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New Directions of Maternal Factors and Ultrasound Markers in the Prediction of Early and Late Pre-Eclampsia

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Abstract

Pre-eclampsia (PE) is one of the hypertensive pregnancy disorders, de novo protein-uric hypertension that develops after 20 weeks of gestation and it is a systemic disorder associated with high maternal and neonatal morbidity and mortality. The aim of this study was to determine the usefulness as a screening method for early- and late-onset pre-eclampsia of a combination of a series of measurements, including maternal characteristics and UtA Doppler measured at 11 + 0 to 13 + 6 weeks of gestation and 22 to 24 weeks of gestation. This is a retrospective cohort study, during January - December 2017, of women who have had Pre-eclampsia at a tertiary referral University Hospital of Obstetrics and Gynecology "Koço Gliozheni" in Tirana, Albania. In total were 62 women with Pre-eclampsia during this period of time. Maternal and neonatal data were collected from the case notes and was done uterine artery color Doppler examination at 22-24 weeks of gestation. The ultrasound machine used was Aloka Echo Camera L. All data were calculated with SPSS 15.0. T-test, Chi-Square test, Fisher test and Correlation were used for statistical analysis. In total, 62 women with Pre-eclampsia were classified: 32% Early PE and 68% Late PE. In Doppler examination 26 % had bilateral notch at uterine artery, 12 % notch at AU Dexter, 15 % notch at AU Sinister and 47,1 % without notch. 58.8 % Apgar score in the first minute was 8 and

67.6 % in the fifth minute was 9. Mean Fetus Weight at Early PE 1543.18 g and at Late PE 2623.91 g and mean NICU was 37.82 days at early PE and 6.87 days at Late PE. There is a very significant correlation between Fetus Weight (g) and NICU (R=-0.84, p<0.001) also there is a significant difference between the presence of IUGR on early and Late PE (Fisher's Exact Test = 8.192, p=0.008). There is a significant difference on CPR values on early and late PE (T-test = -2.127, p=0.041).

Keywords: pre-eclampsia, maternal characteristics, screening, uterine artery Doppler

Introduction

Pre-eclampsia (PE) is one of the hypertensive pregnancy disorders, de novo proteinuric hypertension that develops after 20 weeks of gestation, which affects from 3 to 5% of pregnant women. It is a systemic disorder associated with high maternal and neonatal morbidity and mortality (Roberts JM. 2001.) In addition, PE frequently coexists with intrauterine growth restriction (IUGR, also called fetal growth restriction), placental abruption, and the need for iatrogenic preterm delivery, which are additional major causes of adverse outcomes. (Poon LC et al. 2010). Its diagnosis is based on clinical features, such as high blood pressure and proteinuria, which are the terminal events of a cascade of phenomena that are likely initiated during placental formation and development in the late first trimester of gestation (Redman CWG. 2009). Increasingly, early-onset pre-eclampsia is considered to be a more severe form of the disease than is the late-onset condition (Romero R. 2008). Many groups have focused on methods to predict pre-eclampsia in order to identify accurately pregnant women who are at risk (Nicolaides KH. 2007). Pregnancy-related HD are thought to be the consequence of impaired trophoblastic invasion of the maternal spiral arteries, resulting in maintenance of vessels of high resistance, inadequate perfusion of the placenta, tissue injury, and increased production of vasoconstrictive substances. In these cases, there are qualitative and quantitative changes in the maternal uterine artery (UA) Doppler waveforms. Maternal uterine artery (UtA) Doppler at 22–24 weeks of gestation has become the most reliable tool for prediction of pre-eclampsia; this diagnostic test has the ability to predict nearly 50% of instances of any form of the disease and approximately 85% of cases of severe or early-onset disease (Parra M et al. 2005), (Yu CK et al. 2005). However, UtA Doppler performed in the final weeks of the first trimester of gestation (11 + 0 to 13 + 6 weeks) varies much more in its predictive ability for early-onset pre-eclampsia than it does at the second-trimester scan. (Martin AM et al. 2001), (Plasencia W et al. 2007) The majority of the studies evaluated the UA Doppler in the second trimester of pregnancy, supposedly because the trophoblastic invasion of the maternal spiral arteries has finished at this point. On the other hand, there is now strong evidence demonstrating that abnormal UA Doppler in the first trimester of pregnancy is also

associated with abnormalities in trophoblast invasion. The concept of early and late PE is more modern, and it is widely accepted that these two entities have different etiologies and should be regarded as different forms of the disease. (Von Dadelszen P et al. 2003), (Huppertz B. 2008). Early-onset PE (before 34 weeks) is commonly associated with abnormal uterine artery Doppler, fetal growth restriction (FGR), and adverse maternal and neonatal outcomes. (Ness RB et. al. 2006), (Murphy DJ et al. 2000), (Walker JJ. 2000). In contrast, late-onset PE (after 34 weeks) is mostly associated with normal or slight increased uterine resistance index, a low rate of fetal involvement, and more favorable perinatal outcomes. (Ness RB. 2006), (Sibai B. 2005). Early-onset PE and FGR are placenta-mediated diseases (Crispi F et al. 2006) who reported placental growth factor (PIGF) as a useful second-trimester screening test for this form of the disease, but not for late-onset PE/FGR. Maternal risk factors: age, parity, previous obstetric history, etc. Maternal echocardiography might identify at 24 weeks gestation patients who subsequently develop early severe maternal and fetal complications through the assessment of maternal hemodynamics suggesting an involvement of the whole cardiovascular system in the placental mediated disorder. (Vasapollo B et al. 2008), (Valensise H et al. 2006), (Novelli GP et al. 2003), (Bosio PM et al. 1999). The abnormal placentation that characterizes pre-eclampsia is associated with an increased resistance in the utero-placental circulation. Ultrasonography evidence of this resistance includes the presence of a diastolic 'notch' in the Doppler waveform of the uterine artery or an increase in that vessel's pulsation index (PI). (Campbell S et al. 1983) Being an objectively measured continuous variable, the latter is preferable to the somewhat subjective assessment of 'notching'. (Lees C. 2010) It has been suggested that Doppler studies might be most predictive if performed in a sequential fashion in both the first and second trimesters. (Napolitano R et al. 2012) However, such an approach would preclude the early initiation of prophylaxis. Other potential ultrasonography parameters for the prediction of pre-eclampsia include 3D power Doppler assessment of placental volume and vascularity, maternal MCA Doppler indices (Belfort M et al. 2012). Further research will determine whether any of these is superior to uterine artery Doppler analysis.

Materials and Methods

This is a retrospective cohort study, during January - December 2017, of women who have had Pre-eclampsia at a tertiary referral University Hospital of Obstetrics and Gynecology "Koço Gliozheni" in Tirana, Albania. In total were 62 women with Pre-eclampsia during this period of time. Maternal demographic characteristics, ultrasonography measurements (uterine artery color Doppler examination at 22-24 weeks of gestation) and neonatal data were collected from the case notes (medical records and were recorded in a computer database). The ultrasound machine used was Aloka Echo Camera L. All ultrasound examinations were performed by an obstetrician. PE cases were managed by medical team, obstetric consultants. Data were collected on patient age, parity, gestational age at time of delivery, history of previous PE, mean arterial pressure and Doppler ultrasound parameters. Neonatal

evaluation included neonatal birth weight, Apgar score at 1 and 5 minutes, neonatal gender, generality admission to the neonatal intensive care unit. All data were calculated with SPSS 15.0. T-test, Chi-Square test, Fisher test and Correlation were used for statistical analysis.

Results and Discussions

In total, 62 women with Pre-eclampsia were classified: 32% Early PE (before 34 weeks) and 68% Late PE (after 34 weeks). At the table Nr.1 we can see that the mean age of mothers with PE was 32.65 years old, Std. deviation = 5.851 years. It was interesting to see how maternal age was different in the two groups of preeclampsia: early onset PE are older with a higher percentage of women over 35 years than late onset PE. Although it is well known that an age more than 35 years is linked to a higher risk for preeclampsia, the importance of age in early and late preeclampsia has not been clearly reported so far. An intriguing hypothesis could be that an older age might negatively influence the placental process, but this should be confirmed on larger numbers with the whole set of hemodynamic data. The mean age of mother at Early PE was 34.45 years old and at Late PE was 31.78 years old. (Table nr.2).

Parity was also a maternal characteristic that could interfere in the trophoblastic invasion of the maternal spiral arteries in the present study. Pre-eclampsia is more common among women who: has had a baby (50% second parity, 14.7% third parity, 2.9 % multiparity). At the Table Nr.1 are summarized the neonatal complications, like as: Low Birth Weight (mean 2200-2300 g) and some of them IUGR. It has also been observed that women carrying male fetuses (62%) are at slightly greater risk for PE than are women carrying female fetuses (38%). We can admit that 29 % of women of PE have had previous PE in their pregnancies.

The mean arterial pressure is calculated by dividing the sum of the systolic and twice the diastolic blood pressures by three and is thus easily measurable. As we can see that the mean systolic blood pressure is 160 mm Hg (for Early PE 167.7 and for Late PE 156.3 mm Hg) and mean diastolic blood pressure is 96.5 mm Hg (for Early PE 99.55 and for Late PE 95 mm Hg). (Table Nr.1 and Nr.3, Fig. Nr.1).

The utility of Doppler analysis of the uterine artery in predicting pre-eclampsia has been extensively studied initially in the mid-second trimester and more recently in early pregnancy. The abnormal placentation that characterizes pre-eclampsia is associated with an increased resistance (RI) in the utero-placental circulation. Ultrasonography evidence of this resistance includes the presence of a diastolic 'notch' in the Doppler waveform of the uterine artery or an increase in that vessel's pulsation index (PI). In our study, the mean UA RI was calculated in both trimesters of pregnancy.

We considered abnormal values greater than 0.85 and 0.77 in the first and second trimester, respectively. Being an objectively measured continuous variable, the latter is preferable to the somewhat subjective assessment of 'notching'. At the table Nr.3

we can see that mean CPR at Early PE is 1.3 (around 1) and at Late PE 1.79. We can see that in Doppler examination 26% had bilateral notch at uterine artery, 12 % notch at AU Dexter, 15 % notch at AU Sinister and 47,1 % without notch (figure nr.2).

PE is associated with an increase in preterm birth and neonatal outcome. Fetal intrauterine growth retardation (IUGR + PE 38 %), Low birth weight (< 2500 g), low Apgar score which needs admission in neonatal intensive care unit. Mean Fetus Weight at Early PE 1543.18 g and at Late PE 2623.91 g and mean days that neonatal had stayed in the Intensive Care Unit was 37.82 days at early PE and 6.87 at Late PE. (Table Nr.2) In the figure Nr.4 we can see that 58.8 % APGAR score in the first minute was 8 and 67.6 % in the fifth minute was 9. From the table nr.4. we can see that exist a very significant correlation between Fetus Weight (g) and NICU, Apgar min 1 and Apgar min 5. The lower fetus weight, higher is NICU (R=-0.84). On the other side the lower fetus weight, lower is the APGAR min 1 and min 5 (R=0.574 and R=0.688). Also as higher the APGAR min 1 and min 5 as lower the NICU. There is a significant difference between the presence of IUGR on early and Late PE. As we can see from figure nr.5 the presence of IUGR is higher on early PE (Fisher's Exact Test = 8.192, df=1, p=0.008 (2-sided). There is a significant difference on CPR values on early and late PE (T-test = -2.127, p=0.041). (see the tab. Nr. 5)

Conclusion

Abnormal uterine artery Doppler studies in the first and second trimester combining with maternal factors are useful to predict PE in low-risk pregnant women and have been associated with subsequent adverse pregnancy outcomes including preeclampsia, fetal growth restriction, and perinatal mortality. Early PE showed: an increased percentage of patients >35 years old, an increased PI and an elevated RI of uterine artery Doppler, a higher prevalence of bilateral notching at 24 weeks gestation, a lower gestational week at delivery, a lower neonatal weight centile and some days at the NICU.

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Table Nr.1 Maternal and Neonatal parameters

	Minimum	Maximum	Mean		Std. dev.
	Statistic	Statistic	Statistic	Std. Error	Statistic
Maternal Age	18	45	32.65	1.003	5.851
Parity	1	4	1.88	0.132	0.769
Maternal Weight(kg)	66	127	83.82	1.941	11.318
Maternal Height(cm)	153	169	161.53	0.643	3.752
SBP	140	190	160.00	2.214	12.910
DBP	75	110	96.47	1.204	7.020
PI UA	0.70	1.39	1.0318	0.03527	0.20567
PI MCA	0.60	2.80	1.6597	0.09690	0.56504
CPR	0.70	3.59	1.6388	0.11498	0.67046
Fetus Weight (g)	975	3600	2274.26	130.236	759.398
APGAR Min 1	2	9	7.8529	0.20740	1.20937
APGAR Min 5	6	9	8.6176	0.11182	0.65202
NICU	0	62	16.88	3.453	20.137

Table Nr.2: Mother's Age

	PE	Mean	Std. Deviation	Std. Error Mean
Age	Early PE	34.45	6.758	2.038
	Late PE	31.78	5.308	1.107

Table nr.3. Blood Pressure, Doppler Parameters, Fetus Weight and NICU

PE		SBP	DBP	PI UA	PI MCA	CPR	Fetus Weight (g)	NICU
Early PE	Mean	167.73	99.55	1.1245	1.5100	1.3027	1543.18	37.82
	Std. Dev	14.029	6.105	.16299	.60656	.42800	446.667	16.424
Late PE	Mean	156.30	95.00	.9874	1.7313	1.7996	2623.91	6.87
	Std. Dev	10.789	7.071	.21216	.54323	.71241	615.864	12.715
Total	Mean	160.00	96.47	1.0318	1.6597	1.6388	2274.26	16.88
	Std. Dev.	12.910	7.020	.20567	.56504	.67046	759.398	20.137

Tab. Nr. 4. The correlation between Fetus Weight (g) and NICU, APGAR min 1 and min 5.

		Fetus Weight (g)	APGAR min 1	APGAR min 5	NICU
Fetus Weight(g)	Pearson Correlation	1	.574(**)	.688(**)	-.841(**)
	Sig. (2-tailed)		.000	.000	.000
APGAR min 1	Pearson Correlation	.574(**)	1	.810(**)	-.659(**)
	Sig. (2-tailed)	.000		.000	.000
APGAR min 5	Pearson Correlation	.688(**)	.810(**)	1	-.800(**)
	Sig. (2-tailed)	.000	.000		.000
NICU	Pearson Correlation	-.841(**)	-.659(**)	-.800(**)	1
	Sig. (2-tailed)	.000	.000	.000	

Tab. Nr.5. CPR values on early and late PE

	PE	Mean	Std. dev	Std. Error Mean
CPR	Early PE	1.3027	.42800	.12905
	Late PE	1.7996	.71241	.14855

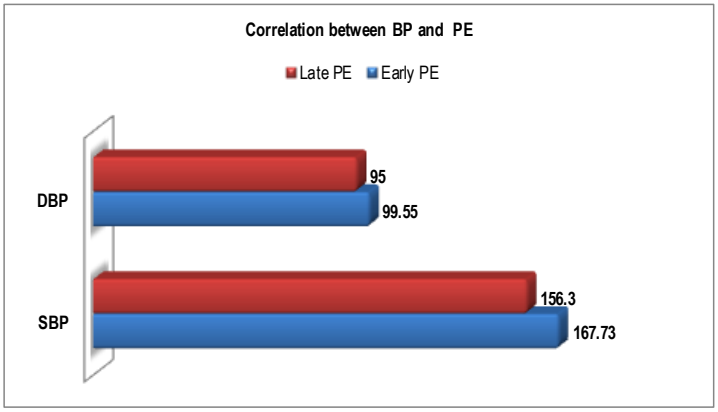
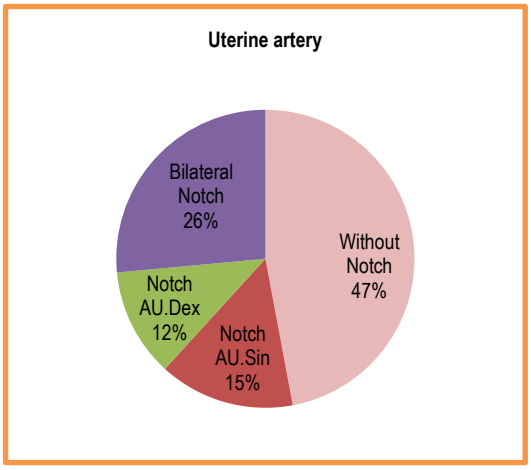


Fig. Nr. 1. Sistolic and Diastolic Blood Pressure



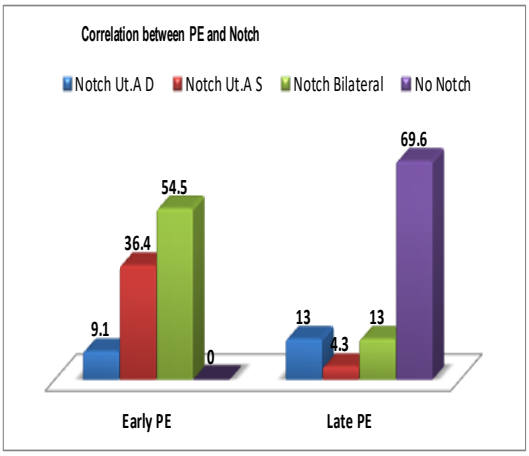
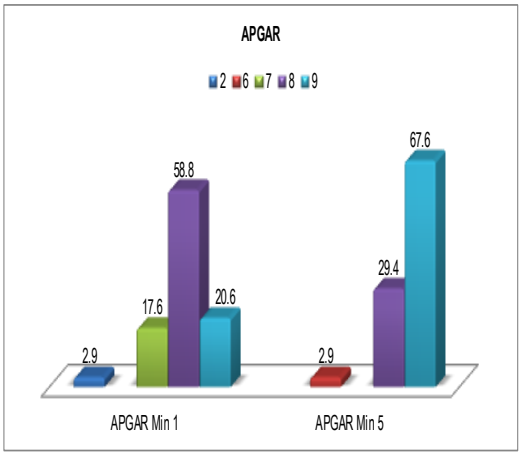


Fig. Nr.2. Doppler of Uterine Artery Fig. Nr.7. Doppler of Uterine Artery



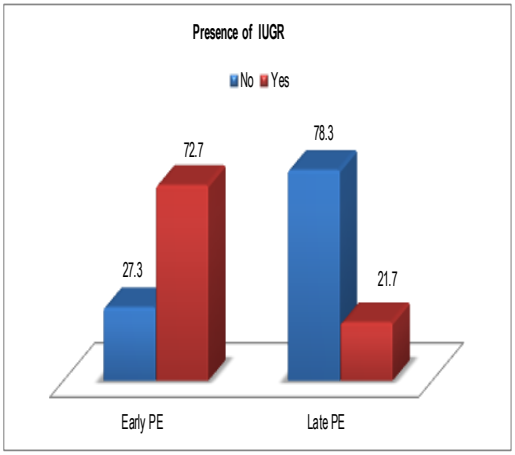


Fig. Nr.4. APGAR minute 1 & 5Fig. Nr.5. The presence of IUGR

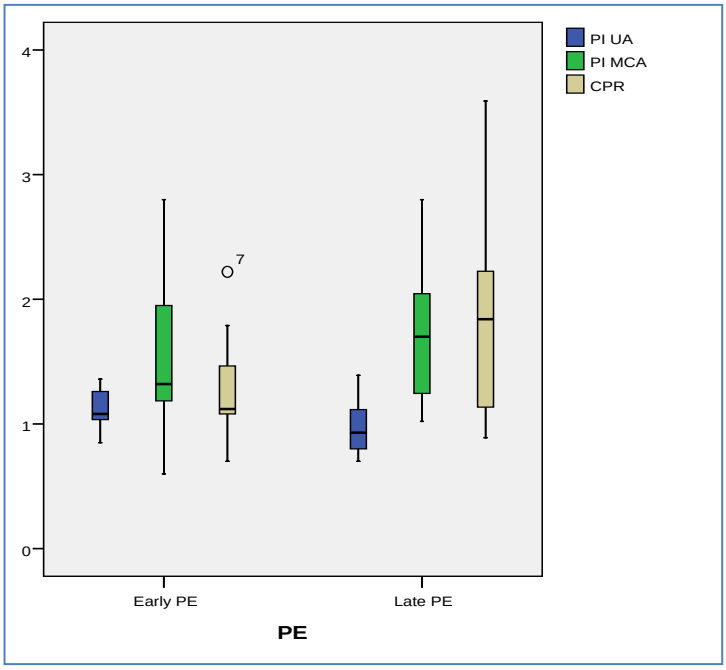


Fig. nr. 6. The values of PI UA, PI MCA, CPR on early and Late PE

A Study on the Effectiveness of Spiritual Intervention on Perception of God and Attitude toward Death in Women with Breast Cancer

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Abstract

Desperation, death threat, recurrence of disease, anxiety about the future, suffering from pain, personal, family and social problems arising from bad performance has made it necessary to pay attention to this important disease. Using spiritual intervention has an important role in reducing mental complications and promoting the patients' health. This study was a quasi-experimental with pre-test and post-test, and control group. The statistical population included women with breast cancer referred to the Cancer Research Center of Shohada Hospital in 2015 that 24 people were selected by available method and were divided into two groups randoml. The experimental group was exposed to spiritual intervention and the control group was not exposed to any intervention. For measuring research variables, 72 items of God's perception and 32 items of attitude toward death (DAPR) questionnaires were used and the covariance analysis was used for analyzing data. The results of the research showed that using spiritual intervention ($P<0.05$) in-group was effective significantly in improving perception of God and reducing the fear and avoidance of death in the women's group with breast cancer. Reminding this attachment, sense between the creator and creature creates a good relationship between patient and God. The death anxiety will reduce with the help of focusing on the kindness and forgiveness and attempts to the good acts in this universe and the reality of the human survival in another universe, which is a movement from the potential perfection to the active perfection.

Keywords: spiritual intervention, perception of god, attitude toward death, breast cancer

1. Introduction

The attention of the different psychological schools to the human and his needs and spiritual studies in this level is an important and fundamental matter and it is increasing in many countries. Meaning as an introduction for discussing about spirituality, connects with the internal aspects of human and spirituality contains the self-perceptions and combination of characteristic factors and fundamental beliefs about the being and having a meaning in life which relates to the aspect and spirituality of different life relations such as social, physical and psychological aspects (Yang & Mao, 2007). The fundamental research has found the positive relations between increasing the spirituality and health results, about the relationship between the spirituality and health (Peach, 2003). Many research showed that spirituality, from a normal prayer to the meditation and attending in religious ceremonies have such an effect on human health from increasing life expectancy, enhancing the immune system, improving the body's response to stress, recovering from depression and helping the patients to recover from severe illnesses such as cancer, cardiovascular disease and other diseases that science is incapable in proving it (Paloutzian & Park, 2014; Yang & Mao, 2007). Some cancer patients have concluded that spirituality can increase resistance against the physical and psychological crises that are followed by the diagnosis and treatment of these diseases. In addition, it has been observed in women with breast cancer that encouraging toward spirituality could be as an effective source to deal with physical and psychological responses to cancer (Meraviglia, 2004).

Spirituality sets a goal in an individual's beliefs and affects important cognitive assessments in the process of confrontation, and helps the person to assess the negative events in a different way and create a stronger sense of control (Simoni, Martone, & Kerwin, 2002). As the human ability in controlling stressful events will increase, his ability to adapt to the environment will be more and stress-induced side-effects such as anxiety and depression will appear less (Seligman, 1974). Human nature is spiritual and religious. Until this spiritual dimension of a person does not connect to a person's psychological structure and does not integrate with it, his real treatment does not happen (Jung, 2014). Spiritual and religious beliefs provide hope and a sense of control over one's destiny and if the believer has a complete trust in God, he could obtain a good result in any condition and it is not surprising that such a belief may have a powerful psychological outcome. Human in health and disease, is like a unit with different aspects of biological, psychological, social and spiritual. Thus, it is appropriate to avoid a one-dimensional encounter in the treatment. Given that, social, psychological, and spiritual factors are directly associated with a patient's beliefs and culture, so to recover from disorders and diseases, these beliefs and resources are used. New research with statistical considerations are growing up in finding the beneficial effects of spirituality and religion.

So religious and spiritual beliefs and new scientific advances can be used together in the treatment of disorders and diseases (Riley et al., 1998). Among the diseases and the accidents, cancer is known as one of the most important causes of death in the world that is estimated by 2020; more than 15 million people worldwide will experience it (Daher, 2011). In Iran, the third largest cause of death is influenced by genetics and environment. The occurrence of this disease is reported in adult age groups and in different regions of Iran, 48-112 cases per hundred thousand people for females and 51-144 cases per hundred thousand for men (Seyedfatemi, Borimnejad, Hamooleh, & Tahmasebi, 2014). In this regard, it is predicted in 2030, due to the increasing average age of the population, relative control of communicable diseases and increased carcinogenic factors, cancer will be the most important and the first factor of death in human (Mohaghegh & Hamta, 2008). This disease is a manifestation of chronic injury (Henson, 2002) that causes physical and emotional symptoms and has negative effects on people's quality of life (Borimnejad, Hamooleh, Seyedfatemi, & Tahmasebi, 2014). Among them, the breast cancer is the most common cancer among women (Forouzanfar et al., 2011). In 2010, 16 million women in the world were diagnosed with breast cancer and 425 thousand people have lost their lives due to this cancer (Henson, 2002) and by its increasing growth of 32.2 per hundred thousand people, it has become the most common malignancies in Iran among women (Yavari, Mosavizadeh, Sadrol-Hefazi, & Mehrabi, 2005). Age incidence of breast cancer in Iran is 41 to 60 years, and statistics show that 34.3% of all cases is occurred less than 40 years (Sirus & Ebrahimi, 2009). The disease, like all chronic diseases, is including the changing risks and problems that over time often find intensity. Distress and suffering caused by this disease are more focused on the threat, death, recurrence, and the concern about the future and the suffering caused by pain (Petro-Nustas, 2002). Therefore, it seems necessary to manage more than ever the symptoms of disease and to improve quality of life for cancer patients as well.

2. Research Method

This study was a quasi-experimental with pre-test and post-test, and a control group and its statistical population include women with breast cancer referred to the Cancer Research Center, Shahid Beheshti University of Medical Sciences, in 2015. In this population, 24 patients were selected with available sampling method and divided randomly into two groups included 12 people in the control group and 12 people in the experimental group. Inclusion criteria in the study were:

1. Having a minimum reading and writing ability.
2. Stage one and two in breast cancer.
3. Completion of treatment (surgery, chemotherapy, radiotherapy, hormone therapy) from six months to one year.
4. Not having the same clinical disorder.

5. Not receiving any psychological or medication treatment from the six months prior to the intervention time and during spiritual intervention.

Exclusion criteria for the study included:

1. Significant Clinical impairment after the interview.
2. Patient's refusal from participating in the group for any reason.

Participants receive complete details of this study and its objectives and gave their consent, and have entered the study, and then the experimental group has received spiritual intervention in 10 sessions of 90 minutes. The control group did not receive any intervention. Groups were tested before and after intervention, by God Perception and Attitude toward death questionnaires.

Components of spiritual intervention were performed by using of the funds of Quranic and Islamic and international standards. They have all emphasized the peace and human growth and development and the acceptance of God as the power of the kind, which leads to confidence and reduce anxiety and stress inhibition. This intervention was performed during 10 sessions, once a week and each time was for 90 minutes. The framework of the each therapy session, as an example, is following as Table 1:

Table 1. Framework of the Each Therapy Session

Row	Detail of Therapy
1	Prayer beginning of the session, with the aim of reminding attended in the spiritual and emotional meeting and closeness to the Lord
2	Literature review and revise the homework session
3	Clarification of this meeting subject with the participation of the members
4	Session topics discussed by member use the components of the spiritual-religious and Islamic
5	Summaries
6	Homework
7	End of session with prayer
8	Individual and specific guidance
9	Publishing an overview of the issues

The content of the meetings in 10 sessions is as following:

- Session One: Introduction and preparations. A) Introduction of the members with each other, awareness of the reasons for forming the groups, B) reminding Challenge (personal and implications awareness of spirituality and its definition from the perspective of each member, considering the presence

of the belief in the superior force and calls on Member and client perceptions and beliefs about spirituality).

- Session Two: introspection and descriptions. Focus on inner feelings and identifying them in the time that they had spiritual experiences.
- Session Three: Sources of fear and anxiety and our resources against them. Trying to find out what causes fear and anxiety in patients' lives and partnership to address and resolve them.
- Session Four: inexhaustibility and inheritance. Defining the inexhaustibility and unfailing. Try to inexhaustible. Heritage in our life and the impact on the others.
- Session Five: Inherited on love or hate. The definition of love and hate and that is which one brings us peace? How to bring love and consider the results and what affects this love or hate bring to others?
- Session Six: meditation. Addressing the effects of behaviors based on love or hate on ours and others and the world. Trying to keep our behaviors based on love and keep away from hate.
- Session Seven: patience. Addressing the world and its hardships. Human explains to suffer and emphasizes the waiting for the problems that is necessary for life. Provide experience based on waiting and its implications for patients. Compare the experience of waiting with no waiting.
- Session Eight: forgiveness and resolve anger. Focus on forgiveness and resolve anger toward self, others and the world and trying to revive behaviors based on acceptance, patience, persistence, responsible action and social and personal benefits.
- Session Nine: trust, to discuss and provide comments about who is better to trust than the God is since he knows better than we know and rules the world. He knows our favor and universe is ruled by his wisdom. Addressing the effort combined with trust. Assigning the whole life affairs to the God. Offering the experiences of trust, this is what happened then? Was there a peace?
- Session Ten: calculating, meditation and sustainability. Discuss the increasing self-control to maintain awareness in behaviors based on love and virtuous and avoiding behaviors based on hate and malicious. Trust on what leads to personal and community benefit (Akbari M, Vaziri S, & Lotfi Kashani, 2016).

The God Greeley perception test is a test of 72 items that has six sub-scales of the existence, challenge, acceptance, compassion, impact and Providence, and runs as a Likert. For normalization, 455 students were selected from the University of Ferdowsi in Mashhad, Iran. The reliability of the test was in:

- The scale of the existence: 0.94
- Challenge: 0.86
- Acceptance: 0.90
- Compassion: 0.91
- Impact: 0.92
- Providence: 0.92
- Total reliability: 0.91

Additionally, in order to determine the validity criterion, another validated questionnaire with 27 questions called the image of God test has been used that had the alpha coefficient equal to 0.89. Based on 158 raw scores (number of classes) that have obtained in two samples, the "Z" normative scores and "T" normative scores have been reported that the highest score achieved was 288. The minimum score obtained in the experimental implementation of the "Z" is (- 24.2) and score "T" is obtained (6.27).

