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The New Public Health and what it means for Albania

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I have had the privilege of helping to train seven Albanians in public health at our International Master of Public Health program at the Braun School of Public Health of the Hebrew University in Jerusalem, including leaders in public health in Albania such as Professors Enver Roshi and Genc Burazeri.

I have visited Albania many times in the past decade working with the Institute of Public Health and the Faculty of Medicine to develop public health professional education in the country. Thus, it is an honor to accept the invitation to write an editorial in your new Albania Medical Journal to address the relevance of the New Public Health for Albania. Public health has evolved and shown remarkable successes, much like the evolution from the era of the dial to iPhone telephone with many more useful applications during the past half Century (Figure 1).

Figure 1. Classical and New Public Health

Classical Public Health



Classical public health is a strong tradition which goes back several centuries with many governmental activities to ensure health protection of the population from many hazards causing premature deaths of uncounted millions in epidemics, food

New Public health



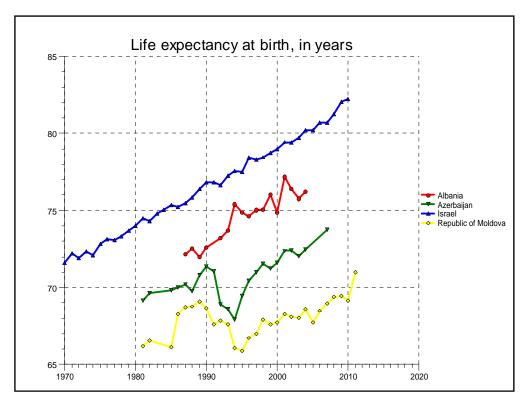
borne disease, poor maternal and child health and unsafe workplaces. Public health systems evolved in keeping with traditions of various societies. In western countries local governmental authorities were the primary agencies for public health including sanitation, food control, business licensing vital records and other facets of public health. State and national governments began to assist and develop services beyond the financial and professional capacities of local authorities. Gradually national governments became the overarching agency responsible to protect the health protection of the nation's population (1).

Epidemiologic challenges have changed with dramatic success in communicable disease control. Today, non communicable diseases and trauma are the key threats to human life and well-being. Cardiovascular diseases and cancers are leading killers in high and in mid level income countries, and increasingly in low income countries as well. There have been myriad efforts to find ways to control these pandemics, with no single "magic bullets" like a vaccine for their control. Epidemiologic studies have identified key "risk factors" and potential

interventions including health promotion and lifestyle measures of have became a major part of the public health endeavors.

The advent of HIV/ AIDs and Hepatitis C in the 1980s with no biomedical control capacity led to innovations such as condoms usage for sexual safety, needle exchange programs, and education as the major tools to fight these deadly diseases. In short, we had to learn to work with human behavior because biomedical methods were not available initially. When effective antiretroviral therapy came along in the 1990s, it provided revolutionary tools along with education to control this pandemic; education or treatment alone were not sufficient to bring these diseases under control. As with cardiovascular diseases, the risk factors are many and disease management involves both public health and direct clinical care in a shared set of responsibilities with the patients, their families, the health system and society at large (2).





Albania is doing well in improving life expectancy at birth (see Figure 2), but progress with stroke mortality reduction is not progressing as should be expected (Figure 3). Albania would benefit from making control of non communicable diseases a

central target of the health system. Moldova, a poor country with lower life expectancy and with a higher stroke mortality rate is placing much effort on education for non communicable disease control and showing early positive effect with a major drop in stroke mortality.

SDR, cerebrovascular diseases, all ages per 100000

250

200

Albania Azerbajan Israel Republic of Moldova

Figure 3: Standardized Mortality Rates from Cerebrovascular Accidents, Albania and Selected Countries 1970-2010

Emphasis on control of non communicable conditions to improve population health is crucial to public health today. This involves change not only at the policy level, but in integrated organized programs to promote awareness and safe interventions by physicians, patients and their families. It also means food and nutrition security need to change with more vegetable production and consumption, reduced salt (and sugar) consumption. Legislation is needed to ensure fortification of basic goods with essential trace minerals and vitamins in food manufacturing and standards for imported food products (3).

New discoveries open new opportunities. Managing hypertension and reducing salt intake reduces strokes and related mortality. Routine aspirin, statins and anti hypertensives act to prevent strokes, coronary heart events and mortality. Stopping smoking, improved diet and moderate exercise reduce cardiovascular disease and cancers. Folic acid in flour reduces neural tube birth defects by 60-70 percent. Finding Helicobacter pylori bacteria as the cause of chronic peptic ulcer disease and gastric cancer, an easily and cheaply treatable has reduced much suffering from these common conditions. Surgical wards are emptied of many forms of surgery common even a decade ago. Cancer of colon can be controlled by colonoscopy screening. Cervical cancer is controllable by Pap smear screening and management, but the finding the cause in the Human Papilloma Virus and effective vaccines opened a more complex potential to control this disease.

These are life saving public health interventions, and with other similar applications improve individual and population health. But they require strong leadership, policies, education, resources, training and persistence for implementation.

The New Public Health incorporates many more professions, scientific findings, skills, and applications than were available a generation ago. Training and standards for public health practitioners, academics and policy makers are needed for the rapidly evolving capacity of public health. Defining health targets and revision of health funding priorities are vital to promote prevention, health promotion and rapid adoption of the new standards of protecting population health. Legislation and education are essential to protect the public's health, and to raise the level of involvement of people in their own health status.

Albania is moving in a good direction by developing training capacity in public health (4). This should help to gain political support and perhaps financial help from donor agencies such as is being done in Moldova to tackle the complex but straight forward issue of cardiovascular disease and other non communicable disease prevention. Controlling avoidable disease and death has innumerable societal benefits. Development of education for the New Public Health in Albania with strong international cooperation will help prepare the next generation of health system leadership to face new and old health challenges. Collaboration with the Braun School of Public health has not only led to training of key leaders in public health in Albania and published research in international peer reviewed journals (5-7).

Public Health Reviews is a European based journal is focused on review of health theme topics in the European and global context. It tries to bring best practices and science in high quality review articles to students, teachers and policy makers in usable forms to bring science to practice in countries with many social, economic and health challenges. It is available free of charge at

www.publichealthreviews.eu readily accessible to read and download articles, including an article on Albania (8). Albania is represented by a founding member (Dr. Silvia Bino) of the Editorial Board. I wish your new Albanian Medical Journal all success in working toward the same goals.

References

- 1. Tulchinsky TH, Varavaikova EA. What is "The New Public Health?" Public Health Reviews 2010;3:25-53. Available at: www.publichealthreviews.eu (Accessed 8 May 2013).
- 2. World Health Organization. Global Status Report on Non Communicable Diseases 2010. WHO, Geneva, 2010. Available at: http://www.who.int/chp/ncd_global_status_report/en/ (Accessed 8 May 2013).
- 3. Allen L, de Benoist B, Dary O, Hurrell R. Guidelines on food fortification with micronutrients. Geneva: World Health Organization, Food and Agricultural Organization of the United Nations; 2006. Available at: http://www.who.int/nutrition/ publications/ guide_food_fortification_micronutrients.pdf (Accessed 2 April 2013).
- 4. Roshi E, Bino S, Burazeri G, Ylli A, Laaser U, Tulchinsky T, Goodman J. Development of a Master of Public Health programme in Tirana, Albania. Journal of Public Health (Springer) 2006;14:229-232.

- 5. Burazeri G, Goda A, Kark JD. Religious Observance and Acute Coronary Syndrome in Predominantly MuslimAlbania: A Population-based Case-Control Study in Tirana. Annals of Epidemiology 2008;18:937-945.
- 6. Burazeri G, Kark JD. Hostility and acute coronary syndrome in a transitional post-communist Muslim country: a population-based study in Tirana, Albania. The European Journal of Public Health 2011;21:469-476.
- 7. Zaletel-Kragelj L, Kovacic L, Bjegovic V, Bozikov J, Burazeri G, Donev D, Galan A, Georgieva L, Pavlekovic G, Scintee SG, Bardehle D, Laaser U. The use and exchange of teaching modules published in the series of handbooks prepared within the frame of the "Forum for Public Health in South-Eastern Europe Network. Zdravstveno Varstvo 2012;51:237-250.
- 8. Ylli A. Health and Social Conditions of Older People in Albania: Baseline Data from a National Survey. Public Health Reviews. 2010;32:549-560.

Strasbourg 2012 SGS session on education for health

Chateau Klingenthal SGS 2012 Session on Education for Health, It is worldwide known that health is the most precious wealth.

Children and youth are the most vulnerable groups of population, They need empowerment for health through continuous education.

Beyond ideas of right and wrong thinking there is a field to share, A broad challenging field of creativity, we should all meet there.

Many causes of disease and ways to create health are unknown, Somewhere, something incredible is still waiting to be known.

New global health promotion concepts we spread everywhere, We are rich as much as others enrich by our knowledge to share,

We tackle the social determinants to reduce health inequalities, Initiate inter-sectoral cooperation to include health in all policies.

We tend to design new approaches and programs by our creation, Experience and wisdom is the greatest gift to another generation.

Educated healthy people for the future is our goal and real price, Discovery isn't always seeking new land but seeing with new eyes.

Knowledge for healthy life protects the one's health like a dome, The strength of each nation derives from integrity of the home.

From early childhood the healthy habits we induce and feature, Every child grows, in school everything depends on the teacher.

Education for health and health promotion are powerful tools, Pupils require healthy choices and health promoting schools.

Healthy eating habits and safe food, physical activities and sport, Good social networks for emotional and practical social support.

To reduce tobacco smoking and harmful alcohol consumption, Violence and injuries, STDs, obesity and drug use prevention.

Teachers open the door, but each one must enter by oneself, Life isn't about finding yourself, life is about creating yourself. To protect health each one needs knowledge and taking action, For moving the quality of life forward for personal satisfaction.

The life is a school and each one is obliged for lifetime to learn, To approach problems which appear and dissolve each concern.

Let's create light for every shadow and relief for every sorrow, Each one who has health, has hope and everything for tomorrow.

We are all educators for health, each one in his/her own way, We know, the future belongs to those who prepare for it today.

Priority settings for health promotion the schools should become, The Foundation Goethe has great impact for generations to come.

Strasbourg, June 10, 2012

Prof. Doncho Doney, Republic of Macedonia

http://www.poetry.com/poems/318181

Internalized stigma and perceived discrimination among people with a mental illness in six European countries

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Abstract

Aim: Little is known about the degree to which the diverse sublevels of self-stigma are experienced by people with a mental illness from different countries. This study aims to describe and compare the sublevels and intensity of self-stigma across six European countries.

Methods: A cross-sectional study was conducted including 1223 persons with a psychiatric disorder who were members of a national mental health non-governmental organisation in the following countries: Croatia (N=101), Israel (N=125), Lithuania (N=200), Malta (N=115), Romania (N=104) and Sweden (N=151). The "Internalized Stigma of Mental Illness Scale" was chosen to measure internalized stigma.

Results: Moderate-to-high levels of internalised stigma ranged from 15.2% in Sweden to 57.4% in Croatia. Mean of perceived discrimination and devaluation was predominantly above the midpoint, and hence showed a high level of perceived discrimination and devaluation across the countries. Nevertheless, there was evidence of a huge amount of variation from 27.2% of the Israeli participants to 88.7% of the Swedish individuals reporting a moderate-to-high level. General Linear Models with self-stigma as the dependent variable showed very divergent results with no, positive, and negative significant relationships between internalised stigma and the psychometric measures as covariates. Concerning socio-demographic characteristics, only in Lithuania two variables were to a certain degree related to self-stigma, the highest level of education and the number of social contacts.

Conclusion: These findings suggest that in of the six countries a certain amount of people with a psychiatric disease suffer both self-stigma and perceived discrimination and devaluation. However, between-country variations in self-stigma and perceived discrimination and empowerment exist. It seems that the "one size fits all" approach does not apply to interventions against self-stigma.

Keywords: alienation, discrimination experience, psychiatric disorder, self-stigma, social withdrawal, stereotype endorsement, stigma resistance, sublevel.

Introduction

Etymologically, the term stigma was originated by the Greeks "to refer to bodily signs designed to expose something unusual and bad about the moral status of the signifier." (1). Nowadays it denotes a mark of disgrace "that extensively discredits an individual, reducing him or her from a whole and usual person to a tainted, discounted one." (2). Research regarding the concept of stigma emerged in the second half of the 20th century. In 1963 Erving Goffman published his pioneering book 'Stigma: Notes on the Management of Spoiled Identity' (1). Most topics that researchers on stigma have addressed since then have been associated with health conditions, especially HIV/ Aids, and mental illness (3). Generally, stigma adds additional distress to the already existing disease burden. Considering psychiatric disorders stigma takes an especial position. It can be both an effect and the cause of a mental illness.

The amount of people suffering from a mental illness is not exactly known and so the caused burden cannot be calculated exactly. Hence, a variety of estimations are published. Based on these between 27 % (4) and 38 % (5) of the EU population is affected by a psychiatric disorder yearly, and the impacts are divergent. Regarding the quality of life it is estimated that all neuropsychiatric conditions are responsible for 30 % of the total burden of disease of women and 23 % of men (5). Thus, the disease burden of mental illnesses is larger than that of all cancer diseases together. Furthermore, globally five of the top ten leading disability causes are mental illnesses (6).

The burden of psychiatric disorders is exacerbated by stigmatisation. Hence stigma can become a 'second disease'. Due to the fact that stigmatisation is both a risk factor and a consequence of mental disorder, it can cause a critical downward spiral. Accordingly stigma is a major public health issue. Though there is no consensus in the scientific community about the concept of stigma, but that there is no consent. That is why over the years stigma has converted to an under-defined, vague and overused concept (7,8). Nevertheless, Crocker et al. give an elementary definition: "Stigmatized individuals possess (or are believed to possess) some attribute, or characteristic, that conveys a social identity that is devalued in a particular social context." (9).

All in all, it is evident that stigma addresses three

interacting levels, as well the individual, and therefore psychological (self-stigma), as well as the interpersonal (social stigma) and the institutional (structural stigma) level (10,11). Essential of the concept of self-stigma is that the awareness of social stigma is necessary, but not sufficient; only agreement to the stigma about oneself leads to self-stigma (12). Thus, self-stigma develops through internalization of public beliefs, that are social stereotypes, by the stigmatized person (13,14). Ritsher et al. provide an explicit definition: "Internalized stigma is the devaluation, shame, secrecy and withdrawal triggered by applying negative stereotypes to oneself'. (14).

In contrast to the difficulty of definition there is unanimity that self-stigma in people with a mental illness affects several levels with diverse consequences. On societal level it can lead to 'lost productivity' and lower rates of employment and income, and a higher amount of benefit payments (15). On individual level it can cause lower self-esteem (16), selfefficacy and empowerment (17-19), less treatmentseeking (20,21), and more hospitalizations (22).

Even though a huge amount of studies from all over the world show a negative association between selfstigma and both psychosocial and psychiatric variables, as stated above, some mentally ill persons remain unaffected or develop righteous anger (23,24). That is the reason why this association is often called as the "paradox of self-stigma and mental illness" (23). Thus, it is hypothesised that the development of self-stigma is highly conditional upon the social context (2,23). Therefore, studying variations between self-stigma-concepts in different countries is essential for understanding the underlying processes.

To the best of our knowledge, only two studies explored differences in more than two nations (10). Therefore, this paper aims to identify countryspecific disparities relating to self-stigma of people with mental illnesses according to Ritsher et al. (14). They developed a concept of internalized stigma which encompasses five dimensions - alienation, stereotype endorsement, discrimination experience, social withdrawal and stigma resistance.

Cross-national research on self-stigma can be an essential basis for a variety of groups, such as policymakers to choose and support interventions, clinicians to take the impact of self-stigma into account and researchers themselves.

Methods

The following analyses were based on the sample of a survey conducted by Gamian-Europe in 24 countries in 2010. Gamian-Europe, the 'Global Alliance of Mental Illness Advocacy Networks-Europe' is a patient-driven, non-profit organisation, which acts for persons with mental illnesses. Currently more than 80 national associations from 37 countries are members of Gamian-Europe. Central to the pan-European federations' work are the following overarching goals "advoacy, information and education, anti-stigma and discrimination, patients' rights, co-operation, partnerships and capacity building' (25).

Study design and sample

Overall, 1223 persons with a psychiatric disorder partook in the survey. Because of scarce participation in some nations those countries which had less than 100 cases were excluded from the data analysis so that the participants of the following six sites are analysed in this paper: Croatia (N=101), Israel (N=125), Lithuania (N=200), Malta (N=115), Romania (N=104), and Sweden (N=151). Hence, this cross-sectional study includes 796 participants with a mental illness.

Firstly, Gamian-Europe sent an e-mail with detailed information about the study to all partner organisations and the request to invite their individual members to partake in the survey. Means to reach potential participants comprised announcements in monthly magazines, distribution of paper questionnaires, information at meetings and mostly a link on the associates' website. Due to this the sample is both not representative and no response rate can be calculated.

Translation procedure

In accordance with the cross-cultural adaptation process the survey packets were translated into each national language by professional translators. Additionally, the coordinators of the partner organisations reviewed the material and modifications were made when required.

The Internalized Stigma of Mental Illness Scale (ISMI)

The 'Internalized Stigma of Mental Illness Scale' was chosen to measure internalized stigma. This instrument was selected, because the 29-item questionnaire assesses five separate dimensions of self-stigma among people suffering mental illness and it is the most commonly used scale to measure subjective experience of stigma due to positive rating of all measurement properties, i.e. internal consistency, test-retest reliability, content and construct validity (26). Another advantage is the existence of numerous foreign-language versions of the ISMI (10). The scale encompasses the following five subscales: alienation, stereotype endorsement, discrimination experience, social withdrawal, and stigma resistance. Each item is composed of a first person statement and respondents rate on a fourpoint Likert scale whether they strongly disagree (1), disagree (2), agree (3), or strongly agree (4). Thus, higher scores imply higher self-stigma (14).

The alienation subscale (α =0.80) consists of six items and addresses the subjective feeling of not being a full member of society, e.g. I feel out of place in the world because I have a mental illness'. The stereotype endorsement scale (α =0.74) is composed of seven items, like 'Because I have a mental illness, I need others to make most decisions for me' and measures the respondents agreement to public stereotypes about people with psychiatric disorders. The discrimination experience subscale (α =0.76) encompasses five items, which reflect the feeling of being disadvantaged because of having a mental illness. One item is: People ignore me or take me less seriously just because I have a mental illness' Furthermore, the subscale social withdrawal (α =0.80) consists of six items, such as 'I don't talk about myself much because I don't want to burden others with my mental illness' At last, the stigna resistance subscale (α =0.60) is reverse coded and reflects opposition or not being influenced by stigma. This scale contains items like 'In general, I am able to live life the way I want to' (14,27).

With regard to the 29-item version of the total scale both a good internal consistency (Cronbach's α=0.90) and a good stability over time (test-retest reliability coefficient: r=0.92) has been attested. Furthermore, construct validity has been positively rated by comparisons against instruments, which measure related constructs with the same methodology. This encompassed the 'Center for Epidemiological Studies-Depression scale', the 'Rosenberg self-esteem scale', the 'Perceived devaluation-discrimination scale' and the 'Boston University Empowerment Scale' (14,26).

Because of weaker psychometric properties and in accordance with previous studies the stigma resistance subscale was excluded in the data analysis regarding the overall ISMI scale (14,17,26).

Socio-demographic, clinical and social contact items

In addition to the measures stated above questions about the socio-demographic, illness-related and social contact were asked, too. These included sex, age, the highest level of education obtained, employment status, housing situation, and source of income representing the socio-demographic items. Items with regard to clinical questions consisted of self-reported diagnosis, age at first diagnosis, agreement with diagnosis, present treatment status and current main type of mental healthcare. Concerning social contact variables, participants were asked about their living situation, relationship status, degree/ extent of contact with the family, existence of a friend and existence of a best friend.

Data analysis

The data analysis was carried out using SPSS Statistics

Version 20. The between-country differences were assessed in calculating a descriptive analysis of ISMI. This contains the mean averages and standard deviations of all subscales. In this regard a high level of self-stigma is experienced if a score above the average of 2.5 is attained (14,27). Based on several previous studies four categories of self-stigma can be differentiated: scores of 2 or less are labelled 'minimal stigma', scores between 2 and 2.5 are termed 'low stigma', scores between 2.5 and 3 'moderate stigma', and scores higher than 3 are labelled 'high stigma' (17,18,28).

Results

For internal consistency Cronbach's alpha was calculated for each scale and subscale comprising the selected countries. Thus, the internal consistency of the overall ISMI scale was α =0.91 (excluding the stigma resistance scale). The subscales of the ISMI showed the following internal consistencies: alienation (α =0.79), stereotype endorsement $(\alpha=0.67)$, discrimination experience $(\alpha=0.62)$, social withdrawal (α =0.79), and stigma resistance (α =0.60). Table 1 presents the country-specific distribution of the 'Internalized Stigma of Mental Illness Scale' (ISMI) and the according subscales.

Table 1. Cou	try-specific distribution of ISMI: mean ((SD)
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Variable	Croatia	Israel	Lithuania	Malta	Romania	Sweden
ICMI (analandin a CD)	2.65	2.02	2.3	2.25	2.02	1.62
ISMI (excluding SR)	(1.11)	(0.86)	(0.69)	(0.84)	(0.86)	(0.79)
Alianation (A)	2.54	2.01	2.33	2.35	2.16	1.51
Alienation (A)	(1.16)	(0.98)	(0.84)	(1.01)	(1.00)	(0.77)
Stangatung Endorgoment (SE)	2.57	2.09	2.01	2.14	1.87	1.45
Stereotype Endorsement (SE)	(1.13)	(0.89)	(0.74)	(0.82)	(0.93)	(0.70)
Discrimination experience	2.68	2.14	2.14	2.11	2.10	2.17
(DE)	(1.07)	(0.90)	(0.82)	(0.99)	(0.96)	(1.08)
Social withdrawal (SW)	2.59	1.70	2.28	2.10	1.91	1.46
Social withdrawal (SW)	(1.13)	(0.87)	(0.80)	(0.92)	(1.03)	(0.78)
Stigma registance (SD)	2.08	1.77	2.59	3.02	1.86	1.86
Stigma resistance (SR)	(1.07)	(0.84)	(0.73)	(0.81)	(0.96)	(0.90)

Overall, with regard to an average level above the midpoint of 2.5 it seems that a high level of selfstigma was experienced in Croatia only. However, averages below 2.5 do not imply that self-stigma does not exist in those countries. The calculated mean scores just represent averages of the experienced self-stigma of all participants in the particular nation. With regard to the standard deviation it is evident that in each country people with mental illness suffered self-stigma. Hence, the mean plus and minus the standard deviation represents the level of experienced self-stigma of 95% of the participants.

Thus, the ranges of 95% of the respondents in the

particular nations were from 1.54 to 3.76 in Croatia, between 1.16 and 2.88 in Israel, from 1.61 to 2.99 in Lithuania, between 1.41 and 3.09 in Malta, from 1.16 to 2.88 in Romania and between 0.83 and 2.41 in Sweden. These ranges indicate that in each country self-stigma exists, but the span is very divergent. On average, Croatians with a mental illness experienced the highest level of self-stigma (2.65), followed by Lithuanians (2.3), Maltese (2.25), Israelis and Romanians (both 2.02) respondents. Swedish participants with a psychiatric disorder suffered the least (1.62). Thus, the studied countries could be categorised according to their mean ISMI score as follows: first Croatia with the highest level of selfstigma (2.65), second Lithuania and Malta (2.25 and 2.3), third Israel and Romania (2.02) and Sweden (1.62). With regard to this classification it is expected that a grouping pursuant to the stigma resistance subscale would reflect this, as this scale is reverse-coded. However, the data did confirm this hypothesis partially. Countries with the lowest level of selfstigma, Israel (1.77), Romania and Sweden (both 1.86), revealed also the lowest stigma resistance scale and therefore yielded high stigma resistance. These are followed by Croatia (2.08), which showed the highest level of self-stigma. At last, countries with an average level of self-stigma showed the lowest stigma resistance, Lithuania (2.59) and Malta (3.02). Concerning the remaining subscales of the ISMI, solely Croatia showed levels above the midpoint of 2.5 and therefore moderate self-stigma on average. Astonishing are the diverse levels of the subscales between the countries. With regard to all subscales in Croatia, Israel and Sweden the discrimination experience subscale yielded the highest level. In Lithuania, Malta and Romania the alienation subscale showed the highest level. This could indicate that the concept of self-stigma differs according to the culture or country.

Altogether, it is crucial to notice the widespread standard deviations in each country. This shows the broad range of levels of self-stigma in the studied nations and could be a sign of intra-countrydifferences.

Discussion

The primary aim of this paper was to describe and

compare the levels of self-stigma and according subscales across six countries. Despite low mean scores in five countries, it can be suggested that various participants in each country reported moderate or even high levels of self-stigma. Furthermore, due to the fact that all respondents were members of a mental health charity organization they could feel more comfortable regarding their psychiatric disorder. Hence, the levels of both self-stigma and its' subscales could be higher in the total population of people with a mental illness.

In general, the results of this study indicate that the concept of self-stigma is context-dependent and the shares of the subscales contributing to the overall self-stigma vary considerably. This suggestion is in accordance with the concept of Corrigan and Watson (23), who emphasize that stigma is not inherent in the person but in a social context.

Therefore potential sources of self-stigma with regard to the context are addressed in the following section. First of all, the connection of public view, respectively social stigma, and self-stigma seems to be obvious at first sight. If a society keeps internalised negative beliefs, attitudes and behaviours towards people with a psychiatric disorder it is assumed that self-stigma of individuals with a mental illness is higher. However, a recently published study by Evans-Lacko et al. (29) does not support this suggestion. The authors found just one very weak, significant negative correlation between the country-level attitude 'Feeling comfortable when talking to someone with a mental health problem' with self-stigma (r=0.03; p<0.0001).

Additionally, public stigma can arise through the negative representation of mentally ill people in the media, which also varies across the studied countries (30).

Besides this, persons with psychiatric disorders perceive stigmatising attitudes and discrimination often via people with whom they are in regular contact. Usually these are family members, partners, friends, and certainly mental health care professionals. The last mentioned persons take a particular position, because of frequently, sometimes even daily contact with the mentally ill and their specific relationship to them as therapists, psychiatric nurses, or psychologists. Though essential initiators of social stigma, and therefore origin of self-stigma

Table 2: Mental health indicators [Sources: Health for All Database (33,34)]

Country	Croatia	Israel	Lithuania	Malta	Romania	Sweden
Mental Health Index (2008)	56	*	58	53	54	67
Mental disorders incidence per 100,000 (HFA 2009)	*	65.21	267.17	103.38	1149.72	*
Number of psychiatrists per 100,000 (2008)	8	8.8	18	4	4.7	24
Share of the total health budget or expenditure (%)	*	6.1	9.0	6.0	3.0	10.0
Access to community-based early intervention (2008)	No	No	No	No	Yes	Yes

* No information available

Since this paper directs the question of cultural, respectively national differences in mental illness stigma health statistics can be beneficial. In general there is huge variation in the public health status across the nations measured, according to presented health indicators. This divergence is partly caused by diverse law regulations and health systems, but is additionally due to social and economic inequalities which affect the (mental) health status of citizens substantially. The European Quality of Life Survey (EQLS) used the WHO Mental Health Index to give an overview about the mental health status of European citizens. The Mental Health Index is the average of the answers to five statements about the participants' feelings in the last two weeks (34).

With regard to the studied countries it is evident that the Swedish seem to have the best mental health, and both Maltese and Romanian the worst. Unfortunately for Israel no index is available. This could indicate that in nations with overall happier and satisfied citizens, mentally ill people do not internalise stigma immediately. Further possible connections between the presented mental health indicators and self-stigma cannot be made, as for instance a higher number of psychiatrists or a higher share of the total health budget do not inevitably lead to lower levels of internalised stigma (Lithuania) or access to community-based early interventions (Romania).

These results indicate that a closer look at each country is needed to explore mental health care indicators and their effect on internalised stigma and therefore to understand the underlying processes of self-stigma. For instance in Lithuania the allocated mental health care budget is solely spend on the treatment by medical professionals, like general practitioners or psychiatrists, but not psychologists or social workers (35). And the fact that the expenditure on mental health care in Malta has decreased over the last years from about 10% of health budget in 2005 to 6% in 2008 (33,35). Or that all beds available for psychiatric care in Sweden are in general hospitals (36). And at least the fact that scarce rehabilitation and employment programs for Croatian with severe mental illness exist (37).

It is evident that these indicators are very specific and would lead to an in-depth analysis of each country. However, exploring cross-cultural differences probably requires an analysis from a different angle. Detailed explorations with regard to the interconnection of mental illness stigma and cultural dimensions are lacking. Nevertheless, concerning general mental health and the development of psychiatric disorders Papadopoulos states that "the more individualistic or collectivist a partiallar alture is, the more likely it will be effective in explaining positive or negative mental health attitudes respectively." (38).

Thus, going back to the definition of self-stigma, it is the "co-occurrence of its components-labelling, stereotyping, separation, status loss, and discrimination—and [furthermore] for stignatization to occur, power must be exercised." (8). It is evident that power emerges in a specific situation and therefore the degree depends on the setting. Nonetheless, culture is a framework which defines the general power distance between members of each society.

Table 3: Dimensions of Culture (Source: reference no. 39)

Country	Croatia	Israel	Lithuania	Malta	Romania	Sweden
Power Distance Index	73	13	42	56	90	31
Individualism Index	33	54	60	59	30	71

According to Hofstede one cultural dimension is 'Power Distance'. It is "[t]he extent to which the less powerful members of institutions and organisations within a country expect and accept that power is distributed unequally." (39). Thus, the higher the Power Distance the higher the acceptance of hierarchical relationships as natural, like in Romania. Vice versa, the lower the Power Distance the higher the emphasis on egalitarian values and decentralised power (39). Status differences within a society are defined by various specific values. These differ across cultures and countries and cannot be explored at this point. Nonetheless, two facts are noticeable. First of all participants from a country with a high Power Distance Index (Croatia, Malta and Romania) experienced a higher level of self-stigma, too. Furthermore, those nations revealed a higher level on the subscale alienation, too. Especially in Malta and Romania alienation showed the highest score among all subscales. This could be an indication that the degree of Power Distance existing in a culture influences the development of specific sublevels of self-stigma. Precisely, a high value level of Power Distance could be connected with a higher degree of alienation. This subscale comprises statements like "I am embarrassed or ashamed that I have a mental illness" or "I feel inferior to others who don't have a mental illness". This could be explained with the fact that in nations with a high Power Distance Index usually the underdog is blamed (39).

In addition to this, the Individualism Index is another cultural dimension, which expresses the degree of interdependence in a society. Generally in cultures, which score higher on the Individualism Index, each person is mainly responsible for her-/ himself or for the own family. In a society with a high level of Individualism the independent sense of worth, including self-determination and selfefficacy is central. In more collectivistic countries the ties between individuals are strong and self-worth is dependent on the degree of complementing the goals of members of the in-group, usually the extended family (40). This dimension could partially explain that Swedish participants did report high stigma resistance, even though suffering mental illness and experiencing discrimination. This could be due to the fact that in Sweden the self-worth is largely independent from the public's opinion according to the high Individualism Index.

All in all, this paper focuses on the concept of explicit self-stigma of people with mental illness, but evidence suggests that implicit self-stigma is a distinct aspect of internalised stigma. Additionally, implicit self-stigma seems to be negatively associated with various outcome variables, like quality of life. Thus, solely simple questioning is not always sufficient to investigate whether patients with a mental illness experience stigma against themselves (41,42).

Conclusion

The aim of this paper was first of all recognising national disparities of self-stigma, and also giving a thought-provoking impulse about the divergence, which exists between countries and possibly within them, too. Overall these findings suggest that in each studied nation a certain amount of people with a psychiatric disease suffer internalised stigma.

It can be suggested that the concept of self-stigma, especially the diverse subscales, varies according to the country, respectively culture. Consequently, on the basis of the presented information there should be caution in implementing similar interventions across countries against stigma of mental illnesses. For instance, tackling discrimination against people with a mental illness is frequently supported as an intervention against internalised stigma. But, as the results of this study indicate, this strategy does probably not suit all patients across countries. The mean discrimination experience scores varied a lot. That is why a distinction between interventions directed at the public and those addressing people with a psychiatric disorder is essential.

Consequently, cultural specific analyses of all three concepts of stigma, which entails structural, public

and self-stigma (including implicit self-stigma), with regard to potential (health) effects could contribute essentially to the understanding of the concept of self-stigma and its predictors. Additionally, it needs to be examined whether psychometric limitations are present across countries.

Concluding, there is initial evidence that self-stigma acts and occurs on the basis of diverse mechanisms in different cultural settings and circumstances. At first sight it seems disillusioning that interventions

against self-stigma should be adjusted to the country. But then exploring the divergence of (cultural) variations can offer further opportunities, learning from experiences among the countries and exchanging knowledge and information.

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References

- 1. Goffman E. Stigma: Notes on the Management of Spoiled Identity. Englewood Cliffs, NJ. 1963.
- 2. Major B, O'Brien L. The Social Psychology Of Stigma. Annual Review of Psychology 2005; 56:393-421.
- 3. Parker R. Stigma, prejudice and discrimination in global public health. Cad. Saúde Pública 2012; 28:164-169.
- 4. World Health Organization. Facts and figures. Prevalence of mental disorders. Retrieved May 10, 2012, from http://www.euro.who.int/en/what-we-do/healthtopics/ noncommunicable-diseases/ mental-health/ factsand-figures.
- 5. Wittchen H, Jacobi F. The size and burden of mental disorders and other disorders of the brain in Europe 2010. European Neuropsychopharmacology 2011; 21:655-679.
- 6. Palpant R. Stigma research to build better mental health. Global Health Magazine 2011.
- 7. Manzo J. On the Sociology and Social Organization of Stigma: Some Ethnomethodological Insights. Human Studies 2004; 27:401-416.
- 8. Link B, Phelan J. Conceptualizing Stigma. Annual Review of Sociology 2001; 27:363-385.
- 9. Crocker J, Major B, Steele C. Social stigma. In Fiske S, Gilbert D, Lindzey G. Handbook of Social Psychology, 2nd ed., Boston, 1998. pp. 504-553.
- 10.Livingston J, Boyd J. Correlates and consequences of internalized stigma for people living with mental illness: A systematic review and meta-analysis. Social Science & Medicine 2010; 71:2150-2161.
- 11. Yang L, Cho S, Kleinman A. Stigma of Mental Illness. In Patel V, Woodward A, Feigin V. Mental and Neurological Public Health: A Global Perspective. 2010:484-495.
- 12. Rüsch N, Angermeyer M, Corrigan P. Mental illness stigma: Concepts, consequences, and initiatives to reduce stigma. European Psychiatry 2005; 20:529-539.

- 13.Lauber C. Stigma and discrimination against people with mental illness: a critical appraisal. Epidemiologia e Psichiatria Sociale 2008; 17:10-13.
- 14. Ritsher J, Otilingam P, Grajales M. Internalized stigma of mental illness: psychometric properties of a new measure. Psychiatric Research 2003; 121:31-49.
- 15. Sharac J, McCrone P, Clement S, Thornicroft G. The economic impact of mental health stigma and discrimination: A systematic review. Epidemiologia e Psichiatria Sociale 2010; 19:223-232.
- 16. Wright E, Gronfein W, Owens T. Deinstitutionalization, Social Rejection, and the Self-Esteem of Former Mental Patients. Journal of Health and Social Behavior 2000; 41:68-90.
- 17. Brohan E, Elgie R, Sartorius N, Thornicroft G. Selfstigma, empowerment and perceived discrimination among people with schizophrenia in 14 European countries: The GAMIAN-Europe study. Schizophrenia Research 2010; 122:232-238.
- 18. Brohan E, Gauci D, Sartorius N, Thornicroft G. Selfstigma, empowerment and perceived discrimination among people with bipolar disorder or depression in 13 European countries: The GAMIAN-Europe study. Journal of Affective Disorders 2011; 129:56-63.
- 19. Vauth R, Kleim B, Wirtz M, Corrigan P. Self-efficacy and empowerment as outcomes of self-stigmatizing and coping in schizophrenia. Psychiatry Research 2007; 150:71-80.
- 20. Vogel D, Wade N, Hackler A. Perceived Public Stigma and the Willingness to Seek Counseling: The Mediating Roles of Self-Stigma and Attitudes Toward Counseling. Journal of Counseling Psychology 2007; 54:40-50.
- 21. Bathje G, Pryor J. The Relationships of Public and Self-Stigma to Seeking Mental Health Services. Journal of Mental Health Counseling 2011; 33:161-176.
- 22.Rüsch N. Self-stigma, group identification, perceived legitimacy of discrimination and mental health service use. The British Journal of Psychiatry 2009; 195:551-552.

- 23.Corrigan P, Watson A. The Paradox of Self-Stigma and Mental Illness. Clinical Psychology: Science and Practice 2002; 9:35-53.
- 24.Rüsch N, Lieb K, Bohus M, Corrigan P. Self-Stigma, Empowerment and Perceived Legitimacy of Discrimination Among Women With Mental Illness. Psychiatric Services 2006; 57:399-402.
- 25.GAMIAN-Europe. GAMIAN-Europe 2007-2010. Retrieved May 9, 2012, from Homepage: http://www.gamian.eu
- 26.Brohan E, Slade M, Clement S, Thornicroft G. Experiences of mental illness stigma, prejudice and discrimination: a review of measures. BMC Health Services Research 2010; 10:1-11.
- 27.Ritsher J, Phelan J. Internalized stigma predicts erosion of morale among psychiatric outpatients. Psychiatry Research 2004; 129:257-265.
- 28.Lysaker P, Roe D, Yanos P. Toward Understanding the Insight Paradox: Internalized Stigma Moderates the Association Between Insight and Social Functioning, Hope, and Self-esteem Among People with Schizophrenia Spectrum Disorders. Schizophrenia Bulletin 2007; 33:192-199.
- 29. Evans-Lacko S, Brohan E, Mojtabai R, Thornicroft G. Association between public views of mental illness and self-stigma among individuals with mental illness in 14 European countries. Psychological Medicine 2011; 16:1-13.
- 30.Corrigan P, Markowitz F, Watson A. Structural Levels of Mental Illness Stigma and Discrimination. Schizophrenia Bulletin 2004; 30:481-491.
- 31.Schulze, B. Stigma and mental health professionals: A review of the evidence on an intricate relationship. International Review of Psychiatry 2007; 19:137-155.

- 32. Thornicroft G, Rose D, Mehta N. Discrimination against people with mental illness: what can psychiatrists do? Advances in psychiatric treatment 2010; 16:53-59.
- 33. World Health Organization. Policies and practices for mental health in Europe - meeting the challenges, 2008. Copenhagen.
- 34.European Foundation. Second European Quality of Life Survey - First Findings 2008. Retrieved May 28, 2012, from http://www.eurofound.europa.eu/pubdocs/ 2008/ 52/en/1/EF0852EN.pdf
- 35. World Health Organization. Mental Health Atlas: 2005. Geneva.
- 36.OECD. Mental Health in OECD Countries. Policy Brief 2008: 1-8.
- 37. Ivezic S, Kuzman M, Radic M. Mental health services in Croatia. International Psychiatry 2009; 6:91-92.
- 38.Papadopoulos C. Stigma towards people with mental health problems: An individualism-collectivism crosscultural comparison. Doctoral dissertation 2009. Middlesex University.
- Hofstede G. Culture's consequences: Comparing values, behaviors, institutions and organizations across nations 2001. Beverly Hills, CA: Sage.
- 40.Hofstede G, McCrae R. Personality and Culture Revisited: Linking Traits and Dimensions of Culture. Cross-Cultural Research 2004; 38:52-88.
- 41.Rüsch N, Corrigan P, Todd A, Bodenhausen G. Implicit Self-Stigma in People With Mental Illness. The Journal of Nervous Mental Disease 2010; 198:150-153.
- Teachman B, Wilson J, Komarovskaya I. Implicit and explicit stigma of mental illness in diagnosed and healthy samples. Journal of Social and Clinical Psychology 2006; 25:75-95.

Factors associated with pregnancy and live birth after in-vitro fertilization techniques in Albania, 2006-2012

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Abstract

Aim: The aim of this study was to retrieve information regarding the results of in-vitro fertilization procedures (IVF) and factors associated with pregnancy and live birth after IVF procedures in order to shed light into this under-researched topic in Albania.

