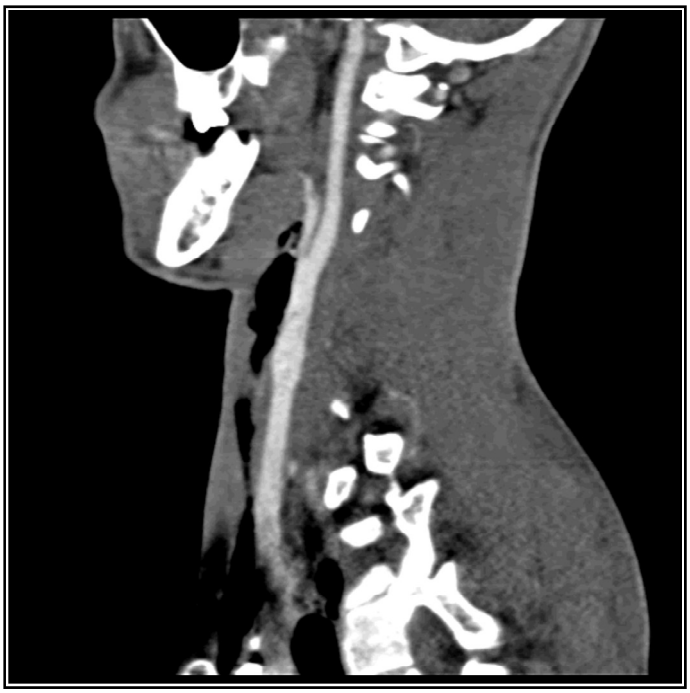

Figure 3. Stenosis of the right CCA noted during the angioCT of the neck

It was difficult to evaluate the extent of the dissection through the lumen of the right CCA, because of the orientation of the dissection and the displacement of the intima freshly dissected from the blood flow.

The intracranial circulation was unremarkable. There

was no evidence of right and left ACI and ACE damage. There was no evidence of vertebral arteries injury, bilaterally.

The patient underwent carotid surgery. An arterial bypass was performed. The actual conditions of the patient are satisfying.

Discussion

Carotid artery dissections should be considered in patients presenting with localized signs after severe trauma. They have varied presentations that depend on the location and the vessel involved. The heterogeneous clinical pictures associated with carotid artery dissections often lead to delays in diagnosis and treatment. The condition may be asymptomatic or result in minor symptoms, in stroke, or even death.

The diagnostic protocol for the neck arteries injuries included Doppler sonography. When a carotid bruit is auscultated, a duplex ultrasound examination should be done with quantification of the injuries. The report of the duplex ultrasonography findings should stratify the degree of stenosis based on a combined view of spectral Doppler ultrasonography velocity broadening (1,7).

If the patient is found to have a greater than 60% asymptomatic stenosis, then evaluation should include additionally a CT scan of the region (2,8).

If CT scan results negative for stroke or bleeding and the patient has a stenosis greater than 60%, then a carotid endarterectomy should be considered.

In our case, performing the right protocol was very important in diagnostication of this traumatic pathology. This influenced the prompt treatment with very satisfied results.

In conclusion, carotid artery dissections are rare lesions following head and neck injuries. They are usually suspected in the case of direct trauma to the neck, or if there is evidence of osseous fractures along the course of one of the major cranial arteries. They should be considered in patients after severe trauma presenting with localizes signs and minimal findings on CT scan, as is the case reported above. A multidisciplinary approach is needed to establish the diagnosis and initiate the appropriate treatment.

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ALBANIAN MEDICAL JOURNAL – INSTRUCTIONS FOR AUTHORS

Scope of the Albanian Medical Journal (Revista Mjekësore)

Albanian Medical Journal (Revista Mjekësore) is an international peer reviewed journal open to scientists from all fields of health sciences. Contributions that enhance or illuminate public health disciplines are particularly welcome. Furthermore, our special interest lies in public health and medical developments in transitional countries of the Western Balkans. From this point of view, we aim to provide a medium for reporting scientific findings to researchers from Southeast Europe, particularly Albania and Kosovo, who otherwise would face enormous difficulties in publishing their articles elsewhere.