Wing & Rucker and Geser in 1994 developed the revised profile view of death in 1994. The scale has 32 words and five dimensions and its measures fear of death, avoidance of death, neutral acceptance, acceptance of tendency and avoidance acceptance. The subjects are identified in a Likert scale of seven degrees. They have reported the retest to avoid death as (0.61), fear of death (0.71), neutral acceptance (0.64), and acceptance of tendency (0.95), and avoidance acceptance (0.83). Sub-scale of fear of death has a positive correlation with death anxiety scale. The sub-scale of admission trend and neural acceptance and avoidance acceptance have a positive correlation with Attitude Scale of death. The existence of such a relationship reflects the desirable structural validity of five sub-scale of the test. To compare the scores of God perception and attitude towards death to test and control groups, the covariance analysis was used and data were analyzed with *SPSS* software by version 21.

3. Analysis Result

The study descriptive scales in Table 2 are provided in pre-test and post-test in experimental and control groups. As can be seen in the perception of God scale, the average of the experimental group in the post-test stage shows an increase compared to pre-test. According to the results in Table 2, it can be described as spiritual therapy has resulted in a significant increase in positive perception of God. Also, among the sub-scales of attitudes toward death in the experimental group, avoidance of death and fear of death is declined and somewhat trend acceptance and the neutral acceptance are increased.

Table 2. Descriptive Information of Variable Scores on the Breakdown of the Measured Stage in Groups

Variable	Group		Numbers	Mean	Standard Deviation
Perception of God	Experiment	Pre-test	12	175.33	16.04
		Post-test	12	198.08	16.11
	Control	Pre-test	12	168.58	26.56
		Post-test	12	170.91	28.09
Attitude toward Death					
Fear of Death	Experiment	Pre-test	12	5.15	1.84
		Post-test	12	4.36	1.22
	Control	Pre-test	12	3.95	1.88
		Post-test	12	3.96	1.86
Death Avoidance	Experiment	Pre-test	12	5.49	0.94
		Post-test	12	4.49	1.22
	Control	Pre-test	12	3.78	1.69
		Post-test	12	3.75	1. 68
Neutral Acceptance	Experiment	Pre-test	12	5.10	1.09
		Post-test	12	5.55	1.87
	Control	Pre-test	12	4.76	1.74
		Post-test	12	4.61	0.81
Tendency Acceptance	Experiment	Pre-test	12	5.2	0.95
		Post-test	12	5.61	1.70
	Control	Pre-test	12	5.45	1.71

		Post-test	12	5.23	0.81
Avoidance Acceptance	Experiment	Pre-test	12	4.39	1.86
		Post-test	12	4.42	0.95
	Control	Pre-test	12	3.28	1.57
		Post-test	12	3.38	1.78

As mentioned earlier in this study, the variables were examined in both experimental and control groups and hypotheses are designed according to the subject that after confirming the assumptions, the multivariate covariance analysis test was used to measure them in Table 3, and Table 4.

Table 3. Tests of Multivariate Covariance Analysis

Statistic Indicator Effect	Test	Value	F	df Hypothesis	df Error	Sig
Differences Between Groups	Pillay Effect	0.71	4.43	6	11	0.01
	Lambda Wilks	0.29	4.43	6	11	0.001
	Hotelling Effect	2.42	4.43	6	11	0.001
	The Roi Largest Root	2.42	4.43	6	11	0.001

Results of Table 3 show that with the multivariate analysis of covariance, there is a significant effect of the factor group. This effect shows a significant difference at least between one of the components of research in the two treatment groups and the control group (Wilks' Lambda = 0.29, $p < 0.05$).

Table 4. One-Way Analysis of Variance in the Multivariate Analysis of Covariance

Statistic Indicator Variables	Change Source	SS	df	F	Significance Level	Effect Size	Ability Test
Perception of God	group	1483.01	1	17.62	0.001	0.52	0.97
Attitude toward Death							

Fear of Death	group	0.81	1	0.55	0.46	0.04	0.11
Death Avoidance	group	0.02	1	0.02	0.89	0.001	0.05
Neutral Acceptance	group	2.32	1	2.49	0.13	0.15	0.31
Tendency Acceptance	group	0.47	1	0.77	0.39	0.05	0.13
Avoidance Acceptance	group	0.04	1	0.03	0.88	0.002	0.05

As can be seen from the results in Table 4, a significant level of perception of God is smaller than the level obtained from the modified Benferroni significance 0.008 (dividing the significance level of 0.50 on six dependent variables). The effect of the experimental group "Practical Significance" for understanding God was 0.52; it means 52% of the variance or individual differences intervene in conflicts related to the perception of God in testing group. In addition, high power of statistical tests in this research indicates that the null hypothesis is rejected correctly with a high probability. In addition, none of attitudes to the death sub-scale had a significant change.

4. Conclusion and Discussion

This study aimed to determine the effectiveness of the spirituality intervention of God perceptions and attitudes toward death in women with breast cancer. In the long years, various studies have investigated the relationship between religion and spirituality with health (Abu-Ras & Laird, 2011; Shreve-Neiger & Edelstein, 2004). In expressing a variety of health-threatening diseases, cancer causes an increase in patients' spiritual needs significantly, and consequently the role of seeking spirituality as an effective source to deal with physical and psychological responses to breast cancer will be considered (Moss & Dobson, 2006). Spiritual intervention is a religious - cultural process by considering the transcendent dimension of clients, leading to God (Ghobari, Motavalipoor, Hakimirad, & Habibi, 2009), exploring the issues and spiritual issues and aims at improving the health and recovery (Richards, Hardman, & Berrett, 2007). Among the considerable amount of studies on the relation between religion and spirituality with health (Abu-Ras & Laird, 2011; George, Larson, Koenig, & McCullough, 2000; Shreve-Neiger & Edelstein, 2004), many of them are considered the effectiveness of spiritual intervention as a source to deal with psychological problems and mental health and quality of life in cancer patients (Breitbart, 2002; Koszycki, Raab, Aldosary, & Bradwejn, 2010).

Research results showed that spiritual intervention leads to an optimistic attitude toward the perception of God. However, accessing the imaginations of God or the perception of God is difficult (Gattis, 2001). However, this becomes clear different in

people's own experience that is in contact with the spiritual perception system of them, and at different levels, including search and maintain the presence of God, God is as a safe haven, separation as a source of anxiety and worry and God is like an omnipotent and omniscient (McDonald, Beck, Allison, & Norswortby, 2005). Now cancer as a disease that in appearance, the person did not involve in creating it directly and has negatively affected the course of his life is effective in the type of relationship between the Lord and patients. Attention of mind in this regard that the cancer was a retribution from the Lord for him changes the perspective of the merciful Lord to the hardship Lord, the God who puts an obstacle on the path of the patient's life to making sickness that inhibits the growth of him. He prays the Lord, but the severity of disease does not decrease and he is suffering from the disease and it seems like he does not hear the patient's voice and the disease happened because of not accurate worshiping him. This kind of thinking is providing anxiety that seems he has been left behind. Some research has shown this type of relationship based on anger in cancer patients (Exline, Prince-Paul, Root, & Peereboom, 2013).

After a spiritual intervention, suffering from the disease will be changed significantly for patients affected by the disease, now the suffering God, is a God that because of the disease, he seeks a stronger and better communication with his servant. The disease has provided a way for him/her that he/she is thankful and his specific experience has provided new direction of growth for him/her; what is known in psychology as post-traumatic growth and various research confirm what was said (Denney, Aten, & Leavell, 2011). Not significant waiting has changed to meaningful patience and hope for recovery. His mercy is everlasting and if he does not properly worship him, he believes his generosity. Because of the correction of vision, patients are more properly resolving the problems caused by their disease and improving their quality of life and mental health (Koszycki et al., 2010). On the other hand, the spiritual intervention, focusing on higher behaviors such as forgiving self and others, self-sacrifice, charity and kindness, are focused on improving relationships with other human beings that with improving this relationship, the attitude of a person to self and others will shape that is effective in the way that experiences the God emotionally (Granqvist, Mikulincer, & Shaver, 2010). Therefore, understanding of God is the psychological structure of the knowledge of mental traits (Lawrence, 1997), it can indicate cognitive development and moral development of the individual and the individual's mental life quality of communication (Alcorn et al., 2010). The dissatisfaction sense of God has a significant relationship with frustration, the feeling and symptoms of depression and guilty feeling (Braam, Mooi, Jonker, Tilburg, & Deeg, 2008). Instead, people with a positive mental image of God have High psychological coping and evaluate situations positively (Newton & McIntosh, 2010).

The results of Brady et al. study showed that in patients with cancer, spirituality is associated with the quality of life as the same as the physical health and emotional health (Brady, Peterman, Fitchett, Mo, & Cella, 1999). Some patients with cancer have considered it as a fight or a divine experiment that was designed by God for their faith,

while others have considered it as a threat (Taylor, 1983). Thus, the perception of God is as an inner mental functional model that person imagines the God in that way and it can represent growth rate and the psychological maturity level and in a deeper look, it shows the wheel-person's character. God perception is a cognitive-emotional model and a coherent set of the final level of the person's perception in metaphysical matters (Taylor, 1983). With the help of spirituality intervention structure, this growth was obtained from breast cancer patients.

However, the death can be verified as a full stop and no return in the vital functions from the various aspects. Researchers believe that the process of dying is different depending on the type of disease and individual differences in emotional responses (Taylor, 1983) and probably it creates a complex interplay of emotions and swaying thoughts of acceptance and the rejection of the death that tends consistency to one of the parties of acceptance and denial (Taylor, 1983). Different psychological approaches such as existentialism (Henoch & Danielson, 2009), humanism (Henoch & Danielson, 2009), Cognitive (Moorey et al., 2009), behaviorism (Redd & Andrykowski, 1982) and etc., have tried to solve this concept in patients close to death (Redd & Andrykowski, 1982). Cancer patients are a group of patients that feel more closely with the concept (Lange, Thom, & Kline, 2008). Hard and painful nature of cancer and increase knowledge of its risk and death and the false beliefs that equal cancer to death are causing the patient fear unrealistically of death (Farsi, Dehghan Nayeri, & Negarandeh, 2010). Death, due to the ambiguous nature of many human beings, appears as a threat, the fact that people respond in different ways (Farsi et al., 2010). The fear is because of thinking about the process of dying or events that occur after death (Bahrami, Dadfar, Lester, & Abdel-Khalek, 2014). Fears and emotions related to end of life (Firestone & Catlett, 2009), that for a patient who is facing it provides more anxiety and affect various aspects of their lives (Firestone & Catlett, 2009). In spiritual intervention, addressing and promoting the evidence is an inexhaustible and eternal life of man, which is accepting another world thought; it provides the background so that the short life of this world causes less anxiety for them.

Patients knew that suffering is in different forms for all people and the spirituality helped them cope with the nature of death, and endure the pain of life significantly (Tsevat, 2006). Emphasizing the hope of mercy of God and doing righteous and good and trying to leave a good inheritance that realize with helping each other and kindness and many other behaviors, reduces the suffering from the lack of life in this world and is given more constant motivation to live on love. Thus, in numerous studies, hope has a significant positive relation to an increase in compatibility (Farran, Herth, & Popovich, 1995) and despair has a contrary conclusion (Farran et al., 1995). The fact that in the human history, there is not a human being deprived of facing death causes experiencing less frustration. On the other hand, the disease gave them the opportunity as a favor from the Lord to take care of themselves and their actions and work more and to improve the quality of their lives. So, the attitudes

toward death test, in subjects with breast cancer had evidence that after spiritual intervention, not only it reduced the sense of avoidance of death, but also with the elimination of irrational fears of the death and life after death that according to Islamic sources, it is such as removing dirty clothes from the body and wear clean clothes, trying to achieve eternal life in the light of Divine Mercy was also tending them. Therefore, in another aspect, the spirituality could reduce the fear of death (Levin, 2000), that it modified the flawed thinking of God and religion that consider the death as entering into a world full of pain (Naderi & Kh, 2012). Spirituality, especially when the patients are facing death, plays an important role in the physical and mental well-being of them (Aten & Leach, 2009; Leung, Chiu, & Chen, 2006).

Because of spirituality brings the relation and integration of human beings beyond the confines of time and space and material and unity in the universe can be seen by spiritual people (GHOBARI et al., 2009) and on this subject, numerous research studies have been done on the effectiveness of spiritual intervention to reduce anxiety and avoid confrontation with death (Al-Sabwah & Abdel-Khalek, 2006; Wachholtz & Pargament, 2005). According to what was said, Addressing the spiritual dimension of patients not only should not be neglected, but also it must be addressed more; Where the human tendency to spirituality is increased (Cook, Cook, Powell, & Sims, 2009) and patients tend to talk to their doctors about their spiritual dimension (Peach, 2003), thus, spiritual approaches are useful interventions in the treatment of clients, by using the language of respect and therapist value toward patient spiritual matters, and in order to use the potential power of faith and spirituality (Richards et al., 2007).

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Psychological Biases, Main Factors of Financial Behaviour - A Literature Review

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Abstract

In the context of the sophistication of financial relationships, investment alternatives, risk and recurrent recent financial crises, human factor has become increasingly important in investor decision-making. Studies on investment behavior of a number of authors at different times and places, encouraged this new widely accepted inter-disciplinary field of finance: Behavioral Finance. In order to understand and explain individual decision making and investment behavior, it is necessary to study behavioral factors which impact it. Various scholars have studied factors of financial behavior and their impact on financial decision making, and in particular a special focus has been given to psychological biases. Usually investors are not aware of their behavioral biases. If investors become conscious of biases they can face, they can act more rationally. This way of thinking might increase the quality of their decision-making. The paper aims to help decision-makers and investors get to know with psychological biases, in order to make better decisions when investing, reducing the chances of being vulnerable to behavioral deviations, as the consequences of individual errors are inevitably reflected at a macro level, causing instability and economic - financial crisis.

Keywords: financial behavior, investor, psychological biases, decision - making.

Introduction

"The investor's chief problem - and even his worst enemy - is indeed to be himself."

Benjamin Graham, and a well-known investor, economist professor in USA.

Studies of several authors at different times and places on investment behavior have created a new field of finance that has been widely accepted: Behavioral Finance. This new way of analyzing an increasingly important factor of investment decision-making, basically examines why people do not make the decisions they need to take and why markets don't react the way they are expected and should react. Behavioral Finance is based on the assumption that the information structure and characteristics

of market participants systematically effect individual investment decisions as well as the performance of financial markets.

In order to understand and explain individual investment behavior and decision making, it is necessary to study behavioral factors which affect it. Researchers have studied financial behavior factors and their influence on financial decision making, such as psychological biases, socio-demographic factors, investor personality type, risk-taking, culture, etc.(Durand, Newby and Sanghani 2008; Venter, Michayluk 2007, Grabova 2013).Among the above - mentioned factors, we highlight the psychological biases on which the academics of Behavioral Finance, have done a colossal work to verify their existence. Two well-known israeli psychologists, Kahneman and Tversky have played a very important role in developing theories and discovering psychological biases in the field and a great number of other researchers have contributed to their theoretical and empirical findings.

In many cases, investors are not aware of biases in their behaviors. If investors are aware of the psychological bias they face, they can make financial decisions in a more rational manner. Thus, it would increase the quality of their decisions. If an investor knows himself better, he can earn more or preserve his property (Zweig, 2011). The paper aims to introduce investors to the psychological biases so that they can make more logical decisions when investing, reducing their chances to 'fall for it', because the consequences of the mistakes of these micro-actors are inevitably reflected at the macro level, causing instability and the economic-financial crisis.

The paper is organized as below: First, we are introduced with the psychological biases and their classification based on literature, then we list other psychological biases out of this classification, but not less important and finally we present a theoretical summary of the studies on psychological biases, executed by various scholars in the field of financial behavior.

Psychological Biases

Investors' way of thinking and feeling affects their behavior when making investment decisions. These impacts are known as psychological or behavioral biases. They affect all investors and vary depending on the investor's nature. According to Pompian (2011), they can be cognitive or emotional. Cognitive bias include: overconfidence, representativeness, anchoring, framing, cognitive conflict, availability, mental accounting etc. Emotional prejudices include: loss aversion, optimism and *status quo* bias.

Shefrin (2000) classifies psychological biases in biases based on Heuristic theory and biases based on Framing theory. Heuristic biases include: overconfidence, excessive optimism, representativeness, anchoring, and availability. Framing biases include: loss aversion, mental accounting, disposition effect, etc. Kahneman and Tversky were the first researchers to study the biases involved in heuristic factors such as representability, anchoring, and availability (Kahneman & Tversky, 1974). Waweru

et al. (2008), add two other biases to this factor: gambler's fallacy and overconfidence. The same authors classify into Perspective Theory the following biases: loss aversion, regret aversion, and mental accounting. They study the Herding bias as a specific factor of financial behavior, because of the importance it has.

Investors should be aware of presence of these deviations. Most of them being a natural part of human behavior, they can negatively affect the ability to improve the financial position. Accordingto the above classification (Waweru et al., 2008), we present psychological biases categorized by: Heuristics, Perspective Theory and Herding.

Biases based on Heuristics

Representativeness

Representativeness is stereotyped decision-making as a "representative" of all members of a group. The bias is manifested when we judge the probability that A belongs to class B, seeing the degree to which A resembles B. When we do this, we neglect the information about the general probability that B will occur, its base rate (Kahneman & Tversky, 1972). Let's refer to the example below: Problem 6: Ben likes the opera, and in his spare time, he likes to visit art museums. When he was a kid, he enjoyed playing chess with family members and friends. What do you think is Ben's profession as an adult?

A. Ben plays in a symphonic orchestra.

B. Ben is a merchant.

Many people will choose A, because Ben's description matches the stereotype we can relate as a classical musician instead of the merchant. In reality, the probability that B is true is much higher because merchants make up a larger percentage of the population.

Assessments based on similarity are generally a short-term cognitive approach commonly used in all areas of life. For example, a customer can attribute a relatively high quality to a product if its packaging is designed to resemble a famous brand (Kardes, Posavac, & Cronley, 2004).

In investment, representativeness is a bias to be more optimistic about the recent well- performing investments and more pessimistic for past bad-performed investments. Thus investors prefer to buy stocks that have had recent abnormal high returns as an indicator of a good investment (Chen et al., 2007). The bias presents when investors label an investment as good or bad based on its recent performance. Consequently, they buy stocks after prices have risen, expecting these growth continuation and ignore stock purchases when their prices are below their basic values (Baker and Ricciardi,2014).

Availability Bias

This bias is defined as the preference of decision-makers for the easily called to memory information or events. Bias of availability refers to the human bias to judge the probability of an event to occur or its frequency, from the facility it can be recalled. This happens when we overrate the probability of something happening either because a similar event has happened recently, or because we feel very emotional about a previous similar event.

Due to availability biases, our perception of risk may be wrong, it distorts real risk understanding, which can have fatal impacts. Easy recalling suggests that if something is easier to remember, then there is a higher probability that it will happen. When we make decisions, we tend to get impacted from what we remember. What we remember, is influenced by various elements like beliefs, expectations, emotions and feelings, as well as frequency of exposure. Media (internet, radio, television) also affects our memory. Rare events are very noticeable to us when they occur, because they get a great coverage from the media, increasing the probability to remember them, especially after the event has happened. But remembering an event and its assessing its probability are two different things. For example, if you have a car accident, you are more likely to estimate the chances of having another car accident far higher than the real probability. A study by Karlsson, Loewenstein and Ariely (2008), showed that people are more likely to buy insurance to protect themselves after a natural disaster they have just experienced than to buy insurance before the disaster happens. Another example is that in the case of an aircrash, the airline company's stocks suffer a drastic fall of their prices until the first week after the disaster strikes. When the event starts to be forgotten, stock prices begin to rise again (Kahneman, 2011).

Anchoring

Anchoring occurs when an individual allows specific information to control his cognitive decision-making process. When people want to estimate an unknown quantity, they refer to a certain value and the evaluation they make is close to the value they are referring to (which serves as an "anchor"). If you need to think about how much you have to pay to buy a home, you will be influenced by the seller'sprice. Any number you are required to consider as a possible solution to a problem that requires assessment, will be influenced by the anchoring phenomena. Anchoring effects are easily applied in auctions, where the initial offer has a powerful impact. In the investment context, one consequence is that market participants exhibiting the anchor bias, tend to hold investments with a reduced value because they "anchor" their fair value estimation at the initial purchase price, rather than their internal value.

As a result, market participants get higher risk by keeping the investment hoping that the asset price will rise again up to the purchase price level. Anchoring may be the reason an investor refuses a proper decision (to buy an undervalued asset / to sell an

overvalued asset), or to accept a wrong decision (ignore an undervalued asset or buy or hold an overestimated asset). Historical values like purchase prices usually serve as "anchors", which we refer to achieving certain objectives as a specific level of return or net income.

Anchoring Index - Anchoring Deviation can be measured by an indicator called the Anchoring Index which is clearly illustrated in the following example[1]. Answer the questions below, addressing them separately from each other:

Was Gandhi more than 114 when he died? How old do you think it was when he died?

Was Gandhi more than 35 years old when he died? How old do you think it was when he died?

The answer you would give to the second question would differ from the answer to the first question, as it would be respectively a smaller number than it, best showing the anchoring effect. Both questions above served as an experiment to measure the anchoring index and from the calculations it turns out that the average of the first answer was 95 years old, and the second answer was 52 years old. The anchoring index expresses the ratio of the difference between the averages of the answers given with the difference of the "anchors" given and expressed in percentage. Specifically: (95-52) / (114-35) = 54.4%, meaning that the anchoring effect has been significant. This index is 100% for people who use the value "anchor" to estimate and 0% for people who ignore “anchor”.

Inreal estate context, Northcraft and Neale (1987) studyanchoringwithin a group of students and real estate agents. These researchers require that entities make decisions about prices related to real estate properties. In accordance with the studies of Slovic P & Lichtensteln, (1971) and Tversky and Kahneman (1974) on the Anchor bias, Northcraft and Neale predict that an "anchor" random selection will affect real estate pricing value. In their experiment, they discover that the initial required price of a house served as an “anchor” in the acquisition process, where all other information about the property and its location remained the same.

In investment, investors often base their decisions on the first source of information to which they are exposed (e.g. an initial purchase price of an asset) and have difficulties adjusting their viewpoint towards the new information. To avoid anchoring, investors need to consider a wide range of investment alternatives and not focus their financial decisions on a specific reference point of information (Ricciardi, 2012).

Gambler’s fallacy

The inability to understand probability can lead to false assumptions and predictions regarding the occurrence of events. According to this bias, an individual believes by

[1] “Thinking fast and slow”, Kahneman 2013

mistake that the occurrence of a certain random event is less likely to occur after a series of events occurs. This way of thinking is not, right, because past events do not change the possibility for certain events to occur in the future. For example, if we toss a coin 20 times and it flips 'heads', anyone can predict that the next time is more likely to flip 'tails'. This way of thinking represents an incorrect meaning of probability because the possibilities that a coin lands "heads" are always ½. Each toss is an independent event, which means that the previous do not impact the next ones.

We can find other examples such as people and their relationship with slot machines. There are people who "block themselves" in a single machine for hours. Most of these people believe that any single losswill bring them closer to winning. They do not realize that due to the way the machines are programmed, the chances of winning a first prize from a slot machine is equal to any withdrawal, so it does not make any difference if you play with a slot machine in which you just won, or with another one which hasn't made a winner recently.

Under certain circumstances, investors may easily fall for this bias. For example, some investors believe they have to close a position (sell one share), as the stock is overtraded and highly estimated for a long period of time, and they do not think that this position will continue to improve (the price will rise). On the other hand, other investors may continue to hold shares that have dropped in value several times because they seea further drop in price as "impossible".

When the events are independent, the odds for any future specific result remain the same regardless of the previous result. Selling a share just because of your belief that prolonged bias is likely to change at any moment is irrational.

Overconfidence Bias

Overconfidence is a psychological bias in which people overestimate their accuracy or the probability that a certain outcome will occur (Campbell, Goodie and Foster 2004; Glaser and Weber 2010). People tend to have excessive self-esteem for their skills and knowledge to carry out a particular task successfully. There is a genuine bias in which a person's subjective belief in his judgments is greater than the objective accuracy of those judgments. Overconfidence is defined in three forms: (1) overestimating current performance; (2) Overlapping the person's performance compared to others; (3) Overestimate the accuracy of the information he possesses.

This bias affects the financial decisions of investors and managers. Managers' overconfidence can explain the high rate of failure of newly-established businesses (Camerer and Lovallo, 1999). In a survey[1] of 300 professional fund managers, resulted that 74% of them believed that they had a performance above average, while 26% considered themselves average, so almost 100% of respondents believed that their

[1] "Behaving Badly", James Montier, 2006

work performance was average or above average. It is considered as the most widespread psychological bias victim of which human beings are.

The most common way in which high self-esteem is studied is by asking people how confident they are for their answers. The data collected, shows that overconfidence systematically surpasses accuracy, implying that people are more confident than accurate. If human self-confidence had a perfect calibration, 100% confident judgments would be 100% correct, with 90% confident judgments would be 90% accurate, and so on for other levels of confidence[1]. There is a thin line between confidence and overconfidence. Confidence implies realistic faith in one's own abilities, while overconfidence usually implies an overly optimistic reliability of the knowledge or control of a situation.

There is a positive connection of overconfidence and the level of trading volume on the stock exchange (Grinblatt and Keloharju, 2001), (Odean, 1998). Overconfident investorstend to believe that they are more capable than others in stock selection and finding the best moment to enter or leave a position while those who overtrade, usually have aweaker performance compared to that of the markets (Barber and Odean 2000, 2001[2]), (Ricciardi 2008).

Individual investors are less likely to have better information, intuition or analytical skills than others.In reality, the market has "fooled" many sophisticated professionals with high self-esteem.

According to an experimental study, less informed investors have more confidence than their more informed counterparts (Bloomfield, Libby and Nelson, 1999). In real estate markets, an inexperienced individual who has recently sold his property with a gain is likely to exhibit a high level of self-confidence when seeking to purchase a future real estate. As a result, he is likely to pay a higher amount of money to buy it or reject a potentially appealing investment opportunity. Wang (2000) studies the builders' self-confidence in the real estate market and notice that overconfidence relates to excessive building in markets where prices rise quickly.

Bias based on the Theory of Perspective

It describes a mental condition that affects the individual decision-making processes, including Regret Aversion, Loss Aversion, and Mental Accounting (Waweru et al., 2008, p. 28).

[1]Investor Behaviour, Baker and Ricciardi 2014

[2]Barber and Odean (2001) study trading behavior and gender differences for a sample of 35,000 individuals over six-year period. Their findings show that men trade more often than women. Compared to women, men tend to sell stocks at an inappropriate time with higher trading costs. Women generally trade less and have lower trading costs.

Regret Aversion

Regret is a sense of responsibility for loss or disappointment. Past decisions and their outcomes inform your current decisions, but regret may divert your decision-making. Regret can strongly anchor you in your past experience and prevent you from seeing new opportunities. People anticipate to suffer the feeling of "regret" if they make a wrong choice and take this prediction into consideration when making decisions. The fear of feeling repentance can play a major role in preventing or motivating someone to do something. The bias of disliking regret describes the desire to avoid the feeling of remorse experienced after making a decision with negative outcome. Investors who are influenced by this bias take less risk, to reduce the potential of bad results. The bias may explain the investor's hesitation to sell the investments that have suffered losses, in order to avoid confronting the fact that they have taken bad decisions.

2. Loss Aversion

Loss aversion is a form of feeling of regret.This bias may encourage an investor to overestimate potential short-term losses and underestimate long-term returns and diversification profits.

Myopic loss aversion is a situation in which investors being extremely worried by the negative impact of losses compared to the positive impact of the same amount of profits, take a very short-term position towards investments.What is happening, is that investors pay more attention to short-term fluctuations in their investments. Although is not unusual for an average share to fluctuate a few percentages over a very short period of time, a myopic investor (or short-sighted) may not react in favor to negative changes. Therefore, it is believed that the shares must give a sufficiently high premium to recompense investor's great loss aversion.

Mental Accounting

A concept introduced for the first time by Richard Thaler (1999), mental accounting attempts to describe the process by which people code, categorize and evaluate economic outcomes. People may have multiple mental accounts for the same source. A person may use different monthly budgets for purchasing food and dining in restaurants, as well as limiting a purchase when his budget expires, without limiting another type of purchase, even though both purchases are applied from the same source.Mental Accounting is a term that describes our bias to categorize or group money into different "boxes" in our minds and then make decisions on how to use that money. It is our mental way to say, "This amount of money will be used for this purpose and this amount of money for another purpose" and this happens unconsciously. Mental Accounting can be useful. Maybe you have a stored account specifically for an emergency that you will not touch for any other reason. Or you can mentally determine a portion of your bank account that goes for your children's

education. Sometimes it would be better that the money is split into different "boxes" for short, medium and long term purposes, so that you can invest in the right time.

Imagine a player who wins in a casino. The player, like the income-earning investor, did not have that money before, so he is more likely to play with the money "he earned" rather than the money he has saved. But the important thing is the total amount, not the origin of money. Another example of mental accounting is the greater willing to pay for goods when using credit cards than when using cash, and buying more goods when paying with a debit or credit card than in cash. Investors tend to think of their assets separately and not in total and cannot see interactions between different classes of assets (Thaler, 1985, 1999).They see income from real estateinvestments, investment in the stock market, or income from their job as separate investment decisions.

Herding Effect

Shiller (2005) claims that herding behavior plays a decisive role in the human decision-making process. Herding behavior is a source of price bad estimation and speculative bubbles (Shiller, 2005). Financial crises have occurred and are often repeated in financial markets. How is the repetition of these catastrophes possible? The answer to this is believed to be impacted by a human trait: behaving according to the "crowd", which is the bias for individuals to imitate actions (irrational or wrong) actions of a larger group. There are several reasons why this bias happens. The first is the social pressure of conformity. Most people have a natural desire to be accepted in a group, rather than being labeled as excluded, so following the group's behavior is an ideal way to become a member. The second reason is the collective reasoning that it is unlikely for such a large group to be wrong. Even though you are convinced that a particular action is irrational or inaccurate, you can still join the crowd, believing that they know something you do not know. This happens particularly when an individual is inexperienced.

The market and its participants are interdependent, which means that people's reactions affect market developments and vice versa. Investors as social beings seek to belong somewhere.