Methods: We included 246 infertile couples who showed up at the "lakentro" IVF dinic during 2006-2012. Estradiol level, endometrium thickness and the number of embryos transferred were measured in all cases. In addition, basic socio-demographic information was collected. Binary logistic regression was used to assess the association of socio-demographic and laboratory parameters with pregnancy and live birth after IVF.

Results: The rate of pregnancy after IVF was 45% Among these, 67.3% of pregnancies resulted in live births. In our total sample, the rate of live births was 30.3% whereas the abortion rate after IVF was 14.7% Upon multivariable adjustment, the higher number of embryos transferred was significantly associated with higher odds of pregnancy and live birth after IVF.

Conclusions: Our findings indicate that pregnancy and live birth rates after IVF in Albania are comparable to those in developed countries. In the future, information regarding IVF procedures and their results in Albania should be more complete and accurate in order to ensure the quality of IVF services and improve the regulation of this sector.

Keywords: Albania, infertility, in-vitro fertilization procedures, live birth, pregnancy.

Introduction

Infertility is defined as failure to achieve pregnancy after at least 12 months of regular unprotected sexual intercourse for women aged up to 35 years or after 6 months for women aged more than 35 years (1).

Infertility, which constitutes a permanent problem with worldwide implications, has been proclaimed as the challenge of the millennium (2). It might affect 50-80 million women across the globe, and this might be just an underestimation (3). In developing countries, the incidence of secondary infertility is estimated up to 50% (4).

There are numerous known and unknown factors which might affect the capabilities of human reproductive system. The single most important independent factor affecting the couples' chances to conceive and give birth either naturally or artificially is the age of the woman. This issue is gaining increasing importance in the context when women are postponing their maternity, a tendency made obvious during last decades (5). The reasons for delaying pregnancy include the use of contraception, education and career issues and marriage at older ages (6). Factors associated with infertility could be the paternal age (7-9), duration of efforts to remain pregnant (10), contraceptive use (11), environmental and occupation pollutants (12), obesity (13), lifestyle issues such as smoking (14), caffeine use (15) and alcohol (16), stress and anxiety (17), and infectious diseases (18).

Global trends of infertility are being increasingly studied. According to a literature review, the yearly prevalence of infertility among women aged 20-44 years varied between 3.5%-16.7% in the developed countries and between 6.9%-9.3% in developing countries whereas the median prevalence was 9%. This means that around 72 million women aged 20-44 years in the world were infertile during 1988-2005 (19). Parallel with the global reduction of fertility and the increasing of demand for medical treatment of it, the percentage of women with one or two children who are at risk of remaining pregnant is reduced since 1990 literally in every region of the world, resulting in a reduction of the share of women affected by secondary infertility (20). The information regarding the prevalence of infertility in Albania is very limited. However, in

2012 the Minister of Health reported that approximately 12% of Albanian couples face difficulties in conceiving (21). Information regarding the factors associated with infertility and about indicators of the results of IVF procedures and factors associated with the success of such procedures is currently lacking.

Causes of infertility are different and can be classified into female or male causes, mix or idiopathic ones. The treatment of these causes not always results in a live birth. In cases when conventional treatments fail, the assisted reproduction techniques (ART) are suggested. These techniques have started to being used since 2003 after the respective legislation was approved and there are now at least 10 private clinics offering such services in Albania. However, the information from these clinics is difficult to be obtained due to informality issues.

Even though scientific information regarding infertility is abundant in the international literature, in Albania such information is lacking or, in the best of cases, is extremely limited, a situation which is not helpful for policymakers to take the appropriate measures for changing or improving the potential problems associated with this phenomenon.

In this context, the aim of the present study is the retrieval of the information regarding the results of the IVF procedures and factors associated with pregnancy and live birth after IVF in order to shed light upon this under researched topic in our country.

Methods

Study design

This was a cross-sectional study, covering the time period 2006-2012.

Study population and sampling

The study population included all infertile couples which showed up at the "Iakentro" infertility clinic during 2006-2012 and for whom there was information available regarding certain socio-demographic and laboratory parameters. The inclusion criterion was the showing up of the couples at our clinic for the treatment of problems impeding them from having the first child or having another

child, despite of their place of residence. This is why, apart from infertile couples residing in Albania, in our study were included some couples living abroad as well. As a result, no sampling technique was employed since we included all infertile couples showing up at our clinic during the aforementioned 7-year time period of the study. In total, from the 473 infertile couples showing up at our clinic during this period of time, only for 246 of them there was available complete information and therefore this is our study population.

Data collection

The data collection was done during the initial assessment (interview) of the infertile couple as well as through various laboratory and clinical examinations. The basic socio-demographic data such as age of the woman, place of residence and the level of education were retrieved during the initial assessment.

Besides the interview, the following examinations were performed: endovaginal ultrasound, measurement of hormones in day two and six of the menstrual cycle; hysterosalpingography. In these days the level of estradiol and thickness of endometrium was measured. The level of estradiol was measured in serum (blood) and analyzed in MINIVIDAS equipment using the immunofluorescence methods. The thickness of endometrium was measured by ultrasound probe with

Results

The mean age of participants was 32.9 years (± 5.1 years). There was a statistically significant increase of

baseline, in millimeters, respecting its echogenic borders. Values of endometrium thickness reported in the tables of this study refer to its measurement at the day of the eggs pick-up.

Statistical analysis

For numerical variable the measures of central tendency (arithmetic mean) and dispersion (standard deviation) were reported. For categorical variables absolute numbers and their respective percentages were reported.

For the assessment of the associations between variables the appropriate statistical tests were used. For numerical normally distributed variables the student "t" test was used. For comparing of categorical variables, the chi square test was used. To determine the factors associated with pregnancy and live birth after IVF procedures the Binary Logistic Regression (BLR) was used. We employed three models of BLR: in Model 1 we controlled (adjusted) only for the effect of age; in Model 2 we additionally controlled for place of residence and education level; in Model 3 we simultaneously controlled for all of the potential confounders presented in the tables.

In all cases, a value of P<0.05 was considered as statistically significant. The whole analysis was performed using the SPSS (Statistical Package for Social Sciences) statistical package, version 17.

2.1 years in the mean age of women showing up at the beginning and the end of the study period (data

Table 1. Distribution of the subjects under study according to the results of IVF treatment

Variable	Number	Percentage
Results after IVF treatment		
Negative (pregnancy not achieved)	127*	55.0
Positive1 (pregnancy achieved, one fetus)	89	38.5
Positive 2 (pregnancy achieved, two fetuses, multiple pregnancy)	9	3.9
Positive 3 (pregnancy achieved, \geq 3 fetuses, multiple pregnancy)	6	2.6
Results among IVF pregnant women (n=104)		
Live birth	70	67.3
Abortion	34	32.7
Overall results of IVF treatment		
Negative result (no pregnancy achieved)	127	55.0
Positive results (pregnancy achieved)	104	45.0
Live birth (pregnancy ended in live birth)	70	30.3^{\dagger}
Abortion (pregnancy ended in abortion)	34	14.7 [‡]

^{*} Discrepancies with the total number of subjects are due to missing data.

[†] Proportion of women experiencing a live birth among all women under study.

[‡] Proportion of women experiencing an abortion among all women under study.

not shown). Regarding the results of IVF procedures, in 55% of cases the procedures didn't achieve pregnancy whereas in 45% they did so. Among those who remained pregnant after IVF, 67.3% gave birth to at least on living child, whereas 32.7% resulted in abortion. In our total sample, the rate of live birth after IVF was 30.3% whereas the abortion rate was 14.7% (Table 1).

Table 2 presents data on pregnancy and live birth

after IVF according to socio-demographic and laboratory parameters. Two-thirds of infertile couples resided in urban areas and the same proportion were 35 years of age or younger. One in five infertile women had 8 years or education or less. The prevalence of primary infertility was 77.3%. Also, in almost two-thirds of cases (65.3%) three to four embryos had been transferred.

Table 2. Distribution of pregnancy and live births after IVF by socio-demographic factors and laboratory parameters

¥7 • . 1.1.	TD - 4 - 1	Pregr	nancy	Live b	irth
Variable	Total	No	Yes	No	Yes
Residence		A		A	
Urban	156 (66.7)	87 (58.8)*	61 (41.2)	109 (73.6)	39 (26.4)
Rural	78 (33.3)	34 (47.2)	38 (52.8)	46 (63.9)	26 (36.1)
Age-group	, ,	В	Ì	В	
≤35 years old	165 (67.3)	78 (50.0)	78 (50.0)	102 (65.4)	54 (34.6)
>35 years old	80 (32.7)	48 (64.9)	26 (35.1)	58 (78.4)	16 (21.6)
Education level	, ,	В	Ì	В	, ,
8-years	36 (16.4)	14 (42.4)	19 (57.6)	17 (51.5)	16 (48.5)
High school	94 (42.9)	57 (64.8)	31 (35.2)	70 (79.5)	18 (20.5)
University	89 (40.6)	42 (50.0)	42 (50.0)	58 (69.0)	26 (31.0)
Type of infertility		A	, ,	A	
Primary	187 (77.3)	96 (55.2)	78 (44.8)	118 (67.8)	56 (32.2)
Secondary	55 (22.7)	31 (58.5)	22 (41.5)	42 (79.2)	11 (20.8)
Number or		C	, ,	C	
transferred					
embryos	76 (34.7)	56 (73.7)	20 (26.3)	64 (84.2)	12 (15.8)
1-2 embryos	143 (65.3)	64 (44.8)	79 (55.2)	88 (61.5)	55 (38.5)
3-4 embryos					
Protocol		A		A	
P2	107 (43.7)	50 (48.5)	53 (51.5)	67 (65.0)	36 (35.0)
P5	138 (56.3)	76 (59.8)	51 (40.2)	93 (73.2)	34 (26.8)
Estradiol level		D		A	
<842	82 (33.3)	45 (60.8)	29 (39.2)	55 (74.3)	19 (25.7)
843-1499	82 (33.3)	47 (59.5)	32 (40.5)	57 (72.2)	22 (27.8)
>1499	82 (33.3)	35 (44.9)	43 (55.1)	49 (62.8)	29 (37.2)
Endometrium	, ,	A		A	Ì
thickness	48 (24.1)	24 (54.5)	20 (45.5)	34 (77.3)	10 22.7)
<9mm	97 (48.7)	49 (52.7)	44 (47.3)	64 (68.8)	29 (31.2)
10-11mm	54 (27.1)	26 (49.1)	27 (50.9)	33 (62.3)	20 (37.7)
>11mm	• •	, , ,	, ,		

^{*} Row percentages. Discrepancies with the total number of subjects are due to missing data.

Tables 3 and 4 display the associations of pregnancy and live birth after IVF procedures with sociodemographic and laboratory parameters. In ageadjusted analysis (Model 1 in both tables), the likelihood of pregnancy and live birth was significantly higher among women aged d" 35 years (OR=1.8 and OR=1.9, respectively, P<0.05) compared to women over 35 years old. The odds

^A P>0.05 (chi-square test).

^B P<0.05 (chi-square test).

^c P<0.001 (chi-square test).

^D P=0.087 (chi-square test).

of live birth were significantly higher among low education women compared to those having university education (OR=2.3, P=0.055, borderline significance). In addition, women with 3-4 transferred embryos were significantly more likely to remain pregnant after IVF (OR=3.2, P<0.001; Table 3) and to give birth to a living baby (OR=3.1; P=0.002; Table 4) compared to women who received 1-2 embryos. The other associations resulted not statistically significant.

In multivariable-adjusted analysis (Model 3 in Table

3 and in Table 4), the general picture remained more or less the same, but the association with age turned not significant. The association with education was of borderline significance regarding pregnancy, whereas the association with the number of transferred embryos retained its significance (for live birth there was borderline significance), but the associations weakened (OR=2.1, P=0.019 for the association with pregnancy; Table 3 and OR=2.1, P=0.082 for the association with live birth, Table 4).

Table 3. Association of socio-demographic and laboratory factors with pregnancy after IVF treatment: odds ratios (ORs) from binary logistic regression

Variable	Model	1	Model	2	Model	3
Variable	OR (95% CI)*	P	OR (95% CI)	P	OR (95% CI)	P
Residence	, ,		,		,	
Urban	1.0 (reference)	0.107	1.0 (reference)	0.018	1.0 (reference)	0.095
Rural	1.6 (0.9-2.8)		2.8 (1.2-6.5)		2.3 (0.9-6.1)	
Age-group						
≤35 years old	1.8 (1.0-3.3)	0.035	2.0 (1.1-3.8)	0.029	1.4 (0.6-3.1)	0.420
>35 years old	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Education level		$0.020(2)^{\dagger}$		0.020(2)		0.076(2)
8-years	1.0 (reference)	-	1.0 (reference)	- '	1.0 (reference)	-
High school	0.7 (0.2-1.7)	0.380	0.7 (0.3-1.7)	0.380	0.6 (0.2-1.9)	0.427
University	1.7 (0.6-5.3)	0.338	1.7 (0.6-5.3)	0.338	1.6 (0.4-6.2)	0.483
Type of infertility						
Primary	1.1 (0.6-2.0)	0.859	0.9 (0.5-1.9)	0.825	1.0 (0.4-2.3)	0.990
Secondary	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Number or						
transferred						
embryos	1.0 (reference)	< 0.001	1.0 (reference)	0.001	1.0 (reference)	0.019
1-2 embryos	3.2 (1.7-5.9)		2.9 (1.5-5.6)		2.3 (1.2-4.8)	
3-4 embryos						
Protocol						
P2	1.4 (0.8-2.5)	0.212	1.6 (0.8-2.8)	0.155	1.5 (0.8-3.2)	0.238
P5	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Estradiol level		0.143 (2)		0.293 (2)		0.280(2)
<842	1.0 (reference)	-	1.0 (reference)	-	1.0 (reference)	-
843-1499	0.9 (0.5-1.8)	0.935	1.0 (0.5-2.0)	0.905	1.0 (0.4-2.3)	0.998
>1499	1.7 (0.9-3.3)	0.103	1.6 (0.8-3.4)	0.207	1.8 (0.8-4.4)	0.168
Endometrium		0.924(2)		0.910(2)		0.888 (2)
thickness	1.0 (reference)	-	1.0 (reference)	-	1.0 (reference)	-
<9mm	0.9 (0.4-1.9)	0.862	1.2 (0.5-2.6)	0.729	0.9 (0.4-2.3)	0.942
10-11mm	1.1 (0.4-2.4)	0.863	1.2 (0.5-3.0)	0.674	1.2 (0.5-3.1)	0.734
>11mm						

Model 1: adjusted only for age.

Model 2: adjusted for place of residence and level of education.

Model 3: adjusted simultaneously for all the variables presented in the table.

^{*}Odds ratios (ORs) and 95% confidence intervals (in brackets).

[†]Overall p-values and degrees of freedom (in brackets).

Table 4. Association of socio-demographic and laboratory factors with live birth after IVF treatment: results from Binary Logistic Regression

Variable	Model	1	Model	12	Model	13
variable	OR (95% CI)*	P	OR (95% CI)	P	OR (95% CI)	P
Residence	,		,			
Urban	1.0 (reference)	0.084	1.0 (reference)	0.337	1.0 (reference)	0.553
Rural	1.6 (0.9-3.4)		1.6 (0.6-4.0)		1.4 (059-4.2)	
Age-group	,		, ,		,	
≤35 years old	1.9 (1.0-3.7)	0.047	2.3 (1.1-4.7)	0.025	1.4 (0.6-3.5)	0.449
>35 years old	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Education level		0.006 (2) [†]	,	0.025 (2)	, , ,	0.020(2)
8-years	2.3 (1.0-5.4)	0.055	1.5 (0.5-4.9)	0.472	2.3 (0.6-9.8)	0.248
High school	0.6 (0.3-1.1)	0.095	0.5 (0.2-1.1)	0.066	0.5 (0.2-1.3)	0.145
University	1.0 (reference)	-	1.0 (reference)	-	1.0 (reference)	-
Type of infertility						
Primary	1.7 (0.8-3.6)	0.168	1.6 (0.7-3.8)	0.270	1.6 (0.6-4.2)	0.391
Secondary	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Number or						
transferred						
embryos	1.0 (reference)	0.002	1.0 (reference)	0.011	1.0 (reference)	0.082
1-2 embryos	3.1 (1.5-6.3)		2.6 (1.2-5.6)		2.1 (0.9-4.7)	
3-4 embryos						
Protocol						
P2	1.3 (0.7-2.3)	0.390	1.3 (0.0.7-2.6)	0.382	1.5 (0.8-3.2)	0.332
P5	1.0 (reference)		1.0 (reference)		1.0 (reference)	
Estradiol level		0.374 (2)		0.758 (2)		0.930(2)
<842	1.0 (reference)	-	1.0 (reference)	-	1.0 (reference)	-
843-1499	1.0 (0.5-2.1)	0.933	1.1 (0.5-2.4)	0.896	1.0 (0.4-2.5)	0.979
>1499	1.5 (0.8-3.1)	0.225	1.3 (0.6-2.9)	0.494	1.2 (0.5-2.9)	0.758
Endometrium		0.427 (2)		0.152 (2)		0.129(2)
thickness	1.0 (reference)	-	1.0 (reference)	-	1.0 (reference)	-
<9mm	1.4 (0.6-3.2)	0.465	2.1 (0.8-5.6)	0.053	2.1 (0.7-5.8)	0.166
10-11mm	1.8 (0.7-4.5)	0.197	2.9 (1.0-8.3)	0.043	3.2 (1.1-9.9)	0.043
>11mm						

Model 1: adjusted only for age.

Model 2: adjusted for place of residence and level of education.

Model 3: adjusted simultaneously for all the variables presented in the table.

Discussion

The present study for the first time presents information regarding the results of IVF procedures in Albania. The main findings of our study are summarized as follows: the rate of pregnancy after IVF procedures was 45%. Among those who remained pregnant, 67.3% experienced a live birth whereas the remaining 32.7% ended in abortion. The overall rate of live birth after IVF procedures was 30.3% and the factors significantly associated with pregnancy and live birth after IVF were the level of education and number of transferred embryos. However, despite not achieving statistical significance for other independent factor included in the study.

the clinical significance of the findings is clear: women d"35 years old, those highly educated, women with primary infertility, those being transferred 3-4 embryos, those treated with P2 protocol, those with higher levels of estradiol and women with thicker endometrium were more likely to remain pregnant and to give a live birth after IVF procedures compared with their respective counterparts.

Infertility is largely understudied in Albania, whereas its treatment through contemporary methods of assisted reproductive techniques (ART) is being implemented on large scale only recently, favored

^{*}Odds ratios (ORs) and 95% confidence intervals (in brackets).

[†] Overall p-values and degrees of freedom (in brackets).

by the increasing of the proportion of infertile couples and the "liberal" legislation in place regulating such procedures.

The legal basis for regulating infertility issues in Albania is to be found in the Law Number 8876, dated 04.04.2002 "On reproductive health", and changed with the Law Number 10137, dated 11.05.2009 (22), which regulates all the activities of reproductive health, in the public and private sector, through protecting the reproductive rights of the individual and the couple in accordance with national and international policies and practices. Point (ë), article 3 of the law refers to the prevention and treatment of infertility. Article 10 guarantees to all individuals and couples the right to benefit from the use of affordable and acceptable methods for the correction of infertility. Section V of the law deals with the assisted reproductive techniques, which includes clinical and biological methods which enable the in-vitro conception, embryos' transferring and artificial insemination as well as all other similar techniques which allow for the reproduction process to occur apart from the natural processes (22).

In essence, the law "On reproductive health" in Albania does not impede any in-vitro fertilization technique, and as so, it literally allows egg donation, sperm donation, or embryo donation and it does not limit the number of the later which can be transferred and this is the reason why the number of infertile couples residing abroad and seeking help through IVF treatment in Albania is increasing. Even though there is no scientific research, this issue has recently been brought into the attention by the media. For example, a recent article reported that a considerable number of couple coming from different countries have decided to treat their infertility in Albania due to relatively lower prices, liberal legislation in place which allows the pickingup and transferring of a high number of embryos and the favorable religious climate as well as the lack of waiting times to treatment (23).

In Albania there are no exact figures regarding the prevalence of infertility. Meanwhile, the Ministry of Health reported that around 12% of couples in this country face some sort of difficulties to conceive (21), but according to gynecologists this number could jump up to 15% (24). In Tirana, during 2004-2012, among approximately 33 thousand births occurring in "Koco Gliozheni" maternity hospital, 497 women benefited pregnancy from ART techniques. According to these numbers, it is estimated that across the country there are about 1000 babies born through ART procedures during the same period (21). Other data regarding infertile couples are scarce.

The socio-demographic changes which have taken place in Albania during the last 23 years suggest for lifestyle and morbidity and mortality trends similar to those observed in the developed world: the increasing of sedentary lifestyle, increasing of calorie intake, increasing of chronic morbidity (25-30), decreasing of fertility rates (31) and delaying of first pregnancy. Under these conditions, it is estimated that the prevalence of infertility in our country is on the rise and, therefore, it is indispensable to obtain detailed information regarding this issue.

Some of the findings of our study are in concordance with those reported in the literature. We observed a significant increase of 2.1 years in the mean age of infertile women presenting at our clinic in the beginning and the end of the 7-year period of the study, which implies that women are delaying in time the moment of their first pregnancy, a finding similar to that reported in the literature (5,6). The main problem with this finding is that women are not really aware of the importance of age for achievement of pregnancy and first live birth and by doing so they delay their first pregnancy until it is too late. This is favored by the image being conveyed by the mass media which advertises the pregnancy of famous persons occurring at advanced ages, even though only a few know that these pregnancies were achieved artificially and not naturally. For this reason, it is very important to educate women regarding age as a crucial factor for achieving pregnancy.

On the other side, we reported that higher levels of estradiol and thicker endometrium was associated with higher likelihood of pregnancy and live birth after IVF (even though we didn't succeed to observe significant results, still the trend and clinical significance is clear, as we mentioned earlier in this section), findings which are supported by the literature as well (32,33).

In our study we reported that transferring of 3-4 embryos was significantly associated with increased likelihood of pregnancy and live birth after IVF. Literature findings are ambiguous regarding this issue.

For example, a recent article (34) reported that, after assessment of 124148 IVF cycles resulting in 33514 live births (or a live birth rate of 27% per cycle), the likelihood of live birth were higher among women aged 40 or older compared to those less than 40 years old when two embryos were transferred compared to one embryo, but the rates of live births did not increase when three or more embryos were transferred, whereas the risk of birth associated adverse effects increased, suggesting that the transferrin of three or more embryos should be avoided (34). Yet, another study reported similar findings to those reported by us (35). However, we admit that the increasing of the number or transferred embryos can increase the risk of multiple pregnancy and twin or triple live births, which are accompanied by their own considerable costs for the individual and the society.

The level of live births after IVF procedures in our study was comparable to that reported in the literature. We found that 30.3% of infertile couples undergoing IVF procedures managed to give birth to at least one living baby after a cycle of treatment. In literature this level is being reported similarly to our finding. For example, in a study among 750 infertile patients reported, after a cycle of treatment, a live birth rate of 21.4% in 1997, 23.3% in 1998, 30% in 1999 and 25% in 2000 (36), around 31%

was reported by another study (37), and 27% was yet reported by an additional large cohort study (34) This level of close comparability means that the IVF procedures in Albania are being performed using a similarly developed and modern infrastructure and employing a similarly appropriately trained medical staff as in developed countries.

In summary, we conclude by stating that the prevalence of infertility is maybe quickly increasing in this Southeast European country, closely following the important "western type" changes of lifestyle, morbidity patterns, as well as reduction of fertility rates and delaying of first pregnancy. In this perspective, Albania is following the trends observed in developed countries, which implies that infertility will be an increasing concern to our society and an increasingly important topic of therapeutic medicine, favored by the liberal legislation in this regard. Treatment of infertility through IVF techniques in our country is still in its infancy but, however, the results of these procedures are still comparable with those observed in developed world. Despite this, the information regarding the activities of private clinics or hospitals offering these procedures must and should be much more accurate and complete in the future in order to guarantee the quality of IVF services offered and the better regulation of this rapidly expanding market in Albania.

References

- 1. Definition of infertility and recurrent pregnancy loss. The Practice Committee of the American Society for Reproductive Medicine. The American Society for Reproductive Medicine, Birmingham, Alabama. Fertil Steril 2008; 90:S60.
- Vayena E, Rowe PJ, Griffin PD (eds). Medical, ethical & social aspects of assisted reproduction. Current practices & controversies in assisted reproduction: Report of a WHO meeting, 2001: Geneva, Switzerland.
- World Health Organization. Infertility: a tabulation of available data on prevalence of primary and secondary infertility. Geneva, WHO, Programme on Maternal and Child Health and Family Planning, Division of Family Health, 1991.
- Cates W, Farley TM, Rowe PJ. Worldwide patterns of infertility: is Africa different? Lancet 1985; 2:596-598.
- Mathews TJ, Hamilton BE. Delayed Childbearing: More Women Are Having Their First Child Later in Life. Hyattsville, MD: National Center for Health Statistics; 2009. NCHS Data Brief; No. 21.

- Mills M, Rindfuss RR, McDonald P, TeVelde E, ESHRE Reproduction and society Task Force. Why do people postpone parenthood? Reasons and social policy incentives. Hum Reprod Update 2011; 7:848-860.
- 7. Speroff L. The effect of aging on fertility. Curr Opin Obstet Gynecol 1994; 6:115-120.
- Vermeulen A. Environment, human reproduction, menopause and andropause. Envir Health Perspect 1993;101(Suppl 2):91-100.
- 9. Sartorius GA, Nieschlag E. Paternal age and reproduction. Hum Reprod Update 2010; 16:65-79.
- 10.Schwartz D, Mayaux MJ. Female fecundity as a function of age: results of artificial insemination of 2193 nulliparous women with azoospermic husbands. Federation CECOS. N Engl J Med 1982; 306:404-406.
- 11.Hassan MAM, Killick SR. Is previous use of hormonal contraception associated with a detrimental effect on subsequent fecundity? Hum Reprod 2004; 19:344– 351.

- 12. Rowland AS, Baird DD, Weinber CR, et al. Reduced fertility among women employed as dental assistants exposed to high level so nitrous oxide. N Engl J Med 1992; 327:993-997.
- 13. Ryley DA, Bayer SR, Eaton A, et al. Influence of body mass index (BMI) on the outcome of 6,827 IVF cycles. Fertil Steril 2004; 82:S38-S39.
- 14. Bolumar F, Olsen J, Boldsen J. Smoking reduces fecundity: a European multicenter study on infertility and subfecundity. European Study Group on Infertility Subfecundity. Am J Epidemiol 1996; 143:578-587.
- 15. Bolumar F, Olsen J, Rebagliato M, et al. Caffeine intake and delayed conception: a European multicenter study on infertility and subfecundity. European Study Group on Infertility Subfecundity. Am J Epidemiol 1997; 145:324-334.
- 16. Hakim RB, Gray RH, Zacur H. Alcohol and caffeine consumption and decreased fertility. Fertil Steril 1998; 70:632-637.
- 17.Domar AD. Infertility and the mind/body connection. Female Patient 2005; 30:24-28.
- 18. Thonneau P. Femaile and male risk factors: results of a case control study. Hum Reprod 1992; 7:55-58.
- 19. Boivin J, Bountin L, Collins JA, Nygren KG. International estimates of infertility prevalence and treatment-seeking: potential need and demand for infertility medical care. Human Reprod 2007; 22:1506-1512.
- 20. Mascarenhas MN, Flaxman SR, Boerma T, Vanderpoel S, Stevens GA. National, regional, and global trends in infertility prevalence since 1990: a systematic analysis of 277 health surveys. PLoS Med 2012; 9:12.
- 21. Konferenca Rajonale "Fertiliteti i ndihmuar medikalisht", Tiranë, Tetor 2012. Njoftim për shtyp i Ministrisë së Shëndetësisë (In Albanian). Available at: http://www.moh.gov.al/index.php/ shtator-2012/524-fillon-punimet-konferenca-rajonale-fertilitetii-ndihmuar-medikalisht-mjekesia-e-se-ardhmes. Accessed on February 2013.
- 22.Qendra për cështje të informimit publik. Ligji numër 8876, datë 04.04.2002 "Për shëndetin riprodhues" (In Albanian). Available at: http://www.infocip.org/ al?p=6843. Accessed on February 2013.
- 23. Shqipëria, "destinacion turistik" për bebe në epruvetë. Gazeta Shqip, 8 Mars 2013 (In Albanian). Available at:http://gazeta-shqip.com/lajme/2013/02/18/ shqiperia-destinacion-turistik-per-bebe-ne-epruvete/. Accessed on March 2013.
- 24.Rreth 15 për qind e shqiptarëve nuk mund të sjellin në jetë një fëmijë në rrugë natyrale. Gazeta Shqip, 8 Mars 2013 (In Albanian). Available at: http://gazetashqip.com/lajme/2012/10/19/riprodhim-i-asistuaredhe-ne-spitalet-private/. Accessed on March 2013.
- 25. Gjonça A, Bobak M. Albanian paradox, another example of protective effect of Mediterranean lifestyle? Lancet 1997; 350:1815-1817.26. Shapo L, Pomerleau J, McKee

- M, Coker R, Ylli A. Body weight patterns in a country in transition: a population-based survey in Tirana City, Albania. Public Health Nutr 2003; 6:471-477.1.
- 26.Shapo L, Pomerleau J, McKee M, Coker R, Ylli A. Body weight patterns in a country in transition: a population-based survey in Tirana City, Albania. Public Health Nutr 2003; 6:471-477.
- 27. Shapo L, Pomerleau J, McKee M. Epidemiology of hypertension and associated cardiovascular risk factors in a country in transition: a population based survey in Tirana City, Albania. J Epidemiol Community Health 2003; 57:734-739.
- 28. Shapo L, McKee M, Coker R, Ylli A. Type 2 diabetes in Tirana City, Albania: a rapid increase in a country in transition. Diabet Med 2004; 21:77-83.
- 29. Shapo L, Pomerleau J, McKee M. Physical inactivity in a country in transition: a population-based survey in Tirana City, Albania. Scand J Public Health 2004; 32:60-67.
- 30. Spahija B, Qirjako G, Toçi E, Roshi E, Burazeri G. Socioeconomic and lifestyle determinants of obesity in a transitional southeast European population. Med Arh 2012; 66(3 Suppl 1):16-20.
- 31.Studimi demografik dhe shwndetesor i Shqipwrise, 2008-2009. Available at: http://www.measuredhs.com/ pubs/pdf/FR230/FR230.pdf. Accessed on February 2013.
- 32.Kondapalli LA, Molinaro TA, Sammel MD, Dokras A. A decrease in serum estradiol levels after human chorionic gonadotrophin administration predicts significantly lower clinical pregnancy and live birth rates in in vitro fertilization cycles. Hum Reprod 2012; 27 :2690-2697.
- 33.Al-Ghamdi A, Coskun S, Al-Hassan S, Al-Rejjal R, Awartani K. The correlation between endometrial thickness and outcome of in vitro fertilization and embryo transfer (IVF-ET) outcome. Reprod Biol Endocrinol 2008; 6:37.
- 34.Lawlor DA, Nelson SM. Effect of age on decisions about the numbers of embryos to transfer in assisted conception: a prospective study. Lancet 2012; 379:521-527.
- 35. Schieve LA, Peterson HB, Meikle SF, Jeng G, Danel I, Burnett NM, Wilcox LS. Live-birth rates and multiple-birth risk using in vitro fertilization. JAMA 1999; 282:1832-1838.
- 36. Witsenburg C, Dieben S, Van der Westerlaken L, Verburg H, Naaktgeboren N. Cumulative live birth rates in cohorts of patients treated with in vitro fertilization or intracytoplasmic sperm injection. Fertil Steril 2005; 84:99-107.
- 37.Olivius K, Friden B, Lundin K, Bergh C. Cumulative probability of live birth after three in vitro fertilization/intracytoplasmic sperm injection cycles. Fertil Steril 2002; 77:505-510.

Association of carotid atherosclerosis with anthropometric parameters and inflammatory markers in dialysis patients

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Abstract

Aim: Cardiovascular disease is the leading cause of morbidity and mortality in patients in dialysis treatment. Atherosclerosis is accelerated in long-term maintenance haemodialysis. Several reports have investigated carotid artery intima-media thickness (CIMT) and the presence of carotid artery plaque (CAP), as surrogate markers of carotid atherosclerosis in ESRD patients. The aim of this study was to assess the prevalence of atherosclerotic carotid artery changes in dialysis patients and determine the potential link with classic and non-classic risk factors contributing to its development.

Methods: 72 dialysis patients who agreed to participate (40 males) were included in this study: 39 patients on peritoneal dialysis (PD) and 33 patients on haemodialysis (HD). Mean age was 53.8±12.1 years old. Mean time on dialysis 40.0±35.6 months. CMT and presence of CAP were obtained by B-mode ultrasonography. CRP, fibrinogen, calcium, phosphate, PTH, alkaline phosphataze, uric acid, serum albumin, and lipid profile were examined. In addition, anthropometric indices were measured. We analyzed the differences of these parameters in groups with and without atherosclerosis and their link to atherosclerosis.

Results: Atherosclerosis was found in 50 (69.4 %) patients, in 44 (62 %) men, in 25 (75.7%) HD patients and in 25 (64%) PD patients. Old age, diabetic nephropathy (DN), high phosphate (P), high pulse pressure (PP) and high BMI were found to be significantly linked with atherosclerosis. High CaxP product and fibrinogen were marginally significantly linked to atherosclerosis.

Conclusion: Atherosclerosis was highly prevalent in dialysis patients in this Albanian study. In our study, the older, the obese, the more inflamed and the high phosphoremic patients were more prone to atherosclerosis.

Keywords: atherosclerosis, carotid artery, dialysis.

Introduction

Chronic renal failure (CRF) is associated with premature atherosclerosis and increased cardiovascular morbidity and mortality in predialysis and haemodialysis (HD) patients (1,2). In patients with CRF, cardiovascular disease (CVD) is twice as common as in the general population (3). Compared with the general population, dialysis patients have more than 10 times higher relative risk for cardiovascular mortality (1).

Many studies have revealed that haemodialysis patients have advanced arterial wall changes as shown by increased intima-media thickness (IMT) of the carotid arteries as an index of thickening of arterial wall (4,5). Increased carotid artery IMT is considered a marker of early atherosclerotic changes (6) and carotid artery intima-media thickness (CAIMT) is increasingly used as a surrogate marker of early atherosclerosis. It was also shown that CAIMT is a strong predictor of future myocardial infarction and stroke (7).

Also, atherosclerosis and calcifications of vascular wall are found highly prevalent in peritoneal dialysis patients (8).

Several reports have investigated carotid artery intima-media thickness (CIMT), carotid artery calcification (CAAC) and carotid atherosclerosis (CAP) in ESRD patients. The CAIMT was found to be increased in subjects with impaired renal function (9-11), though contrasting results have also been published. Correlation between atherosclerosis and age, diabetes, diastolic blood pressure, acute phase proteins (such as CRP and fibrinogen), obesity, waist circumference as well as lipoprotein (a) and fetuin A were observed in CKD patients with and without dialysis treatment (8,13-19).

The aim of this study was to assess the prevalence of carotid artery atherosclerosis in dialysis patients and to analyze the potential link between various classic and non-classic factors and atherosclerosis.

Methods

This study consisted of 72 stable dialysis patients (40 males) who agreed to participate and treated for more than 6 months. Of these, 39 patients were on peritoneal dialysis (PD) and 33 pts on maintenance haemodialysis (HD). Mean age was 53.8±12.1 years old and mean time on dialysis 40.0±34.6 months.

These subjects were randomly selected from our database. All HD patients had native fistulas or arteriovenous grafts, haemodialysed 3 times per week, 4 hours per treatment, with standard bicarbonate-containing dialysate bath, using high-flux dialysis membrane. PD patients were on continuous ambulatory PD (4-5 exchanges/day with 2000 ml) dialyzed using conventional lactate-buffered glucosebased PD solutions (Dianeal PD4; 40 mmol/ L lactate, pH 5.3 to 5.5 containing 1.36, 2.27, or 3.86% dextrose as appropriate; Baxter Healthcare).

Doppler of carotid arteries

Carotid artery intima- media thickness (IMT) and presence of plaque were measured by B-mode ultrasonography using a real-time ultrasonograph with a 10-MHz in-line. The carotid artery was scanned bilaterally in the longitudinal and transverse projections. The examination included approximately 4 cm of the common carotid artery, the carotid bulb, and 1 cm each of the internal and external arteries. The image was focused on the far wall of the arteries. The site of the most advanced atherosclerotic lesion that showed the greatest distance between the lumen-intima interface and the media-adventitia interface was located in both the right and left carotid arteries. Was considered thickened intima-media > 0.9 mm.

Figure 1. Mode ultrasound view of carotid artery



Covariates

Blood pressure was measured with a standard mercury sphygmomanometer, after the patient had rested for at least five minutes in the supine position. Pulse pressure was calculated as the difference between systolic and diastolic blood pressure. The average of three measurements was used for analysis.

Laboratory test of serum albumin, lipids, calcium, phosphorus, PTH, alkaline phosphataze fibrinogen, PCR, uric acid, lipids were taken on dialysis day, before dialysis session on the mid-week day for HD patients and in a normal day for peritoneal dialysis patients.

Data for age, gender, time on dialysis, cause of CKD, smoking habits and medication were taken from patients file.

Weight, height, waist circumference were measured for each participant after dialysis session and BMI was calculated.

We analyzed the differences of these parameters in groups with and without atherosclerosis and their link with atherosclerotic carotid artery changes in our study population.

Statistical analysis

The Statistical Package for Social Sciences (SPSS), version 19.0, was used for all the statistical analyses. Mann-Whitney U test, a non-parametric equivalent of the t-test, was used for comparison of mean values of numerical variables. Conversely, Fisher's exact test was used for comparison of proportions of the categorical variables.

Results

Mean age was significantly higher among patients with atherosclerosis compared to individuals without atherosclerosis (57.8 years vs. 45.1 years, P<0.001). Conversely, there were no significant sex differences (P=0.125).

There was a statistically significant difference in the cause of CKD between groups (overall P=0.030), but no significant difference in the ratio PD/HD (P=0.316).

Body mass index was significantly higher among atherosclerotic patients (P=0.05). Waist circumference was also higher in atherosclerotic patients, a finding which nevertheless was not statistically

significant most probably due to the small sample size.

Fibrinogen level were higher in atherosclerotic patients, with borderline statistical significance (P=0.069). There was no significant difference between groups with regard to CRP.

Mean P level and PP were significantly higher in atherosclerotic patients (respectively P=0.022 and P=0.045).

On the other hand, there were no significant differences between groups with regard to the other parameters.

Discussion

The prevalence of atherosclerosis in our study was 79.8% in the overall sample, 75.7% in the HD group and 64% in the PD group, which are similar to the previously reported prevalence rates of atherosclerosis in dialysis patients (12).

Older age is known to be associated with atherosclerosis in HD patients (13) and PD patients (8) as well as in the general population. In our study, also, this finding was evident with a mean age significantly higher among patients with atherosclerosis compared to individuals without atherosclerosis (57.8 years vs. 45.1 years, P<0.001).

In respect to CKD underline cause Sanchez-Alvares et al (14) and Ekart et al (15), respectively, pointed to diabetes mellitus and hypertension as contributors to increased risk for atherosclerosis in dialysis patients. Similarly, in our study there was a statistically significant difference in the cause of CKD between groups (overall P=0.030) with ND in first place, followed by nephroangiosclerosis being the diagnosis most commonly associated with atherosclerosis.

We found no significant difference regarding the dialysis modality PD vs. HD (P=0.316), although PD was expected to be associated with higher atherosclerosis, considering more expressed metabolic and lipid profile derangements of the treated patients.