Manuscript Types

The Albanian Medical Journal (Revista Mjekësore) publishes five types of manuscripts:

- original research reports;
- reviews;
- brief communications;
- case reports, and;
- book reviews:

1. Original research reports have a maximum of 3000 words (excluding abstract, tables/ figures and references), a maximum of 4 tables/ figures, a structured abstract of no more than 250 words, and up to 50 references. Such full-length manuscripts typically describe investigations related to different aspects of the health field. These may include randomized trials, intervention studies, cohort studies, case-control studies, epidemiologic assessments, other observational studies, cost-effectiveness analyses and decision analyses, and studies of screening and diagnostic tests. Each manuscript should clearly state an objective or hypothesis; the design and methods (including the study setting and dates, patients or participants with inclusion and exclusion criteria and/ or participation or response rates, or data sources, and how these were selected for the study); the essential features of any interventions; the main outcome measures; the main results of the study; a comment section placing the results in context with the published literature and addressing study limitations; and the conclusions. Criteria include relevance of research question, quality of design, sound implementation procedures, thorough outcome analysis of research findings, and implications for practice and policy.

2. Reviews are usually solicited by the editors, but we will also consider unsolicited material. Please contact the editorial office before writing a review article for the Albanian Medical Journal (Revista Mjekësore) in order to use the preferred review format. All review articles undergo the same peer-review and editorial process as original research reports. They should include up to 50 references and have 2000-2500 words (excluding abstract, tables/ figures and references) providing a clear, up to date account of the topic in the field being covered. The abstract for reviews should be unstructured and should contain no more than 200 words. The review should include a broad update of recent developments (from the past 3-5 years) and their likely clinical applications in primary and secondary care. It should stimulate readers to read further

and should indicate other sources of information, including web based information. The article should also try to highlight the bridge between primary and secondary care and offer specific information on what public health specialist or general practitioners should know about certain diseases or conditions.

3. Brief communications are reports of no more than 1500 words, 10 references and 2 tables/ figures. Brief Communications begin with a brief unstructured abstract of no more than 100 words.

4. Case reports should be drawn from an actual patient encounter, rather than a composite or fictionalized description. Case reports have a maximum of 1200 words and should include: introduction, aim, case description, discussion/conclusion and up to 10 references.

5. Book reviews (up to 1000 words) provide reviews of current books and other publications of interest to individuals involved in public health and medicine. Only reviews of recently published books will be considered. Book reviews are solicited by invitation; however, persons interested in doing a review may contact the editors.

Manuscript Preparation

Manuscripts should meet the general requirements agreed upon by the International Committee of the Medical Journal Editors, available at www.icmje.org. Contributions should be organized in the following sequence: title page, abstract, text (Introduction, Methods, Results, Discussion), source of funding, acknowledgments, conflict of interest statement, authors' contributions, references, tables, figures.

Title page

The title page should contain the following information:

- The article title (concise, yet comprehensive);
- Full names (first, middle [if applicable] and last names) of all authors;
- Names of the department(s) and institution(s) to which the work should be attributed. If authors belong to several different institutions, superscript digits should be used to relate the authors' names to respective institutions. Identical number(s) in superscript should follow the authors' names and precede the institution names;
- A short running head of not more than 100 characters (count letters and spaces);
- The name and mailing address of the corresponding author, telephone and fax numbers, and e-mail.

Abstract

The abstract for full-length articles (original research reports) should contain no more than 250 words structured in four headings: Aims, Methods, Results, and Conclusion. The Abstract should be followed by 3 to 5 keywords.

Text

Introduction: In the Introduction section, the contributors should briefly introduce the problem, particularly emphasizing the level of knowledge about the problem at the beginning of the investigation. At the end, authors should provide a short description of the aim of the study, specific objectives and study hypotheses.

Methods:

In the Methods section, details regarding the material, samples, methods and equipment used in the study should be included, so that another individual could repeat the work. The selection of the observational or experimental participants (patients or laboratory animals, including controls) should be stated clearly, including eligibility and exclusion criteria and a description of the source population.

Subsequently, the period of research and the institution where it was conducted should be clearly mentioned. Papers covering research on human or animal subjects should contain a statement indicating patient permission and clearance by the institute research or ethics committee or animal experimentation committee. The methods and procedures should be given in sufficient detail to allow reproduction of the results. Give references to established methods, including statistical methods; provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Results:

In this section author should describe the main findings in the text as well as the particular statistical significance of the data, and refer the reader to the tables and figures, implying that details are shown there. Information on significance and other statistical data should preferably be given in the tables and figures. Do not combine the Results and Discussion sections for full-length papers.