Besides the social part, they also get information from interactions with others. This is especially important in times of crisis and insecurity when someone perhaps inexperienced chooses to follow the others, using the principle "the others know better". This is an important bias when explaining market bubbles and crises.

The bias is usually not a very profitable investment strategy. This means that many investors who follow the "crowd" probably enter the game too late and are likely to lose money, while investors ‘infront’ of the bias start with new strategies.In the securities market, investors following this bias, base their investment decisions on the ‘crowd’ decisions to buy or sell shares.

There are some elements that influence the behavior of an investor that shows this bias, such as: excessive self-confidence, type of investors, investment volume, etc. The more overconfident the investors are, the more they base on their own information to make investment decisions. On the er side individual investors tend to follow crowds when making investment decisions more than institutional investors (Goodfellow, Bohl & Gebka, 2009, p. 213).

Waweru (2008, p. 37) identifies investment decisions on which the investor may be influenced by others: purchase, sale, choice of investment type, length of its retention and trading volume. In capital markets, the herding bias is followed daily. People with limited information follow those who think they have more information or better knowledge.The same thing happens with investors when they copy each other's portfolio. This behavior once again rejects the *homo economicus* proposition. In fixed income securities market, the media coverage of debt securities since the 2008 crisis has put the interest rate on investor's focus, intensifying their daily moves. In addition, the lack of independent opinion from many fixed-income institutional investors display the 'group thinking' phenomena (Paul & Jonson, 2014).

Other Psychological Bias

Confirmation Bias

It is a psychological phenomenon that explains people's bias to seek that sort of information that confirms their existing thoughts and to ignore the sort of information that denies their beliefs. It affects our perceptions and our decision making process, hence we may take non-optimal choices. For example, many TV viewers prefer that television channel that represents their political views, avoiding those that display opinions of different thoughts. People do the same when it comes to financial issues.

Confirmation bias can create problems for investors. When an investor wants to make an investment, he may be inclined unconsciously to seek information that supports his belief concerning his investment andhe may not be able to see the information that presents different ideas. The result is a unilateral view of the situation which may cause that investors make poor decisions about the kind of investment they choose or the moment of buying or selling the asset. Confirmation bias serves as a self-confidence source for investors. It helps explaining why the markets doesn't always function rationally. However, an investor who is aware of his confirmation bias, may be able to overcome it and seek contradictory advice. Confronting people of different thoughts from ours can help us we overcome confirmation biases and helps taking better decisions.

Disposition Bias

Investors tend to label investments as "winners" or "losers". The disposition bias may encourage an investor to holdan investment for too long that no longer provides any benefit. The bias consists in the bias of selling an asset that has increased in value and resist selling an asset that has fallen in value.

The bias to sell "winners" to the "losers" is called the Disposition Bias. If investor would focus on his wealth rather than his emotions, he would sell the "losers" and hold the "winners". Besides, one of the documented abnormalities in the financial markets is that the shares increasing its value recently, will continue to increase its value at least for a short time ahead. It is understood that experienced investors who are more 'vigilent' fall less for this bias than the inexperienced one or beginners.

Retrospective Bias

A bias that tends to happen in a situation after an event has occurred, the person believes that the occurrence of that event was predictable and obvious, while in reality the event could not have been rationally predicted. Finding the wrong connection between the cause and effect of an event, may result in incorrect excessive simplification. Financial bubbles are often the subject of this bias. After almost every financial bubble, experts and analysts tried to show that how a past event, unimportant at the time, was actually a warning to future financial problems, the signs were very obvious. This is a clear example of retrospective prejudices: If the bubbles' signals were clear at that time, it might not have been escalated and eventually exploded. The illusion that we understand the past, stimulates the confidence in our ability to predict the future (Thinking Fast and Slow, pg. 218).

Familiarity and Home Bias

It happens when investors prefer to invest in known assets for them. If you have to choose to invest in one of the 2 investment funds: the one you have heard sth. about and the other not. Which of them would you choose? If we surrender to the familiarity bias, we would choose the fund that we have heard somewhere. Familiarity and security are two different things. Familiarity can contribute to a lack of diversification, thus increasing the risk. If people know a certain section because they work for it every day, they feel they know very well this section, thus they can decide to distribute a large part of their investments in the section. The risk is that if the section has a crisis, they are exposed to double risk (employment and investment).

The influence of familiarity on investments choice, relates also to the country where investors live (the bias to invest in local assets - home bias). Some investors tend to buy shares from companies in their country instead of risk-sharing through investment in different countries. Just as a potential risk rises of excessive investment in a particular section, it can also extended from excessive investment in a certain country.

Self-attribution Bias

Investors who suffer from self-attribution bias, tend to attribute the successful results to their personal ability and the bad results to 'bad-luck' (Shepherd, pp. 101, 1999). They often manifest this bias as self-defensive. Investors affected by the self-attribution bias can gain excessive self-confidence. When their portfolio grows, they

take the credit, but when they lose, they blame immediately external factors outside of their control, for example: market forces.

Although this tends to make you feel better, you simply fooling yourself, instead of taking advantage of thiscase to improve your investment intelligence. The higher the return to the previous period, the more investors confirm that the recent performance reflects their investment capabilities and vice versa (ArvidO.I.Hoffmann and Thomas Post 19 ...).

Optimism Bias

It's the bias to believe that the future will be better than the past and the present. Hoping to help you achieve your goals and cope with the obstacles. Various researches shows that people are more optimistic than realistic.When people predict the future, they overrate the chances of positive events and underestimate the chances of negative events. In a world full of insecurities and competition, being positive without disconnecting from reality, is useful. Nobel Prize winner Daniel Kahneman writes in his book Thinking Fast and Slow, that optimistic individuals play an important role in our lives.They are often inventors, entrepreneurs, leaders who have reached where they are, seeking for challenges and risks. On the other hand, unrealistic expectations for the future may result in impulsive behavior, as borrowing more than what people can afford, negligence on insurance, etc.

To manage this bias, it is recommended to perform a pre-mortem (Gary Klein, 2007). A pre-mortem is the hypothetical opposite of a post-mortem. The idea is simple: before taking a risky decision (such as starting a business or investing in shares), imagine that the it was taken months ago and resulted in a dramatic failure. Now think about all possible reasons of this failure. This method forces people to act against their own confirmation bias, the natural bias to seek only evidences that support an original belief. Pre-mortem will reduce the post-mortem pain that hits when the reality does not match the optimistic expectations.

Optimism bias is considered to be one of the most important psychological biases of all.

Planning Fallacy

This bias is a phenomenon that was first proposed by Daniel Kahneman and Amos Tversky in 1979, according to which the prediction of the necessary time to complete a task in the future, shows the bias of optimism and underestimates the necessary time. It describes the bias for people to overestimate their work pace or to underestimate the time they need to complete things. It is a stronger bias for long and complicated tasks and disappears or fades for simple tasks that are easier to complete (Buehler, Roger, Griffin, Dale, Ross, Michael, 1994).

This bias only affects the expectations for its tasks. When external observers predict the timing of a task, they exhibit a pessimistic bias overestimating the necessary time.

An extended definition includes the bias to underestimate future actions concerning time, costs and risk as well as overestimate the benefits of the same actions (Lovallo and Kahneman 2003).

The phenomenon can be explained by the concept of 'wishful thought' by which people feel that tasks will end quickly and easily because that's what they want to (Roger Buehler 19.).Some real examples illustrating this bias:

1. The Sydney Opera Theater was expected to be completed in 1963 at an estimated cost of $ 7 million. A diminished version of it opened a decade later at a cost of 102 million dollars.

Endowment Effect

It happens when we overestimate the goods we possess, regardless of its objective market value (Kahneman, Knetsch, &Thaler, 1991). Studies have repeatedly shown that people will estimate something they already have, more than just a similar item they don't have, especially true of goods that are normally not bought or sold on the market, usually items of symbolic or emotional importance. According to an old saying: "It is better to have a bird on your hand, than two in the tree".

The impact is an illustration of the bias of the status quo (the preference to not change the situation in which you are which is taken as a reference point and any change from which is perceived as a loss) and can be explained by loss aversion. According to this effect, investors are inclined to hold on certain assets due to familiarity and comfort, even if they are inappropriate or become useless. The endowment effect is an example of an emotional bias.

Literature summary on empirical findings about psychological biases

The following is a summary of the literature of studies on psychological factors influencing the investor's behavior:

Bias	Author	Findings
Availability	Tversky and Kahneman (1973, 1974)	The facility certain cases come to mind. It creates a selective bias in decision-making.
	Kliger and Kudryavtsev (2010)	Price feedback is stronger when is associated with the same course of index return.
Anchoring	Tversky and Kahneman (1974)	People's bias to estimate unknown quantities with the help of an initial "anchor" value.
	Campbell and Sharpe (2009)	Expert forecasts are biased (anchored) to the results of previous months

Overconfidence	Odean (1998)	Investors' bias to overestimate the precision of their knowledge of the value of securities
	Daniel, Hirshleifer and Subrahmanyam (1998)	Investors' overconfidence leads to a negative serial correlation in prices.
	Barber and Odean (2000)	Overconfidence leads investors to excessive trading, which reduces their wealth due to higher trading costs.
	Gervais and Odean (2001)	Past successes enhance investor's self-confidence and increase future trading volume.
Optimism (Pessimism)	Heifetz and Spiegel (2001)	The investor's bias to over/underestimate the expected average return of risk asset.
	Toshino and Suto (2004)	Optimistic investors select only the good news in their decision-making process.
	Shefrin and Statman (2011)	Excessive optimism creates speculative bubbles in financial markets.
	Hoffman and Post (2011)	Identifying the optimism and pessimism (expected return, tolerance and risk perception).
Loss aversion	Kahneman and Tversky (1979)	Loss leads to regret and people try to avoid losses so that they don't feel bad afterwards.
	Coval and Shumway (2003)	Studied loss aversion in intraday trading. A loss in the morning leads to taking higher risk in the afternoon.
	Berkelaar and Kouwenberg (2008)	Investors become less risk averse when they experience profits, increasing securities' price.
	Hwang and Satchell (2010	The level of loss aversion depends on the market terms, being higher

		in the 'bull'[1] market than in the 'bear'[2] market.
Representativeness	Tversky and Kahneman (1974)	Individuals' bias to estimate the probability of an event to occur, comparing it with an earlier incident that already exists in their minds.
	Kumar (2001)	The past price bias is representative of the future price bias as investors tend to buy shares with positive above-average returns.
Mental accounting	Thaler (1999)	Investors preserve mental accounts of their property, which affects the decisions on stock selection.
	Barberis and Huang (2001)	Changes in the investor's mental accounting system affect asset prices.
Endowment effect	Shefrin and Statman (1985)	Investors' disposition to sell winners too early and hold on losers for too long.
	Grinblatt and Keloharju (2001)	Evidence of endowment effect on Finnish stock market.
	Alok Kumar (2009)	To avoid regret, investors hold 'losers' shares hoping there will get future profits.
Herding	Scharfstein and Stein (1990)	Examined this bias on managers. The reputation and the effect of "sharing the guilty" lead to join herding behavior.
	Christie and Huang (1995)	Examined the bias using the standard cross-sectional deviation. They analyzed the presence of this bias in market's extreme periods.

Table 1.5: Literature summary of the main psychological bias

[1] The financial market of a group of securities in which prices are rising or are expected to grow. The term is most often used to refer to the stock market, but it can be applied to everything that is traded, such as bonds, currencies, and commodities. *Bull* markets are characterized by optimism, investor confidence, and expectations that the trend should continue.

[2] The opposite of the bull market; is characterized by price declines and pessimism. Using the terms "bulls" and "bear" to describe markets comes from how animals attack their opponents. Bulls keeps horns up in the air, whereas the bear slams the paws on the ground. These actions are metaphors for market movement. If the trend is up, it's a bull market, if it's down, it's a bear market.

Source: Prosad, Kapoor, Sengupta, 2015

Conclusion

The way investors think and feel, affects the way they behave when making investment decisions. These impacts are known as psychological biases. They affect all investors and vary depending on the type of investor. Based on theories developed in the field of financial behavior, *heuristics* is that approach which uses short mental methods, fast, efficient rules, in order to reduce mental efforts during decision-making process. While it can lead to right decisions, it can also lead to wrong decisions as a result of errors in judgment or psychological deviations. Such tendencies included in heuristics are: Representativeness, Availability, Anchoring, Gambler's Fallacy, Overconfidence. Another theory developed by Behavioral Finance is Perspective Theory, which has a high level of explanatory power about individual behavior during decision-making. Psychological biases which are included in this theory are: Loss aversion, Regret aversion, Mental Accounting. Other behavioral biases are consequently listed in the paper, each of them being quite important in individual financial behavior. Markets reflect the collective independent decisions of millions of people and when market forces unify with human ones, it can result in financial crisis, which have actually happened throughout human history. That's why all of us have to by wary of learning how to deal with situations which require logic, processing and analysis of information and because of our limitations in time, sources, and knowledge we are prone to our psychology. In such cases we should know ourselves better, know our vulnerability to behavioral biases and try to reduce the errorness of our actions.

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The Examination of the Profile of Leadership and Management in Healthcare Institutions in Kosovo

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Abstract

Traditionally, the management of healthcare institutions and clinics in Kosovo come from clinical background rather not being familiar with and lacking know-how and skills in management and leadership, which would make possible to focus on organizational development and growth, proper staff management, management of institutional resources, having better client/patient-oriented focus, as well as engaging in better strategic planning and implementation. The aim of this exploratory study was to examine the current profile of leadership and management in healthcare institutions in Kosovo at primary, secondary and tertiary healthcare public sectors. Methodology: Secondary data were collected about the managers from 253 healthcare institution of primary, secondary and tertiary healthcare sectors. The data were about the managerial position (clinic manager or service manager), gender, age group, educational background, work experience, and healthcare sector, and were analyzed at individual level by further forming clusters of professions that dominate in leading respective institutions. Results and discussion: As assumed, the data showed that all included healthcare isntitutions in the study had employed managers with clinical background without proper profile of leadership skills and know-how. The only indication these managers have got management skills is work experience on the position, as a kind of on-the job training. Work experience was stressed much longer to service managers, while the clinic managers mostly have one or maximum two mandates (one mandate 4 years) as managers. The study further discusses findings against the manager profile promoted by the International Hospital Federation, and concludes also future research references in order to bring a better understanding and knowledge of leadership practices and behavior in healthcare institutions in Kosovo.

Keywords: healthcare, management, leadership, quality of service

Introduction

I.I Demographic characteristics and living statistics of the population

The Republic of Kosovo covers an area of 10,908 km2 and has a total population of 1,804,944. It is located in the south-eastern part, bordering south-west with Albania, north-west with Montenegro, north-east with Serbia and south with Macedonia. Population density is 162.41 inhabitants per km2. It has a total of 38 municipalities. Based on the general population number, 28% are under the age of 15 and half of the population are younger than 28.2 years old. The average age of the Republic of Kosovo population estimated in 2011 is 30.2 years old (Kosovo Statistics Agency, 2016). The average life expectancy for men in Kosovo for 2011 is estimated to be 76.6 years, for women 79.4 years (Kosovo Agency of Statistics, 2016). The health sector in the Republic of Kosovo is financed by income tax, co-payments and taxes, while private pocket payments account for 40% of expenditures for health services (Ministry of Health, 2016).

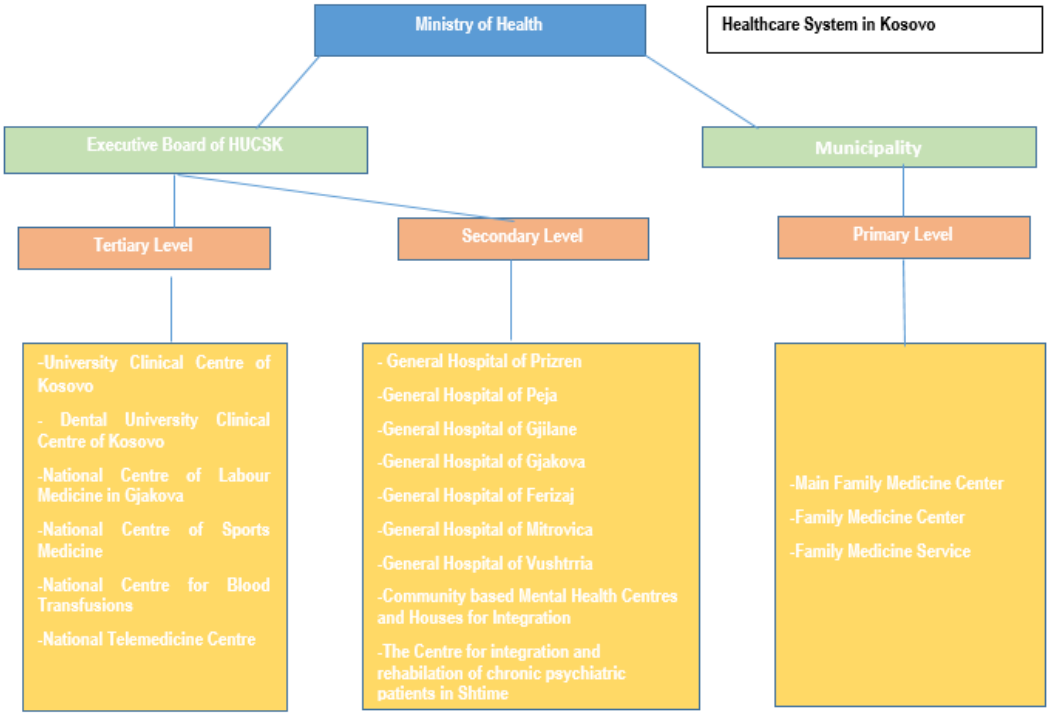
I.II. History of Health Development

The health care system in Kosovo has undergone a transition since the end of the war and has been one of the country's many challenges since 1999. With the help of European countries mainly UNMIK, the Kosovo Health System has begun to taking care of health care management and management, raising the potential of services, hiring healthcare staff and enhancing the renovation of various facilities for providing health services to all citizens regardless of our country. Along with these aids, various donations were provided, including various tools, medicines and technologies that helped improve the quality of health care services (Ministry of Health, 2009). In setting up the quality of health services, in the post-war period of the public sector, the formation of the provisional structures of self-government and division of responsibilities was greatest, and was then transformed into UNMIK Regulation no. 2002/5, which delegates UNMIK's full powers to the country's leading structures. From this period, Kosovo takes over the governance of health institutions. The key document defining the strategic direction and the medium-term approach of the Kosovo Health System is the Health Sector Strategy (SSSH), a document in which are written priorities that need to be achieved in the field of health (Ministry of Health, 2016). Part of the implementation of the Health Sector Strategy 2017-2021 is the Action Plan (PV), which presents the activities to be carried out during the period 2017 - 2019, in particular the PV reflects the strategic directions for healthcare institutions for SSS realization, which offers in detail how to achieve the objectives that are part of HSS. For MOH Action Plan is a measuring instrument for monitoring the applicability of SSSH, as well as an information tool for achieving strategic objectives (Ministry of Health, 2016). The Action Plan is based on the principles and commitment set out in the Tallinn Card Health and Safety System approved by the World Health Organization and the member states of the European region in June 2008 (Action Plan, 2010).

I.Ill Organizational Structure and Health Care Levels

Health care institutions in Kosovo are the same as in the public, private and public-private sectors Institutions by which public health services are provided are classified in three levels of care provision:

- Primary level;
- Secondary level;
- Tertiary level (Ministry of Health, 2009)



The primary level includes the starting point of providing health care, which includes preventive measures through the implementation of the concept of family medicine. The municipalities have the responsibility for primary public health care and for evaluating the health status of citizens in their territory. Within this level, the Main Family Medicine Centers (MFMC), Family Medicine Centers, and Family Medicine Points operate. Emergency Centers (Law No. 04 / L-125, 2012) also exist in countries with over 150,000 inhabitants. Secondary level includes services provided through regional hospitals. They provide stationary treatment (with patient extension) as well as specialized services that include oral care services. Within these services, the Mental Health Professional Service, through the institutions of Mental Health Centers (MCIs), Communities Integration Houses (SHIB), and the Center for Integration and Rehabilitation of Chronic Psychiatric Sickness in Shtime (Ministry of Health, 2012). The tertiary level includes the specialist services provided in public health

institutions, the basic lecture at the Faculty of Medicine for students as well as postgraduate studies and scientific research work (Health Law, 2012). Health institutions that are part of KPSHK are autonomous units that organize and manage their regular administrative and professional duties in the function of fulfilling their duties and responsibilities, in addition to the duties and responsibilities that under the Law on Health and this Statute are assigned to HUCSK (Statute of HUCSK, 2013). According to the Statute of HUCSK, HUCSK is organized on the basis of a functional network model that integrates administrative and financial functions with professional and scientific functions in the public health sector, through close cooperation between health institutions - organizational unit of HSCUKK and related services professional (Statute of HUCSK, 2013).

The operational organization of HSUCK is composed of the Steering Board (BD), which is the highest decision-making body of HUCSK. The Steering Board consists of seven (7) members: one (1) representatives from the University Clinical Center of Kosovo (UCCK), one (1) representative from the University Clinical Center of Kosovo, one (1) representative from the National Institute of Public Health Institute, one (1) representative from General Hospitals, based on the rotation and fulfillment of quality health service indicators, one (1) representative from the Primary Health Care Services, based on the proposal of the Association of Municipalities of the Republic of Kosovo, one (1) representative of the Ministry of Health and one (1) Financial Director - experts of economics or health management with high professional and scientific qualifications selected on the basis of a public competition (Statute of HUCSK, 2013).

I.V Health Profiles in Kosovo

Our country still does not have full information on all health profiles that are practicing their profession in Kosovo. According to the Ministry of Health, this is due to the lack of adequate functioning of the Health Information System (HIS) (Ministry of Health, 2009). Health profiles assessed by the Ministry of Health are the worst in Southeast Europe. Based on the results of the Kosovo Information System availability of health profiles is very low compared to other countries where in Kosovo there are 0.94% doctors, 1.61% nurses and 0.06% dentists (Ministry of Health, 2009). Lack of standards for services or protocols increasingly makes it difficult to achieve quality and work management. Managerial jobs are managed through some past technical assistance that is not inconsistent with any regulation or legal framework and can not be used systematically throughout the country.

Based on the Health Law, no. 04 / L-125, the existing profiles that provide health services in public, private and public-private health institutions are: Doctor of Medicine, Doctor of Dentistry (specialist, sub-specialist), Graduate Pharmacist - Master of Pharmacy (specialist, -specialist), Psychologist (specialist, sub-specialist), Nurses, Physiotherapist. Senior Medical Worker, Graduated speech therapist,

Graduated Audiologist, Graduate Phonemic and Other Qualified Medical and Senior Professionals, defined in the Ministry's official register (Law on Health, 2012).

The number of staff employed in Primary Health Care is 5,453 of which 4,579 are health workers and 842 non-health workers, out of health profiles, 1,326 doctors, out of which 476 are family medicine specialists and 3,050 are nurses, of which 2,118 are trained family nurses.

According to WHO (2007), health profiles should be properly described and formalized, they should contain:

- clarity about their roles and degree of authority at all levels of the health system;
- clarity about the competences that must be at each level of the health system;
- job descriptions based on the two upper criteria.

In the Health Sector Strategy 2017-2021, the Ministry of Health (2016) aims to improve governance and management of the healthcare system by strengthening and enhancing managerial capacities, including issues related to strategic management and enhancement of professionalism, as a prerequisite requires the comprehensive functioning of the integrated health information system. The Ministry of Health (2016) intends that Sectoral Health Strategy 2017-2021 "be a political and professional guide to the development of the health sector that aims to improve the health status of the population and the satisfaction of patients with health services in the Republic of Macedonia Kosovo "(pg. 9). The Ministry of Health has established the health system reform, one of its priorities is the reorganization of the health sector by increasing the managerial autonomy of health institutions (Ministry of Health, 2016).

Strategic Objective for 2017-2021, the Ministry of Health has the reorganization of the health sector by strengthening the targeting of the Hospital Service and Clinical University of Kosovo; strengthening the managerial structure of HUCSK, enhancing the capacities of the Health Inspectorate, building professional capacities based on identified needs as well as contractor services defined by each organizational unit of HUCSK (Sectoral Health Strategy 2017-2021, 2016).

I.Vl Theoretical framework in healthcare leadership

The health system in Kosovo, despite the numerous attempts through Strategies to improve the managerial quality, still results in very poor performance. This is being influenced by many different factors, ranging from frequent changes to organizational health pillars, political influences, and inadequate managerial education. As health care is growing more and more, then the need for management increases. Leaders of healthcare institutions even though they have academic education, they should also develop the professional development part of the management in order to meet all the requirements for quality achievement, which is essential in health (West, Armit, Loewenthel, Eckert, West & Lee, 2015).

Through HSCUK statute, the scope is determined, organization and functioning of the components of Hospital Service units and University Clinical Kosovo (HUCSK), ways of conducting its activities, as well as the powers, rights, duties, and responsibilities of the management structures of HUCSK (Ministry of Health, 2013). The criteria to be met by the Heads of Health Institutions, based on the Law on Health, Labor Law and in accordance with the Statute of HUCSK are:

- In addition to the specialized qualification, they must have a professor's academic appeal, or in absence, have the title of a doctor of sciences or high professional qualification, as well as the organizational unit to be full-time employees;
- Have scientific degrees in the field of economics or health management of a master's or doctor's degree;
- Have published a university book in the relevant professional field, or in absence, have published three (3) scientific or professional papers in professional or scientific journals of the international rank in the last five (5) years.
- In the absence of candidates who meet the criteria set out above, the final decision on the selection of the Director shall be received by the Minister of Health from among the three (3) candidates proposed by the Governing Board of HUCSK;
- The General Director is appointed by the Board of Directors for a term of three (3) years with a possibility of re-election in the case of outstanding performance (Statute of HUCSK, 2013).

In the Sectoral Health Strategy 2012-2016, it is presented as a conclusion that management skills and knowledge are very scarce for persons in management positions (Ministry of Health, 2012). Leadership and leadership development are vital for health care. According to West (2015), there are no special methods to develop successful leaders because leadership is a sensible process, but development needs to be achieved by formal or informal analysis of the current capacities of the leaders they own or that they should achieve. Leadership and management are complex concepts that are relevant to many different parts of the health system, including private and public sectors (WHO, 2007). As management is one of the pillars of the existence of the health system and has the main purpose of achieving quality performance, it should also take on the knowledge and managerial skills of each person possessing these positions. Leadership competencies can be seen as a result of the leadership's experience, wisdom, and ability to effectively carry out the leadership duties that are presented to them in an organizational context and which have cognitive, behavioral, and emotional components (West, 2015).

Management and leadership are very important to provide good health services (WHO, 2007). Though both are similar in some respects, they can differ in terms of perspective, skills and behaviors. Good managers should strive to be good leaders and

good leaders, need leadership skills to be effective. Leaders will have a vision of what can be achieved and then communicate this to others and develop vision vision strategies (WHO, 2007). Leadership and management are the key to achieving the most effective quality of service to a low-risk healthcare system. Good managers ensure effective organization and use of resources to achieve results and meet health goals (WHO, 2007).

Model of Competency of Heads of Health Institutions under the International Federation of Hospitals (2015)

Source: International Hospital Federation (2015)

The Model of Competency of Heads of Health Institutions under the International Federation of Hospitals (2015) consists of five pillars which are:

- Leadership competences, including: (Skills and leadership behavior, culture and organizational climate, leadership change and innovation support);
- Communication skills and interpersonal relationships where: (Management of staff reports, communication skills, support and negotiation);
- Professional and social responsibility, including: (Personal and professional accountability, continuous professional development, self-reflection and support of ethical values);
- Knowledge of the health and healthcare system environment for: (Knowledge of health systems and organizations, knowledge of health professionals, access to patient-oriented health care, recognition of the public health system);
- Competence of business.

WHO suggests that for achieving health through leadership and management in low income countries, such a low-income example is the Republic of Kosovo should work towards the creation of these objectives; Establish a framework for strengthening leadership and health management in enhancing the quality of health services:

- agreement on management issues in enhancing the quality of health services;
- a set of good practice principles for strengthening leadership and health management in low income countries;

- recommendations on actions (for WHO and others) to further strengthen health care (WHO, 2007).

WHO has drafted a framework for creating the necessary conditions for good management and management. This framework encompasses four dimensions that are interrelated, one of which does not work, and others are affected. The Framework makes clear that management and management activities are a means of achieving effective management of the healthcare system and services, and the integral strengthening of the health system, which includes the provision of adequate number of managers and their placement across the health system, how many managers are employed? How many of their "managers" have the title in their work? How do you combine the managerial role with that of clinical work? Which health levels are managers? Providing managers with the right competencies such as knowledge, skills, attitudes and behaviors that include: Is there a practical competence framework for knowledge, skills, attitudes, and behaviors? What is needed for managerial positions? How do competencies grow? Is there any system for increasing competencies? What qualifications and experiences do managers have? Existence of functional critical support systems (to manage money, staff, information, supplies, and self-management performance (WHO, 2007). The use of different Frameworks in order to improve and improve the leadership's performance is not all the achievement of success, because the problem does not stand in the framework but also in the non-managerial preparation of the leaders (West, 2015). The Ministry of Health (2016), based on the Performance Analysis of Health Institutions, concludes that the health sector needs reassessment and reorganization of the health care network for the purpose of their rational use. Leaders and decision-makers in cooperation with the Ministry of Health should set priorities that address the most important health needs and precede the management of the national health strategy and plan (Terwindt, Rajan & Soucat, 2016). Leadership success plays a major role in co-operation within the institution as well as with other actors outside the institution, achieving the building of an integrative leadership culture, where results the more successful collective leadership than the individual (West, 2015). Therefore, leaders need to work together and build cultures where the success of patient care in general is the priority of every leader, not just the success of their individual areas of responsibility (West, 2015). For a health system to be successful before prioritizing, the current health situation should be analyzed not only through quantitative data but with a qualitative assessment of factors affecting the performance of the health system (Terwindt et al, 2016). In leadership the experience is really valuable to enable leaders to develop their skills in particular when they have the right guidance and support (West, 2015).