Body mass index was significantly higher among atherosclerotic patients (P=0.059). Waist circumference was also higher in atherosclerotic patients, a finding which nevertheless was not statistically significant most probably due to the small sample size. In a recent study in PD patients, waist

Table 1. Distribution of characteristics by atherosclerosis status

Variable	No atherosclerosis (N=22)	Atherosclerosis (N=50)	P-value*
Age (years)	45.05±13.63	57.78±9.17	< 0.001
Men	9 (40.9%)	31 (62.0%)	0.125
Time on dialysis (months)	43.14±26.52	38.70±39.13	0.083
CKD cause:			
NAS	2 (9.1%)	9 (18.0%)	0.030
ND	-	10 (20.0%)	
Other	20 (90.9%)	31 (62.0%)	
PD	14 (63.6%)	25 (50.0%)	0.316
P	4.35±1.44	5.01±1.30	0.022
Corrected Ca	8.49 ± 0.90	8.32 ± 0.84	0.599
CaxP	36.91±12.63	42.05±12.83	0.069
PTH	459.71±416.22	513.04±481.05	0.821
ALP	162.82±234.31	139.42±108.16	0.769
Fibrinogen (mg/dl)	412.64±129.33	475.04±131.38	0.069
PCR	6.30±5.83	6.62±6.59	0.932
Uricemia	5.70±1.11	5.90±1.00	0.466
S-albumine (g/dl)	3.56±0.49	3.49±0.48	0.632
Cholesterol (mg/dl)	183.86±46.65	169.56±50.21	0.165
Triglycerides (mg/dl)	158.14±89.05	162.28±85.16	0.691
RRF (ml/min)	2.68±2.69	2.63±2.85	0.944
PP (mmHg)	43.64±17.94	50.40±16.19	0.045
LV-i	140.75±57.47	157.09±50.23	0.146
Ca salts therapy	17 (77.3%)	39 (81.3%)	0.752
Vit D suppl.	17 (77.3%)	35 (72.9%)	0.776
Statin therapy	4 (18.2%)	19 (39.6%)	0.102
BMI	22.71±3.81	24.57±4.17	0.05
Waist circumference	0.92±0.13	0.98±0.16	0.208

^{*} Mann-Whitney test was used for comparison of numerical variables and Fisher's exact test for comparison of the categorical variables.

circumference was found to be linked to CAIMT (16). Inflammation may be involved in atherogenesis in predialysis patients as well as in those treated with haemodialysis. High serum CRP (17) and low serum albumin (18) has been found associated with atherorosclerosis in other studies, which noted the presence of inflammation in atherosclerotic patients. These findings were not confirmed in our study. Anyway, fibrinogen level were higher in atherosclerotic patients, with borderline statistical significance (P=0.06). These findings could be linked to relatively small number of patients in our study. Mean Phosphate and CaxP product level were higher in atherosclerotic patients in our study

(P=0.022 and P=0.069, respectively), a similarfinding to that of Ishimura et al (19), that found an association of serum phosphate with carotid intimamedia thickness in haemodialysis patients.

PP was significantly higher in atherosclerotic patients (P=0.045).

On the other hand, there were no significant differences between groups with regard to the other parameters examined in our study.

In conclusion, atherosclerosis was highly prevalent in CKD patients on dialysis treatment in this Albanian sample. In our study, the older, the obese, the more inflamed and the high phosphoremic patients were more prone to atherosclerosis.

References

- Foley RN, Parfrey PS, Sarnak MJ. Clinical epidemiology of cardiovascular disease in chronic renal disease. Am J Kidney Dis 1998; 32:S112-S119.
- Goodman WG, Goldin J, Kuizon BD, Yoon C, Gales B, Sider D, et al. Coronary-artery calcification in young adults with end-stage renal disease who are undergoing dialysis. N Engl J Med 2000; 342:1478-1483.
- Collins AJ, Li S, Gilbertson DT, Liu J, Chen SC, Herzog CA. Chronic kidney disease and cardiovascular disease in the medicare population. Kidney Int Suppl. 2003; 64:S24-S31.
- Kawagishi T, Nishizawa Y, Konishi T, et al. Highresolution B-mode ultrasonography in evaluation of atherosclerosis in uremia. Kidney Int 1995; 48:820-826.
- Shoji T, Kawagishi T & Emoto M et al. Additive impacts of diabetes and renal failure on carotid atherosclerosis. Atherosclerosis 2000; 153:257-258.
- Grobbee DE, Bots ML. Carotid artery intima-media thickness as an indicator of generalised atherosclerosis. J Intern Med 1994; 236:567-573.
- Lorenz MW, Markus HS, Bots ML, Rosvall M, Sitzer M. Prediction of clinical cardiovascular events with carotid intima-media thickness.A systematic review and meta-analysis. Circulation 2007; 115:459-467.
- Wang AY, HO SS, Liu EK et al. Differential associations of traditional and non traditional risk factors with carotid intima/media thickening and plaque in peritoneal dialysis patients. Am J nephrol 2007; 27:458-465.
- Zhang L, Zhao F, Yang Y, Qi L, Zhang B, Wang F, et al. Association between carotid artery intimamedia thickness and early-stage CKD in a Chinese population. Am J Kidney Dis 2007; 49:786-792.
- Ishizaka N, Ishizaka Y, Toda E, Koike K, Seki G, Nagai R, et al. Association between chronic kidney disease and carotid intima-media thickening in individuals with hypertension and impaired glucose metabolism. Hypertens Res 2007; 30:1035-1041.

- 11. Lisowska A, Musia WJ, Lisowski P, Knapp M, Mayszko J, Latocha-Korecka G, et al. The influence of renal function and selected cardiovascular risk factors on the thickness of the intima-media complex in the peripheral arteries. Cardiol J 2007; 14:59-66.
- 12. Malatino LS, Benedetto FA, Mallamaci F et al. Smoking, blood pressure and serum albumin are major determinants of carotid atherosclerosis in dialysis patients. CREED Investigators. Cardiovascular Risk Extended Evaluation in Dialysis patients. J Nephrol 1999; 12:256-260.
- Kuang D, H You, F.Ding, J.Xue, J. Chen, C Ronco, Y. Gu. Intima-media thickness of the carotid artery and its correlation factors in maintenance hemodialisis patients. A cross - sectional study. Blood Purif 2009; 28:181-186.
- Sanchez-Alvarez J.E, P. Delgado- Mallen, A. Gonzales- Rinne, et al. Carotid ultrasound: Prevention of heart disease and mortality on haemodialysis. Nefrologia 2010; 30:427-434.
- Ekart R, R. Hojs, B. Pecovnik- Balon, S. Bevc B. Dvorsak. Blood Presure measurements and carotid intima media thickness in hemodialysis patients. Ther. Apher Dial 2009; 13:288-293.
- 16. Asicioglu E, Kahveci A, Arikan H, Koc M, Tuglular S, Ozener CI. Waist circumference is associated with carotid intima media thickness in peritoneal dialysis patients. Int Urol Nephrol. 2013 Apr 4. [Epub ahead of print]
- Tirmenstajn Jankovic B, Dimkovic N. C-reactive protein as an independent risk factor for carotid atherosclerosis in hemodialysis patients. Med Pregl 2005; 58:127-135.
- Sezer S, Ozdemir FN, Arat Z, Turan M, Haberal M. Triad of malnutrition, inflammation and atherosclerosis in hemodialysis patients. Nephron 2002;0 91:456-462.
- Ishimura E, Taniwaki H, Tabata T, Tsujimoto Y, Jono S, et al. Cross- sectional association of serum phosphate with carotid intima- medial thickness in hemodialysis patients. Am J Kidney Disease 2005; 45:859-886.

Fetal fibronectin and cervical length measurement in women with preterm labor

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Abstract

Aim: Preterm birth still remains a major cause of perinatal morbidity and mortality and its rate has not declined over the last two decades despite the improvement in perinatal management. The aim of our study was to assess the use of fetal fibronectin (fFN) testing and cervical length (CL) measurement to predict preterm delivery.

Methods: This was a prospective study including all patients admitted between November 2009 and June 2011 to the University Obstetric-Gynecologic Hospital "Mbretëresha Geraldinë" in Tirana, with the diagnosis of increased preterm uterine contractility and intact membranes between 22 and 34 weeks of gestation (N=254).

Results: Among 245 women with complete data, the mean gestational age at recruitment was 29.4±2.5 weeks. Six women (9.6%) delivered within two weeks of assessment and 14 (22.5%) women delivered before 34 weeks. A positive fFN test resulted in a sensitivity of 83%, a specificity of 84%, a positive predictive value of 36%, and a negative predictive value of 98% for delivery within two weeks. For CL <25 mm, these figures were: 50%, 52%, 10%, and 91%, respectively.

Conclusion: In our study conducted in the capital city of Albania, fFN screening provided the best predictive capacity for preterm delivery. Cervical ultrasound after fFN triage appears to be an acceptable option, depending on the resources available.

Keywords: cervical length, fetal fibronectin, preterm delivery, ultrasonography.

Preterm birth remains a major cause of perinatal morbidity and mortality (1) and its rate has not declined over the last two decades despite the improvement in perinatal management (2).

Assessing the probability of preterm delivery is still a clinical challenge and is important to reduce the clinical interventions (tocolysis, corticosteroid administration, and transfer to a tertiary care facility) which are risky and expensive. Several studies have shown that a diagnosis of preterm labor based on digital examination was not as reliable as the diagnosis based on tests such as detection of fetal fibronectin in cervicovaginal secretions and ultrasound measurement of cervical length (3). Fetal fibronectin, an extracellular matrix glycoprotein localized at the maternal-fetal interface of the amniotic membranes between the chorion and the decidua, is found at very low levels in cervicovaginal secretions under normal conditions. Levels of e"50 ng/mL at or after 22 weeks of gestation have been associated with an increased risk of spontaneous preterm birth (3-6). A recent meta-analysis has shown that births before 37 weeks significantly decreased in patients whose management was based on knowledge of fFN results compared with controls whose fFN results were unknown (7).

Transvaginal CL measurement is the other validated test to predict preterm birth in women with threatened preterm labor, as well as in asymptomatic high-risk and low-risk women (3,8-14). A CL measurement of 25 mm or less is generally considered as an excellent indicator of an increased risk of preterm delivery, particularly among women with preterm labor. Several studies have reported that fFN screening and CL measurement provide similar results in predicting the risk of preterm delivery (15-20). However, it remains unclear whether combined fFN and CL measurements improve the prediction of preterm delivery and the means of such a combination (3). Availability of one of the two tests may be an issue in some facilities because the ultrasound expertise for CL measurement may not be always available in small centers. On the other hand, the additional cost of fFN testing may be difficult to justify in centers where CL measurement is readily available. Therefore, the use of CL or fFN as the first-line test might be a more rational option, limiting the

use of a second test to selected cases in a contingent approach.

Nevertheless, the evidence regarding preterm delivery issues among Albanian women is scant. In this context, the aim of our study was to determine the performance of FN testing and ultrasound CL measurement for the prediction of preterm delivery in patients with preterm labor in Albania.

Methods

This was a prospective cohort study of patients admitted between November 2009 and June 2011 to the Obstetric-Gynecologic University Hospital "Mbretëresha Geraldinë" in Tirana, with the diagnosis of increased preterm uterine contractility and intact membranes between 24 and 34 weeks. Preterm labor was defined by the presence of regular uterine contractions, lasting at least 30 seconds and occurring at least four times in 30 minutes, and significant cervical changes on digital examination. Women were excluded if they had a confirmed or suspected rupture of membranes, cervical dilatation > 3 cm, cervical cerclage, vaginal bleeding, placenta previa, placental abruption, severe intrauterine growth restriction, preeclampsia, or medically indicated preterm delivery before 34 weeks. The study investigations were carried out either on admission or within 24 hours of admission if a digital examination had been performed in the 24 hours before the patient's inclusion in the study. Each subject was first examined with a vaginal speculum. A Dacron swab was rotated in the posterior fornix of the vagina and sent to the laboratory. The presence or absence of fFN was measured by a qualitative test (Fibronectin collection kit, Adeza Biomedical), and results were expressed as positive or negative. A concentration of 50 ng/ mL in the vaginal fluid was indicative of a positive test. The outcome of the pregnancy was recorded in a database with other relevant information. The outcomes of interest were delivery within two weeks of admission to the study and delivery before 34 weeks. Predictive values and likelihood ratios with their respective 95% confidence intervals were first calculated for each test considered separately and subsequently for different combinations of both markers. Predictive values were compared using the McNemar test. All analyses were performed with SPSS software, version 16.0.

Results

Two hundred fifty four women were included in the study. The outcome of pregnancy could not be determined for five women who had been discharged and delivered in another centre. Among the 249 remaining women, two had an fFN assessment but no CL measurement, and further two women had CL measured but no evaluation of fFN. These cases were excluded from further analysis.

Two hundred forty five women were included in

the final analysis, including seven twin pregnancies, and 147 (60%) women were initially transferred from another centre because of preterm labor. Twenty four women (9.6%) delivered within two weeks, and 55 women (22.5%) delivered before 34 weeks.

General characteristics and pregnancy outcomes in study subjects are summarized in Table 1. The values of the different tests in predicting delivery within two weeks and before 34 weeks are presented in Table 2. Fetal fibronectine was the best single test

Table 1. General characteristics, pregnancy outcomes, and test results of the individuals under study (N=245)

Characteristics	Mean value (±SD) / n (%)
Maternal age in years (mean±SD)	27.6±6.2
Nulliparous [n (%)]	115 (46.8)
Maternal transfer [n (%)]	146 (59.7)
Gestational age at inclusion in weeks (mean±SD)	29.4±2.5
Gestational age at delivery in weeks (mean±SD)	36.5±3.2
Received tocolytics [n (%)]	174 (71.0)
Delivery within 2 weeks [n (%)]	24(9.7)
Delivery before 34 weeks [n (%)]	55 (22.6)
Delivery before 37 weeks [n (%)]	91 (37.1)
Admission to delivery interval in days (mean±SD)	49.9±22.8
Median cervical length in mm (range)	26.5 (0-51)
Cervical length <15 mm [n (%)]	12 (28.8)
Cervical length <25 mm [n (%)]	20 (48.4)
Cervical length <30 mm [n (%)]	16 (38.7)
Positive fFN [n (%)]	10 (22.6)

for the prediction of delivery within two weeks (with a sensitivity of 83% and a specificity of 84%), whereas CL measurement had a slightly better sensitivity than fFN (71% vs. 50%, respectively) for predicting delivery before 34 weeks. The specificity of fFN was significantly higher than the CL measurement (P<0.001). Overall, there was no significant difference between the sensitivity of fFN testing, CL measurement, and their combinations.

Table 2. Predictive values for preterm birth of cervical length, fFN

Delivery	Parameter	Sensitivity % (95% CI)	Specificity % (95% CI)	LR + % (95% CI)	LR – % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
Within 2 weeks	fFN +	83(36-100)	84(72-92)	5.2(2.6-10.4)	0.2(0.0-1.2)	36(13-65)	98(89-100)
(prev 9.7%)	CL <25 mm	50(12-88)	52(38-65)	1.0(0.4-2.4)	1.0(0.4-2.2)	10(2 -26)	91(75 -98)
<34 weeks	fFN +	50(23-77)	85(72-94)	3.4(1.4-8.1)	0.6(0.3-1.0)	50(23-77)	85(72-94)
(prev 22.6%)	CL <25 mm	71(42-92)	58(43-72)	1.7(1.1-2.7)	0.5(0.2-1.2)	33(17-53)	87(71-96)
<34 weeks	fFN +	48(35-60)	92(86-99)	6.2(1.9-20.0)	0.5(0.4-0.8)	79(68-89)	75(64-86)
(prev 37.1%)	CL <25 mm	74(52-90)	67(50-81)	2.2(1.3-3.7)	0.4(0.2-0.8)	57(37-74)	81(64-93)

Discussion

Findings from our study confirm that both cervicovaginal fFN testing and endovaginal CL measurement provide good prediction of delivery within two weeks or before 34 weeks in women with threatened preterm labor. In addition, we have tested two different strategies combining both tests, with the aim of improving the predictive value while decreasing the need for additional resources. For the prediction of delivery within two weeks, the best performance was provided by the fFN testing alone. However, the sensitivities did not differ significantly between the various combinations; this means that, depending on local resources, a choice can be made among these options. In facilities where vaginal ultrasound equipment and expertise are readily available (especially in tertiary care centres), CL measurement is a good test for the initial triage. When CL results are in an intermediate range, fFN testing clearly provides useful additional information to decide whether the woman with resolved preterm labour can be discharged. In facilities where vaginal ultrasound is not routinely offered, fFN testing offers an excellent option to decide if a woman with preterm labor requires treatment and referral to a tertiary facility. Regardless of the strategy employed, it is important to perform the fFN swab sampling before any other vaginal examinations (CL measurement or digital examination) as routinely recommended for fFN testing. The swab is simply discarded if the test is deemed unnecessary on the basis of CL measurement.

There is no agreement about the benefits of combining fFN testing and CL measurement in women with preterm labor. Rozenberg et al. (16)

using a one-step combination (both tests performed for every patient), found the combination of tests to have limited value, whereas several other studies reported increased predictive values when both tests were combined in various ways (15,18,20). The selective use of fFN after CL measurement, was proposed by Hincz et al. (18) and by Schmitz et al. (20). Both studies reported an improved specificity when fFN testing was limited to cases of intermediate measurement of CL (21-31mm for Hincz, and 16-30mm for Schmitz). Gomez et al. (19) found a significant improvement in the prediction of preterm delivery when fFN was tested after a CL of <30 mm. However, numerous reports have confirmed that both cervical length measurement and fFN testing had a good to excellent reproducibility (3). Depending on the type of facility and staff availability, the choice of the first-line test, fFN testing, or CL measurement, provides similar predictive values among women with threatened preterm labor.

Conclusion

We have confirmed that fFN testing in patients selected by use of cervical sonography is more specific for predicting preterm birth than cervical length measurement alone, and it is as effective as fFN testing in all women. Cervical ultrasound after fFN triage is an acceptable option, depending on the resources available.

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References

- Goldenberg RL, Culhane JF, Iams JD, Romero R. Epidemiology and causes of preterm birth. Lancet 2008; 371:75-84.
- Iams JD, Romero R, Culhane JF, Goldenberg RL. Primary, secondary, and tertiary interventions to reduce the morbidity and mortality of preterm birth. Lancet 2008; 371:164-75.
- 3. Iams JD. Prediction and early detection of preterm labor. Obstet Gynecol 2003; 101:402-12.
- Leitich H, Egarter C, Kaider A, Hohlagschwandtner M, Berghammer P, Husslein P. Cervicovaginal fetal fibronectin as a marker for preterm delivery: a metaanalysis. Am J Obstet Gynecol 1999; 180:1169-76.
- Goldenberg RL, Mercer BM, Iams JD, Moawad AH, Meis PJ, Das A, et al. The preterm prediction study: patterns of cervicovaginal fetal fibronectin as predictors of spontaneous preterm delivery. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Am J Obstet Gynecol 1997; 177:8-12.
- Lockwood CJ, Senyei AE, Dische MR, Casal D, Shah KD, Thung SN, et al. Fetal fibronectin in cervical and vaginal secretions as a predictor of preterm delivery. N Engl J Med 1991; 325:669-74.
- 7. Berghella V, Hayes E, Visintine J, Baxter JK. Fetal fibronectin testing for reducing the risk of

- preterm birth. Cochrane Database Syst Rev 2008; CD006843.
- 8. Iams JD, Goldenberg RL, Meis PJ, Mercer BM, Moawad A, Das A, et al. The length of the cervix and the risk of spontaneous premature delivery. National Institute of Child Health and Human Development Maternal-Fetal Medicine Unit Network. N Engl J Med 1996; 334:567-72.
- 9. Coleman MA, Keelan JA, McCowan LM, Townend KM, Mitchell MD. Predicting preterm delivery: comparison of cervicovaginal interleukin (IL)-1beta, IL-6 and IL-8 with fetal fibronectin and cervical dilatation. Eur J Obstet Gynecol Reprod Biol 2001; 95:154-8.
- 10. Owen J, Yost N, Berghella V, Thom E, Swain M, Dildy GA, 3rd, et al. Mid-trimester endovaginal sonography in women at high risk for spontaneous preterm birth. JAMA 2001; 286:1340-8.
- 11. Berghella V, Roman A, Daskalakis C, Ness A, Baxter JK. Gestational age at cervical length measurement and incidence of preterm birth. Obstet Gynecol 2007; 110(2 Pt 1):311-7.
- 12. Grimes-Dennis J, Berghella V. Cervical length and prediction of preterm delivery. Curr Opin Obstet Gynecol 2007; 19:191-5.
- 13. Crane JM, Hutchens D. Transvaginal sonographic measurement of cervical length to predict preterm birth in asymptomatic women at increased risk: a systematic review. Ultrasound Obstet Gynecol 2008; 31:579-87.
- 14. Schmitz T, Kayem G, Maillard F, Lebret MT, Cabrol D, Goffinet F. Selective use of sonographic cervical length measurement for predicting imminent preterm delivery in women with preterm labor and intact membranes.

- Ultrasound Obstet Gynecol 2008; 31:421-6.
- 15. Rizzo G, Capponi A, Arduini D, Lorido C, Romanini C. The value of fetal fibronectin in cervical and vaginal secretions and of ultrasonographic examination of the uterine cervix in predicting premature delivery for patients with preterm labor and intact membranes. Am J Obstet Gynecol 1996; 175:1146-51.
- 16. Rozenberg P, Goffinet F, Malagrida L, Giudicelli Y, Perdu M, Houssin I, et al. Evaluating the risk of preterm delivery: a comparison of fetal fibronectin and transvaginal ultrasonographic measurement of cervical length. Am J Obstet Gynecol 1997; 176:196-9.
- 17. Goldenberg RL, Iams JD, Das A, Mercer BM, Meis PJ, Moawad AH, et al. The Preterm Prediction Study: sequential cervical length and fetal fibronectin testing for the prediction of spontaneous preterm birth. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Am J Obstet Gynecol 2000; 182:636-43.
- 18. Hincz P, Wilczynski J, Kozarzewski M, Szaflik K. Two-step test: the combined use of fetal fibronectin and sonographic examination of the uterine cervix for prediction of preterm delivery in symptomatic patients. Acta Obstet Gynecol Scand 2002; 81:58-63.
- 19. Gomez R, Romero R, Medina L, Nien JK, Chaiworapongsa T, Carstens M, et al. Cervicovaginal fibronectin improves the prediction of preterm delivery based on sonographic cervical length in patients with preterm uterine contractions and intact membranes. Am J Obstet Gynecol 2005; 192:350-9.
- 20. Schmitz T, Maillard F, Bessard-Bacquaert S, Kayem G, Fulla Y, Cabrol D, et al. Selective use of fetal fibronectin detection after cervical length measurement to predict spontaneous preterm delivery in women with preterm labor. Am J Obstet Gynecol 2006; 194:138-43.

Socioeconomic determinants of hypertension in the adult population of transitional Kosovo

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Abstract

Aim: Hypertension is an important risk factor for cardiovascular disease including the transitional countries of the Western Balkans. Our aim was to assess the prevalence and socioeconomic determinants of hypertension in the adult population of post-war Kosovo.

Methods: A cross-sectional study was conducted in Pristina in 2012-2013 including a representative sample of 1793 consecutive primary health care users aged e"35 years (mean age: 51.2±6.7 years; 52.5% women; overall response rate: 95%). All participants were measured their systolic and diastolic blood pressure. Information on demographic factors and socioeconomic characteristics was also collected. Binary logistic regression was used to assess the association of hypertension with demographic and socioeconomic characteristics.

Results: Overall, the prevalence of hypertension was 33.6% (38.9% in men vs. 28.8% in women). In unadjusted logistic models, there was evidence of a positive and significant association of hypertension with male gender, urban residence, unmarried civil status, unemployment and retirement, and a lower income level. Upon multivariable-adjustment, significant "predictors" of hypertension were male gender, unemployment, and a lower income level.

Conclusions: Our findings indicate a relatively high prevalence of hypertension in the adult population of post-war Kosovo, especially among men and the most disadvantaged socioeconomic groups. Health care professionals and policymakers in Kosovo should be aware of the high burden of morbidity and mortality-related outcomes associated with hypertension.

Keywords: diastolic blood pressure, high blood pressure, hypertension, Kosovo, systolic blood pressure.

Kosovo is currently undergoing a rapid process of transformation to an independent state after the war and the liberation from the Serbian regime in 1999 and almost a decade under United Nations administration. The independence of Kosovo was formally declared in 2008, hence constituting the newest state in Europe. Kosovo has the youngest European population, as evidenced in the Demographic, Social and Reproductive Health Survey conducted in 2009 (1). However, Kosovo is one of the poorest countries in Europe, with a large proportion of the population living below the national poverty line – according to recent estimates from the World Bank (2). Similar data on the poverty levels of Kosovo population are also supported by the International Labor Organization (3). In Kosovo, mortality trends of chronic diseases including cardiovascular diseases resemble adult mortality trends and life expectancy in both sexes. In particular, regardless of the absence of official reports, stroke mortality in Kosovo is considerably higher than in the European Union member states, a situation which is similar to many countries in the Western Balkans. Therefore, changes in cardiovascular disease mortality account for the apparent changes in the overall mortality patterns in post-war Kosovo. However, according to the Household Budget Survey conducted in Kosovo in 2011, the prevalence of smoking in the population of Kosovo aged e"15 years (13.0% in the overall population) is lower than in other countries of the Western Balkans (4).

Hypertension is a well-established risk factor for cardiovascular morbidity and mortality in both sexes. This was well-documented and confirmed by the Global Burden of Disease Study update for 2000 (5), and the fairly recent update for 2010 (6,7). Arterial hypertension is among the leading global risks for mortality, being responsible for 9.4 million deaths in 2010 (8). This considerable burden linked to hypertension has been documented in many studies (7). Increased blood pressure contributes to cardiovascular and cerebrovascular endpoints, such as myocardial infarction, heart failure, cardiovascular death and stroke (8).

However, data on the prevalence and correlates of hypertension in the adult population of Kosovo are scarce. In this context, our aim was to assess the prevalence and socioeconomic determinants of hypertension in the adult population of Kosovo, a transitional country in the Western Balkans undergoing rapid changes after a decade of war with Serbia.

Methods

A cross-sectional study was conducted in Pristina, the capital city of Kosovo, in 2012-2013.

Study population and sampling

A sample of 2000 consecutive primary health care users aged e"35 years was invited to participate in the study. Calculation of the sample size was made by use of WINPEPI (Program for Epidemiologists) for a number of hypotheses related to the prevalence and socioeconomic correlates of hypertension such as sex, age, level of education and employment status. The significance level (two-tailed) was set at 5%, and the power of the study at 80%. Based on the most conservative calculations, the required minimal size for a simple random sample was about 1700 individuals. We decided to recruit 2000 individuals in order to account for nonresponse. Of the 2000 targeted individuals, 207 did not participate in the study (113 individuals were not eligible, whereas further 94individuals refused to participate). Overall, 1793 primary health care users were included in our study (response rate: 1793/ 1887=95%). The response rate was similar in men and women.

Data collection

All participants were measured their systolic and diastolic blood pressure. Measurement of blood pressure was done with an electronic sphygmomanometer three times in the right arm (with a oneminute pause in between), after the subject was seated for five minutes in a quiet room, during which the cuff was attached. The average of the 2nd and the 3rd measurements was used in the analysis. Hypertension was defined as systolic blood pressure e"140 mmHg, or diastolic blood pressure e"90 mmHg, or self-reported treatment for hypertension regardless of the measurement values.

Data on socio-demographic factors (sex, age, place of residence [urban vs. rural area] and marital status

[married vs. single/divorced/widowed]) and socioeconomic characteristics (educational level [low, middle, high], employment status [employed, unemployed, pension] and income level [low, middle, high]) were also collected.

The survey was approved by the Kosovo Board of Biomedical Ethics. All individuals who agreed to participate in the study gave their informed consent.

Statistical analysis

Binary logistic regression was used to assess the association of hypertension (dichotomous/binary variable) with socio-demographic socioeconomic characteristics (age, sex, place of residence, education level, employment status and income level). Crude/ unadjusted odds ratios (ORs) and their respective 95% confidence intervals

(95%CIs) were initially calculated. Subsequently, multivariable-adjusted ORs and their respective 95%CIs were calculated. Hosmer-Lemeshow test was used to assess the goodness of fit of the logistic regression models. Statistical Package for Social Sciences, version 17.0, Chicago, Illinois, was used for all the statistical analyses.

Results

Mean age of study participants was 51.2±6.7 years (Table 1). There were 851 (47.5%) men and 942 (52.5%) women in the study sample. Overall, about 57% of survey participants were urban residents and 86% were currently married. Unemployment rate was relatively high in this sample (33%), which was also reflected in a high proportion of self-reported low income level (39%).

Table 1. Distribution of demographic and socioeconomic characteristics in a large representative sample of adult men and women in Kosovo (N=1793) in 2012-2013

Demographic and socioeconomic factors	Distribution
Age (years)	51.2±6.7*
Educational level (years)	8.76±3.49*
Sex:	
Men	851 (47.5) [†]
Women	942 (52.5)
Place of residence	
Urban area	$1019 (56.8)^{\dagger}$
Rural area	774 (43.2)
Marital status:	
Married	$1539 (85.8)^{\dagger}$
Single/divorced/widowed	254 (14.2)
Employment status:	
Employed	763 (42.5) [†]
Unemployed	591 (33.0)
Pension	439 (24.5)
Income level:	
High	267 (14.9) [†]
Middle	826 (46.1)
Low	700 (39.0)

^{*} Mean values ± standard deviations.

Overall, 602 participants were hypertensive and, therefore, the prevalence of hypertension was 602/ 1793=33.6%. The prevalence of hypertension was higher in men (331, or 38.9%) than in women (271, or 28.8%).

Table 2 presents the crude/unadjusted association of hypertension with demographic factors and socioeconomic characteristics. There was evidence of a positive and significant association of hypertension with male gender (OR=1.36, 95% CI=1.18-1.57), urban residence (OR=2.14, 95% CI=1.74-2.51), unmarried civil status (OR=1.63, 95%CI=1.12-2.04), unemployment (OR=2.28, 95% CI=1.79-3.01) and retirement (OR=3.41,

[†] Numbers and column percentages (in parentheses).

95% CI=2.06-4.13), and a lower income level (OR=2.34, 95%CI=1.60-3.27).

Upon multivariable-adjustment, significant "predictors" of hypertension were male gender (OR=1.27, 95%CI=1.12-1.43), unemployment (OR=1.72, 95%CI=1.34-2.86), and a lower income level (OR=1.89, 95%CI=1.39-2.81) [data not shown in the tables].

Discussion

The main findings of our study include a relatively

Table 2. Association of hypertension with demographic factors and socioeconomic characteristics in a large representative sample of adult population in Kosovo (N=1793) in 2012-2013

Variable	OR (95%CI)*	\mathbf{P}^*
Age (years)	1.02 (1.01-1.03)	0.03
Educational level (years)	1.01 (0.98-1.03)	0.49
Sex:		
Women	1.00 (reference)	0.02
Men	1.36 (1.18-1.57)	
Place of residence		
Urban area	1.00 (reference)	0.01
Rural area	2.14 (1.74-2.51)	
Marital status:		
Married	1.00 (reference)	0.04
Single/divorced/widowed	1.63 (1.12-2.04)	
Employment status:		<0.01 (2) [†]
Employed	1.00 (reference)	-
Unemployed	2.28 (1.79-3.01)	0.01
Pension	3.41 (2.06-4.13)	< 0.01
Income level:		0.04 (2) [†]
High	1.00 (reference)	-
Middle	1.29 (0.83-1.92)	0.27
Low	2.34 (1.60-3.27)	0.01

^{*}Odds ratios (ORs), 95% confidence intervals (95%CI) and p-values from binary logistic regression.

high prevalence of hypertension in the adult population of Kosovo, which raises serious concerns for health care professionals and decision makers in the health sector. The prevalence of hypertension was considerably high particularly among men and the most vulnerable socioeconomic segments of the population (the unemployed and the low-income groups).

The prevalence of hypertension in our study was higher compared with a prior report from Albania (9). On the other hand, there are very few scientific articles addressing the issue of hypertension in the adult population of Kosovo, which makes it difficult to compare our findings.

Similar to other countries, in our study there was evidence of an age-dependent positive correlation between systolic blood pressure and diastolic blood pressure (8). There is considerable evidence from the international literature linking high levels of systolic and diastolic blood pressure with stroke, and the ischemic heart disease (7,8). Therefore, there have been consistent reports suggesting that hypertension is the number one risk for mortality because of its dominant role in cardiovascular pathogenesis (7,8). In addition, for transitional countries of the Western Balkans including Albania and Kosovo, the rapid pace of transition and its inherent association with hypertension (10), including also the reduced energy expenditure and resultant obesity, bear important implications for both the health care and health promotion sectors in these countries.

Despite the evidence on a fall in blood pressure levels during the last decade in Europe, it has been argued that hypertension will remain one of the

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

most important cardiovascular risk factors given the ageing trend of the population worldwide (8). Therefore, in order to control and prevent the magnitude of hypertension at a population level, the well-known suboptimal hypertension control rates should be of great concern to health care professionals (8). In parallel, intensive efforts should be done in order to identify and test new strategies for an improvement in awareness and effective treatment for hypertension, which are crucial measures to control the extent of hypertension at a population level (8,11).

Our study may have several limitations including the sample representativeness and potential information biases. In our study, we included a large sample of consecutive primary health care users of both sexes. In addition, the response rate in our study was very high (95%). Also, respondents and non-respondents did not differ significantly in terms of age and sex. As for the possibility of information bias, we

applied standard procedures of systolic and diastolic blood pressure measurements in all study participants. However, the information on socioeconomic characteristics was based on self-reports. Therefore, we cannot exclude entirely the possibility of differential reporting of the socioeconomic characteristics between different groups of individuals distinguished by the presence of hypertension. Finally, associations reported in crosssectional studies should be interpreted with extreme caution, because they are not considered to be causal. Therefore, future prospective studies in Kosovo should confirm the validity of our findings.

In conclusion, our findings indicate a relatively high prevalence of hypertension in the adult population of post-war Kosovo, especially among men and the most disadvantaged socioeconomic groups. Health care professionals and policymakers in Kosovo should be aware of the high burden of morbidity and mortality-related outcomes associated with hypertension.

References

- 1. Statistical Office of Kosovo. Demographic, Social and Reproductive Health Survey in Kosovo, November 2009. Pristina, Kosovo, 2011.
- 2. The World Bank. Europe and Central Asia Region. Poverty Reduction and Economic Management Unit. Statistical Office of Kosovo. Consumption Poverty in the Republic of Kosovo, in 2009. Western Balkans Programmatic Poverty Assessment. 2011.
- 3. International Labour Organization. Profile of the social security system in Kosovo (within the meaning of UNSC Resolution 1244 [1999]). 2010. Available from: http://www.ilo.org/public/english/region/eurpro/ budapest/ download/ socsec/ socsec_system_kosovo.pdf (accessed: June 2013).
- 4. Household Budget Survey. Pristina, Kosovo, 2011.
- 5. World Health Report. Reducing risks, promoting healthy life. 2002. Available at: www.who.int/whr/eng.
- 6. Global Burden of Disease Study 2010. Available http://www.thelancet.com/themed/globalburden-of-disease (accessed: June 2013).

- 7. Lim SS, Vos T, Flaxman AD, Danaei G, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012; 15:380:2224-2260.
- 8. Kintscher U. The burden of hypertension. EuroIntervention 2013; 9 Suppl R:R12-5.
- Burazeri G, Goda A, Sulo G, Stefa J, Roshi E, Kark JD. Conventional risk factors and acute coronary syndrome during a period of socioeconomic transition: population-based case-control study in Tirana, Albania. Croat Med J 2007; 48:225-233.
- 10. Shapo L, Pomerleau J, McKee M. Epidemiology of hypertension and associated cardiovascular risk factors in a country in transition: a populationbased survey in Tirana city, Albania. J Epidemiol Community Health 2003; 57:734-739.
- 11. Law M, Wald N, Morris J. Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy. Health Technol Assess 2003; 7:1-94.

Assessment of medical, socioeconomic and psychosocial needs of HIV positive children in **Albania**

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Abstract

Aim: The aim of this study was to evaluate the medical, social and psychological treatment of children living with HIV/AIDS and identify the rate of discrimination they are facing, as well as the role and problems of the Convention on Children Rights and Albanian legislation in this regard in order to shed light into the situation of children living with HIV and their families in Albania. Methods: We used a semi-structured questionnaire, which included open-ended questions as well, to assess the needs of 19 children living with HIV. Also, focus groups with family members, community, local authorities and health services' members were organized. The information obtained was analized in a qualitative manner.

Results: 26% of the children included in this study were stigmatized and discriminated because of their disease, whereas the rest had not made public their HIV status in order to avoid potential stigma and discrimination. 16% and 32% of HIV children had lost their mother or father, respectively, making them more vulnerable and seriously aggravating their socio-economic status. Late diagnosis has not only affected children's health, but it has also had a high financial cost for families seeking medical help for many years.

Conclusions: Children affected by HIV and their families face medical treatment related problems, lack of other supporting services and a number of barriers to ensure normal living conditions on a daily basis. There is a serious call for urgent actions in order to address the specific needs of this vulnerable subgroup in Albania.

Keywords: Albania, children, HIV, psychosocial.

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HIV/AIDS represents a major health problem with AIDS-related diseases being amongst the top causes of death in the world. It is estimated that HIV/ AIDS will continue to be one of the main causes of premature death even in the next ten years (1). UNAIDS estimated that 33.3 million people were living with HIV in 2009 and, among them, 2.5 million (1.6 million-4.3 million) were children under 15 years old. Also, around 2.6 million (2.3 million -2.8 million) new HIV cases were recorded in 2009 (1). Meanwhile, as a result of an increased access to mother-to-child prevention services, a decrease in the total number of children born with HIV has been observed. About 370,000 new cases were diagnosed in 2009 marking a 24% decrease compared to five years ago. The number of deaths related to AIDS has decreased from 2.1 million (1.9 -2.3 million) in 2004 to 1.8 million (1.6 - 2.1 million) thus reflecting the positive effects of treatment and support services. However, unfortunately, death rates continue to rise in Eastern Europe (1).

Deaths among children under 15 years of age are also decreasing. Estimates show that 260,000 (150,000-360,000) individuals have died from AIDS-related diseases in 2009, a figure which is 19% less compared to 2004 expectations. Once again, this trend reflects the extent of services to prevent transmission of HIV. Around 16.6 million children under 18 years of age have lost one or both parents due to AIDS. Most of the children living with HIV/ AIDS and those affected by this disease live in Sub-Saharan Africa (90%) (1).

In Albania, the first diagnosed child with HIV/ AIDS was reported in 1997. Up to December 2012, there were 28 children infected with HIV/ AIDS, of whom 20 were infected vertically (motherto-child). Most children cases were in the phase of HIV infection at the time of diagnosis but in 2010 a child was diagnosed in late phases of AIDS. He died several weeks later. Apart from the motherto-child transmission, after 2003, there started to appear also cases which had been infected through blood transfusion, especially among children suffering from diseases requiring frequent supply of blood (2).

Seroprevalence studies on pregnant women do not provide valuable data on countries with low HIV prevalence, such as the case of Albania. According to two seroprevalence studies conducted in 1999 and 2003, among 500 pregnant women who were randomly selected across the country, the prevalence was zero at a time when the prevalence of hepatitis B remained high at about 8% in this population group. Despite the evident improvement of data and assessment studies, we do not have yet accurate estimates of the number of children infected with HIV, beyond the number of recorded cases or those who already live with AIDS.

HIV-affected children face particular challenges during their everyday activities. They might face discrimination, stigma and peer pressure. Very little information is available about these important aspects and issues in Albania. In this context, the aim of this study was to evaluate the medical, social and psychological treatment of children living with HIV in Albania and identify the rate of discrimination they are facing, as well as the role and problems of the Convention on Children Rights and Albanian legislation in this regard in order to give a contribution towards building of a positive local environment for children living with HIV and their families.

Methods

In this study, parents or relatives of HIV positive children were interviewed with the support of the Institute of Public Health (IPH) in collaboration with the People Living with HIV/AIDS Organization. The conditions in which these children lived were specifically assessed. The instrument used in this study consisted of a questionnaire including semi-structured and open questions that allowed respondents to freely express their opinions regarding the more subtle and complex issues of HIV/AIDS.

Besides providing general information for the child and his/her family (age, education, employment), the questionnaire also included open questions about the experiences of these persons, the effects of the disease on their daily life, attitudes of the community towards it, their experiences in health, social and psychological services, what they would like to change and what their plans for the future were. These questions aimed to shed light into the situation of Albanian children infected with HIV and affected by HIV/ AIDS. Also, the purpose of this study was to document data on the situation, protection and support services offered to children living with HIV/ AIDS in transitional Albania.