Discussion:

This section should not repeat results. The discussion section should discuss study findings, and interpret them in the context of other trials reported in the literature providing evidence or counterevidence. In this way the validity of the results and the significance of the conclusions for the application in further research are assessed, with respect to the hypothesis, relevance of methods, and significance of differences observed.

References

The Albanian Medical Journal (Revist Mjekësore) employs the ICMJE recommendations for reference formatting (http:/ / www.nlm.nih.gov/ bsd/ uniform_requirements.html), with sequential numbering in the text, and respective ordering within the list. References cited in the manuscript are listed in a separate section immediately following the text. The authors should verify all references. Consult Index Medicus or PubMed (http:/ / www.ncbi.nlm.nih.gov/ entrez/) for standard journal abbreviations.

Each reference should be numbered, ordered sequentially as they appear in the text, methods, tables, figure, and legends. When cited in the text, reference numbers are in parenthesis. Only one publication can be listed for each number. Only articles that have been published or submitted to a named publication should be in the reference list. Published conference abstracts, numbered patents and preprints on recognized servers are not encouraged to be included in reference lists.

All authors should be included in reference lists unless there are more than seven, in which case only the first six authors should be given followed by 'et al.'

Examples of proper referencing:

Citing a journal artide:

1. Roshi E, Pulluqi P, Rrumbullaku L, Bejtja G, Bregu A, Ylli A. Trends of smoking in Albania during 2000-2010. Croat Med J 2003;12:639-42.

2. Smith AT, Haiden S, Seman RE, et al. Public health challenges in a transitional country in Southeast Europe. Eur J Public Health 2008;38:938-46. 4

Citing a book:

Trimi G, ed. Albania: Facts and figures. Tirana, AL: Albanian Society of Medical Doctors; 2010.

Book chapter:

Trimi G, ed. Albania: Facts and figures. Tirana, AL: Albanian Society of Medical Doctors; 2010:948-59.

Online Journals:

Larva A, Keci M. Diabetes and lifestyle patterns in transitional Kosovo. BMJ. 2011;339:737. http:/ / www.bmj.com/ cgi/ content/ full/ 339/ 7596/ 737. Accessed September 10, 2012.

Tables

Tables should bear Arabic numerals. Each table should be put on a separate page. Tables should be self-explanatory, with an adequate title (clearly suggesting the contents), and logical presentation of data. The title should preferably include the main results shown in the Table. For footnotes use the following symbols, in this sequence: ***, †, ‡, §, II, ¶, **,……**

Figures

Figures should be numbered in sequence with Arabic numerals. The legend of a figure should contain the following information:

- (a) the word "Figure", followed by its respective number;
- (b) figure title containing major findings presented in the figure.

Writing Style

- Articles should be written in English (spellings as in the Oxford English Dict ionary),

Times new Roman, size 12, double spaced, using left alignment.

- Set all margins to 2,54 cm.
- Format for A4 paper.
- Type all copy upper and lower case – do not use all capitals or small capitals.
- Do not use footnotes.

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Acceptance Criteria and Conditions of Publication

Authors are encouraged to write in a manner that is maximally communicative, interesting, and informative. Manuscripts should be submitted solely to the Albanian Medical Journal (Revista Mjekësore) and should not be considered for publication elsewhere, nor should they have been previously published. Consideration for publication can be given to material that has previously had limited circulation elsewhere. If an article has appeared previously in any form, authors must clearly indicate this in their cover letter. Include copies of potentially duplicative material that has been previously published and provide links to duplicative material on the Internet.

Manuscript Submission

All manuscripts should be submitted by e-mail at: AMJ@ishp.gov.al

The submission should be accompanied with a Letter to the Editors (a separate Word document) stating the following:

- Manuscript type (original research; review; brief communication; case report; book review).
- Major findings of the research work.
- Novelty and relevance of the manuscript.

All manuscripts submitted to the Albanian Medical Journal will be regularly analyzed by plagiarism detection software. In-house decision will be within 7-10 working days.

If manuscripts are sent for external peer-review, authors will be notified about editorial decision no later than 8 weeks after the date of manuscript submission.