Leadership development benefits can go beyond individual level and apply to organizations and patients if participants can transfer their workplace development and improve quality and efficiency in health care (West, 2015). The strategy's success depends on how it is adapted by health care providers, failure to conduct proper

behavior can lead to failure of the health strategy. Therefore, leadership plays a key role in the functioning of the strategy, which if implemented as planned, will reflect on the positive performance of patients and all of this is achieved by changing their behavior in order to adapt to the goal of the strategy (Caldwell, Chatman, O'Reilly, Ormiston & Lapiz, 2008). Leadership development leads to increased quality, developed education, and concentration of organizational attention on strategic priorities, but it remains true that leadership experience is a much more valuable factor in enabling leaders to develop their skills especially when they have proper guidance and support (West, 2015). Leadership can have a positive impact on the implementation of the health strategy by cooperating with their clink team and by adapting their behavior based on the requirements of the strategy, but they can also adversely affect by not adopting a management approach to the health strategy (Caldwell et al., 2008). Leadership performance depends on link building and their impact on health institutions and professionals, trying to achieve the highest goals that increase healthcare performance (Goodwin, 2000). The success of the strategy is achieved by co-operating the Ministry of Health together with the leaders of health institutions in order to adapt adequate behaviors that lead to increased performance in patients (Caldell et al, 2008). Effective leaders always emphasize as a top priority safe, high quality and tooth care, making the voice of patients heard at each health level about their experiences, needs as well as the positive or negative reactions that are part of the work (West, 2015). Leadership is the most influential factor in shaping an organizational culture that provides the core leadership, strategy and quality development that is most essential (West, Armit, Loewenthel, Eckert, West & Lee, 2015). Engagement should be manifested by all institutions by taking responsibility and making it a personal priority that helps secure the success of the institution as a whole instead of individual focus or isolated leadership (West, 2015). Facts-based leadership is possible and becomes a reality and is a powerful tool for leading teams to set strategies and goals, and to generate faster results. Leaders have a major impact on the performance of Health Institutions, according to Punka, (2013) if the hospital performance is high then the leader is managing the right course on the path to performance improvement but if the performance results to be low then the direction leadership is wrong. When we have an overview of leadership profiles we can more easily reflect on the current state of health care. Leadership is a powerful tool for leading teams to set strategies and goals, as well as to generate faster results (Punke, 2013). We can appreciate leadership and this is important because we thus advance leadership gaps. Since the managerial and managerial part is of poor quality in Kosovo, as there is a lack of a legal framework for leading positions, this research is needed to reflect on who is managing today in Health Institutions in the Republic of Kosovo and what competences have the current leaders?

The purpose of this research is to examine leadership profiles in the institutions of three public health levels in Kosovo.The main research question: Who is leading the health institutions today in Kosovo?

Follow up questions:

1. What is the professional development of the leaders of institutions and health services in Kosovo?
2. Is education distinct in the management of medical services to nurses?
3. What is the managerial experience of the current leaders?
4. What is the age of managing institutions and health services?
5. What is the current governing gender of institutions and health services?

II. Methodology

The method of this research is a quantitative approach, with explorative-descriptive design, which examines profiles of current managers and managers in primary, secondary and tertiary public health institutions in Kosovo.

II.I Participants

The sample of this study consisted of 253 participants, who were 48 leading educational institutions and 205 services a leader. According sex 101 participants were women and 151 men. Part of the study were 49 public institutions, 11 of which have been centers of Family Medicine, Mental Health Center 4, 7 and 27 Hospitals Clinic HUCSK 's total of 15 of the Republic of Kosovo. Leaders of institutions of MFMC were (3.95%) participants from HUCSK (11:07%) participants, from being included hospitals (2:23%) participants and the MSC have been (1:58%) participants. Leaders of the services from the Main Family Medicine Centers were (10.28%), from Hospitals participated (70.75%), from the Kosovo Clinical Hospital Clinical Service and the Mental Health Centers we did not have any research participants.

Table 1. Demographic data of participants in Health Institutions

Sample	253	Leade / Manager
Leader Institutions	48	Participants
Leader Services	205	Participants
Gender	F – 101 / M - 151	Participants
Public Institutions	49	Participants
MFMC	11	Participants
MHC	4	Participants
Hospitals	7	Participants
Clinics of HUCSK	27	Participants
Municipalities	15	participants
Leader Institutions	MFMC-3.95%	HUCSK 11.07%
	Hospitals - 2.23%	MHC - 1.58%
Leader services	MFMC- 10.28%	HSCUK- 0%

Hospitals- 70.75% MHC- 0%

II.II Procedure

Data collection for this research has been done in public health institutions of primary level (MFMC), secondary (hospital) and tertiary (HUCSK). Prior to the implementation of the data collection process, applications were made in each institution that was a target for research, presenting the purpose of the research, as well as explaining which data would be relevant to the research. After the approval of the requests, the process of data collection has begun, where all ethical rules have been respected regarding the data we have requested. For collecting the data that were collected for research we have found legal support to LAW NO. 03 / L-215 on access to legal documents.

This law guarantees the right of every natural and legal person, without discrimination on any ground, to have access, upon request, to documents held, drafted or received by public institutions. Research data are secondary data, as they are readily available from each health institution that was the target of the research. The focus of the research was only the managerial positions of the three levels of Health Institutions (senior, middle and low management). The data we collected for research includes: gender, type of institution, institution health level, managerial experience, clinical experience, education, age and type of management. Data on HUCSK have been obtained from the Health Information System (HIS), while some Hospitals and Main Family Medicine Centers (MFMCs) have been taken from those institutions. The data collection period began on June 15 and lasts until August 30, 2017, while data analysis is done through the SPSS (Social Science Statistics) version 21 and Excel. The data collected will be used only for research and will be treated with caution.

III. Results

The results of this research convey the answer to the main research question: Who is leading health institutions today in Kosovo? Institutions and health services are run by professional health professionals, namely in the clinical field based on the research results, of which the institutions are 8.16% with general practitioners, with 4.08% surgery, with (3.40%) doctors of family medicine. Whereas, health services (4.06%) are specialist doctors (3.40%) are specialist in gynecology, pulmonology and dermatology specialists, and (2.72%) are specialist in cardiology and ophthalmologists.

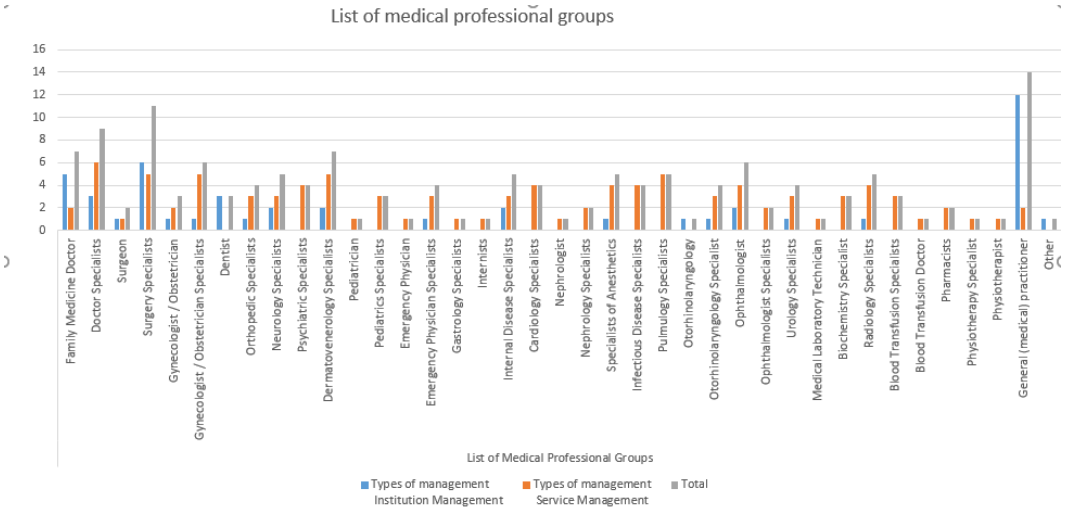


Figure 1. Professional Development of Leadres of Institutions and Services

Research question: What is the professional development of the leaders of health institutions in Kosovo? According to the type of health institutions, the professional development of the managers of institutions and services in MCMF has a higher percentage of specialized education with (5.65%), in hospitals is preceded by education with specialization with (29.44%), in HUCSK we have education with specialization with (8.47%) as well as in mental health education centers integrated studies with (1.61%).

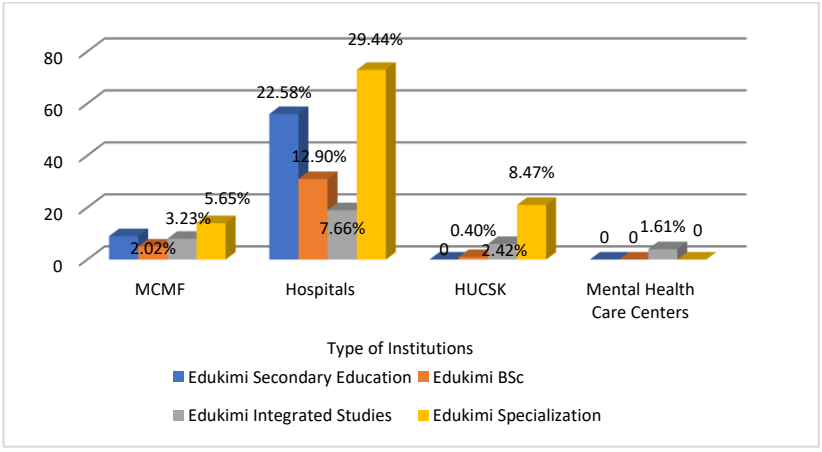


Figure 2. Professional Development of Leaders of Institutions and Services by the Type of Institutions that Lead

According to the education of the health levels in the health institutions we have the secondary level which dominates the four educational levels with a higher percentage than the primary and tertiary level.

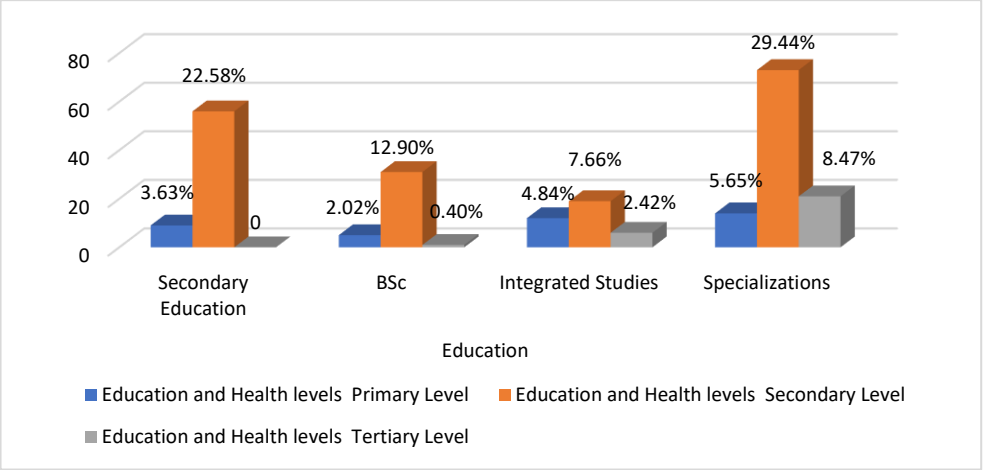


Figure 3. Education and Health levels

The professional development of the leaders of the institutions and services is exaggerated by the following results: leaders of institutions with secondary education do not have, with BSc we have (0.40%), with integrated studies (8.47%) and with specialization (10.48%). Heads of secondary education are (26.21%), with BSc (14.92%), with integrated studies (6.45%) and with specialization (33.06%).

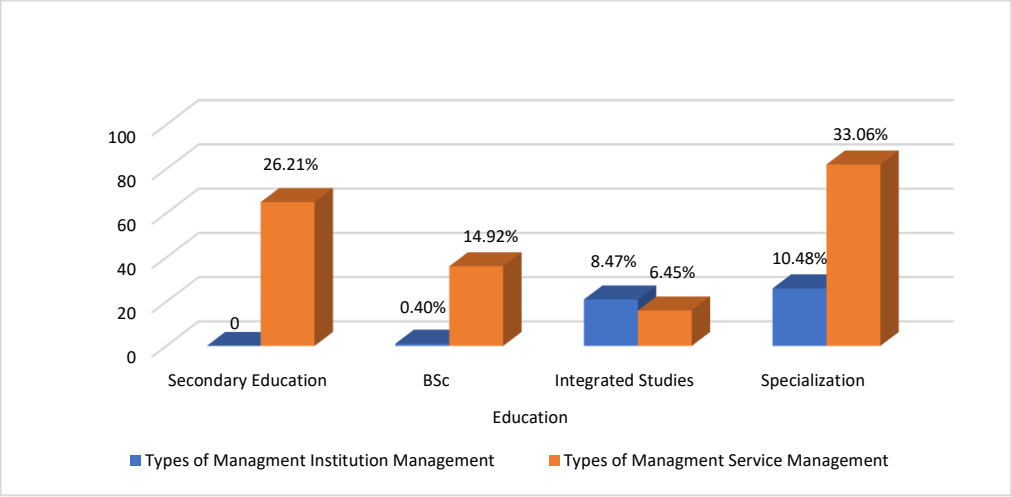


Figure 4. Professional Development of Leaders and Institutions and Services

To the research question: does education differ in the management of medical services to nurses? The results of the research reflect the difference of professional development in the management of medical services to nurses, of which 40.70% medical specialists are with specialization, with integrated studies (8.04%) and BSc

(1.01%), (32.66%), with BSc (17.59%), with integrated studies and specialization we do not have in nursing management.

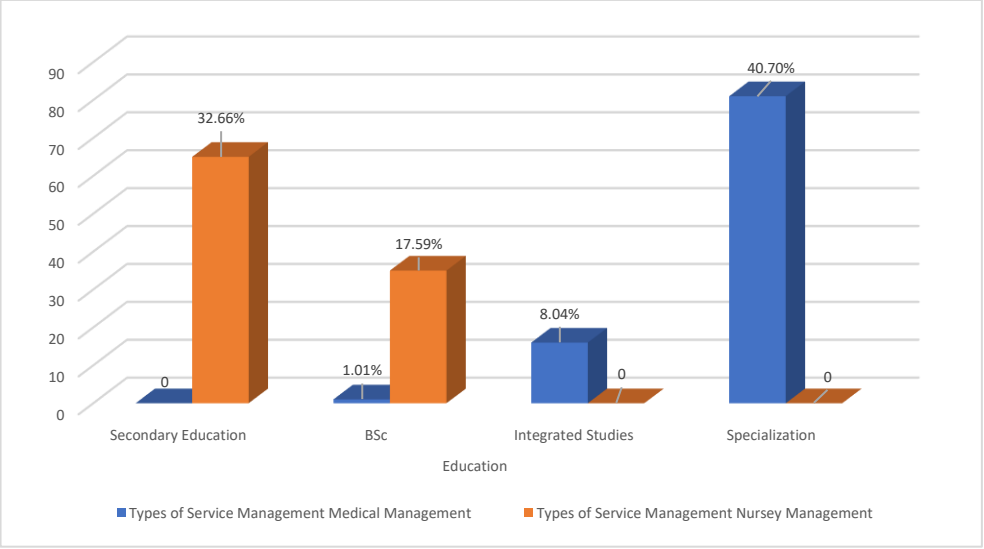


Figure 5. Physician Education and Nursing Management

Heads of Institutions and Health Services in secondary education dominate age 46-55 (9.86%), BSc education dominates age 26-45 (7.79%), integrated studies are aged 46-55 and over 56 years as well as specializations are over 56 years old (23.36%).

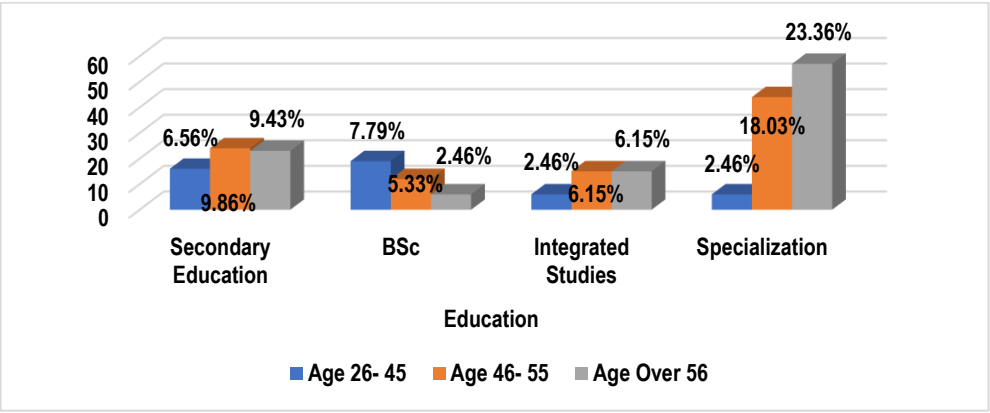


Figure 6. Professional development according to age

The professional development of Heads of Institutions and Services by gender is reflected in the following results: in secondary education we have feminine gender with (18.15%), BSc dominates with (11.29%) females, in integrated studies we have male gender with (12.50%) and in the specializations we have male gender with (35.89%).

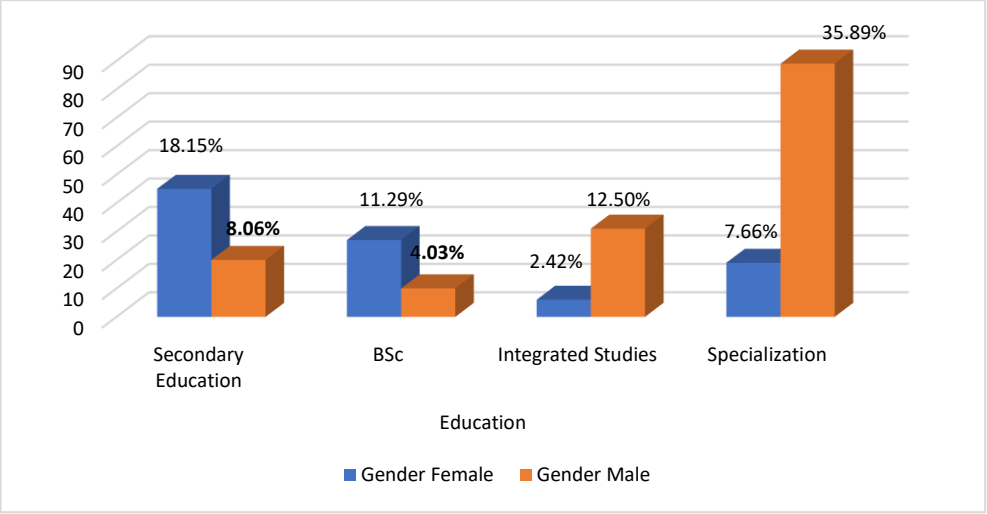


Figura 7. Ngritja profesionale në bazë të gjinisë tek Udhëheqësit e Institucioneve dhe Shërbimeve

Refering the research question: What is the managerial experience of the current leaders? The survey reflects the fact that the managerial experience of the current leaders of healthcare institutions and healthcare services with 1-5 years, 6-10 years and 11-20 years dominates the secondary level.

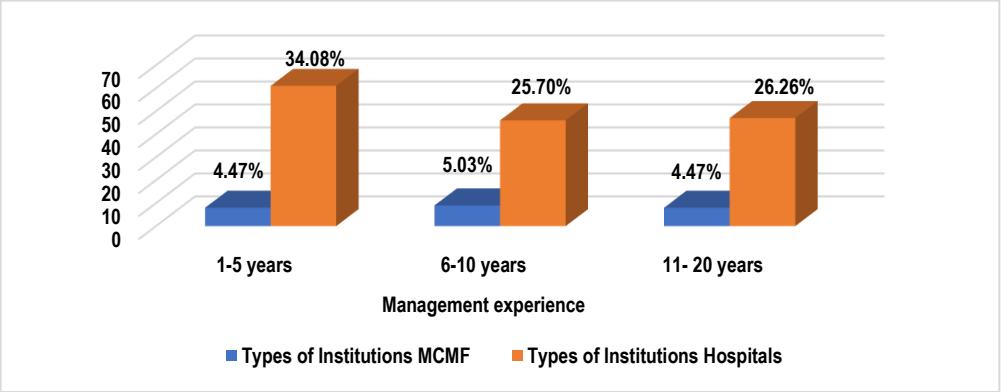


Figure 8. Management Experience of Leaders by Health Sector

Based on the results obtained from the research, the professional growth of managers with 1-5 years of high school and BSc managerial experience is (8.52%), with integrated studies (1.14%) and specialization (19.89%). Management experience 6-10 years for highschoolleaders is (7.39%), with BSc (5.11%), with integrated studies (1.70%) and specialization (16.48%). As for managerial experience11-20 years, leaders with secondary education are (14.77%) with BSc (3.41%), with integrated studies (1.14%) and specialization (11.93%).

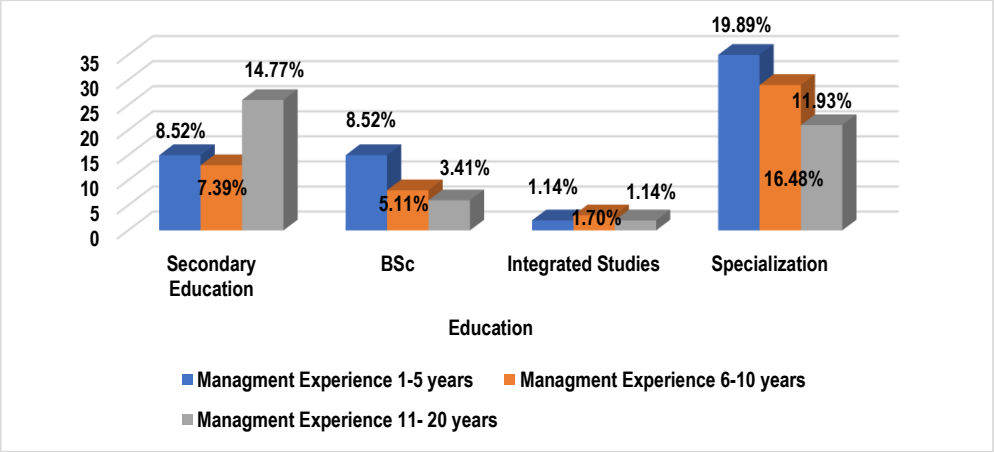


Figure 9. Managerial experience of leaders by education

Managerial experience 1-5 years of female leaders was (17.32%), while male leaders (21.23%), managerial experience 6-10 years were (10.61%) leading women and (20.11%) male leaders while with 11-20 years of managerial experience were (16.20%) leading women and

(14.53%) male leaders

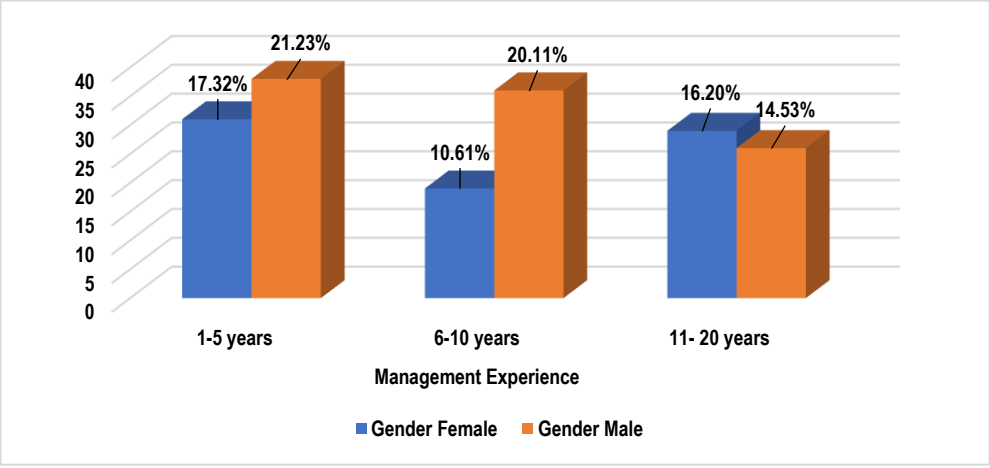


Figure 10. Management experience by gender

In research questioning what age is leading health institutions? The research shows that the age that leads institutions and health services on the basis of research results reflects the age of 26-45 years with (1.20%) leading institutions while with (18.47%) service leaders, aged 46-55 years (8.43%), while with (30.52%) service leaders, while over the age of 56, we have (9.24%) leading institutions and (32.13%) service leaders.

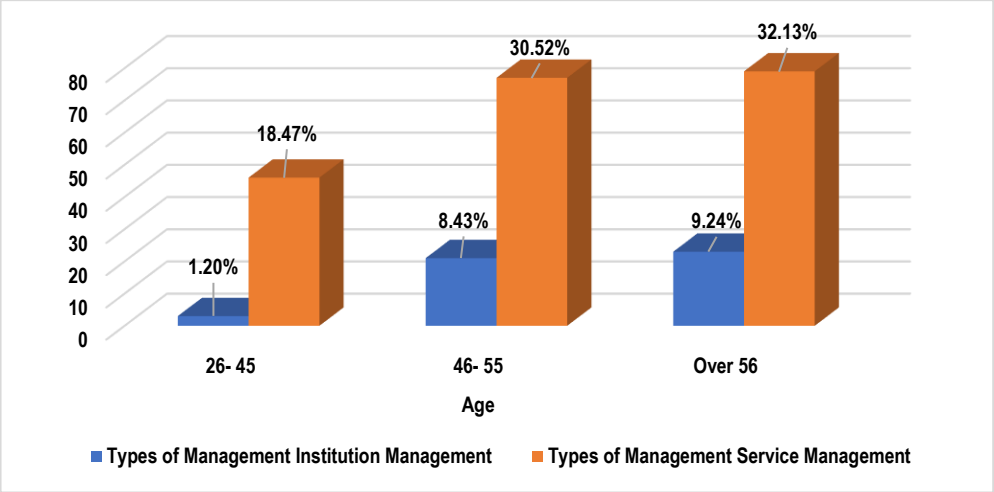


Figure 11. Age of Institution Managers and Service Managers

The service leaders, divided into leaders of medical services and nursing care services by age, have the following results: with age of 26 to 45 years (4.48%) are medical leaders while with (18.41%) years are nurses leading 46- 55 years are with (18.91%) medical leaders and with (18.41%) are nurses, while over 56 years are (25.87%) medical leaders, and with (13.93%) are nurses.

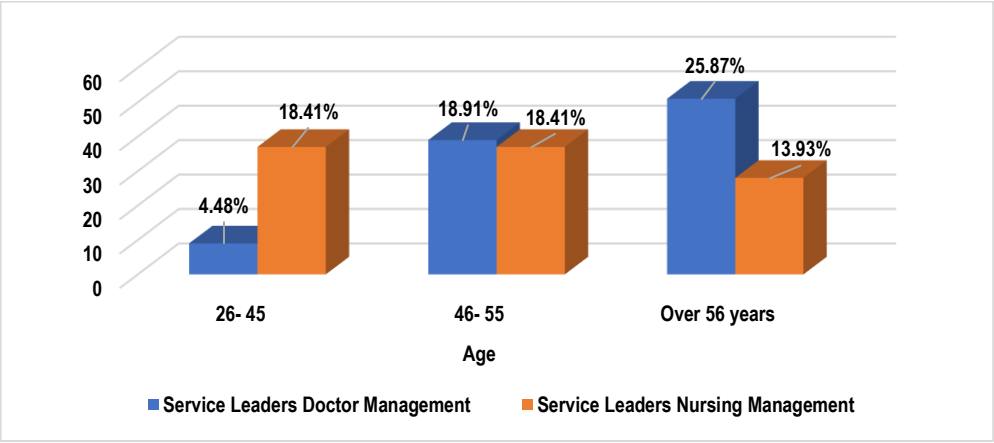


Figure 12. Age of physician managers and nursing managers

Research results of the research question: What is the gender that is leading the institutions and health services? The result is that women (3.57%) are leaders of institutions and (36.51) are leaders of services, while men with (15.48%) are leaders of institutions and (44.44%) are leaders of services.

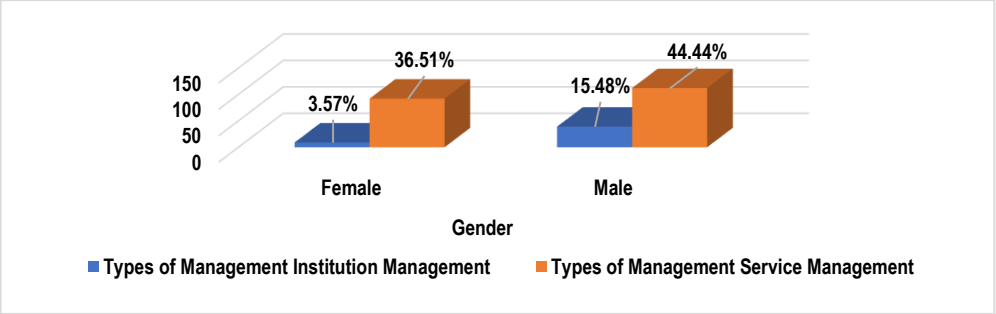


Figure 13. Gender by type of leadership

Iv. Discussion

Who is leading the health institutions today in Kosovo has been the general research question. And this research based on facts justify the research supports that health institutions are governed by educational profiles in clinical areas and not in those management.

Research question 1. What is the professional development of the leaders of health institutions in Kosovo?

Health care institutions are managed and managed by the clinician profile, not by the adequate profile of the managerial management section. Professional growth of professionals results only in clinical areas, institutional leaders dominate with vocational advancement, while those with integrated and secondary education services. This shows that, besides the current leaders, they do not have the proper professional growth in the managerial fields, they are also with a low level of professional development in clinical fields. This reflection of the professional upgrading of institution and service leaders shows an indication why the performance in healthcare institutions is not so enjoyable as leaders with adequate managerial competencies are key to the success of Institutions and Health Services. However, one thing that is borne out by this research is the criterion for institutional leaders, which includes the statute of HUCSK, which are more criteria for the clinical part than for the managerial, and that are not in line with the models of different European. If we compare it to the model of the International Hospital of Hospitals (2015), which represents the basic competencies for a leader, none of them is included in the statute of KPSHK, which used as a basis for selecting the leaders of health institutions. According to West (2015), each leader should have in-depth knowledge and managerial skills.

Research question 2: Is education distinct in the management of medical services to nurses?

Based on the results of the research this research question has two answers, firstly, the distinctiveness of education is not observed in their education profile because

they all belong to the clinical field but their level of education presents the distinction between medical management in the field their clinical studies have integrated studies and specialization, unlike nursing management, most of them with secondary education. This raises the concern that health institutions are being run by persons who are not in the relevant field but also that the clinical part is not even professionally established. This situation has an impact on the Health System in Kosovo, because there is no model on which the share of leadership of institutions and health services is based, which if existed there would be a foundation whereby the most obvious leadership path would be and with safe steps towards improving healthcare performance.