This exploration was further deepened during the second phase of the study, through focus groups organized with families of children living with HIV, Tirana University Hospital Center "Mother Teresa" (TUHC) medical staff who deal directly with the treatment of these children, as well as round tables in the districts with representatives of local authorities. The third phase consisted of a substantial discussion of results at central level with various actors, analysis of the data (qualitative analysis) and the inclusion in the joint report of all findings and recommendations arising from the activities of the first two phases.

Results and Discussion

This survey included 19 children living with HIV/AIDS and their family members. Most of them were living in rural areas.

Stigma had affected the family, sisters or brothers of children infected with HIV/ AIDS despite the fact that they had not been infected with this virus. The economic situation of families of these children is very difficult but sometimes we found that despite these precarious conditions they did not

receive any social support (for example KEMP revenue) due to stigma and discrimination, that they might be facing when others would come know about their disease. The right to education is a basic right for every child. Nevertheless, the majority of HIV positive children were facing violations of this right, which often revealed in the form of an expulsion behavior from parents whose children are not affected by the virus.

Medical care and treatment for children with HIV/ AIDS are offered only at the pediatric service while children older than 14 years of age are treated at the infectious disease service for adults in TUHC. When talking about vertical transmission, it often happened that the child's health problems led to his/ her diagnosis of HIV and subsequently the mother was diagnosed (or sometimes both parents). But the situation is different when parents are diagnosed earlier and then the child/children are found to be HIV positive as well. In some cases the disease was diagnosed in late stages of AIDS condition which poses an urgent task for our healthcare system, such as the establishment of a National Program for Prevention of Transmission from mother-to-child. Diagnosis timeline ranges from 1-13 years (Table 1). Late diagnosis has had not only serious consequences

Table 1. General information about HIV diagnosis among children in Albania

HIV cases	Year of diagnosis	Possible year of infection	Diagnosis period
1	1997	1996	1 year
2	2003	2002	1 year
3	2003	2001	2 years
4	2003	1995	8 years
5	2003	2001	2 years
6	2004	1996	8 years
7	2006	2002	4 years
8	2006	2004	2 years
9	2006	1998	8 years
10	2007	2006	1 year
11	2006	1998	8 years
12	2007	2005	2 years
13	2007	2006	1 year
14	2007	2007	Within the year
15	2008	1999	9 years
16	2009	2008	1 year
17	2009	2009	Within the year
18	2010	1997	13 years

on children's health, but it also has had a high financial cost for families going from one hospital to another one for many years. Two cases were diagnosed abroad (in Austria and Italy, respectively).

In general, there were problems with the treatment of HIV positive children and the treatment scheme had not been always applied. HIV-infected women affected with opportunistic pathogens might be more likely than women without HIV infection to transmit these infections to their infants (3). The major problem for these children is the provision of drugs used for treatment of Opportunistic Infections (OI), which have to be provisioned by their own families. Particular attention is required for children with thalassemia. Lack of blood is identified as a serious problem especially in the hot summer season. For example, the affected individuals had to go twice a month at the blood bank in the district of Lushnja to obtain blood and once a month they had to come to Tirana, thus overburdening further their economic situation.

These children and their parents need specific psychosocial support. To ensure that, in the pediatrics and infectious disease service at TUHC there is a number of psychologists who deal directly with counseling and psychosocial support for children living with HIV and their families (4,5).

We observed that a large proportion of parents of HIV positive children, were unemployed, which makes even more difficult facing the economic, psychosocial and emotional problems accompanying HIV/ AIDS. In none of the cases were the mothers or the fathers employed in the public sector and unemployment prevailed. This probably relates to the fact that the majority of these children (63%) were living in rural areas where access to employment is minimal. There is little doubt that stigma and discrimination against HIV/ AIDS are still barriers that prevent parents of HIV children to find a job.

Housing was another major problem worsening their living conditions. Often parents of HIV children were forced to be isolated in one of the house's rooms. "We were living together with my husband's family, but when the latter became aware for the three of us, they isolated us in a room. This room should serve as a living room, kitchen and bedroom for us and our little child", stated one respondent.

Living in rural areas adds up to the already difficult situation of children living with HIV and their families. In these conditions, any social benefit would serve to improve their conditions. However, only 12 or 63% of them received this kind of assistance. Four or 21% of them did not receive it as a result of stigma and discrimination and in one case the child was orphan and his relatives neglected him by jeopardizing his life. However, the KEMP assistance is too little to cover the numerous needs these children have, such as medicines for treatment of IO, or the transportation costs for the next visits. Regarding the transportation costs, 21% of these children currently resided more than 200 km away from Tirana, 11% of them 125 km away from Tirana, 16% of them 80 km away, 11% around 40 km from Tirana and the others were living in Tirana. The transportation cost is not negligible. Since services to HIV positive children are offered only at the pediatric section of the UHC in Tirana, these children had to come at least once a month to be visited by the doctor. None of these children and their companions had received reimbursement for transportation costs despite the fact that this is a right based on the Albanian Law No. 9952 (6). Losing parents at a young age is a tragedy, because the loss is associated with the lack of attention, care and love of other people, relatives or society. It affects psychologically, socially and economically the child. But losing parents from HIV/ AIDS comprises a greater trauma. Apart from losing their beloved parents they also face the abandonment from the society. Loss of parents exposes these children to many threats and challenges, risks that are increasing with the rising incidence of AIDS. For this reason, the decision-making structures should plan intervention that is directly linked with HIV positive orphans, as well as their families and communities (7). Out of 19 HIV positive children included in our study, five children had lost one parent due to AIDS while further two children had lost both parents and currently live with their relatives.

It should be emphasized that these children need a special treatment that according to pediatric medical staff should be offered by a specialized center (8), which actually is lacking.

There are two documents defining the rights of children infected with HIV.

- 1. Convention on Children Right (9);
- 2. The law on HIV/AIDS approved since 2000, reviewed and adopted in 2008.

There is a need for this Law to be introduced and recognized from all institutions that are dealing with the people living with HIV/ AIDS. Based on our findings, there is an urgent need to establish mechanisms and guidelines for its implementation as well as to evaluate its related economic costs.

Conclusions

This study clearly illustrates that there are still numerous problems waiting to be resolved for HIV positive children. Integrating HIV testing and counseling for pregnant women in the basic package of antenatal care services will reduce mother-tochild HIV transmission (10). It is of crucial importance to offer psychosocial and financial support for children with HIV/ AIDS and their families. Prior to a blood transfusion to a child, parents should be explained the window period and should explain the risk that this transfusion may cause. Factors such as development level, health condition, and home situation all impact the optimal disclosure process for the child, which may involve a long period of partial disclosure - where the child is given health and preventive information, but is not told that he or she has HIV - leading to full disclosure, when the child is mature enough to understand the information. Given the central role of the parent/ caregiver in deciding what information will be

References

- 1. UNAIDS Report on the Global AIDS. Accessed April 2013. Available at: http://www.unaids.org/ globalreport/ global_report.htm
- 2. ISHP, Annual Report on HIV/AIDS, 2012.
- 3. CDC. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children, August 2009. Accessed March 2013. Available at: http://www.cdc.gov/mmwr/preview/ mmwrhtml/ rr58e0826a1.htm?s_cid=rr58e0826a1_e
- 4. USAID. Meeting the psychosocial needs of Children living with HIV in Africa. USAID, June 2011. Accessed March 2013. Available at: http://www.aidstarone.com/focus areas/care and support/ resources/technical_briefs/foundation_future
- 5. WHO. Strategic Approaches to the Prevention of HIV Infections in Infants. WHO, Switzerland, March 2002. Accessed March 2013. Available at: http:// www.who.int/ hiv/ pub/ mtct/ en/ StrategicApproachesE.pdf

shared with the child and when, several promising approaches build parent/caregiver capacities to understand disclosure-related issues and how to communicate with their child (10).

It is very important to encourage local governments to implement social policies for employment of people living with HIV/AIDS which will make them less vulnerable.

Despite the evident improvement of data and assessment surveys, we do not have yet accurate estimates of the number of children infected with HIV, beyond the number of assessments recorded or those who are sick with AIDS. Even though this number is considered small, it reflects HIV/ AIDS situation in our country with a low prevalence, but simultaneously through identification of transmission routes it highlights our two main public health problems namely the lack of programs for prevention of transmission from mother to child and the fragile system that provides secure blood. Stronger linkages between PMTCT services and community-based support, family planning, STI and general health services are needed to ensure that women receive services that cover their wide range of health needs (11). Providing HIV testing and counseling for pregnant women free of charge in public and private institutions, and advice on maternal and child health as part of the National Program for Transmission Prevention from Mother to Child (NPTPMC) will reduce the number of HIV positive newborns resulting from their respective HIV-infected mothers (12,13).

- 6. Ligji Nr.9952, datë 14.7.2008 "PËR PARANDALIMIN DHE KONTROLLIN E HIV/ AIDS-IT".
- 7. IATT. Expanding social protection for vulnerable children and families. Inter-Agency Task Team (IATT) on Children and HIV. Accessed February 2013. Available at: http://www.unicef.org/aids/files/ $Expanding_Social_Protection.MTemin.May 2008.pdf$
- 8. UNICEF. Enhanced Protection for Children Affected by AIDS, March 2007. UNICEF. Accessed March 2013. Available at: http://www.unicef.org/publications/files/ Enhanced_Protection_for_Children_Affected_by_AIDS.pdf
- 9. UNICEF. Implementation handbook for the convention on the rights of child. UNICEF. Accessed March 2013. Available at: http://www.unicef.org/publications/files/ Implementation_Handbook_for_the_Convention_ on_the_Rights_of_the_Child_Part_1_ $of_3.pdf$

- WHO. Priority Interventions , HIV/AIDS prevention, treatment and care in the health sector. WHO. Accessed April 2012. Available at: http://www.who.int/hiv/pub/ priority_interventions_web.pdf
- WHO. Towards Universal. WHO. Accessed 2010. Available at: http://www.who.int/hiv/toronto2006/ towardsuniversalaccess.pdf
- 12. WHO. Policy requirements for HIV testing and counseling of infants and young children in health
- facilities, 2010. WHO and UNICEF. Accessed June 2010. Available at: http://whqlibdoc.who.int/publications/ 2010/ 9789241599092_eng.pdf
- 13. UNAIDS, Voluntary Counselling and Testing. UNAIDS. Accessed March 2012. Available at: http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub01/jc379-vct_en.pdf.

Pulmonary involvement in scleroderma

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Abstract

Aim: The purpose of our study was the identification of pulmonary manifestations in patients with scleroderma, their assessment in relations to immunological alterations, their relations to gender, and the assessment of the sensitivity in the examinations that are used to detect lung injuries.

Methods: This is a cross-sectional study including 58 patients with scleroderma during January-September 2011. Patients' history of disease was carefully extracted and recorded. Patients were underwent immunological tests such as anti-nuclear antibody test, anti-topoisomerase and anticentromere tests. Furthermore, chest X-ray, pulmonary high-resolution computed tomography, pulmonary function tests and echocardiography Doppler were also performed. Chi-square test was used to assess potentially statistically significant associations.

Results: Mean age of the patients (86.2% females) was 49.38±8.92 years. Mean duration of the disease was 7.29±4.5 years. Pulmonary involvements were found in 42 (72%) patients. Interstitial lung diseases were found in 42 (72%) patients, pulmonary arterial hypertensions in 6 (10%) patients and restrictive ventilator insufficiency in 32 (55%) patients. The proportion of individuals with pulmonary injuries was significantly higher among patients with immunological alterations compared with patient without immunological alterations and among females (both P<0.001).

Conclusions: In our study, pulmonary manifestations were common in patients with scleroderma. These injuries are anatomical and functional. Our findings confirm that immunological alterations are an important factor in pulmonary injuries. Sex was also associated with pulmonary injuries in this sample of Albanian patients. High-resolution computed tomography is the most sensitive examination for the detection of pulmonary injuries in scleroderma.

Keywords: interstitial lung disease, pulmonary disease, scleroderma.

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Pulmonary diseases are an important manifestation in scleroderma (SSc) and 80% of patients have pulmonary injury (1). Lung injuries in scleroderma occur frequently and include interstitial lung disease, vascular, pleural and airways disease (2,3). Pulmonary arterial hypertension (PAH) and interstitial lung disease (ILD) are the two most common lung manifestations in scleroderma (4,5). Restrictive ventilator insufficiency was observed in patients with scleroderma and pulmonary injury (6,7). Serum antitopoisomerase (Scl-70) correlates with the development of ILD and is more frequently found in patients with diffuse cutaneous involvement; anticentromere (ACA) antibody is more frequently associated with limited cutaneous scleroderma and pulmonary vascular disease (8). Unfortunately, systemic sclerosis lung disease is often not detected or diagnosed until the late stages. High resolution computed tomography (HRCT) of the lungs, pulmonary function tests (PFTs), chest x-ray (CXR) and echocardiography Doppler for pulmonary arterial hypertension (PAH) have shown interest in the assessment of scleroderma lung disease.

The purpose of our study was the identification of pulmonary injuries in patients with scleroderma, their assessment in relations to immunological alterations, their relations to gender and the evaluation on the sensitivity of the examinations for the detection of scleroderma lung disease.

Methods

This was a cross-sectional study involving 58 patients with scleroderma during January-September 2011. The patients in this study were recruited from outpatient consultations in the Rheumatology clinic at the University Hospital Center "Mother Theresa" in Tirana and outpatient consultations at the University Hospital Center of Lung Diseases "Shefqet Ndroqi" in Tirana. These patients were then hospitalized in the respective clinics.

We only included patients that met the criteria of the American College of Rheumatology for the diagnosis of scleroderma (9). Scleroderma patients who have suffered in the past or were actually suffering from other diseases (e.g. sarcoidosis, tuberculosis, emphysema, congestive heart failure, congenital heart disease, cirrhosis of the liver) which may influence the pulmonary injuries, smoking patients, pregnant women and those breastfeeding, and also patients with a history of any occupational exposure to inorganic or organic dusts (e.g. asbestosis, silicosis, coal worker's pneumoconiosis) were excluded from the study.

Patients were examined by immunological tests such as: anti-nuclear antibody (ANA), anti-topoisomerase and anti-centromere test. Chest X-ray and high resolution computed tomography of the lung were also performed and their findings were recorded in consultation with the radiologist. Patients were considered to have ILD when they showed CXR and HRCT of the lung findings compatible with ILD such as: nodular, reticular, reticulonodular, ground-glass opacities, honeycombing, dominantly on lung bases (10). Lung function was measured with a spirometer. Indicators of pulmonary function included forced vital capacity (FVC), forced expiratory volume in the first, second (FEV1), and FEV1/FVC ratio. Based on the American Thoracic Society criteria, patients with normal FEV1/FVC ratio and decreased FVC < 80% were diagnosed as having restrictive disease (11). These data were expressed as percentages of the predicted values, based on patient's sex, age, height and weight. The patients were referred to the pulmonologist for spyrometry and interpretation of the related findings. Furthermore, patients were examined with echocardiography Doppler for PAH and were referred to the cardiologist for interpretation of the findings. The systolic pressure in the pulmonary artery was evaluated based on tricuspid regurgitation peak flow velocity m/s using the Bernoulli equation 4 x (tricuspid regurgitation jet)² + right atrial pressure of 5 mm/ hg. The value of pulmonary artery systolic pressure (PASP) > 36 mm/ hg was considered as PAH (12).

To determine if the immunological alterations were associated with pulmonary injury, patients were classified into two groups. The first group included patients with positive anti-nuclear antibodies, positive anti-topoisomerase and positive anti-centromere. The second group included patients with negative antinuclear antibodies,

negative anti-topoisomerase and negative anticentromere. Sex-specific analyses were performed to assess the scale of pulmonary injuries.

Statistical analysis

Continuous variables were expressed as mean values and their respective standard deviations. Categorical variables were presented in absolute values and their respective percentages. Differences between the categorical variables were assessed with the chi-square test. A p-value d"0.05 was considered as statistically significant. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 19.0.

Results

Mean (\pm SD) age of the patients was 49.38 \pm 8.92 years. Mean (\pm SD) duration of disease was 7.29 \pm 4.55 years. There were 50 (86.2%) female

patients and 8 (13.8%) male patients. Patients with positive anti-nuclear antibodies were 46 (79%), antitopoisomerase positive were 23 (40%) and anticentromere positive were 16 (28%) patients. Lung X-ray changes were observed in 10 (17%) patients, pulmonary injuries in HRCT were found in 42 (72%) patients, pulmonary arterial abnormalities were found in 6 (10%) patients with echocardiography Doppler and pulmonary function tests abnormalities were found in 32 (55%) patients. Lung injuries were more prevalent in HRCT compared with CXR and pulmonary function tests. ILD was identified in 42 (72%) patients and pulmonary arterial hypertension was found in 6 (10%) patients. ILD was significantly different (P<0.001) in patients with scleroderma versus PAH (Table 1).

Table 1. Pulmonary manifestations in scleroderma

Condition	Number of patients	Column percentages	P-value
ILD	42	72.4	
PAH	6	10.4	رم مرم ا
Normal	10	17.2	< 0.001
Total	58	100.0	

Pulmonary function tests abnormalities were observed in 32 (55%) patients and all patients had restrictive ventilator insufficiency. There were 46 (100%) patients with positive anti-nuclear antibodies, anti-topoisomerase positive and anti-centromere positive, of whom 39 (85%) represented pulmonary injuries whereas 7 (15%) patients were normal (group 1). Conversely, in group 2, of 12 (100%) patients who did not have positive anti-nuclear antibodies,

anti-topoisomerase and anti-centromere, only 3 (25%) patients had pulmonary injuries and 9 (75%) patients were normal. The proportion of patients with pulmonary injuries was significantly higher among patients with immunological alterations compared to patient without immunological alterations (P<0.001) (Table 2).

Among 8 males, 2 (25%) had pulmonary injuries

Table 2. Pulmonary injuries by immunological alterations

Patients' group	Total	Pulomonary injury	No pulmonary injury	P-value
Group 1	46 (100.0)	39 (85.0)*	7 (15.0)*	< 0.001
Group 2	12 (100.0)	3 (25.0)	9 (75.0)	<0.001

^{*} Absolute numbers and row percentages (in parentheses).

and 6 (75%) resulted normal. In 50 females, 40 (80%) had pulmonary injuries and 10 (20%) were

normal. The proportion of patients with pulmonary injuries was significantly higher among females (P<0.001) (Table 3).

Table 3. Pulmonary injuries by sex

Sex	Total	Pulomonary injury	No pulmonary injury	P-value
Female	50 (100.0)	40 (80.0)*	10 (20.0)*	۰۵ ۵۵1
Male	8 (100.0)	2 (25.0)	6 (75.0)	< 0.001

^{*} Absolute numbers and row percentages (in parentheses).

Discussion

The main finding of this study was that pulmonary injuries are more frequent in patients with scleroderma and in our opinion this indicates that pulmonary manifestations are important complications in such groups of patients. Pulmonary involvements in this study were found in 72% of the patients. The rate of this kind of injuries is reported at the level of 70%-90% in the literature (13). This study showed that in patients with scleroderma pulmonary anatomical injuries such as parenchymal and vascular injuries occur quite frequently. ILD and pulmonary arterial hypertension are often found in this type of patients. Some authors have noted that interstitial lung disease and pulmonary arterial hypertension are the two most common lung manifestations in scleroderma (4,5). In the present study, ILD was found in 72% of the patients and pulmonary arterial hypertension in 10% of the patients. ILD is reported to be present in nearly 60% of SSc patients with clinical involvement and approximately 80% of SSc patients in the autopsy (14). Pulmonary arterial hypertension is a frequent and serious form of pulmonary complication affecting 10%-20% of SSc patients (15,16). Pulmonary arterial hypertension occurs in at least 10% of SSc patients, and is associated with high mortality (17).

Another finding of this study is that pulmonary anatomical injuries are associated with injuries of pulmonary function, which are not always manifested with pulmonary anatomical injuries. In our study, 55% of the patients had pulmonary function testing abnormalities. Other authors have reported that 40%-75% of scleroderma patients have changes in pulmonary function tests (18). Different studies show that pulmonary injury in scleroderma is associated with restrictive ventilator defect (6,7). It has been estimated that 40% of the patients with scleroderma have a predicted FVC of less than 75%, indicating the presence of ILD (19).

A finding of this study is that scleroderma pulmonary injuries occur more frequently in patients with alterations of the immune system. According to our study, in patients with positive antinuclear

antibodies, anti Scl-70 positive and anti-centromere positive pulmonary manifestation occurred frequently in 85% patients. Other authors have shown that the presence of anti-topoisomerase positive and anticentromere positive in patients appear to be associated with the development of ILD and pulmonary arterial hypertension (8). Specific autoantibodies such as the anti-topoisomerase, ribonucleoprotein and anti-histone antibodies have been reported to be associated with an increased risk of ILD in SSc (20). Anti-centromere antibodies, known to be associated with limited SSc, are also linked to SSc-PAH (21). In our study, the pulmonary manifestations of scleroderma were observed more frequently in women than in men. In this study, HRCT were more sensitive than the chest X-ray and PFTs. HRCT is the standard method for the noninvasive diagnosis of SSc-ILD and can detect mild abnormalities even when chest the X-ray and pulmonary function tests result normal. HRCT is more sensitive than chest X-ray and is the imaging technique of choice for detecting and characterizing ILD (22).

Study limitations

The patients in our study were selected from a university hospital, which could potentially be prone to selection bias by including patients with more severe stages of the disease compared to patients at the community level. However, we tried to minimize this bias by recruiting also all the patients from the hospital's outpatient consultation clinics.

Conclusion

In conclusion, pulmonary manifestations are common in scleroderma. These injuries are anatomical and functional. ILD and restrictive ventilator insufficiency are injuries that occur more frequently in patients with scleroderma. Immunological alterations are important factors in pulmonary injuries. Sex is a factor that might be associated with the pulmonary injuries. Finally, HRCT is the most sensitive examination for the detection of pulmonary injuries.

References

- 1. Scholand MB, Carr E, Frech T, Hatton N, Markewitz B, Sawitzke A. Interstitial Lung Disease in Systemic Sclerosis: diagnosis and management. Rheumatology 2012; S1:008.
- 2. Highland KB, Heffner JE. Pleural effusion in interstitial lung disease. Curr Opin Pulm Med 2004; 10:390-6.
- 3. Pontifex EK, Hill CL, Roberts-Thomson P. Risk factors for lung cancer in patients with scleroderma: a nested case-control study. Ann Rheum Dis 2007; 66:551-3.
- 4. Latsi PI, Wells AU. Evaluation and management of alveolitis and interstitial lung disease in scleroderma. Curr Opin Rheumatol 2003; 15:748-55.
- 5. Le Pavec J, Launay D, Mathai SC, Hassoun PM, Humbert M. Scleroderma lung disease.Clin Rev Allergy Immuno 2011; 40:104-16.
- 6. Pocock G, Richards CD. The respiratory system. Human Physiology: The Basis of Medicine, 3ed: Oxford, 2006; 324.
- 7. Jacob M. van Laar, Jan Stolk and Alan Tyndall. Scleroderma Lung Pathogenesis, Evaluation and Current Therapy. Drugs 2007; 67:985-96.
- 8. Lamblin C, Bergoin C, Saelens T, Wallaert B. Interstitial lung diseases in collagen vascular diseases. Eur Respir J Suppl 2001; 32:69s-80s.
- 9. Subcommittee for scleroderma criteria of the American Rheumatism Association Diagnostic and Therapeutic Criteria Committee: Preliminary criteria for the classification of systemic sclerosis (scleroderma). Arthritis Rheum 1980; 23:581.
- 10. Travis WD, King TE Jr, Bateman ED, Lynch DA, Capron F, Center D, et al. American Thoracic Society/ European Respiratory Society international multidisciplinary consensus classification of the idiopathic interstitial pneumonias. Am J Respir Crit Care Med 2002; 165:277-304.
- 11. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al. Standardisation of spirometry. Eur Respir J 2005; 26:319-38.
- 12. Galie N, Hoeper MM, Humbert M, Torbicki A, Vachiery JL, Barbera JA, et al. Guidelines for the diagnosis and

- treatment of pulmonary hypertension: the Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS), endorsed by the International Society of Heart and Lung Transplantation (ISHLT). Eur Heart J 2009; 30:2493-537.
- 13. Miani OA, Dweik RA, Arroliga AC. Manifestations of scleroderma pulmonary disease. Clin Chest Med 1998; 19:713-31.
- 14. Luo Y, Xiao R. Interstitial Lung Disease in Scleroderma: Clinical Features and Pathogenesis. Rheumatology 2011;
- 15. Pope JE, Lee P, Baron M, Dunne J, Smith D, Docherty PS, et al. Prevalence of elevated pulmonary arterial pressures measured by echocardiography in a multicenter study of patients with systemic sclerosis. J Rheumatol 2005; 32:1273-8.
- 16. Wigley FM, Lima JA, Mayes M, McLain D, Chapin JL, Ward-Able C, et al. The prevalence of undiagnosed pulmonary arterial hypertension in subjects with connective tissue disease at the secondary health care level of communitybased rheumatologists (the UNCOVER study). Arthritis Rheum 2005; 52:2125-32.
- 17. MacGregor AJ, Canavan R, Knight C, Denton CP, Davar J, Coghlan J, et al. Pulmonary hypertension in systemic sclerosis: risk factors for progression and consequences for survival. Rheumatology 2001; 40:453-9.
- 18. Steen VD, Conte C, Owens GR, Medsger TA Jr. Severe restrictive lung disease in systemic sclerosis. Arthritis Rheum 1994; 37:1283-9.
- 19. Highland KB, Silver RM. New developments in scleroderma interstitial lung disease. Curr Opin Rheumatol 2005; 17:737-45.
- 20. Steen VD. Autoantibodies in systemic sclerosis. Semin Arthritis Rheum 2005; 35:35-42.
- 21. Hesselstrand R, Scheja A, Shen GQ, Wiik A, Akesson A. The association of antinuclear antibodies with organ involvement and survival in systemic sclerosis. Rheumatology (Oxford) 2003; 42:534-40.
- 22. Schurawitzki H, Stiglbauer R, Graninger W, Herold C, Polzleitner D, Burghuber OC, et al. Interstitial lung disease in progressive systemic sclerosis: high-resolution CT versus radiography. Radiology 1990; 176:755-9.

Resource efficiency and cleaner production in the olive oil industry

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Abstract

Aim: The olive oil industry generates big amounts of by-products: pomace and waste water that may result in very negative environmental impacts if there are no accu-rate management strategies. The Cleaner Production (CP) is a continuous application of an inte-grated preventive environmental strategy applied to processes and prod-ucts to increase efficiency and reduce risks to humans and the envi-ronment. This study was carried out to demonstrate the application of Cleaner Production Technology in the olive oil industry.

Methods: The CP demonstration was carried out during the period 2011-2012, in an olive oil mill. The methodology used for conducting on-site evaluation of the CP included: i) pre-assessment of the company (description of the company and the processes, input-output analysis through in-terviewing staff of the company); ii) material and energy flow analysis, with the aim to identify pollution sources and the related pollution causes; iii) option generation and feasibility study from technical, economic and environmental view, identification of feasible measures, and; iv) implementation of feasible measures by the company and monitoring of the achieved effects.

Results: The identified CP measures included the following: development of the information system, monitoring and saving of water consumption, improvement of the quality of olives, process modification: installation of the sec-ond centrifuge in the oil deaning process, processing the pomace to be used as fuel (drying and pressing of the pomace), treatment of waste waters before discharging into municipal sewage system (op-tional treatment system "reed bed system" or "constructed wet-land").

Conclusion: This study demonstrates how CP can be implemented successfully in the olive oil industry using efficiently the available resources.

Keywords: cleaner production, economic and environmental ben-efits, olive oil, pomace, waste waters.

The olive oil sector is an important segment of the Albanian agro-industry. There are 130 processing mills and their average size in terms of volume of processed olives per year is small, between less than 100 and 1,500 t/year (1). Regarding the extraction technology, most of mills apply three-phase centrifugation system and only two use dual phases. The olive oil industry generates big amounts of by-products: pomace and wastes water that may result in very negative environmental impacts if there is not an accu-rate management strategy (2). The Cleaner Production is the continuous application of an integrated preventive environmental strategy applied to processes and products to increase efficiency and reduce risks to humans and the environment (3). Resources (water, energy and raw material) can be used more efficiently thus reducing at the same time losses and environmental pollution and improving health and safety. Economic profitability together with environmental improvement is the aim of CP. The CP demonstration was carried out in the dive oil mill, called "Musaj Olive Oil" in the V lora, which mostly provide to farmers the service of processing olives into olive oil, against a fee (80%) and produces and trades "organic olive oil" and "extra virgin olive oil" (20%) for itself. It applies continuous three phase centrifugation system and the production is seasonal from October to March. In 2011-2012 was processed 520 t olives, when 100 t for company itself and 420 t for farmers.

The company has a good performance regarding the food safety & quality, it produces and trades the best categories "organic olive oil", "extra virgin olive oil" and "virgin olive oil, but doesn't know the environmental legislation although it is aware about negative environmental impacts of the olive oil industry. In order to improve its environmental performance and to increase economic profitability the company decided to join us in this CP study.

The aim of this study is to demonstrate how Cleaner Production (CP) can be implemented in the olive oil industry, thus increasing the economic profitability together with environmental improvement. By the extraction process of oil, the following non products outputs are obtained (5): Vegetable waters or waste waters, made up of the vegetable waters of the olives mixed with water added in the process, relatively in high amounts

(approximately 1L/1 kg of olives processed) with high organic loads. These highly polluted waste waters are not treated and are discharged into municipal sewage system (6).

The pomace or solid waste, which is discharged in open area, causes environmental pollution and contamination of the final product (olive oil).

We performed the in site visit in the company during operation, when we took photos and collected the data on process, materials, water and energy consumption. Then we carried out a material and energy flow analysis with goal to identify pollution sources and related pollution causes.

After the evaluation were identified eight CP options for improvement, mainly related to water consumption, optimize the process and reusing of solid waste (pomace).

Among these options, seven were selected for feasibility study as following: Development of the information systems; Installation of water meter for total consumption and for washing process; Reducing the water capacity of washing machine, Improvement of quality of olives; Pavement of the outside part, where is discharged the pomace and covering of waste water channel, Installation of the second centrifuge in the oil cleaning process, Processing the *pomace* to be used as fuel.

Six of above CP measures were implemented until on March 2013 (Table 3). The benefits of the implementation of the CP measures were: reducing the water consumption, reducing the waste water and its pollution load, increasing the production efficiency and quality of olive oil. This study demonstrates how CP can be implemented successfully in the olive oil industry using efficiently the resources.

Material and Methods

The CP is the continuous application of an integrated preventive environmental strategy applied to processes and products to increase efficiency and reduce risks to humans and the environment. Resources (water, energy and raw material) can be used more efficiently thus reducing at the same time losses and environmental pollution and improving health and safety. Economic profitability together with environmental improvement is the aim. CP

typically includes measures such as "good housekeeping", process modifications and control, input material change, on-site recycling or recovery, production of useful by-products or product modification.

The demonstration of application of the CP was carried out, in the olive oil mill, called "Musaj Olive Oil" which operates in Vlora. The period of study was from November 2011 to March 2012 and monitoring of implemented measures during the 2013.

The methodology of CP Audit follows the following steps:

- 1) Pre-assessment (forming of the CP-team, description of the company and the processes, input-output analysis, setting up baseline the baseline data for key performance indicators for selected priority area(s).
- 2) Material and energy flow analysis with goal to

identify pollution sources and related pollution causes.

- 3) Option generation and feasibility study generation of CP options based on the understanding of pollution causes and their evaluation from technical and organizational point of view as well as from the economic and environmental perspective.
- 4) Implementation of feasible measures by the company and monitoring of achieved effects.

Results

The general input-output analysis was performed for the whole company (Table 1), enabling us to set up the priority areas to estimate potential for improvement, respectively: Raw material (olives) and water consumption. In Table 1 are presented data for key input such as olives, water and energy and non product output, such as waste waters and *pomace* which were not turned into desired products, but appear as process losses.

Table 1. General input-output analysis for the whole company

Input	Annual consumption	Unit cost (€)	Annual costs(€)	Included in product (%)	NPO (%)	NPO cost (€)	Total NPO costs (€)
olives	520 ton	714	371429	20% oil			
					40 % pomace	148572	148 572
					40% waste water	148572	148 572
water	643 m ³	0.5	330		100% waste water	330	330
energy	31250 kWh		1786				1786
Fuel	20 m3	7.1	142				142
Cleaning agents (caustic soda)			114				114
Packages materials: Plastic contains 6 L Bottles ½ L Carton boxes	3000 400 100 piece		172,9				
Labels	500 piece						
Filter	10 pack						

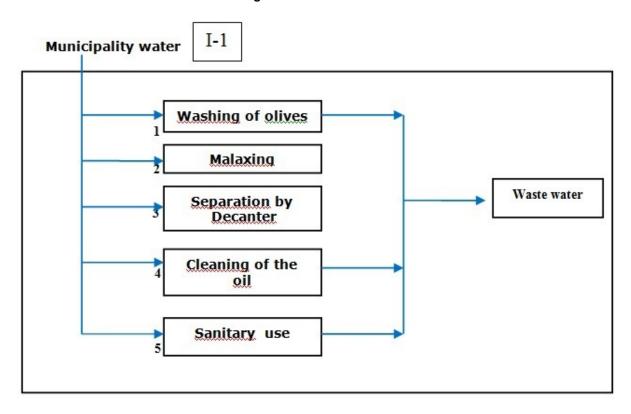
NPO - Non product output - input materials, water and energy which were not turned into desired product (appears as losses, pollution and waste flows)

Diagram 1 presents a flowchart of the industrial process with the aim to identify pollution sources and the related pollution causes.

AREA / INPUTS PROCESSING STEPS EQUIPMENTS OUTPUTS 1.- RECEIVING AREA WEIGHT CONTROL balance Olives manually UNLOADING Pneumatic +moving Leaves, sticks,... stones, soil, other trash screens cleaner CLEANING Cold water 520 L Washing machine Washing water WASHING 2.- EXTRACTION AREA Hammer MILLING Optional (add hot water, Malaxer moisture olives <45%) 80 L MALAXING SEPARATION pomace hot water 500 L 3-phase centrifugal Water + oil Oil +water decanter + sreen filter Waste water Cleaning and separation of oil l vertical high-speed SEPARATION centrifuge Vegetable hot water 120 L (Lack of the second) Discharge waste water Olive oil Cleaning waste water 3.- OIL STORAGE AREA Stainless-steel tanks STORAGE 4. BOTTLING AREA Semi automatic machine FILTERING 6 L container - mamually BOTTLED OIL ½ L bottles - semi automatic machine BOTTLING

Diagram 1: General outline of the industrial oil mill process

Diagram 2. Howchart for water



Worksheet: Water data sheet

Balance scope: Entire company Balance period: 2010 Company: "Musaj Olive oil"

No.	Walter input	Quantity	Unit ²	Data source ³ /notes
I-1	Potable water (Municipality water)	40	m³	Water bill (without metering)

No.1	Water consumption	Quantity	Unit ²	%	Data source ³ /notes
1	Washing of olives	270,4	m ³	42	Calculated
2	Malaxing	41,6	m ³	6.3	Calculated
3	Separation by decanter	260	m ³	40	Meter and calculated
4	Cleaning of oil	62,4	m ³	9.7	Calculated
5	Sanitary use	18	m ³	2.7	Calculated
	Total	643.4		100	

No.	Water output	Quantity	Unit ²	Notes	
	Wastewater discharge	759	m³	Important materials: Important limit values: COD, BOD, T, pH	
	O direct x indirect			Description of on-site wastewater treatment:	

¹ = Position no. from flowchart 3-1

² = Balance in m³ not precise (general assumption: density 1 kg/l)

³ = EDP, books, routine measurement, own measurement, information from production, documentation of equipment, calculation, estimate, etc.

The contamination load of the waste water before and after the implementing the CP measures is shown in Table 2.

Table 2. Waste water contamination load

Indicators	Unit	Before the CP	After the CP	National Norms	
		implementation	implementation		
BOD ₅	mg/l	2950	1577	50 mg /l	
COD	mg/l	4600	2320	250 mg/l	

Based on the general input-output analysis for the whole company were set up the priority areas for improvement and were performed the fea-sibility study for CP generated options. The CP measures identified and their feasibility study and implementation are shown in the Table 3.

Table 3. The feasible CP measures identified in the olive oil

Measures	Cost for implementation	Economic benefits	Environmental benefits	Implementation		
Establishment of the	•	Better management and	Better management and	implemented		
information system	500 €	planning the activity	monitoring of wastes			
Installation of water meters	100 €	Saving and using efficiently the water	Reduction of waste water and its pollution load	implemented		
Pavement of the outside part, where is discharged the pomace and covering of waste water channel	7142 €		Minimize the environmental pollution and avoid oil contamination from foreign odors.	implemented		
Reducing the water capacity of washing machine (Filling in a smaller volume 1500 L / 8 hour by 2000 L /8 hour)	No investment needed	Reduction of the water consumption	Reduction of the waste water	implemented		
Improvement of quality of olives		Reduction of the water consumption, improving the production efficiency and quality of oil	Reduction of the waste waters and its pollution load	implemented		
Installation of the second vertical centrifuge in the cleaning oil process	21 000 €	Reduction of the water and energy consumption, Reduction of the Labor costs, Increasing the production efficiency and quality of olive oil	Reduction of waste waters and its pollution load through reduction of the Phenol (water soluble) and residual oil concentration in generated waste water	implemented		
Processing the pomace to be used as fuel;	82.400 €	Increase the company profits since the processed <i>pomace</i> is very demanded and avoid the cost for manipulation and transport of <i>pomace</i> ,	Reducing the environmental pollution, oil contamination and saving the natural source (energy) by reusing efficiently the by product (<i>pomace</i>).	not yet, it is an long term measure		
Pre treatment of waste water, before discharging into municipal sewage system.	To be decided after identification of the commercially used alternative		Minimizing waste water pollution load: Reducing the environmental pollution	not yet, it is an long term measure		

Discussion

The general input-output analysis in Table 1 shows that the main input are olives, from which are generated greater process losses or wastes, where the only 20 % of olives are returned into the product, while 80% are losses, respectively 40% pomace and 40% vegetable waters.

By the input output analyses we have identified the

raw material (olives) as a priority area for detailed analyses and defining the CP measures. The raw material (olives) should be analyzed in all its processing cycle, from quality of olives up to non products obtained from its processing (waste water and pomace) which constitute the major process losses. Regarding the water, it is used in considerable amounts in the production processes, respectively in the washing, malaxing, extraction and cleaning of oil. The water added in the process, is considered 100 % waste waters and source of environmental pollution, so we have identified *the water consumption as priority* area for detailed analyses and defining the CP measures for improvement.

The detailed analyses of the water consumed is shown in the Diagram 2 and worksheet, where is resulted that are consumed large amounts of potable water. The water input (municipality water, it isn't metered, because there isn't any installed water meter), so the amount of water billed it isn't equal to the water actually consumed.

The water datasheet, regarding the water consumption and waste water discharged, were collected and calculated, by in site survey with help of very experienced manager. So we defined as CP: Installation of water meter for total consumption and for washing and rinsing process (see table 3), since in this process are consumed large amounts of water (42%). A lso, in the washing process are used large amounts of water because of poor quality of olives brought by farmers. In order to save the washing water we defined as CP: Improvement of quality of olives (see table 3). The Cleaning and rinsing process is closed cycle. The washing machine usually is filled in volume 2000 lit/ 8 h or 6 ton and the dirty water is discharged. Also in this process is consumed fresh water for rinsing of olives. During the washing process the water overflow so are discharged 80 lit/ton. In order to manage efficiently the water, we have identified the CP: Reducing the water capacity of washing machine; filling it in a smaller volume 1500 lit/8 hour. By implementing this measure was saved 80 lit / ton or 41600 lit/yr water (see table 3).