Research question 3: What is the managerial experience of current leaders?

As far as managerial experience is concerned, we only reflect results for primary and secondary level as the reason for lack of data from the tertiary level, at both levels as primary level as secondary level, is a managerial experience roughly 1-5 years of managerial experience, with 6-10 years, as well as 11-20 years of managerial experience. This shows a wide variety of managerial experiences of leaders, of which we have a leader who is in the first mandate second, but we have leaders who have more than 6 mandates to lead institutions and services. If based on research, leadership competencies can be seen as a result of the leader's experience (West, 2015), which is not so present in us.

Research question 4: What age is leading institutions and health services?

The age that dominates the heads of institutions and health services is between the ages of 46-55 and with a similarity with leaders over the age of 56. Likewise, this is also related to managerial experience, rather than the fact that leaders are older they also have the greatest managerial experience.

Research question 5: What is the gender governing the institutions and health services?

Health institutions and services are mostly driven by men rather than women, men dominate both institutional leadership and service leadership, this may be related to the reason that education is lower among women than men, although in management areas do not have both sides professional upgrades and both sides are equal. The results of this research tell us the situation of the leaders of Institutions and Services, which are affecting the current state of health development. Organization of institutions and services by people who are very affluent in the clinical part and have professional upgrading of the clinical field, leading institutions and health services without having any competence in the field of management and management in health. This shows that Health is run by persons who are not relevant to leadership and management.

V. Conclusion

Leadership is the most influential factor in shaping organizational culture, providing leaders' essential behaviors, strategies, and quality development that is essential to health. Training and management skills are key to the leader's success in the right direction. From this research, we have provided a foundation for profiles of leading institutions and public health services in Kosovo. The research points out that the current leaders of health care institutions and services are educated in the clinical, not managerial, field of education that needs to be adequate. They do not have the basic foundation that fits in with managerial competencies for the managers of institutions and management services. Also, the education of doctor's managers is higher in contrast to nursing management. As for managerial experience at primary and secondary level, there is little difference between years, where we have different managers, from 1 to 6 mandates. The age that is leading healthcare institutions is 46-55 years as well as over 56 years. As far as gender is concerned, masculine dominance is also in the leadership of services and in the leadership of the institutions. From this research we can say that Health Institutions and Services are guided by health profiles with professional advancement in clinical areas rather than those of adequate managerial profile. This shows an indicator that may influence the not so good quality that is prevalent in current health in the Republic of Kosovo.

But for the performance enhancement in the leadership aspect is accompanied by a set of recommendations ...

VI. Recommendation

Based on the literature review and actual results, the health system in the Republic of Kosovo should have a Framework for Management and Management of Institutions and Health Services, it should review and adapt the criteria of HUCSK to Heads of Health Institutions, Current Leaders with academic degrees in managerial profile in Healthcare, have trainings and managerial advancements for the actual leaders, assess the performance of leaders from their work team, make division of clinical work from managerial to leadership, obtain managerial models from countries that have good quality healthcare performance and the adaptation of the WHO Framework, which is a framework that contains the basic criteria for leadership, a framework that is made for countries with low financial incomes and states that jan transition such as Kosovo.

Continuity of research- Continuing research in knowing practices and management experience, investigating managerial behavior and their impact on the quality of services, as well as sharing managerial and clinical aspects.

Limits of Research

As with any other research we have encountered some limitations during the research process, which was the non-cooperation of some health instructors for the conduct of the research, the short time for data collection in all Public Health

Institutions of the Republic of Kosovo, the scope of the research in both other public and private institutions, lack of data on service management for HUCSK, and lack of data on managerial experience and clinical experience for HUCSK.

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Regulations on Occupational Health and the Role of Labor Inspection

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Abstract

Over the years the international community has developed a framework with international standards which intend to protect employees from injuries and occupational diseases. While progress is being achieved in preventing this problem, in many cases the rights contained in these standards are not fully applied or implemented in practice. In accordance with the need for prevention in this aspect, our Parliament adopted the Law "For Health and Safety at Work" in 2010 and greater attention is paid to 'safety at work regulations' by specific amendments to Albanian Labor Code taking place in 2015.[1] The above legislative changes represent new challenge as it mostly states the 'prevention plan of measures', regardless of multiple difficulties which should be considered as well. Legislative measures and the national policies are implemented through by the State Labor Inspectorate but specific measures in respect of strengthening workplace through inspection and labor administration are in need. Labor Inspectorate needs to enforce collaboration with specific institutions and social partners and also providing technical assistance is another important aspect.

Keywords: safety, workplace, labor inspection, prevention

1. Introduction

All over the world, issues of occupational safety and health are presented nowadays as one of the most sensitive issues that deserve the proper attention from all the countries that implement the principles of safety and health, in respecting human rights to life as well as dignity.

Over the years the international community has developed a framework with international standards which intend to protect employees from injuries and occupational diseases.

[1] *Specific amendments in this respect, to Albanian Labor Code are made by 'Law No 136/2015"*

According to ILO estimates, a worker dies from a work-related accident or disease every 15 seconds. Every day, some 6,300 workers die from occupational accidents or work-related diseases, amounting to more than 2.3 million deaths a year. Furthermore, over 313 million workers suffer non-fatal occupational injuries each year, or in other words 860,000 people are injured on the job every day.[1]

2. Regulations on Occupational Health According to Albanian Legislation

During the last decade in particular our country has approximated its legal framework with the European Union's 'acquis communitaire', in regard to implementing the Stabilizations and Association Agreement. Thus, in the field of occupational safety and health, the Law "On occupational safety and health" was adopted,[2] as well as a series of regulations and by laws[3] to facilitate its implementation, followed by amendments in the Labor Code of the Republic of Albania.[4]

In 2009 Albania implemented the 'Strategy for occupational safety and health 2009-2013', a document compiled in the spirit of international standards and internal problematic in this field which determines the relevant measures especially those in regard of enforced control.

Furthermore, we should mention that Albania ratified the majority of International Labour Organization's conventions, such as the Convention No. 155 "Occupational safety and health", of 1981, its protocol in 2002, Convention No. 187 /2006 "Promotional framework for occupational safety and health", as well as the Convention No. 167/1988 "Safety and health in construction".

Meanwhile, we can detect that the Convention No. 187 of the International Labour Organizations focuses in two main goals:

- Developing the preventive culture and
- Establishing a suitable system in a national range to administer occupational safety and health[5]

During the collaboration with representatives of governments from different countries, representatives of employers and employees, the International Labour

[1] *www.ilo.org/publns, ILC.106/III/1B, International Labour Conference, 106th session, 2017 : " Working together to promote a safe and healthy working environment" pg. 2, prgh. 5, International Labour Office, Geneva*

[2] *For more information see : www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, Number 22, published on 18.03.2010, Law No 10 237, dated 18.02. 2010 "On occupational safety and health", pg. 672*

[3] *In implementation of the Law On occupational safety and health", the Council of Minister adopted a series of by-laws such as: CMD No 107, dated 09.02.2011 "On the structure, rules of organization and function of the Security Council for occupational health and employee representatives"; CMD No.562, dated 03.07.2013 "On the minimal requirements of safety and health when using work equipment in the work place"; CMD No.563, dated 03.07.2013 "On minimal requirements of safety and health in using work equipment in the work place"; CMD No. 564, dated 03.07.2013 "On minimal requirements of safety and health in using work equipment in the work place"*

[4] *See, : www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, No.220, dated 22.12. 2015: "Law No. 136/2015, dated 05.12.2015 " On some extentions and amendments in the Law No. 7961, dated 12.07.1995 'Labour Code of the Republic of Albani, amended"*

[5] *See: www .ilo.org "Working together to promote a safe and healthy working environment", International Labour Conference, 106th session, 2017, prg 30, page no 13*

Organization highlights the necessary attempts each country must make to avoid national problematic, to consolidate legal measures and further develop national programs in the field of occupational safety and health.

In Albania, the relevant legal framework in regard to occupational safety and health, places special importance to the aforementioned legal sources, conventions and international laws ratified by our country, which request the implementation of important legal obligations by the parties involved in the work relations, as well as the institutional interaction and collaboration between social actors in order to detect and prevent occupational injuries of employees.

The Labour Code of the Republic of Albania, amended, adopted again in 1995, in a special chapter, regulates occupational conditions providing legal obligations in the framework of workplace maintenance, hygiene, workplace area, the use of hazardous equipment, noises, vibration, heavy loads, scaffolding, as well as the regulations for workplace fire prevention.[1]

Regarding the implementation of measures of a general nature, the provisions if the Labour Code provide the employer's obligation to take the necessary preventive measures to protect the life and health of the employees, which includes the organization of advisory and awareness sessions for employees.

Another obligation of the employer, when the nature of the labor potentially submits employees to special risks, is to organize at his own expense periodical medical check-ups.[2]

In respect to implementing the legal provisions for occupational safety and health, the employer is obliged to evaluate the workplace risk, as well as report it in a special document wherein he must also define the relevant measures that aim to eliminate this risk.

The defining of the employer's special obligation, with the purpose of protecting employees and preventing workplace accidents and professional illnesses constitutes a very positive novelty for our legislation in the field of occupational safety and health.

In the meantime, to answer an emergent need related to the situation created in our country because of workplace accidents especially in certain sectors of activity such as in construction, mines, agriculture, the Law "On occupational safety and health" was adopted, the provision of which aim to guarantee the protection of health through preventing dangers in the workplace by eliminating hazardous factors in the workplace, continual informing and consultation.[3]

[1] *For more see "Labour Code, updated with judicial practice", Judicial Publications Albjuris, 2016, pg 45, Chp. VIII*
[2] *See "Labour Code, updated with judicial practice", Judicial Publications Albjuris, Tirana, 2016, pg 46, Art. 40, prgrh*
[3] *See : www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, Number 22, dated 18.03.2010, Law No. 10 237, dated 18.02. 2010 "Occupational Safety and Health", Art. 2*

This law[1] places upon the respective parties employer and employee obligations in regard to implementing measures that aim to prevent occupational health injury of employees, however the obligations that belong to the employer are many compared to those that fall upon employees in the field of safety.

Moreover, the law contains and refers to important principles but I'd like to address (without underestimating in any way the value of other principles in the spirit of which the law is established and should be implemented) the principle that states "employees' obligations in the framework of occupational safety don't impinge on the principle of employer's responsibility",[2] reinforcing the idea that employers are the party that should monitor and control the employees' implementation of their occupational safety obligations.

Another novelty that the law for occupational safety and health brings about is the establishing of the Occupational Safety and Health Council. This special institution of collaboration between parties, with the participation of representatives of employees and employers is considered an institution with advisory functions in the field of safety and health with the main goal being the prevention of workplace risks.

In this way, the provisions of this law, also aim to include employers in issues of safety and health by establishing such advisory institutions with the participation of select representatives from the ranks of employees, as well as the demand for collaboration between social actors, consequently striving to raise awareness in the employees themselves in regard to identifying and elimination negative practices in this field.

According to the data in the document of the Strategy for Occupational Safety and Health, the low rate of occupational safety and health regulations' implementation in practice by subjects seems to be caused by diverse factor, the most important ones being: poor consciousness, wrong approach and behavior, lack of information from both employers and employees, poor level of awareness, high unemployment rate, lack of stimulating mechanisms like reward, lack of technical regulations in the field of occupational safety and health, lack of consultation, lack of capacity for trainings[3], etc.

3. Administration of Labour Relations and the Role of Labour Inspection

Among the main institutions which ensure the labour law implementation is the State Labour Inspectorate, an institution that acts based on a special law.[4]

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[1] Law No. 10 237, dated 18.02. 2010 " Occupational Safety and Health" compiled based on requirements from the Framework Directive 89/391/EEC

[2] For more, see: www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, Number 22, dated 18.03.2010, Law No. 10 237, dated 18.02. 2010 "Occupational Safety and Health", Art. 4, prgrh.4

[3] For more information regarding the strategy for occupational safety and health, see www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, Number 90, in 2016, published on 27.05.2016, CMD No371,dt 18.05.2016 " On adopting the Political Document for occupational safety and health 2016-2020 , and the action plan for its implementation"

[4] The State Inspectorate that covers the field of labour is the institution that ensures the labour law implementation based on Law No 9634,dt 30.10.2006 'On Labour Inspection", amended with the Law No 24/2013, dt 14.02.2013, and Law Nr 57/2017, dt 20.04.2017

Beside the main mission of this organism to control and monitor the legal provisions' implementation in the framework of occupational safety, to detect violations committed by subjects of the labour law in this field, it should also face newborn problems that might stem from certain social as well as technological developments.

The widespread implementation of new technologies and new forms of work organization might reduce old risks but may also lead to new problems.[1]

The State Inspectorate that regulates the field of labour, also must advice, inform, prevent and impose respective sanctions depending on the violations detected by it in compliance with the provided procedure.

Just like the respective law on labour inspection provides, the main sanction is the fine that can be imposed by the Labour Inspector.[2] In cases detected by Labour Inspectors where continuing the activity would constitute in immediate, considerable and inevitable risk to the employees safety and health and when their evacuation from the workplace is necessary, they take urgent measures.

Urgent measures, as defined by the law[3], include interrupting the carrying out of an action or activity or a part of it, prohibiting the use of an equipment, machinery etc.

Aiming to obtain and give information in regard to implementing the legal framework on occupational safety and health, the State Inspectorate that covers the field of labour also collaborates with other state institutions, employees and employers, becoming thus an interactive organism.

In my opinion the framework of this institution's activity has to face other challenges the likes of the need to create efficient mechanisms to encourage collaboration and facilities of a technical and infrastructural nature, the need to offer the possibility for further qualifications in this field, but also to encourage the complete implementation of legal provisions that guarantee occupational safety and health.

An important role in reviewing the main problems regarding occupational safety is played by the National Labout Council, which is a three-party institution where representatives of the government, employees and employers participate.[4]

In accordance to the Labour Code provision, this institution acts like a main mechanism of consultation in compiling and implementing the legal framework, and it should encourage collaboration to efficiently implement policies for occupational safety and health, as a vital necessity for better conditions and results in the production activity.

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[1] "Glossary of labour law and industrial relations (with special reference to the European Union)", General Editors: Gianni Arrigo, Giuseppe Casale, Geneva, International Labour Office, 2005, pg.154

[2] Based on Law No. 9634,dt 30.10.2006 'On Labour Inspection", amended by Law no. 24/2013, dt 14.02.2013, and law no. 57/2017, dt 20.04.2017, see art. 33, pg 5

[3] For more see: Law No. 10 433, date 16.06.2011 " On Inspection in the Republic of Albania", Article 43/2

[4] Creation and competencs of the National Labour Council by the "Labour Code of Albania", art. 200

The policies for occupational safety and health 2016-2020 strive to improve the situation by demanding an efficient implementation of the law by evaluating the work of the Labour Inspectors, establishing a national system to manage the information, education and research processes, as well as raising public awareness and increasing social collaboration.[1]

The above legislative changes represent new challenge as it mostly states the 'prevention plan of measures', regardless of multiple difficulties which should be considered as well.

4. Recommendations

- Collaboration is one of the most efficient means to achieve the goal of eliminating negative practices such as the violation of provisions that guarantee occupational safety of life and health.
- The effective increase of collaboration between employees or their representatives and employers, including the participation of the Labor Inspectorate, would serve to identify the realistic means and manner used by employers to avoid the provisions in this field or the actual negative practices, and it would also bring about the implementation of the accurate measures in this aspect.
- Furthermore, I think that consolidating cooperation between governmental structures and the Labor Inspectorate is a necessity in regard to exchanging the necessary information as well as in creating the possibilities for further qualification of the labor inspectors.
- Raising awareness of employees in regard to their legal bound rights, including the right to be informed, advised and represented decently from the employees' organizations, I think would be an adequate mechanism to incite larger union activity.

Of course, the implementation of real measures in order to improve legal provisions' implementation in the field of occupational safety and health is linked closely to implementing efficient economic and social policies and of measures that fight negative phenomena and practices in all the aspects of implementing law. That is why I believe that the factual engagement in consolidation social dialogue and collaboration is essential to the current policies in the field of occupational safety and health.

[1] *See www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center Number 90, of 2016, date 27.05.2016, CMD No.371,dt 18.05.2016 " On adopting the Political Document for occupational safety and health 2016-2020 , and the action plan for its implementation"*

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[3] www.ilo.org/publns, ILC.106/III/1B, International Labour Conference, 106th session, 2017 : " Working together to promote a safe and healthy working environment" pg. 2, prgh. 5, International Labour Office, Geneva

[4] www.qpz.gov.al, Official Journal of the Republic of Albania, Official Publications Center, No.220, dated 22.12. 2015: "Law No. 136/2015, dated 05.12.2015 " On some extentions and amendments in the Law No. 7961, dated 12.07.1995 'Labour Code of the Republic of Albani, amended"

[5] www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, Number 22, dated 18.03.2010, Law No. 10 237, dated 18.02. 2010 "Occupational Safety and Health"

[6] www.qpz.gov.al, Official Journal of the Republic of Albania, published by Official Publications Center, Number 90, in 2016, published on 27.05.2016, CMD No371,dt 18.05.2016 " On adopting the Political Document for occupational safety and health 2016-2020 , and the action plan for its implementation"

[7] Law No 9634,dt 30.10.2006 'On Labour Inspection", amended with the Law No 24/2013, dt 14.02.2013, and Law Nr 57/2017, dt 20.04.2017

[8] Law No. 10 433, date 16.06.2011 " On Inspection in the Republic of Albania"

[9] CMD No 107, dated 09.02.2011 "On the structure, rules of organization and function of the Security Council for occupational health and employee representatives"

[10] CMD No.562, dated 03.07.2013 "On the minimal requirements of safety and health when using work equipment in the work place"

[11] CMD No.563, dated 03.07.2013 "On minimal requirements of safety and health in using work equipment in the work place"

[12] CMD No. 564, dated 03.07.2013 "On minimal requirements of safety and health in using work equipment in the work place"

The Success Models of Financing the Artificial Reproductive Techniques and the Albanian Case

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Abstract

The development of the artificial reproduction techniques (ART) is obviously one of the biggest achievements of medicine of the XX Century accompanied by many ethical, moral, social and economic disputes. Even if its applicability makes the dream true for many couples, the high costs of the (ART) makes it realizable only for a few of them, fearing so to create another limitation on the access of these techniques. While aiming at the realization of the reproductive health of their citizens, states are still confused on whether to include (ART) in the health care policies and fund it fully or partially or to leave the cost of its implementation to the individual. Success cases of different European countries will be analyzed in this paper where the (ART) are fully or partially funded by the health care scheme. The reproductive health service in Albania is provided by law as a funded service, but until now (ART) is offered only by private clinics and although its cost is lower than that of European countries, it still remains high compared to the personal income. Having in consideration the success cases of European countries, this paper will try to analyze if there is the possibility in the Albanian legislation of financing the artificial reproduction techniques by the national health insurance fund.

Keywords: artificial reproductive techniques, costs, health care policy, funded health services

1. Introduction

The scheme of funding the health care services is a social and economic mechanism as well as political too. The purpose of any refund scheme is to ease the economic expense of a person and make it more affordable for the individual. The funding scheme can be seen as a cost transfer from the individual to the society. Therefore the economic burden of ART (artificial reproductive techniques) on the national health

care is much easier for developed countries and as such the funding scheme aims to be more generous too.[1]

But regardless of the opportunities of funding, to what extent should the generosity of financing the ART be extended?

The health insurance scheme is mainly created as a result of these two components; poverty and disease.[2] At the beginning, the aim of the health insurance scheme was to create possibilities of treatment in cases when disease is combined with poverty. The generosity and solidarity are the main principles of the health care system.[3] All the individuals contribute to improve their health status, and also that of other individuals who are in a financial inability. Therefore the generosity in funding from the health care scheme is primarily based on the identification of a disease affecting the health status of the individual, and on the possibility of treatment for everyone without financial prejudice. The financial help from the health care system is not applied in cases when a certain health element doesn't affect the deterioration of the individual's health status.

The health coverage plans have expanded in accordance to the individuals need for health and financial insurance. The spread of new diseases, the evolution of medical technologies, and the expansion of medical benefits has redefined the concept of health coverage.[4] The International Covenant on Economic, Social and Cultural Rights (ICECR), in Art 12 promotes and recognizes "… the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"[5], known as the right to health, which was firstly articulated in 1946 in the preamble of the Constitution of the World Health Organization, and in 1948 was mentioned in the Universal Declaration of Human Rights.[6] The right to health is considered as a fundamental human right, indispensable for the exercise of other human rights, and it is a duty of the State to take the necessary measures for its full realization.[7] The right to health refers to the right to the enjoyment of a variety of goods, facilities, and conditions which are necessary for having the highest attainable physical and mental health.

The United Nations International Conference on Population and Development (ICPD), defines reproductive health as "a state of complete physical, mental and social well being and not merely the absence of disease or infirmity, in all matters relating to the

[1] *Ata B. Seli E. (2010) "Economics of assisted reproductive technologies", Current opinion in obstetrics & gynecology , 22(3): 183-8.*
[2] *Peto Zh, (2006), "Sistemet e mbrojtjes shoqërore", Shtypshkronja Ekpres, Tirane.*
[3] *N. A. S, N.A.E, I.M and N.R.C, (2001), "Crossing the Quality Chasm: A New Health System for the 21st Century", NA Press.*
[4] *American Academy of Actuaries, "Fundamental of Insurance: Implications for Health Coverage", July 2008 https://www.actuary.org/pdf/health/coverage_ib_08.pdf retrieved 1/14/2018*
[5] *Art 12 of the International Covenant on Economic, Social and Cultural Rights, Adopted on 3 January 1976, United Nations of Human Rights.*
[6] *WHO, UN High Commissioner of Human Rights, "The Right to Health", Fact Sheet No.31, retrieved 1/14/2018 http://www.ohchr.org/Documents/Publications/Factsheet31.pdf*
[7] *Committee on Economic, Social and Cultural Rights, "CESCR General Comment No.14: The Right to the Highest Attainable Standard of Health (Art 12), http://www.refworld.org/pdfid/4538838d0.pdf*

reproductive system and to its function and processes"[1] Therefore reproductive health implies the "… the right and the capability to reproduce and the freedom to decide if, when and how often to do so". It implicit in the last condition "… the right to have access to different methods of their choice, for regulation of fertility which are not against the law, and the right of access to appropriate health care services that will enable women to go safely through pregnancy and childbirth…"[2] This affirms that individuals have the right to choose the application of different forms of artificial reproduction to avoid infertility and also to pretend health care services, which can lead to a pregnancy and childbirth.

The artificial reproduction is one of the forms of exercising reproductive rights of the individuals, part of the right to reproductive health. In this sense, countries where the artificial reproduction techniques are allowed to avoid infertility should include within the health insurance scheme the ART as long as they relate and serve to the reproductive health. But the application of the ART is not only limited to infertility avoidance. Many European countries have allowed the access on ART for purposes beyond that of infertility. (United Kingdom, Belgium, France, Spain)

Since in the 1980, the definition of the legal criteria and that of the possibility of funding the reproductive techniques has been an important issue. According to some authors the purpose and the aim of using these techniques should be the main criteria. If these techniques would be considered and used to cure certain disease such as infertility, or they would be considered as techniques tended to meet a certain human need such as reproduction.[3]

The World Health Organization (WHO) has defined infertility as a "... disease of the reproductive system, a health restriction that connotes the individual to an inability to normal carry his natural functions".[4] This leads to the conclusion that the artificial reproduction techniques, when they are intended for the reproduction of the infertile individuals, should be part of the health care scheme and the costs associated with these techniques, as well as the costs incurred to treat infertility, should be financed by the state.

Other authors assume that the impossibility to have children, regardless the infertility issue can be a cause of suffering for individuals, as suffering from the lack of children comes not only from the impossibility to have children, but at the same time because of the function of the social structure. In this sense, it may be justified to finance ART even for these groups of individuals.[5]

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[1] UN, International Conference on Population and Development, Program of Action, 5 – 13 September 1994, https://www.unfpa.org/sites/default/files/pub-pdf/programme_of_action_Web%20ENGLISH.pdf
[2] idem
[3] Martin J. (1996), "Prioritizing assisted conception services: A Public health perspective" Evans "Creating the child", Kluwer edt.
[4] WHO, ICMART, "Revised glossary on ART terminology, 2009", Human Reproduction, Vol. 24, No. 11, 2009 http://www.who.int/reproductivehealth/publications/infertility/art_terminology.pdf
[5] Holm S., (1996), "The need for treatment", ed. Evans "Creating the child", Kluwer edt. 1996.

The application of ART is a recent phenomenon in Albania and it is not well- defined. It is of a great importance to determine the importance of funding the ART as its important impact in increasing fertility rates.

2. Methodology

The methodology adopted for this paper is that of the bibliographic review on the subject matter that of the funding of the artificial reproductive techniques, as part of the reproductive health services in European countries and in Albania. The article seeks to examine the actual situation of the artificial reproductive health services in Albania and its possibility to include them as part of the health insurance scheme. In order to have a complete view on the reproductive health services, insurance schemes of different European countries are taken into consideration and compared between them. The content of the law on the reproductive health is examined and also the Albanian health insurance scheme is taken in examination in order to identify the problem leading to the lack of funding. Given that in Albania the legislative framework of reproductive health is not completed, a special attention is given to the National Health Strategy, in which the possibility of financing reproductive techniques is foreseen.

3. Some European Experiences

Developed European countries consider infertility as a medical condition or as a disease, rather than "a socially constructed need" as it is considered in the US.[1] This leads to a greater use of IVF in countries that subsidize the expenses, than to countries in which the ART is not included in the insurance scheme.[2] Even if they differ in the access policies of the ART, most of the European countries have deemed infertility as a health care good and their national policies fund all or some portion of infertility treatment. The coverage scheme depends on historical, social and economic considerations which combined with the medical and ethical ones define the coverage scheme. In compliance with the level of financing some of the European countries restrict access to the treatment by introducing eligible criteria such as age, marital status etc. Here are some successful cases on how European countries provide the possibility of funding the application of the artificial reproductive techniques.

Belgium funds ART in 100 % of the first six cycles only for women under the age of 43.[3] But the marital status is not a restriction according to the Belgium law.[4]

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[1] *Katz P., Nachtigall R., Showstack J., "The economic impact of the assisted reproductive technologies", Institute for Health Policy Studies, California USA, retrieved on 20.12.2017 https://www.nature.com/fertility/content/pdf/ncb-nm-fertilitys29.pdf*

[2] *Idem*
In 1998 the use of IVF was three times greater in France, Netherlands, Norway and Sweden, than in US and five times greater in Denmark, Finland and Iceland.

[3] *Service Public Federal Santé Publique, Securité de la Chaine Alimentaire et Environment 20032403, June 4, 2003, The Royal Decree of June 2003*

[4] *Belgium Law Concerning Medically-Assisted Insemination, 2007, art 4.*

French legislation provides only the access on ART of infertile, heterosexual couples. France provides full public funding of ART but limited only to heterosexual married couples, who are on a procreation age, under the age of 43. Funding is limited to four cycles.[1]

Germany, like French provides the funding only for heterosexual married couples. There are age limitations too. In Germany only 50% of the cost is reimbursed.[2]

Great Britain the funding scheme covers fully or partially, when the service users have to pay only some of the medicines. The funding applies on heterosexual couples, single women and also to same sex couples and is covered by the National Health Plan.[3]

Nordic Countries seems to have a more liberal approach to artificial reproductive issues, including here that of financing the reproductive techniques. Denmark is known as the more liberal among them. In Denmark, from May 1997, the Danish Parliament decided that the artificial reproduction would be offered at the public hospitals free of charge. This was limited only to heterosexual couples.[4] In 2004 an amendment of the '97 Bill agreed to limit the treatment of the heterosexual couples in public hospitals up to the birth of only one child. It was not until 2006 that artificial reproduction techniques were also made available to single women. From 2015, ART in Denmark is covered by the public health service for all involuntary childless women residing in Denmark, up to the age of 45, regardless their sexual orientation or social status.[5]

The criteria used to regulate the ART public coverage are more restrictive than the general criteria for the access to these techniques. Establishing restriction criteria is seen as a mean to limit the budget spending, which should be oriented towards the health system priorities. According to the ESHRE[6] survey 2013, the first most common restriction is that of the age, followed by that related to limitations of coverage only for the first child, or limits on the total number of cycles offered.[7]

The criteria, on which different countries have assessed or not the financing of ART, are based on the cost - effectiveness analyses and to the ratio of the conventional forms of treating infertility and ART.[8] Cost analysis is based in the so called availability

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[1] *French Human Fertility and Embryology Bill, 2007-2008*
[2] *German Social Code V.*
[3] *Keane M., Long J., O'Nolan G., Farragher L., (2017), "Assisted reproductive technologies: International approaches to public funding mechanism and criteria. An evidence review" , Health Research Board 2017, http://health.gov.ie/wp-content/uploads/2017/03/HRB-AHR-Funding-Evidence-Review.pdf*
[4] *Nordic Committee on Bioethics, "Assisted Reproduction in the Nordic Countries. A comparative study of policies and regulations", Nordic Council of Ministers 2006.*
[5] *Mohr S., Koch L., (2016), "Transforming social contracts; the social and cultural history of IVF in Denmark." ELSEVIER Journal, Volume 2, https://www.sciencedirect.com/science/article/pii/S2405661816300181#bbb0080*
[6] *European Society of Human Reproduction and Embryology.*
[7] *International Federation of Fertility Societies, (2013), "IFFS Surveillance 201" https://c.ymcdn.com/sites/iffs.site-ym.com/resource/resmgr/iffs_surveillance_09-19-13.pdf*
[8] *Stephenson P., Wagner M. G., (1993), " Tough Choices: In Vitro Fertilization and Reproductive Technologies", Temple University Press Philadelphia.*

– utility, which means all the cost for equipment, personnel and locations that would be needed to fulfill a certain ART program. Costs effectiveness ratios for the ART treatment are expressed as the average direct cost of treatment per live birth, calculated as the total ART treatment costs divided by the number of live births.[1] The effectiveness of this procedure will not be calculated on the basis of the number of the ART performed, but on the basis of successful ART that resulted in the birth of a child.[2]

What is common to all the countries that provide funding to ART, regardless of the extent to which they finance, is their social approach toward the procreative technologies. They don't consider artificial reproduction only as a personal matter, which the individual should provide at his own expenses. Reproductive techniques have an individual as well as a social dimension, as they affect the structure of a society by resizing the concept of the family. The approach of these countries over the artificial procreation shows that the society and the state are sharing the responsibility over the new features of artificial procreation.