The main wastes generated in the olive oil mill are waste waters and solid waste (pomace). The processing of olives produces relatively high amounts of vegetable water (approximately 1lit/1 kg of olives processed). The contaminated load of the waste waters, analyzed in the Public Health Institute have resulted highly polluted before and after implementation of the CP (see table 2). As the waste waters are discharged into municipal sewage system without any treatment, we suggest the optional CP: Pre treatment of waste water before discharge into municipal sewage system. By the literature (UNEP, Regional Activity Center for Cleaner

Production 2000: Pollution prevention in olive oil production), are listed some alternatives on waste water treatment, when we suggest as appropriated the "reed bed system" and "constructed wetland"). Solid waste (pomace) is in considerable amounts and it is discharged into the open area out of the premise. The pomace is considered as process losses, so its processing will be profitable for the company, from economical and environmental point of view. The most of the amounts of the pomace is sold to use as feedstock (fresh) and as fuel, against a modest fee, but if it processed it would be more profitable for the company. The CP is: The processing the pomace to be used as fuel (see table 3).

As shown in Diagram 1, the current process of separation and cleaning of oil, is made by one vertical centrifuge, instead of two as required by three phase decanter technology. So we have identified this CP option: Installation of the second vertical centrifuge in the deaning of the oil process.

This process modification CP measure, despite its high cost, has been implemented immediately, because of the numerous benefits derived from its implementation (see Table 3), such as improving the mill oil recovery efficiency, increasing the production efficiency, reducing the water and energy consumption, improving the quality of oil and reducing the waste waters and its pollution load through reduction of the Phenol (water soluble) and residual oil concentration in generated waste water.

Conclusions

Recognition and implementation of Cleaner Production Technology by the food business operators in the food industry and in the olive oil industry particularly, is very important for its environmental and economic benefits.

Water consumption in the olive oil industry in Albania is relatively high, there-fore CP measures should be implemented for saving and using the water efficiently, such as "good housekeeping" (monitoring and saving the water, using the water meters), process modifications (reducing the water con-sumption in washing machine) etc. Using the water efficiently, reduce the waste water and its pollution load.

From the olive oil mills are generated large amounts of the highly polluted waste waters that are

discharged without any pre - treatment into municipal sew-age system. By literature many options are proposed for treat-ment of olive mill waste waters such as "reed bed system" or "constructed wetland", but their complexity, high capital and operation costs, are limiting factors on the identification and implementation of efficient treatment options.

In this context we recommend as necessity building capacities of the food business op-erators and CP national experts, on identification implementation of the most efficient options for treatment of waste water.

Regarding the technology used in olive oil

production, by literature is recommended that dual phase centrifugation system is the best from the environmental point of view, but this study reports that the three phase centrifugation technology can be used efficiently in small mills (most of mills in Albania are small), if an appropriate management system is put in place for the solid waste (pomace), minimizing the environmental pollution.

We recommend that owners of the mills develop a plan for the collection of the *pomace* in the regional level and it's processing for producing the fuel (briquettes). This initiative needs the financial support by foreign agencies such as UNIDO, in order to improve the environmental performance of olive oil mills.

References

- 1. Studim "Gjendja aktuale e ullishtarisë dhe perspektiva e zhvillimit të saj". Ministria e Bujqësisë Ushqimit dhe Mbrojtjes së Konsumatorit. Tirana, Albania,
- 2. UNEP, Regional Activity Center for Cleaner Production. Pollution prevention in Olive oil production, 2000.
- 3. Regional training: 19-21 March 2012, Greece: "Best environmental prac-tices in olive mill waste management and new technologies". Greece, 2012.
- 4. Dr. Adnan I. Khdair, PM "Cleaner Production (CP) in Olive Oil Industry in Jordan "Integrated Waste Management for the Olive Oil Pressing Industries in Lebanon, Syria and Jordan" UNDP-MoEnv. The 2nd Arab Cleaner Production Workshop, Amman, August 28-30, 2007.

- 5. National Cleaner Production Programme for Albania 2011. Report of Environmental Centre for Administration and Technology (ECAT) Albania. Tirana, Albania, 2011.
- 6. Nicolas Kalogerakis. Chania, Crete, Greece LIFE07/ INF/IT/00438 "Implemented technologies for OMW treatment across the Mediterranean basin The OLEICO + Experience". Greece, 2012.
- 7. Luciano Leonetti, Drini Imami, Andi Stefanllari, Edvin Zhllima. The olive and olive oil value chain in albania .Tirana, May 2009.
- 8. Magali Outters. Towards Sustainable Consumption and Production in the Mediterranean Region. Regional Activity Center for Cleaner Production, H2020 National Training, Albania 30th of June-1st of July 2011.

Child development and Internet use

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Abstract

Aim: This research is an exploratory and descriptive study on the way the Internet use influences the child development. It has three objectives: i) to provide an overview about the spread of the Internet in Albania; ii) to indicate how adolescents' online activities affect their well-being, and; iii) to suggest the efficient ways used by parents to assist children on the problems created by such addictive behaviors.

Methods: The most recent studies of the intersection between technology and development as young people confront and deal with the challenges and issues that are present in their lives were reviewed. Results were presented based on the data from seven countries that are part of the World Internet Project (WIP; see at: www.worldinternetproject.net). The WIP is a global international survey on the impact of the Internet on individuals and societies, coordinated by the Center for the Digital Future at the USC Annenberg School for Communication.

Results: Digital media, such as computers, the Internet, video games, and mobile phones, have come to occupy a central place in the lives of today's youth. It is important to consider the implications of young people's online living, especially for their development and well-being. The Internet is a fundamental tool and, therefore, the particular ways that teens employ the Internet will ultimately determine the effects on their well-being.

Conclusion: Te current review of the literature supports the conclusion that Internet use during childhood is associated with both positive and negative developmental outcomes.

Keywords: child development, information technology, Internet use, well-being.

In today's world, the youth view the internet as the main means of communication for staying in touch with their peers.

Internet use in Albania started in the late 1990s. However, Internet had massive distribution in Albania only after 1997. Actually, the teenagers' use of the internet in Albania does not contrast to the global trend which points to an increase in the number of users.

Table 1 presents the distribution of Internet users in Albania in the past decade.

Table 1. Percentage of Internet users in Albania (source: ITU Statistics, http://www.itu.int/ict/statistics)

2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
0.11	0.33	0.39	0.97	2.42	6.04	9.61	15.04	23.86	41.20	45.00	49.00

According to *Internet World Stats*, in June 2012, more than 2.4 billion people, over a third of the world's human population, have used Internet services. Overall, Internet use has seen tremendous growth, as displayed in Figure 1.

Figure 1. International Telecommunication Union (ITU) (1)

70 **6**5 Developed world 60 ∇ World globally Developing world 50 40 30 20 10 2006 2008 1996 2000 2002 2004 1998 2010 2012 Year * Estimate

Internet users per 100 inhabitants

The Internet users under the age of 25 years represent 45% of the total number of global Internet users (ITU).

The use of the Internet has always had an impact on the development of the youth. The most common question about the use of the Internet is connected with the effects that are caused by the use of this technology in the youth development. The Internet has enabled entirely new forms of social interaction, activities, and organization, thanks to its basic features such as widespread usability and access. In the first decade of the 21st Century, the first generation is raised with widespread availability of Internet connectivity, bringing consequences and concerns in areas such as personal privacy and identity, and distribution of copyrighted materials. These "digital natives" face a variety of challenges that were not present among prior generations. The use of the Internet by the youth has effects in their personal life, the family relation and the way they get along with their peers.

What is the internet?

The Internet is a global system of interconnected-computer networks that use the standard Internet protocol suite (*TCP/IP*) to serve billions of users worldwide. It is a *network of networks* that consists of millions of private, public, academic, business, and government networks, of local to global scope, that are linked by a broad array of electronic, wireless and optical networking technologies. The Internet carries an extensive range of information resources and services, such as the inter-linked hypertext documents of the World Wide Web (WWW) and the infrastructure to support email.

What do youths do online?

Historically, panic surrounds the introduction of new technologies, particularly in relation to children and youth (2). Social network sites, online games, videosharing sites, and gadgets such as iPods and mobile phones are now fixtures of youth culture. They have so permeated young lives that it is hard to believe that less than a decade ago these technologies barely existed. Today's youth is struggling for autonomy and identity as their predecessors did, but they are doing so amid new worlds for communication, friendship, play, and self-expression (3).

Understanding the influence of the Internet

Wedged between childhoods and emerging adulthood, adolescence is a period of tremendous change – biological, psychological, and social. In fact, adolescence is a period characterized as "storm and stress" and this belief remains strong in popular culture and in the minds of many parents (4). Although researchers have come to recognize that adolescence is not always a turbulent period from the storm and stress view, for better or worse, has come to frame much of the discourse about the role of interactive technologies in adolescent life (5). Digital worlds have become a part of adolescent life, and some see it as a threat or obstacle to an already difficult transition.

Changes during adolescence

The biological changes of puberty include rapid changes in height and weight as well as in sexual maturation leading ultimately to adult body size and capabilities, including sexual reproduction. Compared to children, adolescents engage in more advanced and sophisticated thinking, but some aspects of cognitive functioning are still developing, especially those governed by the pre-frontal cortex of the brain. Recent research indicates that these areas of the brain, particularly in parts of the frontal lobe, are still developing during adolescence and are not completely developed until the early 20s or so (6).

The ecology of child development

Ecological theory provides a comprehensive view of environmental influences on development by situating the child within a system of relationships affected by multiple levels of the surrounding environment (7). Bronfenbrenner (8) organized the contexts of development into five nested environmental systems, with bi-directional influences within and among systems. The microsystem refers to direct or immediate interactions (i.e., family, peers, and school). The mesosystem is comprised of connections between immediate environments (e.g., homeschool interactions). The exosystem includes settings that indirectly affect child development (e.g., parent's workplace). The macrosystem refers to social ideologies and cultural values. The *chronosystem* highlights the effect of time on all systems and all developmental processes. As his theory evolved, Bronfenbrenner (9) proposed a bio-ecological perspective, which views the child's biology (e.g., genetics) as part of the microsystem.

Johnson and Puplampu (2008) recently proposed the ecological *techno-subsystem* a dimension of the microsystem which includes child interactions with both human (e.g., communicator) and non-human (e.g., hardware) elements of information, communication, and recreation digital technologies. Presented in Figure 2, the developmental impact of the Internet use during childhood is, theoretically, mediated by techno-subsystem interactions which occur in the microsystem. To illustrate, in industrialized nations, elements of children's microsystem (e.g., home, school, and community) are affected by the Internet (e.g., online communication with peers).

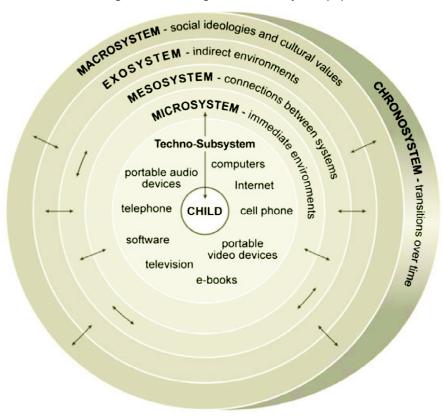


Figure 2: The Ecological Techno-Subsystem (10)

Research questions

- 1- How do adolescents' online activities influence their well-being?
- 2- Does spending time on the Internet make youth obese and lonely?
- 3- Are teens becoming sleep-deprived because they stay up late talking with their friends?

A review and critical analysis of the recent literature In addition to the changing nature of their bodies, adolescents have to deal with many social changes, especially in their relationships with their peers and parents, as well as in their increased autonomy. Perhaps the most vexing question of all is the extent to which time spent online relates to well-being. In the *HomeNet* study, greater use of the Internet was associated with declines in adolescents' well-being and with weaker social ties (11); but in the follow-up study, time spent online was not related to aspects of social networks, such as size of local and distant social circles and amount of face-to-face communication (12). In contrast, Mesch has found that frequent Internet users in Israel were more likely

to report lower levels of attachment to close friends (13). Frequency of the Internet use was also found to be negatively related to adolescents' perception about the quality of family relationships. Yet, other studies have not found a link between adolescents' time online and their dispositional or daily well-being) (14) as well as their loneliness (15).

Extrapolating from findings that use of computers and video games are associated with injuries and changes in physiological arousal, such as heart rate (Subrahmanyam et al., 2000), we expect that Internet use has the potential for injuries and may affect arousal and consider these possibilities next. According to arousal theory, media-induced arousal lingers after exposure, and may have an energizing effect leading to agitation and restlessness in children's behavior (e.g., while playing or interaction with peers) (16); features of media that may trigger arousal include violent content, lots of action, fast pace, and loud music. Meta analyses have confirmed that exposure to violent video increases physiological arousal, generally measured by systolic blood

pressure, diastolic blood pressure, and heart rate (17,18). Although systematic research on the effects of teen Internet use on arousal is lacking, there are indications that the two are related.

Different studies have related the use of the Internet on obesity levels. Relevant to this concern are trends about the prevalence of obesity among youth. In the USA, between 2003 and 2006, 31.9% of children and adolescents between 2 years and 19 years were at or above the 85th percentile of the body mass index (BMI) for their age, with 16.3% considered obese as they were at or above the 95th percentile for their age (19). These prevalence estimates of overweight children and adolescents were found in the 2003-2004 and 2005-2006 National Health and Nutritional Examination Survey (NHANES), a nationally representative sample. According to the CDC, although the rates of obesity have not increased in recent years, the current rates of obesity among adolescents is triple of what it was in the late 1970s (about 5%) (Centers for Disease Control and Prevention, 2004). As obesity increases, the risk for a variety of health conditions ranging from hypertension and osteoarthritis to type 2 diabetes, stroke, and gall bladder disease, current prevalence rates among young people, become all serious public health issues.

Older adolescents start sleeping later and this leads to a new sleeping pattern. According to some studies, teens that spent more time online slept later on weekdays, and during the weekend got up later on the weekend, slept less overall and also reported feeling more tired (20). The aforementioned studies suggest that the use of Internet and other mobile technologies by adolescents may be extending their already delayed bedtime leading to sleep deprivation and excessive sleepiness during the day. Such chronic lack of sleep is not without its costs, some relatively minor and others more serious and even fatal. Chronic lack of sleep among adolescents is associated with mood regulation problems, learning and memory problems, poorer school performance including school tardiness and absenteeism, impulsivity and risk taking as well as substance abuse (21,22).

Main findings from the literature review

The research based on the literature review consists

of the following major findings:

- · Internet may cause psychological effects and, in some cases, may even influence the safety of youth.
- · Youth needs to be educated to use the Internet and mobile devices moderately and safely, and in ways that will not cause harm.
- · When adolescents, particularly younger ones, are not able to self-regulate their technology use, parents must help them and be more proactive.
- · The Internet is a fundamental tool and therefore the particular ways that teens use it will ultimately determine its effects on their well-being.

Discussion

Most youths first start using the Internet at home, which remains an important context where much of their online activity takes place. Adults often view children in terms of developmental "ages and stages," focusing on what they will become rather than seeing them as complete beings "with ongoing lives, needs and desires" (23). Parents therefore have a critical role to empower and safeguard their teen while they are online. Parents' success in this regard will depend on both what they know about objectionable online content and their teens' access to such material, and what they actually do to monitor and limit such access.

Evaluative mediation techniques entail parent and child co-viewing and discussion to evaluate and interpret media content. Specific evaluative mediation techniques that parents can adopt to help children deal with online content include the following (24):

- · Jointly visiting websites and other online content with their children.
- · Having frank and open discussions with their teens about online content, and specifically addressing violent, hateful, and other more harmful kinds of content.
- · Evaluating with their teens online websites and other formats (e.g., music videos, YouTube videos) for violent images, hateful themes, and other negative content.

Restrictive mediation consists of rules regarding media use, specifically parental rules as to the "where," "when," and the "what" content their teens access online (24)

Specific examples of this strategy include the following:

- · Placing the computer in a public space.
- · Having rules about the time spent online.
- · Having content restrictions, in other words, having rules about the kind of content that a teen can consume.

Technological mediation refers to parents' use of technological strategies to mediate their children's use of the Internet. Examples include software to track application usage and browser history, filtering software, and installation of a firewall (24).

References

- 1. International Telecommunications Union, Geneva. Internet users per 100 inhabitants 2001-2011. Retrieved 4 April 2012.
- 2. Johnson GM. Internet use and cognitive development: A theoretical framework. E-Learning 2006; 4:565-573.
- 3. The John D and Catherine T MacArthur Foundation Reports on Digital Media and Learning, November, Living and Learning with New Media, 2008.
- 4. Hall GS. Adolescence: Its psychology and its relations to physiology, anthropology, sociology, sex, crime, religion and education, and education. New York, NY: D Appleton & Company, 1904.
- 5. Steinberg L. Adolescence. New York, NY: McGraw-Hill, 2008.
- 6. Sowell ER, Thompson PM, Tessner KD, Toga AW. Mapping continued brain growth and gray matter density reduction in dorsal frontal cortex: Inverse relationships during postadolescent brain maturation. Journal of Neuroscience 2001; 21:8819.
- 7. Johnson GM. Cognitive processing differences between frequent and infrequent Internet users. Computers and Human Behavior 2008; 24:2094-2106.
- 8. Bronfenbrenner U. Ecological systems theory. Annals of Child Development 1989; 6:187-224.
- 9. Bronfenbrenner U. Making human beings human: Bioecological perspectives of human development, Thousand Oaks, CA: Sage, 2005.
- 10. Johnson GM, Puplampu P. A conceptual framework for understanding the effect of the Internet on child development: The ecological techno-subsystem. Canadian Journal of Learning and Technology 2008; 34:19-28.
- 11. Kraut RE, Patterson M, Lundmark V, Kiesler S, Mukopadhyay T, Scherlis W. Internet paradox: A social technology that reduces social involvement and psychological wellbeing? American Psychologist 1998; 53:1017-1031.
- 12. Kraut RE, Kiesler S, Boneva B, Cummings J, Helgeson V, Crawford A. Internet paradox revisited. Journal of Social Issues 2002; 58:49-74.

- 13. Mesch GS. The family and the Internet: The Israeli case. Social Science Quarterly 2003; 84:1039-1050.
- 14. Gross EF, Juvonen J, Gable SL. Internet use and well-being in adolescence. Journal of Social Issues 2002; 58:75-90.
- 15. Subrahmanyam K, Lin G. Adolescents on the net: Internet use and well-being. Adolescence 2007; 42:659-677.
- 16. Valkenburg PM. Children's responses to the screen: A media psychological approach. Mahwah, NJ: Lawrence Erlbaum Associates, 2004.
- 17. Anderson CA, Bushman BJ. Effects of violent video games on aggressive behavior, aggressive cognition, aggressive affect, physiological arousal, and prosocial behavior: A metaanalytic review of the scientific literature. Psychological Science 2001; 12:353-359.
- 18. Anderson CA. An update on the effects of playing violent video games. Journal of Adolescence 2004; 27:113-122.
- 19. Ogden CL, Carroll MD, Flegal KM. High body mass index for age among us children and adolescents, 2003-2006. The Journal of the American Medical Association 2008; 299:2401-2405.
- 20. Van den Bulck J. Television viewing, computer game playing, and Internet use and selfreported time to bed and time out of bed in secondaryschool children. Sleep 2004; 27:101-104.
- 21. Fredriksen K, Reddy R, Way N, Rhodes J. Sleepless in Chicago: Tracking the effects of sleep loss over the middle school years. Child Development 2004; 74:84-95.
- 22. Tarokh L, Carskadon MA. Sleep in adolescents. In L. R. Squire (Ed.), Encyclopedia of neuroscience, 2008, pp. 1015-1022. Oxford: Academic Press.
- 23. Corsaro WA. The Sociology of Childhood. Thousand Oaks, CA: Pine Forge Press, 1997.
- 24. Eastin MS, Greenberg BS, Hofschire L. Parenting the Internet. Journal of Communication 2006; 56:486-504.

Exploring the ethical scope of health literacy – A critical literature review

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Abstract

Aim: Health literacy is named as one prerequisite of promoting patient education and enabling citizens to take informed choices concerning their own health, as well as for the health of their families and communities. Underlying ethical questions become apparent when the problems of limited health literacy are addressed. This paper intends to provide an overview of ethical aspects of health literacy in public health policy and research.

Methods: The basis for this ethical analysis is a framework of seven biomedical and public health ethical principles: beneficence, non-maleficence, respect for autonomy, efficiency, health maximisation, social justice and proportionality. A systematic literature search was conducted for articles on ethical issues of health literacy.

Results: Only 11 articles dealing explicitly with health literacy and ethical issues were identified. The topics most widely discussed relate to the principles of respect for autonomy and social justice.

Conclusions: Awareness of the ethical scope of health literacy is not sufficiently developed yet in health policy and public health research. The study emphasises that a health system change is required and should be induced in order to secure basic rights, transparency and autonomy and to overcome barriers of health literacy. Following ethical practices to improve health literacy will secure just health care, in both prevention and promotion, and eventually better health for all.

Keywords: autonomy, ethics, health literacy, justice.

The concept of health literacy broadly relates to an individual's ability to place their own health, their family's health, and the health of their community into context. It is mainly concerned with how people understand factors that may influence their health, and how they understand their own ability to control these factors. Over the last two decades many different definitions of health literacy have been published in international literature. Predominantly, definitions of health literacy diverge between the field of medicine and the field of public health. Definitions derived from either field consistently place emphasis on different dimensions of the concept, such as a particular skill or specific type of knowledge ('e.g.'numeracy or knowledge of bioscience). A recent review resulted in an integrative definition, which states: "Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain and improve quality of life during the life course" (1).

Although the concept of health literacy was first used in the 1970's (1), in recent years it has become an emergent topic within both health care and public health settings, and is now a key issue in both EU and US political health agendas. In 2007, the European Commission published 'Together for Health - A Strategic Approach for the EU 2008-2013' (2,3), which emphasized the need to improve EU health literacy and aimed to achieve this by promoting health literacy programs. Similarly, in 2010, the US Department of Health and Human Services outlined its 'National Action Plan to Improve Health Literacy' (4) which argued for a more systematic approach to improving the health literacy of US citizens. The high level of political interest in health literacy follows the emergence of evidence that associates limited health literacy to poorer health outcomes and the possibility of increased financial burden to health systems (5,6). The negative impact of limited health literacy is observable in a broad variety of issues: improper use of medications; inappropriate use or no use of

situations; poorer health outcomes; lack of selfefficiency and self-esteem; financial drain on individuals and society; social inequity (7). These findings are confirmed, and developed, by Berkman et al. (6) in a comprehensive systematic review of low health literacy and health outcomes. Berkman et al.'s (6) review was also able to demonstrate a disparity between social groups in their ability to understand, evaluate and apply health information within different settings, demonstrating that this can be multifaceted and the result of a variety of different causes.

For any individual with limited levels of health literacy "the capacity to make sound health decision's in the context of everyday life" (8) can be hampered. This can influence life "at home, in the community, at the workplace, in the health care system, the market place and the political arena" (p. 8) (8) and thus raises the following ethical concerns:

- · Is limited health literacy and related problems only the concern of the individual or is it the responsibility of society and the health system to address?
- · What ethical values are relevant to this argument and how can they be used to interpret issues of health literacy?

In spite of the developments in the field of health literacy, little attention has been paid to identifying the ethical issues pertinent to addressing the problem of limited health literacy. This paper attempts to address this issue, performing a review of the literature on health literacy that either directly discusses or indirectly highlights moral issues of limited health literacy. Results are discussed within a combined biomedical ethical and public health ethical framework in order to provide ethical criteria that are easily transferred to either a medical health care or public health setting. Findings may serve as both a point of orientation for literature discussing ethical considerations of health literacy, or as guidance for policy makers, public health professionals and health care professionals when facing potential issues of morality associated with limited health literacy.

Methods

Data were collected through a systematic literature review of the following databases and online resources: PubMed, GoogleScholar, BELIT, Stanford Encyclopedia of Philosophy, and

health services; poor self-management of chronic conditions; inadequate response in emergency Routledge Encyclopedia of Philosophy. The following search items were used in different combinations to identify relevant academic work: "ethics", "health literacy", "health competences", "health communication", "health skills", "health abilities", "health education", "respect for autonomy", "autonomy", "social justice", "justice", "efficiency", "respect for human dignity", "social utility', "proportionality". After excluding articles that were not written in English, German, Danish, Norwegian or Swedish, 11 articles remained. The content of each article was then scrutinised in order to identify ethical issues that were relevant to health literacy. Ethical issues that were judged to be relevant to the conceptual dimensions of health literacy where then assessed using a combined biomedical and public health ethical framework.

Biomedical ethical and public health ethical framework

The theoretical framework used for the analysis combines the four principle approach for biomedical ethics by Beauchamp and Childress (9), with the five principles approach of public health ethics proposed by Schröder (10). This synthesis yields an analytical framework of seven core ethical principles: beneficence, non-maleficence, respect for autonomy, health maximisation, efficiency, social justice and proportionality. These seven principles address all dimensions of health literacy derived from the fields of medicine and public health. The use of the combinatory biomedical and public health ethical framework improves the sensitivity of the ethical analysis to issues derived from both medicine and public health, and therefore, enhances the relevance of findings to health policy development, and to either medical or health care settings. Beauchamp and Childress' (9) four principles frame ethical issues derived from the biomedical realm: respect for autonomy, non-maleficence, beneficence and justice. 'Respect for autonomy' demands that an individual's (negative) freedoms are not violated but rather a person can decide about his or her own life. It demands that there should be no interference with personal choice, as long as this does not have negative impacts on others. 'Non-maleficence' concerns the health professional's obligation not to cause harm to the patient. Whilst 'beneficence' is highly associated with non-maleficence, beneficence more closely mirrors the core of the Hippocratic Oath in that it prioritizes helping the patient. Therefore, when the advantages and disadvantages of health interventions or treatments are judged under beneficence, the benefit to the patient should be of primary concern. The last principle, 'justice', demands that benefits, risks and costs are fairly distributed among patients, health care professionals and all other persons involved (9).

Schröder's (10) five principles of public health ethics are health maximisation, respect for human dignity, social justice, efficiency, and proportionality. The first principle of 'health maximisation' corresponds, on a social level, to the individual ethical principle of 'beneficence' proposed by Beauchamp and Childress (9). It concerns the maximisation of the overall health of the whole population (or subgroup of the population) for the primary goal of increasing the well-being and utility of all. The second principle, 'respect for human dignity', helps protect the individual's rights by respecting individuals' free will. It includes the avoidance of constraint, promotion of self-determination and respect of informed consent. Under this principle, respect for free will is considered to be a duty that also helps to prevent individuals from being used (only) for the benefit of others. This principle is highly relevant to Beauchamp and Childress' (9) principle of 'respect for autonomy' and can be considered as (approximately) synonymous with it. The principle of 'social justice' is balanced with 'health maximisation' which helps to mediate between action that prioritizes overall health gains and action that priorities fair distribution of advantages and disadvantages (i.e. equitable distribution). A strong theme of social justice is to demand the reduction of health inequalities to empower individuals and high risk social groups to gain access to health promotion and maintenance programmes. Social justice also encourages non-discrimination and stigmatisation of disadvantaged social groups. In this respect, empowerment also demands that health information should be accessible to all individuals, that public health decisions are made transparent, and that individuals are free to participate in any related health action. The principle of social justice is incorporated into Beauchamp and Childress' (9)

principles under 'justice. 'Efficiency' is important as public means are frequently limited. Therefore, the efficient distribution of resources should be considered a moral duty, which can help guarantee that the greatest net benefit for all is attained. It especially applies to the area of research that encourages public health practitioners to use costbenefit analyses and evidence-based methods for public health interventions. The last principle of 'proportionality' can primarily be understood to, where possible, use the least infringing of all options to act. Furthermore it can be seen as a crosssectional principle that should be applied to all other principles to balance them well against each other (10).

When excluding duplicate or overlapping principles, a set of seven core principles remain, thus forming the biomedical ethical and public health ethical analytical framework: beneficence, non-maleficence, respect for autonomy, health maximisation, efficiency, social justice and proportionality.

Results

The literature review identified 11 relevant scientific papers dealing with ethical aspects of health literacy, which are shortly introduced. Loss and Nagel (11) focus on ethical conflicts arising in health communication. They propose their own framework of ethical criteria needed to assess health communication. Volandes and Paasche-Orlow (12) summarise empirical evidence of the association between health literacy and poor health outcomes. They elaborate on how limited health literacy is an outcome of injustice in the healthcare system. Along these lines Goldberg (13), Banja, (14), Schillinger (15) and Trachtman (16) offer similar arguments on health literacy and poor outcomes (12). Goldberg (13) refers to ethical conflicts that arise in clinical research with subjects. Schillinger (15) argues that literacy is a broader issue that is not only confined to areas within the healthcare system. It also affects disenfranchised populations and therefore relates to a wider injustice occurring outside the healthcare context. Banja (14), Trachtman (16), Marks (17) and Gazmararian et al. (18) are especially concerned with the clinician's role with respect to the levels of health literacy of their patients. Both Marks (17) and Banja (14) identify strategies to reduce the negative impact of low health literacy among different groups. Banja (14) for example describes four barriers to health literacy: impact of illness on cognition, inadequate medical knowledge, medical jargon and medical uncertainty. The author also proposes guidelines to help physicians and their patients in overcoming these barriers. Pirsi (19) and Wilson (20) highlighted ethical issues arising from the influence of health literacy levels on health outcomes. Pirsi (19) addresses the issue of inequality in access to care due to varied levels of health literacy. Sass (21) discusses health literacy with respect to health care policy, the status of health care, and health insurance. He points out that there is a moral obligation to empower patients, promote their health literacy, and promote their general health competence.

The ethical aspects were identified and scrutinized according to the seven ethical principles outlined in the analytical framework. The results of the assessment is outlined in Table 1 and described in detail in the following subsections.

Table 1: The characteristics of ethical concerns of health literacy identified in the literature review

Ethical principles	Explanations	Ethical concerns of health literacy identified in the literature				
Beneficence	Maximise health of the individual, Hippocratic oath of helping the patient	Communication gap Physician' unaware of her responsibility Lack of skills of the patient Negative impact on health outcome				
Non- malefincence	Do not harm the individual, Doctor's obligation to not harm the patient	Harmful consequences of low health literacy: • low health, knowledge, • lack of understanding of medical forms and instructions, • increased chronic disease and mortality rates, • limited prevention use, • adherence problems, • compromised information, improper medication use, • missed appointments, • loss of access entitlements, • unwarranted fear, • compromised health outcomes, and • misjudgement of information.				
Respect for autonomy	Respect the free wills and decision making capacities of individuals	Loss of autonomy Compromise rights to health Impairs self-determination Risk of victim blaming Manipulation instead of means of empowerment				
Efficiency	Use the scarce resources effectively	Economic burden in terms of poor or unrecognised levels of health literacy High program costs to improve health literacy skills. Tax revenues of tobacco to pay for promotion				
Health maximisation	Net benefit for the whole population	Impaired political decision-making Inefficiency Lack of knowledge Need of systematic, systemic change Introducing principles of education, solidarity, responsibility and active participation to health systems.				
Social justice	Avoid discrimination, stigmatisation, unfairness and exclusion	Unfair system design Unequal access Increased divide between advantaged and disadvantaged groups Disadvantaged groups such as minorities, elderly and mentally disabled Stigmatisation and discrimination Need for transparent information Incorporating people in programmes Solidarity and responsibility				
Proportionality	The probable public benefits should outweigh the infringed general moral considerations	Distortion and scandalising of health in media				

Beneficence

In relation to beneficence, many of the authors have argued that it is the responsibility of physicians to recognise limited health literacy in their patients and thus to communicate health information according to the patient's level of health literacy. Thus, patients will be able to benefit more from health information (14-18, 20). Gazmararian et al. (18) states that the ethical responsibility of physicians is to formulate health information in a way that is unambiguous to the patients. However, they also stress that such communication issues "address only the 'side effects' of limited health literacy without addressing the underlying problem" (p. 319) (18). In their view, it is necessary to identify people of limited health literacy and educate them in such a way that they become health literate or have the ability to become health literate. The improvement in people's health literacy will simultaneously help improve health, and therefore, is in line with the principle of beneficence. Marks (17) identifies health literacy as a relevant outcome predictor for how well patients are informed and educated by their physicians. If a doctor tried to identify the health literacy level of a patient and adapted the way they communicate health information to them, this would be visible in the degree to which the intended health outcome was achieved. Pirsi (19) proposes that the problem consists of two features: (i) patients are not usually familiar with the vocabulary used by physicians; (ii) physicians are not always aware of this problem. In this respect it would be beneficial for patients if doctors could communicate with them in a way that is in accordance with their own level of health literacy. From this context Wilson (20) points out that doctors should never expect their patients to be health literate and thus to be able to fully understand their advice. Sass claims that health is not merely a status, but "more a balanced result of health-literate and risk-competent care of one's own physical, mental, emotional, and social well-being" (p. 563) (21). Because of this association, Sass implies that a person's health status is directly linked to a person's level of health literacy.

In summary, the main ethical concern under the principle of beneficence is the existence of a communication gap between health professionals and patients. The patient may not have the skills to fully comprehend the health information they are given and the physician may not be aware of their responsibility to communicate this information in a way that can be understood by the patient. Since patients with limited health literacy may not fully meet the conditions set out by the physician for a particular intervention or treatment, then there is the possibility of an impact on health outcomes.

Non-maleficence

Volandes and Paasche-Orlow, (12) Marks (17), Pirsi (19), and Wilson (20) provide numerous examples of how limited health literacy can negatively influence disease outcomes in a medical setting and lead to poorer levels of health. In particular, the possibility of misunderstanding medication instructions was identified as a major problem associated with limited health literacy that can negatively impact health outcomes and result in poorer health. This contradicts both the principle of non-maleficence and the principle of health maximisation. Volandes and Paasche-Orlow (12) also note that in numerous studies health literacy has been shown to be a more important outcome predictor of health status and health related behaviour than ethnicity or education. They state that "limited health literacy is associated with low health knowledge, increased incidence of chronic illnesses, poorer intermediate disease markers and less than optimal use of preventive health services" (p. 6) (12). Marks (17) lists various problems arising due to poor health literacy: adherence, compromised information and health care seeking practice, compromised and adverse health outcomes, improper medication use, missed appointments, loss or inability to access entitlements and unwarranted fear (19). Wilson (20) considers the strong link between poor health literacy and chronic illnesses and communicable diseases since the incidence of chronic illnesses is higher among the health illiterate. Similarly, mortality in chronic and communicable diseases is also higher with the health illiterate. Trachtman (16) criticizes biomedical research for not fully accounting for the effect of health literacy. Patients' knowledge gaps of fundamental health information lead to misjudgements miscalculations of risk when evaluating biomedical research on therapeutics. Sass (21) stresses that people often obtain misleading information from the internet that is frequently incorrect, which might also lead to worse health outcomes.

Accordingly, the primary ethical concern of non-maleficence is that severely negative health consequences may occur when practical issues of health literacy are not taken into account e.g. by healthcare providers.

Respect for Autonomy

First, it is important to note that an improvement in health literacy can increase individual autonomy and decision-making capacities (12). Yet, there are still ethical issues that conflict with respect for autonomy, which arise from the methods used to enhance health literacy. Volandes and Paasche-Orlow (12), Gazmararian et al. (18) and Schillinger (15) point out the general problem that patients with limited health literacy may not understand basic health information such as that contained within medication package inserts. Consequently, they experience a loss of autonomy as they are not able to make fully informed decisions concerning the use of their medication. Several authors emphasize the impact that this problem can have when patients provide informed consent as patients with limited health literacy are often unable to understand consent forms (12,13,17). Volandes and Paasche-Orlow (12) apply this issue to simple educational materials such as the explanation of benefit services, notices of privacy protection and advanced directives, which can often be written in language that is too complex for most people to comprehend. These issues highlight that patients with limited health literacy cannot always provide informed consent, an issue that Goldberg (12) suggests can impact clinical trials. The inability to understand the terms and conditions of a clinical trial can lead to the exclusion of a subject. Therefore, subjects with limited literacy may be more frequently excluded from trials and in turn may bias the trials' outcomes. Schillinger (15), Marks (17) and Wilson (20) further describe how impaired health literacy affects patients' ability to understand their rights and entitlements in health care. In this respect, Wilson (20) argues that people with low health literacy are often unable to express themselves orally and describe what they need. Consequently, patients often do not gain access to medical

procedures that they require and are entitled to receive. Moreover, Schillinger (15) argues that limited literacy in verbal communication impairs the ability of patients and doctors to make decisions together. This can also further inhibit the patient's ability to apply technical information relating to self-care and thus limit the patient's self-determination. Trachtman (16) discusses the problems of only viewing patient autonomy as positive. Often patients have to take decisions by themselves without being sufficiently informed of their options, thus patients may actually lose some autonomy. Loss and Nagel (11) address ethical conflicts that might arise when formulating and promoting health messages. When messages specify a target group they can sometimes be interpreted as accusatory (i.e. victim blaming), and therefore, undermine the human dignity of the target group. The same issues arise when some health messages use manipulative methods over methods of empowerment. Sass (21) accuses current health systems worldwide of not doing enough to empower their patients to be able to avoid health risk and act responsibly with their own health, an issue that Sass argues is evident within developed countries. However, the disease management and insurance systems of poorer countries are not fully developed and there is often inequality in the access of services. Consequently, such systems may withhold their citizens' basic right of education and self-determination within the sphere of health (21). Hence, the main ethical concerns when considering respect for autonomy relate to methods of informed decision making that can impair selfdetermination and enhance the risk of victim blaming. In addition, when considering preventative health care, the patient's autonomy is undermined when methods are designed to manipulate rather than to empower the patient.

Efficiency

Loss and Nagel (11), Marks (17), Wilson (20) and Sass (21) considered ethical issues that arise when addressing issues of health literacy under resource constraints. Loss and Nagel (11) describe the need to be highly cost efficient in health literacy programs as the costs of interventions to improve health literacy should, ultimately, relate to their utility. Marks (20) identifies the problem of higher health care

costs as a result of poor or unrecognised health literacy. According to Wilson "poor adherence and high hospitalisation rates among people with low health literacy, along with related factors" (p. 875) (20), are responsible for costing the American health care bill an extra \$30 to \$73 billion annually. Sass (21) identifies the positive influence that improving health literacy can have on the efficiency of health care. A more active role for citizens that take greater responsibility for their health in all areas, including disease prevention and health promotion, can improve the efficiency of health care.

Accordingly, the literature reveals that limited levels of health literacy can result in an increased economic burden for the provision of health care. However, an investment in advancing health literacy by promoting and maintaining skills so that patients may take a more active role in their health may be hampered by the high cost of health literacy programs.

Health maximisation

Trachtman (16) and Sass (21) are concerned with the broader influence of limited health literacy on the whole of society. Trachtman (16) states that "health illiteracy is merely one symptom of a broader devaluation and ongoing political assault on science as a worthwhile discipline" (p. 28). He believes the core issue of limited health literacy is a general, widespread deficiency of the population's knowledge of bioscience. Trachtman (16) reasons that this is most likely due to political decisionmaking. For Sass (21), improvements in patient health literacy enhances the efficiency of health care systems as patients take on a more active role in decisions concerning their health care, health promotion and disease prevention. Consequently, improving health literacy simultaneously contributes to health maximisation. According to Sass (21), current health systems are ineffectually organised into institutions and financed by insurance providers. They are frequently too focused on the treatment of disease, rather than prioritizing health promotion or disease prevention activities. Sass (21) claims that a restructuring of the system of insurance and health providers is needed in order to promote the principles of education, solidarity and responsibility. Principles which Sass (21) identifies as cornerstones

of a more effective system of the future.

Therefore, the ethical considerations of health literacy, required under the principle of health maximisation, should account for impaired political decision-making, inefficiency within systems and a general lack of bioscience knowledge throughout populations.

Social Justice

Ethical issues concerning social justice were discussed by all authors except for Banja (14). Generally, inequality of access to health care services in individuals with limited health literacy was identified by the authors as the main issue of social injustice. The reasoning behind this was that information is either too difficult to access or too difficult to understand for people with limited levels of health literacy. Loss and Nagel (11) argue that people with limited education are excessively demanding within health care systems yet, their access to health information is limited. Loss and Nagel (11) emphasize the importance of making health information and health campaigns transparent so that people with limited health literacy are able to assimilate the information provided. Despite this, it is also important to consider the population as a whole when developing health literacy programmes. This ensures that interventions do not inadvertently, and unfairly, impact upon populations removed from the issue of health illiteracy. Loss and Nagel (11) suggest that in the context of social justice, health communications may be both positive and negative. Population wide health communications might lead to an improvement in the health of socially disadvantaged groups. However, the communications may overly benefit socially advantaged groups which are more able to assimilate the health information due to higher levels of health literacy. Therefore, a population wide health communication might negatively impact the level of inequality between the two groups, and thus, facilitate a social injustice. Volandes and Paasche-Orlow (12) expand on this type of social injustice and argue that it is unfair that the health care system "is organised for the most literate and powerful members of our society". Gazmararian et al. (18) also consider how people with the greatest healthcare needs are often those who are unable to

process the information needed to benefit from their respective health care system. Marks (17) builds on this topic, discussing how limited health literacy inhibits the patient's ability to gain access to information relevant for the treatment of their illnesses. He considers limited health literacy as a barrier to equality in the access of care. Wilson (20) connects the health literacy barriers associated with health insurance applications to an inability of patients to access care.

Another problem relates to limited health literacy in disadvantaged groups. According to Marks (17), minority populations struggle more with information and services that are not appropriate for people with limited health literacy. Furthermore he argues that health educators should be providing services that are equitable to all (17). Wilson (20) outlines disadvantaged groups, such as ethnic minorities, where health literacy levels are considerably lower. In these groups it is stated that low levels of literacy are the "result of cultural barriers, language variations, and differing educational opportunities" (p. 876). The socially disadvantaged, mentally disabled, or the elderly may suffer more from limited health literacy. Schillinger (15) addresses this problem and allocates responsibility for limited health literacy to disenfranchised populations outside of the healthcare system who may only occasionally interact with it. Trachtman (16) also identifies that poorer patients are not offered the same treatments or tests as provided to other, richer patients. Goldberg (13) discusses the issue in the context of clinical trials, arguing that some people who "bear a disproportionate burden of disease are dramatically underrepresented in clinical research" (19), possibly due to difficulties in understanding and agreeing to informed consent forms. Such documents are often too long, complicated or entail too many technical terms to be understandable for patients with limited health literacy. Therefore, it can be considered to be an injustice that these groups are not given more attention. Finally, Loss and Nagel (11) and Pirsi (19), touch upon the problem of stigmatisation and discrimination. This can become an issue when health campaigns display certain negative health behaviours in a humorous way, a practice that can make particular social groups appear 'foolish'. Sexual images may also be used to communicate health messages and thus, can inadvertently impact some social groups (i.e. women) more than others (11). Pirsi (19) sees the stigma attached to people with limited health literacy as a barrier that prevents them from making full use of services and treatments.

Hence, the principle of social justice is associated with numerous concerns with respect to health literacy. It emphasises that the design of healthcare may be unfair and favour social groups that are better off in terms of income or education. Furthermore, when improving health literacy there may be a divide in gains between advantaged and disadvantaged groups that leads to a disproportionate benefit to advantaged groups. Health literacy programs should consider any impact on levels of inequality affecting disadvantaged groups such as minorities, the elderly or the mentally disabled. Limited health literacy can induce a risk of stigmatisation and discrimination in relation to health initiatives.

Proportionality

The principle of proportionality was only addressed by Loss and Nagel (11) and Schröder (10). The authors discuss the principle connecting it to the distortion and scandalising of health issues within the general media. Therefore, issues of health literacy can also apply to methods used to communicate health information to the public, and not only to the health information itself. Scandalising and distortion of health issues in the media can lead to panicked populations, which would not benefit the overall health of the public.

Discussion

The ethics of health literacy is an area of research that is still in its infancy. This is shown by the limited volume of literature attained from the field of health literacy that explicitly discusses issues of morality. The number of occasions where authors have cited each other's work also demonstrates how limited the development of this field has been.

The article by Loss and Nagel (11) focussed primarily on ethical issues concerning the provision of health information and the channel through which it is communicated. The article only indirectly addresses 'health literacy'. For instance, the authors discuss a

variety of problems which they suggest are the result of patients misunderstanding health information. They also discuss relevant moral issues, arguing that health information is a basis for patient empowerment as it enables patients to make their own decisions. However, they do not directly identify or comment on 'health literacy' and just infer (indirectly) that elements of health literacy are important and influential factors of health care.

The article by Volandes and Paasche-Orlow (12) appears as a primary article to which the articles by Goldberg (13), Banja (14), Schillinger (15) and Trachtman (16) relate. It is one of the most detailed articles in the field of ethics and health literacy. The authors are primarily concerned with the issue of justice and the position of the least well-off in health care systems. Contrary to Loss and Nagel (11), Volandes and Paasche-Orlow (12) raise the issue of individual decision making within health care settings and criticise ongoing processes that give more responsibility to individuals. They claim that this does not make the system less complex and more easily accessible since the least well-off, in terms of health literacy, may not have the capacity to make such decisions. Volandes and Paasche-Orlow (12) state "poor health outcomes deriving from limited health literacy ought to be understood as a fundamental injustice of the health care system" (p. 5). According to them, the health care system should be organised in a way that most benefits users with limited health literacy. The approach of Volandes and Paasche-Orlow (12) only concerns the principle of 'social justice' in the proposed framework of this paper. Thus, their discussion on ethics in health literacy is limited to just one domain. This is criticised in articles by Goldberg (13), Banja (14), Schillinger (15) and Trachtman (16), where it is argued that wider ethical issues should be considered.

Generally, the articles discuss health literacy from a medical and health care perspective. Therefore, dimensions of health literacy derived from public health definitions of health literacy are often not addressed. Banja (14) interprets the discussion by Volandes and Paasche-Orlow (12) as only focusing on the situation of socially disadvantaged groups, instead of paying more attention to how limited health literacy affects all patients. Whilst Banja (14) focuses on the medical context, and in particular to the role of health professionals, Banja (14) also stresses how important it is to consider ethical values in health literacy, even if this seems incongruous at first glance.

Goldberg (13) supports the approach taken by Volandes and Paasche-Orlow (12) to improve health literacy levels in the population in order to reduce poor health. However, he also argues that the approach is a micro-level intervention that will not touch upon the underlying problem of limited health literacy. Goldberg (13) claims that socio-economic disparities are a primary cause of limited health literacy, which in turn may lead to poorer health outcomes. Thus, he questions if interventions intended to address social determinants of health do not also simultaneously address health literacy. Goldberg (13) suggests that narrowing socioeconomic disparities through macro-level interventions, while simultaneously attempting to address issues of health literacy directly (i.e. at a micro-level), may lead to better health outcomes.

Schillinger (15) is a proponent of the approach by Volandes and Paasche-Orlow (12), however, Schillinger (15) also argues that their perspective is too narrowly focused on the health care system. Limited health literacy in underprivileged populations is the result of a basic form of social injustice which occurs outside the health system but might only manifest itself in a clinical context. If physicians' were to share this opinion, they may limit themselves in promoting the health literacy of their patients because the problem may appear to be beyond their capacity to act. However, Schillinger (15) does not elaborate on this claim, and instead, focuses on the issue of ineffective communication and how this might influence health outcomes. Schillinger (15) also discusses how health care systems and clinical trials can act to improve health outcomes when included in strategies to improve communication. However, the article does not provide any further insight into issues of morality concerning health literacy. It only provides examples relevant to principles of social justice and autonomy.

Trachtman (16) criticises Volandes and Paasche-Orlow (12) for concentrating primarily on the socioeconomically deprived when addressing groups with limited health literacy, a view that is also

shared by Banja (14). Trachtman (16) claims that all patients experience shortcomings in health literacy, arguing that the ongoing "medicalization of contemporary life" (p. 27) increases the number of options for diagnosis and treatment. An effect that requires patients to perform increasingly more comprehensive evaluations of health information. As patients frequently lack general knowledge of the biosciences they are not always able to manage their own health, which in turn leads to a loss of autonomy.

Gazmararian et al. (18) points out that health information is only useful if the intended audience is capable of accessing it, and understanding it. Gazmararian and colleagues (18) provide a broad and comprehensive definition of health literacy, where they introduce the concept of functional health literacy. They elaborate on a set of steps which act at multiple levels to improve health literacy amongst the population, and ultimately, achieve a public health literate society. These steps demand the following action: to define and measure levels of health literacy, to evaluate communication techniques (especially those of physicians), to be aware of other influential factors on behaviour change, and to encourage collaboration between all stakeholders. Gazmararian et al. (18) actually anticipate most of the problems raised by Volandes and Paashe-Orlow (12), Goldberg (13), Banja (14), Schillinger (15) and Trachtman. They argue that closing the gap in health literacy provides advantages for the groups at highest risk and will also benefit the population as a whole. Whilst they state that this will improve overall health, they also argue that the underlying problem must be addressed instead of just 'treating the symptoms' of limited health literacy. The main shortcoming of the article was that it focussed on the "ethical responsibility to clearly communicate information that affects the public" (p. 319) (18) rather than discussing in detail which ethical challenges might arise from issues of health literacy.

Marks (17) primarily focuses on the role of health educators in bridging the gap between limited health literacy (and other cross-cultural factors) and the negative impact this can have on health outcomes. He provides a detailed description of the different aspects of health literacy, outlines the key problems that arise from it, and identifies the most likely social

groups to have limited health literacy. However, whilst the problems identified may be relevant to ethical principles, these principles are not discussed in the article. For example, Marks (17) describes issues of limited health literacy and how they may result in impaired decision making, diminished ability to critically reflect on situations, and reduced selfmanagement. These issues are all relevant to the principle of respect for autonomy, however, this is never discussed within the article. He also refers to peoples' dignity, which is diminished if health literacy remains unrecognised, or if the delivery of health messages (particularly to diverse groups) does not ensure equity. Though the article states that it discusses the ethics of patient education, a profound ethical discussion linked to any ethical theory is missing. Pirsi (19) summarises the findings of health literacy research concerning the physician's role, access of care and the influence of limited health literacy on health outcomes. She also discusses how other factors relate to health literacy, such as cultural, language and age related factors. Pirsi (19) argues that it is the responsibility of physicians to communicate medical information in a way that is understandable to patients. However, as identified by Goldberg (13)

Wilson (20) elaborates on the association between health literacy and health outcome, summarising the results of previous studies addressing this association. Many of these factors are linked to the ethical principles applied in this paper. She also proposes reasons for the limited health literacy of certain risk groups. However, this article also focuses primary on the physician's role.

no discussion is made of the underlying causes of

health literacy, therefore, the strategy may only

address the surface of the problem.

Sass (21) argues in favour of changing the current organisation of health care systems worldwide. He critically assesses the current systems, especially those of Germany and the United States, for being based only on the principle of solidarity. He argues that health care systems should instead be built upon a combination of new principles namely "education, solidarity and responsibility" (p. 563) (21). In any system based on these principles, Sass (21) stresses that health literacy will have significant value. He suggests that health literacy will enable patients to make autonomous decisions concerning their health,

and therefore, encourage them to act in an educated and responsible way for their own benefit and for the benefit of their community (solidarity). Sass (21) also emphasizes the responsibility of governments to change current health care systems so that they are able to function more efficiently and encourage educated patients to take greater responsibility of their own health care. He further accuses the current healthcare systems of not recognising the individual's right to decide on their own care and argues that health systems should instead promote selfdetermination in patients. However, contrary to Sass's (21) opinion, the problem of health literacy may lie elsewhere. In recent years, patients have actually received (and taken) more opportunities for decision making regarding their own health care. The problem however, is that many patients are still unable to make such decisions due to their limited health literacy.

Limitations of the theoretical framework.

Only articles published in English, German, Danish, Norwegian and Swedish could be considered. While using the framework to analyse the sampled literature it became clear that some issues could be allocated to more than one ethical principle. For example, limited health literacy leading to poorer health outcomes is connected to the principles of non-maleficence, health maximisation, and the principle of social justice (people with higher health literacy levels often experience better health outcomes which is an injustice). It is also clear that by applying the proposed ethical framework of the seven principles, the attention was drawn to specific dimensions of moral issues within health literacy that might have resulted in the neglect of other ethical issues that are still relevant to the topic. Furthermore, only articles that explicitly discussed ethical issues were considered. Other ethically relevant issues that were implicit may have inadvertently been omitted. Finally, some of the aspects of health literacy that were ethically evaluated in the sampled literature were often built upon assumptions made by the authors, and were not evidence based. For example, some authors assumed that health care systems may become more efficient when the health literacy of the population was improved (6). Therefore, one should remain critical of some of the aspects that are discussed.

Conclusions

This paper has provided an overview of ethical concerns currently discussed in the area of health literacy. The ethical scope was developed on a framework based upon seven principles combining both biomedical ethics and public health ethics: beneficence, non-maleficence, respect for autonomy, health maximisation, efficiency, social justice and proportionality. In accordance with the theoretical framework, a critical literature review provided eleven articles explicitly concerning both health literacy and ethical issues. Respect for autonomy and social justice were the principles most widely discussed however, some issues that were identified could not be allocated to just one ethical principle. This illustrates that the separations of principles or domains of public health and biomedical

cannot be considered as rigidly set. This is especially true if onewould separate the biomedical or clinical world (of patients) too rigidly from the world of public (population) health. Rather, the division of these domains within the context of health literacy, which appears to be relevant to all fields of health, requires a holistic discussion and should therefore not be too strict.

The results of this critical review of ethical issues emerging from the health literacy literature calls for action in several key areas. First, there is a need to improve health literacy in order to overcome or change current disease and mortality patterns that are associated with limited health literacy. Second, health professionals must adapt their role to meet the health literacy needs of patients and their communities. The physician must develop the skills needed for overcoming limited health literacy and take greater responsibility for promoting health literacy in their patients and their communities. Third, patients should be encouraged to take a more active role in shared decision-making, self-management and selfdetermination in order to improve personal health literacy. Fourth, there is a need to change the unjust design of health systems to account for health literacy and avoid compromising basic rights to health.

The ethical scope of this paper serves as a starting point for decision makers that wish to stimulate action to improve public health literacy in response to the moral obligation, and growing political relevance, of this issue. The findings of this review support the argument that health system change must be induced to overcome barriers of health literacy. Such change will secure basic rights, promote transparency and deliver autonomy in providing more just health care to the benefit of all.

References

- Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, Brand H. Health literacy and public health: A systematic review and integration of definitions and models. BMC Public Health 2012;12:80.
- European Commission. Together for health: A strategic approach for the EU 2008-2013 (Commission staff working document: Document accompanying the White Paper). 2007 (cited 2011 Jan 24). Available from: http://ec.europa.eu/health-eu/doc/working_doc_strategy.pdf.
- European Commission. Together for health: A strategic approach for the EU 2008-2013 (White Paper). 2007 (cited 2011 Jan 24). Available from: http://ec.europa.eu/ health/ph_overview/ Documents/ strategy_wp_en.pdf.
- U.S. Department of Health and Human Services. National Action Plan to Improve Health Literacy. 2010 (cited 2013 Apr 13). Available from: http://www.health.gov/communication/hlactionplan/pdf/Health_Literacy_Action_Plan.pdf.
- Berkman ND, Dewalt DA, Pignone MP, Sheridan SL, Lohr KN, Lux L, Sutton SF, Swinson T, Bonit AJ. Literacy and health outcomes. Evid Rep Technol Assess (Summ) 2004;87:1-8.
- Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Viera A, Crotty K, Holland A, Brasure M, Lohr KN, Harden E, Tant E, Wallace I, Viswanathan M. Health literacy interventions and outcomes: An updated systematic review. RTI International—University of North Carolina Evidence-based Practice Center. Rockville (MD): Agency for Healthcare Research and Quality (US); March 2011. Report No.: 11-E006.
- Zarcadoolas C, Pleasant AF, Greer DS. Health literacy, why is it a public health issue. In: Advancing health literacy, a framework for understanding and action. San Francisco: Jossey-Bass; 2006. p. 1-20.
- Kickbusch I, Wait S, Maag D. Navigating Health: The Role of Health Literacy (Report). 2006 (cited 2013 Apr 13). Available from: http://www.emhf.org/ resource_images/NavigatingHealth_FINAL.pdf.

- Beauchamp TL, Childress JF. Principles of biomedical ethics. 6th ed. New York: Oxford University Press; 2009.
- Schröder P. Public-Health-Ethik in Abgrenzung zur Medizinethik (A separation of public health ethics from medical ethics). Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz 2007;50:103-111. German.
- Loss J, Nagel E. Probleme und ethische Herausforderungen bei der bevölkerungsbezogenen Gesundheitskommunikation (Problems and ethical challenges in public health communication). Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz 2009:52:502-511. German.
- Volandes AE, Paasche-Orlow MK. Health literacy, health inequality and a just healthcare system. Am J Bioeth 2007;7:5-10.
- 13. Goldberg DS. Justice, health literacy and social epidemiology. Am J Bioeth 2007;7:18-20.
- 14. Banja JD. My What? Am J Bioeth 2007;7:13-15.
- Schillinger D. Literacy and health communication: reversing the 'inverse care law'. Am J Bioeth 2007;7:15-18.
- Trachtman H. Illiteracy ain't what it used to be. Am J Bioeth 2007;7:27-28.
- Marks R. Ethics and patient education: health literacy and cultural dilemmas. Health Promot Pract 2009;10:328-332.
- Gazmararian JA, Curran JW, Parker RM, Bernhardt JM, DeBuono BA. Public health literacy in America, an ethical imperative. Am J Prev Med 2005;28:317-322.
- 19. Pirsi A. Low health literacy prevents equal access to care. Lancet 2000;356:1828.
- 20. Wilson JF. The crucial link between literacy and health. Ann Intern Med 2003;139: 875-878.
- Sass HM. New options for health care policy and health status insurance: citizens as customers. Croat Med J 2003:44:562-567.

Scientific and research work and academic periodicals

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Abstract

The revolution in information-communication technologies has led to the appearance of a "real tide" of different types of information sources that are offered in digital form. These new resources, far more than it was the case with traditional sources (books - handwritten and printed, contributions in scientific periodicals, archives and museums' holdings, etc.), placed members of the scientific and research community at a serious dilemma: "Which sources to choose, how to evaluate and use them in a useful manner in scientific research?"

This paper discusses aspects of the influence of modern information technology in scientific research. It also provides a review of the most important products and sources of knowledge necessary for scientific research, issues of information preservation, digital libraries, e-books, and information resources in the digital environment, databases and the use of sources of scientific information. Finally, it discusses how to validate the results of professional scientific work through the procedures of statistical processing, analysis, interpretation, technical and linguistic preparation and review, evaluation and impact of the dissemination of knowledge in various scientific publications.

Keywords: ICT, IMRAD, publications, quoting literature, review of the articles.

1. Introduction

Science and technology have a crucial role in the development of modern societies and scientific research and, if based on ethical principles, they can certainly provide answers to many questions that modern humankind faces in daily life (1-3). Production and exchange of knowledge about most current issues of human existence are determined by the relevant scientific communication that is established and implemented by the relevant scientific publications which, in addition to the books, are usually represented by scientific journals and contributions to the scientific meetings (4-6). Reliability and soundness of scientific knowledge of scientists/ researchers should be important to them, to their professional community and, of course, to the society where they belong. Communicating within the communities, the authors/researchers describe the results which they reached by their research activities, and submit their scientific and professional articles for publication in peer-reviewed scientific journals. In this way, they are opening the door for a potentially successful scientific, or possible academic career. In doing so, individual contributions to the scientific knowledge constitute a subject of interest and evaluation by peers in the context of their scientific work. Authors of scientific achievements should be able to convince the institutions in which they work and the members of their professional community, especially those who are otherwise referred to as reviewers (peer reviewers), about the quality and, in some cases, verifiability of these practical achievements (7-10).

Options for objective authentication of one's original contribution to science are nowhere more obvious, nor have larger implications, as in the types and extent of the sources used by other authors. This conclusion is equally valid in specific scientific fields such as literary criticism, but also the latest scientific achievements in the field of e.g. biomedical research. Hence, the knowledge of sources of scientific information, methods of their evaluation and methodology of their use is crucial for any serious scientific research and publication of its results. Scientists are of course aware that science is going on and exist within a broader social environment, although undoubtedly influenced by the inherited historical context. The social

environment determines its substance, the orientation and the appropriate ranking of methods of each individual's scientific achievement.

Traditionally, societies have imposed "canons of conduct" and "rules of the game" to the scientific activities. Specifically, scientific knowledge is still largely generated from processes that are, at least in the initial phase, mainly individual. Thus, research and scientific work is commonly performed and is largely dependent on the creativity and skills of talented individuals. From this point of view, some of the basic characteristics that differentiate professionals with scientific ambitions should be identified and acknowledged. A distinction should be made between professional papers/reports and scientific articles. Professional papers commonly refer to pieces of work that do not have obvious pretense of research and do not deal with scientific problems. The primary goal of a professional paper is to familiarize the readers with facts and findings that are not new to science, but nevertheless transfer knowledge and enable the acquisition of knowledge to certain professional communities. Conversely, scientific papers/ articles basically aim to solve a scientific question, with the use of scientific apparatus, style of expression and argument, and their manner of presentation provides a solid basis for ensuring that they are treated as scientific contributions to a certain scientific field.

According to the complexity of the topic and the time required for its development, scientific papers can be classified into several categories: one can speak about the debates - or studies, monographs, contributions in journals, papers at scientific conferences, critical reviews, or peer reviews. Infrequently, journalistic contributions communicate also some important innovations in science and technology, especially if published in reputable journals such as *Science*, or *Nature*.

Scientific activity during the last couple of decades received additional incentives by the progress made in information science and technology which offered a series of many innovative opportunities to scientists, researchers and scholars in general for new areas of activity, particularly in synergic interpenetration of science, culture and art. Information technology, particularly through various digital resources enables implementation of creative

industry ideas that involves combining text, images, sound and performance.

2. Journals and other forms of publications for presentation of the scientific research results

Journals are among the most important products and sources of information necessary for scientific research and represent an important link for progress in science (1,2). Communication of knowledge that occurs as a result of the latest scientific research is achieved mainly through reputable scientific journals in printed or electronic form. In order to ensure adherence to quality standards and scientific validity, scientific journals contain articles that are in the process of acceptance for printing after having undergone a strict review process. Careers of many university professors and researchers in academic institutions largely depend on a positive outcome of the evaluation of their published articles. This evaluation is an important part performed on the basis of the assumption that these papers were published in reputable periodicals, especially those referenced and indexed in international databases.

Contributions to the journals are usually in a format according to the general scheme IMRAD (I-Introduction; M-Methods or Material and Methods; R-Results: A-and: D-Discussion and Conclusion). recommended by the International Commission of Medical Journal Editors (ICMJE) (11). These articles begin with an abstract, which is a summary of the paper. The introduction describes the previous research as a basis for writing the text, including consideration of similar studies by other authors. Materials and methods used, or the part that relates to experimentation, contains specific details on how the survey was carried out. Results and discussion describe the outcome and implications of the research work, while concluding remarks are placed in the context of the current work and suggest potential future research directions.

The starting point for determining the relevance of a published paper and material for evaluation and bibliometric analysis often is the assumption that the article was published in a respectable scientific journal. However, recent studies of several authors drew attention to the fact that other forms of

literature are subject to evaluation and citation too. In the case of social and humanistic sciences, it has been demonstrated that contributions to periodicals represent 50% of the most cited documents. Important content, including scientific discoveries of the first order, may be published in other kinds of formats, such as contributions to scientific meetings, not only in journals or monographic publications (6). Although important, especially for computer science and technology, the problem with this kind of literature involves its relatively rapid "aging" compared to other types of scientific sources. Methodological frameworks and processes of scientific research and in particular the results disclosed to undergo evolutionary criteria, including the determination of the impact factor, are usually applied.

3. Digital libraries and their establishment

At the end of the second and beginning of the third millennium, new media for the exchange of knowledge and its storage in the database appeared which become possible by the advent of digital libraries in the areas of science and business, in the social and humanistic sciences, biomedicine, as well as several other areas. These new circumstances imply also necessary obligations for precise understanding of the role of heritage institutions (libraries, museums, archives, galleries) in creating conditions (normative, technological and financial) for the development and growth of digital depository of knowledge.

Even during the last months of the Second World War, there have been indications of what would later gain worldwide promotion and importance under the name of the digital library. Specifically, Vannever Bush, a professor at the Massachusetts-Institute of Technology (MIT), in the Atlantic Monthly journal in July 1945 published an article titled "As We May Think" in which he outlined the basic idea of the need for fresh innovative methods in the use of technology to organize and made available knowledge and information at a much more efficient and more cost-effective way than before. As a support to this effort, he planned a system, which he called the *Memex*. This idea was relying solely on barcode microfilm and preceded the earliest example of an electronic computer and forerunner of the later of such devices in the form of machines constructed in the UK 1943 under the name "Colossus" to be used during war time to *break* the coded messages.

Later, the need for relevant information, particularly about the scientific content, was one of the main driving motives for building the global information infrastructure. Technology for creation, distribution and storage in a digital environment eventually underwent profound changes including status and activity, not just a library but also institutions such as archives, galleries, museums and mediathek. All this had a strong influence on the acceleration of the process of acquisition and distribution of knowledge which is mainly taking place nowadays in schools and universities. This is inspired by the transformation of scientific institutions and types of academies of science, other scientific institutions and international professional associations, whose normative and professional activities are focused on research and development. The convergence point of these changes is currently referred to as digital library - a term commonly used to describe "...the advancement of information technology enabling insight into memory organization".

The first phase in this process, one can safely say, involved a revolutionary change in the field of information science during the Nineties of the Twentieth Century, characterized by rapid information-technology innovations that have enabled *online* access to the catalogs of library collections, although it also has not led to a solution for the issue of access to their contents as well as traditional memory depositories.

The earliest project of Virtual Library (12) which, in fact, is the oldest catalog of the World Wide Web, was invented in 1991 by Tim Barnes-Lee, working at the European Organization for Nuclear Research - CERN in Geneva. Currently, Tim Berners-Lee is the Director of Consortium of worldwide network - W3C (13). W3C achieves its mission primarily by creating Web standards and guidelines and most directly assists in the implementation of a virtual library, striving to survive all the hardships that accompany these kinds of innovative ideas. Unlike commercial actors, this work is done by a loosely bound group of professionals - volunteers, who

compile pages of key links for particular areas of human knowledge. Eventually, this initiative gained considerable reputation as a relevant guide in each segment of the network. The subject areas with narrower thematic units available through this service include: agronomy, business and economics, information technology, communications and media, education, engineering, humanities, library science, international relations, law, recreation, regional studies, natural science, social science and religion. Shortly after the appearance of a virtual library, there were numerous initiatives whose primary goal was just publishing the original texts in electronic form and ensuring their availability in the form of full text. Until now, there have been implemented such pursuits, in addition to valuable critical editions of medieval sources, old and rare books and manuscripts, cabinets and contemporary authors in various languages, books, referential works, journals and training materials. For the preparation of this kind of materials, publishers combine the expertise of distinguished scholars in specific subject areas of knowledge, including experts in copyright, librarians and information consultants. Thanks to such archives. a far larger number of members of the academic community and interested members of the public in general can effectively access collections of texts which, until recently, was very hard to reach.

To the experts engaged in these tasks, computers serve in at least five different categories of activities to provide access to information resources of general type, such as online library catalogs, bibliographies, dictionaries, and encyclopedias such as Wikipedia (14). These machines offer the possibility of retrospective conversion of manuscripts or printed sources, in a machine-readable format, opening up space for publication of the results of these authors in the Internet. They make possible the creation of specific tools such as databases, special browsers, enabling the extraction of summaries - a part from much more comprehensive sources, as well as creating conditions for computer-based research and testing of a given model.

Using computers to test scientific hypotheses based on the availability of complex and voluminous databases has led to new discoveries and improvements, not only in the natural and technical

sciences. The Internet is to researchers a discipline such as the study of language, literature, history, legal theory, philosophy, comparative religion, ethics, art criticism, archeology and those aspects of social sciences which have humanistic content have opened a number of opportunities to access new knowledge in areas that until recently were thought to be quite resistant to any form of technology-based innovations (3,4).

With the arrival of a tide of new digital media and services, in addition to their classic role as depository memory stored primarily on paper, libraries are reformed in order to become more able to accommodate the new system that is the digital formats in which the content is currently stored.

The term digital library serves as a convenient and clearly catchword to indicate the detronic collection which includes a richer content and provides a greater access for concepts such as databases or information system retrieval. Just starting from the standpoint of one librarian, an American researcher namely Donald I. Waters has made a working version of the definition of digital libraries: "Digital libraries are organizations that provide the use of resources, induding professional staff that selects, organizes, provides an intellectual approach, explains, distributes, preserves its integrity and ensures durability of collections of digital articles so that they are ready and economically available for use of one or more communities" (3).

Teufik-Tefko Saracevic from Rutgers University has stated that 'The digital library deals with documents of human knowledge in the form of electronic and networked environment". At the same time, Saracevic reminded that this technological innovation has induced the need for clarification of a number of issues including an understanding of objects in digital libraries in various formats, including non-text material and its presentation: the metadata, cataloging, indexing, conversion, digitizing, organizing voluminous collections, collections' management, compression, security, archiving, interoperability, standardization, computer-human interaction, the discovery of information, searching, retrieval, reading, natural language processing, reliability, metrics, performance, evaluation, social, legal and economic issues, the impact on scientific research, education and other areas, and the impact on diverse beneficiary populations (4).

Under these new conditions and new technological possibilities, the idea of continuity and maintenance of information sources which is often accumulated for centuries, with special care for what we call cultural heritage, is preserved despite the technology, or perhaps thanks to it. Thanks to innovations occurring in the wake of new digital media, there has been a revitalization of certain subject areas in the social sciences and in the humanities, not to speak of medicine and engineering, and the like. On the other hand, despite a relatively painless landing to the world of chips and bytes, members of the IT professional community in the new library environment now use the database orientation with an emphasis on the organization of resources and access to online resources rather than the shelving the books and binding the journals published over the years.

Digital library, as a collection of information that is digitalized and organized to customer preferences, offers tools and features that traditional libraries could not provide. Resources of digital libraries provide browsing options by different keywords, can be accessed from any geographical point on the planet and the respective sources can be copied without any errors. However, these types of libraries inevitably draw the attention of its customers on the regular problems that normally accompany the process of finding information, their delivery and their preservation for the future. Nevertheless, digital information certainly occupies less space than paperbased information, which greatly helps libraries to reduce the price of their services. They can supply information on the reader's desk, their contents can be searched by keywords, without physically going to the library and can provide access to information that is not degraded on the way from rotting material on which is written, whether it is about words, sounds or images, movies, or still pictures. Another important fact that should be mentioned in connection with the digital technology consists of an easier access to different parts of the textbook, its use simplifies writing, the book facilitates archiving its content - in fact, archiving is greatly facilitated in terms of the letter, image, and sound. At the same time, one gets a lighter and more efficient way of preparing and publishing the final book in printed form (hard copy). There is a frequently asked question in professional circles: "What is the purpose of a book, if nobody reads it, and what is the purpose of a library induding its contents if no one uses it?!". Even the emotional reasons based motivation keeping documentary evidence for the future may give way to the harsh logic contained in the question: "Who is actually using this kind of materials nowadays?". Remaining free readers, we will have even fewer reasons in the future to deal with traditional libraries leading to even more justifications for "ignoring" their existence.

On the other hand, the buzz word from time to time in public places on the information saturation can be justified only if we are talking about mass production of information on new media that has no goals. The owner of the information certainly gave it a role: either it educates, makes one aware of, or informs. Therefore, the issue of digital library should be approached with due respect, but also with caution and concerns about its usefulness and its added value or, as pointed out by Teufik-Tefko Saracevic, one should "take care on its relevance" (5). An additional argument by this author states that 'In evaluating digital libraries, as, after all, in the evaluation of any system or process, sets the following serious questions, which obviously affect the final result: Where to begin to evaluate the digital library, which is valued? Where is the end? Where are the limits? What is involved? What is excluded? To what environment or context to concentrate on? These questions define the construct of a digital library ..."

Michael Leske quite whimsy lists the conditions that are required to build a digital library stating that: "You need to enter content into it, you need to be able to take content out of it, and you have to be able to pay for it" (6).

As for the software for building of digital libraries, especially bearing in mind the cost of its creation and technological accessibility, here is an opportunity to draw attention to two early examples of freely available software like *Greenstone* (15) and *DSpace* (16). The purpose of the Greenstone software was to allow especially university institutions and other public institutions to build their own digital library without much cost. Complete Greenstone interface is available in English, French, Spanish, Russian and Kazakh language and it is possible for volunteers to provide translations into other languages.

The *DSpace* project, about which much more can be found at: www.dspace.org (17), is also a freely

accessible digital depositary system that is used for different purposes of digitization. It is developed by a common effort of experts from libraries of MIT (Massachusetts Institute of Technology) in Boston and specialists of Hewlett-Packard Laboratories. DSpace is adaptable for the processing of different types of digital material, including text, images, videos, and other formats. This initiative provided support to the community of intellectual property in the digital environment and in 1998 it was founded the International DOI Foundation (18) and through the development and promotion systems it was materialized the DOI system (Digital Object Identifier - identifier for digital objects as a common infrastructure for managing digital content). The Foundation was registered in Washington as a non-profit organization and is currently managed by an Executive Committee which includes elected members of the Foundation. DOI system is processed as a formal standard by the International Organization for Standardization (19).

4. Electronic books

An electronic book (e-book, eBook, digital book, or even: e-adition) is a book published in digital form, consisting of text, images, or both, and that is readable by computers or different electronic devices (e-reader) like Amazon Kindle, Apple iPad, Nook, or Sony eBook Reader. This innovation is the product of the first order information revolution of the late Twentieth and early Twenty-first Century. Form and manner of usage resembles the classical books, but its text is not printed on paper, but in digital form written in the memory of computer equipment belonging to a networked world. This new kind of books are usually ordered online and delivered electronically into the memory of e-reader on customer order.

Access to e-book is available via the Internet for whose profile and functioning is particularly interested the *Internet Society*. It is a non-for-profit international professional organization with more than 150 organizations and 16,000 individual members and it truly represents "Who's who" of the international Internet community. Basic guidelines for which the organization is committed include the following principles: standards, public policy,

education and training, and membership. It is active in the field of freedom of expression and censorship, taxation, government policy towards the Internet and across the spectrum of intellectual property rights (20).

On the path of a new application of digital technology in publishing particularly illustrative example is the Guttenberg project, which was launched in 1992 by Michael Hart, representing the earliest publisher of electronic books freely available on the internet. Implementation of the project is carried out based on the efforts of many volunteers (21). On the other hand, ibiblio (22) claims to be a "collection of all collections" in the Internet that is the depository of freely available information including software, music, literature, linguistics, art, history, geography, biography, science, political science, cultural studies and the like. Google pack (23) provides the ability to access online books that are in the public domain - that is not under copyright protection. In the case of the United States, usually it involves books printed before the year 1923.

With the numerous advantages of this form of books, there are also some disadvantages which induce also resistance, because a fair number of readers of a new medium find it clumsier the ereading compared with the classic books and even the quality of the screen to read text does not provide the satisfaction that is actually obtained by flipping paper pages. However, a number of publishers in this field are growing and, currently, there are more and more companies dealing specifically with the issue of the scientific literature (such as Elsevier, Springer, IOS Press, or John Willey).

Collection and archiving of digital material through a system of *compulsory copies* (legal deposit) has been the subject of legal regulation especially in the more developed parts of the world because, when such materials cannot be collected, a significant part of the national scientific, technical and artistic production would be lost. Collecting these items, however, delivers a range of complex problems including a significant number relating to the status, integrity and durability of the recorded text, images, audio, and movies. Such publications appear in two basic forms. The first is a static electronic publication in the form of a CD-ROM that is distributed as a separate unit and fixed and, generally, their manufacturers can no longer change the content. On the other hand, there are dynamic electronic publications such as online databases and electronic journals and books that are not distributed separately in form and substance, fixed units. In this case, the distribution is done through a subscription or a contractual arrangement that allows access to the manufacturer or publisher at any time to change the contents of its database for updating, adding or deleting existing records. Keeping this in mind, the following question arises: "Should such a publication store copy the entire database at regular intervals or meet the requirement for mandatory deposit copies (legal deposit)? What happens, for example, if the database update stops that is, the publisher ceases its activity and the like?".

From the standpoint of the Council of Europe, electronic publishing is practically bridging the difference between publication in the traditional sense and archival materials as such. The publication: Electronic Publishing, Books and Archives (Strasbourg, Council of Europe, 1999) contains an overview of activities with a focus on making connections and opportunities for cooperation in this field between institutions and organizations within member states. It points to joint work and cooperation with other international professional organizations such as the IPA (International Publishers Association), IFLA (International Federation of Library Associations), EBLIDA (European Board for Libraries, Information, Documentation and Archives Association), and ICA (International Council of Archives). Based on the rules of this document, it is not difficult to conclude that the national libraries or other institutions are responsible for preserving the memory of a society - ignoring the audiovisual and electronic publications, in fact, neglecting their responsibility to collect and preserve the national heritage in the field of information materials. As the time passes, this failure will be difficult to catch up hence, there is an urgent obligation of libraries to establish an effective and prompt communication with the database creators, publishers, and storages of such materials and develop a strategy and effective practices of collecting, storing and facilitating the availability of such materials.

Electronic publishing has significant consequences for bibliographic work when processing this type

of material. Hence, there was an emergence of the International Standard Bibliographic Description for Electronic Resources-ISBD (ER) (Munich, KG Saur, IFLA, UBCIM Publications, 1997), which of course is available in electronic form. Other institutions include the International Association of Scientific, Technical + Medical publishers - STM (24), the International Council for Scientific and Technical Information (International Council for Scientific and Technical information - ICST (25), the International Federation of publishers in the field of science (IFSP) and the International DOI Foundation, whose DOI system provides support for identifying content objects in the digital environment (26).

However, information and technological innovations that have contributed to the revitalization of publishing in the modern world also sparked a number of complex issues, not only on the technical aspects of digitization, archiving and dissemination of this kind of material, but also on the legal regulation of issues of copyright protection. In his book Understanding Digital Library, the American author Michael Leske stated that "Legal issues arising out of intellectual property are the most serious problem faced by designers of digital libraries" (1).

Implementation of the Google company library project (27) put to the test many actors involved in the creation and publication of a book, especially from the standpoint of copyright protection. As a response to this dilemma, several Company representatives have publicly expressed their opinion that their ultimate goal is as follows: "In cooperation with publishers and libraries, to create a comprehensive, searchable, virtual catalog of all books in all languages that will help users discover new books and publishers new readers". In 2008, the Amazon has marketed a new product called the Kindle, which is even a more expanded horizon of possibilities of reading digitized books, newspapers, blogs and similar. Basically, the Kindle is a compact electronic device that provides access to content of about 115,000 books that are otherwise in paper format available to customers through Amazon's sales network.

In connection with the emergence of e-books, the inevitable question certainly involves the intellectual property rights, which touches upon two major groups of rights: the first consists of copyright and its related rights. It is basically a set of legal norms regulating relations in respect to the copyright of products, which are legally protected intellectual creations in the field of literature, science and art. The second group consists of industrial property rights that govern and protect intellectual creativity in the field of technology (2).

The World Intellectual Property Organization - WIPO, based in Geneva, focuses its activities on promoting the use and protection of works of the human spirit. These works consist of intellectual properties, beyond the boundaries of science and technology and enrich the world of art. Standards, recommendations and guidelines of the organization can be found at the following web address: www.wipo.int/ Scite/ standards/ standards.htm/ (28), whereas further information on the issue of copyright law can be found at: www.wipo.int/copyright/en/ (29).

5. Classification of recorded knowledge

Since knowledge outside the human brain is stored in organized manner in libraries, archives, galleries, museums and most recently in various digital depositories. Obviously, these diverse resources should be organized with the help of a system of classification. Thus, in addition to the longestablished institutions for storing the knowledge of the traditional type, there have been developed different means of accessibility of their content through databases to which people have online access (4). This approach can be free-of-charge and may be conditional on the completion of previous clauses such as subscription, for example. Organizations that integrate these activities and make them actually possible are commonly referred to as digital libraries, whose activities are based on elements such as: terminology, structure and complexity, a common function that is the one usually performed by traditional libraries.

As a form of classification and structure in e.g. Bosnia and Herzegovina, in most libraries it is used just the Universal Decimal Classification (UDC), which covers the whole domain of human knowledge the universe of information, or perhaps some part of it.

5.1. Classification of scientific research in Frascati quide

For the classification of scientific research, for more

than four decades, it is used the Frascati Manual of the Organization for Economic Cooperation and Development (OECD), based in Paris. This document established a general methodology for collecting statistical data on research and development. The first version of the manual, from 1963, was created on the basis of agreed conclusions of the expert group of the OECD and the NESTI group of national experts on scientific and technological indicators, relying on the basic document prepared by Christopher Freeman. The sixth edition of the manual was published in Paris in 2002 (1).