4. Financing Artificial Reproduction in Albania

The issue of reproduction is not only seen as an individual need based on his own right to procreate or reproduce himself, but in the same time it shows an individual need to be accepted within the social structure. The Albanian society is still rigidly based on the traditional family. Childless couples are not a common reality in Albania and also cases of artificial reproduction are not easily accepted. The state of the Albanian society toward the reproductive techniques is also reflected in the limited efforts of the Albanian legislator to have a complete legal framework on the issue. The reproductive techniques would not be a priority for the legislator as long as the Albanian society will not show interest on the topic. Despite the cultural and social attitudes, other factors that affect the ART provisions are also economic. As a developing country, the Albanian economy is struggling in financing the basic health care. It is important to underline the fact that the health care system in Albania covers the necessary services during pregnancy and after the childbirth, but not the attempts to avoid infertility.[3] The basic health care financing packet provides the funding of health care services of the reproductive health, including the counseling services before the pregnancy and curative and rehabilitation services during and after pregnancy.[4] The artificial reproduction is not mentioned. The infertility treatment is also not mentioned even in the purpose of the reproductive health care. So far, despite the provisions of Reproductive Law, this service is only provided by private clinics.

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[1] Connolly M.P, Hoorens S., Chambers G.M., on behalf of ESHRE Reproduction and Society Task Force (2010), "The costs and consequences of assisted reproductive technology; an economical perspective", Human Reproduction Update, Volume 16, Issue 6, 1 November 2010 https://academic.oup.com/humupd/article /16/6/603/739127

[2] Idem, pg 86

[3] Ligj Nr. 8876, datë 4.4.2002 "Për Shëndetin Riprodhues"

[4] Ministria e Shëndetësisë, "Paketa bazë e shërbimeve në kujdesin shëndetësor parësor", pg 27 http://www.shendetesia.gov.al/files/userfiles/Shendeti_Publik/Paketa_e_rishikuar_e_miratuar.pdf

In 2017 the Ministry of Health approved the National Health Strategy 2017- 2021.[1] The National Health Strategy recognizes the lack of legislation in the field of artificial reproduction and expresses the necessity to revise the legislation as soon as possible in accordance with the best European practices. The Strategy provides as one of its strategic objectives the need of strengthening sexual and reproductive health services, with an approach throughout the life cycle, based on evidence and vision towards universal coverage, but it avoids any clear specification on artificial reproductive techniques. The fact that the Strategy stresses the need for infertility treatment and sets as a strategic objective the effort to include in the universal coverage of the reproductive health services is a green light for a possible funding of the artificial reproductive techniques in the future.

Private clinics in Albania, which offer the ART services, seems to be very attractive for foreigners as the cost of their services is lower than those of clinics in other European countries, but they still remain relatively high considering the economic living standard in Albania. The cost to benefit from the ART services of a couple is about 5 000 Euros. For an individual the cost tends to be even higher since there are no sperm banks in Albania, and the individual should bear even the cost of its import. In a country like Albania, where the average gross monthly salary is calculated to be about 380 Euros[2], the cost of the ART services seems to be unbearable for the individual.

The possibility of financing reproductive techniques depends mostly on the demand for such services. The cost of infertility management is determined by the percentage of patients seeking treatment for infertility, its impact on population and the quality of treatment. But until now the Ministry of Health does not possess any data on the number of individuals undergoing through ART, which makes this kind of infertility treatment immeasurable and so impossible to include it as a fundable service. As a first step, it is necessary to calculate the real cost of the artificial reproductive services, what is the need for funding and which should be the requirements in order to avoid unnecessary costs? The legislator, in order to reduce the cost of ART may decide to finance it only in public hospitals. An attempt to include ART services in the public hospitals was made in 2012, when the former Director of the Gynecological University Hospital "Koco Gliozheni", announced that in accordance to the EU project "Medicine of the Future" the ART services would already be offered by the public hospitals and funded by the Security Health Scheme, but until now it remained only a statement.[3] In accordance to the WHO recommendations the treatment of infertility should be considered as a disease treatment. The WHO emphasizes the need of a universal access to infertility treatments, but their high cost leads to a restriction of

[1] *Albanian National Health Strategy 2017 – 2021.*
[2] *INSTAT (The institute of Statistics), The average monthly salary and the minimal monthly salary T3 2014 – T3 2017 http://www.instat.gov.al/al/themes/pagat-dhe-kosto-e-pun%C3%ABs.aspx*
[3] *Llambro Z., (2012, October 19), "Fekondimi "In vitro" do te kryhet edhe ne spitalet publike", Panorama Newspaper http://www.panorama.com.al/fekondimi-in-vitro-do-te-kryhet-edhe-ne-spitalet-publike/ retrieved on 24 January 2018*

access. Only those who can afford to pay can have the possibility to cure infertility through the conservative way or through the application of ART.

Conclusions

The fertility treatment is a long and expensive process, which results take time and its productivity is not sure. For this reason the use of reproductive techniques seems to be the other alternative to avoid the infertility consequences. In many European countries artificial reproduction is seen as a health service provided fully or partly by the state. The purpose of this service justifies the fact that these techniques are included in health policies by the states, as infertility is seen as a problem for many European countries and the goal of these techniques is to avoid, whenever it is possible, its consequences. But the inclusion in the health care system of the ART implicates political, social and economic matters. As a post communist country, the Albania economy and its health insurance scheme has faced numerous challenges and the infertility issues were not at the top of the list.[1] Neither is at the moment. As the Albanian legislator is making the necessary efforts to join the European Union, assisted reproduction can't attract the political attention. But as the number of infertile couples is growing rapidly there are still no concrete policies for the infertility treatment. According to the statistics of the Albanian Institute of Statistics, infertility is becoming a serious concern for our country[2] In front of this situation is the duty of the legislator to take the necessary measures to reduce and treat infertility. A first step is that of considering the infertility as a disease, as a state of health restriction, which is becoming a really serious health concern for the Albanian society. Including fertility as a prevalent health problem would provide the necessary justification for a future infertility financing plan. As a developing country, Albania can try to include infertility treatment in its national health plan, by trying to finance ART services partially and in accordance with other status or age requirements.

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[1] *Other post communist countries have gone through the same experience.*
Nordic Committee on Bioethics, (2006), "Assisted Reproduction in the Nordic Countries. A comparative study of policies and regulations", Nordic Council of Ministers.

[2] *INSTAT data on infertility: It is shown that the natural addition of the population changes from 63, 932 in 1990 to 34,821 in 2000 and only 14,273 in 2011. This data reflects a significant decrease in the birth rate, although the number of deaths has not changed significantly. The number of births has decreased from 82125 births in 1990 to 51242 in 2000 and 34285 in 2011.*

[4] Belgium Law Concerning Medically-Assisted Insemination, 2007.

[5] Committee on Economic, Social and Cultural Rights, "CESCR General Comment No.14: The Right to the Highest Attainable Standard of Health".

[6] Connolly M.P., Hoorens S., Chambers G.M., on behalf of ESHRE Reproduction and Society Task Force, "*The costs and consequences of assisted reproductive technology; an economical perspective*", Human Reproduction Update, Volume 16, Issue 6, 1 November 2010.

[7] French Human Fertility and Embryology Bill, 2007-2008.

[8] German Social Code V.

[9] Holm S. (1996), *"The need for treatment",* ed. Evans "Creating the child", Kluwer edt.

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[25] WHO, UN High Commissioner of Human Rights, "*The Right to Health*", Fact Sheet No.31

Serological Survey of Crimean-Congo Hemorrhagic Fever Virus Kukes and Has, Albania

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Abstract

In Albania the first cases of Crimean-Congo hemorrhagic fever was identified in 1986. In Albania, cases with Crimean-Congo hemorrhagic fever occur almost every year. The most endemic region is the northeast part of the country, such in Kukes and Has. Crimean-Congo hemorrhagic fever (CCHF) is an arboviral zoonotic infection which is endemic in some areas of the country. The aim of this study was to assess the seroprevalence of CCHFV in previous and recent endemic areas of the country. This crosssectional serologic study was conducted in period 2010-2013-2014 by the Institute of Public Health in Tirana, Albania. The survey included 121 sera specimen of cattle which were randomly collected from two districts in Albania. All samples were collected from two districts in Albania and were examined for anti-CCHFV IgG. Of the total of 121 samples examined, 97 (75.7%) were positive to anti-IgG with ELISA test. The highest positivity rate was among cows (88.3%) and in recent endemic areas of Kukes and Has. In recent endemic areas humans can potentially contract the disease as compared to other areas of the country.

Keywords: Crimean-Congo hemorrhagic fever, domestic animals, Serological Survey

1. Introduction

Crimean-Congo haemorrhagic fever (CCHF) is among the most frequent diseases of tick-borne viral origin that it is spread and infects individuals in many parts of the world, in as many as 30 countries in every continent. However, in some parts as Middle East. Africa, Asia and Eastern Europe the disease has a continuously low incidence over several decades. (1). The geographic dissemination of CCHF harmonizes with that of ixodid ticks, especially those of the class Hyalomma. In Europe, Hyalomma marginatum is the principle CCHFV vector, while Hyalomma asiaticum seems, by all accounts, to be the foremost vector in Asia. In 2006, H.

marginatum was recognized without precedent for the Netherlands and in southern Germany (2,3). Ixodid ticks, particularly those of the family Hyalomma, are both a repository and a vector for the infection. The CCHF infection (CCHFV), a Nairovirus of the family Bunyaviridae, has been detached from 30 types of ixodid tick (3). Various household and wild creatures, for example, dairy cattle, goats, sheep, little well evolved creatures, rodents, and winged animals, in which the disease is for the most part asymptomatic, fill in as opening up has for the infection (4). There is no particular treatment or antibody against CCHF and it is viewed as a developing arboviral zoonotic illness in numerous nations, potentially because of expanded vector bionomics and environmental change. As of late, the frequency of CCHF has expanded quickly in the nations of the World Wellbeing Association Eastern Mediterranean Locale (WHO EMR), with sporadic human cases and flare-ups of CCHF being accounted for from various nations in the district. Notwithstanding the quickly developing rate of the malady, there are right now no precise information on the weight of the sickness in the locale because of the distinctive reconnaissance frameworks for CCHF utilized as a part of these nations. Also, there is no authoritative preventive and control methodology for CCHF inferable from the way that numerous parts of the malady, for example, the support and transmission of the infection and the pathogenesis of the ailment in people, remain ineffectively comprehended (5). Considering the zoonotic nature and public health importance the aim of this study was to assess the seroprevalence of CCHFV in previous and recent endemic areas of the country.

2. Material and Methods

2.1 Sera from cow, sheep and goats

Blood specimen collection: The survey included 121 sera specimen of cattle which were collected from two districts in Albania over the period 2010-2013-2014. These localities include (Has, Kukes,). Sterile vacutainers were used to draw the blood from jugular veins and were left to clot. The sera were immediately taken to the laboratory and their serum was separated by centrifugation at 3500 rpm for 10 minutes. Each blood sample was stored at -20°C in the Institute of Public Health, Tirana, Albana, until analysis.

2.2 Indirect ELISA

Laboratory examination: Adaptation of a human commercial ELISA test for detection of Crimea Congo Hemoorhagic fever (CCHF) antibodies.

The sera collected from domestic animals were tested by an adapted commercial ELISA test which was used for detection of antibodies to CCHFV in human sera (6).

3. Results & Discussion

Distribution of domestic animals by district is shown in table 1. As noted, most of domestic animals belong to district of Kukes (58.2%) followed by district of Has (41.8%) which are recent endemic areas, with a significant difference as compared to other district ($p<0.01$).

Cows account for 50.7% of animals, followed by sheep (29.6), and goats (2.6%), ($p<0.01$).

Table 1. Distribution of domestic animals by district

District	Type of domestic animals			Total n (%)
	Cow	Goat	Sheep	
Has	58	0	0	58 (58.2%)
Kukes	18	4	20	42 (41.8%)
Total n (%)	76 (50.7%)	4 (2.6%)	20 (29.6%)	100

The serologic results are shown in table 2.

According to ELISA serology the majority of specimens (75.7%) resulted positive for IgG to CCHF [95%CI 74.1 – 85.5] (21.9) resulted negative for IgG to CCHF [95%CI 18.9 – 37.3] . A very small number of specimens (2.4%) resulted cut-off.

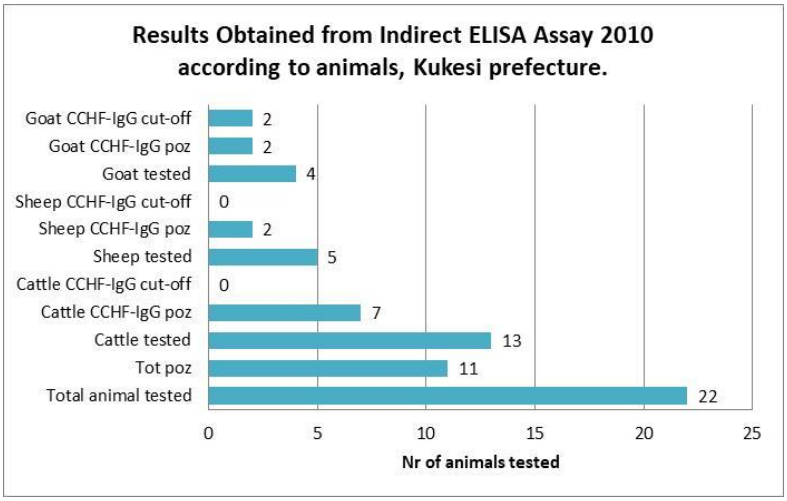
Table 2. ELISA IgG serologic results

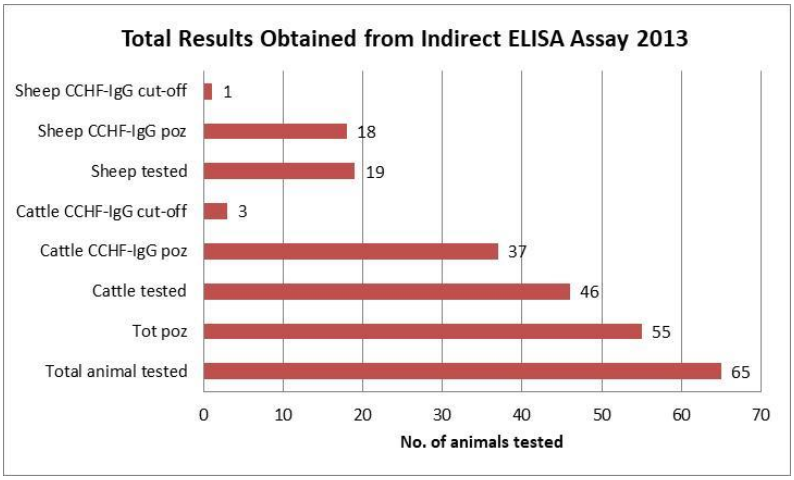
ELISA IgG	N	%	95%CI
Cut-off	6	2.4. %	1.42 – 7.48
Negative	18	21.9%	18.9 – 37.3
Positive	97	75.7%	74.1– 85.5
Total	121	100.0%	

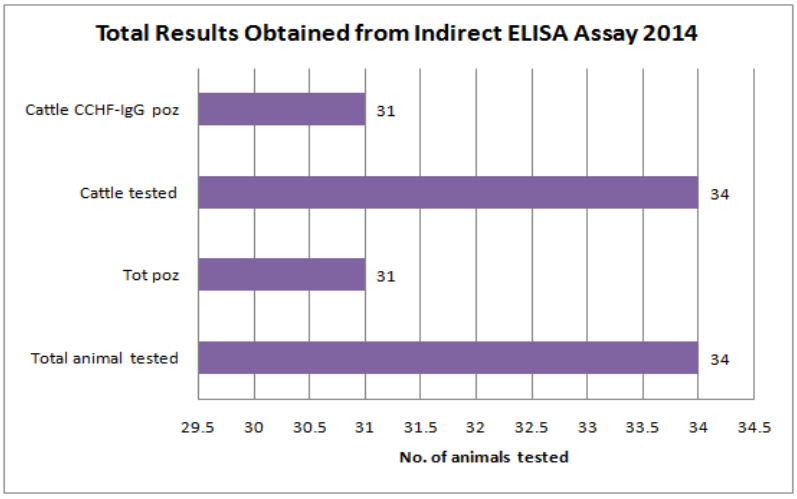
Table 3 presents the serologic result by type of animal. The highest positivity rate was among cows (88.3%), followed by sheep (95.6%), and only one case among goats (25%), $p<0.01$.

Table 3. Serologic result by type of animal

Domestic animals	Total animal tested	Cut-off	Negative	Positive	Prevalence (%) of positive specimens
Cow	93	3	15	75	75 (88.3%)
Goat	4	0	3	1	1 (25%)
Sheep	24	1	3	20	20 (95.6%)


Results Obtained from Indirect ELISA Assay 2010 according to animals, Kukesi prefecture.
Goat CCHF-IgG cut-off
Goat CCHF-IgG poz
Goat tested
Sheep CCHF-IgG cut-off
Sheep CCHF-IgG poz
Sheep tested
Cattle CCHF-IgG cut-off
Cattle CCHF-IgG poz
Cattle tested
Tot poz
Total animal tested
2
2
4
0
2
5
0
7
13
11
22
0
5
10
15
20
25
Nr of animals tested


Total Results Obtained from Indirect ELISA Assay 2013
Sheep CCHF-IgG cut-off
Sheep CCHF-IgG poz
Sheep tested
Cattle CCHF-IgG cut-off
Cattle CCHF-IgG poz
Cattle tested
Tot poz
Total animal tested
1
18
19
3
37
46
55
65
0
10
20
30
40
50
60
70
No. of animals tested


Total Results Obtained from Indirect ELISA Assay 2014
Cattle CCHF-IgG poz
Cattle tested
Tot poz
Total animal tested
31
34
31
34
29.5
30
30.5
31
31.5
32
32.5
33
33.5
34
34.5
No. of animals tested

As noted from the above table the endemic areas of Has and Kukes show the highest positivity rate, 58.2.% and 41.8% respectively.

Crimean-Congo hemorrhagic fever (CCHF) is a well-known infectious nosology in Albania since its first report in 1974; however, CCHF primary serological studies have been commenced since 1969. For this cross sectional study, we have tested the blood samples of previous and recent endemic areas of the country.

From our outcomes we have diverse qualities in various zones. We found the nearness of disease (antibodies) in creatures in zones where cases with hemorrhagic fever were watched more than one to two decades back, where from that point forward has not been watched cases with hemorrhagic fever in people. This marvel is seen in regions other than Has and Kukes. This demonstrates the disease in these zones is as yet present and we figure it can wind up dynamic. We believe that these outcomes ought to be a flag particularly for human administration which should take solid perception in these territories and in dubious cases ought to instantly take fitting measures. The consequences of our investigation are comparative with different examinations directed in Albania in regards to the seroprevalence of CCHFV in dairy cattle (6,7,8). Countries like Turkey and other Balkan countries except for Greece have recorded flow of CCHF strains among creature hosts, ticks, and people, and have set up CCHF endemicity (10). The wide flare-ups that happened in Turkey were gone before by a very long while of serologic proof of a zoonotic CCHF center. Domesticated animals started from endemic zones came about 14% seropositive on CCHF infection, just sheep were 32.6% seropositive (11).

The foundation and support of a CCHF endemic concentration requires a situation supporting an effective contact between able ticks and creature has with moderately high predominance of disease. Heterogeneity in disease levels may happen even inside endemic foci, because of variable atmosphere and ecological reasonableness for ticks and creature has over ongoing decades, adjustments in characteristic biological systems, concentrated farming, an unnatural weather change, and the exponential increment of development of individuals for any reason have given the structure to the extension of a few vector-borne infections all around, from endemic regions to neighboring nonendemic territories and also to far off landmasses. In animal that were infected the virus was amplified to a high level which was sufficiently enough to transmit to the tick vectors, as shown in former investigational surveys which employed cattle inoculation. Seroconversion was detected among infected cattle due to development of a viremia of a low-tire (12).

In the phase of viremia cattle shed the virus and vulnerable humans can contract the disease through bites of infected ticks (13). The outcome of these studies highlight the significant contribution of cattle in the transmission of the infection.

This finding suggested that cattle may play an important role in the epidemiology of the disease. On the contrary, a high rate of lethality from CCHFV infection is observed among humans which reaches up to 30%.

Conclusions

The results of this survey suggest that in recent endemic areas humans can potentially contract the disease as compared to other areas of the country. The results demonstrate a widespread infection among cows, sheep and goats with the CCHF virus.Occupational exposure risk should be reduced among professionals handling with animals by implementing the measures of protection and avoiding risky behaviors (14). Doctors and other medical staff ought to think about this infection in individuals with signs and symptoms similar to CCHFV. Mapping of ticks population in the country and promotion are of paramount importance to prevent future CCHF outbreaks.

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The Views of Directors of Health Institutions Relating to the Current Situation of the Healthcare System in the Republic of Macedonia and Their Expectations for the Future

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Abstract

Health institutions as an integral part of the healthcare system operate in a dynamic and complex environment in which they are constantly faced with numerous shocks from the economic, technical, technological, political, socio-cultural and demographic changes of the uncontrolled external environment that are expected to be much more challenging in the next decade. The purpose of this paper is to identify how the top management of health care institutions assess the current state of the health system and how they prepare for the future of this system. This research is conducted through an anonymous annual survey of responsible persons of the decision-making hierarchy in the public health institutions. Directors of health institutions predict that in the future the new model of value-based healthcare will reformulate and change the future of healthcare. The technological advancement is the one that will significantly improve future healthcare by making the services more accessible, information more transparent as well as prepare the doctors and other medical staff to be able to provide a better healthcare. It can be concluded that healthcare managers feel great uncertainty about the dynamic and complex environment they are operating in, the overall economic situation and the possibility of increasing income. They are focused mainly on the implementation of contemporary technology for creating new values in new forms, developing new and dynamic partnerships and reducing the spending.

Keywords: The views of managers of health institutions; expectations for the future of healthcare system; Value-Based Healthcare Model; Orientation towards patients; the technological advancement

Introduction

The health system in general, lidership in this system and its development is increasingly attracting the attention of society. In front of the institutional leaders, there is a great challenge to understand in a transparent way the world we live in

today and be able to contemplate the future and the possible changes in it. Considering their daily activities, the top managers are required to be more innovative, more flexible, to respect the knowledge and experience of employees at all levels of the institution, to advance teamwork, to advance communication between departments and units and to reward the employees for the quality work accomplished.

Health institutions as an integral part of the healthcare system operate in a dynamic and complex environment in which they are constantly faced with numerous shocks from the economic, technical, technological, political, socio-cultural and demographic changes of the uncontrolled external environment. The directors of the health institutions develop their managerial and economical activity in this complex environment with numerous, fast, and frequent changes that are expected to be much more challenging in the next decade.

The healthcare management model has undergone many radical changes that have significantly influenced the quality of health services and citizen behavior towards this very important segment of social life and its overall functioning. Today, the top management of health institutions composed by two-person directorate - the Medical Director and the Organizational Director present an innovation aimed at increasing managerial efficiency and increasing transparency in the management of human, financial and material resources, respectively in quality management of health institutions.

The Purpose of the Study

Is to identify the views of health care directors about the current state of the health system and their predictions, together with their plans for the future of it, respectively, how the top management of health care institutions assess the current state of the health system and how is preparing for the future of this system considering health reform trends and initiatives.

The Methodology of the Study

This research is conducted through an anonymous annual survey of responsible persons of the decision-making hierarchy in the public health institutions such as: tertiary health institutions, reffering to university clinics, secondary health institutions, reffering to clinical hospitals, general hospitals, special hospitals and entities of the Republic of Macedonia. The research was conducted over a period of one year, from August 2017 to August 2018, regarding the most important issues faced by the managers of health institutions and their impact on the current health system and their expectations with plans regarding future projections.

The findings and results of this research reflect the responses of 80 surveys successfully completed, with the competent persons of institutional management staff, from a total of 100 questionnaires sent to health institutions of different levels in the Republic of Macedonia. For this research survey questionnaires were used,

consisting of standardized questions, focused mainly on how the managers evaluate and prepare for the future health system, which will continue to be dynamic and complex. The respondents' responses to this issue were anonymous. This study is based on thorough and careful processing of survey data and content analysis of responses given using standardized approaches to grouping them.

Results

From this annual survey conducted through survey questionnaires among the top managers of the public health institutions, the following results are obtained about the predictions of directors of health institutions for the future of healthcare system:

The new model of value-based healthcare will reformulate and change the future of healthcare. Health services in hospitals will be paid in different ways, making profitability more difficult. Most of the services will be ambulatory or home-based. Leaders or executives expect this value-based model to set in motion further consolidation, purchases, acquisitions, mergers between hospitals and doctors because it has the potential to improve access to capital, develop the monetary market, and increase the skills and opportunities that are believed to be necessary in order to be successful in contracting of the value-based healthcare.

According to the interviewed leaders, the Value-Based Healthcare Model is the most important trend of hospitals' confrontation for the next five years. Respondents stressed out that the Value-Based Health Care will submerge the traditional healthcare model because they are aware that patients are increasingly demanding fast, quality and efficient health services and health care. As a result of which health institutions will have to respond by reducing stationary use and achieving better performance and results.

Orientation towards patients and the need to be more friendly, direct and closer to patients are part of the future. Hospital staff will need to be more accessible and transparent, and also this staff will have to provide quality services and such interactions at the time and place that the patients require. More than half of the surveyed leaders agree that the healthcare system is transforming into a patient-centered model. Patients are becoming more selective, sharp and shrewd about their medical treatment; they have greater financial responsibility and require that medical care be more convenient and accessible.

Some of the leaders emphasize that with the new patient-centered model, the medical care offered at the clinics by the work teams will be safer, less costly and more appropriate for the patients. To achieve these goals, hospitals need to review and revaluate their existing medical care models, change their organizational culture, and invest in new technologies needed for the implementation of a new model of medical care.

The technological advancement that, according to most leaders, is the one that will significantly improve future healthcare by making the services more accessible,

information more transparent as well as prepare the doctors and other medical staff to be able to provide a better healthcare. Especially in the next decade, around 2028, it is thought that open technology will strongly support electronic visits and will allow providers and patients to exchange relevant and rapid data and information. In addition, it is highly likely that health institutions and medical staff will use multiple analytical processes to achieve better patient health care, better patient health management, and achieve better results.

Respondents also predict that large volumes of healthcare data will support quality findings, cost effectiveness, and medical research through knowledge derived from predictive modeling with extended medical and other data. This modeling could include identifying the high-risk population and forecasting expenditure or outcomes for the specific part of the population - patients. Technological investments will also support the health system's ability to take on the financial risk for the population.

Separate data review includes the promise of cost reduction through identifying efficient healthcare structures and models and high-risk population. Most respondents emphasized that investing in technological risk management capabilities related to patient management is needed from the perspective of spending**. The challenges in the realization of this vision are: numerous and different data from which appropriate decisions should be made; incomplete data interrelated between health systems and doctors; lack of skills for predictive models and experience.**

The talent - respondents agree that the discovery and development of the talent are essential elements for achieving success in the labor market. All respondents highlighted the long-term priorities of the talents:

Doctors / Clinical Leaders who treat and respect other doctors and general medical staff of their institution as true colleagues and as the most valuable asset possible. Leaders who through behavior and correct actions are able to motivate employees and influence them for the successful realization of the organizational goals.

Leaders who can apply knowledge and experience from other areas to bring innovations to health care. Among the most wanted are the leaders who want to undertake moderate risks and change the status quo.

Computer specialists with analytical skills who have the ability to exchange data from different sources and technologies into useful information and knowledge. Particularly, individuals with knowledge of technical and social sciences are also needed to help manage the healthcare of the population through predictive models.

Respondents repeatedly emphasized the need for:

The leaders to be:

Inovative

Visionary

Entrepreneurs willing to take moderate risks

Accepting of new models for health care

Focused on the patient

These leaders also stressed the need for the employees to be:

Able to follow the changes

Ready to work in groups

Engaging and participating in the work processes, motivated and enthusiastic.

Conclusion

Regarding the sources of considerable concerns presented to the directors of healthcare institutions, can be emphasized that healthcare managers feel great uncertainty about the dynamic and complex environment they are operating in, the overall economic situation and the possibility of increasing income. They are focused mainly on the implementation of contemporary technology for creating new values in new forms, developing new and dynamic partnerships and reducing the spendings.

If they carry out good healthcare planning, they manage to attract and retain quality and talented human resources, and build well-thought out and thoughtful strategies; healthcare providers will face multiple shocks of the dynamic and complex environment and will face, manage and efficiently carry out their healthcare activities in the next very challenging decade.

In today's healthcare system there is a lack of innovators and those with high readiness to undertake moderate risk that will be greatly needed in the future.

Therefore, we can say that:

Physician and visionary leaders, even though are scarce nowadays, are much needed.

Some of the interviewed leaders point out that the hospitals have noticed the lack of information technology specialists and those with analytical skills.

Others mentioned that also successful planning is a very important issue. They require the team of leaders to identify clear organizational objectives and goals, to draft plans and strategies and to design adecuate programs and policies for their realization in order to survive, develop, and adapt the institution to the dynamic changes in the dynamic and complex environment.

One of the important objectives of health care providers is to focus their efforts on the development and support of talented staff in order to create the necessary staff to achieve success in the future, which is thought to be very challenging.

Health institutions should also invest in new strategies for motivating, promoting positive employee behavior and raising their behavior awareness in the dynamic, complex environment.

The priorities needed to achieve high performance in the next years are:

Continuous and stable reduction of costs - always by continuing to respond to the phenomenon of reduction of operational boundaries.

Defining an adequate method of how to approach the consolidation and the change in the area of services provided - to gain spending efficiency and provide quality medical care. Huge institutions can exist, each networked or consolidated, if leaders develop their strategies according to the circumstances.

Bringing the decisions that the right services are provided in the right place - the goal is to minimize the phenomenon of providing dual services in different places and concentrate and provide them in places where the cost for their delivery is lower.

The new approach of careful treatment of patients has already begun to change medicine and it is predicted that this development trend will prevail even in next years. The specific changes include:

The patient in the first place - it may happen that within 24 hours the patients asks for a visit and a check up, doctors will need to provide healthcare also during the weekends and the actions taken for such care will be more appropriate even when they are offered at home.

Digital technologies will improve access and will create new opportunities for patients to meet and consult doctors - video and electronic visits will increase, reducing traditional personal visits to doctors' offices or hospitals.

Practices for quality health care will increase in the way that this will be engaged and cared for by other medical staff - internship nurses and other practitians will provide the widest range of services. This category of employees can reduce costs for patients and be in the most suitable places.

One of the biggest challenges for a successful patient-oriented model is to change organizational culture and staff attitudes. To motivate medical staff to be open to change, a powerful authoritative leadership is needed. Industries such as gastronomy, catering, and the various cosmetic services markets have been the source of leading practices in how to connect the market and customers in healthcare.

Therefore, we can conclude that institutional development requires:

Forecasting and precise planning of actions for the future, which is half of the success in this future. Although the leaders of the health institutions have a clear vision and understanding for the future, different obstacles may arise, therefore there should be a set of operational, tactical and strategic objectives and goals on an institutional level.

In strategic terms, the main issue is related to the type of investment that should be made at the moment in order to gain the highest competitive advantage in the future and the decision to be taken for the best positioning of the institution to achieve high success during the next five years but always focusing on maximizing the needs and requirements of patients while being rational in delivering quality health services.

The advanced talent and technology are the top priorities and the development of each one of them can undoubtedly require great investment, effort and expense. It is quite challenging and complex that the directors need to follow and develop these investments on a regular basis to better position their institution towards a quality healthcare model – value-based healthare and an operating environment in which meeting the needs and requirements of the patient is a key issue.

The path to success is different for all market and health institution, so the leaders, along with their leading teams, need to continue with the models of value-based healthcare in the institutions they manage; to improve the quality of the services provided to patients; to strive and seek appropriate purchases or partnerships when they are needed; to develop new technological and analytical skills and learn from the successes of others both inside and outside the health sphere.

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Critical Assessment of An Economic Evaluation of a Healthy Lifestyle Intervention for Chronic Low Back Pain (LBP)

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Abstract

Background: Globally, chronic low back pain (LBP) contributes significantly to the overall burden of disease, placing a heavy load on society through absenteeism and associated healthcare costs. Finding cost-effective measures to treat and prevent low back pain is therefore of utmost importance. Methods: A critical assessment of the study by Williams et al 2018 was performed by using a variation of the well-known Drummond's checklist for the critical appraisal of economic evaluations. Results: The authors performed appropriate statistical analyses using the available data. Means and proportions of baseline characteristics of the intervention group were compared to those of the control group to evaluate their comparability. Conclusion: Upon thorough assessment of the appropriateness of the economic evaluation methods used by Williams et al., it is conclusive that the validity of their results is valuable and trusted to a degree, soundly achieving many of the listed Drummond et al requirements, yet failing to take into account a few aspects that grant some weaknesses to the study.

Keywords: Economic Evaluation, Chronic Low Back Pain, Healthy Lifestyle Interventions

Introduction

The amount of health-related research has experienced a notable growth in the past few decades. Methodological differences, as well as other reasons, have led healthcare providers and other decision makers encounter difficulties when choosing the best alternative to accomplish their goals. Since favoring a particular option also carries an *opportunity cost* [1], decisions should be made in an informed manner and not be left solely to chance. Economic evaluations, defined as the "comparative analyses of alternative courses of action in terms of both their costs and consequences," [2] serve this exact purpose. Economic evaluations may face certain challenges (e.g. technical, ethical), however, they remain a useful framework to elucidate the best way of allocating scarce resources available. In addition, a well-carried out economic evaluation can bring a higher degree of transparency and accountability in the decision-making process by allowing for an evaluation of the underlying judgement

in those decisions. However, since their quality depends on the choices made by those performing them, it is important to critically assess their validity.

Globally, chronic low back pain (LBP) contributes significantly to the overall burden of disease [3], placing a heavy load on society through absenteeism and associated healthcare costs [4]. Finding cost-effective measures to treat and prevent low back pain is therefore of utmost importance.

Williams et al performed an economic evaluation of a randomized controlled trial focusing on a healthy lifestyle intervention in overweight and obese individuals with chronic low back pain [4]. The intervention consisted of a brief advice telephone call, a one-hour-consultation with a physiotherapist, and a referral to a 6-month health coaching service provided over the phone. The researchers investigated whether the lifestyle intervention was more cost-effective than usual care and found that the former could be cost-effective for quality-adjusted life years (QALYs) from the societal perspective.

Aim

The aim of the current paper is to evaluate the appropriateness of the methods used in the study by Williams et al, and the validity of their results through defining the study's strengths and weaknesses. This will help determine the usefulness of the study in making decisions or planning further analysis.

Methods

A critical assessment of the study by Williams et al 2018 [4] was performed by using a variation of the well-known Drummond's checklist for the critical appraisal of economic evaluations [2]. All 33 items on the checklist were reviewed and their relevance was discussed. Points deemed irrelevant in the assessment of the study were excluded. The final list was compiled collaboratively and provided a framework for a critical review of the study.

Results

The authors presented a clear research question. They stated that the purpose of their study was "to undertake an economic evaluation of [a] healthy lifestyle intervention, compared with usual care". In addition, they provided a description of how the randomized controlled trial was carried out, outlining the processes of recruitment, assignment to treatment, and intervention. To put it briefly, patients that satisfied the criteria were randomly assigned into either the treatment or usual care (control) group. The latter could be considered as the *do-nothing* alternative. As previously mentioned, the intervention consisted of telephone advice, a consultation with a physiotherapist, and a referral to a 6-month healthy lifestyle coaching service provided over the phone.

With regard to the costs and consequences, the authors provided an acceptable amount of detail for each alternative. In this study, they dealt with three major

categories of costs: intervention, healthcare utilization, and absenteeism. It should also be mentioned that "[all] costs were converted to Australian dollars 2016 using consumer price indices" [4]. Moreover, the cost of the intervention was micro-costed and made up of three elements: (1) cost to provide the advice over the phone; (2) cost of a one-hour physiotherapy session; and (3) cost for a specialist to conduct a telephone-based healthy lifestyle coaching session multiplied by the number of calls each participant received. However, the authors fail to clarify how they estimated the development and operational costs of these calls. Meanwhile, healthcare utilization costs included costs of medical services or medication(s) used by the participants to manage their low back pain. The participants had to recall the services and medication(s) they had used during the past 6 weeks at two time points (at 6 and at 26 weeks follow-up). Assuming linearity, the average cost of the two time points was used to estimate the healthcare cost over the entire duration of the study. Lastly, absenteeism was calculated based on the number of days the participants recalled not going to work due to their low back pain. The cost of absenteeism was also calculated through extrapolation. The authors did not explicitly identify capital costs. Furthermore, discounting was not performed because the follow-up period of the trial was less than a year.

Costs were included or excluded in the statistical analysis depending on the perspective from which it was conducted. The primary analysis, conducted from the societal perspective, included all cost categories mentioned above while, in the secondary analysis conducted from the healthcare perspective, the cost of absenteeism was excluded. The authors did not perform an analysis from the patient perspective in this study.

In the economic evaluation, the authors divided the consequences, or effects, into primary and secondary outcomes. The primary outcome was QALYs while the secondary outcomes consisted of pain intensity, disability, weight, and BMI. In all analyses, all outcomes were included. These outcomes were enumerated according to self-reported data recorded at baseline and two subsequent time points. The exception to the enumeration method was height, which was only recorded at baseline. Quality of life was assessed using the 12-item Short Form Health Survey. This measurement was converted into a utility score using the British tariff, and this score was multiplied by time to give rise to a QALY. Back pain intensity and disability were also enumerated using validated instruments: Numerical Rating Scale and the Roland Morris Disability Questionnaire, respectively.

The authors performed appropriate statistical analyses using the available data. Means and proportions of baseline characteristics of the intervention group were compared to those of the control group to evaluate their comparability. Missing data on costs and consequences were handled through multiple imputation by chained equations. Ten complete datasets were created to ensure that the loss-of-efficiency was below 5%. Each data was analyzed separately and then the pooled estimates

were calculated using Rubin's rules, taking into account both the uncertainty within a dataset and that due to missing data. In addition, seemingly unrelated regression analyses were performed to enumerate the cost and effect differences for all outcomes. Importantly, incremental analyses of costs and consequences of alternatives were also performed. The incremental cost-effectiveness ratios (ICERs) were calculated for all outcomes "by dividing the difference in total costs by the difference in outcomes" [4]. To test the robustness of the economic evaluation, two sensitivity analyses were performed from the societal perspective. It should be noted that the conclusions were sensitive due to the uncertainty in the results.

Areas of discussion included key findings, interpretation of those findings, comparison with the literature, strengths, and weaknesses. The authors interpret the results of their cost-utility and cost-effective analyses while identifying certain findings that should be viewed with caution. In addition, the authors discuss the trustworthiness of their research by elaborating on the internal and external validity of their research. They also bring light to potential sources of error and bias that could have compromised the methodological integrity of their study.

Discussion

While the study fulfills well some of the requirements set by Drummond et al [2], there are also some aspects that have not been taken into account which contributed to its weaknesses.

The evaluation is based on an RCT, and the source of data is therefore obtained from one of the most accurate data collection methods due to their design characteristics, e.g. randomisation. However, in this context, it lacks many essentials that in turn limits the validity of the results, and subsequently affects the outcome measures available for the economic evaluation. One of the limitations is the sample size which was 160 with a matching rate of almost one control to one case. In addition to that, no information about how they assigned the treatment nor how they assessed the non-compliance has been mentioned. Furthermore, the missing information on several participants and the short duration of the trial could possibly make the generalizability of the results less reliable and could indirectly influence the validity of the results of the evaluation. Also, the data regarding height and weight were collected by self-reporting which makes the final results more prone to bias and uncertainty than when collected with validated instruments and by professionals.

Regarding data on costs and outcome of health utilization and absenteeism, it is unclear how it was obtained from the control group, and whether they have made an assessment at 6 weeks to them as they did with the case group or not. Such information is important to be mentioned clearly in the final report to ensure the credibility of the results. Moreover, costs related to healthcare utilization and absenteeism have relied largely on patients' ability to recall the absent days as well as number of days they utilized healthcare because of low back pain. This can lead to recall bias, which will largely affect the internal and the external validity of the results.

Furthermore, the study ignored the costs related to measures of presenteeism (i.e. decreased productivity at work due to low back pain) that could result in significant cost of chronic low back pain to the society.

Regarding the measurement of the outcome, it depends largely on how patients assessed their own level of pain. Data collected through such a method can be biased as, for example, some patients will tend to exaggerate their symptoms to increase attention.

The program included the societal and healthcare perspective only, and nothing has been mentioned regarding the patient perspective. This could have been useful to evaluate whether patients made any substantial out-of-pocket expenses in order to concur to the advice from the lifestyle intervention (e.g. gym membership), which could potentially deter some participants to follow the guidelines provided. Furthermore, by leaving out this perspective, other potential health benefits beyond the impact of a improved lifestyle on LBP were also not contemplated.

Regarding the analysis, they used 'intention-to-treat' method which assumes that all the participant had adhered to the protocol. Using such a method can lead to greater uncertainty and possible bias in estimating the cost-effectiveness of the trial. Also, when they did the sensitivity analysis, the results came out to be completely different.

Conclusion

Upon thorough assessment of the appropriateness of the economic evaluation methods used by Williams et al., it is conclusive that the validity of their results is valuable and trusted to a degree, soundly achieving many of the listed Drummond et al. [2] requirements, yet failing to take into account a few aspects that grant some weaknesses to the study.

Instances, such as missing data, utilizing a relatively small RCT sample size, lacking information on how treatment was assigned or how non-compliance was assessed, as well as data collection regarding height and weight being self-reported make the final results less of the RCT less reliable. In addition, patients assessed their own pain level as a measure of outcome, which can lead to biased data. All of the above could influence the outcome measures of the economic evaluation.

While the healthcare and societal perspectives were included, the study lacks inclusion of a patient perspective study, which would lead to a better understanding of LBP cost-effectiveness based on treatment from the patient's perspective.

When it comes to cost-effectiveness results, internal and external validity may have been affected due to recall bias from the data depending on patients' ability to recall absent days and number of days they utilized healthcare due to LBP in order to assess absenteeism and healthcare utilization, respectively. Also, it is uncertain how data on costs and outcome of absenteeism and healthcare utilization is collected from the control group.

In the end, it is lack of certain data or uncertainty of method(s) of data collection that make the study not entirely trustworthy and, as suggested by its own authors, use caution when interpreting and putting to practice its results.

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Conflict of Interest

There is no conflict of interest from the author.

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Public health strategies to combat opioid crisis in the United States

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Abstract

Background: The opioid epidemic in the United States is a national public health crisis. Driven by an increase in availability of pharmaceutical opioids and by an increase in their consumption, specifically, for pain treatment, more so in the past twenty years, it has led to an economic cost of prescription opioid abuse, overdose, and dependence in the United States estimated to be 78.5 billion USD. Methods: A thorough evaluation of the relevant extracted literature has been used to answer the question of the most effective ways to regulate health markets to decrease the opioid crisis in the United States, using keywords and phrases such as opioid epidemic in the US, prescription drug abuse, prescription medication abuse in US, medication misuse, cost-effective ways to health market regulation, drug monitoring programs, prescriber continuing education, provider continuing education, and pain management optimization. Results: Overcoming this epidemic nationwide requires improvement in patient utilization of and access to safe and effective treatment options for opioid abuse and overdose, addressing the stigma correlated with opioid use, considering appropriate use of abuse deterrent formulations (ADF) along with patient education, and improving prescribing practices via utilization of drug monitoring programs, CDC opioid prescribing guidelines and provider continuing education. Conclusion: Utilizing and implementing the aforementioned steps has shown to be a challenge. Further and repeated attempts are needed, while at the same time considering possible new steps that could help reinforce their utilization further.

Keywords: Opioid Crisis, Public Health, Public Health Strategies, Opioid Epidemic in the US

Introduction

One of the most common reasons that patients go to seek medical care in United States is pain. And every year, approximately 100 million people in the US suffer from pain, of which 9-12% report the pain to be chronic. As a result, in 2016, about 214 million prescriptions for opioid medications (the most commonly prescribed

medications in the US [6]) were written and dispensed. In turn, this has risen, in parallel, a phenomenon known as the opioid crisis, including opioid overdose deaths and opioid addictions [3,4&5]. While in today's modern medical practice there are numerous ways to treat pain, one way includes use of opiates, which have officially been approved for analgesia (pain relief) for almost 70 years. While this class of drugs has been in use for a very long time, it is in the past two decades that a concern about their safety was raised by many reports. While cases of opiate overdose and toxicity all over the United States are continuously reported, the number of prescriptions for opiates has also significantly increased over the past 20 years [1]. According to the Centers for Disease Control and Prevention, as well as the Drug Enforcement Agency of the US, the opiate diversion rate, number of prescriptions for opiates, and opiate-related deaths have increased exponentially in the past two decades in the US. Pain management experts believe this high incidence of opiate overdose cases to be due to patients trying to manage unrelenting pain and not due to intentional causes [7]. Opioid overdose is a phenomenon that causes a person to have excessive unopposed stimulation of the opiate pathway. This can, in turn, cause respiratory depression and likely, death [1].

Currently in the US, overdose from drugs is a leading cause of accidental death, opioids being the leading drug class. Approximately one thousand emergency department visits everyday are due to opioid misuse. In addition, opioid overdose is responsible for an average of ninety-one US deaths per day [7]. This nationwide public health crisis is continuing to escalate. The national rate of opioid-related hospitalizations between 2005 and 2014 increased 64%, reaching 225 hospitalizations per population of 100,000. There has also been a 27% increase in death rate due to opioid overdose or toxicity from 2015 to 2016, with 42,000 Americans dying from this cause. This epidemic is widespread throughout the United States, while sociodemographic and regional variations exist [2].

While the rate of prescribing opioids in the recent years has declined, the increased use and availability of pain opioid medications have played a crucial role in this modern-day epidemic. The amount of opioid prescriptions in the US was triple in 2016 when compared to its amount in 1999. As a result, more than 17,000 people died from an overdose of pharmaceutical opioids. It's been found that even proper prescribing and use of pharmaceutical opioids leads to adverse events, such as addiction and fatal toxicity or overdoses, showing a statistically spatial and temporal relationship between pharmaceutical opioid availability and mortality due to overdose [2]. The opioid epidemic has been referred to as the 'most consequential preventable public health problem in the US' pointing out that taking appropriate preventable measures, the issue has a chance of improving immensely [10].

Economic cost of prescription opioid abuse, overdose, and dependence from a societal perspective in the US is estimated to be 78.5 billion USD, of which a third of it is due to increased substance-abuse treatment costs and increased healthcare costs,

approximately adding up to 28.9 billion USD. In addition, about 25% of the total burden is borne by the public sector in healthcare, criminal justice costs, lost productivity (such as premature death due to opioid dependence or abuse, incarceration, and loss of productive hours [household productivity or paid employment] due to dependence or abuse), and substance abuse treatment costs [15].

A crucial component in identifying preventive cost-effective strategies is to first understand the economic burden that is produced by adverse health events due to the opioid crisis. The most recent estimate of the overall societal impact of prescription opioid dependence, misuse, and abuse in the US was found to be substantially higher than it was a decade ago, 55.7 billion USD [15]. And while the epidemic has continued to progress throughout the past two decades, understanding the economic burden caused by the adverse health outcomes due to the opioid epidemic is key to identifying appropriate preventive strategies that are cost effective.

Opioid abuse and toxicity epidemic are not solely an American occurrence and concern, it is a global problem. It is estimated that 0.4% of the population (close to 20 million people) regularly use derivatives of opioids, such as heroin or opium [2]. Having a better understanding of effective ways to regulate the market can lead to decreased incidence and prevalence of the opioid crisis not only in the US but internationally as well.

Methods

A thorough literature review has been conducted using trusted sites, such as PubMed, Lund University online library, Clemson University online library and Northwestern Health Sciences University online library. Keywords used included opioid epidemic in the US, prescription drug abuse, prescription medication abuse in US, medication misuse, cost-effective ways to health market regulation, drug monitoring programs, prescriber continuing education, provider continuing education, pain management optimization, etcetera. A thorough evaluation of the relevant extracted literature has been used to answer the question of the most effective ways to regulate health markets to decrease the opioid crisis in the United States.

Results

In order to contribute towards decreasing the incidence and prevalence of opioid abuse and toxicity, both factors leading to the current opioid crisis in the United States, there are several steps that can be addressed and improved upon at this time. First, improvement is needed in patient utilization of and access to safe and effective treatment options for opioid overdose. Second, stigma correlated with opioid use must be addressed. Third, abuse deterrent formulations (ADF) need to be considered in appropriate cases along with patient education. Lastly, prescribing practices must be improved via utilization of drug monitoring programs and provider continuing education.

Improving utilization of and access to safe and effective treatment options

Three main FDA-approved medications are available in the market to treat opioid use disorder. Those include buprenorphine, methadone, and naltrexone. Buprenorphine and methadone are long-acting receptor agonists, providing consistent drug levels systemically in blood and reduce opioid cravings and reduce withdrawal symptoms. According to Lyden et al. numerous studies have shown that buprenorphine and methadone reduce illicit use of opioids, increasing retention of patients in drug treatment plans, and reduce mortality. However, despite the positive evidence, these opioid agonists remain underutilized for multiple reasons, including lack of prescriber and provider training to initiate use of medications and consultations with patients to maintain treatment when needed, misconceptions by healthcare providers and patients about how these treatment drugs work and their outcomes, and worry of criminalization or stigma by the patients. Naltrexone is an opioid receptor antagonist and blocks the effects of opioids, making it impossible for the patient to enjoy the euphoric effects of opioids and, in turn, reducing relapse [2]. In addition, naloxone, which is also a pure competitive antagonist at the opiate receptors is FDA approved to combat opioid overdose. While it can be administered intravenously and nasally by a healthcare provider, recently a hand-held auto-injector has been approved, where caregivers or family members are able to administer the drug and intervene with an overdose of opioid [1].

Addressing the stigma correlated with opioid use

Addressing the stigma that is correlated to opioid use is necessary as it has been found that when restrictive policies are enforced and people breaking said policies are categorized and stigmatized as criminals, drives people to engage in risky behavior, in this case inject in risky conditions, leading to HIV and hepatitis C incidences due to needle sharing. Hence, prohibition of opioid use leads to infectious diseases. Removing the stigma associated with drug use and approaching policy reform through defining drug use as primarily a social and health matter, rather than a criminal matter will allow for a safer and a more effective approach to decreasing the opioid crisis [9]. In addition, stigmatizing drug use will prevent patients willing to get treatment from asking for professional help due to fear of criminalization [2].

In order to address the stigma correlated with drug use, many studies have found that the language used in discussing and treating patients who are dealing with substance abuse or substance use disorders is among the most important factors. Appropriate language, which will be explained, will help remove treatment barriers for patients and remove stereotypes. For example, avoiding use of terms such as ‘substance abuser’ or ‘addict’ will help avoid putting the patient at fault of their situation. In addition, using ‘person first’ language has been found to be successful in addressing stereotypes and stigma in opioid use disorders by multiple studies. In ‘first person’ language, description of the individual precedes the description of their disorder or

diagnosis. For example, use 'woman/man with history of opioid use' instead of 'opioid abuser' [2].

Abuse deterrent formulations (ADF) and patient education

ADF medications are opioid analgesics available with prescription only. They are technologically designed to make them more difficult for the patient to abuse. Their chemical and physical properties resist any attempted manipulation or cause loss of the drugs' psychotropic effects. Post-marketing studies of ADFs have shown that ADF use leads to a less likely result of 'drug-liking' and 'likelihood to take drug again' by the patient, when compared to non-ADF opioid users. Kumar et al. found that in a 5-year study, abuse-related costs using ADF opioids were substantially lower than non-ADF opioid related costs, by 274 million USD. In addition, ADF opioids on average prevent 2300 new abuse cases and about 6600 abuse years when compared to non-ADF opioids [3]. However, ADF opioids are overall more expensive that non-ADF opioids, hence, this option should be considered in a population that is at risk to try therapy manipulation or drug abuse, such as patients with history of drug diversion or abuse, patients with mental health diagnosis or problems, and possibly patients in long-term pain management. According to Kumar et al. it costs the health system approximately 232,000 USD in order to prevent a new opioid abuse case and about 1.4 billion USD in order to prevent one overdose by opioid death when using ADF opioid as opposed to non-ADF opioid [3].

In addition, continuous patient education by healthcare providers on the effects of opioid misuse and abuse should be practiced in order to ensure patients are aware of the seriousness of opioid use and the importance of taking these medications exactly as prescribed due to their highly addictive properties, as well as danger of accidental overdosing as well as drug-drug interactions.

Improving prescribing practices via provider continuing education, CDC opioid prescribing guidelines, and drug monitoring programs

As mentioned earlier, lack of utilization of treatment options, such as methadone or buprenorphine, which show high success rates, is due to lack of provider awareness to initiate and maintain such treatment in qualifying patients. In order to combat this issue, continuous provider continuing education is crucial. Prescribing opioids to treat pain will help patients in the short term, however long term-effects can be detrimental to the patient. In addition, in cases where a provider may know that a patient is highly likely to abuse opioids, he or she may choose to prescribe another alternative, Tramadol. Tramadol (brand-named Ultram) is a classified analgesic of a non-opiate class. It has a length of duration of action of 5-6 hours and it is safer than opiates when treating pain [1].

In addition, in order to address the serious detrimental adverse health outcomes (such as addiction and fatal overdoses) of opioid use even when prescribed by physicians and taken as directed, the CDC created specific guidelines in 2016 in order

to assist clinicians to recognize patients with high-risk of opioid abuse and to properly prescribe opioids for treatment of pain. The 12 specific recommendations can be seen on Table 1 of Appendix A. Utilization of these guidelines needs to be followed in all states in order to avoid overprescribing opioids, especially in acute cases or brief emergency department visits.

Lastly, prescription drug monitoring programs must be utilized nationwide. While these programs have been established in many states in the US, not all are utilizing them, and no interstate data sharing is currently being done. Thus far, their use has been shown to improve prescriber confidence, identify patients that have multiple providers, and reduce overall availability of controlled substances [2,12,13]. Where implemented, these programs decreased opioid-related deaths by 1.12 per 100,000 population [16].

Discussion

Overcoming the opioid epidemic nationwide is a primary public health issue and utilizing the aforementioned factors and services will help in addressing many of the issues that are currently contributing towards the opioid crisis.

Decision makers at the state and federal levels have already responded to the opioid epidemic with multiple attempted strategies, all of which aimed to decrease its burden. For example, in 2011 the National Drug Control Policy had already called for all of the states to provide functional prescription drug monitoring programs and also encouraged the administrations to share the information and data within the monitoring programs both interstate and intrastate in order to catch multiple drug prescribing. However, attempts like these, often face challenges, such as financial constraints that need strategies that are both clinically effective as well as cost effective. In this case, the challenge to some providers seemed to be balancing care for patient that needed pain treatments and addressing the epidemic of opioid overdose at the same time [8,15]. In addition, some providers and dispensers have reported concerns in prescription drug monitoring programs difficulty of use, effectiveness and necessity of their advancement, suggesting that while these programs are effective, they need to be improved in order to increase the likelihood that providers will feel more comfortable using them [11,14].

In order to reinforce the utilization of steps that studies have shown to be successful in reducing the opioid crisis in the US but that are not being utilized sufficiently, such as use of prescription monitoring programs, use of available treatment options for opioid abuse, referral to the CDC opioid prescribing guidelines, it has been suggested that stricter rules and certain reinforcements and requirements may be helpful, such as, for example, making the use of prescription monitoring programs a requirement for physicians in order to receive their state prescriber license. In addition, states can educate physicians about the dangers of the opioids and the importance of identifying patients at risk for opioid abuse or misuse, as well as prescribing the appropriate available treatment options that are not currently being maximally used. States can

even litigate against pharmaceutical manufacturers, as they had done while fighting tobacco companies and can even ask pharmaceutical companies to stop manufacturing a certain drug altogether [8], should they decide that its manufacturing is contributing to a public health issue that is unmanageable otherwise.

Conclusion

While attempts to combat the opioid epidemic have been made, the state and federal governments have only recently started to understand the magnitude of the seriousness of this public health crisis [8]. The methods with promising improvement of the situation have been identified and include utilization of and access to safe and effective treatment options for opioid abuse and overdose, addressing the stigma correlated with opioid use, considering appropriate use of abuse deterrent formulations (ADF) along with patient education, and improving prescribing practices via utilization of drug monitoring programs, CDC opioid prescribing guidelines and provider continuing education. However, utilizing and implementing these steps has shown to be a challenge. Further and repeated attempts are needed, while at the same time considering possible new steps that could help reinforce their utilization further.

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Conflict of Inerest

There is no conflict of interest from the author.

Key Points

- Attempts to combat the opioid epidemic have been made, and the state and federal governments have only recently started to understand the magnitude of the seriousness of this public health crisis.
- The methods with promising improvement of the situation have been identified.
- Utilizing and implementing the existing public health strategies has shown to be a challenge.
- Further and repeated attempts are needed, while at the same time considering possible new steps that could help reinforce their utilization further.

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Table 1.

CDC guidelines for prescribing opioids for chronic pain [2].

When to initiate or continue opioids:
1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred treatment for chronic pain. If used, opioids should be given in combination with non-pharmacologic therapy and non-opioid pharmacologic therapy when appropriate.
2. Realistic treatment goals should be established prior to initiating therapy.
3. Before starting and periodically during treatment, clinicians should discuss risks and benefits with the patient.
Opioid selection, dosing and duration:
1. Immediate release opioids should be used instead of long acting opioids.
2. The lowest effective dose should be prescribed.
3. When treating acute pain, the lowest effective dose of immediate release opioids should be used for a limited duration; typically, 3 days or less, rarely more than 7 days.
4. Clinicians should reevaluate benefits and harms with the patient 1-4 weeks after starting chronic opioid therapy and re-assess risk-benefit of medication.
Assessing risk and addressing harms:
1 Evaluate risk factors for adverse events before initiation and during treatment. Consider naloxone for higher risk patients.
2. Review prescription drug monitor program (PDMP) database before initiating and during treatment.
3. Urine drug testing should be used before initiating and periodically during treatment.
4. Avoid prescribing opioids and benzodiazepines together.
5. Offer treatment or refer patients to treatment if opioid use disorders is expected

Effects of Adverse Drug Reactions and Adverse Drug Events in Hospital Admission Rates and Re-Hospitalization of Patients

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Abstract

Background: ADRs and ADEs have a great potential to hospitalize and/or re-hospitalize patients. According to McDonnell and Jacobs, one ADR or ADE could lead a patient to a hospital length of stay of an average of 6.1 days. This can lead to lost days of work, a longer recovery time and even economic implications. Methods: A thorough evaluation of the relevant extracted literature has been analyzed thoroughly in order to find out how ADRs and ADEs impact the levels of hospitalization and re-hospitalization of patients and whether strategies, such as reporting systems, can aide in decreasing their overall occurrence. Results: As the level of hospital admissions/re-hospitalizations due to ADRs and ADEs depends on different factors, such as age and location, the data is separated in the following categories: pediatric population, general adult populations and geriatric population. Where data were available, location has been specified within each category as well. Conclusion: ADR and ADE-related hospital admission and readmission rates are age-group related, elderly being at the highest risk. However, these rates are not dependent on whether a country is developed or developing. Also, there are strategies that can be utilized by healthcare providers in order to decrease these rates in the future, such as to provide medication reviews and follow-ups.

Keywords: Adverse drug reactions, adverse drug events, hospital admission rates, hospital readmissions

Introduction

Adverse drug reactions (ADRs) and adverse drug events (ADEs) are among the leading causes of hospitalization and re-hospitalization in many patient groups and often lead to significant financial costs, as well as significant morbidity and mortality [12]. However, in order to be able to understand the implications of ADRs and ADEs, it is crucial to understand the definition of each and the difference between the two. An ADR is a reaction or a response to a medication that is not intended to occur at normal doses used as a therapy for treatment of a disease or for prophylactic

purposes. An ADR also differs from the term side effect (SE), as a side effect is generally a documented and an expected reaction to a certain medication therapy, which is not that medication's intended therapeutic outcome. The term side effect has somewhat been criticized as it tends to normalize the notion of damage from drugs. A concrete example of an ADR would be an allergic reaction to a drug expressed by the immune response through its mediation in hives or a rash [22].

An adverse drug event (ADE), on the other hand, is harm that occurs during the use of the drug, whether caused by it or not, including overdoses, dose reductions and medication therapy discontinuation [5]. In addition, about 25% of ADRs leading to hospitalization are at a level measured as serious to life threatening, which are a result of patient noncompliance, inappropriate dosing or insufficient therapy monitoring. All of these causes have been deemed as controllable, rendering ADRs as often preventable through different strategies that can be applied among physicians, pharmacists and other healthcare providers and even patients, including targeting communication and education [12].