5.2. Information resources in the digital environment

To accomplish their scientific goals, scientists and researchers today, including applied researches that also need laboratories, there are essential information resources whose convergence point is no longer just a library, because this type of work can be performed at home or from the office. Intellectual resources used by researchers in the information and documentation process consist of units that make the media, the data on these media and the meaning attributed to these units (1,4).

These resources are usually divided into primary, secondary and tertiary resources. Primary information includes direct (original) research results of scientific work, i.e. new knowledge and new interpretations of familiar ideas and facts. They comprise also artistic (literary, musical, artistic) works, the scientific method, the value-based interpretation and evaluation.

The documents with the primary information include: articles in journals, doctoral dissertations, master's theses and other papers of a similar kind, patent documents, technical reports, papers presented at scientific and professional meetings, works of art, photographs, movies, musical performances of various kinds, museum objects, autobiographies, letters, correspondences, conversations and interviews, original news, official publications, archives, and so on. Secondary information consists of resources that provide content description and/ or location of information sources (2,3). They can appoint brief informational tools for finding relevant information. Scientifically

relevant information is a set of data that have passed, based on the scientific method, practical authentication of the offered facts. In an environment in which the availability of the results of scientific and technical research by different thematic profiles is more global and less local, members of the academic community are increasingly accepting the necessity for a selective approach in the selection of different types of information sources, which can bypass the need to determine their relevance to the theme that would ultimately allow the growth process of knowledge without which social progress is hardly achievable. Experts of the Library of the University of Illinois have prepared a series of instructions for their users on how to critically evaluate their sources. In these hypothetical questions there are provided adequate details as follows (5):

· What is the scientific source?

Scientific sources (also known as academic or reviewed sources) are written by authors/ experts in a specific field of science and serve to other users interested in a specific area providing the most updated knowledge, discoveries and news on a particular scientific area.

· What is a review?

When the source is reviewed it means that it is being examined by a group of experts (usually two) of a given field of knowledge to give their professional opinion and suggest possible corrections before the manuscript is submitted for publication in the journal or proposed for presentation in a scientific conference (7).

The question 'How do I know whether the source is of a scientific nature?" seeks to clarify the following facts:

- Authorship: Involves the list of authors, whether the authors' references are clearly displayed and whether they are relevant to the topic in question.
- · Publishers: Concerns the publisher of information, whether it is an academic institution or a publisher, scientific or professional association, and the purpose of the publication.
- · Content: What is the reason for dissemination of the information and hence publication of the article at hand? Does it have quoted sources? Does the quoted sources include reliable resources in a given subject area? Are there (in the case of natural sciences, or technology) maps, charts, tables or

bibliographic entries? Are the authors' claims supported by the evidence? Are the conclusions based on the presented evidence, and the scope offered by the information source?

· Timeliness and freshness of the information: Is the date of publication clearly indicated? Is the reliability of the offered data and information crucial to the investigation in question? (1).

On the other hand, the Modern Language A ssociation, headquartered in New York, in its instructions for evaluation of the contributions on the topic of digital humanities and digital media puts emphasis on the following: "Digital media is transforming literacy, science, education and services, while also opening up new avenues for research and communication and creating something that can be called networked academic community. Today, information technology is an integral part of the intellectual environment for a significant number of trainers in the field of humanities, but for those who are directly taking part in the implementation and development of new media. This creates new challenges and opens the door to new possibilities. Digital media have expanded and forms and ways to document the contents of humanities and thus includes images, audio, statistics, kinetic attributes as animation and many other forms of preservation and presentation of content that is collectively called multimedia".

6. Terminology standards

In the area of terminology, there are two types of standards: technical standards and terminology standards. The technical standards are also known as specification and terminology standards in the strictest sense. Technical standards define the characteristics of agreed specification for terminological products, services, processes, or systems. Unlike these, the terminology standards as well as standards for the measurement are considered to be fundamental norms. They specify a common set of vocabulary that will be used in a particular standard, or a related group of standards (5).

6.1. Thesauruses

Thesaurus is commonly defined as a vocabulary that includes systematically distributed approved terms (controlled vocabulary) of a subject area, or a scientific discipline in the treasury of human knowledge or experience. This list of terms is very useful for indexing and search procedures in

information sources. Thesauruses are now often used online and CD-ROM databases search, therefore, in the activities of access to knowledge. They are used most often for a specific subject area, for example, in education, social sciences, and the like (4).

6.2. Indexes

The definition of "indexes" by the Society of Indexers (30) corresponds to the description published by the British Standards Institute stating the following: "The index is a systematic arrangement of entries made available to help the user find the information in the document" (British Standard, ISO 99: 1996). This document can be a book, a copy of a journal, newspapers, video, film, computer disk, or any other source of information. In the area of natural sciences and medicine, a popular example includes the *Index Medicus*, probably the best known and most comprehensive index of medicine in the world. A similar thematic orientation has the Excerpta Medica, or the Index to Dental Literature and International Nursing and they make a collective database known as MEDLINE which contains more than 5000 indexed and abstracted journals. A comprehensive description of approximately 20 online biomedical databases has been already provided by Izet Masic and was published in the journal: A da Informatica Medica (1).

6.3. Abstracts

Formally, the abstract is generally a summary of the paper in a scientific journal or other periodical publications and is placed at the beginning or at the end of the text. This summary is usually without valuable judgment, interpretation or criticism and may also contain bibliographic references that refer to the original document. Abstracts which can be descriptive or informative, otherwise, help the reader (before reading the entire article) to decide whether it is useful or not, and allows it to become familiar with the key elements of the text without going into too much detail. Abstract collections can be used to search and select the source for the preparation of professional or scientific research (1).

Introductory remarks, whose title is usually a preface which precedes the main body of the document, mainly help users to get acquainted about the origins, purpose and use of the part contained in the

document, as well as facts on the recognition by others who have helped the author. This part of the document can be written by someone other than the author. Introduction has a similar purpose, except that it takes place in a concise way more concerned with the content of the work itself, but the circumstances under which it was composed. Access to materials is possible, depending on the interests of users also through a list of illustrations, tables, maps and other illustrative materials with the indicator of the material on which the document is located. A list of these materials usually comes after the main text in the form of a "table of contents". Access to a specific part of the document can be obtained through key words or key phrases, which is now a common practice thanks to computer technology. This type of approach is possible, of course, in the case of texts which are stored in the Internet in digital form.

6.4. Methodology for the preparation, writing and publishing of scientific papers

There are opinions that the fluent expression and writing in general creates a natural talent and that literacy as such cannot be learned, as there are people who believe that literacy is a matter of respect for the rules of grammar. However, in addition to natural talent and knowledge of spelling rules, for a good literacy it is also essential to master a line of patience and hard work in order to develop a sense of meticulousness. It involves the art in the first place of thinking clearly and logically and the ability to experience and materialize this kind of intellectuality into a proper written form. The writing should be intrinsically easy for a good author. Autonomy in creating sentences and construction of own ability is one of the prerequisites of good literacy. Ability to correctly read and thorough understanding of reading, especially reading of well-known authors, regardless of the time in which they have published, is precious to enrich one's own written expression. Existing examples of scientific writing should be followed and researchers should record their own mental development through tracking every thought that is considered even remotely creative and highly innovative (4).

Results of reports and essay writing usually consist of a description, a form of written composition that can occur even in elementary school, so they should be differentiated from the literary and artistic works. For this kind of written work, it is important to note the characteristics and details that are essential building blocks of every description. Narration or storytelling is also one of the common themes in educational institutions where writing is particularly important to emphasize, in addition to the chronological display of events and the vitality of the story while the narrative literature papers represent only one aspect of artistic creation of the content.

It should be distinguished the presentation of a work, or activities of a person, a description of an event, or a representation of a set of reports about it, display of some social phenomena, or emotional expression or discussion of a particular topic.

Discussion is the most common form of written composition. It is generally subordinated to all knowledge, logical reasoning and rational distribution of the content in question. Essay is a written form of creative expression usually in a discourse that often goes beyond purely scientific types and in many ways there are artistic and literary approaches to the creation emphasized by a subjective position on a given topic. Subject of interest of essayists may be a current issue of spiritual or cultural life in which the author points out emphatically a personal position on a particular issue that may be of broader social significance.

The earliest stage of research in an academic setting, however, usually starts by creating not too demanding seminar work (essay) in high school, or at the beginning of university studies.

Seminar paper, presents a sort of didactic resources on the basis of which students must demonstrate that they have mastered the technique of applying the basics of research methodology, the proper use of resources, a solid implementation of the rules of spelling and grammar, logical reasoning skills, analytical ability to read written sources and writing text on a given topic.

Research papers that are written during undergraduate studies are certainly more demanding than the previous ones and as such should show a high degree of skill to master the basics of expression and professional research methodology. After all, it is the individual author who is being prepared for scientific and professional work.

Graduate paper at the end of undergraduate studies, as a rule, defended in front of a commission and represents something more complex and demanding creation in which the final version should meet both formally and substantively demands of the candidates – the author of such work – set by its educational institutions.

Specialist and master thesis are prepared and defended by a special procedure, which is prescribed by the statute of the university at which the student becomes a candidate. The aim of developing such work is to show that the candidate is qualified for scientific research in a particular scientific field and is able to contribute for solving a set of research tasks whether by presenting completely new facts, any newer higher quality presentation of familiar names in science before this present knowledge. Doctoral dissertation, which is approved and defended by the prescribed complex procedure, as a rule need to be independent and original scientific work, which should represent a contribution to the attained level of solving certain scientific questions in a specific scientific field and the rigorous application of scientific methodology.

7. Steps for preparation and publication of the scientific research results

In order for a man to devote himself to science and research, it is necessary to have the following qualities: intelligence, skill of analysis and synthesis, the power of observation, perseverance, creativity, ethics and responsibility (2). After the selection of a research topic, choosing a mentor, associates and conducting the research, it follows the writing of the articles. The concept of scientific research is based on the division into specific sections. Each article should contain the title, abstract, introduction, materials and methods, results, discussion, conclusion and the list of references (2-5).

Title: Title should be as short as possible, as well as concise as possible in describing the content. One can say that the title is a summary of an abstract (2).

Abstract: Is a summary of the work and is placed at the beginning of the text. This summary is usually without judgment, interpretation or criticism, while it may also contain bibliographic references that refer to the original document. The abstract can be descriptive or informative, otherwise, it helps the reader before reading the entire article to decide whether it is valuable to him/her or not. In addition, the abstract allows the reader to become familiar with the key elements of the text without going into too much detail.

Introduction: The introduction should provide information that will help the reader to understand the methods and results of the research. The introductory section should contain a definition and a formulation of the problem being investigated. In experimental and clinical research it is necessary to specify the goal(s) of the research and hypotheses (assumptions) which are included in the study. There are a few rules to comply in writing the introduction: a) Clearly describe the problem for which the research should give an answer; b) Indicate why something is investigated; c) Avoid stating facts from standard textbooks; and d) Do not clarify the title of the publication.

Material/Subjects and Methods: In the description of the methods used in the research work, the study design employed should be emphasized in the first place. It is necessary to describe the main features of the study, describe the tested sample, standard values for the tests, and so on. In this section, it is necessary to explicitly specify the parameters that are evaluated and controlled during the study. This part should contain complete description of the statistical methods used. **Results:** The section in which are presented the results of research begins with a description of the tested population and clearly identifies the size of the sample and its demographic characteristics. The results obtained by statistical analysis should be presented in tables and/ or charts. When presenting the results it is necessary to mark the interval of its deviation and their levels of statistical significance. In a comparative study the interval of deviation must relate to the differences between the groups. Discussion and Conclusion: The discussion is the most important part of the article and it begins by summarizing the key findings obtained during the study. Promoted are the most important results and compared with those obtained in previously conducted studies. If they are significantly different, it is necessary to give a possible explanation for these differences. Finally, the discussion should provide confirmation of reaching required objectives (goals) and confirm or reject the hypotheses. In the conclusion, there should be presented the most important facts that were obtained during the research.

References: In scientific circles, references present information that is necessary for the readers to identify and find out the sources employed. The basic rule when listing the sources used is that references must be accurate, complete and should be consistently applied. On the other hand, citation implies an exact written or verbal reference to parts of the text or words of others that can be checked in the original source.

7.1. Using scientific information sources and citation of the scientific literature

An organized list of sources cited at the end of journal articles or book chapters plays an important role, not only to be acknowledged as a "debt" to the sources the author used, but it also provides an opportunity for anyone who is interested to verify the methods and the relevance of the sources to which the author referred to. Also, from the quoted material, without great difficulty, it can be determined by the subject of the author's research interests, as well as how factually substantiate their views are. Bibliographical list contains all the sources that are individually cited in the text. The list can be arranged in alphabetical order by the authors. If there are more papers from one author, it is in the list chronologically arranged: from the earliest to the latest. The first element in the list of bibliographic references is the author's last name, followed by the name or initial of the first name. When there is more than one author, their names are listed in the order in which they appear in the source and are separated by a coma (2,3,5).

Regarding the citation of references from published articles in the biomedical journals, authors usually use Vancouver style, PubMed style, Harvard style, and so on.

The Harvard method of quoting sources (www.makecitation.com) is used especially in exact sciences, such as the case with natural-mathematical. technical sciences and in some social science disciplines (information science, education, education, demography, political science, sociology, or economics) (1).

The method of citation, therefore, implies that whenever an author is cited in the main part of the paper, essays, reports and publications, in general, the author must be mentioned stating: last name and year of publication in a closed parenthesis, and this is followed by a reference to complete description of the elements appearing in the alphabetical list of sources at the end of the text. In the case of citing a specific piece of text after the tag name of the author and date of publication should include the page, chapter, table, etc.

The purpose of the list of references is to enable readers to easily locate and track the source that the authors relied on for their work. Different types of resources require different volumes of information, but it can be said that there are some common elements to all of them including: author, title, place of publication, year of publication, publisher, and possibly extended. All units of this list should be cited in the alphabetical order by the author or authorship, regardless of the format in which they occur (books, articles in magazines, Web sites, or emails). In the event that there are more papers by one author it is needed to cite them chronologically, with the first originally published article in the first place.

Citing references can be conducted in two ways (1):

- · In the text when is given a brief description of the information source;
- · At the end of the document where are provided detailed bibliography information for each source. References are often cited according to the Vancouver nomenclature or alternatively the socalled ICMJE style (International Committee of Medical Journal Editors). In the literature review. there should be used only those references that are directly related to the topic of the current study. Publication of the article: At the end, the article should be prepared for its publication, and there are numerous reasons why researchers should publish their work. Some of them include the following (1):
- · The possibility of conducting scientific dialogue;
- Receiving critical review;
- · Showing respect for the participants and partners;
- Facilitation of future research;
- · Personal satisfaction.

7.2. Scientific assessment of published articles in biomedical journals

Measuring the scientific validity and relevance of articles is made by appropriate scientific methods. This is an area of a scientific discipline - scientometrics. Scientometrics is a part of scientology (the science of science) that analyzes scientific papers and their citation in the selected sample of scientific journals (5). The name bibliometrics was introduced during the 1970s to denote a quantitative study of the communication process using mathematical and statistical methods for books and other media of communication. Almost simultaneously, in the former communist countries in Europe, the name scientometrics was derived from the Russian word. More specifically, in 1969 it was introduced the name scientometrics relating to a scientific field that deals with the study of science as an information process by applying quantitative (statistical) methods. Later on, in 1977, Tibor Braun established an international journal namely Scientometrics, introducing thus the name scientometrics (6).

Some of the indicators used in the evaluation of the scientific research include the following:

- · Impact factor;
- · Number of article citations;
- · Number of journal citations;
- · The number and order of the authors.

Impact Factor is the number of citations of articles published in a given journal during the previous two years divided by the total number of articles published in that journal during the same period. The impact factor depends on: the quality of the journal, the language in which the journal is published, the area it covers, the magazine distribution system, and so on (1,5).

Scientometrics is the science of measuring and analyzing science. In practice, scientometrics often uses bibliometric methods to measure the impact of scientific publications. Modern scientometrics is largely based on the work of Derek J. de Solla, Price

and Eugene Garfield. Garfield founded the ISI - *Institute for Scientific Information* and is considered to be the father of scientometrics and methods for evaluation of scientific publications. Research methods of publication's scientific importance include qualitative and quantitative methods, as well as computer analysis (5,6).

Trying to establish a mathematical representation, Garfield developed a number of factors that allow the assessment of the value and importance of the scientific publications, among which the most factors include the Impact Factor (IF) and the H-index.

The Impact Factor (IF) of an academic journal is a measure that reflects the average number of citations of articles published in the journal. For a given year, the Impact Factor (IF) of a journal is the average number of citations per article published in that journal during the previous two years. For example, if a journal had an IF=3 in 2008, then the papers that were published in 2006 and 2007 were cited on average three times in 2008.

In general, the IF for the year 2008 of a given journal would be calculated as follows: A/B, where the letter A represents the number of cited articles published in 2006 and 2007 in the journal during 2008, while letter B is the total number of articles published in the journal in 2006 and 2007 (thus, IF for 2008 is: A/B). The impact factor is used to compare different journals within a certain field. H-index is an index that attempts to measure the productivity and impact of published scientific articles. The index is based on the most cited articles and the number of citations that the articles received in other publications. This index can also be applied to the productivity and impact of a group of scientists, such as a department or a faculty, as well as to a scientific journal. As a useful tool for determining the relative quality, the H-index was proposed by Jorge E. Hirsch, a physicist at the UCSD (7).

Table 1. Review of biomedical journals in Bosnia and Herzegovina ranked by the h-index values

Title	SJR	H index	Total Docs. (2011)	Total Docs. (3years)	Total Refs.	Total Cites (3years)	Citable Docs. (3years)	Cites / Doc. (2years)	Ref. / Doc.	Country
1 Medicinski Arhiv	0,121	10	101	281	0	69	277	0,29	0,00	
2 Bosnian Journal of Basic Medical Sciences	0,204	7	53	221	1.120	108	212	0,56	21,13	
3 HealthMED	0,190	5	260	280	6.329	114	279	0,44	24,34	
International Journal of Collaborative 4 Research on Internal Medicine and Public Health	0,196	3	43	47	1.061	21	46	0,46	24,67	
5 Sport Science	0,186	2	36	87	680	14	87	0,17	18,89	
6 Acta Medica Saliniana	0,101	1	34	32	580	1	27	0,04	17,06	

1 - 6

Scimago Lab, Copyright 2007-2013. Data Source: Scopus®

From Table 1 it is clear that the h-index of the oldest biomedical journal namely Medical Archives (Medianski A rhiv) is significantly higher (with an Hindex of 10), which means that scientists who have published in this journal 10 papers have, on average, at least 10 citations for each article in other journals. Citation provides guidance for scientific work because it encourages scientists to deal with the most current research areas. So actually "terror from scientometrics indicators" is organizing scientific work at the global level, it shapes and directs it (7). The citation is impacted by: quality of the articles, understanding of the articles, the language in which the work was written, the loyalty of a group of researchers, type of work, the benefit in terms of "I quote you, and you quote me", benefit in terms of "I will not quote it because he/ she is my competitor", and the like. Most of the scientific articles are cited by "inertia", because every scientist has a collection of articles cited whenever he/she writes about a certain topic. Other articles are quoted so the researcher gains citations, others because of reviewers' or editors' requests. Only a small portion, perhaps only every fifth or tenth paper, is cited properly. This includes those articles whose data the author uses directly and/or those articles the author directly relates to in his/her article. All persons listed as authors of the article must meet the following criteria: they should have significantly contributed to the planning and preparation of the article or the analysis and interpretation of results and participated in writing and editing of the article,

and that they agree with the final version of the text. Persons who are involved in data collection or other field work duties, but are not actively involved in the development of the article, cannot be listed as authors. The editor has the right to ask the author to explain the contribution of each author listed. The contribution of one author is "1" and if the work was written by several authors ("n") their contribution is: 1/n. In doing so, the contribution of each of the following authors is half in size of the previous one. Sequence is determined by the author's agreement.

7.3. The role of the International Committee of the Biomedical Journal Editors

The International Committee of the Biomedical Journal Editors has developed detailed guidelines for the preparation of articles in biomedical journals and related disciplines. How was this reached? A small group of editors of general medical journals met in Vancouver, Canada, in 1978, with the aim of establishing guidelines for publications in biomedical journals. This group subsequently became known as the "Vancouver group". Their recommendations for manuscripts submission related to bibliographic citation which was published in 1979 by the National Library of Medicine in Bethesda, USA. With time, the "Vancouver group" expanded and evolved into the International Committee of Medical Journal Editors (ICMJE) (11), which meets once a year and, in the meantime, the domain of its interests has expanded. Thanks to the work of this committee, there have

been established clear instructions referred to as "The uniform requirements for manuscripts submitted to biomedical journals". This document has been revised several times and has been recommended to be used in the published version starting from the year 1997. These instructions may be reproduced and used for non-for-profit educational purposes. Furthermore, the committee encourages potential users to distribute these instructions widely.

The group of publishers who met in Vancouver in 1978 decided to create uniform technical propositions for publications. These were adopted in 1979 by the National Library of Medicine and subsequently by the SCMJE which, starting from 1982, performs audits with the official application in approximately 300 international journals.

Articles for publication in biomedical journals involve predominantly the following citation styles: Spruce, PubMed style, ICMJE, Web style, APA style, and so on. In this article we provide examples of all of these styles of citing in order to facilitate their proper use. Also, in this article, as a form of review, it is presented the problem of plagiarism, which is becoming more common in the writing of scientific and professional articles in biomedicine.

There are several systems of citation and referencing and the most commonly used systems include the "author-date" (such as the Harvard system, or APA) and numerical systems (such as CSA, IEEE, Vancouver, and a few other systems). Often, the preferred system of citation and referencing depends on the scientific discipline in which the author writes. Thus, the way of referencing in a paper in mathematics differs from a biomedical article. Also, the authors are sometimes faced to respect pre-set requirements for citing sources from the institutions, journals and book publishers (1,4). For example, there are different requirements of higher education institutions in terms of references in the master thesis from the publisher demands (e.g. a journal) that are indexed in the international databases (e.g., Web of Knowledge, PubMed, or Scopus). Each of the systems implies precisely a defined set of rules for citation of sources in the text of scientific or professional articles and their way of quotation. The goal is to ensure that in the text it can be recognized what belongs to the author

and what is taken from other authors/sources. Once adopted a certain style of quotation, it must be applied consistently throughout the text of the article.

7.4. Citation of references in scientific publications: Harvard system of citation

The Harvard system of references represents the most common way of quoting in the natural and social sciences. This system is often referred to as the "author-date" system. In the same category relies the APA system of references which differs from the Harvard system basically in the use of punctuations and conjunctions. A characteristic of the Harvard system is to specify only the basic information in the text (author's name, and year of publication), while the complete data of the article cited are listed at the end of the text in the reference list. In medical sciences, it is common to found in the literature only pieces of work that are directly used (cited) in the text. Authors may read and scrutinize many more articles, however, these sources are not cited in the literature unless they are directly used. Robert Harris has designed simplified diagrams to indicate what needs to be cited (Harris, 2001, quoted by Central Queensland University, 2007).

Citing references in the text

Authors in preparation for creating specific research works, face with different kinds of secondary data. For example, the publication can be written by one or by a number of authors, but also that the authors are not listed anywhere but only organization that has published the article. Bearing this in mind, in citing sources, publications are marked differently in the text. During the writing, authors may refer to different sources. The section below provides examples of proper citations.

Citing references in the text is presented on the example of abstract available at webpage www.scopemed.org (Figure 1).

Masic I, Milinovic K. On-line Biomedical Databases—the Best Source for Quick Search of the Scientific Information in the Biomedicine. Acta Inform Med. (2012), [cited January 25, 2013]; 20(2): 72-84. doi:10.5455/aim.2012.20.72-84.

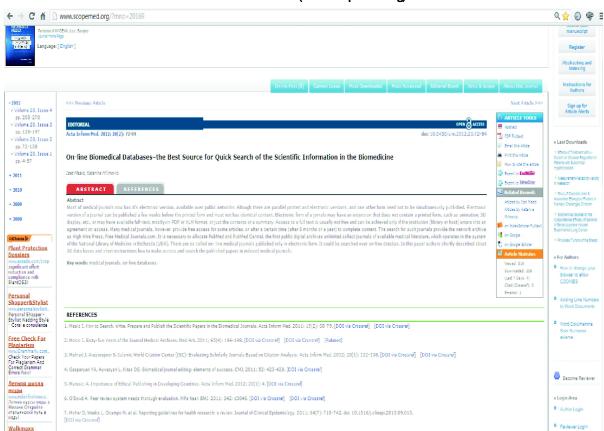


Figure 1. On-line Biomedical Databases - the Best Source for Quick Search of the Scientific Information in Biomedicine at the SCOPEMED (www.scopemed.org)

When we want to quote scientific articles in our text (biomedical disciplines), there are several recognized ways to quote the text.

In SCOPEMED, there is specified a manner in which we will quote this text, in all styles, as presented in Figure 2:

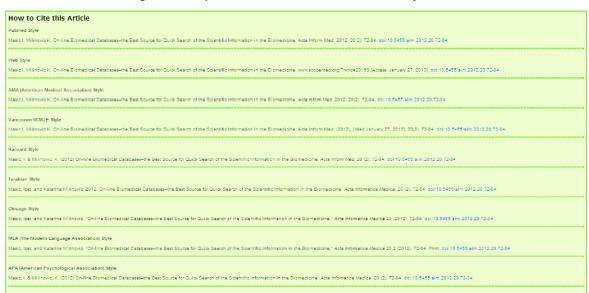


Figure 2. Examples for citation of articles in biomedical journals

Citation employing PubMed Style is presented in Box 1:

Box 1. The PubMed Style citation rules

Masic I, Milinovic K. On-line Biomedical Databases—the Best Source for Quick Search of the Scientific Information in the Biomedicine. Acta Inform Med. 2012; 20(2): 72-84. doi:10.5455/aim.2012.20.72-84

National Library of Medicine (NLM) uses the ANSI/NISO Z39.29-2005 (R2010) Bibliographic References standard as the basic format of Pubmed/MEDLINE citation.

The last item in the above quotation is the unique identification number in the PubMed database and the status of citations indexed in MEDLINE.

In November 2008, the NLM changed the way of quotation so that the first to be cited is the author and then the title of the work.

Characteristics of citations by applying the Vancouver/ ICMJE Style (the most common citation in articles published in biomedical journals) are presented in Box 2:

Box 2. The Vancouver/ICMJE Style citation rules

Vancouver/ICMJE Style

Masic I, Milinovic K. On-line Biomedical Databases-the Best Source for Quick Search of the Scientific Information in the Biomedicine. Acta Inform Med. (2012), [cited January 27, 20131; 20(2): 72-84. doi:10.5455/aim.2012.20.72-84

Authors: The initials of the first and second name should be used, include up to five co-authors. If there are more than six authors, the names of the first three authors should be stated followed by "et al". Characteristics of citations by applying the AMA (American Medical Association) Style are presented in Box 3:

Box 3. The AMA/American Medical Association Style citation rules

AMA (American Medical Association) Style

Masic I, Milinovic K. On-line Biomedical Databases-the Best Source for Quick Search of the Scientific Information in the Biomedicine. Acta Inform Med. 2012; 20(2): 72-84. doi:10.5455/aim.2012.20.72-84

AMA citation rules are presented in Box 4:

Box 4. The AMA Style citation rules

AMA Citation Style American Medical Association Manual of Style, 9th edition							
Follow these color codes:							
Author(s)	Date	Title of Book	Title of Book Title of Article Title of Periodical				
Volume	Pages	Place of Publication	Publisher	Other Information			

Characteristics of citations by applying Web Style manner are presented in Box 5:

Box 5. The Web Style citation rules

Web Style

Masic I, Milinovic K. On-line Biomedical Databases—the Best Source for Quick Search of the Scientific Information in the Biomedicine. www.scopemed.org/?mno=20169 [Access: January 25, 2013]. doi:10.5455/aim.2012.20.72-84

It differs from the other systems in that, after the basic information about the author, the article contains the web address. It is usually used in online portals, or different websites.

Basic bibliographic elements are: author/s, title, journal title, numerical data on the journal, city, publisher, year of publication. Data on the quoted unit (reference), in the text should appear twice: first in the text, and subsequently in the list of references. References in the text are labeled by Arabic numerals starting with number "1" and a list of references is sorted by the order as they appear in the text. Certain types of data are separated by the original punctuation symbols which are in standard references structure accented with red. From this structure we are using bibliographic elements which occur in described publication, and skip all the others. When skipping some elements of the bibliographic description there are not used any preceding punctuation symbols.

For example, if the publication has no subtitle, semicolons preceding the subtitle of the article should not be used; instead, a full stop should be employed indicating the end of each group of data.

7.5. Plagiarism

A particularly important problem in publishing and generally in scientific research is plagiarizing of others ideas, articles, or research work. Plagiarism (form Latin: plagium - kidnapping) is copying from others' works and illegal taking of spiritual ownership (3). Plagiarism (from Latin: Plagiarius - a thief, a kidnapper) is an illegal use of spiritual ownership, or any use of other people's ideas, opinions or theories, either literally or paraphrased, when the author or the source of information is not cited and listed.

Such a "copy-paste" act constitutes theft of authorship, which is completely unacceptable in scientific, professional and student works.

In the wider academic community, plagiarism is a serious breach of ethical standards and implies accountability with a disciplinary sanction.

The biggest problem that the participants in the academic process meet is plagiarism. This is one of the most common ways of compromising the academic integrity of the author and cause of constant conflict in the students - teacher relationship. Copy, use or other exploitation of other people's ideas, words, or creations, without quoting sources in the appropriate form is strictly forbidden. It is not enough to change a few words in a phrase from the source material into "own words". Changing the order of words in a sentence is also not acceptable, as well as the use of synonyms, such as e.g. the change from "air" to "atmosphere".

When writing papers, it is possible to use other people's words and ideas, but with mandatory labeling and listing the sources from which these words and ideas are taken. People who read the article can easily recognize the very sentences written as original work which are actually taken from different parts of articles from other authors. The references, as an essential part of any scientific and technical article, contribute to the quality and the sources and thus the depth of information on the subject to which the article is dedicated. The process of preparation of each article should start by consulting existing sources, possible research and then writing the article by giving its own personal signature.

8. The process of article review

Publication of the results of scientific research is a key phase of scientific activity, and the standard way for this is by publishing a book or an article in renowned scientific journals, either domestic or foreign periodicals. Of course, it is preceded by the evaluation and review of such contributions, regardless of the topic area to which it applies.

'Review means that the manuscript or a research proposal is read and evaluated by experts in a certain period of time, subject area, language and a document that deals with the author. As prominent experts in the field of knowledge that deals with the author, reviewers are preparing an analysis for the committee of experts on the scientific significance of institutions articles in question: Does the author demonstrates knowledge of current developments in the area? A re the research procedure, processes and methodologies, for example, in accordance with professional standards? Does the author offers an original argument and provides valid facts to support their work? If certain statements are weak or absent in the presented contribution, the reviewers suggest the revision that will correct the article offered and ask it again for review before approval of financing a project or to be accepted for publication" (1,4).

Reviews are used in many professional areas, such as academic and scientific research, in medicine, engineering, law, and so on. In other cases, it is particularly relevant to government institutions when selecting projects to be financed by public funds.

9. Evaluation and impact of articles in scientific publications

Evaluation of the quality and relevance of the papers after they are accepted and published in scientific publications, which should be the result of serious scientific research activities, relies mainly on the reception by individual experiences - first round by an identical professional direction and then in the wider plan within reference publications in which such work is shown, quoted, criticized, or praised. In the circles of members of the academic community involved around use, collaborate and edit the scientific and technical publications, there are frequently encountered such terms as indexing, referencing, or citing. According to Tibor Toth, which wrote in an article published on the pages of Open Encyclopedia of Information: "Indexing is a term that is derived from the concept of indexing publications such as Index Medicus, Science Citation Index, and Current Contents, as has been customary, for example, for the Chemical Abstracts or Biological Abstracts called abstract journals, not indexed publications. These are, in fact, along the secondary referral or periodicals, or, more recently, the bibliographic database". Thus, according to Toth, the notion of reference should be more correctly referred

to as indexing. It points to the fact that some secondary information services (Abstracting and Indexing Services) are selected, edited and ranked by bibliographic recording in escalator concepts and/or summaries of the referral publication, or bibliographic databases.

Evaluation of the scientific performance of each scholar, and thus indirectly determining the reputation in the scientific community of the authors - associates of these publications, especially journals, as previously reviewed in this paper, is done through the so-called Impact Factor and the H-index. Currently, journal impact factors are extracted from the publication: Journal Citation Reports (JCR), which is produced by the publisher Thomson Reuters.

10. Selective databases distributed on the basis of Frascati manual

10.1. Databases

The answer to the question of what a database is and its relevance to the scientific research is not easy to address. We may not be wrong if we say that it is, basically, a kind of information resource, often incomparably richer than it is, for example, a single book or magazine (1).

It is a form of storing and retrieval of the knowledge, appearing in the information age, which we have just participated and witnessed. Thanks to the technical possibilities of information networks, databases can be searched for a number of more or less relevant information, and scientific and profound contents.

The contents of the databases typically include such basic information as authorship, title of the article, place of publication, year of publication and, possibly, the volume of content. When it comes to the type of stored records, most of them relate to articles published in the journals. However, in a significant number of cases, there are also records relating to the announcements of scientific meetings published in proceedings, as well as other types of publications such as books, master's theses, doctoral dissertations, technical reports, patents, and, more recently, audio and video records.

The creation of databases involves several types of professionals. Among them are librarians, computer specialists and indexers. Users of the information sources search on topics that are the subject of their research and academic interest.

According to their structure and content, databases can be divided into the following categories (4):

- Bibliographic databases;
- Citation databases, and;
- Databases containing full-text.

10.1.1. Bibliographic databases

Bibliographic databases usually contain bibliographic records proficiently prepared with the structure of the description consisting of the following elements: authorship, title of the article, source, summary, year of publication, publisher, publication type and information about the original language in which the paper was written. These databases differ, particularly in terms of volume of data that present themselves and can contain abstract and index terms as keywords or descriptors. Their topics may include scientific, or commercial resources, as well as daily news. They are usually used to search and locate relevant sources of information and provide a pathway to the original documents referenced in the database. Currently, there is a growing phenomenon of the records in these databases associated with records in other databases, especially full versions that are located somewhere else on the World Wide Web. In addition, such databases may contain electronic addresses of the authors, web-page of the documents, the holder of the copyright, and the like. These databases are, in short, used to get acquainted with the scope and level of research literature in a particular scientific field.

10.1.2. Citation databases

Unlike bibliographic databases, with which they are in close affinity, citation databases process also references and citations that the authors present at the end of the articles. Citation databases, important to mention, offer an answer to the question: "Which are the most atted papers and how relevant are they within a particular scientific field?". Thus, they play a special role in the citation indexing options, with is the most recently quoted from some platforms such as Scopus, for example, which could result in selfquotation. This platform is normally used to gain insight into the relevance of a work within a

particular scientific field.

10.1.3. Full-text databases

After bibliographic searches and insight into the extent of the scientific literature from each area of interest of a certain scholar, experts may want to access databases containing full-text articles. Most often this term refers to the complete recordings of a scientific paper that was published in the form of a journal, book, or proceedings of a symposium. Complete record is usually offered in a truly convenient HTML format (which can be displayed in a Web browser such as Internet Explorer, Mozilla Firefox, Opera, etc., or a PDF format using Acrobat Reader). This resource is used to get familiar with the research work within a particular scientific field.

11. Instruments to access recorded content

Thanks to the digital resources available through access to databases and Internet dissemination of information, including those of a scientific nature, it is much easier and the methodology of access to knowledge has acquired new forms and contents. For a wise search and use of resources in the Internet, there are different types of subject directories (such as About.com, Dmoz.org, Google Directory, Yahoo Directory, Infomine, Librarian's Internet Index, ipl.org, Academicinfo, Bubl.com, and so on).

To this type of instruments, there should be added searching engines such as Scirus, Scitopia, Google Scholar, The Internet Archive, Science Research.com, WorldWideScience, Scitation, TechXtra, Yippi. As for metacrawlers, there should be mentioned the following: www.metacrawler.com, Dogpile, Mamma, and the like.

Back in 1967, Eugene Garfield's drew attention about the fact that the majority of scientific papers published in the world see their public promotion in the English language. In some areas, more than 50% of professional papers are published in the English language, as a means of lingua franca of the global academic community (1). Besides this, languages of small nations remain an important medium for the preservation of the collective memory and the papers in such languages, in the tide of history, contribute to the preservation of national identities. Unfortunately, a number of languages, preserved in communication between members of small ethnic groups in some areas of Asia, Africa and South America are "sentenced to death" (2). On the other hand, increasing specialization in different segments of the scientific research and, consequently, intensive development of technology with international communications, were one of the main reasons that the global exchange of goods and knowledge and language as the medium starts to have more attention. This especially applies to the fact that intensive international exchange follows a

growing number of sophisticated goods with them and a growing number of technical terms, a glossary, and concepts that are at the same time used in the documentation. This process inevitably led to the need for terminology corpus which is used in this process to adequately transmit content from one language to another (3).

The need for harmonization of terminology has led to its standardization, which is illustrated in a series of published bilingual and multilingual dictionaries especially in the field of international trade including ideas and goods (statistical multilingual dictionary is already present on the internet, customs too).

References

- 1. Jacobsen K. Introduction to health research methods. A practical guide. Jones and Bartlett Learning, 2012: 11-80.
- 2. Masic I. How to Search, Write, Prepare and Publish the Scientific Papers in the Biomedical Journals. Acta Inform Med. 2011; 19(2): 68-79. doi: 10.4555/ aim.2011.19.68.79.
- 3. Masic I. Plagiarism in Scientific Publishing. Acta Inform Med. (2012), [cited December 23, 2012]; 20(4): 208-213.
- 4. Masic I, Milinovic K. On-line Biomedical Databases - the Best Source for Quick Search of the Scientific Information in Biomedicine. Acta Inform Med. 2012; 20(2): 72-84. doi: 10.5455/aim.2012.20.72-84.
- 5. Masic I. Ethical Aspects and Dilemmas of Preparing, Writing and Publishing of the Scientific Papers in the Biomedical Journals. Acta Inform Med. 2012 Sep; 20(3): 141-147. doi: 10.5455/aim.2012.20.141-147.
- 6. Gasparyan YA, Ayvazyan L, Kitas DG. Biomedical journal editing: elements of success. CMJ. 2011; 52: 423-428. doi: 103325/cmj.2011.52.423.
- 7. O'Dowd A. Peer review system needs thorough evaluation. MPs hear. BMJ. 2011; 342: d3046. doi: 10.1136/bmj.d3046.
- 8. Lusher FT. The codex of science: honesty, precision and truth - and its violations. European heart journal. 2013; 34: 1018-1023. doi: 10.1093/eurheartj/eht063.
- 9. World Association of Medical Editors. WAME recommendations on Publication Ethics and Policies for Medical Journals. Available: http:// www.wame.org/resources/ethics-resources.
- 10. Committee On Publication Ethics. COPE. Code of Conduct and Best Practice Guidelines for Journal

- Editors. Available at: http://publicationethics.org/ resources/guidelines.
- 11. International Committee of Medical Journals Editors. Uniform Requirements for Manuscript Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. (Updated October 2008). Available: http://www.icmje.org/
- 12. http://vlib.org. Accessed: June 2013.
- 13. www.w3.org. Accessed: June 2013.
- 14. www.wikipedia.org. Accessed: June 2013.
- 15. www.greenstone.org. Accessed: June 2013.
- 16. http://dspace.org. Accessed: June 2013.
- 17. http://dspace.org. Accessed: June 2013.
- 18. www.doi.org. Accessed: June 2013.
- 19. www.iso.org. Accessed: June 2013.
- 20. www.internetsociety.org. Accessed: June 2013.
- 21. www.gutenberg.org. Accessed: June 2013.
- 22. www.ibiblio.org. Accessed: June 2013.
- 23. http://books.google.com. Accessed: June 2013.
- 24. www.stm-assoc.org/about-stm. Accessed: June
- 25. www.icsti.org. Accessed: June 2013.
- 26. www.doi.org. Accessed: June 2013.
- 27. www.books.google.com. Accessed: June 2013.
- 28. www.wipo.int/Scite/standards/standards.htm. Accessed: June 2013.
- 29. www.wipo.int/copyright/en. Accessed: June 2013.
- 30. www.indexers.org.uk. Accessed: June 2013.