What makes ADRs important in healthcare and likely to cause unexpected hospital admissions and re-hospitalizations is that they are not all discovered during the mandatory clinical trials (established to determine drug efficacy and get drug approval and release it into market). The most important method to detect unknown and additional ADRs of drugs is through ADR reporting in reporting systems by healthcare providers and by patients themselves. This reporting is done through reporting systems that are different depending on which country the ADR is being reported (for example, in United Kingdom they have a system called the UK Yellow Card scheme). Ultimately, updating reported ADRs would detect the possibility of ADR occurrences and enable their early detection of prevention of hospital admissions/readmissions due to them [5].

ADRs and ADEs have a great potential to hospitalize and/or re-hospitalize patients. According to McDonnell and Jacobs, one ADR or ADE could lead a patient to a hospital length of stay of an average of 6.1 days [12]. This can lead to lost days of work, a longer recovery time and even economic implications. Hence, the level of hospitalization and re-hospitalization due to ADRs and ADEs, as well as their impact on patient outcome, burden to the healthcare system, lifestyle and economy will be studied and discussed in this paper.

The purpose of this study is, therefore, to understand the level of ADR and ADE-related hospital admissions and re-hospitalizations, what causes them (whether the incidences are age-related or related to socio-economic status of the locations), and to explore possible strategies that can be utilized by healthcare providers and patients in order to decrease their overall incidence and prevalence, as decreasing ADRs and ADEs would lead to a significant decrease in healthcare costs and would lead to better quality of life of patients under ADR and ADE-prone drug therapies.

Methods

A systematic literature review via PubMed, Lund University libraries, and Rochester Institute of Technology online library database searches were conducted in an iterative manner during the year of 2018 and 2019, to retrieve articles related to adverse drug reactions and adverse drug events and their impact in hospitalization and re-hospitalization of patients. The searches included literature from 2000 to 2018, including keyword searches, such as adverse drug reactions, adverse drug events, hospitalization, re-hospitalization, reporting systems, side effects, clinical trials, etcetera, under both basic and advanced searches. A collection of relevant articles was extracted from this secondary literature review and analyzed thoroughly in order to find out how ADRs and ADEs impact the levels of hospitalization and re-hospitalization of patients and whether strategies, such as reporting systems, can aide in decreasing their overall occurrence.

Results

Patients have been categorized in pediatric and geriatric categories, as well as patients living in developing or developed countries. While different variables may predict the level of potential hospitalization within a population, it has been stated by Pirmohamed et al. that the burden of ADRs and ADEs is high and it accounts for a significant level of morbidity and mortality, as well as extra healthcare costs, in this case in England. While these drugs that cause ADRs and ADEs are used to treat conditions in order to improve patient health, it is crucial to also look at the harm versus benefit ration to determine whether certain treatments are worth the risk of potential ADRs and ADEs leading to health harm and healthcare burden [17]. However, looking at a harm versus benefit ration, ADRs cannot all be generalized at the same level of potential danger, as they have been categorized in different levels depending on their potential to be avoided: Definitely avoidable, Possibly avoidable and Unavoidable. Using this categorization system, Pirmohamed et al. found that out of 1225 hospital admissions due to an ADR, 80% of the cases were directly related to an ADR and the median bed stay was eight days. These admissions accounted for four per cent of total hospital bed capacity, leading to a 446 million British pounds annual cost and an overall fatality of 0.15%. These ADRs that led to hospitalization were deemed as either definitely or possible avoidable, shining a light on the potential for improvement. Common drugs that lead to ADRs in this study included aspirin, NSAIDs, diuretics and warfarin; the most common ADR being gastrointestinal bleeding [17]. In addition, Menendez-Conde et al. found that immunosuppressants and antineoplastic therapy caused 38% of ADRs [13].

As the level of hospital admissions/re-hospitalizations due to ADRs and ADEs depends on different factors, such as age and location, the data is separated in the following categories: pediatric population, general adult populations and geriatric population. Where the data was available, location has been specified within each category as well.

ADRs and ADEs causing hospital admissions in pediatric population (aged 19 and under)

In a study done in the Czech Republic, it was found that ADRs cause a significant number of pediatric hospital admissions. 2.2% of hospital admissions were due to an ADR, of which 35% were due to anticancer drugs, 18% due to antibiotics, 9% due to vaccines and 9% due to immunosuppressants [9]. In addition, Feinstein et al. found that 3% of hospital admissions per day were due to possible drug events [4].

ADRs and ADEs causing hospital admissions in general adult population

As a point of comparison to the other population categories, hospital admissions in the adult population represent 8.1% of total hospitalizations in Singapore [3]. 2.4% to 3.6% of ADR-related hospitalizations among the adult population occurred in Australia, and 3.1% to 6.2% in the United States. The mortality rate was found to be similar in both countries (0.21%) [18].

ADRs and ADEs causing hospital admissions in geriatric population

It has been found that the highest incidence of ADR and ADE--related hospital admissions is among the geriatric population. According to Nair et al., 6% to 12% of all hospital admissions among older patients are due to ADRs, a percentage higher than in any other patient population [14]. However, Laatikainen et al., found that up to 23.1% of hospital admissions were likely medication-related (including ADRs and ADEs) [8]. A similar study found the rate to be 8.37% in the emergency department [15]. In addition, 22% of re-hospitalized patient cases were considered avoidable [6]. Four per cent of urgent hospital admissions were due to ADRs, most of which (90%) occurred in older patients who were on multiple medications at once [16].

Population within a developed country versus underdeveloped country

A comprehensive review of prevalence of ADR and ADE-related hospitalizations in developing and developed countries led to conclusions that 6.3% and 5.5% of hospitalizations occurred in developed and developing countries, respectively. In addition, of those hospitalizations, 71.7% and 59.6% were preventable reactions and events in developed and developing countries, respectively [1]. In addition, a study of incidence of ADR-caused hospital admissions in France found that 3.6% of admissions were due to ADRs, 32% of which were preventable and 16.5% potentially preventable [2].

Studies exploring the rate of ADR-related hospital admissions in England found that within the period of 1999-2009, 0.9% of total hospital admissions pertained to ADR causes [21]. Veeren and Weiss also found that in 2014/2015 the number of emergency hospital admissions increased by 12.1% in England as well [20].

Conclusion

In order to handle healthcare problems caused by ADRs and ADEs it is also very important to create a utility of tools in order to be able to identify high-risk patients,

such as older patients in order to intervene and prevent ADR and ADE-related hospital admissions. At this time there are no validated tools that help evaluate the risk of adverse drug reactions in a primary care setting [14]. It was also found to be beneficial to provide medication reviews with follow up services on hospital admissions in older polypharmacy patients. Pharmacists were found of particular help and benefit in this case. They found that the percentage of ADR related admissions in patients receiving follow-up medication review was significantly lower [10].

In conclusion, ADR and ADE-related hospital admission and readmission rates are age-group related, elderly being at the highest risk. However, these rates are not dependent on whether a country is developed or developing. Also, there are strategies that can be utilized by healthcare providers in order to decrease these rates in the future, such as to provide medication reviews and follow ups.

Discussion

While hospitalization and/or re-hospitalization among patients due to ADRs and ADEs is a problem in public health, studies such as that of Pirmohamed et al. (2004) make it clear that there is a possible solution to the problem, regardless of how major it is. They found that the ADRs causing hospitalizations were avoidable or definitely avoidable. When an ADR is in an 'avoidable' category, it means that something can be done about it, some strategy can be applied in order to avoid the ADR. They also found that the major ADR was gastrointestinal bleeding due to aspirin, NSAIDs, warfarin or diuretics. This implies that the problem is possible at the level of patient drug education. There are several steps patients can take in order to avoid GI bleeds due to these drugs, such as the time of day the drugs are taken, foods with which they are mixed, proper dosing, appropriate tests, etcetera. These steps can be achieved by also improving patient-provider communication and follow-up appointments. There are also steps that can be taken to avoid ADEs. While ADEs can occur during the process of drug prescription, administration or purchasing, etcetera, physicians and pharmacists can play a major role in avoiding ADE-related hospital admissions and re-hospitalizations by recognizing and selecting patients that have a potential to be at a higher risk for ADE-occurrence and involving multi-disciplinary team work within the healthcare setting, providing the maximal care and greatest possible avoidance of ADEs by providing a more thorough patient education, having two or more healthcare providers review new and old prescribed medications of patients and recognizing possibilities of events beforehand [17].

Overall, it seems that older patients (ages > 65 years) have the highest incidence of hospital admissions due to drug reactions or events. However, when it comes to location, whether a developed or underdeveloped country is being studied, the incidence of ADR and ADE-related hospital admissions does not differ significantly. Hence, these cases do not seem to be a problem of poverty but more so of patient education and awareness of the effect that the drugs they take may have on their

health. This makes the challenge of ADR and ADE hospitalization hopeful in the sense that application of additional patient education in the future may have an effect in decreasing the issue of the current situation. This could also open many doors for improvement in the future. A possible future study could include examining the effect of thorough patient education about their medication lists, including administrations route, handling, storage, etcetera, on the rate of ADR and ADE-related hospital admissions and re-hospitalizations.

In addition, it was stated by Klarskov et al. that drug safety profile updates are impaired due to most ADRs and ADEs not being reported to authorities, as clinical trials are not a mirror of drug use in real life situations [7]. This being said, better methods to increase rates of ADR reporting to authorities should be established as knowing possible drug ADEs and ADRs would make it possible for them to be seen as possible side effects and foreseen as potential events, not unexpected or even surprise occurrences. A relevant future study would be to survey healthcare providers on the type of reporting system that they would prefer and would be more likely to use (paper-based system, or online) and to find out reasons why they may avoid reporting an ADR or ADE. This data would help us understand current issues of under-reporting of recognized ADRs and ADEs by healthcare providers and lead us into designing a reporting system that would be easier and friendlier to use, ultimately leading to increased ADR and ADE reporting.

A particular strength of this study is the inclusion of different age-groups in understanding the levels of hospital admission and readmission rates due to ADR and ADE (as susceptibility is age-related), and this leads to better understanding of which group population needs greater attention in order to decrease the overall rates. Also, the study focused on whether the level of country development plays a role on these rates. This is important as it finds out whether the solution to this problem is possible achievable without having to first focus on a much larger issue, such as poverty level, etc.

A limitation of this study includes lack of further literature review of current ADR and ADE reporting rates by healthcare providers and their effect on lack of recognition of possible ADRs and ADEs. Recognizing this rate can lead us to future study avenues that could potentially decrease lack of recognition of ADRs and ADEs before they occur. Another limitation includes the lack of further research of the link between level of patient education (by provider, about the drug(s) being taken) and the incidence of ADR and ADE-related hospital admission and readmission rates.

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There is no conflict of interest from the author.

Key Points

- Adverse drug reactions (ADRs) and adverse drug events (ADEs) have a great potential to hospitalize and/or re-hospitalize patients, which can lead to lost days of work, a longer recovery time and even economic implications.
- ADR and ADE-related hospital admission and readmission rates are age-group related, elderly being at the highest risk.
- Hospital admission and readmission rates are not dependent on whether a country is developed or developing.
- Public health strategies that can be utilized by healthcare providers in order to decrease these rates in the future, such as to provide medication reviews and follow ups, have been utilized.

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A Mind Genomics Cartography of Shopping Behavior for Food Products during the Covid -19 Pandemic

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Abstract

The study presents a new approach to understand the mind of the persons in order to drive desired action in crisis situation, specifically the COVID-19 pandemic. Understand the mind of the shopper in a pandemic situation, with massive uncertainty, should provide direction for governments and the retail trade to adopt practices and communications which will reassure their customers. This study investigates the nature of what people will do to reassure themselves in the pandemic, and has been executed during the period of the pandemic, making the study relevant to the actual events taking place. The focus of the study is on the likelihood of buying ordinary food, given certain descriptions. The study revealed three mind-sets, clusters of individuals who respond to the pandemic in one of three ways. These are: Mind-Set 1: Focus on sanitation & supply; Mind-Set 2: Focus on budget for lifestyle; Mind-Set 3: Focus on shopping, personal needs, consumption. These mind-sets are distributed through the population, and are not limited to specific age or gender. The paper closes with the PVI, personal viewpoint identifier, to assign a new person to one of the three mind-sets.

Keywords: Pandemic; Covid-19; shopping behavior.

Introduction

Since the first death in China in early January 2020, the coronavirus (COVID-19) has spread across the globe, dominated the news headlines and led to fundamental changes in the health, social, political and economic landscape (Schroeter, 2018).

Attributed to the recent COVID-19 pandemic, panic buying is now a frequent occurrence in many countries, leading to out-of-stocks and disruptions to the supply chain. Consequently, it has received much attention from academics and the retail industry (Yuen, Wang, Ma, & Li, 2020),

The pandemic has been addressed by requirements for behavioral change, the most important being social distancing. Social distancing manifests itself in reduced store capacity, more difficult shopping, insecurity about one's safety in the store, and a sense of diminished finances as jobs disappeared. Social distancing has ushered in a sharp change in consumer lifestyles which almost certainly will produce long-term effects on the ordinary shopping behavior of the typical consumer (Duckett, 2020).

The keywords for today are foresight, anticipation and of course preparations. Some aspects of consumer behaviour and marketing response will be seen to have permanently changed. Brands which prepare will emerge stronger from the disruption (Shaikh, 2020). The COVID-19 crisis overwhelmingly plays into the reality of worries shared by many regarding current food systems. The issues are complicated, involving a rainbow of issues, some technical such as biophysics, but the others softer, more people-relevant, such as demographics, business infrastructure, socio-cultural responses, and of course political responses to the pandemic.

The outbreak and spread of the COVID-19 virus make the shortcomings of our current food system, already frequently 'called out', once again painfully clear. Combined with an already growing feeling of "being fed up" with present food systems and the call for radical change, the crisis provides opportunities to carry out a "re-set" of our food systems, to determine what is important and what is not, to revalue the role of public goods, to reconsider "basic income" for all, etc. (Ruben, McDermott, & Brouwer, 2020).

Mind Genomics, systematic experimental design of test stimuli

"Helping with a good cause" is a way for struggling retailers to stay relevant as they attempt to capture demand, which may be changing due to the behavior of their customers. We focus in this study on understanding the mind of the struggling consumer, living through the pandemic. The focus is on the consumer as a person going to the store, selecting the product, and taking the product home. Rather than focusing on the shopping experience, which for much of the pandemic becomes a fast trip the store, we focus on the mind of the shopper thinking about what to do, what to buy. Simply stated, we focus on the customer shopping from home base, and focus on the decisions made from this focus, viz., people at home who are shopping in a situation where shopping is no longer recreational (Viberg, 2020).

We use the method of experimentation, following the tenets of Mind Genomics. The emerging science of Mind Genomics has as its objective to understand the dimensions of the ordinary, everyday experience. In doing so, Mind Genomics identifies what specific characteristics of everyday experience are positive versus negative, costly

versus inexpensive (cognitive economics), and finally what is the nature of the link between the characteristics of shopping and the expected accompanying emotions. For this study, we limit our focus to what people look for in the store, what they think they want to buy, how do they feel they want to budget their money, and what do they do when they get the product home.

Mind Genomics constructs an empirical, inductive science of perception and experience, layer by layer. The ultimate objective of 'mind genomics' is a large-scale, inductive science of the human experience, 'from the bottom up,' based upon emergent commonalities across many different types of daily experience (Moskowitz 2012.) The tools of Mind Genomics uncover different groups of people holding opposite or perhaps unrelated patterns of ideas about the same specific, granular topic (so-called Mind-Sets), and then create a system to assign a person to one of these mutually exclusive, exhaustive mind-sets.

Mind Genomics, systematic experimental design of test stimuli

Mind Genomics begins by requiring the researcher to choose a topic, then, create four questions which 'tell a story,' and finally for each question provide a set of four different answers. The questions and answers are simple phrases, with each question or answer 'standing on its own.' The approach is 'Socratic,' designed to promote critical thinking about the topic, and to focus on the everyday. For this study, the topic is a 'story' about shopping. The questions and answers are framed in the language of the ordinary, as Table 1 shows.

	Group (Binary Ratings)
	Base Size
	Additive Constant
	Question A: How is Covid-19 changing your shopping behavior?
A1	*Analyze every purchase for affordability*
A2	*Maintain what I did before*
A3	*Focus on essential products*
A4	*Focus on products to maintain my personal health*
	Question B: Where is the place that you shop mostly in this situation?
B1	*Supermarket*
B2	*Retail stores*
B3	*Online Stores*
B4	*Local Bakery and Nearby Farms*
	Question C: Which products do you buy most?
C1	*Basic products (water, bread, vegetables, cereals, fruits and dairy products)*
C2	*Alcohol (wine, beers, colored alcohol drinks)*
C3	*Cookies, sweets and snacks*
C4	*Personal care products*
	Question D: Based on this situation, do you trust the food products?
D1	*Buy packaged foods products & unwrap myself*

D2	*Disinfect every product that I buy and bring home*
D3	*Buy every needed, trust stores to be clean and careful*
D4	*Buy extra of key products to ensure my supply*

Table 1 – *The raw material for the Mind Genomics study, comprising four questions which "tell a story" and fou answers to each question*

The Mind Genomics process combines these answers into small vignettes, combinations of answers. The questions never appear. The vignettes, comprising 2-4 answers, at most one answer from a question, produce little "stories" about the topic area that the respondent rate. Each respondent rates a unique set of 24 vignettes, set up according to an individual experimental design. All 16 elements are statistically independent of each other, allow for OLS (ordinary least-squares) regression to be used to estimate the contribution of each element to the rating. The OLS regression is run on the data from each respondent as preparation for clustering, and on the total data for relevant groups, such as Total Panel, and Mind-Set. Finally, the 24 vignettes for each respondent are different from those of all other respondents, much as in the fashion of the MRI, which takes pictures of the same tissue, but from different angles and vantage points. With 135 respondents, the Mind Genomics system creates 134x24 or 3240 DIFFERENT vignettes

Each respondent read an orientation, telling them about the study:

We have created this study, in order to better understand how the situation of Covid-19, is affecting consumer buying and what are they buying mostly, in the category of products.

Each vignette represents a situation. The rating scale is: How likely are you to buy basic food products in this situation? 1=Unlikely … 5=Likely

The analysis begins by transforming the ratings so that ratings of 1-3 are transformed to 0, and ratings of 4-5 are transformed to 100. Managers understand binary scales, no/yes. After the transformation, a small random number is added to the transformed numbers. The OLS regression analysis generates a single equation of the form: Binary Transformed Rating = $k_0 + k_1A1 + k_2 A2 \ldots k_{16}D4$.

The additive constant is the expected percent of responses 4 and 5 in the absence of elements. The additive constant is an estimated parameter, having no concrete value because it is a correction factor. It is useful, however, as a baseline or proclivity to say 'likely' in the absence of elements. Each positive coefficient shows the driving force of an element towards saying 'yes.' There are negative coefficients, driving to neutral or no. They are not relevant for this discussion, and have been left out of the paper to make the exposition clear. Finally, the standard error of the coefficients is around 4, so a strong and significant 'driver' to yes (likely, rating 4 or 5) is about 7.51 or higher.

Table 2 shows the positive coefficients for the Total panel, for gender, and for the different age groups having a sufficiently large base size. It is clear from Table 2 that

although we have several drivers towards 'Likely', most are small and statistically non-significant, except for a few elements rated by respondents ages 18-24.

The foregoing is the typical outcome for Mind Genomics studies. The total panel does not show strong 'drivers', perhaps because the total panel comprises groups with different points of view those differences canceling each other out. The differences do not emerge based on WHO the respondent IS. Even though the common wisdom is that age cohorts or genders think alike, the Mind Genomics data contraindicate that generalization.

	Group	Total	Male	Female	18 - 24	25 - 34	35 - 44
	Base Size	135	35	100	71	25	23
	Additive Constant	54	50	56	57	52	61
	Question A: How is Covid-19 changing your shopping behavior?						
A1	Analyze every purchase for affordability				1		
A2	Maintain what I did before						
A3	Focus on essential products						
A4	Focus on products to maintain my personal health	3	6	2	4		
	Question B: Where is the place that you shop mostly in this situation?						
B1	Supermarket					6	
B2	Retail stores			1		9	
B3	Online Stores	1		2	1	9	
B4	Local Bakery and Nearby Farms					8	
	Question C: Which products do you buy most?						
C1	Basic products (water, bread, vegetables, cereals, fruits and dairy products)		5			10	
C2	Alcohol (wine, beers, colored alcohol drinks)	1	5			10	3
C3	Cookies, sweets and snacks		2			5	
C4	Personal care products					3	
	Question D: Based on this situation, do you trust the food products?						
D1	Buy packaged foods products & unwrap myself						
D2	Disinfect every product that I buy and bring home						
D3	Buy every needed, trust stores to be clean and careful						
D4	Buy extra of key products to ensure my supply						

Table 2– *Model for the key subgroups, for 'Likely' related to the presence/absence of the 16 elements*

Emergent mind-sets for positive shopping experiences

One of tenets of Mind Genomics is that within any experience, especially micro-experiences, such as shopping, people differ from each other in systematic ways called mind-sets. The analogy is to the genome. Genomes have alleles, different forms, which express themselves in different traits, possibly in different behaviors. Carrying that analogy forward, Mind Genomics creates these mind-sets by clustering the pattern of coefficients of the individual models relating the binary rating (here positive emotion) to the presence/absence of the elements in a study (here 16 answers to the questions, i.e., elements). The within-subjects experimental design allows the researcher to create the model (equation) separately for each respondent, and then cluster the respondents based upon the pattern of coefficients (excluding the additive constant.) The metric for 'distance' upon which the clustering is based is defined as (1-Pearson R). The metric takes on the value 0 when the coefficients for two respondents show a Pearson R of 1.0. The metric takes on the value 2 when the coefficients for two respondents show a Pearson R of -1. As a rule of thumb, there should be fewer mind-sets, rather than more (parsimony) and tell a story (interpretability).

Three mind-sets emerged for these data, and for clustering based upon the coefficients for 'Likely'. The additive constant and the coefficients for three mind-sets appear in Table 3. All three mind-sets show low to moderate coefficients 43-48, so that it is the elements which will drive the rating of 4-5, viz., 'likely.'

It is clear from Table 3 that there are three different mind-sets, with strongly positive coefficients, reaching and exceeding the cut-off for statistical significance. The mind-sets can be named by considering the commonalities of the elements generating the highest coefficients.

Mind-set 1 - Focus on sanitation/ supply

Strong positive coefficient for answer

D2 Disinfect every product that I buy and bring home

Mind-set 2 – Focus on budget for lifestyle

Strong positive coefficient for answer

A4 *Focus on products to maintain my personal health*
A3 *Focus on essential products*

Mind-set 3 – Focus on shopping, personal needs, consumption

Strong positive coefficient for answer

C1 *Basic products (water, bread, vegetables, cereals, fruits and dairy products)*

	Group	Total	MS1	MS2	MS3
	Base Size	135	47	45	43
	Additive Constant	54	52	58	58
	Mind-Set 1 - Vigilants - Focus on sanitation/ supply				
D2	Disinfect every product that I buy and bring home		17		
D3	Buy every needed, trust stores to be clean and careful		16		
D1	Buy packaged foods products & unwrap myself		15		
D4	Buy extra of key products to ensure my supply		13		
	Mind-Set 2 - Focus on budget for lifestyle				
A4	Focus on products to maintain my personal health			15	
A3	Focus on essential products			15	
A2	Maintain what I did before			13	
A1	Analyze every purchase for affordability		2	8	
	Mind-Set 3 - Focus on shopping, personal needs, consumption				
C1	Basic products (water, bread, vegetables, cereals, fruits and dairy products)				15
C2	Alcohol (wine, beers, colored alcohol drinks)	1			14
C3	Cookies, sweets and snacks				11
C4	Personal care products				9
B1	Supermarket				8
	Not a strong focus in terms of mind-sets				
B4	Local Bakery and Nearby Farms				6
B2	Retail stores				6
B3	Online Stores	1			5

Identifying the mind-sets of new individuals in the population for more effective communication

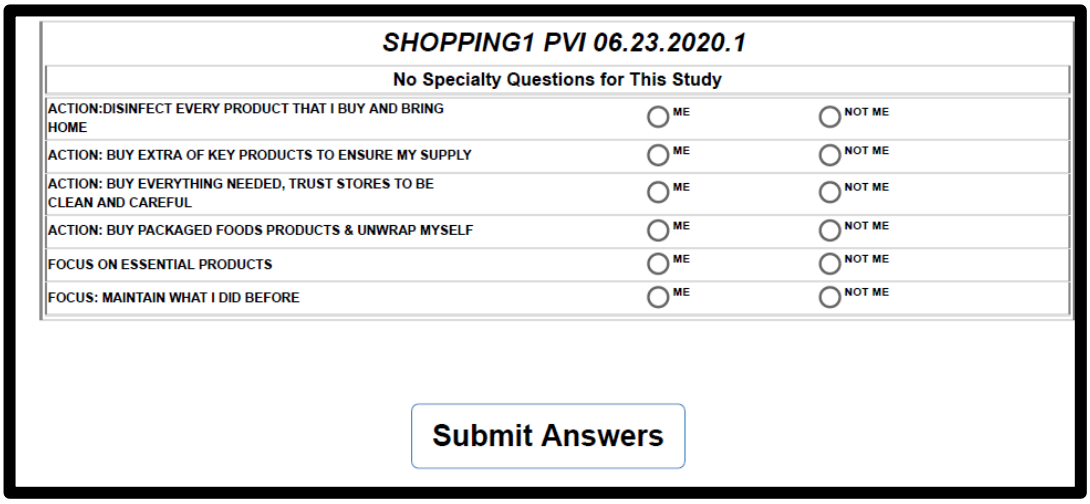
Research scientists, marketers and many others find the notion of Mind Genomics attractive because it works from the micro-level, rather than working from the macro-level. The results can be immediately put into action because they deal directly with the topic. The messages are the raw material from which the mind-sets are derived. The only recurring problem is that it is difficult to assign a new person to a mind-set segment based upon either behavioral data that one can capture, or attitudinal data from larger-scale segmentation studies. How does one know the 'attitude of a respondent' in terms of imputing emotions to the shopper? There is no such data, at certainly no data of the granularity provided by Mind Genomics.

For practical use of these data, e.g., communicating and reassuring customers, it is necessary to identify the mind-set of a new individual. The data shown here suggest that it will probably be hard to link individuals to mind-sets simply on the basis of

who they are. In study after study, Mind Genomics data suggest that the mind-sets distribute across the normal classification variables of who a person IS, what the person DOES, and even what general BELIEFS a person holds about a topic.

A different approach is necessary, one which uses the profile of coefficients to identify elements which differentiate among the specific mind-sets uncovered in the study. Author Moskowitz and a colleague, Prof. Attila Gere, have developed a Monte-Carlo-based system for identifying the combination of six elements, presented as questions, with two answers. These elements are created from the original data used to uncover the mind-sets, and so the system, the PVI (personal viewpoint identifier), can work anew at any level of granularity covered in the original Mind Genomics study leading to the mind-sets.

The PVI system creates 64 possible patterns of answers and identifies the most likely mind-set corresponding to each pattern, when the coefficients are subject to random permutation, noise in the results. Figure 1 shows an example of the PVI, the personal viewpoint identifier, created for this study. The PVI is located at: https://www.pvi360.com/TypingToolPage.aspx?projectid=192&userid=2018



Discussion

The global market of eCommerce is growing fast and bigger in the past years. After this situation, from the Covid-19 situation consumers are more careful on their purchases and they do not have contacts with other to protect themselves.

The Mind Genomics cartography about shopping during the pandemic suggests that the direct statements about online shopping are only modest drivers of responses. The coefficients are low. We conclude that it is NOT online shopping per se which emerges from the pandemic but rather the specifics about the shopping behavior. This focus on the specific is the most important finding of the study.

When studying behavior, the data suggest that there are different mind-sets. People think differently from each other. Emerging from this study are three very clear groups, the Vigilants, the Budget-Conscious, and the Product-Oriented. These three mind-sets distribute equally in the population, and show the same likelihood of basic agreement, and indicated by similar additive constants. It is only their 'minds' which differ. When we merge all three mind-sets together into one group, the total panel, we lose sight of the individual foci, the different driving forces for the mind-sets, and end up with bland results, insignificant coefficients, often around 0 or negative.

The importance of mind-sets cannot be over-stated. Successful coping and adaptation in the years to come may well emerge from knowing how the person THINKS, rather than increasingly refined measures of who the person IS, or what the person has DONE in the past. Furthermore, the success may come quicker, and less expensively, in days, and on a very low budget, by focusing the topic, by being granular, and by developing knowledge from the ground up, from the specifics of everyday life.

Conclusion

This paper presents the emerging science of Mind Genomics as a way to bridge the gap between the impersonal, quantitative dimension of social science and the qualitative, story-telling, emotion-filled and narrative-rich material provided by qualitative methods and by literature. The contributions of this paper to the literature may be summarized as follows:

Experimental design of the shopping situation, which creates a verbal experiment. The Mind Genomics method is an experiment, with controlled conditions, and defined measures.

Ability to identify mind-sets in the population, and then to create a short, easy-to-administer tool to assign a new person to a mind-set. This tool, the PVI, makes it possible to extend the application of the science to new people, as well as do in context validations of the results.

Ability to 'scale knowledge', rapidly, inexpensively, from the 'ground up,' from the granularity of life, to build a 'Wiki of the Mind.'

From this Virtual Experiment it is easy to understand from the strong positive emotions, which specific types of productsthat will be sought during the pandemic crisis, where respondents feel they would like to shop, and how do they perceive different actions which communicate 'safe.'

The granularity of this first experiment suggest ways that companies might organize their selling efforts, and the nature of the products that they might find to be in strong demand. The study can be replicated, with each topic (e.g., venue, safety, product, etc.) explored with increasing granularity. The speed of the procedure, hours and days, and the depth of the information, provide a learning system which can 'keep up with

changing conditions,' producing knowing in virtually 'real time,' hours after the Mind Genomics virtual experiment, our so-called 'Cartography' has been launched.

The PVI, the personal viewpoint identifier, provides the potential for online shopping to present specific landing pages 'tuned' to the mind-set of the respondent. The feedback from the PVI, viz. the mind-set, can move from informing the person as 'nice-to-know-about-me' into more directed, focused landing pages containing the appropriate information and 'tonality' for the mind-set. Marketing now becomes a path, from meeting the respondent, 'gamifying' the PVI to discover the mind-set, and immediate presentation of the 'right information to the right person at the right time.'

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