Determinants of self-perceived health status in population-based studies

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Abstract

Self-perceived health status reflects people's overall perception of their health, including both physical and psychological dimensions. Based on longitudinal analyses, it has been demonstrated that self-perceived health is a predictor of chronic disease incidence, recovery from illness, functional decline and use of medical services, even when more objective health measures are taken into account. Besides physical health and health behaviors, factors that may contribute to differences in self-perceived health include age, sex, education, income and psychosocial characteristics. Epidemiological data indicate that higher levels of education, higher income, non-smoking status, recreational physical activity, being male, psychological well-being and high self-esteem are all associated with higher scores of self-rated health status. While physical conditions have been reported to be strongly related to health perceptions, some lifestyle factors, socio-economic characteristics and psychosocial factors have also been shown to be statistically significant predictors of self-perceived health status.

Perceived health status reflects people's overall perception of their health, including both physical and psychological dimensions. It is a relative measure and the evidence suggests that people assess their health in relation to their circumstances and expectations, and their peers. To ensure healthy ageing of the population, the later part of the life span of an individual should be free from chronic diseases and impairments. Besides these objective measures of health, the self-perceived health (also referred to as self-reported health) has received considerable

attention in the recent literature. This is due to its strong association with life expectancy on the one hand, and with the future state of health on the other (1). Individuals' self-assessment of their health status may include some aspects that are difficult to capture clinically, such as incipient disease, disease severity, physiological and psychological reserves and social function. When people rate their health, they think not only of their current situation, but also of declines and improvements.

Self-perception of one's own health reflects the

capability to function in a definite social and organizational situation (1). It is regarded as a prognostic indicator of prevalence of various chronic diseases, affecting their prognosis. Thus, individuals with low values of self-perceived health status may use more frequently medical services and have higher absence from work compared to those with opposite attitudes towards their health (2). Perceived health is often more effective than clinical measures for predicting help-seeking behaviors and health service use. Also, health status is strongly associated with the presence or absence of disease and, therefore, health is by definition a subjective state (3).

Based on longitudinal analyses, it can be concluded that self-perceived health is predictor of chronic disease incidence, recovery from illness, functional decline and use of medical services, even when more objective health measures are taken into account (4,5). Research indicates that people rate their health based on more than their physical status. People without specific health problems do not always rate their health at the top of the scale, many describe it as good, rather than very good or excellent (6).

As well as physical health and health behaviors, factors that may contribute to differences in perceived health include age, sex, education, income and psycho-social characteristics. Epidemiological data indicate that higher levels of education, higher income, non-smoking status, recreational physical activity, being male, psychological well-being and high self-esteem are all associated with higher scores of self-rated health status (7).

According to the Statistics Canada's National Population Health Survey (NPHS), 62% of Canadians aged 25 years or older reported very good or excellent health. Just 11% reported fair or poor health and the remaining 27% described their health as good. Not surprisingly, at older ages the prevalence of very good/excellent health declined. Older people more frequently reported their health as poor and very poor compared to those younger than 25 years of age, due to the presence of chronic diseases and physical conditions which are significantly more prevalent among older individuals (8).

To get a clearer picture of the determinants of selfperceived health, multivariate models that control for age were used (2). When physical status, socioeconomic variables, health behaviors and psychosocial characteristics were taken into consideration, the association between self-perceived health and age largely disappeared. This suggests that the association between age and self-perceived health is often not actually attributable to age, but to these other factors. The findings according to the age groups may partly result from individuals assessing their health in relation to social roles. Hence, if people feel they cannot fulfill these social roles, their health perceptions may be more negative.

According to NPHS, men were more likely than women to describe their health as very good/ excellent (63% versus 60%, respectively). Conversely, a higher percentage of women than men described their health as fair/poor. Women consider a broader set of factors when making general ratings of health. They are more likely to take into consideration psychological factors and the presence of non threatening illnesses.

Educational level is a strong determinant of perceived health and also an important component in the socioeconomic concept that reflects not only living conditions, but also attitudes and health behavior in general. People with lower levels of education have lower odds of reporting very good/ excellent health compared with those with higher levels of education (9). On the other hand, people with a higher socio-economic status report better health than those with lower socio-economic levels (8).

Numerous studies have reported the existence of an association between the level of income inequality and the population health outcomes: average health among people living in high-inequality areas appears to be lower than their counterparts living in low-inequality areas. Also, several studies have reported that state-level income inequality significantly affects self-reported health status even after controlling for individual incomes and other demographical variables (10). Recently, the European Community Household Panel reported that income inequality was negatively and consistently related to self-rated health status in the European Union member states in both men and women. However, despite its statistical significance, the magnitude of the impact of the inequality on health is small (11). When people rate their general health, psychological

factors play a role in perceptions. Therefore, the degree to which physical and mental factors contribute to associations between community belonging and perceptions of general health is unknown (12). People with a very strong sense of community belonging had higher odds of reporting excellent or very good perceived health compared with those whose sense of community belonging was weak, even when other potentially confounding factors were taken into account (age, sex, marital status, socio-economic factors, chronic conditions, employment status, and geography). People who are socially isolated are more likely to suffer from poor physical and mental health and to die prematurely. However, studies on the associations between acute health problems and perceived health status are rare. As for the physical activity, men indicating no leisuretime physical activity, describe significantly more frequently their health as poor and very poor compared to men with satisfactory levels of physical activity. The same pattern was observed for women but it was not statistically significant (8).

In conclusion, while physical conditions have been reported to be strongly related to health perceptions, some lifestyle factors, socio-economic characteristics and psychosocial factors have been also shown to be statistically significant predictors of self-perceived health status. Heavy smoking, irregular exercise and overweight have been associated with fair/poor health ratings in several reports. Unhealthy changes in lifestyle have been associated with fair/poor rather than good health. Distress, low self-esteem and low socio-economic status have been reported to be negatively associated with very good/excellent health. The most significant demographic factors that influence self-assessed health are age and the level of education. The accumulation of evidence from different countries on the association between various diseases and self-perceived health status has increased the interest and has raised new research questions about this useful health indicator. Although its precise links with the presence of specific diseases are still not well known, the concept of self-perceived health status is currently used widely in different population-based studies. However, within this very massive literature, very few studies exist that try to establish whether the relationship persists even in lowincome settings, especially in the developing world.

References

- 1. Bond J, Dickinson HO, Matthews F, Jagger C, Brayne C. Self-rated health status as a predictor of death, functional and cognitive impairment: a longitudinal cohort study. European Journal of Ageing 2006; 3:193-206.
- 2. Shields M, Shooshtari S. Determinants of selfperceived health. Health Reports (Statistics Canada, Catalogue 82-003) 2001; 13:35-52.
- 3. Los Angeles County Health Survey, 1997.
- 4. Shadbolt B. Some correlates of self-rated health for Australian women. American Journal of Public Health 1997; 87: 951-956.
- 5. Idler EL, Kasl SV. Self-ratings of health: Do they also predict change in functional ability? Journal of Gerontology: Social Sciences 1995; 506:S344-53.
- 6. Blaxter M. Health and Lifestyles. London/New York: Tavistock/Routledge, 1990.
- 7. Piko B. Health-related predictors of self-perceived health in a student population: the importance of physical activity. J Community Health 2000; 25:125-137.

- 8. Kaleta D, Polañska K, Dziankowska-Zaborszczyk E, Hanke W, Drygas W.Factors influencing selfperception of health status. Cent Eur J Public Health 2009; 17:122-127.
- 9. Faresjö T, Rahmqvist M. Educational level is a crucial factor for good perceived health in the local community Scand J Public Health August 2010; 38:605-610.
- 10. Mellor JM, Milyo J. Income inequality and health status in the United States. Journal of Human Resources 2002; 37:510-539.
- 11. Hildebrand V, Van Kerm P. Income Inequality and Self-Rated Health Status: Evidence from the European Community Household Panel. SEDAP Research Paper No. 127.
- 12. Berkman LF, Glass T, Brissette I, et al. From social integration to health: Durkheim in the new millennium. Social Science and Medicine 2000: 51:843-857.

Cross-cultural adaptation of an instrument measuring older people's health needs and priorities in Albania and Kosovo

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Abstract

Aim: The objective of this study was to validate the EASY-Care tool, an international instrument addressing older people's health needs and current priorities in Albanian settings.

Methods: This validation study, conducted in August-September 2010, included a sample of 38 older people who were users of primary health care services in Pristina (N=20) and in Tirana (N=18). All participants were administered the finalized version of EASY-Care Standard 2010 which was agreed by the EASY-Care International Research Network and already validated in many countries worldwide. The EASY-Care assessment instrument consists of two sections: i) basic information (personal data, biography, medical history), and; ii) assessment of needs and current priorities (visibility, hearing and communication, self-care, movements, security, accommodation and financial circumstances, physical health, mental health and well-being).

Results: Overall, there were 18 men (47.4%) and 20 women (52.6%) included in this validation sample. Median age was 68.5 years (interguartile range: 65.0-76.0 years). Overall, 71% of participants could use telephone without help; 89% could look after their personal appearance; 87% could dress on their own; 92% were able to use toilet and shower; 66% could do household tasks; 79% could cook their own meals; 97% could feed themselves, and; 87% could use medicines on their own. Overall, 79% of older people had not had falls in the last 12 months; 42% of individuals perceived their health status as good; 60% had suffered any body pain in the last month; 58% had been worried by the feeling of desperation, depression or hopelessness in the last month; 74% had been worried due to lack of interest or pleasure to do something in the last month, and; 63% of study participants were worried in relation to los of their memory.

Conclusions: In Albanian settings, we provide evidence on the process of cross-cultural adaptation of a useful instrument employed internationally assessing older people's health and social needs and their current priorities.

Keywords: Albania, EASY-Care, Kosovo, older people.

Introduction

The EASY-Care program has a legacy of continuous research and development, since the need and conceptual basis for an assessment instrument for holistic, preventive care for use in primary care was identified during a Public Health Research Fellowship undertaken by Professor Ian Philp with Professor Robert Kane at the University of Minnesota in 1989 (1).

Prior to developing and validating the EASY-Care instrument, there has been little experience with use of standardized assessment instruments for older people in primary health care settings and community care settings (2). A proper assessment practice involves both health and social needs of older people in a balanced way supporting decision making with evidence based screening tools. From this point of view, EASY-Care provides a simple, valid and reliable assessment for early identification of a range of health care needs (1).

The EASY-Care assessment is derived from a collection of well-established instruments where these are available for the EASY-Care domains. Source instruments have been modified where necessary to ensure consistency in format and flow (1). The items and domains of the assessment were agreed and refined in validation studies under taken in several European studies in the 1990s (1-7).

From 2000-2008 Professor Ian Philp, the EASY-Care Program Director, was appointed National Tsar for Older People at the Department of Health in the UK, where he lead the development and implementation of the National Service Framework for Older People. During this period, the EASY-Care program of research continued, but it was following a successful re-launch in 2008 that the scope of use of EASY-Care instruments has been broadened from mainly European to global use, with work on cross-cultural translation and validation undertaken in more than 30 countries from the developed and developing world in all six WHO regions (1).

Research and user feedback has indicated that the EASY-Care instrument is particularly useful for obtaining a rounded assessment of need and personal response in at-risk older people and living in the community. A number of studies have been undertaken by researchers around the world and have demonstrated: i) good reliability and validity in psychometric studies (3-7); ii) high levels of costeffectiveness in improving functional outcomes and reducing hospital admissions with an increase in community service provision (8,9); iii) population studies in several countries using EASY-Care data have shown the value of the instrument in identifying the prevalence of population health and care needs of older people (1,10).

In this context, our aim was to validate the EASY-Care tool, an internationally validated instrument employed for assessment of older people's health needs and current priorities in Albania and Kosovo, two transitional countries in the Western Balkans.

Methods

A sample of 38 older people who attended primary health care services in Pristina (capital city of Kosovo) and Tirana (capital city of Albania) were included in the EASY-Care validation procedures in August-September 2010.

All participants were administered the finalized version of EASY-Care Standard 2010 which was agreed by the EASY-Care International Research Network and already validated in many countries worldwide. The EASY-Care Standard 2010 instrument ensures a record of needs and priorities about the health and care for older people who can fill the assessment form themselves or under the guidance of health professional or social care professional. In addition, older people may prefer that a member of their family or friend be involved in filling the assessment form. The EASY-Care assessment instrument consists of the following two sections:

- · Basic information: personal data, biography, medical history;
- · A ssessment of needs and aurrent priorities: visibility, hearing and communication, self-care, movements, security, accommodation and financial circumstances, physical health, mental health and well-being. The EASY-Care Standard 2010 instrument was translated from English into Albanian and subsequently back-translated from Albanian into English following the standard methods of translation and cross-cultural adaptation of the questionnaires (11). The aim of the cross-cultural adaptation was to provide a version of the instrument that was

conceptually as close as possible to the original questionnaire, considering nevertheless Albania and Kosovo older people's perspective understanding (11).

Results

In this validation sample of older people in Albania (N=18, or 47.4% of the overall sample) and Kosovo (N=20, 52.6%), median age was 68.5 years (interquartile range: 65.0-76.0 years) [Table 1]. Overall, median educational attainment was 8.0 years (interquartile range: 4.0-12.0 years). Overall, there were 18 men (47.4%) and 20 women (52.6%). About 79% of participants resided in urban areas compared with 21% of rural residents. About 66% of individuals were currently married, whereas 34% were either single or widowed. About 32% of participants reported that their finances were not sufficient to meet the end of the month, whereas a similar proportion of older people reported that they could save some money at the end of the month. About 40% of older people reported living in a nuclear type of family, compared with 60% of those who reported an extended family type. Finally, about 16% of the sample participants were currently employed vs. 84% who were retired.

Table 2 presents the distribution of the items related to the sense of autonomy in the EASY-Care validation sample in Albania and Kosovo. Overall, 71% of participants could use telephone without help; 89% could look after their personal appearance; 87% could dress on their own; 92% were able to use toilet and shower: 66% could do household tasks; 79% could cook their own meals; 97% could feed themselves, and; 87% could use medicines on their own.

Table 3 presents the distribution of the items related to health and well-being among study participants. Overall, 79% of older people had not had falls in the last 12 months; 42% of individuals perceived their health status as good; 60% had suffered any body pain in the last month; 58% had been worried by the feeling of desperation, depression or hopelessness in the last month; 74% had been worried due to lack of interest or pleasure to do something in the last month, and; 63% of study participants were worried in relation to los of their memory.

On the whole, about 84% of participants reported that the duration of the evaluation process had the right amount; 60% reported that the evaluation was entirely clear; 50% believed that the evaluation was useful, and; about 58% reported that they would be willing to recommend the current evaluation procedure to their peers (Table 4).

Discussion

Our study provides evidence on the process of cross-cultural adaptation in Albanian settings of the EASY-Care tool, an internationally validated instrument assessing health needs and priorities of older people (1-10). Findings from this pilot study revealed a satisfactory duration of the evaluation process as reported by the majority of older people both in Albania and Kosovo. Furthermore, half of respondents in this validation study considered the evaluation useful and the majority of study participants found the assessment form rather clear, which reflects a great potential for a wider use of the EASY-Care tool in population-based studies in Albanian speaking countries.

Our study adds to the current body of international literature indicating the worldwide usefulness of EASY-Care assessment as a reliable and valid instrument (3-7), a tool with high levels of costeffectiveness in improving functional outcomes and reducing hospital admissions with an increase in community service provision (8,9), and a valuable instrument in identifying the prevalence of population health and care needs of older people (1,10).

Potential limitations of our study include the small sample size and differential reporting of older people based on their demographic and socioeconomic characteristics. Nevertheless, on the face of it, there is no plausible reason for older people's categories differing in their sociodemographic and socioeconomic characteristics to have reported differently on the EASY-Care domains included in the evaluation form.

In conclusion, in Albanian settings, we provide evidence on the process of cross-cultural adaptation of a useful instrument employed internationally assessing older people's health and social needs and their current priorities. Future studies in Albania and Kosovo should involve large population-based samples of older people in order to assess their health and social needs and current priorities as evidenced by the already validated EASY-Care instrument.

Table 1. Distribution of demographic and socioeconomic characteristics in the EASY-Care validation sample of older people in Albania and Kosovo (N=38) in 2010

Variable	Median (IQR) / N (%)	
Age (years)	68.5 (65.0-76.0)*	
Educational level (years)	8.0 (4.0-12.0)*	
Country:		
Albania	18 (47.4) [†]	
Kosovo	20 (52.6)	
Sex:		
Men	18 (47.4) [†]	
Women	20 (52.6)	
Place of residence		
Urban area	30 (78.9) [†]	
Rural area	8 (21.1)	
Marital status:		
Married	25 (65.8) [†]	
Widowed/single	13 (34.2)	
Finances at the end of month:		
Not enough	12 (31.6) [†]	
Enough	14 (36.8)	
Could save some money	12 (31.6)	
Type of family:		
Nuclear	$15 (39.5)^{\dagger}$	
Extended	23 (60.5)	
Profession:		
Employed	byed $6 (15.8)^{\dagger}$	
Pension	32 (84.2)	

^{*} Median values and interquartile ranges (in parentheses).

[†] Numbers and column percentages (in parentheses).

Table 2. Distribution of the autonomy items in the EASY-Care validation sample of older people in Albania and Kosovo (N=38) in 2010

Variable	Numbers	
	(column percentages)	
Can you use telephone?		
Without help	27 (71.1)	
With help	11 (28.9)	
Can you look after your personal		
appearance?		
Without help	34 (89.5)	
With help	4 (10.5)	
Can you dress on your own?		
Without help	33 (86.8)	
With help/unable	5 (13.2)	
Are you able to use toilet and shower?		
Without help	35 (92.1)	
With help/unable	3 (7.9)	
Can you do household tasks?		
Without help	25 (65.8)	
With help/unable	13 (34.2)	
Can you cook your own meals?		
Without help	30 (78.9)	
With help/unable	8 (21.1)	
Can you feed yourself?		
Without help	37 (97.4)	
With help	1 (2.6)	
Can you use medicines on your own?		
Without help	33 (86.8)	
With help/unable	5 (13.2)	

Table 3. Distribution of the items related to health and well-being in the EASY-Care validation sample of older people in Albania and Kosovo (N=38) in 2010

Variable	Numbers
	(column percentages)
Have you had falls in the last 12 months:	}
No	30 (78.9)
Yes	8 (21.1)
General health status	
Good	16 (42.1)
Poor	22 (57.9)
Have you suffered any body pain in the l	ast month?
No	23 (60.5)
Yes	15 (39.5)
During the last month, have you often be	en worried by the feeling
of desperation, depression or hopelessner	ss?
No	22 (57.9)
Yes	16 (42.1)
During the last month, have you often be	en worried due to lack of
interest or pleasure to do something?	
No	28 (73.7)
Yes	10 (26.3)
Are you worried in relation to loss of me	mory?
No	24 (63.2)
Yes	14 (36.8)

Table 4. Evaluation opinions of older people included the EASY-Care validation sample in Albania and Kosovo (N=38) in 2010

Variable	Numbers
	(column percentages)
Evaluation duration	
About the right amount	32 (84.2)
A little less or a little more than needed	8 (15.8)
Was the evaluation clear?	
Everything clear	23 (60.5)
Partly clear	15 (39.5)
Was the evaluation useful?	
Very useful	19 (50.0)
Somehow/little useful	19 (50.0)
Would you recommend this evaluation to your peers?	
Definitely	26 (68.4)
Maybe yes, maybe not	16 (31.6)

References

- 1. EASY-Care Organization. Available at: http:// easycare.org.uk/about/content/39/developmentand-evaluation (accessed: June 2013).
- 2. Lowles RV, Philp I. Simple Measures for Assessing the Physical, Mental and Social Functioning of Older People. Generations Review 2001; 11:12-14.
- 3. Melis R, Van Eijken M, Achterberg T, Teerenstra S, Vernooij-Dassen, Lisdonk E, Rikkert M. The effect on caregiver burden of a problem-based home visiting programme for frail older people. Age and Ageing 2009; 38:542-547.
- 4. Parker C, Philp I. Screening for cognitive impairment among older people in black and minority ethnic groups. Age and Ageing 2004; 33:447-452.
- 5. Parker C, Philp I, Sarai M, Rauf A. Cognitive screening for people from minority ethnic backgrounds. Nursing Older People 2007; 18:31-36.
- 6. Philp I, Hoyle E, O'Brien E, Parker C. Screening tools for older people at risk of adverse outcomes. Geriatric Medicine 2007; 37:10-13.
- 7. Philp I. EASY-Care: A systematic approach to the assessment of older people. Geriatric Medicine 2000; 30:15-20.

- 8. Melis RJF, Adang E, Teerenstra S, van Eijken MIJ, Wimo A, van Achterberg T,van de Lisdonk EH, Olde Rikkert MGM. Cost effectiveness analysis of multidisciplinary program to intervene on geriatric syndromes in frail older people who live at home (Dutch EASYcare Study) The Journal of Gerontology: Medical Sciences 2008; 63:275-282.
- 9. Perry M, Draskovic I, van Achterberg T, Borm GF, van Eijken MI, Lucassen PL, Vernooij -Dassen MJ, Olde Rikkert MG. Can an EASYcare based dementia training programme to improve diagnostic assessment and management of dementia by general practitioners and primary care nurses? The design of a randomized controlled trial. BMC Health Serv Res 2008; 8:71.
- 10. Bath PA, Philp I, Boydell L, McCormick W, Bray J, Roberts H. Standardised health check data from community-dwelling elderly people: the potential for comparing populations and estimating need. Journal of Health and Social Care in the Community 2000; 8:17-21.
- 11. Sperber AD, Devellis FR, Boehlecke B. Crosscultural translation: methodology and validation. Journal of Cross-Cultural Psychology 1994; 25:501-524.

Morphological variations of gallbladder in the **Albanian population**

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Abstract

Aim: In surgical settings, it is important to understand the anatomy and different types of variations of the gallbladder and the biliary tract, because these structures are in close connection with the adjoining organs and may show various anomalies and anatomic variations. Our aim was to assess the level of morphological variations of gallbladder in the Albanian population. Methods: A sample of 9481 primary health care users aged d"80 years was examined in Tirana, the Albanian capital city, during 2011-2012 (response rate: 95%). All participants underwent an ultrasound examination of the gallbladder.

Results: Overall, the length of gallbladders ranged from 5 cm to 12 cm. However, in 81% of study participants, the length of gallbladders ranged from 7 cm to 10 cm. Conversely, the width of gallbladders ranged from 2.5 cm to 5.0 cm (mean value: 3.89±0.75 cm). There was evidence of a moderate positive correlation between length and width of gallbladders (r=0.34, P=0.008). Overall, there were 74 (0.78%) cases with gallstones (95%Q=0.61%0.98%). About 85% of study participants had a pear-type gallbladder.

Conclusion: Our study provides novel evidence on the morphological variations of gallbladder in the Albanian population. Our findings pertinent to the prevalence of gallstones and anatomical variation of the gallbladder are generally compatible with similar reports from other countries.

Keywords: anatomic variation, biliary tract, gallbladder, gallstone, morphological variation.

Introduction

The gallbladder 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 gallbladder 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).

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 (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 a study conducted 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 is a rare variance and is considered as a consequence of an incomplete cavitation of the developing gall bladder bud (9-12). 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 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 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). Distribution of dimensions and shapes of the gallbladder in the Albanian population has not been reported to date. From this point of view, the information about morphological variations of the gallbladder in the general Albanian population is scarce. In this context, the aim of our study was to assess the level of morphological variations of the gallbladder examined in a large and representative sample of primary health care users in Tirana municipality, the Albanian capital city.

Methods

A sample of 10000 primary health care users in Tirana (aged d"80 years) was targeted for inclusion in our study during 2011-2012. Of the overall target population, 285 individuals were not eligible for inclusion in this study, whereas a further 234 individuals refused to participate in our study. The final sample which was examined consisted of 9481 individuals who agreed to participate in the study (response rate: 94.81%).

All participants underwent an ultrasound examination of the gallbladder after being informed about the aims and procedures of the study. The lengths, widths and shapes of gallbladders were measured and defined among all individuals who agreed to participate in the study.

The descriptive analysis consisted of presentation of the distribution of dimensions and shapes of gallbladders among our study participants. Absolute numbers, percentages and their respective 95% confidence intervals (95%CI) were calculated with use of WIN-PEPI (Program for Epidemiologists).

Results

The length of gallbladders ranged from 5 cm to 12 cm in the total sample included in this study. Overall, 334 (3.52%, 95%CI=3.16%-3.91%) of the study participants had a gallbladder length from 5.0 cm. to 7.0 cm; 7679 individuals (80.99%, 95%CI=80.19%-81.78%) had a gallbladder length from 7.1 cm to 10.0 cm, and; 1468 further participants (15.48%, 95%CI=14.76%-16.23%) had a gallbladder length from 10.1 cm to 12.0 cm (Table 1).

Table 1. Distribution of gallbladder length in a large sample of primary health care users in Albania (N=9481)

Gallbladder length	Number	Percentage	95%CI
5.0-7.0 cm	334	3.52	3.16-3.91
7.1-10.0 cm	7679	80.99	80.19-81.78
10.1-12.0 cm	1468	15.48	14.76-16.23
Total	9481	100%	-

On the other hand, the width of gallbladders in the total sample ranged from 2.5 cm to 5.0 cm (mean value: 3.89 ± 0.75 cm). Overall, 1089 (11.49%, 95% CI=10.85%-12.15%) of the study participants had a gallbladder width from 2.5 cm to 3.0 cm; 6371 individuals (67.20%, 95% CI=66.24%-68.14%) had a gallbladder width from 3.1 cm to 4.5 cm, and; 2021 participants (21.32%, 95% CI=20.50% -22.16%) had a gallbladder width from 4.6 cm to 5.0 cm (Table 2).

Table 2. Distribution of gallbladder width in a large sample of primary health care users in Albania (N=9481)

Gallbladder width	Number	Percentage	95%CI
2.5-3.0 cm	1089	11.49	10.85-12.15
3.1-4.5 cm	6371	67.20	66.24-68.14
4.6-5.0 cm	2021	21.32	20.50-22.16
Total	9481	100%	-

There was evidence of a moderate positive correlation between the length and width of gallbladders (r=0.34, P=0.008).

Table 3. Distribution of callbladder shapes among study participants (N=9481)

Gallbladder shape	Number	Percentage	95%CI
Pear	8039	84.79	84.05-85.50
Cylindrical	321	3.39	3.03-3.77
Balloon	493	5.20	4.76-5.67
Sand watch	329	3.47	3.11-3.86
Inverted	158	1.67	1.42-1.94
Disordered	141	1.49	1.19-1.84
Total	9481	100%	-

Table 3 presents the distribution of gallbladder shapes among study participants. Overall, 8039 (84.79%, 95%CI=84.05%-85.50%) individuals had a pear-type gallbladder; 321 (3.39%, 95% CI=3.03%-3.77%) had a cylindrical type of the gallbladder; 493 (5.20%, 95%CI=4.76%-5.67%) had a balloon shape of the gallbladder; 329 (3.47%, 95%CI=3.11%-3.86%) had a sand watch shape of the gallbladder; 158 (1.67%, 95% CI=1.42%-1.94%) had an inverted type of the gallbladder, and; a further 141 individuals (1.49%, 95% CI=1.19%-1.84%) had a disordered-type of the gallbladder.

Overall, there were 74 (0.78%) cases with gallstones (95% CI = 0.61% - 0.98%) [data not shown in the tables].

Discussion

This is the first report from Albania presenting the morphological variations of the gallbladder in a large representative sample of the Albanian population

attending primary health care services in Tirana. Our study provides valuable evidence on the distribution of gallbladder dimensions (length and width) in the general population. In addition, this study informs about the distribution of the major shaper of gallbladders in the Albanian population.

Generally, our findings are compatible with prior international reports involving population-based studies conducted in different countries worldwide (1,3,4). From this point of view, our findings pertinent to the prevalence of gallstones and anatomical variations of gallbladders are generally compatible with similar reports from other countries (5-15).

Another 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. The hospitalized patients underwent an ultrasound examination for assessment of anatomic variations of the gall bladder (findings from this study are currently under review in another scientific journal). 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. Findings from this study including hospitalized patients are comparable with the current survey involving primary health care users in Tirana. From this perspective, the distribution of dimensions (length and width) and shapes of gallbladders were essentially similar in both study populations (that is hospitalized patients and primary health care users). Our study may have several limitations. Notwithstanding its relatively huge size, the sample included in this study may not be representative of the overall Albanian population given the fact that our study participants were recruited from primary health care services in Tirana. However, we included in our study primary health care users selected at random over a defined time period.

In conclusion, our study provides novel evidence on the morphological variations of gallbladder in the Albanian population. Future studies in Albania should involve population-based samples and should explore in detail the link between gallbladder shape and size with morbidity outcomes.

References

- 1. Onder H, Ozdemir MS, Tekbao G, Ekici F, Gümüo H, Bilici A. 3-T MRI of the biliary tract variations. Surg Radiol Anat 2013; 35:161-167.
- 2. Mortele K, Ros PR. Anatomic variants of the biliary tree: MR cholangiographic findings and clinical applications. AJR Am J Roentgenol 2001; 177:389-394.
- Puente SG, Bannura GC. Radiological anatomy of the biliary tract: variations and congenital abnormalities. World J Surg 1983; 7:271-276.
- 4. Schwartz SI (1999). Gallbladder and extrahepatic system. In: Schwartz SI, Shires GT, Spencer FC et al (eds.) Principles of surgery, 7th edn. McGraw-Hill, New York.
- 5. Basaranoglu M, Balci NC. Recurrent cholangitis associated with biliary sludge and Phrygian cap anomaly diagnosed by magnetic resonance imaging and magnetic resonance cholangiopancreatography despite normal ultrasound and computed tomography. Scand J Gastroenterol 2005; 40:736-
- 6. Cook J, Hou PC, Ho HC, McFadzean AJ. Recurrent pyogenic cholangitis. Br J Surg 1954; 42:188-203.
- 7. Bortoff GA, Chen MY, Ott DJ, Wolfman NT, Routh WD, et al. Gallbladder stones: imaging and intervention. Radiographics 2000; 20:751-766.

- 8. Hakansson K, Leander P, Ekberg O, Hakansson HO. MR imaging in clinically suspected acute cholecystitis. A comparison with ultrasonography. Acta Radiol 2000; 41:322-328.
- 9. Simon M, Tandon BN. Multiseptate gallbladder: a case report. Radiology 1963; 80:84.
- 10. Türkvatan A, Erden A, Celik M, Olçer T. Ectopic hypoplastic and multiseptate gallbladder with coexisting choledochal cyst: evaluation with sonography and magnetic resonance cholangiopancreaticography. J Clin Ultrasound 2006; 34:88-91.
- 11. Kapoor V, Federle MP, Peterson MS, et al. Long term sonographic follow-up of stable imaging findings of multiseptate gallbladder. J Ultrasound Med 2002; 21:677.
- 12. Tan CE, Howard ER, Driver M, et al. Non-communicating multiseptate gallbladder and choledochal cyst: a case report and review of publications. Gut1993; 34:853.
- 13. Jena PK, Hardie RA, Hobsley M. Multiseptate hypoplastic gallbladder. Br J Surg 1977; 64:192.
- 14. Nakazawa T, Ohara H, Sano H, et al. Multiseptate gallbladder: diagnostic value of MR cholangiography and ultrasonography. Abdom Imaging 2004; 29:691.
- 15. Pradeep VM, Ramachandran K, Sasidnaran K. Anomalous position of the gallbladder: ultrasonographic and scintigraphic demonstration in four cases. J Clin Ultrasound 1992; 20:593.

Primary health care visits in the Albanian population during 2005-2012

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Abstract

Aim: Our aim was to describe the level of primary health care visits conducted by family physicians in Albania in the past decade.

Methods: We reviewed the number of primary health care visits conducted in each of the 36 districts of Albania separately for urban areas and rural areas for the period 2005-2012. The information was collected from the files of the Institute of Health Insurance.

Results: For both urban areas and rural areas, there was evidence of a significant increase in the number of the overall primary health care visits performed by family physicians in Albania. In urban areas of Albania, the overall number of primary health care visits increased from 2436314 in 2005 to 3767941 in 2012 (linear trend: P<0.01). Conversely, in rural areas of Albania, the overall number of primary health care visits increased from 1001990 in 2005 to 1863592 in 2012 (linear trend: P<0.01).

Conclusion: There has been a considerable and consistent increase in the overall number of health visits conducted by general practitioners and family physicians in Albania over the past decade. Future studies should explore the putative link between the frequency of health visits and the quality of health care services provided by primary health care professionals in Albania.

Keywords: family physicians, general practitioners, health visits, primary health care, rural areas, urban areas.

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Introduction

There is a considerable amount of literature linking the rate of primary health care visits with demographic factors (age, sex, marital status and place of residence) and socioeconomic characteristics (1-3). Furthermore, differences in the rates of primary health care visits may reflect differences in health beliefs, health-seeking behavior and doctorpatient relationships between groups (1,4).

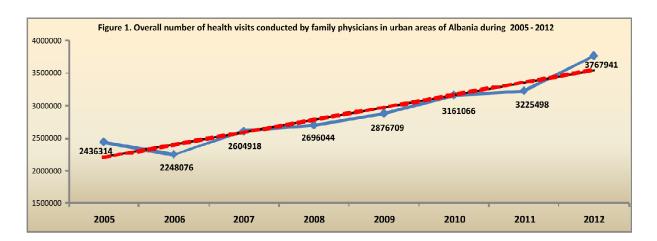
On the other hand, quality of care is associated with health outcomes (5,6) and this holds especially true for primary health care services (7). From this perspective, the primary health care users receive considerable attention in most of the industrialized countries. Users' satisfaction is relevant to the success of the "gate-keeping" function of primary health care. This is particularly important for the former communist countries in Europe including transitional Albania which is currently undertaking deep reforms in the health sector moving from hospital-based system to the primary health care model. The current health care reforms in Albania, however, face enormous challenges with regard to the effectiveness of the referral system.

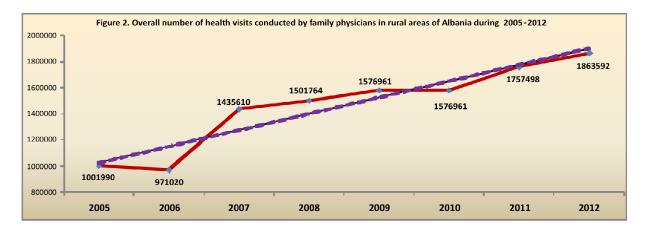
In this short report we describe the primary health care visits conducted by family physicians in Albania in the past decade.

Methods

For the current analysis, we reviewed the number of primary health care visits conducted in each of the 36 districts separately for urban areas and rural areas of Albania for the period 2005-2012. The information was collected from the files of the Institute of Health Insurance, which receives detailed records on the performance of the primary health care professionals in each district of Albania.

Statistical Package for Social Sciences (SPSS, version, 19.0) was used to assess the statistical significance of linear trends in the overall number of health visits conducted in urban areas and in rural areas of Albania for the period under investigation.





Results

The overall number of health visits conducted by family physicians in urban areas and in rural areas of Albania is presented in Figures 1-2.

For both urban areas and rural areas, there was evidence of a significant increase in the number of the overall primary health care visits performed by family physicians in Albania.

In urban areas of Albania, the overall number of primary health care visits was 2436314 in 2005, 2248076 in 2006, 2604918 in 2007, 2696044 in 2008, 2876709 in 2009, 3161066 in 2010, 3225498 in 2011 and 3767941 in 2012 (Figure 1).

The consistent increase in the number of health visits from 2436314 in 2005 to 3767941 in 2012 was statistically significant (linear trend: P<0.01).

On the other hand, in rural areas of Albania, the overall number of primary health care visits was 1001990 in 2005, 971020 in 2006, 1435610 in 2007, 1501764 in 2008, 1576961 in 2009 and in 2010, 1757498 in 2011 and 1863592 in 2012 (Figure 1). The consistent increase in the number of health visits from in 1001990 in 2005 to 1863592 in 2012 was statistically significant (linear trend: P<0.01).

In both urban areas and rural areas of Albania, there was evidence of a slight decrease in the number of health visits for the year 2006, which corresponds to the transition towards the new reforms in the Albanian primary health care sector which was finally introduced in early 2007.

Discussion

Our analysis revealed a significant increase in the overall number primary health care visits in both urban areas and rural areas of Albania. The increasing trend in the rates of health visits was similar in most of the districts of Albania.

Different studies have reported a positive association between patient satisfaction and quality of primary care (8) and health outcomes (9,10). In addition, it has been reported that the number of primary health care visits is associated with age, socioeconomic status, and urban/rural location, indicating that such visits may reflect differences in health beliefs, health-seeking behavior and doctorpatient relationships between groups (1-4). It would be appealing to conduct a stratified analysis by agegroup, sex, and socioeconomic characteristics of the Albanian population in order to determine the link between the rate of health visits with demographic factors and socioeconomic characteristics.

A limitation of our analysis concerns the lack of disaggregated data on the type of health visits performed by family physicians in both urban areas and rural areas of Albania. From this point of view, we cannot distinguish whether the apparent increase in the overall number of primary health care visits concerns e.g. preventive services and periodic checkups of the adult population, or treatment of chronic conditions among older people. In addition, the lack of disaggregated data does not inform about the number of health visits performed at an individual level. From this perspective, the increase in the overall number of health visits might imply an increase in the number of new users of primary health care services in Albania, but might also reflect an increase in the number of health visits performed by the same individuals (who maybe e.g. chronic patients). Hence, it would be interesting to break down the number of health visits by users of primary health care services (new users vs. chronic patients) and also by type of the visits performed (preventive services and checkups vs. treatment of chronic diseases).

In conclusion, our analysis indicates that there has been a considerable and consistent increase in the overall number of health visits conducted by general practitioners and family physicians in Albania over the past decade. However, such an increase in the number of primary health care visits may not necessarily relate to an overall improvement of the quality of care. Therefore, future studies should explore the putative link between the frequency of health visits and the quality of health care services provided by primary health care professionals in Albania.

References

- 1. Cowling TE, Cecil EV, Soljak MA, Lee JT, Millett C, Majeed A, Wachter RM, Harris MJ. Access to primary care and visits to emergency departments in England: a cross-sectional, population-based study. PLoS One 2013; 8(6):e66699. doi: 10.1371/ journal.pone.0066699.
- 2. Agarwal S, Banerjee J, Baker R, Conroy S, Hsu R, Rashid A, Camosso-Stefinovic J, Sinfield P, Habiba M. Potentially avoidable emergency department attendance: interview study of patients' reasons for attendance. Emerg Med J 2012; 29(12):e3. doi: 10.1136/emermed-2011-200585.
- 3. Baker R, Bankart MJ, Rashid A, Banerjee J, Conroy S, Habiba M, Hsu R, Wilson A, Agarwal S, Camosso-Stefinovic J. Characteristics of general practices associated with emergency-department attendance rates: a cross-sectional study. BMJ Qual Saf 2011; 20:953-958.
- 4. Andersen R, Newman JF. Societal and individual determinants of medical care utilization in the United States. Milbank Mem Fund Q Health Soc 1973; 51:95-124.
- 5. McElduff P, Lyratzopoulos G, Edwards R, Heller RF, Shekelle P, Roland M. Will changes in primary

- care improve health outcomes? Modelling the impact of financial incentives introduced to improve quality of care in the UK. Qual Saf Health Care 2004; 13:191-197.
- 6. Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q 2005; 83:457-502.
- 7. Atun R. What are the advantages and disadvantages of restructuring a health care system to be more focused on primary care services? Health Evidence Network report. Copenhagen, WHO Regional Office for Europe 2004. Available at: http://www.euro.who.int/document/ e82997.
- 8. Heje HN, Vedsted P, Olesen F. General practitioners' experience and benefits from patient evaluations. BMC Fam Pract 2011; 12:116.
- 9. Van Walraven C, Oake N, Jennings A, Forster AJ. The association between continuity of care and outcomes: a systematic and critical review. J Eval Clin Pract 2010; 16:947-956.
- 10. Hush JM, Cameron K, Mackey M. Patient satisfaction with musculoskeletal physical therapy care: a systematic review. Phys Ther 2011; 91:25-36.

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.

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

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- brief communications;
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The title page should contain the following information:

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Methods:

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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.

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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

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

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- 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.
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